Tuberculosis or TB is a very serious problem in India and worldwide, and generally lacks attention in the public domain. Scientists, medical doctors, health staff and community workers make heroic efforts but the innovative potential of India remains underused. This limits flexible responses to changing challenges and opportunities — such as, for example, increasing multi-drug resistance, co-infection with HIV, migration, new global health actors and funds, progress in technology — that TB control is faced with. More innovation and innovations of a different kind than new diagnostics, drugs or vaccines are possible and necessary. In order to strengthen innovative capacity, it helps to understand the efforts of coping with TB in India as a continuous struggle for innovation and control. Understanding this struggle and then strengthening the mechanisms to balance different practices of innovation and control are crucial for the future of TB control in India. Such understanding and experimentations would also offer instances of learning about how to improve TB control to other countries and to the World Health Organisation’s global efforts.

TB is an infectious disease caused by the Mycobacterium tuberculosis which is commonly transmitted through inhalation of bacteria and, in its most common form, affects mainly the lungs (pulmonary TB). The disease, if untreated, will lead to gradual destruction of lungs, the increasing incapacity of bodily functions and eventually death. TB is in principle curable with a cocktail of anti-TB drugs that have to be taken for at least six months and which are provided free of charge by national control programmes according to international guidelines of the World Health Organisation (WHO). Yet, TB remains the first among the world’s infectious killers, mainly due to its close links to social problems such as poverty, sanitation, population density, malnutrition, and stigma (Benatar 2003; Farmer 1997; Farmer 2003). More than nine million cases are reported globally each year (WHO 2004).

India is the country with the highest number of TB patients in the world. It has been estimated that there are 1.9 million new cases occurring in India every year of which 0.8 million are expected to have pulmonary TB (CTD 2007b; CTD 2010). The huge death toll and the long-term impact on patients, affecting them mainly in their most productive years, lead to a severe economic burden and immense human suffering and death on a daily basis. The Central TB Division of the Ministry of Health and Family Welfare, Government of India, is responsible for TB control and implements the Revised National Tuberculosis Control Programme (RNTCP). The RNTCP has at its core the DOTS+ strategy of the WHO, the main focus of which is the delivery of anti-TB drugs and adherence to treatment. The targets have been set: To cure at least 85% of all newly detected pulmonary TB cases and to detect at least 70% of the estimated incidence of smear-positive pulmonary TB cases (Arora and Gupta 2002; CTD 2009). The RNTCP claimed coverage with the DOTS strategy of the whole country in March 2006 (meaning geographical coverage of services, since the RNTCP has not reached out to every TB patient), and has consistently maintained the treatment success rate of >85% and the detection rate of new sputum positive patients close to the global target of 70% (CTD 2009). Yet, more needs to be done. It is estimated that about 80% of TB patients initially seek treatment from the non-governmental sector, including private practitioners, where diagnosis is often inadequate and thus diagnosis of TB according to the RNTCP guidelines tends to get delayed, ranging from one to six months (Uplekar et al 2003). Furthermore, poor prescribing practices in the private medical sector where inadequate, insufficient or non-standardised treatment regimes are common (Das 2004; Uplekar and Shepard 1991) are creating failure cases and are breeding drug resistance. The poor often end up indebted when searching for care in the private sector and...
following an unsuccessful treatment regime or shopping around for the right treatment. These patients then access the public sector in an advanced stage of the disease: indebted, demotivated, frustrated and seriously ill. They spread the disease further and risk developing drug resistance.

There has been increasing international attention to the threat of multi-drug resistant tuberculosis (MDR-TB) and extreme multi-drug resistant TB (XDR-TB) fuelled by the outbreak of XDR-TB in South Africa in 2006 which was widely published (Gandhi et al 2006). It is feared that in India the potential effect of MDR-TB on ongoing control efforts might be devastating, eliminating the successes achieved so far. Next to increasing drug resistance, the current public TB control efforts in India are challenged by increasing co-infection with HIV (CTD 2007a, 2009), an increasing migratory population and urbanisation, an unregulated private medical sector, as also by social stigma, lack of awareness and the challenges of integration with other health programmes (Arora and Sarin 2000). Increased international attention to TB and MDR-TB in recent years, portrayed as pressing global public health challenges, has also brought new opportunities in the form of new international actors, new financial resources and progress in technology and medicine. The latter are urgently needed since the current tools mainly used in endemic countries, such as India, are in need of renewal. The main diagnostic test, sputum microscopy, is 130 years old and notoriously inadequate (Perkins et al 2006). Furthermore, there has been no new drug since the discovery of the main drug Rifampicin in 1963 and concerns about increasing over-use and drug resistance are rising. Lastly, the vaccine currently used, Bacillus Calmette-Guérin (BCG), is ineffective for adult TB and only works for certain forms of paediatric TB.

