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Flexibility and innovation in response to emerging infectious diseases: Reactions to multi-drug resistant Tuberculosis in India

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Emerging infectious diseases regained substantial international attention in recent years and it has been argued that flexibility and innovation in public health systems is needed in order to react to changing challenges. This paper will take these policy claims as a starting point to examine the case of multi-drug resistant Tuberculosis (MDR-TB) in India.
Based on fieldwork results it will be examined how the existing control efforts of TB in India respond to the emergence of MDR-TB, what solutions are discussed for diagnosing, treating and preventing MDR-TB and what can be learned from that with regard to innovation and flexibility of a public health system in a country like India. The discussions and reactions to MDR-TB indicate that arguments for flexibility meet constraints of the existing control system and the Indian public health and wider social system. However, the flexibility that is argued for goes beyond what has been envisaged in international policy arenas (mainly focusing on preparation of various capacities in surveillance, detection and research). Rather it involves localized learning and experimenting within existing control structures that are claimed to have become too rigid in trying to keep up quality standards faced with a weakening public health system.
Furthermore, the case shows that existing challenges in TB control resurface with the emergence of MDR-TB and reflect a difficult balancing act between biomedical values, socio-cultural values and operational feasibility.
However, various actors are striving for change and it is in these instances that one can start to understand what flexibility and innovation could mean for a public health challenge such as TB in India. The paper concludes with an argument for a detailed analysis of these changes from an innovation perspective.

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1. Introduction

Emerging infectious diseases[1] have regained a great deal of international attention in recent years, not least with the outbreak of SARS and bird flu (Glass, 2004, Fidler, 2004). Public health specialists agree that dealing with new and re-emerging infectious diseases requires a multipronged approach (WHO, 2003b, Alan, 2003). For an adequate public health and policy response it is therefore important to stay flexible and foster diverse forms of innovation processes in order to be able to react to uncertainties created by continuously changing challenges (EASAC, 2006). These uncertainties are increasing with regard to possible future outbreaks, sudden mutations of viruses, possible drug resistance, poor health infrastructure, failing vaccine strategies and additional unknown challenges of international trade and travel, global warming and ageing societies (Eurosurveillance, 2005).

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[2] (EASAC, 2006), the challenge is to develop new public health solutions that are affordable, acceptable and applicable to local setting (WHO, 2003). Forecasting techniques, computer-modelling or disease epidemiology can help to measure potential impact and set priorities (Pompe, 2005). Flexibility is thus understood as the ability of a control system to detect and respond to new challenges quickly by being able to make use of a diverse set of potentially beneficial disciplines, actors and capabilities at various levels. As Owen and Roberts (2005) put it:

> *"SARS served to clearly demonstrate the key requirements of robust health policies that are required to enable a state to be 'resilient' to health challenges. These are: ability to assess potential health challenges; prevention as part of the policy mind-set; preparation; capacity to respond; and ability to rapidly recover. To succeed also requires the involvement and consent of empowered civil society. The problem is global*

[1] The WHO (2005) defines emerging infectious diseases as "... diseases of infectious origin whose incidence in humans has increased within the recent past or threatens to increase in the near future." This definition includes newly emerging, re-emerging and infectious diseases that appear in new geographic areas, in new forms or increase abruptly.

[2] In addition to R&D in basic microbiology, immunology and molecular biology to understand pathogens, their host interaction and to develop improved antimicrobial drugs, diagnostics and vaccines (EASAC; 2006) it is important not to forget research in delivering the medicine, operational research about people's behaviour or cost-effectiveness of various delivery methods. Research by economists, psychologists, sociologists, health services and health delivery researchers is important (Embo, 2003)

and international but much of the solution must be local and social." (Owen & Roberts, 2005)

With these policy claims in mind this paper will focus on the emergence of multi-drug resistant Tuberculosis (MDR-TB) in India. It will examine how the Indian TB control system is reacting to MDR-TB, what solutions are discussed for diagnosing, treating and preventing MDR-TB and what we can learn from that with regard to innovation and flexibility of a public health system in a country like India. By examining ongoing discussions and debates around MDR-TB the paper will simultaneously provide insights into the general practices and struggles of Tuberculosis control in India and the challenges in reacting to changing circumstances.

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 available for 50 years there have not been enough serious efforts 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, 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). The dynamics of TB in terms of spread and treatment (it is highly infectious but transmission is slower and it has characteristics of a chronic disease in treatment efforts) are different than the dynamics of fast-spreading infectious diseases like SARS or avian flu. International policy claims may thus fit less to the potential threat of MDR-TB. However, as this paper shows, the emergence of MDR-TB is asking for reactions of high speed and quality similar to the ones stated at the outset; but the response has to meet and fit within an existing control structure. It is thus interesting to examine how the problem is defined and what reactions are discussed.

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) fuelled by the outbreak of XDR-TB in South Africa which was widely published (Neel, Gandhi, et al., 2006)

Public health experts fear 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, international PPP, Pune, 29.1.2008).

Given the above stated need for flexibility in reaction to emerging public health challenges such as MDR-TB one would expect the Indian TB control system to be receptive and open to whatever changes and new opportunities might appear and to foster what might be called innovation for TB[3].

However, if one takes a closer look at the field level realities the picture that emerges is far more complicated with challenges and constraints inherent to the system that hamper learning, experimenting and thus flexibility in the response. This paper shows these challenges.

The paper is based on evidence that 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, patient homes and treatment sites. The following is a first analysis of the data with the aim to identify areas for further theoretical and empirical research.

In the next section, a brief overview on TB control efforts in India will be provided in order to better understand the current developments in reaction to MDR-TB which will be examined in chapter 3. The last section concludes with reflections along innovation and flexibility in the TB control system in India.

