Local adaptation versus standardization?

Treatment delivery for multi-drug resistant Tuberculosis in India

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Treatment of Tuberculosis (TB) and multi-drug resistant Tuberculosis (MDR-TB) is a public good, due to the risk of transmission of infectious strains and the potential amplification of drug-resistance. The provision of this public good by government programmes has to bear a tension between standardized guidelines within programmatic constraints and local adaptation responding to needs for individual care. This tension is central to Tuberculosis control and is rendered more urgent for the prolonged and complicated MDR-TB treatment. This paper focuses on the first treatment sites for MDR-TB of the public TB programme in India. My fieldwork shows that actors here struggle with the interplay between local adaptation and standardization in service delivery. The literature casts this relationship often in terms of ideological opposites and thus actors would have to make normative choices for one over the other. My results show that there is indeed a risk of being caught in dilemma-thinking, namely that local adaptation goes at the expense of control through standardization and vice versa. Yet, the dilemma-thinking prevents a content-related discussion on the different forms of local adaptation and standardization which actors engage in. Their practices and understandings demonstrate that the relation between local adaptation and standardization can be better characterized in terms of effectiveness; with the actors defining effectiveness differently. To avoid seemingly opposite ethical stands, favouring standardization or local adaptation, it is helpful to analyse different practices engaged with standardization and local adaptation, and to understand how actors relate to them.

[standardization, local adaptation, MDR-TB, treatment delivery, ethical dilemma, India]

Treatment of Tuberculosis[1] (TB) and multi-drug resistant TB is a public good.[2] The risk of transmission of (resistant) strains to other people and the potential amplification of drug-resistance require collective action. The public good character of TB control implies that treatment outcome in one patient has consequences for others. 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 an 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 (CTD 2007). In countries like India, with high numbers of TB patients, weak health systems and an unregulated private medical sector, the fear is that MDR-TB might eliminate the successes of TB control achieved so far and render TB practically uncontrollable (Udwadia 2008). Given the close links between poverty and TB, MDR-TB treatment through the public TB programme is urgently needed in order to provide free second-line drugs to patients.

The particular challenge of providing this public good by public programmes in resource-poor settings is to balance between the individual level of suffering, represented by the patient, and the programmatic level with its aims and constraints of the public control programme and the health system. There is an inevitable tension: On the one hand, control through standardized guidelines aims at preventing further transmission and amplification of drug resistance. On the other hand local adaptation is needed in order to respond to needs for individual care. This tension is common for public health challenges. Yet, MDR-TB renders it more urgent, because the prolonged and complicated MDR-TB treatment enhances the need for local adaptation.

MDR-TB treatment is complicated and more expensive than routine TB treatment with only a 60% chance of cure. Patients require complicated follow-up investigations (clinical, radiological and bacteriological) and sometimes surgery or hospitalization (Sharma & Mohan 2004). The pattern of drug resistance of an MDR-TB patient can vary from person to person and throughout the TB treatment. Ideally, the drug regimen of the second-line drugs is adjusted accordingly, to avoid side-effects, to enhance chances of cure, to protect the second-line drugs and to avoid the amplification of further resistance (WHO 2006). However, since diagnosing MDR-TB requires a certain technical capacity of laboratories that is not readily available in low-resource settings, drug resistance is often clinically defined and the standard drug regimen has to cover the possibility of the different drug resistances (Ormerod 2001).

Furthermore, MDR-TB treatment is long, toxic, painful, frustrating and more difficult to bear for patients than the routine TB treatment strategy DOTS (see endnote 3). Most of the steps involved, such as diagnosis, treatment set-up, follow-up test schedules, reporting and recording activities, are longer and more extensive and complicated than in routine TB treatment. The second-line drugs of the DOTS Plus drug regimen for MDR-TB are more toxic and can cause worse side effects (severe adverse drug reactions) than the standard cocktail of anti-TB drugs in the DOTS regimen. According to the guidelines for India, the MDR-TB treatment takes 24 to 27 months (CTD 2010). In the intensive phase of six months, the treatment involves a daily injection and drugs intake of 10-13 different drugs (drugs only on Sundays) under direct supervision of a DOTS Plus provider.[3] The patient needs to visit the DOTS Plus provider daily. MDR-TB has a strong, long-term impact on the patient's life and the fragile organizational set-up of the treatment strategy DOTS Plus can be easily disturbed by the challenges of daily life. Adherence to DOTS Plus poses operational challenges to patients, such as the accessibility of infrastructure and the side effects of drugs, but also the skills of health volunteers who might not be trained enough.[4] Next to

operational challenges, patients face challenges such as stigma, acceptance of their disease in the community or the risk of losing their job or daily wages, all of which can interfere with their treatment adherence efforts. Many of the MDR-TB patients have already spent several years of unsuccessful treatment and thus generally need more motivation. The nature of MDR-TB treatment enhances the need for individual operational arrangements in drug delivery, extra support, resources, motivation and counselling for patients.

In resource-poor countries, such elements of individual care are nearly impossible to provide within a public healthcare context, particularly because the cost for treating MDR-TB reach far beyond the cost for treating routine TB (Moore-Gillon 2001). MDR-TB treatment needs to be sustainable and replicable across the country because the TB programme aims to provide uniform service delivery to the whole population. Governments therefore apply a standardized drug regimen and drug delivery process. This means that the tension between standardization and local adaptation is rendered more urgent for MDR-TB treatment than routine TB treatment.

