Achieving accessible and sustainable tuberculosis control in high TB burden countries

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CHAPTER 1

Introduction

Chapter 1 Introduction

This chapter will first give an overview of modern tuberculosis control and its embeddedness in the health system. Subsequently, a brief review will provide an overview on existing knowledge on access to TB care in fragile states. Thereafter the rational for this thesis with the corresponding research questions will be introduced, followed by the conceptual framework that will form the theoretical basis of this thesis. Finally, the outline of the thesis will be explained.

Tuberculosis and tuberculosis control

With 1.1 million deaths and 8.8 million new cases in 2010 [2], tuberculosis (TB) continues to be among the deadliest diseases in the world. Its widest presence is generally connected with co-infections suppressing the immune system, foremost HIV/AIDS, and with deprived living standards, poor hygiene, crowded living conditions and malnutrition. It is therefore not surprising that the TB endemic areas of this world are the poorest countries where HIV ravages. The World Health Organization (WHO) regularly publishes a list of 22 countries which carry 80% of the world's burden of TB cases [2]. These are mainly the population-rich countries such as China, India and Russia as well as the sub-Saharan countries highly affected by HIV/AIDS. For the global fight against TB, the Stop TB department of WHO together with the Stop TB Partnership developed a plan for countries addressing all aspects of TB control, the Stop TB Strategy [1]. It contains the globally accepted TB control approach (DOTS) which emphasizes early case finding to stop continued transmission of the TB bacillus in the respective community and the guided treatment of TB patients under institutional or private supervision to ensure positive treatment outcomes. The Stop TB Strategy is embedded in each country in the national health agenda and is carried out by the national TB control programs (NTP) within the respective Ministry of Health (MoH). TB control therefore can only be effective, if it finds its place within a functioning national health system.

The Stop TB Strategy [1]

1. **Pursue high-quality DOTS Expansion and Enhancement**
   - Political commitment with increased and sustained financing
   - Case detection through quality-assured bacteriology
   - Standardized treatment with supervision and patient support
   - An effective drug supply and management system
   - Monitoring and evaluation system, and impact measurement
2. **Address TB/HIV, MDR-TB and other challenges**
   - Implement collaborative TB/HIV activities
   - Prevent and control multidrug-resistant TB
   - Address prisoners, refugees and other high-risk groups and special situations
3. **Contribute to Health System Strengthening**
   - Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems
   - Share innovations that strengthen systems, including the Practical Approach to Lung Health
   - Adapt innovations from other fields
4. **Engage all care providers**
   - Public-Public, and Public-Private Mix (PPM) approaches
   - International Standards for TB Care (ISTC)
5. **Empower people with TB and communities**
   - Advocacy, communication and social mobilization
   - Community participation in TB care
   - Patients' Charter for Tuberculosis Care
6. **Enable and promote research**
   - Programme-based operational research
   - Research to develop new diagnostics, drugs and vaccines

Interaction of national TB control programs with national health systems

Although a national TB control program cannot be seen as a separate entity from the rest of the health system, it often is. The reason lies in its structure, finance and management, as promoted by the founders of modern TB control and carried forward by the WHO. When TB patients started to overwhelm health system structures with sheer numbers, it was quickly observed that increased case finding and good treatment outcomes could only be achieved, if some elements of the process from diagnosis to cure received extra attention [3]. This is one the one hand because of the long treatment duration which was previously 8-12 months and is now generally 6-8 months, the quick, airborne transmission of TB which is difficult to control and the substantial risk of drug resistance development as a cause of non-adherence to treatment and dosing guidelines by doctors and non-adherence to medicine intake by patients [4]. Therefore, special ("vertical") elements were introduced in almost all existing TB programs [5]. It is rare that a national TB program is fully integrated into a health system, meaning that it does not have its own, separate elements; (perhaps only seen in some western countries that have a very low TB burden).

These separate elements are usually in respect to a) treatment adherence whereby the TB program establishes a system which ensures that the TB patient is supervised during his/her entire treatment duration. This is sometimes still called DOTS (directly observed treatment, short-course) describing the daily observation of drug intake at a health facility by a health worker or by a relative or community-volunteer at home [1]. The second separate element is b) the establishment of district, regional and national supervisors whose role it is to ensure that health facilities follow the national TB control guidelines and who provide anti-TB drugs, and collect and transfer the TB specific patient data to the national level [6]. The third and much influential element c) is funding [5]. National TB control programs have substantial needs for laboratory supplies, drugs, and (senior) human resources who are solely responsible for TB control on the national level in the management, planning and policy unit, on the regional level for supervisory and planning functions and on sub-regional levels for service delivery. Additional funding usually comes from non-domestic sources (donors)

and is earmarked. The TB programs thus usually have their own operational budget with planning and reporting cycles. The fourth element d) is data. TB programs usually collect their own data which they pass on in an aggregated form to the national health information system units. Because specific TB indicators have been defined at international level by the World Health Organization's Stop TB Department, all TB programs collect the same data around the world, which makes it easy to compare TB program results across countries [6-8].

WHO [5] calls some elements of TB control the "non-negotiables". These are the inclusion of 1) TB in the health sector strategy of the country, 2) TB services in the essential package of services, 3) anti-TB drugs on the list of essential medical products, and 4) TB specific indicators in the national health information management system. Some TB programs even went as far and took central elements out of the national system, such as anti-TB drugs and laboratory supplies for AFB smear microscopy including their quantification, ordering, storage and delivery.

The aim of a TB control program is to find TB suspects as soon as possible and to treat them successfully without relapse [4]. If a program managed to do that, the diagnosed patients would show TB symptoms, but would not have the full-blown disease with severe illness and they would not die. No TB program in the world has so far demonstrated to achieve this on a large, nation-wide scale. Patients often seek help only very late, when they are very ill and have already infected their family members, friends and neighbors [9, 10]. At the start of our studies, it was however not completely clear in the literature, which barriers patients face that keep them from being diagnosed and cured, where they go and how much they spend on the way to the cure. Are potentially all TB patients confronted with such issues and are these systematic to TB control programs hindering access to care? To what extent do these questions depend on particularities of certain health systems, and how can the programs address these issues in a sustainable way?

While developing countries have already considerable problems of ensuring access to care, countries with unstable security situations and weak governance have additional problems in ensuring the provision of services in the first place.

TB care in fragile states

Tuberculosis care has elements such as DOTS and follow-up tests that require continuous and stable services. This is all the more difficult in countries facing problematic security situations, intermittent or no health care services, and lack of funding for basic medicines, laboratory supplies and staff. Fragile states are defined by the OECD Development Assistance Committee [11](p.15), as a state that "lacks the capacity (effectiveness) and/or willingness (legitimacy) to sustain itself over time. It is unable to perform the basic functions of a state: to maintain security across its terrain, to enable economic development, to ensure the essential needs of its population are met". Violence and war result in the displacement of staff and patients, the collapse of infrastructure, disruption of supply lines and interruption of routine supervisory work [12, 13]. Because TB treatment lasts for at least six months and treatment adherence is essential, WHO/UNHCR [14] advises to start TB control programs only when certain conditions are met, such as guaranteed funding for at least 12 months, an end of the emergency situation, and the provision of basic sanitation, food, water and clinical services.

Rationale and research questions

The rationale for this thesis is investigating the interactions between TB control and the health system with regard to access to care. A particular focus will be taken on the financing of health services and service delivery from the patient and health system perspectives.

The primary research question of this thesis is: "How can accessible and sustainable tuberculosis control be achieved in high TB burden countries?"

It will be addressed by four sub-questions. These are:

1. How can TB control function in fragile states given a limited governance and human resource situation?
2. What are the challenges for the poor and vulnerable in accessing health services, information and medical products?
3. What kinds of costs do TB patients face before/during diagnosis and during treatment in high TB burden countries?
4. Are high TB burden programs sustainably funded?

Conceptual Framework

For this purpose, the health system building blocks as defined by WHO (2010) will serve as an overall concept for the primary and secondary research questions. These six building blocks (figure 1) are central to a functioning health system. WHO [15] considers targeted investments into these building blocks paramount to keeping health systems on track towards achieving results in combating diseases and quality services.

Figure 1: The health system building blocks

The building blocks are briefly explained here:
Authorities exercising **leadership and governance** take responsibility for steering the health sector by formulating policies, strategies and guidelines for all aspects of the health system. **Health information systems** need to provide the necessary information on the performance of the health system for decision-making and for evaluating access to pharmaceuticals, infrastructure and quality services through surveys, routine data, civil registration systems, and epidemiological surveillance. **Health financing** is important to achieve universal coverage by removing financial barriers to accessing quality care, and preventing financial hardship because of (catastrophic) expenditures. **Human resources for health** include recruitment, education, and training to advance productivity and performance through regulatory mechanisms, incentives, norms and support systems with the aim to retain health care workers in an enabling working environment. **Essential medical products and technologies** of assured quality and cost-effective are important for the successful treatment of patients according to diagnostic and treatment protocols who have access to these products through a functioning supply system. **Service delivery** is guaranteed through a basic package of patient-centered, effective services according to primary care concepts by providers who are accountable for adhering to quality and safety standards.

Outline of Thesis

The introduction chapter will be followed by a comprehensive literature review on patient costs in **chapter 2**. The literature review will help identify what kinds of costs are incurred by the patient on his or her pathway from symptoms to cure. The review therefore forms the basis to develop a tool to estimate patient costs. This tool will then be used for the studies that are later presented in chapters 4, 5 and 6. The tool itself is included in this thesis in Annex 1.

As shown in figure 2, **chapter 3** will look at the functioning of TB control in fragile situations taking the example of four fragile states, where common parameters of a functioning state are not given, such as a stable government, basic security and

basic service provision. Health care delivery is particularly problematic in fragile states often connected with increased incidence of communicable diseases, among them tuberculosis. A structured inventory to extract common themes specific for TB control in fragile states is conducted among twelve providers of technical assistance who have worked in fragile states. The themes are applied to the TB control programs of Afghanistan, DR Congo, Haiti and Somalia.

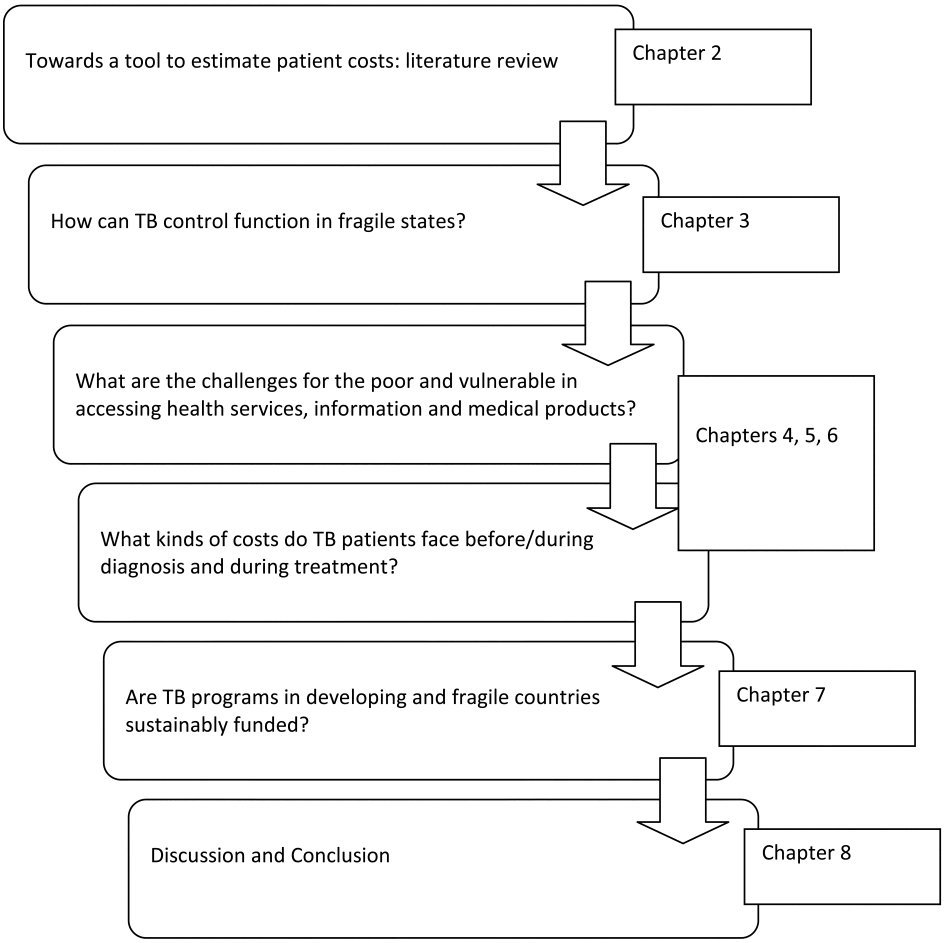
Chapter 4, 5 and 6 will answer research questions 2 and 3. Chapter 4 introduces the 'Tool to Estimate Patients' Costs' and its pilot results in Kenya. It is developed to determine the kinds of barriers and costs that TB patients face before/during diagnosis and treatment. Furthermore, its usability for TB programs and non-governmental organizations, as well as its strengths and weaknesses are assessed. Having introduced the Tool, **Chapter 5** describes the tool's implementation in the Dominican Republic in 2009 to answer research question 3. The direct (out of pocket) and indirect (opportunity) costs of new, retreatment and multi-drug resistant TB patients before and during diagnosis and during treatment are investigated. The aim of the study is an evidence base upon which recommendations and interventions can be formulated. As a next step, **Chapter 6** then presents comparative data on patient costs in three countries on three continents allowing the confirmation of similar patterns across countries, overall conclusions and policy recommendations. The settings are the national tuberculosis programs of Ghana, Viet Nam and Dominican Republic. The objective of the study is to assess the direct and indirect costs of TB diagnosis and treatment for patients and households in all three countries; furthermore the chapter aims to compare the results of three countries and to draw conclusions from potentially similar patterns.

Chapter 7 takes the perspective of the health system for financing TB control to answer research question 4, and discusses the extent and impact of external funding for high TB burden countries. The literature suggests crowding-out effects of government funding for health happen in low-income, high HIV burden countries. In a short survey, we investigate the hypothesis that domestic funding

for TB control has decreased in eleven low income, high TB burden countries in the context of changes in GDP, development assistance inflows, and national health expenditures.

Finally, **Chapter 8** discusses the findings of chapters 3-7, summarizing the answers to the primary and secondary research questions and concluding with six major policy recommendations. Before concluding this thesis, remaining questions will be outlined and a future research agenda will be suggested.

Figure 2: Outline of thesis



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CHAPTER 2

Towards a tool to estimate patient costs: literature review

KNCV-Tuberculosis Control Assistance Program (TBCAP) / Verena Mauch

This chapter is based on the "Tool to Estimate Patients' Costs", published as

TB CAP. Tool to Estimate Patients' Costs. 2009; Available from: http://www.stoptb.org/wg/dots_expansion/tbandpoverty/spotlight.asp
and http://www.tbcare1.org/publications/toolbox/access/

Chapter 2 Towards a tool to estimate patient costs: literature review

ABSTRACT

Objectives

The objective of this review is to provide a detailed account of research findings at which stage what kinds of costs are incurred by tuberculosis (TB) patients. The findings of the review will form the basis upon which a tool to estimate patients costs will be developed.

Methods

Literature was identified through searches of meta-databases and through examining bibliographies and references of published material. Publications in English, French and German from 1990 until including 2007 were sought. Inclusion criteria were applied to identify studies that deal with low or middle-income countries or with methodologies employed to measure cost of illness (including studies not dealing with TB). Studies exclusively dealing with costs to healthcare providers were excluded.

Results

A total number of 29 studies were identified. In addition, three studies that only deal with patient delays were included for comparison of delay times. Costs to patients depend on the nature, frequency and duration of the illness, the healthcare seeking behaviour of affected individuals, the type of treatment, the direct and indirect costs of diagnosis and treatment, the mobilization of resources, and the resources available to the household or patient. The total costs of a TB episode amount to 20-30% of monthly household or per capita income, or 10-90% of annual household income, or 15% of Gross Domestic Product per capita.

Conclusion

Despite difficulties to compare study results and methodologies, this review shows that TB patients incur enormous direct and indirect costs before and during diagnosis and during treatment. The tool to be developed should identify the above mentioned parameters as well as HIV-related costs, coping costs and the value of household work. The tool should be flexible enough to deliver meaningful data with small sample sizes and it should be adjustable to the local context.

1. INTRODUCTION

The objective of this review is to provide a detailed account of research findings at which stage what kinds of costs are incurred. The findings of the review form the basis and context upon which a tool to estimate patients costs is to be developed. The review has been published elsewhere by the author of this thesis [1]. The developed tool is included in Annex 1 of this thesis.

2. METHODS

Literature was identified through searches of meta-databases such as PubMed/Medline, EBSCO host, Elsevier, Science Direct and to a large extent through examining bibliographies and references of published material. Publications in English, French and German, with a special focus on publications from 1990 until including 2007 were sought.[1] Inclusion criteria were applied to identify studies that deal with low or middle-income countries or with methodologies employed to measure cost of illness (including studies not dealing with TB). Studies exclusively dealing with costs to healthcare providers were excluded. Studies were screened for methods employed, the stage of the

[1] Search keywords included TB + patient cost, household cost, cost diagnosis, spending, treatment cost, affordability, cost, cost-effectiveness,TB-HIV, Coinfection, HIV, DTC, VTC, cost evaluation, expenditure, socioeconomic, care barriers, treatment affordability, financial costs, economic costs, economic burden, economic impact, access to treatment, economic evaluation, methods cost evaluation, healthcare costs.

diagnostic/treatment process when costs were assessed and findings related to delays and indirect and direct costs for patients or households.