2. Tuberculosis control in India

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

[3] This paper will entail quite a broad understanding of innovation for infectious diseases based on a definition of innovation in healthcare by Cunningham (2005). Innovation is defined as change in service products & processes, delivery, organizations, system interaction or concepts if it is characterized by introduction of new knowledge. However, it will become clear in the pursuit of this paper that it needs further research in order to better understand what exactly the particularities of an Indian culture of innovation for infectious diseases such as TB are.

The Revised National Tuberculosis Program (RNTCP) is the current 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 which lasts six to eight months. 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.

Opinions about the success or failure of the DOTS program in India differ. Overall the RNTCP is judged by many as a success story particularly because of its internationally unprecedented rapid expansion in 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, 29.1.2008; Chakraborty, 2003; Udwadia & Pinto, 2007)[6].

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 medical officer,

[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] Sputum smear microscopy is the technique which is used to diagnose TB in DOTS. It consists of the examination of sputum (matter thrown up from the lungs) for the detection of a certain type of bacteria. It is the simplest laboratory test. It is cheap and is performed within minutes. 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)

[6] The problems with access and adherence to TB treatment are multifaceted and complex and are dependent on a range of factors from patient characteristics to the social and economic environment. Problems of access to care are illustrated in the delay between onset of symptoms, diagnosis and treatment. Influential factors have been found to be individuals' perception of the disease, severity of the disease, different access to health services, age, gender, social deprivation, economic burden, attitude and expertise of health personnel (Lienhardt et al., 2003). Regarding problems of adherence to treatment, Paul Farmer has suggested that social-structural factors such as poverty, economic inequity, racism, gender, inequalities, drug use, homelessness, overt political violence or civil disturbance are largely to blame. As evidence from operational research studies in Delhi shows, patients who are socially and economically marginalized will be least able to adhere to treatment (Singh et al., 2002).

RNTCP, Government of Andhra Pradesh, 21.1.2008). Many actors outside the program we interviewed criticize the RNTCP for a perspective of pushing patients to take the treatment by ignoring more social and cultural factors that could hinder a patient adhering to a treatment that comes practically to her/his doorstep (such as nutrition, transport, food security, other support mechanisms, gender or stigma). They argue that 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). However, advocates of the RNTCP argue that the program is trying to enhance compliance and access to treatment by increasing communication and education activities and by training DOTS providers (Interview with supervising medical officer, RNTCP, Government AP, Hyderabad, 21.1.2008), that the RNTCP corresponds to the status of the Indian public health system in place (Interview with former senior consultant, World Bank, Delhi, 05.03.2008) and that taking into account or even trying to change social-structural factors is not operationally feasible and would exceed available resources and capabilities (Interview with TB consultant, WHO India office, Delhi, 22.2.2008).

The TB control efforts are based on a strong structure or protocol inherent in the treatment regime itself: The RNTCP is very system-methodic in its treatment approach which is according to some actors important to keep up certain levels of quality across the country and cope with the weak health system (Interview with head of national NGO, Hyderabad, 16.2.2008). There are clear categories to which patients are assigned after the first diagnosis which helps to provide well-defined treatment regimes in settings with low skilled health personnel. Among private physicians particularly category II, the retreatment stage, is subject to discussion (which will be examined in chapter 3.2.1). As per the guidelines a patient is cured when the sputum turns from positive to negative in the last month of treatment and on at least one previous occasion (WHO, 2002). Members of the private medical sector argue that the RNTCP does not take into account the difference between cure and care. They complain that there is no room for care, for patient – practitioner interaction, flexibility in treatment, possibility to adapt to individual conditions or side effects, etc. The focus of the program 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.

These debates show the tensions and an apparent trade-off between individual, flexible treatment and the need for classification, standardization, simplification and thus inflexibility within a public health program that is trying to cater to the whole population in a uniform way.

These tensions touch upon a classic public health dilemma between biomedical values and socio-political values reflected in program design. 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, 1996). DOTS has been criticized internationally for its focus on cases and controlling the spread of disease instead of concern for individual patient; for a lack of attention to the patient's cost, unfair treatment of sputum-negative patients and potentially unethical treatment of patients by making him/her adhere to treatment at all cost (Walt, 1999). In her study on the politics of TB control Walt (1999) argues that an orientation towards rigidity, rapidity and results reflects some of the worst characteristics of vertical program implementation in infectious disease control. Among others, the demands of donors and the international community and the need for results and success stories often lead to programs that are too rigid to take into account local conditions and culture, that focus on rapidity without allowing health worker and communities to mobilize and thus demand health solutions that are too much target-driven, leading to falsification and undermining of results.

Several public health scholars we interviewed 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 indigenous policy development which often reflected socio-political conditions of that time (Bannerjee, 1993; Narayanan et al, 2003). There was a lot of political attention to TB in 1960s, when some of the important TB institutes were set up. Pioneering studies were conducted in Indian research institutes, showing the effectiveness of domiciliary treatment[7] and the need for direct observation of treatment which revolutionized TB control worldwide and provided the basis for today's worldwide TB control strategy by the WHO as early as 1958 (Narayanan et al., 2003). But

[7] The demonstration in the 1960s that ambulatory treatment of tuberculosis was as effective for patients and their families as bed rest and treatment in a sanatorium meant the end of the sanatorium era and the beginning of domiciliary treatment in TB control. Thus, TB treatment could be made widely available to many patients in countries with high prevalence.

subsequently the focus shifted to other issues more geared towards population control (Interview with director research centre, Hyderabad, 10.3.2008) generally neglecting maintenance of TB control infrastructure. The strong focus on population control and family planning during the 1980s and 90s led to a slow deterioration of general public health services by focusing attention, distorting resources and skills away from 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.