**Innovation: Challenges and Constraints**

Given the changes in the disease, its context and responses to it, one might 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, understandings and treatment regimes, in order to be able to respond to the changing public health challenge. However, this is not always the case. Partly because TB is a social problem as much as a clinical problem, the ground level realities for innovation are very complicated. Challenges and constraints inherent to the health and wider social system hamper learning, experimenting and thus innovation. But also because of the particular way in which efforts to control TB operate. The particular control practices inherent in the DOTS strategy, for example, have invited criticism for being unethical because of its strong emphasis on controlling patients’ swallowing their drugs through direct observation (Narayan 1998, 1999; Ogden 2000; Pronyk and Porter 1999). These control strategies represent a particular balancing act between operational feasibility, biomedical knowledge and sociocultural factors, whereby often sociocultural factors are compromised because of the others. As we will argue in this article, the efforts of coping with TB are a continuous struggle about the right balance between innovation and control.

Assessing this struggle and strengthening mechanisms to balance different forms of innovation and control will be crucial for the future of TB control, in India and globally.

TB control programmes need to function in an ever-changing environment. Various actors with different perspectives and practices are concerned with TB control. The main goal of infectious disease programmes is to control and orchestrate a variety of actors and elements involved: the disease, healthcare providers, bacteria, data, processes of treatment and diagnosis, public opinion, etc. At the same time, actors need to innovate and be responsive to changing challenges, opportunities and localities. The improvement of TB control is continuously sought after and innovation is therefore an indispensable part of controlling TB. Yet, innovation may also challenge established control practices, may change them or render them obsolete. Innovation and control are continuously changing, but deeply interlinked phenomena of public health efforts. We define innovation as efforts to improve, and we define control as efforts to govern a situation (and the humans and objects therein). How does this tension between different practices of control and innovation play out in ongoing TB control efforts in India?

Actors are engaged in various control practices through, for example, supervision and management of healthcare providers, patients or data; through technologies such as drugs or diagnostics; through standardisation of treatment processes in guidelines; or through redefinition of problems. These control practices are ubiquitous and at the forefront of all TB-related activities.

At the same time, innovation for TB control is urgently needed and is often thought of as new drugs, diagnostics and vaccines that could be developed by the private sector or by global public-private partnerships. Yet, innovation for TB control can and should involve more than just technological aspects such as drugs, diagnostics and vaccines. The ethnographic fieldwork of the first author of this paper shows that innovations for TB control in India happen in organisational, strategic, technological and service-delivery aspects of TB control. Innovation can be found, for example,

- in a village committee meeting, where joint monitoring and collaboration between villagers allow for TB control within the communities;
- in NGO policy meetings, where new collaborations between actors and new advocacy strategies are being organised;
- in a referral slip for patients, by which private practitioners send patients to the TB programme (and back);
- in a document folder of a TB official, wherein new guidelines and service processes are being planned;
- in laboratories, which are being upgraded to higher biosafety levels;
- in a research institute, where microbiologists are trying to simplify TB diagnostics by conducting basic research on host factors;
- in a new diagnostic machine, which allows rapid drug sensitivity testing;
- in a hospital room, where the first patients are being treated for MDR-TB; and
- in a treatment guideline adapted to the local context.

Innovation, understood in this sense, can mean to improve or adapt existing solutions to local contexts or to develop new ones. These examples also show that innovative activity is undertaken by various actors, including public and private, and that it ranges from global to local levels. All these actors struggle simultaneously...
for innovation and control while trying to respond to changing circumstances. International organisations, donors and pharmaceutical companies are concerned with innovating TB control in order to stop transmission of TB. The emphasis is on research and development (R&D) of new drugs, diagnostics and vaccines. Some of these actors are also trying to find responses to global challenges, such as urbanisation, migration or emerging drug resistance. The decision-makers in India, responsible for public TB control, need to meet targets and implement policy guidelines across a large and diverse country. However, their control efforts are also under pressure to adapt to changing environments. These changing circumstances include developments in the demographic and epidemic situation, emerging drug resistance, changing constellations in the international global health world and availability of diagnostic and treatment options. At the field level, health staff, physicians, patients and volunteers are similarly engaged in trying to innovate their practices to react to emerging drug resistance, increased migration, co-infection with HIV/AIDS and changes in social behaviour.