The Central TB Division (the department responsible for TB control at the Ministry of Health and Family Welfare, Government of India,) is adapting the global MDR-TB guidelines, DOTS Plus,[5] to India. The goal is to reach complete country-wide coverage with DOTS Plus by 2015. This would mean that all MDR-TB patients accessing the public TB programme (the Revised National Tuberculosis Control Programme (RNTCP)) would be treated by the program free of charge[6] (Interview RNTCP consultant, Delhi, 15.1.2009) (CTD 2010). Prior to DOTS Plus and still today in places where DOTS Plus is not yet available, TB patients who fail the routine TB treatment have to search for cure outside the TB program. They are offered treatment at their own costs in private clinics or medical colleges or they are left to die if they cannot afford the costly second-line drugs.[7]

This paper focuses on three actors: the public TB programme and its decision-makers, the MDR-TB patients, and the team of physicians and programme staff at the first MDR-TB treatment site by the government. The paper explores how these actors handle the tension between standardization and local adaptation for MDR-TB treatment.

In the literature, the relation between local adaptation (to provide for example more individual care) and standardization in service delivery is often framed in terms of ideological opposites, according to which actors would have to make normative choices between one over the other. Medical sociology has generally heralded patient-centred care and criticized standardization as an ally of medicine's biomedical view and as ignorant to individual non-biomedical patients' needs (Zuiderent-Jerak & Berg 2010; Mead & Bower 2000). An example in relation to TB is the debate between biomedical and socio-political values reflected in programme design (Porter & Ogden 1999; Walt 1999). In these discussions local adaptation is often equalled with responding to socio-political values, rather than only biomedical ones, or with adapting biomedical aspects to socio-political ones. The debate reveals a presumed dilemma or trade-off between local adaptation and standardization.

If biomedical values are central to programme design, TB programmes are characterized in a standardized manner, assumed to be transferable between countries and

evaluated in terms of detection, cure and treatment indicators. If socio-political values are central to programme design, TB is framed as a disease of poverty and programmes are characterized as flexible, accessible to local patients' needs and living conditions, and responsive to local contexts, such as for example effects of stigma. The core of the global TB control strategy, DOTS (see endnote 3), and particularly the aspect to directly observe patients when they swallow their drugs, has been criticized for its strong focus on the drugs and case management and its lack of attention to social factors such as poverty, housing, sanitation, nutrition or work environments that might hinder adherence (Enarson & Billo 2007). Instead, TB is handled mainly as a medical problem and social aspects have been side-lined for many years by a strong medicalization of the problem (Gandy & Zumla 2003). Medical sociologists have emphasized that less standardization and more local adaptation to provide individual care is needed in order to cope with the complex reality and respond to socio-cultural and political factors (Ogden 2000). The view on TB as a primarily biomedical problem (Ogden 1999; Porter & Ogden 1999) has been particularly criticized for creating MDR-TB. Applying a similar approach and perspective for MDR-TB treatment means to fight the problem of MDR-TB treatment delivery with the same tools which have created MDR-TB in the first place.

Yet the proponents of DOTS argue that while socio-economic improvements are important, chemotherapy is increasing the rate of decline of TB much faster and there is not enough time to wait for socio-economic factors to change (Smith 1999). Furthermore, cost-effectiveness is often put forward against arguments to pay more attention to the needs of individual patients and local contexts. Others oppose this and argue that the logic of cost-effectiveness is not feasible in resource poor settings because it ignores the social determinants of access to health services. It does not pay sufficient attention to the social, political, economic, epidemiological and pathophysiological factors influencing the production of health. Approaches that apply the logic of cost-effectiveness will therefore ultimately hinder progress towards effective TB control (Kim et al. 2003). According to Farmer (2003) the concepts of cost-effectiveness, sustainability and replicability which are often used in public health are likely to be perverted if social justice is not central to public health and medicine. Farmer argues that only an inegalitarian system can be considered efficacious when unnecessary sickness and premature death do not matter (Farmer 2003). This shows how the different positions in the debate on standardization and local adaptation are based on different value constellations. According to Walt (1999), there are positive and negative aspects to both biomedical and socio-political values and resolving this dilemma is nearly impossible.

However, debates on the dilemma between local adaptation and standardization, and arguments for one over the other, generally exclude a less antagonistic analysis of how effective care practices are (Zuiderent-Jerak & Berg 2010). In order to do so, standardization should be studied as a process, as politics of standardization in practice (Timmermans & Berg 2003). This would lead to a focus on actual changes in medical practices, renegotiation of orders and autonomies, and outcomes that result from standardization (Zuiderent-Jerak & Berg 2010; Timmermans & Berg 2003). There is

thus a need to get out of the ideological opposition, or dilemma-thinking, between standardization and local adaptation. Dilemma-thinking masks a more content-related discussion on how standardization and local adaptation relate, on how standardization is practiced and on different ways in which notions of effectiveness are constructed (Zuiderent-Jerak & Berg 2010). In this way the researcher engages with the empirical field without pre-conceived ideas of what good and ethical care is, but rather examines how different actors involved in healthcare conceptualize and practice good health-care (Willems & Pols 2010).