The guidelines for TB control are formulated at the political centre in Delhi and there is little capacity or room to adapt them to local conditions[8]. The influence of international actors such as the WHO and World Bank on policy design[9] is according to many members of the civil society too strong and based too much on a particular technical perspective leading to problems in policy design (Interviews: head national NGO, Hyderabad, 16.2.2008, health activist, Bangalore, 26.3.2008; Bannerji, 1993). They argue that these actors can be important in putting certain topics on the agenda but that there is a need for changing power balances and opening up space for discussions and different opinions.

Thus, the challenges that TB control in India is facing originate from within the TB program, the public health system and the wider social system. As will become clear throughout the paper, positions of actors in the debate are not always clear-cut. While most of our interviewees agree that guidelines are needed, they differ in their opinions on how appropriate these guidelines are for local contexts and current status of the health system and how much flexibility they should allow for.

[8] Health is a state subject in India. However, as noted above the guidelines for most of the public health programs and for infectious diseases in particular are designed and formulated at the central level in Delhi. Sometimes the decisions made in Delhi are not very applicable to the local context. There is little room for local policymakers to adjust to local contexts and at the state level capacities are mostly missing to make use of that flexibility (Ramani & Mavalankar, 2005; Interview director public health research centre, Hyderabad, 16.1.2008). "The more guidelines the central government issues, the more straightjacket we become!"(Interivew director public health research centre, Hyderabad, 16.1.2008). The staff still needs clear guidelines and prefers working with targets, but it is observed that governance capacities are in general slowly increasing also at the state level (Interviews: former senior consultant, World Bank, Delhi, 05.03.2008; director public health research centre, Hyderabad, 16.1.2008).

[9] Among the international players especially the WHO as technical advisor and the World Bank influence health policymaking in Delhi with regard to infectious diseases. The WHO influences more on the technical side with daily interaction between its WHO consultants and the Central TB Division. The influence of the Bank is more conceptually, in formulating policy on the operational side of the problem.

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 with medical anthropologist, Hyderabad, 16.1.2008) which might not be operationally feasible. Often a balance has to be found between different solutions. There is a constant struggle between the social and the technical, between scientific knowledge, techno-managerial feasibility of the program and socio-cultural or structural factors. The struggle for this balance also characterizes the reactions to MDR-TB as we will see in the next section.

3. Reactions to the emergence of MDR-TB

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). Although MDR-TB has been an issue for as long as anti-TB drugs have been in use there is concern about an increase in drug resistance and the potential impact it could have on existing control efforts. Since 2005 MDR-TB is officially on the agenda of the Central TB Division and the government is slowly reacting to it- also in response to the pressure of international actors such as the WHO. The emergence of MDR-TB is a politically sensitive issue since it should not increase when a DOTS strategy is working successfully and thus debates revolve around how serious the problem is (China Tuberculosis Control Collaboration, 1996; Interview with director research centre, Hyderabad 10.3.2008). Public health experts outside of the government criticize that the reactions are not fast enough (Interviews: chest physician, Delhi, 21.2.2008; public health consultant, international NGO; Hyderabad, 24.3.2008). But, according to a WHO TB officer, the first priority for the central TB division is still implementing the standard TB treatment, DOTS, given that full implementation was only reached in 2006 (Interview Delhi, 22.2.2008).

This section will review, on the basis of qualitative interviews with key informants, some of the ongoing discussions about reactions to MDR-TB in India. In accordance with the policy claims mentioned at the outset, that changing public health challenges enhance uncertainty and thus need flexibility in response, it will examine what actors perceive to be uncertain, how these

uncertainties are handled[10] and what is debated with regard to the definition of the burden, diagnostic techniques, treatment and prevention for MDR-TB.

3.1 Uncertainties in reacting to MDR-TB

The biggest uncertainties in TB control in India are, according to a WHO TB consultant, the definition of the burden of the disease and the delivery of care. The weak data situation implies that the baseline of the estimates is contested and estimates are very uncertain. Since the whole focus of the RNTCP is based on measurement of detection and cure rates, it means that the program indicators are based on uncertainty (Delhi, 22.2.2008).

The delivery of care and thus outreach of the control efforts is uncertain because of vast differences in program performance between states (of which some are enormous in size) and the huge unregulated and diversified private sector which is difficult to include and where it is literally impossible to calculate incidence or prevalence rate (Interview with TB consultant, WHO India office, Delhi, 22.2.2008). Weak monitoring of activities (is DOTS really happening at the doorstep?) and potentially lacking moral commitment among medical staff are factors further increasing this uncertainty with regard to sustainability of the program (Interview with senior researcher, Tuberculosis Research Center (TRC), Chennai 13.3.2008). According to a medical anthropologist uncertainty of implementation is further enhanced because the skills required of the medical staff for management of these programs are mostly lacking. This is even more so today where public-private partnerships are increasing and one needs a certain set of skills to manage such partnerships and be able to deal with people outside the public health system (Interview Mumbai, 31.1.2008).

With regard to MDR-TB there is additional uncertainty and debate about the prevalence and potential impact of MDR-TB on TB control (Central TB Division India, 2007; Interviews: chest physician, Delhi, 21.2.2008; public health consultant, national NGO, Hyderabad, 16.2.2008). Some years ago the private Hinduja Hospital in Mumbai published data on their TB patients of which 32% had MDR-TB and 8% were XDR-TB cases (Udwadia, 2001; Udwadia, Hakinyan & Rodriguez, 1996) which created quite some debate among public health experts in India. Clearly, the data from these private, tertiary care centres has a strong bias since they are well-known referral centres for failure cases. Currently available data from government sources shows 1-3%

[10] Thus referring to what has been termed ‘uncertainty information’ by Van Asselt and Vos (2006).