3. RESULTS

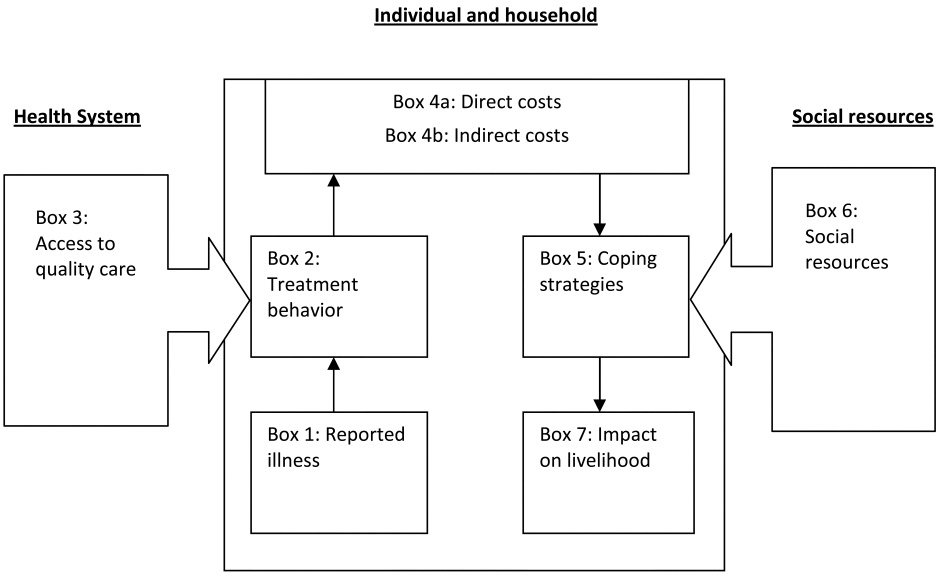
A total number of 29 studies were identified. In addition, three studies that only deal with patient delays were included for comparison of delay times. The studies cover the following countries: Africa: Malawi, Zambia, Sierra Leone, Ghana, South Africa, Ethiopia, Tanzania, Gambia, Uganda; Asia: India, Thailand, Myanmar, Bangladesh, Viet Nam, China; Latin America: Haiti, Bolivia.

3.1. Definitions

Studies on the cost of illness to patients or households aim to get a comprehensive idea of illness costs incurred by patients. The economic unit is either the individual or the household. Since illness costs fall on the caregiver and the patient, the household is generally the preferred unit of analysis, but data is often collected on a per capita level. This review subdivides costs incurred into the stages where they occur: 1) before diagnosis, 2) during diagnosis / pre-treatment, 3) during treatment.

The causal linkages of these factors are depicted in figure 1 (by Russell [2], p.148):

Figure 1: Causal linkages of TB patient costs



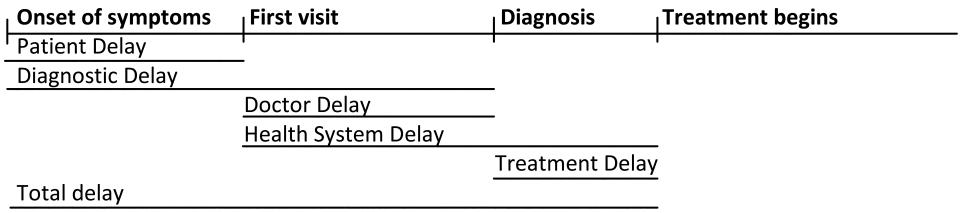
At the stage of boxes 1 and 2, decisions are made whether and how treatment is sought as a response to the event of illness. The health system is captured in Box 3. Direct costs in Box 4 capture expenditures related to seeking treatment while indirect costs are loss of labor time for patients and their caregivers. The severity of illness and characteristics of health services affect direct and indirect costs and influence access to and choice of provider. The coping strategies and social resources to tap into (Box 5 & 6) while struggling with this burden determine household assets and impoverishing processes (Box 7), hence the link between illness and poverty [2].

Boxes 1, 2 and 3: Reported illness, treatment behavior, access to quality care

Delays are usually defined as the time span from the onset of symptoms to diagnosis [3-8]. These delays do not only increase the infectivity of a patient and lead to more serious illness [7, 9] by the time the patient presents him/herself, but also represent a time span in which additional costs are incurred. The delay can be subdivided into the period from onset of symptoms until a patient

presents him/herself at a health facility (patient delay), the period from presentation to diagnosis (diagnostic delay), the period between first visit to a health facility and diagnosis (doctor delay), the period between diagnosis and beginning of treatment (treatment delay) and the time span between first visit and start of treatment (health system delay) (figure 2) [10, 11].

Figure 2: Type of delays



Costs are then also incurred depending on the health care seeking behavior of the patient and his/her access to quality care. Visits to several providers with different outcomes and diagnoses or hospital visits cost more than one visit to a TB clinic with a free, quality ensured sputum test, an additional HIV Test and enrollment into TB treatment on the very same day.

Boxes 4a and 4b: Direct and indirect costs

Studies on the cost of illness to patients or households aim to get a comprehensive idea of illness costs incurred by patients. Illness costs are broken down into direct and indirect costs. Direct costs are out-of-pocket costs linked to seeking diagnosis and treatment including medical expenses, fees, transport, accommodation and food expenditures. Indirect (opportunity) costs differ from financial cost as they include the cost of foregone income due to the inability to work because of the illness and loss of time due to visits to health facilities, time spent on the road to and at health facilities, lost productivity and loss of job.

Boxes 5 and 6: Coping strategies, social networks

Households and individuals try to react to these additionally incurred costs through coping strategies to meet daily requirements despite extra expenditures

or loss of income. These include the sale of assets, taking up debt, lending money from friends, neighbors or family, saving on food or other items, taking a child out of school to care for the patient or taking up another job [2].

Box 7: Impact on livelihood

The economic burden of TB can be well-understood with the help of percentage of income. The poor spend a far greater proportion on meeting basic needs (food etc) whereas the non-poor have more disposable income. The burden of each USD spent is significantly higher for the poor. Russell [2] deems a cost burden of more than 10% of annual household income to be already catastrophic for a household's financial situation.

3.2. Costs incurred before diagnosis

Delays

Studies suggest that the delay caused by the health system is longer than the patient caused delay [6-8, 12-14], in Ghana especially for rural dwellers [7]. Demissie's [15] study found a much shorter system delay than patient delay, but it recognizes its findings to be low compared to findings of other studies. Lonnroth [16] found patient and provider delay to be more pronounced in urban areas because of more options, weak referral and coordination mechanisms.

The times of delay from onset of symptoms to diagnosis vary from study to study to a great extent, ranging from 8 weeks [4, 6, 15] to 19 months [9]. The majority reports time spans between 2-4 months for adults [4-7, 15] and 1 month for children [8] with the number of health encounters during this time ranging between 2.7 and 6.7 [3, 4, 6, 9].

Pre-diagnostic Direct costs

Patients repeatedly cited lack of money in general and transportation costs in particular as reasons for delay [4, 6, 9, 12, 17, 18]. In Needham's study [5] in Zambia, transportation costs amounted to 16% of mean monthly income. The amount of transportation varies with urban or rural location of the patient.

Patients in Zambia living outside Lusaka spent twice as much on transport than those living in the proximity of or in Lusaka [4]. In his study of 687 patients in Thailand, Kamolratanakul [19] determined the direct average cost to households between $55-225. This is in line with findings by Jacquet [20] in Haiti. Russell [2] determines direct costs to amount to 5-21% of annual household income.

Several studies have reported pre-diagnostic costs incurred through visits to private providers, pharmacies and traditional healers [3, 6, 13, 17]. Needham [6] notes that TB infected persons in his study in Malawi paid 10% of their monthly income to traditional healers for consultation. These visits were associated with longer delays between 15 and 41 days. Lonnroth [13] found that 65% of the study population in Vietnam had been treated with TB drugs by more than one provider, while 50% of patients opted for private care. The public program was perceived to be more time consuming with repeated visits for diagnostics and long-waiting times.

Pre-diagnostic Indirect Costs

Most of the studies dealing with pre-diagnostic costs focussed on lost income, days of work lost, decreased earning ability, change in work and costs associated with coping strategies [3, 4, 17, 18]. Indirect cost estimates range from $16 [3, 4] (Malawi, Bangladesh, India, Zambia) to $68 [20] (Malawi, Zambia). In these studies, workdays lost range from 18 [4] to 48 [5] (both Zambia) for patients and 9 to 13 [3] for guardians. Muniyandi [17] (India) reports 71% of patients borrowing money to cope with costs. Croft [18] (Bangladesh) reports similar findings with half of her study population coping by selling land and livestock or taking out a loan.

Pre-diagnostic Total Costs

Total costs (direct and indirect) for patients prior to diagnosis, measured as % of mean monthly income, varies between 127% [4] and 135% [3]. In Dollar terms, this amounts to 59 and 29 US$ respectively. Lonnroth [13] found total costs to lie between 15 and 77 US$. Needham [4] found caregiver costs to amount to 31% of

mean monthly income. Striking is the difference between costs expressed in mean monthly income between the poor and non-poor in Malawi [3]. Whereas the poor have associated costs amounting to 244% of their monthly income on accessing diagnosis, the non-poor's burden amounts to 129%. Needham [4] reports economic loss to be especially grave for self-employed persons.

3.3. Costs during diagnosis / pre-treatment

Costs specifically measured for diagnosis are difficult to discern and rarely addressed by themselves. Most studies combine the assessment of diagnostic costs with costs occurring before diagnosis or during treatment. Netherless, if costs occurring at the diagnostic stage were reported separately in studies, they are reported here as well.

Delays

Two studies in Malawi and Bolivia [3, 21] looked specifically at pre-treatment delays including the delay before diagnosis. Lambert [21] found pretreatment delays to be mostly due to the provider (14 weeks) and less due to the patient (9 weeks), with an average total of 12.6 weeks. Lonnroth [14] reports 15 days delay from first contact with the health system to treatment due to the provider and a total of 26 days (3.7 weeks) from onset of symptoms to treatment start. Kemp [3] in Malawi found that 4.5-6 visits to health centers were necessary before treatment was started.

Direct costs during diagnosis

Direct costs incurred during diagnosis range widely, per household between $2 in Tanzania[22] and $57 in Thailand [19], and per patient between $6 in India [23] and $130 in Bangladesh [18]. The majority lies between $10-50. Russell [2] found pre-& post-diagnosis direct costs to amount to 8-13% of annual household income.

Cases of over-prescriptions, charges for drugs (India) and informal payments occur (China, Sierra Leone and Tajikistan) [9, 17, 24, 25], though this seems to depend

strongly on the setting. Kemp [3] found informal payments to be rare in Malawi. In China, often-times patients are charged for additional, unnecessary drugs and diagnostic tests leading to a substantial increase of the costs to patients (personal communication).

Indirect costs during diagnosis

Indirect costs similarly have a wide-spread range between $16 in Malawi [3] and $115 in Bangladesh [18], with the majority lying between $10-30, however only three studies specify indirect costs incurred exclusively at the diagnostic stage. Workdays lost up to diagnosis lie between 20 [3] and 48 days [23].

Total Costs during diagnosis

A better picture emerges when looking at total costs incurred during diagnosis. Here, the majority lies between $10 and 30, but reports are going all the way up to $245 in Bangladesh. Total costs as a percentage of income are 135% of mean monthly household income in Malawi [3] and 31% of annual income per capita in Bangladesh [18], 58% for the poor in Myanmar [14]. Interestingly, Kemp [3] found that the poor spent 244% of monthly income on diagnosis which is 110% more than the average. This emphasizes the fact, that averages do not adequately represent the economic burden of the poor.

3.4. Costs during treatment

Delays

A multitude of studies deals with treatment delays (capturing patient and system delay) defined as the time elapsed from onset of symptoms until the beginning of treatment. Results from studies that looked at patient costs found treatment delays (capturing herein also pre-diagnostic and diagnostic delay) to lie between 6 and 16 weeks [7, 16, 21, 26, 27]. Taking into account however that pre-diagnostic delays alone were reported to last already between 5 and 17 weeks, treatment delays should theoretically exceed pre-diagnostic delays, assuming that time elapses between diagnosis and start of treatment. On the other hand, these

numbers provide us at least with a time frame of 5-17 weeks in which we can assume that the patient incurs costs due to forgone income because of his/her inability to work and time lost during his/her efforts of seeking treatment.

Direct costs during treatment

Direct costs vary widely across studies which depends of course on local prices for food, transport etc. Starting from $5 in Tanzania [28] up to $150 in Haiti [20], with the majority between $20 and 50. Items requiring most of the expenditures are travel and food and for drugs if they are not provided for free [19, 22, 29]. In India [23], expenditures on health visits, travels and drugs were found to be higher among urbanites than among patients living in rural areas. In South Africa, Sinanovic [29] identified DOT (Direct Oberserved Treatment) visits to be the item accumulating most of the costs. She further found that workplace supervision was much less costly ($11) than clinic supervision ($111). In India [23], direct costs were found to be higher for women than for men.

In Thailand, out-of-pocket direct expenditures of the very poor for diagnosis and treatment amounted to 15% of their annual per capita income [19], in Haiti, they were 49% [20].

Medical expenses amounted to 40% of annual income of Chinese households, for low-income households, they were equivalent to 112% of annual income [30]. Russell [2] determined direct post-diagnosis costs to amount to 18.4% of annual household income. Moalosi [31] investigated in Botswana direct costs for care-givers and found that home-based care cost 23% less for care givers than hospitalization.

Hospitalization during treatment

Floyd [32] found that the average length of hospital stay for patients in South Africa was 17.5 days for those patients entering community DOT after discharge and two months for conventional hospitalization during the intensive phase. Admission to hospital constituted 76% of patient cost, with a day in hospital costing the patient $4. DOT at hospital was more expensive than DOT at health

clinic or community level. A hospital visit cost the patient 5 hours. Okello [33] had similar results in Uganda: one day hospital cost $1.30 for the patient, overall, hospital based care was more expensive than community based care ($252 vs $206). Moalosi [31] found home-based care in Botswana to be 42% cheaper for patients than hospital-based care; while the average hospital stay with home-based care was 21 days, it was 93 days with hospital-based care. Needham [4] found caregiver costs to be greater for in-patients than for out-patients, in his 2004 study however, he attributes less delays for patients seeking hospitalization.

Indirect costs during treatment

Indirect costs in Dollar terms amount to $7 [28] - $50 [20], with a tendency towards $20 [17, 28]. Productivity in household or occupation drops by ca 30%. $150-200 or 15%-20% of annual household income is lost; patients cannot work for ca 2-4 months and 20-75% of patients incur some form of debt.

Table 1 summarizes direct and indirect costs during the treatment phase.

Table 1: Summary of direct and indirect costs during treatment

Direct Cost as % of income	
Household	18 -112%
Per capita	15% - 49%
Indirect Costs	
Productivity	Household activities and childcare fall by 30%-40%
	74% loss of working capacity
Income	9-112% of annual per capita income (majority 10-30%)
	15-89% of GDP/capita (majority ca 15%)
	Loss of 2-45% of annual household income (majority ca. 15%)
Work time lost	2 -14 months (majority 2-4 months)
Coping costs	One person per household cannot follow an occupation during period of illness

Total Costs during treatment

Total costs (direct and indirect) of TB treatment to patients are reported to be between $9.5 [9] and $202 [20], with the majority being below $100 [17, 23, 28, 34]. Total cost of TB treatment is found to be between 20 and 30% of annual household income [18, 35]. Sinanovic [29] found community based care more affordable than clinic based care (due to DOT visits). Wandwalo's [28] cost-effectiveness study in Tanzania supports this finding. On average, sputum-smear positive patients had to make 58 visits to a health facility for DOT, a sputum-smear negative patient had a total of 24 visits, compared to a patient under community DOT with a total of 10 visits.

3.5. Total Costs (pre-diagnosis, pre-treatment, treatment)

In order to assess the costs of a complete, treated TB episode relative to its parts, it is useful to review studies that have investigated the total costs of TB treatment while including costs incurred at each level. Two reviews by Ahlburg [36] and Russell [2] are particularly useful.

Direct costs of total costs

Direct costs vary again strongly by country, starting with $24 in Zambia [37] up to $346 in China [38]. It can be observed however that the most frequent dollar range is between $60 and 130 [2, 19, 23, 36]. Direct costs of TB amount to 3.7 – 15% of annual income (highest for the poor) [2, 19, 23]. In comparison, Jackson [38] found that direct costs to be equivalent to 55% of annual household income in China. Direct cost burdens are exacerbated by widespread use of private providers, particularly in urban settings [2]. In addition, direct costs are unevenly distributed across households, minorities bearing high costs compared to the majority of the population [2]. Russell [2] attributes more meaning to median figures than to mean figures, however mean figures are mostly presented in the literature. Costs vary strongly and the mean is therefore determined by outliers.

Indirect costs of total costs

Indirect costs vary between $28 [2] and $1384 [22] with the majority lying in the range of $100-500 [2, 19, 20, 22, 23, 36, 38]. Russell found TB indirect costs to amount to 5-8% of annual household income, Rajeswari [23] to 26%. In terms of workdays lost, Needham [37] reports two weeks in Zambia whereas others report an average loss of 8 -12 weeks [19, 23, 36]. Interestingly, according to Ahlburg [36], treated patients lose two months of work compared to untreated ones losing 12 months. In respect to coping costs, Jackson [38] reports 66% of patients borrowing money from relatives or friends, 45% sold assets and 8% borrowed money from banks. Rajeswari [23] reports 14% of annual household income forgone for debt redemption.

Overall total costs

The economic burden of TB can be well-understood with the help of percentage of income (table 2). The poor spend a far greater proportion on meeting basic needs (food etc) whereas the non-poor have more disposable income. The burden of each $ spent is significantly higher for the poor. Russell [2] deems a cost burden of more than 10% of annual household income to be already catastrophic for a household's financial situation. Taking this into account, study results point to the enormous burden of households and individuals of 20-30% of monthly income [17, 37] and 10-90% of annual household income [2, 20, 23, 36] (highest for the very poor), the majority being approximately between 10% and 40% [2, 19, 23, 36] (table 2). Ahlburg [36] determined the cost of morbidity of treated TB to be 15% of GDP per capita.

3.6. TB/HIV co-infection costs

There are plenty of studies on mortality cost of HIV deaths to society, but there is hardly any literature on costs for TB patients that are co-infected with HIV. Jacquet [20] bases the time range in which there is a loss of productivity on the number of years anticipated to survive after development of active TB and number of years survived with HIV infection before developing active TB, with a

total average survival of 9.8 years. In his review study, Beck [39] reports a community loss of 0.4 potential years of life lost per person in India; In Uganda, incremental lost income per person with Aids death was $12.256 in 1992. With the lack of studies on this topic, the incremental costs of an HIV co-infection are difficult to determine. In terms of indirect costs, greater mortality, lower productivity, long-term reduced ability to earn and prolonged morbidity of TB-HIV co-infected persons are definite, especially if the patient presents him/herself late [7].

3.7. Gender

A number of studies emphasize higher costs for women than for men. Women take longer to seek care (patient delay) [5, 10] due to stigma and social exclusion, heavier workloads, prioritization of other family members over own well-being, lack of independence, inaccessibility to financial resources and powerlessness in decision-making [5, 10]; they experience longer provider, diagnostic and treatment delays [5, 10]; they are engaged in more activities that need to be replaced in the household, while girls replace these activities more than boys [3]. In addition, women have higher direct costs than men, because they often need somebody to accompany them [17], they are less mobile and have less financial resources [5] and women experience greater loss of income probably because of more lost work days [4].