This paper provides a first step to such an analysis with regard to treatment delivery for public MDR-TB control in India. I examine how different actors handle the relation between local adaptation and control through standardization. The main questions that this paper addresses are: How do actors characterize the relation between standardization and local adaptation? How do they engage in the process of standardization and make MDR-TB guidelines work? It will become clear that actors have different understandings of local adaptation and standardization. I show that actors handle the tension differently based on different understandings of effectiveness and at times dissolve the presumed dilemma in their practices. There is thus a need to analyse the different local adaptation and standardization practices that are being developed and enacted. Such a content-related approach will eventually lead to a debate on what good TB care is.

Lieke Oldenhof emphasizes in her contribution to this issue that a dilemma involves a choice between conflicting values and thereby involves a trade-off. She examines the coping strategies of a particular actor group with an existing dilemma. I examine in this paper how different actor groups define the tension between local adaptation and standardization and show that they not only handle the tension differently but also frame a potential ethical dilemma differently.

My analysis is based on more than a hundred semi-structured interviews (with public health experts, policymakers, scientists, scholars, physicians, medical staff, private practitioners, consultants and members of the civil society, community volunteers, patients and members of the international donor community); visits (to hospitals, rural and urban health centres, research institutes, laboratories, policy meetings, conferences, community projects, patient homes and treatment sites); and document research (government documents, conference proceedings, research articles, news items and the Internet). I collected data in Hyderabad, Krishna and Warangal District (Andhra Pradesh), Ahmedabad, Pune, Mumbai, Delhi, Chennai and Bangalore in two rounds of fieldwork (January 2008 – April 2008 and November 2008 – March 2009). My methodological approach was to follow actors and action (Latour 1987) which is a research heuristic that is common in Science and Technology Studies (STS). This approach does not make any *a priori* distinctions between disciplines, expertise or actors but traces actors and actions involved across different social worlds (Latour 1987; Clarke & Star 2007). It starts from the assumption that one can interact with everyone without having a degree in laboratory sciences, public health or political sciences. This is in contrast to arguing for a particular direction of change more compatible with normative (social) standards which would mean that normativity does not

reside in practices but has to be introduced from outside or from theory. The contribution of an STS-informed analysis can be to entangle the different prevailing normativities (Zuiderent-Jerak 2007). I will examine the different normative claims actors make in the debates surrounding MDR-TB and the challenges of balancing standards and local adaptation.

Handling the challenge of adherence to DOTS Plus differently

According to most actors I spoke to, balancing between standardized treatment and local adaptation is one of the main challenges of MDR-TB treatment in India. This becomes particularly clear in discussions around treatment adherence. In this section I will examine how the TB programme and its decision-makers, patients and the team at the first treatment site respond to the challenge of treatment adherence. The focus on the TB programme and its decision-makers represents the general and widespread position of the TB programme and its proponents at national levels towards standardization and local adaptation.

The TB programme and its decision-makers: Limiting local adaptation with guidelines

From the perspective of a TB programme consultant at the Central TB Division in Delhi, the biggest challenges with regard to MDR-TB treatment delivery are the treatment adherence of patients and of the staff and an expected high rate of defaulters when scaling-up the DOTS Plus services across the country (Interview, RNTCP consultant -1, Delhi, 15.1.2009). According to a TB programme officer, the main challenge is patients' compliance with the treatment, which needs a serious commitment from both the patient and the health workers. The programme officer argues: "in order to prevent MDR-TB, one has to push patients to compliance (…) Compliance is the only thing that matters!" (Interview, Hyderabad, 21.1.2008). The TB programme officers emphasize that the creation of extreme drug-resistant TB (XDR-TB) needs to be avoided and that the curative power of the second-line drugs needs to be protected, which is at risk when MDR-TB is over- or underdiagnosed and treatment is mismanaged, interrupted or inadequate. Effectiveness of MDR-TB treatment means for programme officers to stop transmission of MDR-TB and reach programmatic targets of cure and detection rate. Local adaptation of treatment guidelines is perceived to be risky and is not fostered, because it needs capacity which is often too weak across the Indian healthcare system, it might create demand that cannot be stilled by the TB programme everywhere and it potentially challenges the status quo of established control practices. The programme officers handle the tension between adherence to standardized treatment and response to local challenges by arguing for strict standardization of drug delivery (CTD 2010). Patients need to be directly observed to avoid defaulting and strict guidelines need to be applied to cope with the weak health system capacities. Underlying this perspective seems to be the concern that local adaptation

would come at the expense of control through standardization. This hints at dilemma-thinking between local adaptation and standardization.

This concern stems from a fear that a lack of standardization leads to negative programme indicators. A programme officer responsible for the TB control programme in a district or state needs to ensure that the anti-TB drugs are taken for six months, or 24 months for DOTS Plus. Given these considerations, it is understandable that most TB programme officers tend to first respond to my questions about exceptions, deviation and local adaptation from the guidelines with denial that deviation happens or is ever necessary. They would argue that the guidelines offer a solution to every situation (Interview, physician RNTCP -3, Hyderabad, 14.2.2009; physician RNTCP -4, Hyderabad, 10.12.2009; WHO RNTCP consultant -2, Hyderabad, 10.2.2009). Some interpret deviating from the guidelines as criticism of their work or as resistance to the DOTS (Plus) strategy by actors in the field (Interview, international programme manager -1, Delhi, 17.1.2009).