MDR among new sputum positive cases and 13-17% MDR among retreated cases[11] (Central TB Division, India, 2007). According to a WHO officer the government feels quite well informed about the extent of MDR-TB since the Drug Resistance Surveillance survey and former studies are revealing similar trends of incidence rates (Central TB Division India, 2008).

However, even if the incidence rates are more or less certain there is no data baseline available and it is thus difficult to define whether MDR-TB is increasing. Opinions differ about the extent to which MDR-TB is posing a threat to national TB control and whether it has to be called an emerging infectious disease (Interviews: microbiologist, private hospital, Mumbai 9.2.2008; chest physician, Delhi, 21.2.2008; TB consultant, WHO India office, Delhi, 22.2.2008, public health consultant, national NGO, Hyderabad, 16.2.2008). According to members of civil society organizations, MDR-TB is clearly handled as a threat to the RNTCP; and WHO and other international players are exerting a lot of pressure on the government to react. There seems to be fear that MDR-TB may potentially sabotage the whole program (Interviews: head international NGO India office, Hyderabad, 10.3.2008; medical anthropologist, Mumbai, 31.1.2008; director NGO research centre, Hyderabad, 10.3.2008). More moderate voices are warning of the creation of too much panic among private physicians leading potentially to an overuse of second line drugs and argue that it is rather a big social problem that needs to be addressed than an epidemic (Interview with microbiologist, private hospital, Mumbai, 9.2.2008).

> *"I learnt not to say it has been increasing, there is no denominator! How can we say it? We have a huge bias towards resistance … they come to us when they are not doing well. Telling you numbers of our MDR is meaningless." (Interview with microbiologist, private hospital, Mumbai, 9.2.2008)*

> *"I cannot say definitely, it does seem to be slightly on the rise, but definitely it is not coming down. .. I think it is one of the emerging infectious diseases for which we need to have, if nothing …for it to prevent it, because it's a disease which is infectious, … treatment, cure will become more difficult, and numbers will increase, …" (Interview with chest physician, teaching hospital, Delhi 21.2.2008)*

Still, if we assume that the government figures are more or less correct we are dealing with a huge amount of MDR-TB patients in absolute numbers who can potentially transmit the resistant strains. According to a senior microbiologist at the Tuberculosis Research Centre in Chennai it might not be the right approach to quantify the problem given the weak data basis (suspect to underreporting and not very generalizable data which is from different spots across the country).

[11] Patients who failed the first treatment and started retreatment (Cat II)

Rather there is a need to react to MDR-TB within RNTCP and include policy strategies for dealing with it (Interview microbiologist, Tuberculosis Research Center (TRC), Chennai 14.3.2008).

Thus, uncertainty in TB control in India is not only characterized by how the disease will evolve in the future and the potential impact of MDR-TB, there is as much uncertainty about the present burden of TB and the quality of the delivery of care which makes the response to the "standard" TB case already difficult and might hamper flexible responses to MDR-TB. There seem to be different types of uncertainty involved: about the future development of disease and control efforts (which correspond to international policy claims) and uncertainty which is more characterized by lack of data and knowledge about ongoing activities, thus the present. Literature on uncertainty[12] differentiates between epistemic uncertainty (due to limited knowledge or by complexity) and variability uncertainty (due to variability of system behaviour), whereas limited knowledge can result partly from variability. Further differentiation can be done according to level and source of uncertainty (Van Asselt & Vos, 2006; van Asselt, 2000; Walker et al., 2003; Meijer, 2008). These types of uncertainty seem to exist in the present case as well: uncertainty about sustainability of the program, due to lack of data about private sector, different performances between states and the unknown burden of TB can be characterized as epistemic uncertainty and variability uncertainty can be found in the future development and potential impact of MDR-TB on control efforts. The former depends on sources such as lack of observations, data or ignorance, the latter originates from the natural system but also human behaviour and social, economic and cultural dynamics (acc to Van Asselt & Vos, 2006). What is perceived as the source of uncertainty strongly depends on the context (Meijer, 2008), thus it is important to understand the context of TB control within which these claims are made. Both sources and types of uncertainties are important to understand in order to analyze reactions to it (Meijer et al., 2006). According to Walker et al. (2003) situations of high uncertainty call for robust strategies which will work in various situations (the strategy that RNTCP chose with DOTS) or an adaptive strategy which can be easily modified to fit the encountered situation (the strategy that actors who criticize the RNTCP seem to favour). It seems to be useful to conduct further research on perceived uncertainties involved in TB control in India given that they can play an important role in blocking change by influencing decisions and behaviour of involved

[12] Uncertainty can be defined broadly as "any deviation from the unachievable ideal of completely deterministic knowledge of the relevant system" (Walker et al., 2003:5) which relates to a lack of information or to aspects that are indeterminable.

actors (Meijer et al, 2006). Let us now turn to the discussion about the reactions to MDR-TB in greater detail.

3.2 Reacting to MDR-TB: handling uncertainty

The government is the main actor responsible for public health challenges. How is the Central TB Division coping with the uncertainty mentioned above that characterizes the TB challenge in India?