All this results in a struggle between innovation and control, and understanding this struggle is relevant for practitioners in TB control as well as for researchers studying those practices.

This article reports on an analysis of public health that traces innovation and control dynamics throughout different social worlds of TB control in India from a constructivist perspective. The research approach was exploratory and ethnographical, as practised in Science and Technology Studies (STS) (Collins 1985; Latour 1987). We study the interactions between facts, artefacts, actors and institutions, and how these interactions make these various elements change over time. STS accounts thus trace the developments of a broad range of elements, such as scientific knowledge, technologies, guidelines, bacteria, patients, policies and organisations.

The different actors who are engaged with TB in India live in different social worlds. These range from the world of the laboratory to the world of patients and practitioners, from the world of the national TB programme to the global health policy world. These worlds have their own focus on what TB is and how it should be controlled. They employ different practices and technologies (such as laboratory techniques, drugs and diagnostics, national guidelines, global policies). Actors in these different worlds often do not really coordinate or cooperate with each other. Typically, these worlds are also separately researched by different disciplines (policy studies, medical anthropology, epidemiology). We hope that our comparative analysis of these different worlds, from micro to macro levels, from the level of the TB bacteria to global health policy, will yield new results that mono-disciplinary work cannot offer.

In the remainder of this article we focus on two examples: The efforts to find a new diagnostic test for MDR-TB (a technological innovation) and the efforts to include the private providers into the public TB programme (an organisational innovation).

**A Technological Innovation: New Diagnostics for MDR-TB**

Despite a long tradition of TB research in India (Narayan 1999; Narayanan et al 2003), the R&D situation for new diagnostics in India has been not very supportive throughout the last decades. There is no strategic fostering or coordination of R&D activities for a new diagnostic test within India. Our fieldwork revealed that this is due to a combined effect of three main factors. First, a lack on treatment delivery, good accessibility of drugs and improved cure rates rather than diagnosis in the DOTS strategy left diagnostics somewhat unattended. Second, a lack of coordination and strategic fostering of diagnostic R&D by the Indian health (research) system. According to several public health experts we interviewed, there are too many different agencies involved, all acting in an uncoordinated fashion. R&D for new TB diagnostics is neither actively fostered by the Central TB Division nor by the main government funding research bodies, such as the Council for Scientific and Industrial Research (CSIR) or the Department of Science and Technology (DST). This situation is often related to a lack of assigned funds to TB. 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. This has been a general critique on the Indian health research system (IAVI 2007; ICMR 2004) and TB diagnostics is no exception. Third, a lack of commercial interest among the Indian pharmaceutical companies who conduct hardly any R&D on TB, despite having evolved as an industry from imitative to innovative R&D over the last few decades (Chaturvedi et al 2007; Kale and Little 2007). The lack of R&D in TB diagnostics is generally attributed to the rigid price control of anti-TB drugs and diagnostics by the Indian government, which prevents even established pharmaceuticals from entering the market, as a pharmaceutical consultant explains. This lack of focus, coordination and competition leaves the research potential within India (Chaturvedi et al 2007; IAVI 2007; ICMR 2004; Kale and Little 2007; Lanjouw and MacLeod 2005) for TB diagnosis underused. It means that actors conducting R&D often come from outside and lobby through international donors or organisations.