Local adaptation of guidelines is according to the TB programme largely taken care of by specific sub-guidelines, such as the Public-Private Mix guidelines (CTD 2008)[8] or the scheme for community DOTS providers (conveniently located DOTS providers in the patient's vicinity such as neighbours or local shops) (CTD 2010). The Central TB Division approaches standardization of MDR-TB drug delivery with a similar strategy as for the established routine TB treatment: The patient is framed as passive and the system (e.g. the TB programme) as responsible for cure – for assuring that the patients swallow the drugs, visit the DOTS provider, go for follow-up tests and comply with the treatment. Timmermans and Berg (1997) have pointed out the importance of past infrastructures, procedures and practices in creating new standards. As a former TB programme officer explains:

> Once you put the patient on treatment, he becomes a liability on the system till the end. The liabilities are onward. But it is the responsibility of the system to really see that the treatment is completed. Otherwise if you are leaving an MDR patient like that, he brings in another 10-15 patients with him each year (Interview, former RNTCP officer, Hyderabad, 27.11.2008).

According to the TB programme it is the responsibility of the programme to assure that patients swallow the drugs, visit the DOTS provider, go for follow-up tests and comply with the treatment. This is achieved by applying detailed guidelines, supervising patients and monitoring and reporting targets of cure and detection rates. In comparison to other health programmes, many of the programme officers view the services of the TB programme as an exceptional treatment, given the attention and commitment provided to the patients. The view of the patients and the way the RNTCP treats them is often characterized by a sender/receiver perspective (Interviews, international NGO programme manager -1, Delhi, 17.1.2009; -3, Hyderabad, 27.11.2008). The emphasis on the notion of noncompliance by patients in TB control implies a tendency for blaming the patient for non-adherence to guidelines and a need to control the patient and only to a lesser extent improving the knowledge about the disease (Ogden 1999;

Williams 2001; Narayan 1999). This approach results in patient education and supervision as measures to overcome default.[9] Timmermans and Mauck (2005) argue that generally in healthcare proponents of guidelines often blame the human factor for limited adherence to guidelines. This is in line with the main understanding of TB as a managerial problem and ignores the socio-political context of the patient.

Furthermore, it is generally acknowledged that the guidelines are based on certain trade-offs that need to be made. Public health in India is not necessarily social, as some programme officers argue. One example is the access criterion for patients. Some patients do not have a residential address which makes them non eligible for TB treatment by the TB programme. Programme officers argue that there is no room for treating homeless patients because outcomes are too uncertain, resources might be wasted and targets (cure rates) negatively affected. The relation between local adaptation and standardization as envisioned by the TB programme is that too much local adaptation is risky. The solution is to provide specific, strict standardized guidelines which will ensure that transmission of MDR-TB is stopped and programmatic targets are reached. This might involve trade-offs, such as that patients without a residential address must be excluded. This understanding is partly based on the assumptions that patients are passive, cannot be trusted and need to be controlled.

MDR-TB patients: Limited ability to handle local adaptation and standardization

MDR-TB patients require extra support, resources, counselling and motivation, especially because most of the patients already passed months or years of unsuccessful TB treatment. Their survival is at stake and DOTS Plus might be their last chance. Several of the patients told me they are aware of their special treatment, unique to this site. But from the perspective of patients, the guidelines cannot and should not always be followed too strictly. However, they are limited in their ability to adapt locally and thus in their ability to handle the tension differently. Despite the uniqueness of receiving free MDR-TB treatment, patients respond to these challenges with refusing treatment when side effects become unbearable or operational challenges insurmountable. For example, one young girl on DOTS Plus treatment at the first treatment site in Ahmedabad is controlling her weight. She keeps her weight below the 45kg threshold so that she does not have to take another three additional drugs, which will prevent the extra side effects (the drug regimen increases from 10 to 13 drugs if you weigh above 45kg). Other patients simply refuse to take any more painful treatment or seek out their own treatment in the private sector (the efforts to integrate the private sector into the public TB program and establish referral systems are still fragmented and in very early stages).

According to the guidelines, the DOTS provider for DOTS Plus should be supported by a trained nurse who is able to administer the daily injections (Interview, microbiologist private lab, Mumbai, 17.12. 2008). This complicates the concept of community DOTS provider. For routine TB treatment, the DOTS provider does not have to be a trained health worker but can be a neighbour or local shop-owner who might be in the vicinity or has established trust with the patient. Some of the MDR-TB

patients in Ahmedabad refuse treatment by a trained nurse and prefer receiving the injections from their regular DOTS provider with whom they have established trust and rapport, but who is often insufficiently trained (Interview, NGO treatment supervisor, Ahmedabad, 3.12.2008). Furthermore, the patients face difficulties in coping with the centralized nature of the MDR-TB treatment services. Diagnosis and treatment initiation, including one week of hospitalization,[10] are happening in accredited laboratories and designated DOTS Plus treatment sites that are mostly located in teaching hospitals within big cities. This becomes particularly obvious at the treatment site in Hyderabad which also caters to rural districts. Out of 48 patients diagnosed with MDR-TB in Hyderabad, 13 refused to initiate treatment. According to the local WHO consultant, the heavily centralized services mean that some of them travel 200km to reach the hospital. The patients would lose their daily wages every time they come for follow-ups and also during the hospitalization for pre-evaluation at the start of the treatment (Interview, WHO RNTCP consultant -2, Hyderabad, 10.2.2009).