According to Meijer et al. (2006) standard reactions to uncertainties involved in innovation decisions can be the delay or abandonment of innovation decisions or the ignorance of uncertainty and taking the risk to make false decisions based on imperfect information. Furthermore, if uncertainty is acknowledged then often information is collected in order to reduce it but gathering information might not always reduce uncertainty. It can enhance uncertainty by discovering new uncertainties or harden existing positions because different interpretations are possible. Similar developments can be found in the TB case:

With regard to the uncertainty created by the "standard" TB epidemic (mainly sustainability & quality of delivery) the government is trying to handle it by applying an internationally accepted policy strategy (DOTS) and by focusing on implementation of this strategy across the country with clear targets as measurements of success (cure and treatment rates). We have seen in the preceding chapters that some actors outside the government argue that DOTS is too much focused on the biomedical perspective and does not allow enough flexibility or learning to take place whereas the government is emphasizing the challenge of operational feasibility and the constraints of the public health system in the Indian context.

With regard to MDR-TB, the government is trying to reduce uncertainty about the burden of drug resistance by conducting several Drug Resistance Surveillance surveys to provide a data baseline. Simultaneously they are focusing on capacity building and quality assurance of diagnostic facilities throughout the country because with existing methods in place it is not possible to diagnose MDR-TB. In cooperation with the WHO India office they are fostering the evaluation of new diagnostic tests because rapid diagnosis is regarded as a crucial bottleneck. The potential threat of MDR-TB also calls for strengthening of existing control efforts, since prevention of MDR-TB is expected to be the best strategy to deal with the MDR-TB threat. They are trying to strengthen existing control efforts for example by including the private medical and NGO sector

to improve service delivery. Furthermore DOTS plus, the treatment strategy for MDR-TB cases by the WHO has been adopted and is being tested in a first treatment site.

This sounds like a flexible reaction more or less in line with the policy claims stated at the outset of this paper. However, these reactions are not always straightforward and are debated and contested among public health experts in India. In what follows, a closer look at some of the underlying challenges in defining burden, diagnosis, prevention and treatment of MDR-TB will be undertaken.

3.2.1 Defining the problem of MDR-TB

As mentioned above MDR-TB is a politically sensitive issue because MDR incidences should go down if a DOTS program is working well. According to a private chest physician, there has been initial resistance in the government to accept that there is a serious problem due to the implicit acknowledgment that things might not work as smoothly as they appear. That the program is reacting now to MDR-TB shows to him that there has been a shift in attitude (Interview with chest physician, Delhi, 21.2.2008). According to a former senior TB consultant at the World Bank there has been a certain feeling of accomplishment when implementation of RNTCP across the country was reached which allows now directing more focused attention to emerging issues such as MDR-TB (Interview, Delhi, 05.03.2008).

However, several private physicians complain about the resistance to criticism by the government and the lack of willingness to reflect openly about the reasons for increasing MDR-TB cases. One of the often cited factors by public health experts outside the government is the definition of the category II treatment regime which is, according to them, breeding MDR-TB[13]. It is felt by private physicians that the government doesn't seem ready to think about why these categories have been adopted and whether they ought to be changed (Interview with chest physician, Delhi, 21.2.2008). Besides the contested treatment of category II patients, they complain that the RNTCP does not recognize old patients as retreatment cases since most of the patients present themselves as new cases. The continuing problems with adherence to treatment, neglect of socio-cultural factors and lacking regulation of and cooperation with the private sector are further

[13] Patients under category II (retreatment, failure/relapsed cases) are treated with one additional drug only, in contrast to other countries where 2-3 additional new drugs are added which is of course much more costly. In addition these patients are not immediately tested for MDR-TB, only if they fail the CatII treatment. Many physicians we talked to think that this category is breeding resistance and there is anecdotal evidence confirming these concerns.

breeding drug resistance. Thus, arguments have been made that the RNTCP is actually creating MDR-TB.

The government argues that MDR-TB is mainly a problem of non-compliance with treatment by the patients and of the private medical sector where inadequate, insufficient or non-standardized treatment regimes are common. They argue that treating as many patients as possible under the DOTS regime is the best prevention for MDR-TB (Interview with supervising medical officer, RNTCP, Government AP, Hyderabad, 21.1.2008).

Thus, actors tend to blame each other and define the problem differently. It is internationally acknowledged that MDR-TB is increasing due to mismanagement and repeated mistreatment of TB cases (WHO, 2008). However, the factors responsible for poor treatment in the Indian context are understood differently among actors involved.

3.2.2 Diagnosing MDR-TB

The improvement of diagnostic tests is seen by many researchers as the greatest challenge at the moment in TB control. 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. 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 (Interviews: microbiologist, research foundation, Mumbai, 2.2.2008, 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, required laboratory capacity, feasibility, etc. Various research initiatives by public, private or NGO laboratories are looking into better tests or adopting existing ones for the Indian context. According to several public health experts we interviewed there are too many different agencies involved acting uncoordinated and producing redundancy. This has been a general critique on the Indian health

research system (IAVI, 2007) and the TB case is no exception: there is no long-term road map, no coordination between different governing agencies, limited infrastructure, funding and human resources, and not enough cooperation with industry. A director of a NGO research centre argues that not enough importance has been given to the development of cheap, easy to use technologies for the public health system in general, and that there is not enough strategic research initiated by the government (Interview Hyderabad, 10.3.2008).

So far, none of the diagnostic tools meet the expectations. The TB program manager has to be very convinced of the feasibility and effectiveness when implementing a new diagnostic technique given the huge operational effort involved and that it takes 3-5 years to roll it out in India. What if someone comes up with a better solution within four years? It is therefore crucial to show the utility and operational feasibility of new solutions for the program and the public health purpose (Interview with TB consultant, WHO India office, Delhi, 22.2.2008).