An example of such an international actor is the Foundation for Innovative New Diagnostics or FIND which is evaluating, in collaboration with the government, whether a new diagnostic test to detect MDR-TB, developed by Hain Lifesciences in Germany, would work in the Indian TB programme. They are testing this at a demonstration site with existing capacities of the public TB programme. This evaluation project faces numerous challenges. The change of technology implies changes in practices of controlling TB and thereby in working processes, environment and culture for which existing manpower is not prepared or qualified. The team therefore has had to add manpower and extra funds from outside and develop systems of biosafety or quality control which are nonexistent at the demonstration site. By generating additional resources from outside, these localities and settings are becoming less representative for field conditions. It shows that factors such as lack of standardisation, manpower and costs, were not integrated in the initial development of the test and were not foreseen in the international funds of the demonstration project. This might be based on the assumption that technology can be much more easily transferred to another context and, as a result, some of the local expertise of scientists but also the community remains excluded. There are smaller players in Indian medical colleges, who have developed their own in-house test for MDR-TB based on a similar technology, but who are not considered by the government for these evaluation studies. They feel excluded and blame the
government for not taking them into account, and for choosing instead international actors and tests. The analysis of control practices can provide further explanations. Diagnosing TB is difficult and uncertain. On top of that, the new diagnostics are complicated and mistakes happen easily. In order to cope with this uncertainty of the diagnostic process the government argues that control through standardisation of this process is crucial. What is needed is not only a technology, but a “product in a box”. A test needs to be a test kit, one that is embedded in a whole range of standardised specifications, such as standardised steps to perform, standardised reagents, quality control, colour reactions, instruments for amplification and manufacturing processes. The test needs to be a commercially viable “product in a box”. The ability to achieve control through standardisation of the diagnostic process, within the existing health-care facilities, is therefore an important condition for a new diagnostic test. As a result, actors who want to develop a new diagnostic test for MDR-TB that will be considered by the RNTCP for evaluation need to design it as a “product in a box”, embedded in a deliverable package: they have to standardise it. Smaller players in Indian medical colleges are not able to deliver such a product in a box, because they do not have the capacity, resources or skills to do so and thus remain excluded. However, a diagnostic test, such as the “product in a box” that came from Europe, can also be standardised in such a way that it does not immediately fit the new context where control practices might be different from the ones wherein the test was originally developed, in this case a laboratory in Europe.

This example shows that there is no coordinated fostering of the innovative potential for new diagnostics within India. What is more, the different control practices around standardising diagnostic processes can exclude potentially valid expertise. This, in turn, can cause challenges for the innovation in the field.

Local circumstances of lack of manpower, high costs, lack of political commitment and administrative will, miscalculations by decision-makers and lack of standardisation of work processes may present barriers to any effort to innovate the TB control process. Thus, we need to incorporate social, cultural and political dimensions of TB control in our conception of innovation: partly because technological innovations need to be embedded in supportive social circumstances and partly because those aspects of TB control themselves merit improvement and innovation.

An Organisational Innovation: The Public-Private Mix

The TB programme does not actively foster other, non-technical kinds of innovations, such as in service delivery or organisation or strategy. Furthermore, staff is so overburdened and primarily focused on reaching targets that they often do not have the freedom and flexibility to improvise, improve and try out new ideas. Yet, such improvisations and experimentations on a micro-scale seem very pertinent and crucial elements in any substantive innovation process. As a result innovators are often highly committed individuals who are able to overcome the non-conducive environment for innovation.

The example of the Public-Private Mix (PPM) initiatives, an innovation in organisational aspects of TB control, illustrates this point. Since 1995, a handful of private practitioners, medical anthropologists and activists started advocating for the inclusion of the private sector and NGOs into the national TB programme, under the heading PPM. Highly committed individual innovators developed PPM pilot projects whereby private practitioners referred their patients to the RNTCP or treated them according to the RNTCP guidelines. These initial PPM models showed that, when private practitioners have good case holding and success rates, PPM can improve the TB programme’s indicators, the case detection and the cure rate. However, these individual innovations were not coordinated and were all emphasising different problem definitions and solutions of PPM.

At that time, the Central TB Division was hesitant and to some extent resistant to include external partners, and those early innovators and their PPM initiatives thus faced resistance to their ideas. The Central TB Division regarded it as unnecessary and assumed that patients would approach the RNTCP if it offered a good programme. The Central TB Division also feared that it would potentially threaten the quality and indicators of the RNTCP, given the unregulated nature of the private medical sector.

Despite those concerns, one of the early PPM initiatives, the PPM model by Mahaveer, Hyderabad, managed to gain the attention of the WHO in Geneva during the pilot project and was thereafter sponsored and supported by the Department for International Development (DFID) and the WHO. The Mahaveer project, in combination with data generated from other initial PPM models and research studies from India, led to a shift in global health policy by the WHO (2001). This international detour paved the way for the adaptation of PPM into the Indian TB programme. The local innovative activity had been supported by international policy influence of the WHO. This resulted in official PPM guidelines in 2005 by the RNTCP (CTD 2005a, 2005b). Yet, in order to lead to a sustained shift at the national policy level, the local innovations needed additional support from developments within India, such as general health system development, development of the RNTCP and more sustained international pressure by new actors and their funds. This happened only in 2008 when policy support for PPM was reconfirmed and as a result the initial guidelines were again revised (CTD 2008). Throughout a period of several years, from 1993-2008, a substantial policy shift occurred. The Central TB Division officially recognised that the private medical sector needed to be included in the form of PPM initiatives in order to be able to treat more patients under a standardised treatment, to cut transmission and to avoid the emergence of MDR-TB (CTD 2008; WHO 2009).