Contrary to the passive patient approach emphasized by the TB programme, patients actively handle the tension between adherence to standardized treatment and response to local challenges. However, they do so mainly by making use of refusal. These refusal actions reveal the limited opportunities patients have to manoeuver and handle the tension between local adaptation and standardization, in that the program does not offer options to negotiate local adaptation. Rubincam and Naysmith (2009) demonstrate that poor and seemingly powerless patients can use their noncompliance in health intervention strategies as a bargaining chip to prioritize their primary needs (such as food) over secondary threats (such as sickness from the disease). I argue that this is linked to understandings of effectiveness. Effectiveness of MDR-TB treatment for patients means not only being cured, but also the ability to coordinate the treatment with other aspects of their daily life (such as being able to work, afford travel costs or cope with side effects). Interventions can be assessed on the basis of the contribution to coordination between different worlds of patients (Zuiderent-Jerak 2010). If the guidelines do not offer the opportunity for such coordination, patients have no other choice but to refuse. Patients have to oppose the standardized rules because they are not allowed to handle the tension between local adaptation and standardization in a situated manner. This does not imply an ideological opposition between local adaptation and standardization, but is rather an argument for more flexibility within standards and greater attention to different understandings of effectiveness.

Team at the DOTS Plus treatment site: Dissolving the presumed dilemma between local adaptation and standardization

At the first MDR-TB treatment site of the TB programme in a hospital in Ahmedabad, the DOTS Plus guidelines for India are being implemented, adapted and further refined since 2007. For the team[11] at the first DOTS Plus treatment site, the effectiveness of MDR-TB treatment delivery means to reach TB programme targets and to improve service delivery in order to make the treatment more bearable for patients. The problem of adherence is caused by the painful nature of both the disease (long-

term sickness and its implications on daily life, potentially advanced state and painful symptoms) and the treatment (toxic drugs, long duration of treatment, frustration). The novelty is thereby not so much treating MDR-TB as such. MDR-TB patients have been treated prior to DOTS Plus, also in the Indian public sector, but the treatment was non-standardized and non-funded (at the Ahmedabad treatment site the laboratory has been diagnosing and treating MDR-TB since 1978). The novelty is that the team can now treat MDR-TB under programme conditions and can also try to improve it. The members of the team handle the challenge of adherence by going beyond the guidelines and assessing what the role of the guidelines is in a particular situation. They thereby perform situated standardization and dissolve the presumed dilemma between local adaptation and standardization.

They regularly make additional efforts to motivate and counsel patients. They also assess what the role of the guidelines is in a particular situation which can result in deviation from the guidelines. A physician at the DOTS Plus site emphasizes that patients and DOTS providers are only human beings and both want to get a fair treatment by each other and the programme as such. Since no one can adhere to 24 months of treatment without interruption, deviation from the guidelines will always happen. For example, if the patient needs to travel, the physician would ask for permission from the superiors and give the patient the drugs for those days (Interview, RNTCP physician -1, Ahmedabad, 3.12.2008).

Local adaptation means for the physician to develop mechanisms or models that can eventually be taken up into the guidelines and replicated across the country. Replicating models which work in one region is often not possible due to differences in health system capacities and local contexts. A joint initiative to strengthen motivational support for MDR-TB patients by a pharmaceutical company and the team at the first DOTS Plus treatment faced challenges with replication as well. The programme manager recalls that in Ahmedabad all the MDR-TB patients were from a similar and smaller geographical area, whereas in Maharashtra the MDR-TB patients were scattered all over the state, in hilly terrain and difficult to reach areas. This shows that the same model for pre-treatment counselling could not be replicated across different regions. The programme manager therefore argues:

> It's very important to one, talk to the people, find out what works and work in collaboration with an administrative setup which is in place. (…) However, some things work everywhere: For example we realized that pre-treatment counselling is something very essential which was not thought of. But it would work as well as in Ahmedabad or Maharashtra or in Delhi. (…) But how it will function, how it has to be ensured that counselling takes place or that outreach workers are able to reach out to the patients; that mechanism has to be devised (Interview, consultant pharmaceutical, Delhi, 15.1.2009).

The particular mechanism to counsel the patients prior to their treatment would need to account for on-the-ground realities, such as transport modes, travel time and costs, which can be very different across India. According to the programme coordinator, it is thus necessary to develop mechanisms of local adaptation to support patients or

work with the communities. However, such practices of local adaptation need room to manoeuvre. Actors involved in this particular initiative strategically foster room to manoeuvre by establishing good relationships with decision-makers. They thereby aim to renegotiate the established balance between local adaptation and standardization. By providing additional motivational support, patients find it easier to adhere to guidelines. Thus, adherence to guidelines is actually strengthened when adapting locally rather than weakened as is often feared by the TB programme. This dissolves the presumed dilemma of standardization versus local adaptation or adherence versus deviance.