Table 2: Summary of results by treatment phase and cost type

Pre-Diagnostic costs:

Delay: 2-4 months, 3-7 health encounters
Direct costs: $55-225, 5-21% of annual household income
Indirect costs: $16-68, 18-48 days lost
Total: 127 per capita -135% household mean monthly income

Pre-Diagnostic types of costs	
Direct	**Indirect**
- Travel, food, accommodation during visits to care givers for seeking help in private and public sector including pharmacies, traditional healers etc. - Expenditures on medicines, special foods, tests	- Income reduction due to missed work days/hours, lost job, loss of time to seek job, uptake of less paid labor due to illness - reduced household activities (or cost of other household member replacing household work) - missed work for caretaker - decreased productivity - coping costs: use of savings, reduction of food intake, assets are sold, extra job, kids drop out of school to work, debt / loans

Diagnosis/Pre-treatment costs:

Delay: 3 months (including pre-diagnosis), 5 health encounters
Direct costs: $10-50, 8-13% of annual household income
Indirect costs: $10-30, 20-48 days lost
Total: ca 135% mean monthly household income, ca 31% annual income per capita

Diagnosis/Pre-treatment types of costs	
Direct	**Indirect**
- travel forth and back for tests and receiving test results - accommodation - food and “special foods” - guardian costs - diagnostic tests (if not provided for free) - additional informal payments - charges for drugs - user fees - ‘under the table’ fees	- Income reduction due to missed work days/hours, lost job, loss of time to seek job, uptake of less paid labor due to illness - reduced household activities (or cost of other household member replacing household work) - missed work for caretaker - decreased productivity - coping costs: use of savings, reduction of food intake, assets are sold, extra job, kids drop out of school to work, debt / loans

Treatment costs:

Delay:	1 ½ - 4 months (incl pre-diagnostic and diagnostic delays), total of 5-17 weeks
Direct costs:	$20-50, 15-49% of annual per capita income, 40-112% of annual household income
Indirect costs:	ca $20, 2-4 months of lost work, 15-20% annual household income, 20-75% of patients incur debt, productivity loss of 30%
Hospitalization:	17 – 21 days home-based care; 60-93 days hospital care, $1.3 – 4 per day
Total:	below $100, 20-30% of annual household income

Treatment types of costs	
Direct	**Indirect**
- Costs due to hospitalization Travel, food, accommodation for follow up tests - Travel, food for DOT visits (if applicable) - Travel, food for medicine collection visits (if applicable) - Consultation / user fees (if applicable) - Guardian costs - Informal payments (if applicable): additional diagnostic tests, drugs - Additional costs due to parallel treatment sought by other providers - Additional costs for TB-HIV coinfected patients: travel and food to ARV clinic, screening intake, test result, medicine collection - health insurance up front payments to be reimbursed later (if applicable)	- Income reduction due to missed work days/hours, lost job, loss of time to seek job, uptake of less paid labor due to illness - reduced household activities (or cost of other household member replacing household work) - missed work for caretaker - decreased productivity - coping costs: use of savings, reduction of food intake, assets are sold, extra job, kids drop out of school to work, debt / loans

Total Costs TB episode:

Direct costs:	$60-130, 4-15% of annual per capita income
Indirect costs:	$100-500, 5-16% of annual household income, 2-3 months lost work, 70% borrow
Total:	20-30% of monthly income (household and per capita), 10-90% of annual household income, 15% of GDP/capita

3.9. Coping Costs

In regard to coping costs, two studies [40, 41] have summarized the order of coping strategies used by patients and neatly complement the findings presented in this review. They both found that the household first reallocates tasks. Second, savings (if any) are used; third, consumption is reduced (mostly food); fourth, assets are sold (land, livestock); fifth, loans are taken up and last, income is diversified (additional job); the community is asked for help as a last resort. This means on the one hand, that the household would be a more suitable unit of analysis and on the other, that debt (and interest payments) is not inherently the logical consequence of cost constraints. The sale of assets however reduces future income and therefore TB can stand in the beginning of a spiral into deeper poverty.

3.10. Summary of patient costs

In summary, costs to patients depend on the nature, frequency and duration of the illness, the healthcare seeking behaviour of affected individuals, the type of treatment (community vs health facility DOT), the direct and indirect costs of diagnosis and treatment, the responses and mobilization of resources, and the resources available to the household or patient.

4. DISCUSSION

4.1. Limitations of the literature review

HIV Coinfection

The literature available on additional costs because of HIV coinfections is very limited. Literature on the cost of HIV/AIDS to patients during their lifetime is available, but the nature of the disease (lifelong) makes it difficult to associate these costs with costs incurred by TB patients.

Pediatric, unemployed and elderly TB patients and household work

A limited number of studies [8, 42] focus on children and the economic value of housework. Most studies just capture salaries which excludes unpaid work in the household and the unemployed who lose time to seek new employment.

Additional costs to a household due to elderly patients living in the same household are only captured through guardian costs of travel, accommodation and food.

Similar tools to improve service delivery

There is a multitude of studies on targeting the poor, developing measures to estimate cost burdens and socioeconomic measures, measuring access to healthcare and developing proxies for assessing income. However, the author of this review has not found any study which has reflected on the practicability, design, and impact on service delivery of such a tool for an NTP or other programs. This does not mean that such studies do not exist. Further research is needed here.

Comparative value

Costs associated with seeking treatment, receiving diagnosis and the treatment itself can be divided into three phases: Costs incurred prior to diagnosis, costs incurred during diagnosis (prior to treatment) and costs incurred during treatment. It is difficult to compare study results, because of different methodological approaches and study designs. The same holds true for the distinction between the three periods in which costs are incurred. Some studies include diagnostic costs when calculating treatment costs, whereas others include diagnostic costs when assessing the pre-diagnostic burden. Therefore, studies discussing more than one period were mentioned in both periods.

Other difficulties to compare studies include the different usage of currencies, different definitions and measures of direct and indirect costs and different units of analysis:

Different usage of currencies

Most studies converted results into US$. Results of three studies [17, 19, 23] that reported in local currencies (Thai Baht, Indian Rupees) were converted for this review into US$ to allow for comparison (exchange rate as reported in study,

alternatively year of study). However, US$ amounts can only give a very rough idea of costs, because of different inflation levels in each country and the value change of the US$ relative to other currencies over time, different purchasing power parities and different price levels of services.

Different definitions and measures of direct costs

Some studies distinguished between direct expenditures and medical costs on drugs and laboratory tests. In these cases, medical expenditures were included into direct costs.

Different definitions and measures of indirect costs

Some studies measured indirect costs as self-reported forgone salaries, some as self-reported forgone income, some estimated forgone income on the basis of hours worked per day or per month; some used the average wage rate, some used Gross Domestic Product (GDP) or Gross National Income (GNI) per capita, some used income levels estimated by household surveys. Some included caretaker indirect costs, though most didn't. Data is presented as percentage of monthly or annual household or per capita income. Few calculated lost productivity into forgone income. It is impossible to standardize all of these results. Hence, all numbers declared as indirect costs in these studies are compared as such. Most studies assessed indirect costs according to self-reported data collected through surveys or interviews. Coping costs are not included in indirect cost measurements, but are mentioned here separately.

Different units of analysis

Some studies focus exclusively on per capita data, whereas others focus mainly on the household as preferred unit of analysis.

4.2. Income indicator usage

In order to estimate the impact costs have on a patient, we first need to know the amount that a patient can afford to spend on TB. That is, we need to be able to

judge the proportion of the patient's income that is associated with costs of TB. There are two ways to approach this: either to ask patients with the means of surveys and interviews about their income or consumption expenditures or to use standardized measures of income, such as average wage rates, GNI per capita, or income levels. These standardized measures are usually obtained through household surveys or data supplied by UNDP, the World Bank [43], UNICEF [44], DHS [45] or WHO [46]. However, these databases do not provide recent income data on all countries.

For the purpose of developing a tool for NTP managers to estimate patient costs, both approaches face difficulties. The bottom-up approach requires substantial financial and human resources to conduct representative surveys. During the past years, researchers have become more and more hesitant to use self-reported income data and found asset based assessments household surveys more useful and representative[2]. The top-down approach is more practical, but average wage rates and GNI/capita don't provide the NTP with information specifically about the most vulnerable parts of the population, that this tool aims to target; they only represent averages and therefore underestimate the poor's burden [47]. A good and often used alternative is recent data on household incomes obtained through country-level household surveys. Not every country has conducted such surveys, for they are expensive[3].

Researchers have struggled with these problems and found different solutions. Filmer [48] determined household assets (in India) to be related closely enough to consumption expenditures to serve as a proxy for the latter. Hence, surveys not on income, but on assets or consumption may serve the same purpose. Zhang [30] used the indicator 'annual household medical expenditures during the last 12 months' as a proxy for estimating the costs for diagnosis and treatment. Fabricant

[2] Verbal communication with researchers from McGill and Liverpool School of Tropical Medicine

[3] It is argued that household surveys don't include the poorest of the poor, because many households in urban slums are not interviewed, and where it is considered to be risky or difficult to identify household entities (UN Research Institute for Social Development 2007)

[49] used housing type, food expenditure and self-estimates as proxies for income levels in Sierra Leone and found that a one-day agricultural wage correlates with the average price of an out-patient visit in some countries and therefore serves as an indicator for affordable treatment.

Another difficult issue, and therefore often-times left out, is the method to estimate loss of income for individuals who are active in the household but not in regular employment or waged activities. Recalling what was said on coping strategies, it is known, that in the short-run, activities are reallocated within the household [50]. In the long-run, however, they will need to be replaced. Drummond [50] recommends either using the average wage, the cost of replacing the role, or the opportunity cost of production the individual could have contributed to, if he/she was employed. These measures however run the risk of overestimation.

4.3. Remaining questions

The number of trips to health facilities varies considerably with the availability of DOT services. Community DOT hardly requires travel and food expenditures, whereas health facility DOT does. DOT three times weekly requires fewer trips than daily intake of drugs. The number of trips will also vary with the length and nature of pre-treatment delays, the practised procedure, opening hours of diagnostic and treatment facilities and the distance from facility to the home of the patient. Delay times are periods in which the patient's productivity is already reduced and indirect costs are incurred. It is difficult to generalize the amount of reduction in productivity across all patients. Another question is whether coping costs can or should be included. It would be easy to calculate additional costs due to debt and interest payments, but it is much more difficult to estimate income loss due to sale of assets or children dropping out of school. Furthermore, we have to assume that not all patients will be able to resume their occupation after the end of treatment and not all patients will complete their treatment. Some will have lost their job, some will have defaulted, and some will not be cured. Especially HIV infected TB patients are affected by higher morbidity, less

productivity and are therefore subject to continuing indirect costs. We also wonder what could be done about those who don't come at all to the health facilities because of the economic burden of seeking treatment. How could they be reached?

Interestingly, none of the studies consulted accounted for a learning curve within a family or community. That is, once a family or community member has undertaken the odyssey from healer to private practitioner to public health facility and has learned about the disease and its symptoms, opening hours of facilities, costs, DOT and cure as treatment result, he/she will share this knowledge with his/her family and community and will be of assistance should another family or community member show TB symptoms. The direct and indirect costs for the second and following patients should therefore be lower than to the first patient.

5. CONCLUSION

Despite difficulties to compare study results and methodologies, this review shows that TB patients incur enormous costs before and during diagnosis and during treatment. The tool to be developed should be very precise on the units of analysis and definitions of costs. It should further identify HIV-related costs, the value of household work, the healthcare seeking behaviour of affected individuals, the type of treatment, the direct and indirect costs of diagnosis and treatment, the coping costs of patients, and the resources available to the household or patient. Most tools which were identified by the literature review and which strive for similar aims were survey-based. We conclude that the tool to be developed should be flexible enough to deliver meaningful data with small sample sizes. It should be tailored to the needs of NTPs and usable for organizations that are not per se involved in research work. The tool, therefore, should not require too much time to complete and it should be adjustable to the national and local context.

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CHAPTER 3

Structure and management of tuberculosis control programs in fragile states - Afghanistan, DR Congo, Haiti, Somalia

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Chapter 3 Structure and management of tuberculosis control programs in fragile states - Afghanistan, DR Congo, Haiti, Somalia

ABSTRACT

Objectives

Health care delivery is particularly problematic in fragile states often connected with increased incidence of communicable diseases, among them tuberculosis. This article draws upon experiences in tuberculosis control in four fragile states from which four lessons learned were derived.

Methods

A structured inventory to extract common themes specific for TB control in fragile states was conducted among twelve providers of technical assistance who have worked in fragile states. The themes were applied to the TB control programs of Afghanistan, DR Congo, Haiti and Somalia during the years 2000-2006.

Results

Case notifications and treatment outcomes have increased in all four countries since 2003 (treatment success rates 81-90%). Access to care and case detection however have remained insufficient (case detection rates 39-62%). There are four lessons learned: 1.TB control programs can function in fragile states. 2. National program leadership is essential for quality and sustained TB control. 3. Partnerships with non-governmental providers are vital for continuous service delivery; 4.TB control programs in fragile states require consistent donor support.

Conclusion

Despite challenges in management, coordination, security, logistics and funding, TB control programs can function in fragile states, but face considerable problems in access to diagnosis and treatment and therefore case detection.

Keywords: Afghanistan, DR Congo, Haiti, Somalia, Tuberculosis, Health Systems

1. INTRODUCTION

In recent years, there has been growing interest in implementation of health programs in fragile states[1-12] which is particularly problematic in fragile states and often connected with increased incidence of communicable diseases, among them tuberculosis (TB) [2, 3, 13-30]. TB remains a major public health concern world-wide with 1.7 million deaths annually and 80% of the disease burden in 22 countries, among them also fragile states[10].

Almost all national tuberculosis control programs follow the internationally recommended DOTS approach[1]. It constitutes the technical foundation of the expanded Stop TB Strategy, promoted by WHO since 2006 [31]. TB control is more than just TB care; it is an organized and combined effort to detect and cure all sources of infection [32] which requires a complementary performance of the key functions of a health system[2]. Effective TB case detection and treatment are important in fragile states, conflict and post-conflict settings, as TB transmission is facilitated by crowded living conditions and lack of treatment. Conditions of vulnerability, malnourishment and weakened immune system promote development from infection to active disease [34] which can lead to hotspots of transmission. The threat of multi-drug resistant TB (MDR-TB) [35] and the growing prevalence of HIV with associated TB coinfection, make it all the more pertinent for effective TB control programs to operate in fragile states.

Acknowledging the variety of fragile states definitions in the literature, this paper uses the definition of the OECD-Development Assistance Committee [36] (p.15), because its second half appears in almost all circulating definitions and it is agreed upon by all OECD member countries. It refers to a state as fragile that “lacks the capacity (effectiveness) and/or willingness (legitimacy) to sustain itself over time. It is unable to perform the basic functions of a state: to maintain security across its terrain, to enable economic development, to ensure the essential needs of its population are met”. In collaboration with the World Bank, the DAC, led to the adoption of the Paris Declaration on Aid Effectiveness at the DAC High Level Meeting in 2005 [37], the Accra Agenda for Action[38] and Principles for Good

International Engagement in Fragile States [39]. Here, DAC members agreed on key principles such as strengthening state structures, their legitimacy and accountability, alignment with local priorities, coherent donor approaches, coordination mechanisms and sustainable involvement [37].

Experiences from Afghanistan, Somalia, Uganda, Angola and World War II suggest that TB incidence and mortality increase during wars [3, 13, 24, 40, 41]. Effective TB programs during and after conflict might offset increasing TB incidence[18, 19, 22, 26]. Conflict and state fragility are major impediments to running a well-functioning health care system including TB control. The lack or contestation of government authority leads to precarious security situations, displacement of population, outbursts of violence, collapse of infrastructure and services. These situations result in problems of access, disruption of supply lines, health care provision and monitoring and evaluation, all of which are essential for a functioning health system and TB control according to DOTS. Such situations are exacerbated by a lack of funding and human resources, frequent displacement of staff and patients [2, 25-28, 42-44]. The WHO/UNHCR[33] field manual for TB care and control in refugee and displaced populations recommends to begin TB programs when TB is an important health problem, the emergency phase is over, basic needs including shelter, water, sanitation, food and basic drugs are provided and basic clinical services are available. TB programs require sufficient program funding to operate for at least twelve months [33].

Until now, accounts of tuberculosis control programs and their functioning in fragile states have been mainly limited to individual country reports [13, 15, 18, 22, 24, 25, 28, 41, 45]. A lack of in-depth analyses of TB program structures and cross-country comparisons in fragile states in the published literature has been identified[13, 18, 26, 28]. To address this gap and to share significant experiences in TB control in fragile states from several countries, this paper presents a comparative analysis of TB control programs in Afghanistan, Haiti, DR Congo and Somalia. Its aim is to share lessons learned on public health and TB control in fragile states.

Afghanistan, Haiti, DR Congo and Somalia all have long histories of instability and all suffer under a heavy TB burden. Afghanistan and DR Congo are among the high TB burden countries which constitute 80% of global tuberculosis cases[31]. ***Afghanistan*** has been in conflict on and off throughout the 20th century, since 2001 with a NATO-led military campaign remaining in the country [46]. From 1998-2003, a civil war in DR Congo influenced by neighboring countries cost millions of lives and several factions continue battling each other, especially in the Northeast of the country[47]. Haiti has frequently faced internal turmoil since its independence from France in 1804. Its situation has been exacerbated by the frequent occurrence of tropical storms that have regularly destroyed much infrastructure[48]. Somalia has been in a state of civil war since the 1980s with currently three de-facto states (Somaliland, Puntland, Somalia) in one internationally recognized state, Somalia[49].

2. METHODS

This paper builds on individuals' experiences in fragile states supported by available published and grey literature. It presents experiences and lessons learned shared by all authors regarding the structure and effectiveness of TB control in such settings. These concerns reflect broader discussions in the literature on health care in fragile states.

A structured inventory to extract common themes for comparison was conducted among twelve providers of technical assistance who have worked extensively in fragile states of which eight are also authors of this paper. All of these eight have worked in at least one of the countries described in this paper for an extended period of time. Three authors have worked in more than one of these four countries which further facilitated determination of common characteristics. Authors represent different types of organizations (TB programs, NGOs, WHO, USAID) thereby reflecting different, and sometimes conflicting, personal and institutional viewpoints for which we tried to find a good balance. We acknowledge potential biases due to usage of secondary data sources and the possible omission of views of other stakeholders in these four countries.