Despite the reconfirmed policy support, PPM activities in India continue to face challenges in the field and PPM has not been scaled-up in a manner that is adequate to the urgent need to involve the huge private sector. Resistance and apprehensions against PPM and external partners continue at the field level, by district and sub-district level RNTCP staff. A lack of willingness to interact and conflicting perceptions of collaboration (such as different views on the importance of PPM, lack of trust and belief in a common ground) among healthcare providers in TB control in India are identified as the main obstacles for collaboration (Uplekar et al 2001). We argue that clashes between actors’ different control practices, linked to their professional backgrounds and understanding of TB from an individual health, public health or community perspective, can explain some of the apprehensions and scepticism.
Innovation and Control: Inseparably Related Phenomena of Public Health Efforts: Based on the case studies we presented, what can be said about the relationship between innovation and control? Our analysis shows that the phenomena of innovation and control in public healthcare efforts are not mutually exclusive, but indeed inseparable and inextricably-related – they mutually shape each other.

The innovative efforts with regard to new diagnostics or PPM do not exclude control practices, rather they influence (change, undo, maintain) and even require certain control practices. This means that efforts to innovate and efforts to control cannot be looked at separately. TB control will not succeed when solely focusing on controlling and ignoring innovating; and innovating TB care will not succeed when solely focusing on innovating and ignoring controlling. The need for skilled mediators, weak capacities and detrimental political relations are thus contributing to a non-conducive environment for innovation.

Different control practices of actors matter for innovation, such as PPM or new diagnostic tests, through setting-up/breaking-through barriers for innovation, inclusion/exclusion of actors and through constituting entire cultures of control across different social worlds. Different worlds involved in TB control, such as global health policy, programme officers, private practitioners, health staff and patients, meet in innovation situations and their control practices and resulting problem definitions at times overlap and at other times clash and can lead to contestations, mismatches or apprehensions between actors around innovations. In the case of new diagnostics, different control practices lead to exclusion of potentially valuable expertise. In the case of PPM, clashes between actors’ different organisational control practices can result in acts of blaming and challenge PPM initiatives.

How to Better Use Innovation for TB Control? These examples show that the potential for innovation seems to remain underused. How to learn lessons from these case studies that can help us formulate strategies for making more use of the innovative potential amongst TB workers?

A Non-conducive Environment for Innovation: Innovation is not actively fostered, neither technical R&D nor innovation in organisational aspects. What is more, innovators need to overcome a non-conducive environment for innovation. Innovators need to overcome apprehensions, a lack of coordination and weak capacities. They need to be able to comply with control practices of the TB programme (standardise a diagnostic test), conduct research and provide evidence about impact on programme indicators, have personal relationships at higher bureaucratic levels and deal with replication and sustainability challenges. As a result, most of the innovators one meets are rather impressive personalities. They are skilled mediators between different levels and worlds, between global and local actors. They often act from outside the RNTCP, at times with international support, and unite the skills of practitioners, researchers and lobbyists in one person. Decision-makers tend to be open to innovations when the proposals show a positive impact on programme indicators; when they are supported by external funding, respected actors or international policy pressure; and if there is a window of opportunity at the national level. These are difficult conditions to fulfil for small local players. The need for skilled mediators, weak capacities and detrimental political relations are thus contributing to a non-conducive environment for innovation.

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without controlling. Control of TB needs innovation in order to respond to changing challenges and opportunities, to be continuously critically assessed and negotiated, but also to respond to local contexts. Innovation for TB needs a certain amount of control in order to be replicable, transferable and responsible. This analysis shows that innovation and control both mutually influence and require each other.

The example of new diagnostics reveals this relationship as well. Innovation of a new diagnostic test requires control through standardisation to be feasible for the TB programme. Developing a diagnostic test which is not standardised – as some of the smaller players in Indian medical colleges have done – is not an option for the RNTCP and will fail to be taken into consideration by the decision-makers. However, control through standardisation can also jeopardise innovation. Control practices of standardisation requirements can exclude potentially valuable expertise, such as the smaller players in Indian colleges, and innovations as a result face challenges in the field.