The actors at the first treatment site argue for local adaptation (in this case adding elements of individual care to motivate patients) by going beyond the treatment guidelines. This understanding, however, does not oppose standardization which is perceived to be primarily positive. Rather than limiting the local adaptation to particular sub-guidelines, as the perspective of the TB programme suggests, this implies a continuous process of local adaptation and going beyond the guidelines. The standardization of treatment delivery through guidelines implies for the team at the first DOTS Plus treatment site the potential to simplify treatment and invites improvement and collaboration. By engaging in local adaptation as an on-going learning process actors perform situated assessments of the role of the guideline in that situation, e.g. situated standardization. Zuiderent-Jerak (2010) proposes situated interventions as interventions that are strongly related to the interplay of problems that patients and practitioners encounter in daily care practices. In an interventionist STS research project in haemophilia care Zuiderent-Jerak argues that situated interventions can be a measure to avoid uncritical enhancement of compliance or excuse noncompliance with the complex reality. Adapted to this case I argue that practices of situated standardization dissolve the presumed dilemma between standardization and local adaptation.

To conclude, the problem of adherence, and therefore effectiveness, is defined differently from each perspective. Accordingly, actors have different understandings of local adaptation and standardization and thus frame the ethical dilemma differently. Implicit in the TB programme, driven by the Central TB Division, is a rather narrow definition of local adaptation. This differs from the understanding of local adaptation as an on-going learning process based on field experiences which the team at the first treatment site reveals. The TB programme and its decision-makers thereby prioritize a particular value over the other, whereas the team at the first DOTS Plus treatment site applies a differentiated approach to values (see Oldenhof's distinction between different coping strategies for dilemmas in this issue). Furthermore, actors balance local adaptation and standardization differently: Controlling patients and healthcare providers, coordinating treatment and personal challenges or coping with a complex treatment regime by going beyond the guidelines. For the TB programme and its decision-makers, effectiveness means stopping transmission and reaching programmatic targets. The problem of adherence means that patients need to be directly observed, and strict guidelines need to be applied, due to the weak health system capacities. For patients, adherence and effectiveness means both cure and being able to coordinate the treatment with other challenges in their life. They have only limited room to

balance local adaptation and standardization. For the team at the treatment site the problem of adherence is caused by the painful nature of the treatment and the disease for which patients need extra support. Effectiveness means reaching targets and innovating service delivery of a complex treatment regime by adding onto the treatment guidelines and making the treatment more bearable for patients.

Conclusion

The DOTS Plus guidelines for MDR-TB treatment delivery in India provide standardized care to patients in order to respond to weak capacities and health system constraints. At the same time these guidelines are challenged by the local context through, for example, demands for extra support to individual patients. These challenges between standardization and local adaptation are also characteristic for routine TB treatment delivery, but are rendered more urgent in the case of MDR-TB. The treatment of MDR-TB therefore offers an opportunity to rethink and improve routine TB treatment.

The main conclusion of this paper is that there are differences between actors' practices and understandings of standardization and local adaptation. The relationship between local adaptation and standardization is therefore better characterized in terms of effectiveness which actors define differently rather than as ideological opposites. The programme officers at the Central TB Division, patients and the team at the first treatment site all differ in how they define local adaptation. They argue for different forms of standardization and have different notions of effectiveness. There is a risk of falling into dilemma-thinking, that local adaptation comes at the expense of standardization and vice versa (as particularly the responses of the TB programme show). Yet the relation between local adaptation and standardization is characterized in terms of effectiveness of which actors have different understandings and not in terms of a dominant dichotomy.

Programme officers allow local adaptation with strict guidelines based on their understanding that in order to be effective patients need to adhere and therefore need to be controlled. Patients try to be effective according to their understanding of coordinating treatment with daily life challenges as well, yet are limited in their options to manoeuvre. The team at the first treatment site uses standardization to explore further mechanisms of local adaptation and makes use of its privileged position at the initial treatment site with strong relations to decision-makers. Furthermore, I showed how the actors at the first treatment site dissolve the presumed dilemma in their practices by engaging in situated standardization. This analysis helps to have a more content-related discussion and to avoid clashes of seemingly opposite ethical stands around the question of how to standardize and scale-up treatment delivery for MDR-TB patients. Lieke Oldenhof's contribution to this issue argues in a similar vein that good care (e.g. effectiveness) means different things from different actor perspectives. This paper focused on the different ways in which actors handle the tension between local adaptation and standardization and pays less attention to the relationship between for

example programme officers and physicians. The relationship between different actors (profession and management) is examined more closely in Annemiek Stoopendaal's paper (this issue). The argument for an on-going examination and negotiation of what constitutes good care is, however, a similar one.

The paper thereby provided a first step to analysing standardization as a process rather than as a product that needs to be implemented. An empirical lesson for medical ethics from this paper is that it is important to avoid taking sides in ideological debates on local adaptation versus standardization in public healthcare challenges. Instead, it makes sense to analyse practices and conceptualizations of different actors in order to find out how dilemmas are handled differently across different social worlds of researchers, politicians, practitioners and patients.