The four countries were selected, because of their chronic instability, a high TB burden, available documentation and personal experiences in providing technical assistance. Four countries cannot represent the full spectrum of fragile states, but they do represent experiences in different continents and countries where active TB control efforts have been undertaken.

Developments between the years 2000 and 2006 were explored. Structure and developments described here may have changed in the mean-time due to the volatile nature of fragile states meaning frequent changes in political leadership, organization of health care services and partners involved. These factors often limit good monitoring and evaluation efforts. Information on the validity and quality of data provided in tables and figures was not available. Although this article focuses on a restricted time period, findings applicable beyond a certain time frame were extracted.

3. RESULTS: COMPARISON OF TB PROGRAM STRUCTURES AND MANAGEMENT FOR SERVICE DELIVERY IN FRAGILE STATES

The following themes that are relevant for TB control and for public health in general in fragile states were used for comparison: TB control program management and organization, service delivery network, coordination of donors and non-governmental organizations, funding, security and logistics. The comparison of these themes presented an opportunity to derive and share lessons learned. For all four countries, key program indicators are described in table 1 and figures 1 and 2.

Table 1: Overview of TB programs[4]

	Afghanistan	DR Congo	Haiti	Somalia
Estimated Population (million)	26,09	60,64	9,45	8,45
Number physicians per 1000 population [50]	0.19 (2001)	0.11 (2004)	0.25 (1998)	0.04 (1997)
Number nurses per 1000 population [50]	0.22 (2001)	0.53 (2004)	0.11 (1998)	0.19 (1997)
Number of TB cases notified	25.475	95.666	13.959	11.864
TB case notification rate (all cases) per 100.000 populations	98	158	148	140
Estimated case detection rate all new cases	58%	39%	46%	62%
Treatment success rate all new cases (2005)	90%	85%	81%	89%
Estimated catchment population per treatment center	1 center per 52.180 population [51], unpublished document)	1 center per 55.127 population [52], unpublished document)	1 center per 38.888 population [53]	1 center per 176.041 population ([54], [55], unpublished documents)
HIV prevalence in incident TB cases	≤0,05%	11%	6,8%	1,6%
Estimated prevalence of MDR-TB among new cases [35]	3,4%	1,7%	1,9%	1,8%
Available funding as % of NTP budget	19%	44%	NA	NA
Main donors	CIDA,	USAID via	USAID, Global	WHO, World

[4] in 2006 except where differently indicated

	Government of Italy, USAID, WHO, World Bank, Global Fund, European Commission, Asian Development Bank, Kuwait Patients Helping Fund, World Food Program, JICA, Global Drug Facility [51]	TBCAP (Union), Cooperation Belge, European Commission, World Bank, Damian Foundation, WHO, Global Drug Facility, Global Fund, CDC[52]	Fund, Global Drug Facility, CDC, PAHO [53]	Food Program, Union, Global Drug Facility, Global Fund [54, 55]
Global Fund Round, Principal Recipient & Rating[56]	Global Fund Round 4 (PR MOH), Rating B1	Global Fund Rounds 2, Rating B1, Round 5, Rating B1, Round 6, no rating available (PR UNDP)	Global Fund Round 3 (PR Fondation Sogebank), Rating B1	Global Fund Rounds 3 and 7 (PR World Vision) (no rating available)
Number of in-country technical and implementing partners	45 implementing NGOs, WHO [51]	3 international technical partners and WHO, 5 international implementing NGOs, several local NGOs coordinated by one national NGO [52]	8 international NGOs of which 5 technical partners, 4 local NGOs, PAHO, UNDP [53]	19 international and 6 local NGOs, 2 municipalities, WHO [54, 55]

FIGURE 1: Case notification rate all TB cases per 100.000 population 2000-2006

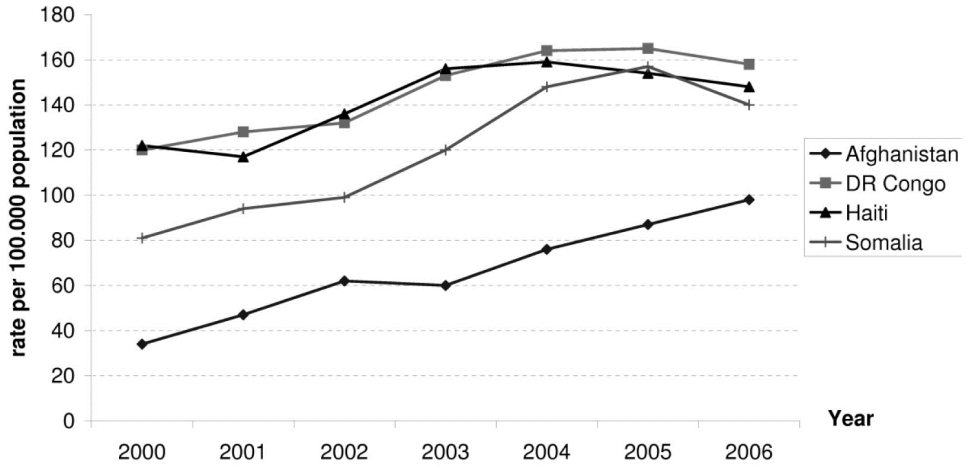
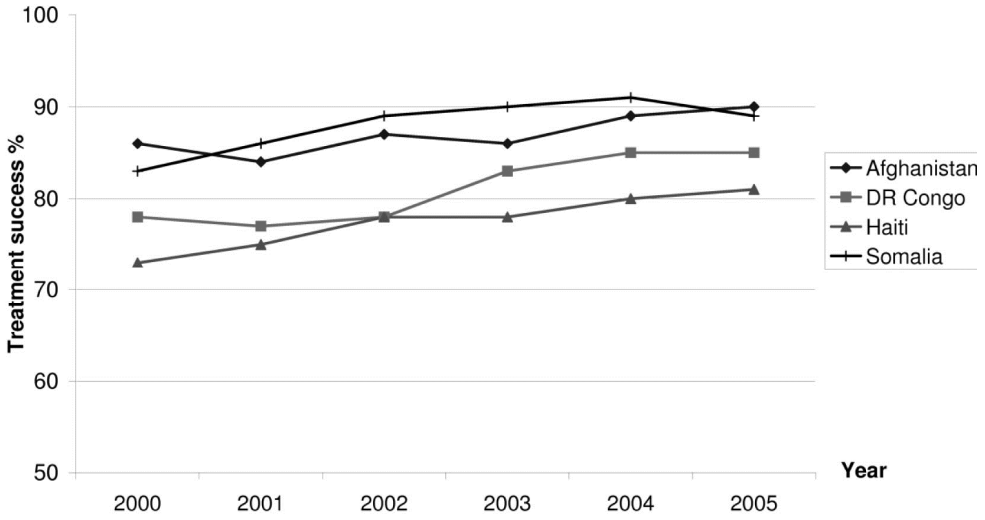


FIGURE 2: Treatment success (%) of DOTS new smear positive TB cases 2000-2005



TB control program management and organization

The national TB control programs in Afghanistan, DR Congo and Haiti have been part of the Ministry of Health. The programs have been structured with a central unit usually located in the capital, which have managed and coordinated the TB program, and regional coordinators usually located in the regional capitals, who have overseen and monitored implementation.[3] In Afghanistan, the TB program has been structured along seven regions and 34 provinces[51]. In DR Congo, 23 provincial coordinators for TB and Leprosy have overseen the peripheral level, supported technically and financially by eight international and Congolese NGOs [52]. In Haiti, 11 departements have supervised local service delivery providers. Three NGOs provided management and technical support on departemental level [53]. Somalia consisted of three politically separated parts and therefore did not have a NTP. Instead, WHO has coordinated four zones with medical, laboratory and administrative focal points in each zone, in three de-facto states (Somaliland, Puntland, Somalia) [55].

Service delivery network

All four countries have faced grave human resource crises with 0.04 – 0.25 physicians and 0.11 – 0.53 nurses per 1000 population (table 1). Access to care has remained a major hurdle in all countries and has been connected with low case detection rates. In Afghanistan, TB has been integrated into the Basic Package of Health Services (BPHS) in 355 districts which covered 77% of the country [14, 15, 20, 21, 24, 43, 51, 58-65]. Services were provided at four levels: provincial, regional and district hospitals, comprehensive health centers, basic health centers and health posts. In total, these were 1267 facilities including 500 diagnostic and treatment centers and 300 DOT centers. The provision of BPHS has been contracted out to 45 NGOs supporting the public facilities; two health workers looked together after 1000 families [51].

In DR Congo, TB has been integrated into general health care provided by around 1100 diagnostic and treatments centers linked each to several treatment centers in 11 provinces[28, 52, 66, 67]. Services have been provided on three levels,

general reference hospitals, health centers and health posts, supported by five international, many local NGOs and locally contracted staff [52, 68, 69].

In Haiti, TB services have been integrated into primary health care. 243 primary healthcare facilities (clinics and hospitals) have served as diagnostic and treatment centers in 11 departements [16, 17, 23, 53, 70-76]. Most were government facilities, supported by the National TB program, provincial TB officers and five NGOs providing overall support for training, supervision and monitoring. Seven more NGOs supported service delivery and community outreach. One NGO established a referral facility for MDR-TB and another NGO temporarily stepped in to function as the national TB reference laboratory (NRL) during difficult political times. The NRL was then later re-established in 2006 with Global Fund support [23].

Similar to Afghanistan, TB services in Somalia have been provided mainly by NGOs: 19 international and six local NGOs and two municipalities operated and supported a total of 48 TB centers in 18 regions [13, 29, 41, 55, 77, 78].

Coordination of donors and non-governmental service providers

In each country, coordination of donors and providers took a different form, however all programs and partners agreed on DOTS as the main TB policy framework. In Afghanistan, ministries, major donors, UN agencies and representatives of NGO-BPHS implementers have formed a Consultative Group on Health and Nutrition. In addition, a national TB technical coordination committee under Ministry of Health (MoH) leadership with representatives of the same agencies met once per month. A contract management unit at the MoH oversaw all NGOs that each signed a contract with a donor and MoH. In addition to quarterly regional TB review meetings, monthly meetings of the provincial health coordination committee took place [15].

In DR Congo, donors, technical partners and service delivery partners have been coordinated by the national TB control program in a forum called Task Force TB. The Task Force TB model has been adopted in three provinces for provincial level coordination. Partners that have been mainly active on provincial and peripheral

level met quarterly. Each NGO signed a Memorandum of Understanding with MoH [28].

In Haiti, the NTP was unable to access funds for meetings and supervision, whereas NGOs could. MSH as a contracting partner of USAID coordinated five NGOs in joint planning and outcome meetings on a quarterly basis. Partner coordination was at times challenging, as quarterly meetings on departmental level stopped due to the security situation and natural disasters caused by tropical storms. This was also related to the situation of weakened NTP leadership[79]. It changed with the onset of the Global Fund disbursements in 2000.

In Somalia, an inter-agency coordination committee of donors, implementing partners and governmental agencies met quarterly in the Somali Aid Coordination Board, the Somalia Health Sector Committee and the TB working group, coordinated by WHO. Each NGO signed a Memorandum of Understanding with WHO [54].

All four TB programs have had a Global Fund grant and therefore a Country Coordinating Mechanism (CCM). The use of a common framework for TB control under the DOTS approach and consistent associated monitoring and evaluation indicators have been key elements in ensuring that diverse service delivery providers and technical assistance and management partners worked towards common goals and produced coherent results.

Funding

In contrast to Afghanistan and DR Congo where interest by donors has been high, Haiti and Somalia's TB programs struggle with limited sources of funding (table 1).

In 2006, Afghanistan underwent a shift from emergency to development funding. Funds that were previously channeled directly to implementing agencies, were then channeled through government to strengthen capacity, legitimacy and leadership. Although this sometimes led to NGOs waiting for funds for several months to continue their work, this policy was respected to strengthen government stewardship.

The NTP in Haiti has been scaled up to national level with the World Bank project which ended in 2001. Under this project, funding had been handed to government agencies with strong financial and accounting controls. Political turmoil at the turn of the millennium resulted in sanctions prohibiting channeling aid through government. USAID stepped in as the main donor for TB and thereby guaranteed the continuation of the TB program. USAID's primary disbursement mechanism was a project implementation unit run by the NGO Management Sciences for Health (MSH). Due to this policy, parallel management, reporting and financial structures developed and capacity-building remained within NGOs [79].

In Somalia, the main program funding has come from Global Fund with additional support from UN agencies and the International Union Against Tuberculosis and Lung Disease [54].

Security and Logistics

In all four countries, functioning logistics for drug procurement and distribution were closely related to the security situation. In Afghanistan, the south was especially insecure. NGOs were at times targeted, because they were perceived to be associated with NATO forces. It is noteworthy that the MoH negotiated with the Taliban for peace-keeping days to allow general immunization by community volunteers. Access to all parts of the country was severely limited during winter causing delays in drug procurement which was done through air transport, coordinated by WHO [51].

In DR Congo during the war and division of the country, the NTP could not send drugs to the Eastern provinces. Drugs were then stored in Goma and entered these provinces through Rwanda, organized by a NGO[28]. NGOs were allowed to cross to the eastern provinces when civil servants couldn't and therefore they also stepped in to supervise the eastern provinces [28]. Given the size of the country, its geographic nature, topography and lack of infrastructure, the TB program in DR Congo faced a severe logistics problem. Remote areas were very difficult to reach, especially during rainy season, therefore supplies were usually transported by air which is expensive [52].

In Haiti, the capital Port au Prince was insecure where raids by militias and gangs as well as kidnapping, looting and violence were common at the climax of the conflict [48]. Procurement, storage and distribution of supplies was shouldered together by the NTP, the Pan-American Health Organization and NGOs.

Security was the number one logistics problem in Somalia, especially in central and south Somalia including Mogadishu where attacks and kidnappings by local militias against government supporting agencies were common[49]. Transport and distribution of supplies was usually done by air. Because Somaliland was stable, most NGOs and UN agencies were based here [49].

4. DISCUSSION: LESSONS LEARNED

A broad overview covering major aspects of TB control in fragile states has been provided. Following, four equally important lessons learned are presented that we deem relevant for TB control and other health care programs in fragile states.

Lesson 1: TB control programs in fragile states can be effective

All four TB control programs applied a common policy framework which is DOTS and reported on program indicators which is indicative of a functioning program. Each TB control program faced severe challenges contingent on the political, economic and geographic situation and the amount of outside support. The main challenges were management, donor and service provider coordination, funding, security and logistics. Patience and creativity in ad-hoc problem solving were necessary to circumvent temporary or continuous obstacles. With the emergence of multi- and extensively drug resistant TB, it is particularly important to ensure the proper and safe delivery of TB treatment. Available treatment outcome data from these four countries showed that achieving good treatment outcomes was possible for patients who accessed DOTS care, but limited access to health services and related low case detection have remained major challenges (figures 1-2). However, case notifications have increased in all four countries since 2003. The Global Fund[80] which plays an increasingly important role in fragile states reported good performances. Three of the four countries described received good Global Fund ratings. The first lesson learned therefore is that TB control programs

can function despite major challenges. Increasing access to care and case detection remain key problems.

Lesson 2: National program leadership and stewardship are essential

For the quality and sustainability of TB control, it is important for the NTP to exercise its stewardship functions. These include normative, technical, capacity-building, supervisory and coordinating functions which are applicable for TB control but not necessarily for all public health programs. They are particularly important in fragile states where core government functions are weakened. Therefore disease control programs often compensate for broader, system-wide problems. Other partners can assist in supporting these functions at intermediate and service level, depending on availability of human, financial and technical resources. However, program leadership, oversight, overall management and guidance should be fostered and supported by national and international organizations. Haiti has struggled with the sustainability of management oversight structures under changing donor arrangements and Somalia with the non-existence of a government-run NTP. Afghanistan showed that channeling funding through government agencies can help strengthen leadership and stewardship[4]. The second lesson learned therefore is that national program leadership and stewardship are essential for quality and sustained TB control. This is relevant for all countries, but it is critical where many partners support service delivery.

Lesson 3: Strong partnerships and coordination are necessary

Each presented TB control program struggled with major impediments to running a well-functioning health care system. The main challenge and opportunity in Afghanistan has been the integration of TB care into general health services. As the four country examples show, it is possible to run TB control programs in fragile states through the coordinated work of non-governmental providers. In all four countries, coordinating mechanisms were established in which agencies involved in TB control participate. NGOs may find a role in opening access to and/or guaranteeing continuity of care. The TB control programs of Afghanistan,

DR Congo, Haiti and Somalia heavily relied on partnerships with NGOs for different functions. NGOs in Haiti and DRC provided primarily financial, technical or management support whereas NGOs in Afghanistan and Somalia were mainly involved in service delivery. Chronic fragile states differ from emergency situations as they require a different kind of response. Whereas healthcare services in acute emergencies are maintained by NGOs and agencies specialized in emergency care, chronically fragile states need a continuous response and therefore stable partnerships between the public sector and donors, private providers, non-governmental, community- and faith-based organizations. Logistics problems in DR Congo were creatively circumvented to ensure a continuous drug supply and political divisions in Somalia have not prevented the functioning of TB control efforts. Lasting partnerships only grow on a basis of mutual trust and committed collaboration on all sides. While well-trained and motivated peripheral health care workers have been crucial in providing TB services in hard to reach areas, all four countries have faced grave human resource crises. NGOs were able to mobilize resources and/or ensured continuous provision of TB services. The third lesson learned is that strong partnerships and coordination of non-governmental providers for consistent technical, financial and human resources support are needed for continuous service delivery.

Lesson 4: TB control programs in fragile states require consistent donor support

By definition, fragile states have weakened core government functions, often paired with a lack of financial and human resources dedicated to public health. In this context, donors can play a significant role to create more stability and may have a considerable positive or negative impact on program continuity and management. Given the strong donor dependency of fragile states, changes in donor commitments tied to changes in policy and/or disruption in services can have important public health impacts. NTP stewardship is strengthened when the TB control program has funds to manage and use. Weaknesses in accountability need to be addressed by adequate financial and accounting controls. Our findings coincide with principles and objectives pledged by donors in fora of the OECD

Development Assistance Committee and the Paris Declaration on Aid Effectiveness. The fourth lesson learned therefore is that TB control programs in fragile states require continuous technical and financial donor-engagement in accordance with internationally agreed norms.