A similar dynamic is at play in the example of PPM. The innovation requires changes in organisational control practices of both public and private providers, yet those can also pose barriers to PPM and shape further development of PPM. This shows a potential tension between innovation and control and how both mutually influence and require each other and need to be balanced.

It also shows that actors handle the relationship between innovation and control differently. The RNTCP decision-makers argue for more standardisation around diagnostic tests than smaller players in medical colleges would favour. Private medical providers would prefer less control through supervision as they feel this threatens their autonomy as a profession, whereas the RNTCP emphasises the need to supervise patients and healthcare providers as mismanagement of treatment is not only bad for the individual patient but also for all TB control efforts as such (since drug resistance might develop). Different actors demand different balances between innovation and control, based on their different control practices.

There is thus a need to assess and constructively discuss differences in control practices across the different worlds of TB in India. These practices are diverse, mean different things to different actors and matter in different ways. As the empirical examples show, assessment and discussion of control practices is complicated due to power relations, hierarchies, interests involved, different capacities, and varying perspectives of actors. Hence the situated character of knowledge and practices must be acknowledged and evaluated. This also holds for how actors understand and handle the relation between innovation and control.

Before stating which requirements need to be met in finding the right balance, these different balances need to be made explicit. The relation between innovation and control needs to be continuously negotiated between different actor groups involved in innovative activities. Complex organisational settings like TB control need to cope with a problem of too much versus too little organisational control for innovation in situated negotiations. They also need to assess for each innovation situation at hand what forms of expertise should be included. In the case of TB, generally, the local actors (be it patients, local researchers, fieldworkers or local private practitioners) have a weaker voice and are at times ignored, excluded, dominated or neglected in these processes. Situated negotiation could help to overcome acts of blaming and exclusion which hamper innovations that often require collaboration between different professional groups and different social worlds.

There is thus also a need for policy innovation: how differences in practices of control and innovation can be constructively discussed and bridged in order to cope with power relations, social hierarchies, vested interests, acts of blaming and apprehensions among actors involved.

**Policy Implications:** Current policy mechanisms that are focused on implementing one solution to a multiple and complex problem such as TB are outdated. These do not work because complexity, different localities, understandings and practices are not taken into account enough. In order to strengthen public health capacity, innovations are needed. However, innovation for TB control is not a linear process of improvement, but rather a complicated, continuous undertaking across many worlds, as different groups have different practices (including different definitions of what important problems and required solutions are). Currently, the innovative potential within India is, we have argued, somewhat underused. This is also reflected in the R&D situation for TB control in India. The research structures in Indian TB control – for example, for operational research on new delivery models but also biomedical research concerned with new diagnostics – remain underused or uncoordinated and isolated from each other. Small local players, on the other hand, do not always have the means to conduct necessary research about their innovations. Yet, research, piloting of ideas and generation of evidence on programme indicators and replication is crucial for innovation in TB control. Not all necessary research needs to happen in a formal R&D laboratory, but there is potential for coordinating and fostering R&D more systematically and creating innovation opportunities for various actors engaged in TB control, including the necessary positive attitudes and incentives for coming up with (local) innovations.

To help innovation be effective, a more conducive environment should be created. Yet, also an acknowledgement is needed of the many worlds engaged in TB control (from the world of the laboratory to the global health policy world), and of the different understandings and practices of actors across these worlds with regard to organisational, strategic, technological, and service delivery aspects of TB control.

Creating a more conducive environment for innovation would require to systematically coordinate different forms of research (formal R&D as well as operational research across different governmental departments), to monitor and assess existing mechanisms of local adaptation across the country, to create opportunities for innovators to document, measure and vocalise their ideas, and to establish local reward and recognition mechanisms. Rather than highlighting on annual TB day and in the annual RNTCP report a handful of selected individual TB champions or success stories, these local mechanisms would nurture and reward innovative activity at the local level and provide sustained encouragement for innovative activities within local TB control. This would create a more conducive environment where staff would dare to try out new ideas.