A continuous negotiation of what good care is can show that presumed ethical dilemmas involved in care delivery are dissolved in actors' daily practices or are resolved during the research process. This represents important practical knowledge particularly during guideline development. The argument is in line with calls for more interventionist approaches in STS (Zuiderent-Jerak 2007, 2010). It is also in accordance with the empirical turn in health care ethics where scholars researching ethics in daily care practices argue that researchers intervene normatively with the field of study. They do so by articulating the ethical content of actors' practices; by placing everyday practices on the agenda alongside big ethical questions; by examining different views without any a priori distinctions between their truthfulness; and by providing actors material for reflection and design for new strategies (Willems & Pols 2010). This paper has taken a first step into the direction of such a normative intervention by analysing a basic dilemma in TB control between local adaptation and standardization which is often accepted as something that cannot be avoided. I showed that actors handle the relation differently based on different understandings of effectiveness and at times dissolve the tension in their practices. It is likely that practices of situated standardization can be found not only at the first MDR-TB treatment sites but across TB control in India. It therefore makes sense to further analyse and make more explicit situated forms of standardization and different conceptualizations and practices related to the interplay of local adaptation and standardization in treatment delivery.

Notes

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1 TB is an infectious disease caused by the Mycobacterium tuberculosis which is commonly transmitted through inhalation of bacteria into the lungs. In its most common form of pulmonary TB, the disease, if untreated, will lead to gradual destruction of lungs, increasing incapacity of bodily functions and death. The disease is curable with a cocktail of anti-TB drugs that have to be taken for at least six months.

2 Public goods are contrary to private goods non-rival (not diminished by use) and non-excludable (if the good is produced, it is freely available to all) and they require collective action (Smith & MacKellar 2007). The free market generally does not provide sufficient public goods for societies which therefore need to be provided or fostered by governments (examples are public security, greenhouse gas emission control, financial regulation, museums or infectious disease control).

3 The anti-TB drugs for the complete treatment come in a box which is transferred to the DOTS Plus provider along with a copy of the patient's record, the TB Treatment Card. The DOTS Plus provider is preferably in the patient's vicinity. During the intensive phase, the patient has to swallow the drugs daily under the supervision of the DOTS Plus provider who ticks off the boxes on the TB treatment card for each visit. In the continuation phase the patient is only supervised during swallowing the first dose of each week when he/she collects the weekly tablet strips from the DOTS Plus provider and during random visits by health workers. The DOTS provider also checks the empty foils of the tablet packs (CTD 2005). The DOTS providers store the anti-TB drugs and report who is completing the treatment. They are supposed to follow-up patients who do not come to swallow their drugs for several days. The aim is to ensure adherence to treatment and quickly identify patients who are defaulting on treatment (Collins, Green & Newell 2002).

4 Those do not differ from routine TB treatment. Yet, these challenges become more urgent in the case of MDR-TB, because the treatment is longer, has to be taken daily, involves additional follow-up tests and drugs that are more difficult to administer and to bear.

5 DOTS Plus is the treatment strategy for MDR-TB. It is based on DOTS, directly observed treatment, short course, which is the strategy for routine TB treatment by the WHO that is being applied worldwide in slightly varied national adaptations. The DOTS strategy consists of five elements: government commitment, case detection by sputum microscopy, standardised treatment regimens of six to eight 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 2010).

6 The costs for the treatment of MDR-TB are much higher than for regular TB: Treating a TB patient costs the RNTCP around Rs600 over six to eight months. Treating a MDR-TB patient costs the RNTCP Rs150'000 over 24-28 months. (Interview, RNTCP consultant -1, Delhi, 15.1.2009) (Sinha 2008) (At the time of my fieldwork this equalled roughly USD8 for regular TB and USD2000 for MDR-TB treatment).

7 The first-line drugs are the ones comprising the standard DOTS regimen. The DOTS Plus drug regimen comprises of six drugs, kanamycin, ofloxacin (levofloxacin), ethionamide, pyrazinamide, ethambutol and cycloserine, during six to nine months of the intensive phase and four drugs, ofloxacin (levofloxacin), ethionamide, ethambutol and cycloserine, during the 18 months of the continuation phase. P-aminosalicylic acid (PAS) is included in the regi-

men as a substitute drug if any bactericidal drug (K, Ofl, Z and Eto) or two bacteriostatic (E and Cs) drugs are not tolerated (CTD 2009).

8   Under the Public-Private Mix (PPM) guidelines, the private medical sector and civil society can be included as partners of the RNTCP, with the aim to strengthen the treatment efforts of the government.

9   If default is understood as poor TB case management, as a result of systemic failures of the health services, then the solution would entail increased funding and improvement of infrastructural functioning and capacity building in public health services (Narayan 1999).

10 During the admission to the hospital for the first week of the treatment, reactions to the drugs are monitored. Before the treatment initiation, pre-treatment evaluations are undertaken where the main bodily functions are tested (to make sure the patient's organs are capable of taking the DOTS Plus treatment).

11 The team at the first MDR-TB treatment site in Ahmedabad consists of several physicians, laboratory workers, field staff and a WHO consultant.

References

Clarke, A.E. & L.S. Star
    2007   The social worlds framework: A theory/methods package. In: E.J. Hackett et al. (eds), *The handbook of science and technology studies.* Third edition. Cambridge MA: MIT Press, pp. 113-37.

Collins, C.D., A.T. Green & J.N. Newell
    2002   The relationship between disease control strategies and health system development: the case of TB. *Health Policy* 62 (2): 141-60.

Collins, H.M.
    1985   *Changing order: Replication and induction in scientific practice*. London & Beverly Hills: Sage Publications.