8. CONCLUSION

This examination looked at themes that have been consistently raised as key concerns by TB technical assistance providers in four fragile states. Despite major challenges in management, coordination, security, logistics and funding, TB control programs can function in fragile states. The major bottleneck is access to diagnosis and treatment and therefore case detection. It cannot be concluded, which factors were most decisive to maintain basic structures and achieve good outcomes and whether some factors were complementary to others. However, this analysis does suggest that national TB program leadership, partner coordination, consistent technical and financial assistance and the use of the DOTS approach as a common framework are all crucial for TB control programs to function in fragile states. The analysis did not reveal any consistent results on ways to improve TB case detection in the fragile states examined. Case detection however remains a major challenge and its improvement is an increasingly important effort of TB control programs[10]. Increasing case detection is recognized to be strongly linked to an overall improvement of the health system's functioning[82]. Therefore, strengthening the general health system in fragile states is paramount for improving access to health care and to elicit a notable effect in disease control. This in turn requires consistency and continuity in the overall development assistance. In addition to health system strengthening, this paper suggests that a specific disease control approach is needed in fragile states to reach the Millennium Development Goal to combat HIV, Malaria and other diseases. Rigorous case documentation and comparative research on health system strengthening, structure and management approaches in other fragile states and disease control areas will be useful. It would be worthwhile to

investigate to what extent improvements in one disease control area could benefit the general health system and strengthen other disease control programs.

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ENDNOTES

[1] The DOTS approach includes five elements:
1. Political commitment with increased and sustained financing
2. Case detection through quality-assured bacteriology (sputum smear microscopy)
3. Standardized treatment with supervision and patient support; standard TB treatment takes 6-8 months to complete.
4. An effective drug supply and management system to avoid interruption of treatment and development of resistant TB bacili.
5. Monitoring and evaluation system, and impact measurement for monitoring treatment and outcomes, identifying problems at different levels and evaluating the performance of the TB program.31. World Health Organization: *The Stop TB Strategy.* Geneva World Health Organization; 2006.

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CHAPTER 4

Assessing access barriers to tuberculosis care with the Tool to Estimate Patients' Costs: pilot results from two districts in Kenya

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Chapter 4 Assessing access barriers to tuberculosis care with the Tool to Estimate Patients' Costs: pilot results from two districts in Kenya

ABSTRACT

Background

The poor face geographical, socio-cultural and health system barriers in accessing tuberculosis care. These may cause delays to timely diagnosis and treatment resulting in more advanced disease and continued transmission of TB. By addressing barriers and reasons for delay, costs incurred by TB patients can be effectively reduced. A Tool to Estimate Patients' Costs has been developed. It can assist TB control programs in assessing such barriers. This study presents the Tool and results of its pilot in Kenya.

Methods

The Tool was adapted to the local setting, translated into Kiswahili and pretested. Nine public health facilities in two districts in Eastern Province were purposively sampled. Responses gathered from TB patients above 15 years of age with at least one month of treatment completed and signed informed consent were double entered and analyzed. Follow-up interviews with key informants on district and national level were conducted to assess the impact of the pilot and to explore potential interventions.

Results

A total of 208 patients were interviewed in September 2008. TB patients in both districts have a substantial burden of direct (out of pocket; USD 55.8) and indirect (opportunity; USD 294.2) costs due to TB. Inability to work is a major cause of increased poverty. Results confirm a 'medical poverty trap' situation in the two districts: expenditures increased while incomes decreased. Subsequently, TB treatment services were decentralized to fifteen more facilities and other health programs were approached for nutritional support of TB patients and sputum

sample transport. On the national level, a TB and poverty sub-committee was convened to develop a comprehensive pro-poor approach.

Conclusions

The Tool to Estimate Patients' Costs proved to be a valuable instrument to assess the costs incurred by TB patients, socioeconomic situations, health-seeking behavior patterns, concurrent illnesses such as HIV, and social and gender-related impacts. The Tool helps to identify and tackle bottlenecks in access to TB care, especially for the poor. Reducing delays in diagnosis, decentralization of services, fully integrated TB/HIV care and expansion of health insurance coverage would alleviate patients' economic constraints due to TB.

1. BACKGROUND

The association between tuberculosis (TB) and poverty has been well established [1-6]. The economically vulnerable are more likely to be exposed to conditions that predispose to infection with mycobacterium tuberculosis [3, 7-11] and that propagate progression to disease [5, 11, 12].

The poor face geographical, economic and health system barriers to accessing care [5, 13] which cause delays in seeking healthcare [14, 15] resulting in more advanced disease and continued transmission of TB in the community. TB affects the most economically-productive age, posing a significant economic burden on affected households [3, 16, 17].

The three main types of economic constraints that TB patients face are 1) charges for health services, 2) costs for transport, accommodation and nutrition and 3) lost income, productivity and time [5, 18-21]. Direct (out-of-pocket) costs for public or private services and indirect (opportunity) costs can trigger a spiral into (deeper) poverty for many families. This situation has been termed 'the medical poverty trap' [22].

By addressing economic barriers and reasons for delay to timely diagnosis and treatment, costs incurred by TB patients can be effectively reduced. A number of studies on patient costs have been published [1, 13-16, 18, 20, 21, 23, 24],

however there was a need to address some of the methodological bottlenecks to assess barriers identified in these studies and make the Tool (including the questionnaire, guidelines, data entry template) available for national TB programs and other organizations working with TB. A consortium of partners (KNCV Tuberculosis Foundation, Japan Anti-Tuberculosis Association, World Health Organization Stop TB department and members of the Stop TB Partnership's TB & Poverty Subgroup) therefore developed a Tool to assist TB control programs in assessing such barriers, funded by the Tuberculosis Control Assistance Program (TB CAP/USAID). It can be used worldwide and is not limited to research organizations. The objective is to establish an evidence base upon which interventions can be designed.

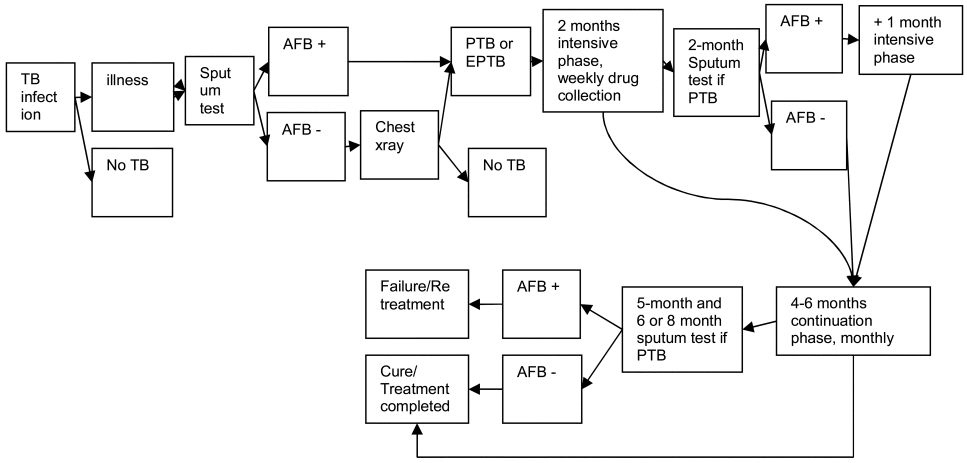
A literature review on studies dealing with patients' costs and methodologies employed was conducted to determine at what stage patients are likely to incur which kinds of costs. The findings of the review formed the basis and context for the development of the Tool. The generic Tool is designed to assess direct (out of pocket) and indirect (opportunity) costs incurred by TB patients at two distinct phases: 1) before and during diagnosis and 2) during treatment. The Tool also includes questions on TB patient information; previous TB treatment episodes; health-seeking behavior and delays; costs to the guardian/treatment supporter of the patient; health facility visit costs; social impact of the disease on the family including children; and the impact of TB on food expenditure; costs of TB on the welfare of the household.

The Tool contains an introduction, a literature review on patient cost studies, a generic questionnaire to be adapted to local circumstances, a brief review of socioeconomic indicators, a list of indicators to be measured by the Tool, guidelines on the adaptation of the questionnaire to local circumstances, methods, sampling and training of interviewers, on interpretation of results generated by the questionnaire, and on possible interventions. An Epi Info template for data entry and an Excel template to summarize results have been added to facilitate data analysis. The Tool can be downloaded for free on the websites of the Tuberculosis Coalition for Technical Assistance (TBCTA;

www.tbcta.org) and Stop TB Partnership TB & Poverty Subgroup (www.stoptb.org/tbandpoverty), see Additional file 1.

The Tool was piloted in Kenya where TB diagnosis (sputum smear microscopy) and treatment at public health facilities are free of charge. The Kenyan national tuberculosis control program (Division of TB, Leprosy and Lung Disease DLTLD) follows the internationally-recommended DOTS approach, promoted by WHO since 2006 [25] with sputum smear microscopy as primary diagnostic tool for TB. Under DOTS, TB patients require a treatment supporter to ensure and document that the treatment has been followed continuously. The procedure followed by TB patients is summarized in figure 1. From a patient perspective, figure 1 shows a simplified process; between illness and diagnosis there are often many different care-seeking episodes. This paper presents the results from this pilot.

Figure 1: Diagnosis and Treatment Algorithm



Abbreviations:
AFB: Acid-Fast Bacili
PTB: Pulmonary Tuberculosis
EPTB: Extra-Pulmonary Tuberculosis

In 2008/2009, the Kenyan TB program has changed its treatment regimen from an eight-month to a six-month regimen. Retreatment cases receive an eight-month regimen.

2. METHODS

Study Sites

Kitui North and Mutomo districts, both in Eastern Province, were purposively selected in consultation with DLTLD, considering proximity to Nairobi and level of socioeconomic development [26]. While 75% of incomes stem from agriculture, this area is prone to persistent droughts and crop failures resulting in food and income insecurity [27].

Nine out of 41 health facilities offering TB services in the pilot districts were purposively selected as pilot sites based on caseload and accessibility (table 1); seven were public health facilities and two were faith-based clinics. Private facilities charging fees for service were not selected with the focus of the pilot on the public sector. The target enrolment was 200 patients for a sample size sufficient to accurately evaluate the Tool and ensure sufficient power of the analysis. Interview quotas based on currently registered cases per facility as a proportion of district caseloads were assigned to each of the nine facilities.

Table 1: Information on pilot districts, 2008

(all data except where otherwise indicated [28])

	Kenya	Pilot District Kitui North	Pilot District Mutomo
Estimated population	38,277,856	473,241	291,576
Annual per capita income 2005 (KSH) [26]	35,480	10,699	n/a
Adult Literacy Rate, 2005 (%) [26]	68.7	69.9	n/a
TB cases (all types) notified in 2008	110,251	1,432	408
TB case notification rate / 100.000 population	338	303	140
Estimated HIV prevalence in general population (%)	7.1 [29]	14 [27]	14 [27]
Number of public health facilities	6,696 [30]	74	17
TB treatment centers	2,228	41	12
TB treatment centers / 100.000 population	6	9	4

Study Population

Every patient or treatment supporter representing a patient (guardian) at the selected health facility who fulfilled the in- and exclusion criteria as listed below was eligible and asked to participate. Interviews were conducted during TB clinic days.

Inclusion criteria:

Patients (or treatment supporters/guardians who came in place of patients) who:

- Were new or re-treatment patients
- Had received at least (≥) 1 month of treatment for TB (for their current diagnosis)
- Were at least (≥) 15 years of age

Exclusion criteria:

- Currently hospitalized patients
- Patients under (<) the age of 15 years

All eligible patients were approached to enroll in the study. All patients who accepted to sign an Informed Consent form after being briefed on their rights as interviewees were enrolled in the study.

Development of the questionnaire

The generic questionnaire of the Tool was adapted to the local setting in consultation with central program and local district staff. The questionnaire was pretested at one of the sites where four patients were interviewed, and adjustments were made as appropriate. The questionnaire was translated into Kiswahili and back translated into English to ensure accuracy of the translation. During extensive discussion with central and district staff, a decision was reached to ask patients about their HIV status. Six interviewers were selected and trained. All interviewers were Kiswahili speakers, and four were native Kamba speakers, the dominant local language. Interviews were conducted primarily in Kiswahili, with Kamba in prompting questions. The research protocol and standard operating procedure manual were approved by the Scientific Steering Committee of the Kenya Medical Research Institute (KEMRI).

Data entry and analysis

Responses gathered from patients were entered into Epi Info 6.0, using double entry to enhance data quality. Consistency and range checks were used to ensure completeness of data.

For the pilot in Kenya, direct costs incurred during TB treatment were calculated per drug collection visit. Direct costs are quantifiable, out-of-pocket costs associated with TB: health care costs such as tests, administrative charges and medicines taken for TB symptoms prior to receiving a TB diagnosis; transport costs to and from health facilities; and associated food and accommodation costs. Any reimbursements received by patients through insurance were deducted. Costs were noted in Kenyan Shillings (KSH). The exchange rate was 65 KSH to one U.S. dollar.

Indirect costs were calculated as income lost due to TB. For income lost prior to treatment, the time off work was multiplied by the median reported individual income prior to the onset of TB. For income lost during treatment, the time off work was multiplied by the median reported individual income since the onset of TB.

Data was analyzed using Epi Info 6.0, Excel 2003 and STATA 9.0 (STATA, Statacorp, Texas, USA). The Shapiro-Wilk test was used to test for normality. Due to lack of normality in the quantitative data, non-parametric tests were used in the analysis. Wilcoxon matched pairs signed ranks test was used when it was not appropriate to use the paired comparison t-test. The Kruskal-Wallis test was used to test the equality of independent variables with two or more levels and an ordinal dependent variable. In the analysis of categorical variables, Fisher's exact test was used to test for association where the cell count was less than 5. Unless otherwise specified, median values were used as a measure of central tendency while inter-quartile range (IQR) was preferred to range in order to avoid extreme values. The level of statistical significance, according to the calculated sample size, was $p = 0.05$ with a confidence level of 95%.

Due to known unreliability of income data [18, 31-36], household food expenditures and assets, partly based on the Kenya Demographic and Health Survey 2003 [37], were analyzed as proxies for income in addition to self-reported individual and household income. All respondents were assigned to five income groups to reflect socioeconomic strata in the study districts. The groups were determined jointly by study investigators and district-level TB program staff.

Six months after the pilot, follow-up interviews with key informants in the districts and at national level were conducted to assess the impact of the pilot and to explore potential interventions based on the findings.

3. RESULTS

A total of 208 patients were interviewed. No patients or guardians refused or stopped the interview.

The majority of interviews (n=188) took place in Kitui North, with 20 interviews in Mutomo. Nineteen guardians/treatment supporters were interviewed (9%). Differences in responses between guardians and patients were not observed. Tables 2 and 3 and figure 2 provide an overview on socioeconomic and TB-related information for the sample population. 59% of the study population was male with the majority between 26 and 40 years of age. 90% were new TB cases. 51% of primary household income earners had only primary education.

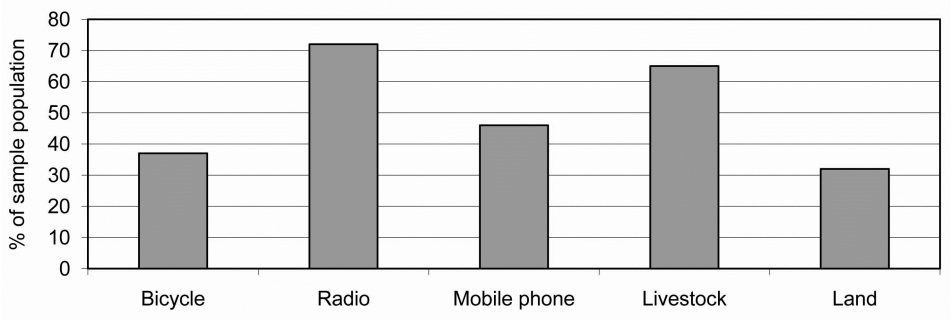
Table 2: Sample population characteristics

Gender (unknown: n=2)	**% (n)**
Male	59 (121)
Female	41 (85)
Age (unknown: n=2)	**%**
≤ 25	21 (43)
26 - 40	51 (105)
>40	28 (58)
Household size (unknown: n=2)	**% (n)**
< 3	10 (21)
3 to 5	44 (91)
> 5	46 (94)
TB Type (unknown: n=2)	**% (n)**
PTB SS+	53 (109)
PTB SS-	39 (80)
EPTB	8 (17)
TB treatment category; HIV	**% (n)**
New cases	90 (187)
Retreatment cases	10 (21)
HIV positive	33 (69)

Table 3: Socioeconomic information of sample population

Education of primary household income earner (unknown: n=2)	**% (n)**
Primary school	51 (105)
Secondary school	32 (66)
Not attended	10 (21)
High school certificate	6 (12)
Adult learning	1(2)
Occupation (unknown: n=2)	**% (n)**
Small business	26 (54)
Casual labour	21 (43)
Housework	21 (43)
Subsistence farming	12 (25)
Civil servant	6 (12)
Transport, Student, Retired, Other	14 (29)
Drinking water source	**% (n)**
Lake, pond, dam, river	46 (96)
Public well	6 (12)
Private well, bore hole	15 (32)
Piped water, bottled water	33 (68)
Type of toilet facility available	**% (n)**
No facility, bush, field	5 (11)
Shared pit toilet, latrine	60 (124)
Own pit toilet, latrine	33 (68)
Flush toilet	2 (5)
Type of housing	**% (n)**
Dirt floor, thatched roof	12 (26)
Dirt floor, metal roof	50 (104)
Concrete floor	38 (78)

Figure 2: Household asset ownership at time of interview



Health Seeking Behaviour

Seventy-five percent of all patients reported accessing a public health facility first. The remaining 25% visited a private clinic or laboratory, and cited waiting times (51%) and distance to the facility (30%) as reasons behind their choice of facility. Only one patient visited a tradtional healer. The median delay between the onset of symptoms and seeking a diagnosis at a public facility was 2 months (IQR 1-3 months).

Pre-Diagnosis/Diagnosis Costs

Median direct costs incurred from the onset of TB symptoms to diagnosis at a public health facility were 860 KSH (13 USD) per patient. This includes costs related to visits to public, private or informal providers. A small number of patients had been hospitalised before their current TB diagnosis was made (n = 12), incurring disproportionately high costs: 2,177 KSH (hospitalized, median) versus 832 KSH (not hospitalized, median).

Patients required a median of three health facility visits, taking a median of 12 hours before receiving a diagnosis. In the pre-diagnosis phase travel to and from health facilities and costs for diagnostic tests accounted for most direct costs (38% and 37% of pre-diagnosis direct costs respectively). Additional costs were food purchased (lunch for health facility visits, vitamins; 19%) and administrative charges at health facilities (6%).