The fact that innovators need to be mediators between various worlds limits the innovative potential among actors because such
skilled mediators are hard to find. The fact that supporting factors for innovations are often from outside the RNTCP or even India is problematic when innovations cause apprehension or do not fit local conditions. Yet, innovation is not per se beneficial for TB control. Innovation and control mean different things at all levels and across the different worlds of TB control in India. It is an ongoing struggle to find the right balance and to negotiate trade-offs. Fostering innovation at any price is therefore not advisable; instead, a balance between innovation and control needs to be continuously maintained. Rather than providing advice on an optimal balancing act between innovation and control, we argue that this balance needs to be found in situated assessments of the relation between innovation and control. Problems are situated and thus solutions need to be found in situated assessments. Assessing and constructively discussing different practices of innovation and control and their interplay is thus essential to cope with the challenges that innovations are faced with, such as diverse local health system capacities, requirements for highly skilled and resourceful mediators and innovators, and challenges of replication, apprehensions and trade-offs. The mechanisms that would need to be fostered in order to create strong, flexible innovation capacities are therefore situated assessments of the relation between innovation and control for every innovation situation.

Are we now drawing paradoxical conclusions? One might issue a warning that situated assessments of the relation between innovation and control are risky, particularly for the case of TB control, where standardised diagnosis and treatment are central to achieve the public good of TB control. Yet, this warning only holds when one assumes that innovation would come at the expense of control. This analysis showed that innovation and control are both necessary and that the nature of both innovation and control is ambiguous. Innovation can have negative implications for control, and all control is not beneficial either. Thus, mechanisms to effectively balance the two must be strengthened. The delivery of public health services in India is in crisis, mainly due to a lack of accountability, resulting in high absenteeism, low quality in care, low levels of satisfaction and widespread corruption (Hammer et al 2007). This article argues that by nourishing the urge for local innovation, which exists despite above mentioned challenges, general problems of too little accountability and too much corruption might lose some of their base. Future research of a more interventionist kind is necessary to examine how situated assessments could work in practice.

While this article is critical of the current control structure as implemented by the RNTCP and its decision-makers (the WHO and the Central TB Division), it also acknowledges their immensely important contribution to TB control in India and the success that has been achieved so far. Since its inception in 1997, more than 12.6 million patients have been treated under the RNTCP and 2.2 million deaths averted. Yet, in 2009 alone, over two million TB cases and 2,80,000 TB deaths occurred in India. The RNTCP has set for 2012-17 the ambitious plan to provide universal access to quality TB diagnosis and treatment for the entire Indian population (CTD 2011). This will require, among others, much more financial resources allocated to TB, a strong involvement of the private sector and improved diagnostics (Pai 2011). However, if TB control in India is to strengthen its capacity to respond to changing challenges and opportunities, it is crucial to reflect on underlying innovation mechanisms. This can only be done while also assessing established control practices. This article, then, is a hopeful and optimistic outlook on the innovative potential of TB control in India, which could be unearthed and used more systematically, yet will only reveal its true potential if it is allowed to do so in a situated manner.