It is furthermore regarded as very challenging to get the new techniques implemented in the system. Often lab technicians are not in touch with cutting edge science and technology and are more comfortable with what they have been doing for years. The ones who could introduce new techniques, the lab supervisors, are often young science graduates (because senior microbiologists are not interested in public sector jobs), supervising older, more senior lab technicians who are not ready to listen to the ideas of young graduates (Interview with microbiologist, research foundation, Mumbai, 2.2.2008). There is a lack of motivation and leadership in the system also due to the huge workload on public laboratories which creates further barriers to change. The absorptive capacity for new technology and techniques for diagnosing MDR-TB is thus an important factor hampering change, strongly connected to challenges inherent to the health and wider social system.

Regardless of which diagnostic test will be introduced for MDR-TB they all require a certain laboratory capacity. Since MDR-TB is defined as a laboratory diagnosis[14] the Central TB division argues that one needs to strengthen laboratory capacities first in order to be able to

[14] Microbiologists argue that the diagnosis of MDR-TB is not purely a laboratory diagnosis. The problem with bacterial resistance is such that if there is resistance in the lab it doesn't mean that you would get the same in the body reaction. It can happen that the patient seems to respond to the treatment from a clinical point of view but still be resistant from a laboratory point of view (Interview with director research centre, Hyderabad, 10.3.2008). Following up the patients and correlating lab and clinical diagnosis would therefore be important but is hardly done. Thus, it is challenging to define, what you can call MDR-TB.

diagnose cases. So far there are only a few quality assured labs that are able to diagnose MDR and thus the government is planning to have 24 laboratories (state-level Intermediate Reference Laboratories, IRLs) accredited across the country by 2020. But it is a long and difficult process given persistent problems in the health system with staffing[15]; so much so that many experts doubt that it will work by 2020 (Interviews: director, research centre, Hyderabad, 10.3.2008; public health consultant, international NGO, 24.3.2008). The staffing of the laboratories highlights structural problems inherent to the health system. According to a WHO advisor this aspect has been underestimated by many in the government and therefore the MDR-TB challenge is far more complicated than expected (Delhi, 22.2.2008).

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The strong focus on quality assurance for culture sensitive laboratories by the government (pushed by the WHO as 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 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). Although accreditation is essential to bring a uniform standard to all the labs, improve quality of diagnosis and allow sharing of data, samples and strains for research, it seems to be a huge challenge to talk about quality control if the skills are not even existing in government laboratories (Interviews: director research centre, Hyderabad, 10.3.2008; public health consultant, international NGO, Hyderabad, 24.3.2008).

A public health consultant who has been working on implementation of RNTCP since it's beginning argues 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. The current microscopy diagnosis, on which the standard DOTS is based, was started without quality control which was only introduced five years later. In the same way states should be allowed to start with diagnosing MDR-TB without accreditation and overall quality control. "If you don't act fast you are further creating a problem, if you act fast at least you will learn from your mistakes" (Interview; Hyderabad 24.3.2008).

[15] These state level laboratories are complicated to run and the jobs are not financially attractive enough for senior microbiologists.

Furthermore there are debates about the timing of MDR-TB tests within the standard TB treatment regime.

> *"…Everyone is treated according to the DOTS regimen, the test for MDR will only take place once a person failed the CATII treatment which is already the retreatment stage. Then they become suspects for MDR and then it takes another four months to find out whether it is actually MDR due to the techniques involved and the time it takes to send the samples to the TRC [Tuberculosis Research Centre] and back. So there is a time gap involved which is very dangerous for the patients." (Interview WHO TB-consultant, Gujarat, 5.2.2008)*

At the moment, the system doesn't allow for the finding of primary MDR-TB since culture sensitivity tests that are necessary to diagnose MDR-TB are only run after the patient is failing standard treatment and the retreatment. With current levels of techniques, skills and capacity, testing each and every patient when he/she enters the TB program is simply not feasible. Although the time saved (around eight months at least) on treatment would benefit the patient and the program.

The struggles and discussions around diagnosing MDR-TB show that there are many barriers to change inherent in current TB control efforts due to constraints by operational feasibility, response capacity and challenges in the public health and wider social system which make a flexible response difficult. The strong influence of the WHO becomes evident for example in the emphasis on quality assurance of laboratories.

3.2.3 Treating MDR-TB

The treatment of MDR-TB is complicated, long, toxic, frustrating for the patient and cannot easily be standardized because it needs a lot of counselling and room for individual care (Interview with chest physician, Delhi, 21.2.2008). The government is piloting treatment in accordance with the DOTSplus guidelines by WHO[16] in a hospital in Ahmedabad.

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

[16] 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.

resistant strains[17]. Some public health experts are favouring again the sanatorium approach (Interview with chest physician, Delhi, 21.2.2008) but hospitalizing every MDR-TB patient for the full treatment time is not feasible from a programmatic and potentially also ethical point of view. The pilot site of the government for patients on DOTS plus treatment is treating the patients during their first week of treatment and in case they develop adverse drug reactions in a separate ward of the TB hospital with natural ventilation providing the infection control.

The effort that is undertaken at the first treatment site for MDR-TB patients clearly corresponds to individualized medical care although the doctors argue that India needs a conform treatment scheme and policy for the whole country and individual care would not be an option (Ahmedabad, 5.2.2008). Our interviews suggest that there seems to be a trade-off between a conform treatment regime and flexibility in treatment and individualized care. According to a chest physician the automatic treatment or factory approach without patient interaction will not be enough and doesn't work for the treatment of diseases. There needs to be room to adapt treatment regimes to respond adequately to both medical and socio-cultural factors that depend on the individual patient (Interview Delhi, 21.2.2008).