Pre-diagnosis/diagnosis costs did not vary significantly by age, gender or income level. However, patients with extra-pulmonary TB (EPTB) experienced significantly higher costs during the pre-diagnosis/diagnosis phase mainly due to additional costs of xrays, reporting a median of 1,450 KSH compared to a median of 860 KSH for patients of all other TB types ($p = 0.0175$).

Treatment Costs

Patients had completed a median of 4 out of an 8 month treatment regimen at the time of the interview. Costs due to DOT visits were not incurred, as all patients interviewed received family DOT at home.

Direct costs during treatment consisted of travel costs to collect drugs or for a follow-up sputum test (54%), food (45%), accommodation, other tests, other drugs and administration costs (together < 1%). Treatment costs did not differ significantly by age, gender, income level or TB type. The median total treatment cost was 105 KSH (1.6 USD; IQR 39-189 KSH) for each visit lasting a median of 3 hours (IQR 2-4.5) each.

Coping Costs

Most patients reported having to borrow money (57%) and/or selling assets (52% of which 90% was livestock) to cover the costs incurred. Patient income did not determine whether or not they borrowed money. However, there was a relationship between patient income and asset disposal ($p= 0.03$; $\chi^2=10.53$ with 4 d.f.), with middle-income patients selling significantly more than low- or high-income patients. Those who sold assets gained significantly less than the market price estimated by the patient ($p = 0.000$).

Indirect Costs

Indirect costs for the entire duration of illness (19,123 KSH; 294 USD) constituted 85% of total costs. For the pre-diagnosis phase, this was calculated using patients' median monthly income before the illness (4,250 KSH), multiplied by the median amount of time they were out of work as a direct result of their illness (4.5

months, n = 174). For the treatment phase, median monthly patient income after the onset of TB (0 KSH implying that patients have not resumed work) was multiplied by the amount of time required for TB treatment over 14 drug collection visits (42 hours).

Total Costs and Change of Income due to TB

Table 4 summarizes all incurred costs. The median total of direct and indirect costs was 22,753 KSH (350 USD). This was equivalent to 45% of median annual individual incomes (50,960 KSH; 784 USD) and 27% of median annual household incomes before TB illness (84,260 KSH; 1,296 USD). Both household and individual incomes dropped due to TB (figures 3, 4). After the onset of TB, total costs increased by 20%, to 47% of median household incomes. Food and healthcare expenditures increased from 46% to 223% of median monthly household income. Figure 5 shows the lowest income group reduced expenditures on food items due to TB while higher income groups tend to increase food expenditures due to TB. Adequate nutrition is important during treatment to make up for weight previously lost due to the illness. In addition, anti-TB drugs can cause nausea and are more easily digested after food intake.

Table 4: Total Costs and Summary

Median Direct Costs	**KSH (IQR)**	**USD**	**% of median annual individual income (pre-TB)**
Pre-Diagnosis/Diagnosis Costs	860 (500-1,670)	13.2 (8-26)	1.7
Treatment Costs (cost/visit x 14 visits)	1,470 (560-2,660)	22.6 (9-41)	2.9
Coping Costs	1,300 (800-2,500)	20 (12-38)	2.6
Sub-Total	***3,630***	***55.8***	***7.1***
Median Indirect Costs			
Foregone income before diagnosis (4.5 months of work lost x initial monthly income)	19,123 (6,750-40,500)	294.2	37.5
Foregone income during treatment: drug collection time x current income. (Total drug collection time = hours/visit x 14 visits)	42 hours x zero income = 0		
Sub-Total	***19,123***	***294.2***	***37.5***
Median Total Costs			
Direct + Indirect Costs	***22,753***	***350***	***44.6***

Figure 3: Household monthly income groups

Reported quintiles are those of the study population.

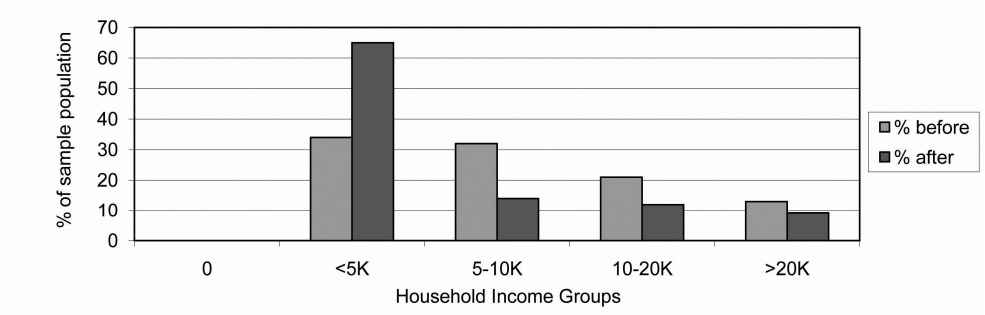


Figure 4: Individual monthly income groups

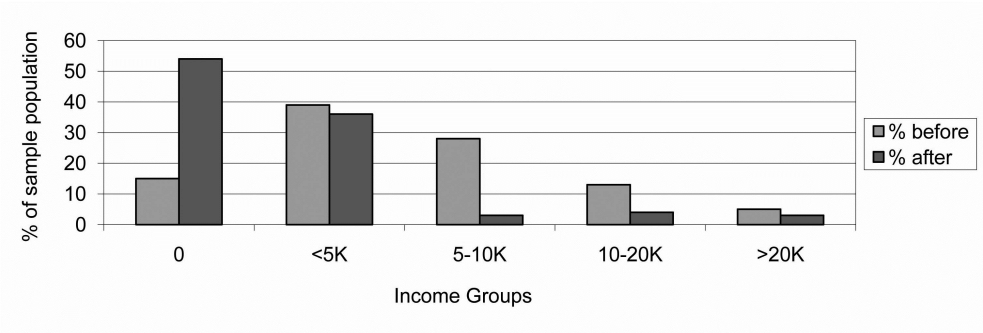
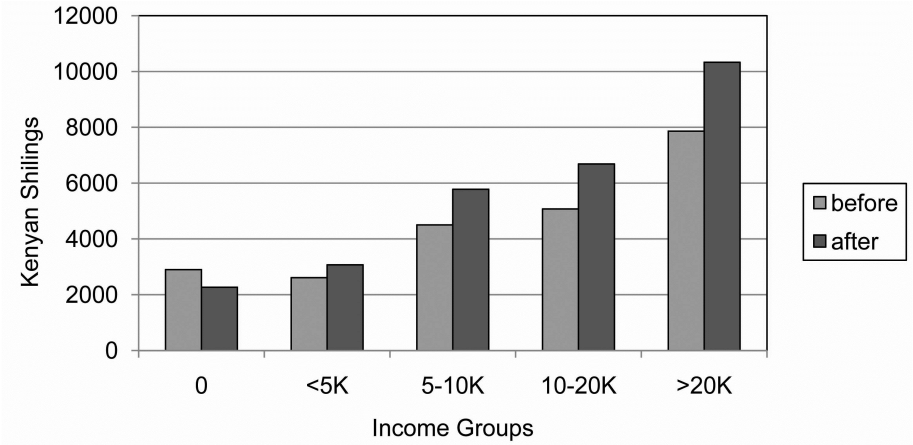


Figure 5: Monthly household food expenditures by income group



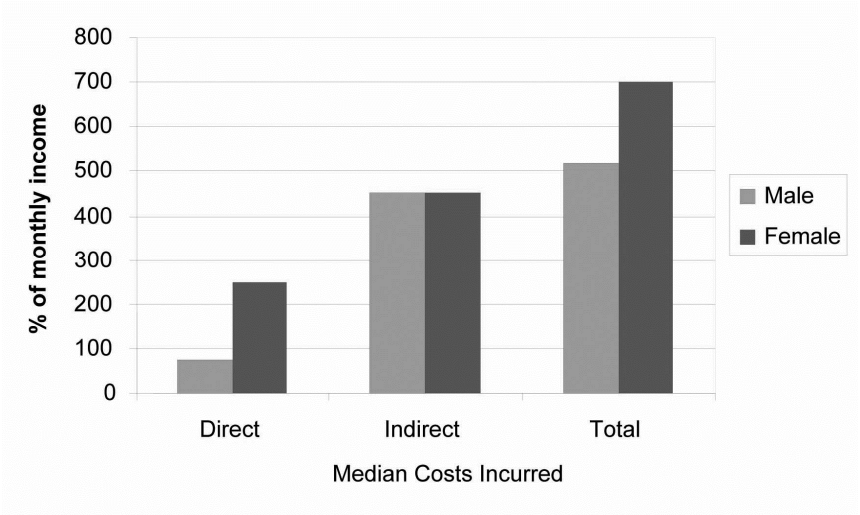
HIV

33% of all patients interviewed reported to be HIV+. Two percent declined to answer the question, 53% confirmed they were HIV-, 4% had not been tested and 8% were unsure. Compared to HIV- patients, HIV+ patients experienced 16% higher direct costs during the pre-diagnosis/diagnosis phase and 48% higher costs during treatment, associated with collection of anti-retroviral drugs, however not statistically significant.

Gender

Men and women did not report statistically significant differences in costs. However, women were more likely to have low incomes and thus devoted a higher percentage of their income to TB-related costs (figure 6). Reported patient delay did not differ significantly between men and women.

Figure 6: Total direct and indirect costs by gender as % of monthly individual income



Productivity and Social Impact of TB

Patients were asked to estimate the number of hours they worked per week before and after the onset of TB. Of the 208 respondents, 85% reported a decrease as a result of TB illness. 15% of those who worked fewer hours had a family member take over their work, in 5% of cases this was a child. However, no child stopped school to undertake this work. Of all respondents, 9% had children that completed school and worked to raise money during the TB illness. 11% of respondents employed someone to do the housework. A house help earned a median of 2,000 KSH per month, which can be used to assign a value to unpaid household work. 28% of respondents reported disrupted social life due to TB,

affecting sexual life (n= 93); job loss (n=20); divorce (n=5) and separation from spouse (n=10).

Insurance

Twelve percent of patients reported having some form of health insurance, with only one patient having inpatient benefits. Higher-income patients were more likely to have health insurance (p = 0.005). However only in one case insurance covered outpatient costs.

Results of follow-up interviews

Six months after the presentation and discussion of the Tool's findings with program staff at national and district level, follow-up interviews were conducted with key informants (Kenyan TB experts and local staff involved in the initial study). The objectives of these interviews were to assess the impact of the pilot, the usefulness of study findings and to explore the feasibility of recommendations. Decentralization of treatment services and HIV service integration were seen to be of greatest benefit in tackling TB-related direct costs.

4. DISCUSSION

Key Findings

The implementation of the Tool to Estimate Patients' Costs showed that TB patients in Kitui North and Mutomo have a substantial burden of direct and indirect costs due to TB. The majority of costs are indirect (38% of annual individual income before the disease). Inability to work is a major cause of increased poverty and contributes to worsening of individual economic situations. The proportion of patients not earning a regular income increased from 15% to 54% after the onset of disease. Individual incomes dropped to zero after onset of TB and household incomes dropped by 43%. Although less than indirect costs, direct costs are still considerable (7% of individual annual income) with transport as the biggest cost item. Results confirm a 'medical poverty trap' [22] situation in the two districts: expenditures increased while incomes decreased.

Usefulness of the Tool

The information generated by the Tool can be used as an evidence base for subsequent interventions to alleviate the financial burden of TB patients. Reducing delays in diagnosis, decentralization of services, integration of TB/HIV care and inclusion of TB in- and outpatient services in health insurance schemes while increasing insurance coverage could alleviate economic constraints due to TB [38]. Recommendations that were based on the findings of the pilot and the follow up interviews included: further decentralization of TB care, realignment of the currently used communication strategy to stimulate TB suspects to seek care early, mobile clinics, stronger TB/HIV program coordination to allow for integrated TB/HIV care, further usage of the Tool in other areas.

Following the study, fifteen more facilities in the pilot districts were equipped as TB treatment centres. The district TB and Leprosy coordinators approached the World Food Program to discuss nutritional support of TB patients and local partners for sputum sample transport to distant diagnostic centres to reduce patients' transport costs and time spent on the road. On the national level, a TB and poverty sub-committee was convened to develop a comprehensive pro-poor approach within the routine TB program.

Comparability of the Tool

TB costing studies done elsewhere in East Africa and Asia show similar results (Table 5) in respect to direct costs (Malawi) and indirect costs (India). Due to study design differences, exact costs comparisons cannot be made, the results are nonetheless informative.

Table 5: TB Patient Cost Study Comparison

Study	Costs Incurred (% of household annual income)			Lost Work (months)
	Direct Costs	Indirect Costs	Total Costs	
India (rural/urban) [17]	13	26	40	2.5
Zambia (rural/urban) [21]	8.3	4.8	13.1	n/a
Thailand (rural/urban) [16]	8.6	2.3	10.9	2.7
China (rural) [13]	n/a	n/a	45	n/a
Kitui (rural/urban)	4.3	22.7	27	4.5
	Costs Incurred (% of individual annual income)			
Malawi (urban) [18]	5	6.3	11.5	
Kitui (rural/urban)	7.1	37.7	44.8	

Study Limitations

Estimating monetary incomes was difficult for those without regular salaries. Disaggregated costing questions about everyday amounts would be more graspable. Asking the same questions at different times of the agricultural year might yield different responses and it is difficult to ensure that patients are reporting incomes, not turnover from business. Furthermore, assigning a monetary value to unpaid housework and health insurance were difficult concepts to communicate. Patient recall declined noticeably after four months on TB treatment and time-sequence prompts were useful. A weighted asset index was not made as it was beyond the purpose of this study. Patients' mobility was omitted, hence migration patterns of TB patients were not assessed. Questions relating gender and equitable access were difficult to convey. More gender sensitization in interviewer trainings may have been necessary. Reporting expenditures for food as done in this study is not equal to food consumption. Therefore reduction in food expenditure does not necessarily imply a reduction in food consumption as households may produce their own food or may receive food from others when in need. Including local program staff as interviewers gave

them an opportunity to speak with patients in-depth and to conceptualize strengths and challenges of the TB program. However, it is possible that the presence of staff influenced the responses of patients.

In Mutomo only 20 patients could be interviewed. This district was therefore relatively undersampled, because 22% (n = 44) were targeted based on case numbers. Due to the small sample, an analysis for sensitivity between the districts could not be done. However, significant differences between Mutomo and Kitui North are not expected as they used to be one district until 2008. Thus, a bias of study results is not presumed.

Sensitivity of income data was not analyzed in this study. When comparing annual per capita income of the Kenya Human Development Report [26] in 2005 Kenya (35,480 KSH; 76 KSH per USD) and Kitui North (10,699 KSH) with our finding of median annual individual income of 50,960 KSH in 2008 (65 KSH per USD), it is likely that self-reported income was over-estimated in this study. If we assume an over-estimate of 43%, median annual income before TB would be 523 USD instead of 748 USD; and median annual household income 906 USD instead of 1296 USD. Total costs would constitute 67% of annual individual income and 39% of annual household income which is 22% and 12% more than what our findings indicate. Future studies and implementers of this Tool are therefore advised to compare income results to recent national demographic and health surveys, data from the national statistics office or Human Development Reports to put results into context. In addition, food consumption and asset indices are recommended as proxies for income. Despite challenges in assessing income, the results of this study nevertheless show a remarkable impact of TB on the welfare of households and individuals.

5. CONCLUSION

The Tool to Estimate Patients' Costs proved to be a valuable instrument to assess patients' costs, the socioeconomic situation of the patients, health-seeking behavior, concurrent illnesses such as HIV, as well as social and gender-related impacts. In addition, the Tool helps to assess the economic impact of TB on

individual and household welfare and to identify bottlenecks in access to TB care. The mere usage of the Tool can already have an impact by involving staff who take responsibility in improving the situation for TB suspects and patients. Challenges such as recall bias and gender-related sensitivities are difficult to address; each cultural setting will need to find its best-suited approach. The improved Tool has been subsequently implemented in the Dominican Republic, Ghana and Viet Nam. Establishing evidence on patients' costs in different parts of the world will be instrumental in advancing the calls for free TB diagnosis, integration of TB/HIV services and comprehensive health and disability insurance for the poor.

LIST OF ABBREVIATIONS USED

AFB	Acid-Fast Bacilli
DLTLD	Division of Leprosy, Tuberculosis and Lung Disease
DOT(S)	Directly Observed Treatment (Short-Course)
EPTB	Extra-Pulmonary Tuberculosis
HIV	Human Immune Deficiency Virus
IQR	Inter-quartile Range
JATA	Japan Anti-Tuberculosis Association
KEMRI	Kenya Medical Research Institute
KNCV	Royal Netherlands TB Association
KSH	Kenyan Shillings
PTB	Pulmonary Tuberculosis
TB	Tuberculosis
TB CAP	Tuberculosis Control Assistance Program
TBCTA	Tuberculosis Coalition for Technical Assistance
WHO	World Health Organization

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CHAPTER 5

Tuberculosis patients in the Dominican Republic face severe direct and indirect costs and need social protection

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Chapter 5 Tuberculosis patients in the Dominican Republic face severe direct and indirect costs and need social protection

ABSTRACT

Objectives

Tuberculosis is a major infectious disease associated with poor living standards. In 2009, the Ministry of Health of the Dominican Republic together with partners conducted a study to investigate the costs of TB patients. The direct (out of pocket) and indirect (opportunity) costs of new, retreatment and multi-drug resistant TB patients before and during diagnosis and during treatment were investigated. The aim of the study was an evidence base upon which recommendations and interventions could be formulated.

Methods

The "Tool to Estimate Patients' Costs" was adapted to the local setting, translated into Spanish and pretested. Patients attending 32 randomly selected health facilities in six chosen study areas on the study days were interviewed. Responses from patients above 18 and below 65 years of age, on treatment for at least one month and with signed informed consent were gathered, entered and analyzed.

Results

A total of 200 patients were interviewed. Responses of two patients were excluded from the analysis due to incomplete data. For most respondents, direct and indirect costs increased while income decreased. This affects the most vulnerable of society. Total costs (pre-diagnostic, diagnostic and treatment costs) amounted to USD 908 for new patients, USD 432 for retreatment patients and USD 3 557 for MDR-TB patients. For the lowest income group, these costs constitute 2215%, 1054% and 8676% of median monthly income, respectively. The percentage of patients without a regular income increased from 1 to 54 because of falling ill with TB. The Ministry of Health has subsequently been

making an effort to allocate public funds for food supplements and to include in- and outpatient TB services in the national health insurance schemes.