CTD
    2005   *Technical and operational guidelines for tuberculosis control*. New Delhi: Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, India.
    2007   *Multi-drug resistant and extensively drug resistant TB in India. Consensus statement on the problem, prevention, management and control*. From the consultative meeting of national experts organized by the TB Research Centre, ICMR, Govt. of India, on 14-15 September 2007. New Delhi: Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, India.
    2008   *RNTCP Revised schemes for NGOs and private practitioners*. New Delhi: Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, India.
    2009   *RNTCP DOTS Plus guidelines*. New Delhi: Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, India.
    2010   *RNTCP DOTS Plus guidelines*. New Delhi: Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, India.

Enarson, D. & N. Billo
    2007   Critical evaluation of the Global DOTS Expansion Plan. *Bulletin of World Health Organisation* 85 (5): 395-98.

Farmer, P.

2003   *Pathologies of power: Health, human rights and the new war on the poor.* London & Berkeley: University of California Press.

Gandy, M. & A. Zumla (eds)

2003   *The return of the white plague: Global poverty and the 'new' tuberculosis.* London, New York: Verso.

Kim, J.Y. et al.

2003   From multidrug-resistant tuberculosis to DOTS expansion and beyond: Making the most of a paradigm shift. *Tuberculosis* 83 (1-3): 59-65.

Latour, B.

1987   *Science in action: How to follow scientists and engineers through society.* Cambridge, MA: Harvard University Press.

Mead, N. & P. Bower

2000   Patient-centredness: A conceptual framework and review of the empirical literature. *Social Science & Medicine* 51 (7): 1087-110.

Moore-Gillon, J.

2001   Multidrug-resistant tuberculosis. This is the cost. *Annals of the New York Academy of Science* 953b (1): 233-40.

Narayan, T.

1998   *A study of policy process and implementation of the national tuberculosis control programme in India.* Doctoral thesis, London University.

Ogden, J.

1999   Compliance versus adherence: Just a matter of language? The politics and poetics of public health. In: J.M. Grange & J. Porter (eds), *Tuberculosis: An interdisciplinary perspective.* London: Imperial College Press, pp. 213-34.

2000   Improving tuberculosis control – social science inputs. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 94 (2): 135-40.

Ormerod, P.

2001   The clinical management of the drug-resistant patient. *Annals of the New York Academy of Science* 953b (1): 185-91.

Porter, J.D.H. & J. Ogden

1999   Public health, ethics and tuberculosis. Is DOTS a breakthrough or inappropriate strategy in the Indian context? *Indian Journal of Tuberculosis* 46: 3-10.

Rubincam, C. & S. Naysmith

2009   Unexpected agency: Participation as a bargaining chip for the poor. *Health & Human Rights in Practice* 11 (1): 87-92.

Sharma, S.K. & A. Mohan

2004   Multidrug-resistant tuberculosis. *Indian Journal of Medical Research [NLM – MEDLINE]* 120 (4): 354-76.

Sinha, K.

2008   Drug-resistant TB to be diagnosed in just 2 days. *The Times of India*, 1 July.

Smith, I.

1999   Stop TB: Is DOTS the answer? *Indian Journal of Tuberculosis* 46: 81-90.

Smith, R.D. & L. MacKellar

2007   Global public goods and the global health agenda: Problems, priorities and potential. *Globalization & Health* 3: 9. http://www.globalizationandhealth.com/content/3/1/9.

Timmermans, S. & M. Berg

1997   Standardization in action: Achieving local universality through medical protocols. *Social Studies of Science* 27: 273-305.

2003   *The gold standard. The challenge of evidence-based medicine and standardization in health care*. Philadelphia: Temple University Press.

Timmermans, S. & A. Mauck

2005   The promises and pitfalls of evidence-based medicine. *Health Affairs* 24 (1): 18-28.

Udwadia, Z.F.

2008   XDR-TB in Inda: When will we heed the alarm? *Journal of the Association of Physicians of India (JAPI)* 56: 409-10.

Walt, G.

1999   The politics of tuberculosis: The role of process and power. In: J.D.H. Porter & J.M. Grange (eds), *Tuberculosis: An interdisciplinary perspective*. London: Imperial College Press, pp. 67-98.

WHO

2006   *Guidelines for the programmatic management of drug-resistant Tuberculosis.* WHO/HTMTB/2006.361.

2010   *Tuberculosis (TB), Pursue high-quality DOTS expansion and enhancement.* http://www.who.int/tb/dots/en (04-05-2010).

Willems, D. & J. Pols

2010   Goodness! The empirical turn in health care ethics. *Medische Antropologie* 22 (1): 161-70.

Williams, G.

2001   Holding the patient. *Annals of the New York Academy of Science* 953b (1): 199-207.

Zuiderent-Jerak, T.

2007   Preventing implementation: Exploring interventions with standardization in healthcare. *Science as Culture* 16 (3): 311-29.

2010   Embodied interventions – interventions on bodies: Experiments in practices of science and technology studies and hemophilia care. *Science, Technology & Human Values* 35 (5): 677-710.

Zuiderent-Jerak, T. & M. Berg

2010   The sociology of quality and safety in healthcare: Studying a movement and moving sociology. In: C.E. Bird et al. (eds), *The handbook of medical sociology.* Sixth edition. Nashville: Vanderbilt University Press, pp. 324-37.