NOTES
1 DOTS, or the directly observed treatment, short course, is the strategy for treating routine TB by the WHO that is being applied worldwide in slightly varied national adaptations. The DOTS strategy consists of five elements: (i) government commitment, (ii) case detection by sputum microscopy, (iii) standardised treatment regimens of six to eight months with direct observation (DOT) of the patient swallowing drugs for at least the initial two months, (iv) regular supply of anti-TB drugs, and (v) a standardised recording and reporting system (WHO 2010b).
2 However, what is coined “irrational practice” from a public health point of view needs to be examined in the broader Indian social, economic and policy context of healthcare demand and supply (Kamat 2001; Kielmann et al 2005). Kielmann et al argue that not following guidelines can be seen as an attempt to effect cultural, market and policy environments.
3 MDR-TB is defined as resistance to at least Rifampicin and Isoniazid, two of the most important anti-TB drugs. It develops due to infection by a resistant strain or due to poor treatment with inadequate drugs or irregular drug intake (CTD 2007a). 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).
4 Most of this critique is levelled at the element of delayed observation of patients while they swallow their drugs. The underlying assumption of the emphasis on DOTS is that patients cannot be trusted to act for the good of the community (Odigon 1999) and therefore need to be controlled in order to avoid treatment failure and protect the drugs from losing their power (Craig 2005; Harper 2005). Yet, it has been argued that it is rather structural violence and social inequalities that cause treatment failures, such as poverty, economic inequality, racism, gender inequality, drug use, homelessness or even political violence or war. These factors structure patients’ vulnerability to the disease and their access to care, but are often beyond control (Farmer 1997, 2002). In line with these arguments, an effective TB policy needs to focus on care, rather than control, by means of local adaptation and partnerships with patients (Odigon 2000).
5 The ethnographic fieldwork of nine months was conducted in two rounds between 2007 and 2009, whereby the researcher followed actors and actions across the country. It consisted of more than 100 semi-structured interviews, observations and document research in Hyderabad, Pune, Ahmedabad, Warangal districts (Andhra Pradesh), Mumbai, Pune, Delhi, Chennai and Bangalore.
6 In STS the term “artefact” denotes anything human-made, notably machines and instruments. Artefact, thus, is not used with a derogatory connotation, as for example when referring to an erroneous finding that is generated by a faulty set-up of an experiment by the researcher.
7 Interview with a director of a research centre in Mumbai, 19 December 2008. It is an exception but does not focus on diagnostics (Interview with director of a laboratory in Bangalore, 25 March 2008).
8 Astra Zeneca, which has an entire centre devoted to the development of new drug molecules for TB, is an exception but does not focus on diagnostics (Interview with director of a laboratory in Bangalore, 25 March 2008).
9 Some of the general constraints of the Indian health research that have been voiced are that the importance of health research is not recognised enough by policymakers; that there is no departmental status of health research in the health ministry; that there is no coordination between health research efforts; that there is no health research climate; that there is no priority given to capacity and human resource development; that intersectoral linkages are weak; that IT and biotech tools are inaccessible; and, finally, that links between health research and services are too weak to be of direct use.
10 Interview with a director of an NGO research foundation for innovative new diagnostics in India, which is an exception but does not focus on diagnostics (Interview with director of a laboratory in Bangalore, 25 March 2008).
11 Interview with a director of a laboratory in Bangalore, 25 March 2008.
12 In a conference to stimulate industry/biotech engagement in TB diagnostics innovation in India at St John’s Research Institute in Bangalore in August 2011 this potential was sought to be unleashed. The conference was sponsored by McGill University & Global Health Strategies with technical support from the Bill & Melinda Gates Foundation, the Foundation for Innovative New Diagnostics (FIN Diagnostics and FND) and the International Centre for Genetic Engineering and Biotechnology (ICGEB), India.
13 FIN Diagnostics and FND is an international, independent non-profit...
foundation, funded by the Bill & Melinda Gates Foundation, the European Union and the Government of the Netherlands, with the aim to foster the development of new diagnostics for selected poverty-related diseases in contractual partnerships with industry and academics. FIND India, entered into a Memorandum of Understanding with the Indian government in 2004, in order to demonstrate and address the introduction of new, rapid and quality-assured diagnostic tests for TB at affordable prices for the public health sector (FIND 2007).

Interview with a microbiologist at a medical college in Delhi, 21 January 2009.

Standardisation is needed to scale-up the test in a cost-effective manner throughout the country (interview with international NGO programme manager in Delhi, 21 January 2009). This is crucial for the TB programme manager, given the huge operational effort involved, and that it takes up to five years to roll out a new technology in India (interviews with central TB officer in Delhi, 14 January 2009, and a TB consultant at the WHO India office in Delhi, 22 February 2008).

Interview with an international NGO programme manager in Delhi, 22 January 2009.

The basic idea of the initial PPM initiatives was that private practitioners refer the TB patients to the RNTCP and can become their DOTS providers. In this way, private practitioners keep their patients and can charge for consultations, but the patient receives the drugs free of charge and follows the standardised DOTS therapy by the RNTCP, supervised by the private practitioner.

Interview with RNTCP consultant -2, in Delhi, 15 January 2009. Also see, Agarwal et al (2005).

Interview with IMA consultants in Hyderabad, 24 November 2008. Also see Upaker (2003).

Interview with an NGO programme manager in Mumbai, 19 December 2008.

Costa et al (2008) found that the mutual lack of confidence between private and public sectors is affecting collaboration in Madhya Pradesh. The public sector perceived the private sector as driven by commercial interests, poorly responsive to partnership initiatives and focused on self-interest. The private sector perceived the public sector as being non-supportive, corrupt and making unrealistic demands under the name of partnerships and therefore saw no benefit in collaborating with it.

Interviews with international NGO fieldworker in Hyderabad, 24 February 2009 and private physicians in Hyderabad, 27 February 2009.


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