Conclusions

Free TB diagnosis and treatment are not enough to alleviate the vulnerable from financial constraints due to the illness. Health insurances covering TB in- and outpatient costs are absolutely critical to prevent TB-related financial hardship.

Keywords: Dominican Republic, tuberculosis, patient costs, MDR-TB

Introduction

Tuberculosis is a major infectious disease associated with poor living standards and the socioeconomic disadvantaged [1, 2]. In Latin America, 214 030 TB cases were notified in 2010 (total population 933 million) of which 3 964 (1.85%) were notified in the Dominican Republic (population 10 million; 1.07%) [3]. In 2007, the Pan-American Health Organization PAHO [4] reported a rise in out of pocket expenses in the Dominican Republic mainly due to low government expenditures on health and a lack of financial security in the form of insurances, which affects particularly the economically vulnerable. While a number of studies on patient costs have been conducted in Africa [5-9], until 2009 little evidence from Latin America was available in the literature and none of the studies included costs incurred by multi-drug resistant (MDR-TB) tuberculosis patients. Studies done in Peru [10], Haiti [11], Mexico [12] and Dominican Republic [13] investigated the economic impact of TB. The last found a great need to expand TB control in the form of DOTS with a patient-centered approach.

In order to investigate the current situation for patients, the Ministry of Health of the Dominican Republic together with partners conducted a study in 2009 to find out the costs that TB patients incur. Both the direct (out of pocket) and indirect (opportunity) costs of new, retreatment and MDR-TB patients before and during diagnosis and during treatment were investigated. This was linked to information on the patients' socioeconomic status, health seeking behavior, HIV status and the

impact of TB on the welfare of the household. The study was aimed to establish an evidence base upon which recommendations and interventions could be formulated to address identified bottlenecks. For this purpose the consortium decided to use the "Tool to Estimate Patients' Costs" which has been described elsewhere in detail [8]. It is designed for use by national TB control programs and non-governmental organizations and has been used in Ghana, Viet Nam, Kenya and Myanmar [8, 14-16]. This article presents the findings of the study and resulting actions.

In the Dominican Republic, TB diagnosis (sputum smear microscopy) and treatment are free of charge and are performed according to the internationally recommended DOTS approach [17]. X-rays are charged. Upon diagnosis new TB patients follow a six month treatment regimen (two months of four drugs daily followed by four months of two drugs taken thrice weekly), while retreatment patients follow an eight month regimen (five drugs for two months daily followed by one month of four drugs daily, followed by five months of two drugs taken thrice weekly). Diagnosis and treatment for multi-drug resistant (MDR-TB) patients is free of charge[5]. Multi-drug resistant TB patients follow a 24 month treatment regimen (six months of five drugs daily followed by 18 months of two drugs daily). All TB patients need to go to health facilities to take their drugs under observation (DOTS) during the entire course of treatment.

Materials and Methods

Study sites

Three provincial health directorates (Santiago, La Vega and San Cristobal) and three health area directorates (Areas IV, V and VIII) were purposively selected. This included urban and rural areas. Santiago and Areas IV, V and VIII were chosen because of high TB case loads (20.7% of the annual national case notification). San Cristobal and La Vega were included for their presence of MDR-TB reference centers. Patients attending 32 randomly selected health facilities in the six chosen

[5] Diagnosis: culture and drug-susceptibility testing are free, any other tests are charged. Treatment: All subscribed medications are for free.

study areas were sampled. This included large and small hospitals, clinics, community centers and dispensaries, including public and private sector institutions. As this was an exploratory study, a target enrolment of 200 patients was considered a sample size sufficiently powerful for statistical analysis.

Table 1 Information on study areas, 2009

	Dominican Republic	Santiago	La Vega	San Cristóbal	Área IV (Santo Domingo)	Área V (Distrito Nacional)	Área VIII (Santo Domingo)
Estimated population [18]	9 755 954 [19]	1 031 447	647 003	647 003	500 846	362 019	254 931
Estimated annual per capita income [20]	4 670 [19]	1 679	1 580	2 035	(…)	1 897	(…)
# TB cases notified [18]	4 256 [21]	193	63	141	280	84	120
CNR per 100 000 pop.	42	21	16	25	58	23	47
Est. HIV prevalence 15-49 years (%) [22]	0.9	0.7-0.9	0.7-0.9	0.5-0.6	0.5-0.6	0.5-0.6	0.5-0.6
# TB patients tested for HIV [18]	397	31	13	20	33	15	18
% HIV positive	9%	8%	14%	7%	7%	8%	9%
# public health facilities per 100 000 population [23]	28	13	22	20	(…)	(…)	(…)
# of TB treatment centers [18]	1068	70	55	75	40	30	18
# TB treatment centers per 100 000 population	10.9	6.8	8.5	11.6	7.9	8.3	7.1

Legend: (…) = data not available; CNR: case notification rate; Est. = Estimated; # = Number of; pop. = population

Study population

Interviews were conducted during TB clinic days. Every new and retreatment patient that attended the selected health facility and fulfilled the in- and exclusion criteria as listed below was asked to participate in the study. All MDR-TB patients who had initiated treatment for at least one month and no longer than three months for a MDR-TB regimen at the selected MDR-TB treatment sites and were previously treated with a standard retreatment regimen were asked to participate in the study. Pre-treatment costs of MDR-TB patients were calculated in the same

way as for new TB patients. All patients who accepted to be interviewed signed an Informed Consent form after being briefed on their rights.

Inclusion criteria

- New, retreatment and MDR-TB patients treated for at least 1 month
- Patients older than 18 years and younger than 65 years of age

Exclusion criteria

- Patients who had initiated treatment and then stopped treatment (defaulters)
- Patients with a modified regimen due to treatment failure or adverse reactions
- Patients who declined to be interviewed

Questionnaire development and interviewer training

The questionnaire of the 'Tool to Estimate Patients Costs' [8] was translated into Spanish and adapted to fit local circumstances, mainly in terms of local language habits. It was pretested in six health facilities representing all study areas. Based on the results of the pretest, the questionnaire was further adapted to fit local circumstances. The questionnaire was translated back into English to ensure accuracy of translation. Four interviewers were trained in a two day course. Special attention was given to confidentiality, informed consent, tuberculosis infection prevention, economic concepts and costs. Interviews were conducted in Spanish. The study protocol including the questionnaire was approved by the Independent Ethics Review Committee of ProFamilia.

Data entry and analysis

Completed questionnaires were delivered to the field coordinator and reviewed for completeness. Thereafter questionnaires were coded and data was entered using Epi Info 3.4. Data was double entered for consistency checks and analyzed using Microsoft Excel and SPSS 13.0. Median values were taken for quantitative comparison to avoid distortion of results by outliers. Costs were reported in

Dominican Republic Pesos (RD$) but converted to USD for analysis. At the time of the study, the exchange rate was 36.06 RD$ to one USD. Costs were distinguished as direct and indirect costs. Direct costs are out of pocket costs such as administrative payments, charges for tests and medicines, transport, food or accommodation. Transport and other costs related to health facility visits were calculated based on the number of trips that need to be made for a full course of treatment. Indirect costs were calculated as income lost due to TB. For income lost before the onset of the TB illness, lost working time was multiplied with the median reported individual income before the onset of TB. Income lost during treatment was calculated by multiplying the time off work with the median reported individual income since the onset of TB. Health insurance reimbursements were deducted. Interviewees were assigned to income groups according to the UNDP Human Development Report Dominican Republic 2008 [20].

Results

A total of 200 patients were interviewed between 1 July and 30 August 2009. Two were excluded from the analysis due to incomplete data. Ninety-eight percent of the interviewees were patients, the remaining 2% were people accompanying the patients (guardians). No patient or guardian refused or stopped the interview. The majority of interviews (58%) took place in a hospital setting, of which 85% at municipal hospitals (Table 2). 74% of all interviewed patients visited a public sector facility and 23% a private clinic. Table 3 presents TB related and socioeconomic information of the sample population. 54.5% of the study population was male. The majority of respondents were in the age group 25-44 years. 80% of respondents had primary education while 5% were illiterate.

Table 2 Distribution of interviews by study site

Study Area	Number of study sites, type	Number of patients surveyed (%)
La Vega	1 hospital	4 (2)
Santiago	3 hospitals	40 (20)
San Cristobal	3 hospitals	12 (6)
Area IV	1 community center	55 (28)
Santo Domigo	5 clinics 4 dispensaries	
Area V	4 hospitals	36 (18)
Distrito Nacional	4 clinics 3 dispensaries	
Area VIII	3 hospitals	51 (26)
Santo Domingo	1 clinic	
Total	**32**	**198 (100)**

Table 3 Sample population characteristics

Gender	**N (%)**
Male	108 (54.5)
Female	90 (45.5)
Age	
18-24 years	40 (20)
25-44 years	106 (54)
45 years +	52 (26)
Type of TB	
Smear positive	136 (69)
Smear negative	22 (11)
Extra-pulmonary	40 (20)
Treatment category	
New (CAT1)	150 (76)
Retreatment (CAT2)	28 (14)
MDR-TB (CAT4)	20 (10)
Treatment site	
Hospital	111 (56)
Clinic	85 (43)
Community	2 (1)
HIV status	
HIV negative	130 (66)
HIV positive	22 (11)
No test	19 (10)
Results unknown	27 (14)
Education interviewee	**N (%)**

Illiterate	10 (5)
Elementary school	159 (80)
Secondary school	1 (1)
University	27 (14)
Other	1 (1)
Type of work before TB	
All year / regular	111 (56)
Seasonal / part-time	14 (7)
Day-to day	31 (16)
Other	6 (3)
Does not work	36 (18)
Education household head	
Illiterate	8 (4)
Primary school	71(36)
Secondary school	39 (20)
University	24 (12)
Other	3 (1)
Not available	53 (27)

Health seeking behavior

Almost 90% of respondents sought first care in the private and public health care sector, of which almost equal numbers went to public clinics (23%), municipal and regional hospitals (23 and 21%, respectively) and private facilities (23%); only 1.5% went to a traditional healer and less than 1% visited a pharmacy; however 9% used homemade remedies as first care. The main reasons mentioned why they did not visit a public health facility first when seeking care were lack of trust in the public health service (27%), distance (16%) and availability of private health insurance (23%). The median delay between onset of symptoms and seeking diagnosis was 6 weeks for men and 4.7 weeks for women.

Pre-diagnosis / diagnosis costs

Direct costs

Most costs before and during diagnosis for new patients were attributed to medications not related to TB (36%), followed by costs for diagnostic tests not related to TB (21%), X-rays (18%) and administrative costs (18%) (table 4). X-rays are a costly component among diagnostic tests (9% of direct costs for retreatment patients and 5% for MDR-TB patients). Administrative costs included consultation

costs and patient registration. Transportation, food and accommodation costs constituted a comparatively small burden (together 7%). New patients spent in total a median of USD 47 on direct costs. Retreatment and MDR-TB patients spent in total more out-of-pocket money: on diagnostic tests related to TB (retreatment 57% of all costs, MDR-TB 72%) and medication unrelated to TB (retreatment 31% of all costs, MDR-TB 7%). Altogether, retreatment patients spent a median of USD 113 and MDR-TB patients USD 154 on direct costs before and during diagnosis. Patients attending non-public sites incurred more median direct costs than those attending public sector sites (USD 53.6 versus 8.3), mainly related to administrative charges, x-rays and non-TB drugs.

Indirect costs

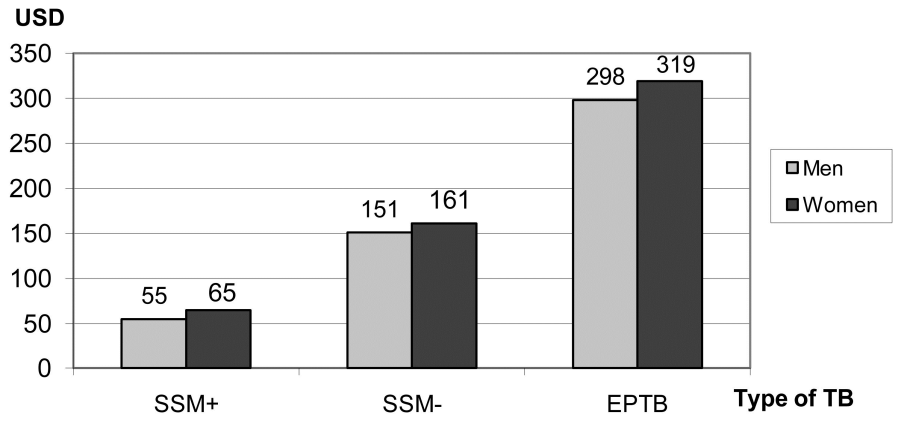
Indirect costs before and during diagnosis are mainly a result of the inability to work due to the illness. 60% of respondents stopped working due to TB (table 5). Of these, 48% stopped for more than six months. There were no significant differences among the respondents with respect to type of TB.

Treatment costs

Direct costs and hospitalization

Patients spent a median of USD 151 on direct costs during treatment. For those patients who had been hospitalized (33% of all respondents, 65 patients), costs associated with hospitalization accounted for 55% of all direct costs. On average, they were hospitalized for 25 days. Hospitalization costs included administrative fees, fees for bed sheets, food, transport, medications, tests and surgeries; these are on average additional USD 61 for new patients, USD 15 for retreatment and 56 for MDR-TB patients. Women reported higher median costs while hospitalized than men (figure 1).

FIGURE 1 Median hospitalization costs by gender and type of TB



Non-hospitalized patients incurred direct costs during treatment mainly for food supplements and transport for treatment (DOTS), to collect TB medicines, to conduct follow-up tests or pick-up test results. Tables 4 and 5 present direct and indirect costs incurred by new, retreatment and MDR-TB patients.

Indirect costs, hospitalization

Indirect costs during treatment were high due to inability to work with a median of USD 728. Only a small proportion (1%) of indirect costs was associated with time spent on the road to and from health facilities, and waiting time. Median monthly indirect costs for treatment follow-up (DOTS) were USD 5, for medication collection USD 1.50 and for follow-up tests USD 2. On average, it took patients 73 minutes to travel to the health care center, pick up medications and return home. Hospitalized patients incurred additional median indirect costs of USD 69, probably due to long hospitalization, severe illness and therefore longer inability to work.

Coping costs

To compensate for the high costs, almost half of all respondents (45%) took up a loan and almost twenty percent sold property. Loans were mainly provided by family members or friends (80%). Among those paying interest on their loan, 37%

paid more than 10% interest rate. Of those respondents selling property, 43% sold household items, 14% sold vehicles, 8% land and 3% a house. When asked how TB services could be improved to relieve the financial burden of respondents, 65% mentioned food coupons, 15% requested more efficient services and 6% suggested transport vouchers.

Guardian costs

Twelve percent of respondents reported to have someone stay with them at home (guardian) to take care of the patient. Guardians fulfill an important role in assisting patients during their appointments at the health facility and as treatment observers. Guardians are often family members who take time off work for this and they therefore incur indirect costs. Seventy-five percent of guardians stayed home longer than two weeks. Guardians of new patients incurred a median cost of USD 117 while guardians of retreatment patients incurred USD 73 and those of MDR-TB patients USD 176.

Table 4: Direct costs by type of treatment in USD

Direct costs before and during diagnosis	New	Retreatment	MDR-TB
Administrative costs	8.3	1.1	22.2
Diagnostic tests costs	10.4	63.8	110.9
X-ray costs	7.8	10.4	8.3
Medication costs	16.6	34.7	10.4
Transportation costs (round trip)	1.7	1.4	1.4
Meal costs	1.7	1.4	1.0
Lodging costs	0.0	0.0	0.0
Insurance reimbursement	0.0	0.0	0.0
Sub-total direct costs before diagnosis	**46.5**	**112.7**	**154.1**
During treatment			
Total direct costs monthly visits to DOTS	23.3	28.6	58.2
Total direct costs monthly visits to pick-up medications	6.2	12.5	13.9
Total direct costs for monthly follow-up visits	16.6	16.6	49.9
Total hospitalization cost	61.0	14.8	55.5
Average monthly costs for food supplements	19.4	20.1	25.0
Total reimbursement received	0.0	0.0	0.0
Sub-total of direct costs during treatment	**126.6**	**92.6**	**202.4**
Co-payment	8.30	5.5	55.5
Total direct costs	**181.3**	**210.8**	**412.0**

Table 5: Indirect costs by type of treatment in USD

Indirect Costs in USD	New	Retreatment	MDR-TB
Inability to work	660.0	180.3	2785.4
DOTS visits	6.1	3.7	9.7
Medication pick-up visits	1.7	1.5	2.4
Follow-up visits	2.0	1.2	2.9
Hospitalization	56.6	34.2	345.5
Total indirect costs	**726.4**	**220.9**	**3145.9**

Total costs by treatment category and income group

MDR-TB patients incurred the highest overall costs. Indirect costs were higher than direct costs for all treatment categories (table 6). Direct costs for new patients were highest during treatment, mainly related to hospitalization. For retreatment and MDR-TB patients, the largest portion of direct costs was attributed to diagnostic tests.

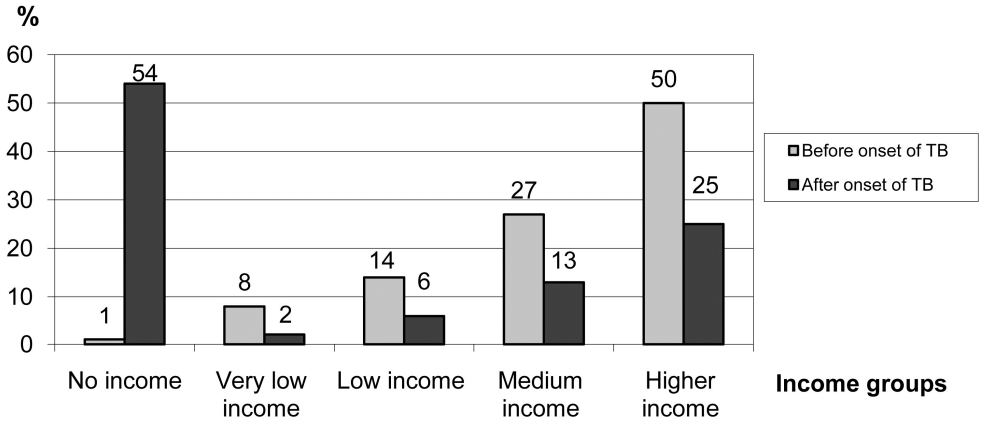
Table 6: Total costs by treatment type

	New patients (CAT1)	Retreatment patients (CAT2)	MDR-TB patients (CAT4)
Median direct costs during diagnosis	47 (26%)	113 (54%)	154 (37%)
Median direct costs during treatment	134 (74%)	98 (46%)	258 (63%)
Total direct costs (USD)	**181 (20%)**	**211 (49%)**	**412 (12%)**
Total indirect costs (USD)	**727 (80%)**	**221 (51%)**	**3 145 (88%)**
Total costs (USD)	**908**	**432**	**3 557**

The financial burden is particularly high on the lowest income group. Total costs for those who earn less than 42 USD per month represent 2 215% of median monthly income. MDR-TB patients are worst off since they incur the comparatively highest costs (8 676%). Except for retreatment patients, indirect costs mean a much higher financial burden than direct costs (approximately four times the direct costs for new patients and seven times for MDR-TB patients). Income groups changed remarkably due to TB (figure 2). Before falling ill with TB,

only 1% did not have a regular income. This proportion increased to 54% after the onset of TB. This effect varied by treatment category: 47% of new patients did not have a regular income after the onset of TB, while this was the case for 65% retreatment and 84% of MDR-TB patients.