The discussion on the treatment of MDR-TB reveals that the central public health debates in TB (Walt, 1999; Porter & Ogden, 1999) around biomedical versus socio-political values reflected in program design becomes evident in the reactions to MDR-TB as well.

As mentioned above the TB program in India has been criticized by scholars and some public health experts we interviewed for being driven too strongly by biomedical values (Porter & Ogden, 1999; Interviews: chest physician, Delhi, 21.2.2008; medical anthropologist, Mumbai 31.1.2008; senior health activist, Bangalore, 26.3.2008), thus reducing the goal of care for the patient to cure as defined by the guidelines and provided in a box full of tablets. Furthermore, as the discussions above have shown even from a pure biomedical perspective private medical physicians claim that it does not allow enough flexibility to adjust treatment regimes. However, individualized and context specific care might not be feasible with the current public health systems in place in India and the government argues that the program needs to have strong

[17] 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).

guidelines in order to keep up quality standards and cope with the weak health system. The debate thus remains unsolved and continues for the treatment of MDR-TB.

3.2.4 Preventing MDR-TB

Prevention of MDR-TB is expected to be the best strategy and many of the public health experts we interviewed emphasize the importance of ensuring that patients adhere to the standard TB treatment as one of the crucial factors preventing MDR-TB.

In addition to compliance and diagnostic challenges, poor prescribing practices in the private sector where 70% of the patients seek initial treatment are further creating failure cases which are breeding drug resistance. Due to the unregulated nature of the private sector there is hardly any data on these patients available that often only access public health services at an advanced stage of the disease.

Thus, in the last couple of 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 private physicians can now refer TB patients to microscopy centres and become DOTS providers (Interview: medical officer, RNTCP, Government of Andhra Pradesh, 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 originated 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 but 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 finally 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).

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.

4. Flexibility and innovation in reacting to MDR-TB

The above discussion shows that there is a dominant belief from the government's side that flexibility in reacting to a public health challenge might not be operationally feasible given the constraints of the Indian public health context. Experts outside the TB program push for more flexibility and criticize what they perceive as resistance to change. This is nicely illustrated by the following quotes of eminent figures in TB control in Andhra Pradesh about the role of change and innovation within the TB program:

> *"…the program is too rigid for any kind of innovation. ..The state officials, program managers are so narrow minded, the minute you mention the word innovation, they back off! 'Why innovation? Everything is there in the guidelines!'" (Interview head of international NGO India office,* 10.3.2008*).*

> *"…very vertical, very, very telescopic and microscopic in their vision!" (Interview chest physician, private hospital, Hyderabad, 12.3.2008)*

> *"The first step of the government is denial, you bombard them with statistics they open up a bit, then third stage is they claim you are not showing solutions, then you show the solution; then: our country is so big, we don't want to act fast..." (Interview public health consultant, international NGO, Hyderabad, 24.3.2008)*

> *"We have to keep pace with the organism, the system has to change and adopt, the simple organism is trying to play with us, we can do.., we have that strength, given opportunity.." (Interview public health consultant, international NGO, Hyderabad, 24.3.2008)*

Thus the emergence of MDR-TB brings one of the main points of critique of the TB control program in India from actors outside the government to the surface: an inherent rigidity and resistance towards change and new ideas. The critics argue that there is a lack of flexibility in implementation and treatment guidelines, a lack of research for improvement and in general a lack of openness in attitude or awareness for adaptation to local contexts, changing circumstances or emerging challenges. According to a medical anthropologist most of the emerging problems that TB control in India is now facing are actually homemade, based on the lack of flexibility of the TB program in dealing with changing environments (Mumbai, 31.1.2008).

The government officials at the state levels are criticized for narrowly following guidelines, focusing on targets and numbers. "…program officers, they are only interested in their numbers: how many detected? How many on treatment? How many cured? How many defaults? That's all!" (Interview with chest physician, private hospital, Hyderabad, 12.3.2008). The Central TB Division and WHO are accused of being mainly concerned with the figures, cure and detection

rates. At the state level there is a lack of adapting the program to local needs and constructive communication between state and national level program managers is missing (Interview with medical anthropologist, Mumbai, 31.1.2008).

Several TB experts who wanted to introduce change or new solutions to the TB program complain about the resistance they encounter from the government, about introduction of social aspects like communication skills, inclusion of civil society and the private medical sector into the system or collaborations with the pharmaceutical sector (Interviews: Public health consultant, international NGO, 24.3.2008; chest physician, private hospital, Hyderabad, 12.3.2008). It is also criticized that the main decision-making power lies with the central TB officer in Delhi and that an equal participation of stakeholders is lacking.

> *"When I wanted to introduce social aspects into the system -we need to understand social factors it is a social problem- they were calling me a fool, the program is about Rifampicin[18] etc!" (Interview with public health consultant, international NGO, Hyderabad 24.3.2008)*

But one also has to acknowledge the perspective of the public health policymaker: Any change in the program implies a huge operational effort and implementation needs an enormous amount of resources, training and time given the size of the program and the country. As the discussions around MDR-TB have shown, 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). In addition, policy change has to be framed and shaped very carefully, because demand is created immediately and withdrawing from a policy change if it turns out not to be successful becomes very difficult (Interview with health economist, Tuberculosis Research Centre (TRC), Chennai, 14.3.2008).

Clearly, the success and the huge operational endeavour of the RNTCP are recognized by every public health specialist and it is not contested that standardization and guidelines are essential. But it is argued that the program would need to start doing much more operational research and allow constant revision and more flexibility within the broader framework and its implementation. It is felt that there is a need to introduce flexibility and learning while implementing and to work around the above mentioned challenges and eventually overcome

[18] One of the main drug molecules of the anti-TB drugs.

them (Interview with public health consultant, international NGO, Hyderabad, 24.3.2008). However, it remains a bit unclear how this could be practically done. It would thus be useful to examine in more detail instances of change in the current TB control efforts.

Such experimentation could be in the form of improvements in program implementation such as the initial pilot projects on the involvement of the private sector which led successfully to a policy shift (as mentioned in chapter 3.2.4).

Another example 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.

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 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[19]. Currently, there is room for change because of shared pressure from WHO and Stop TB partnership and regained international attention (Interview with microbiologist, Pune Foundation for Medical Research (FMR), Mumbai 2.2.2008). In accordance with these changes MDR-TB offers an opportunity to reintroduce flexibility into the control system.

These instances reflect a broader understanding of innovations for infectious diseases going beyond scientific and technological novelty involving more service and delivery aspects. 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 provided useful insights into the processes behind innovation in healthcare, albeit focused

[19] 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

entirely on health systems in Europe. It will be helpful to test and further develop these concepts in an Indian context in a next step.

With regard to flexibility in responding to changing health challenges the following seems to be apparent based on the fieldwork conducted so far:
The emerging reactions and discussions around MDR-TB that have been examined above: show how difficult it is for the TB program to be more flexible in integrating local contexts or reacting to changing challenges such as MDR-TB given barriers and constraints of the public health and wider social system and the strong protocols inherent in the TB program.
Thus, the critique on the TB control structure corresponds to international policy claims for flexibility in infectious disease control. But it seems that the flexibility is understood in a slightly different way: The international policy claims argue for preparation of various different capacities in order to be able to react flexible to emerging challenges and be able to innovate when it is needed. Whereas this is certainly needed for the TB control mechanisms in India as well it is argued that there is a lack of open attitude towards innovation and inputs from different actors. Thus, public health experts outside the government argue for flexibility in learning and experimenting to improve an existing control structure and for more flexibility within the existing program and treatment regime itself. Furthermore, they suggest that one of the reasons for the emergence of MDR-TB is actually this lack of flexibility in the existing control structure. It is thus not only the flexibility in response to an external challenge that is needed but beyond that flexibility in dealing with existing problems in order to avoid emergence of new challenges.

It is believed that concepts such as innovation and flexibility in response to emerging infectious diseases have to be analyzed in greater detail in order to understand what they could imply in a field level context and to better inform national and international policy claims. They seem to contain idealistic assumptions about the normative value of innovation and flexibility in public health systems. The case of MDR-TB shows that this might be justified according to actors outside the government. But it also shows that the understanding of what innovation and flexibility mean can be different. Furthermore, it has to be investigated how exactly rigidities and perceived inflexibilities hamper learning and flexibility in response as claimed by some of the interviewees.

A further exploration of innovation and flexibility both from a theoretical, public policy perspective and in further empirical research of specific examples of innovation in TB control (some of which have been mentioned above) will thus be useful. These cases of innovation might be found in the changes that have been introduced in the TB program since its implementation in 1995 which somehow managed to overcome initial rigidities and system related constraints.

Applying an innovation perspective will be helpful to capture these changes in responses to emerging challenges theoretically, making use of and further developing literature on healthcare innovation (Cunningham, 2005; Consoli et al., 2006; Den Hertog, Groen & Weehuizen, 2005; Koch & Hauknes, 2005). Such an analysis will provide further insights into what flexibility and innovation can mean for a public health system in a country like India that is confronted with an emerging public health challenge such as MDR-TB. Thus, it will ultimately help to explore what public policy can do to create and strengthen response capacities for changing public health challenges.

5. Conclusion

It has been claimed that emerging infectious diseases enhance uncertainty and that in order to respond adequately flexibility and innovation within public health systems are needed.

With these claims in mind we have been visiting the case of MDR-TB in India. We found that the emergence of MDR-TB is enhancing uncertainty mainly with regard to the potential impact on current control efforts and that it adds to the already existing uncertainty (burden of TB and sustainability of care) that is prevalent in the control of the standard TB epidemic. It has been argued that it would be helpful to further examine which types of uncertainties prevail and how they are responded to. In discussing how uncertainty is handled and the reactions to MDR it became clear that actors blame each other for the reasons of the emergence of MDR-TB, that many barriers to change exist within the TB control structure and the public health system and that classic public health debates of TB continue for MDR-TB.

Further, the emergence of MDR-TB makes clear that the Indian TB program, despite being a huge endeavour and having had a certain amount of success, is struggling with challenges (inherent to the program and to the health and wider social system) that perpetuate the problem of MDR-TB and in the same time hamper the response towards it.

We have seen that MDR-TB is meeting an existing control structure that is criticized of being rigid in its treatment protocols and they way it is delivered and that is accused of hampering flexibility in reactions to new challenges that are emerging. However, the flexibility that is argued for by actors outside the government involves more localized learning and experimenting within the existing control structure.

Thus, the reactions to MDR-TB in India bring inherent challenges, rigidities, debates and uncertainties within the current TB control effort to the surface. Flexibility and innovation seem to be needed but are difficult to realize partly because they seem not to be operationally feasible. Nonetheless, change is happening in reaction to MDR-TB, though in bits and pieces, more in an uncoordinated manner and mainly initiated through bottom-up initiatives or pushed by actors outside the ministry of health. It is in these examples that one can start thinking about what flexibility and innovation for TB control in India could mean in practice in order to better understand the possibilities and the usefulness for the Indian public health system to innovate and react flexible to emerging challenges such as MDR-TB.

6. References

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