FIGURE 2 Individual median monthly income groups before and after TB



Legend:

Very low income: less than USD 42 per month

Low income: USD 42 – 83 per month

Medium income: USD 84 – 166 per month

Higher income: more than USD 166 per month

HIV and other co-morbidities

Among the TB/HIV co-infected patients, 29% received anti-retroviral treatment (ART) and 20% had other co-morbidities such as diabetes, high-blood pressure, and arthritis. HIV positive TB patients incurred higher costs than HIV negative patients. These higher costs were mainly related to additional visits to the health facility to collect ART medicines and to follow-up treatment. Additional health facility visits resulted in USD 7 more direct costs and USD 603 more indirect costs for HIV positive TB patients. However, HIV positive patients incurred less total direct costs than HIV negative patients, because they were less often hospitalized and spent less on food and dietary supplements. Reduced spending on food and

supplements was mainly due to inability to spend more. When compared by type of treatment, more new patients were HIV positive (12%) than retreatment (11%) and MDR-TB patients (5%). However, as indicated already in table 3, not all respondents knew their HIV status (10% of new patients, 20% of retreatment patients and 25% of MDR-TB patients were unaware of their status). Thirty-seven percent of HIV positive patients attended services in the largest cities Santiago and Santo Domingo. At the same time, 34% of respondents from these areas did not know their HIV status, which is higher than the reported average.

Insurance

Approximately a third of respondents were covered by a health insurance during the time of the study. Of these, 62% obtained a private insurance and 32% were part of the national health insurance scheme. Two respondents received a median insurance reimbursement of USD 1 000 for expenditures related to TB. The other 196 respondents did not receive any reimbursements. Most health insurance schemes in the Dominican Republic do not cover tuberculosis associated health care costs.

Discussion

Key findings

Findings of this study suggest that TB patients in the Dominican Republic face a severe financial burden as a result of falling ill with TB. Information on the education level of the study population (table 3) suggests that this affects the most vulnerable of society. Due to TB, direct and indirect costs increased while income decreased for the majority of patients. The percentage of patients without a regular income increased from 1 to 54 because of TB. Retreatment and MDR-TB patients are comparably worse off than new patients because of the severity of illness and related inability to work, costly tests and medicines and longevity of treatment. Patients attending private clinics spent more than patients attending public sector sites. HIV infected TB patients were disadvantaged by a lack of TB/HIV integrated services necessitating additional trips to health facilities.

Guardians fulfill an important role in assisting patients during their appointments at the health facility and as treatment observers. The fact that almost half of all interviewed patients incurred debt and 65% of patients mentioned food coupons as means to alleviate their situation underlines the severe impact TB has on the welfare of the household. This situation was exacerbated for those who were hospitalized and therefore incurred higher direct and indirect costs. The high costs of hospitalization and the length of stay could be related to delays in seeking care (5-6 weeks) and therefore late diagnosis and advanced stage of the disease. Women incurred comparatively higher hospitalization costs than men, but it is not clear, whether women were actually charged higher costs or estimated higher costs when interviewed. Collected information on health seeking behavior and HIV status points towards lack of knowledge of HIV and TB among the general population; so does the worryingly high proportion of direct costs spent by new patients on diagnostic tests (22%) and medications (36%) unrelated to TB, particularly in private clinics.

Policy recommendations

Given these findings on hospitalization, HIV-related and diagnostic test costs, the recommendation was made in consultation with the Ministry of Health to improve the quality of care for TB patients in the private and public primary care sectors. Furthermore, given the high hospitalization costs, it was recommended to decentralize TB services at primary care level to reduce involvement of hospitals and shorten paths to diagnosis and treatment. The lack of knowledge on TB and HIV prompted the recommendation to strengthen awareness raising on TB and HIV among health care workers and the general population to reduce delays in diagnosis. The severe impact of TB related costs on the welfare of the household led to the recommendation to advocate for the inclusion of TB services in national health insurance schemes and to consider food and transport subsidies, especially for retreatment and MDR-TB patients. For a better social and labor reintegration of TB patients, it was recommended to collaborate with other government institutions such as Programa de Solidaridad, Comer Es Primero, and Infotep.

Following the study, the Ministry of Health looked in depth into these findings and explored the possibilities for implementation of the recommendations. In 2011, the Ministry of Health then decided and moved forward with increased efforts to allocate public funds for food supplements for TB patients and to include in- and outpatient TB services in the national health insurance schemes.

Study limitations

As high TB-burden areas were purposively sampled and it is known that TB is closely linked to poverty [2], the purposive sampling method might have led to an over-representation of low-income populations. It is known that questions about costs and income are subject to recall bias and seasonal fluctuation [24]. This is particularly true for retreatment and MDR-TB patients who often experience several health care seeking episodes between onset of symptoms and diagnosis of drug resistant TB. Including retreatment and MDR-TB patients in the study was nevertheless a deliberate choice of the study team and requested by the Ministry of Health, as these groups of patients are considered to be the most vulnerable with long treatment duration and severe forms of the disease. Estimating costs and incomes in monetary terms is difficult, particularly when distinguishing between income and turnover. When we compare our 2009 income data with 2004 UNDP income data [20], we can see that half of our interviewees earned more per month (>USD 166) before they became ill than the average population in 2004 (170.5 USD; 1 USD = 28.4 RD$). This could be attributed to overestimation in our study if the economic situation would have remained stable between 2004 and 2009, or it could be due to increasing wages, economic growth and inflation in this period. After onset of TB however, the picture changes dramatically. The majority of TB patients earned less than USD 42 per month which is significantly less than USD 170.5 reported by UNDP.

The contribution of external income sources from relatives or friends working abroad was not explicitly asked for. Premiums paid for health insurances were not deducted when calculating expenditures. As only two patients received significant

reimbursements, however this omission should not have a large effect on results. Differences between the study areas by means of sensitivity testing were not determined, because it was beyond the purpose of this study.

Patient cost studies done in other parts of the world show similar findings [5, 8, 16, 25-27]. Although numbers cannot be directly compared due to different methodologies employed, similar patterns are visible: indirect costs are higher than direct costs and total costs are beyond 10% of annual income. These patterns point out that it is the responsibility of the state to protect its population from TB and to protect its TB patients from falling into (deeper) poverty because of TB. This finding also exemplifies the need to further investigate and limit costs incurred by MDR-TB patients.

Conclusions

Findings of this study confirm a pattern shown by other TB patient cost studies in the world: TB patients in the Dominican Republic face a great financial burden without the necessary social protection. Free TB diagnosis and treatment are not enough to alleviate the vulnerable from financial constraints due to the illness. Health insurances covering TB in- and outpatient costs and integrated TB/HIV services are absolutely necessary to prevent TB-related financial hardship.

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CHAPTER 6

Free TB diagnosis and treatment are not enough – Patient cost evidence from three continents

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Chapter 6 Free TB diagnosis and treatment are not enough – Patient cost evidence from three continents

ABSTRACT

Setting

The National Tuberculosis Programs of Ghana, Viet Nam and Dominican Republic

Objective

Assessing the direct and indirect costs of TB diagnosis and treatment for patients and households.

Design

Each country translated and adapted the "Tool to Estimate Patients' Costs", a structured questionnaire. A random sample of adult, new patients with at least one month of treatment was interviewed in all three countries.

Results

Across the countries, 27-70% of patients stopped working and experienced reduced income; 5-37% sold property and 17-47% borrowed money due to TB. Hospitalization costs (USD 42-118) and additional food items form the largest part of direct costs during treatment. Average total patient costs (USD 538-1268) were equivalent to approximately one year of individual income.

Conclusion

We observed similar patterns and challenges of TB related costs for patients across the three countries. We advocate for global, united action for TB patients to be included under social protection schemes and for national TB programs to improve equitable access to care.

INTRODUCTION

The connection between tuberculosis (TB) and poverty has been well established [1]. Tuberculosis patients face a number of barriers while seeking diagnosis and treatment, among them financial costs related to charges for health services, transportation, accommodation, nutrition, and lost income, productivity and time [1-3]. These barriers cause delays in seeking health-care resulting in more advanced disease and continued transmission of TB [4]. Direct (out-of-pocket) costs for public or private services and indirect (opportunity) costs can trigger a spiral into (deeper) poverty for TB patients and their families [5]. A number of studies have been published on patient costs in developing countries [6-17], however comparing study results is difficult due to different tools employed. So far, comparative studies on patient costs were mainly done in western countries [18, 19]. Hence, our aim was to assess whether similar patterns of cost burdens can be found in different settings using the same cost assessment tool and closely involving the national TB programs. The main objective of this study was therefore to evaluate the direct and indirect costs of TB patients on three continents before / during diagnosis and during treatment using the "Tool to Estimate Patients' Costs"[20] which is described elsewhere in detail [21]. Furthermore, we aimed to identify relevant interventions to reduce patient costs in each country. This article describes the key results of the tool's implementation in Ghana, Viet Nam, Dominican Republic and resulting recommendations and interventions.

STUDY POPULATION AND METHODS

Setting

All countries follow the WHO recommended DOTS approach to TB control. While basic TB diagnostics (sputum smear microscopy) and treatment (first-line TB medicines) are provided for free, x-rays and hospital stays are charged in all countries. With an estimated population of 24 million in 2010, Ghana notified 14 607 TB patients in 2010 and treated 87% of patients notified in 2009 successfully[22]. Dominican Republic had an estimated population of 10 million in 2010, with 3 964 TB patients notified in 2010; 85% of patients notified in 2009

were successfully treated [22]. Compared to the other countries, Viet Nam had the largest population with 88 million (2010) and the largest number of TB patients (94 867). Viet Nam treated 92% of its TB patients notified in 2009 successfully [22]. Ghana is the poorest country among the three (Human Development Report Index Rank 135), followed by Viet Nam (rank 128) and Dominican Republic (rank 98)[23].

Methods

Each country adapted and translated the generic questionnaire[21] based on local circumstances (TB program, economy, culture, language, social values & norms). In Ghana, the questionnaire was translated into English, Twi, Ga, Kassim, Nankam and Frafra. Interviews took place in two purposively selected regions: Eastern, a more endowed region and Upper Eastern, a more deprived region. Urban and rural areas were included. Out of 242 patients registered at all 25 public health facilities in both regions, 159 could be interviewed either at the health facility or at home. Due to inclusion of retreatment patients in the interviews and their exclusion in the analysis, complete information was available for 135 patients.

In Viet Nam, the questionnaire was translated into Vietnamese. Three provinces were purposively selected: Hanoi, Quangnam and Binh Duong. In each province, two districts were randomly selected, one in urban and one in rural areas. Interviews took place at a total of six public sector sites. Out of 300 randomly selected patients recorded at selected facilities, 300 were interviewed. Due to inclusion of retreatment patients in the interviews and their exclusion in the analysis, information is available for 258 patients. Due to the sensitive nature of questions on costs and payments as well as some challenges faced in interviewer training, not all questions were answered by all patients resulting in fewer total records for some sections.

In Dominican Republic, the questionnaire was translated into Spanish. Interviews took place at 32 randomly selected facilities in three purposively selected

provincial health directorates (Santiago, La Vega and San Cristobal) and three health area directorates (Areas IV, V and VIII). This included urban and rural areas, public and private sector institutions. 150 new patients that visited the selected facilities on the days of the survey were interviewed.

All countries back-translated the questionnaire to ensure accuracy of translation, pre-tested the questionnaire with adjustments made as needed, and received approval from appropriate ethical review committees. All participants of the studies provided informed consent (written consent in Ghana and Dominican Republic, oral consent in Viet Nam). All interviews took place with patients on treatment for at least one month. Table 1 provides an overview of the methodologies employed in each country. All three countries followed the tool's guidelines for calculating costs[21]; indirect costs were calculated as income lost due to TB. For income lost prior to treatment, the time off work was multiplied by the reported individual income prior to the onset of TB. For income lost during treatment, the time off work was multiplied by the reported individual income since the onset of TB.

Table 1 Overview of study methodology

Methodology	Ghana	Viet Nam	Dominican Republic
Sample population	135	258	150 (198)[6]
Age of patients interviewed	Over and including 15 years	Over 15 years	Between 18 and 65 years
Types of TB patients interviewed	New patients (Outpatient)	New patients (Outpatient)	New patients (Outpatient)[7]
Treatment regimen	All: 2(RHZE)/4(RH)	245: 2S(RHZ)/6(EH) 13: 2(RHZE)/6(EH)	150 New: $2(RHZE)/4(RH)_3$
Robustness of income data	Assessed	Not assessed	Not assessed

Legend: R: Rifampicin; H: Isoniazid; Z: Pyrazinamide; E: Ethambutol;
S: Streptomycin; $_3$: three times weekly

RESULTS

The results for all countries are summarized and compared in tables 2-5. Factors related to local circumstances and health systems differed, such as patient education levels (table 2), type of facility visited to seek care (table 3), magnitude of specific cost items incurred (table 4), place of treatment provision, and health insurance coverage (table 5). The average time to collect drugs including travel and waiting time was similar across countries at about 1 hour 20 minutes (table 5).

[6] The Dom Rep team also interviewed retreatment patients (Outpatient) and MDR-TB patients (18 hospitalized, 2 outpatient), but in this article we only present data of new patients for ease of comparison. Results of retreatment and MDR-TB patients have been submitted for publication elsewhere.

[7] Please see previous footnote.

Table 2: Characteristics of study population

Sample population	Ghana	Viet Nam	Dom Rep
Type of TB			
Ssm+	65%	58%	69%
Ssm-	26%	23%	11%
EPTB	9%	19%	20%
Place of Treatment provision			
Hospital	72%	5%	56%
Primary care unit (HC)	21%	-	43%
Community	6%	95%	1%
Private facility (PPM)	1%	-	-
Gender			
Male	61%	72%	55%
Female	39%	28%	45%
Age			
15-24 years	10%	9%	20%
25-44 years	38%	36%	54%
45 years +	47%	54%	26%
unknown	5%	1%	-
Education			
Illiterate	38%	3%	5%
Primary school	19%	21%	80%
Secondary school	40%	36%	1%
High school	-	29%	-
College/university	3%	10%	14%
Unknown:	-	1%	-
HIV status			
HIV positive	22%	4%	11%
HIV negative	67%	57%	66%
Not known	11%	39%	23%

Legend: ssm+: sputum-smear positive; ssm-: sputum-smear negative; EPTB: extra-pulmonary TB; HC: health center; PPM: public-private-mix;

Table 3: Health-care seeking behavior

Health seeking behavior	Ghana	Viet Nam	Dom Rep
Type of facility visited:			
Regional hospital	-	35%	21%
District hospital	43%	11%	23%
Private clinic	1%	17%	23%
Primary care unit	28%	12%	23%
Pharmacy	-	1%	1%
Others	28%[8]	24%	9%
Symptoms and delay[9]			
Cough	88%	73%	83%
Fever/chest pain/cold	53%	54%	82%
Weight Loss	51%	45%	78%
Haemoptysis	14%	13%	23%
Night sweats	51%	9%	46%
Mean delay	7 weeks	n/a	6 weeks

Legend: n/a: not available

Table 4: Summary of direct and indirect patient costs[10]

Legend: IQR: inter-quartile range; N (%): % of interviewed patients that answered this question (response rate)

[8] Mission hospital

[9] To a facility with TB diagnostic services.

[10] The sub-total mean and median numbers were calculated using the totals of the sub-costs from each individual answer, therefore the sub-totals may differ from the sum of the mean and median individual cost items.

Costs in USD	Ghana			Viet Nam[8]			Dominican Republic		
	Mean	Median (IQR)	*N (%)	Mean	Median (IQR)	N (%)	Mean	Median (IQR)	N (%)
Sub-total direct pre-/diagnosis	**31**	**14 (4-39)**	**135 (100)**	**92**	**8 (10-87)**	**193 (75)**	**38**	**8 (2-19)**	**149 (99)**
Administrative charges	3	0 (0-4)	135 (100)	8	2 (1.8-5.0)	40 (16)	14	0 (0-0.8)	148 (99)
Non-TB tests	1	0 (0-0)	135 (100)	47	9 (4.1-47.1)	67 (26)	6	0 (0-0.4)	127 (85)
X-rays	3	0 (0-3)	135 (100)	11	3 (1.8-5.9)	108 (42)	17	0 (0-5.5)	125 (84)
Non-TB drugs	12	4 (0-14)	135 (100)	26	12 (5.9-26.5)	51 (20)	2	0 (0-4.2)	117 (78)
Transport	4	1 (0-4)	135 (100)	6	2 (1.2-3.5)	130 (50)	2	0.8 (0.6-2.8)	133 (89)
Food	6	1 (0-4)	135 (100)	27	3 (1.2-29.4)	38 (15)	2	0.6 (0-1.4)	114 (77)
Accommodation	2	0 (0-0)	135 (100)	32	29 (8.8-58.8)	3 (1)	0	0 (0-0)	21 (14)
Sub-total direct treatment	**114**	**18 (5-52)**	**135 (100)**	**73**	**22 (10-64)**	**245 (95)**	**110**	**12 (5-27)**	**140 (93)**
Hospitalization	42	16 (0.1-46)	135 (100)	118	44 (28-61)	58 (22)	94	0 (0-1.7)	49 (33)
Food	17	11 (3.3-21.3)	135 (100)	22	12 (8.8-17.6)	218 (84)	21	8 (0-41.6)	25 (57)
Total Costs for:									
DOTS visits	27	0 (0-25)	135 (100)	18	8 (4-12)	68 (26)	5	4 (2.2-6.7)	130 (87)
Follow-up test visits	1	0 (0-0)	130 (96)	5	3 (2-6)	90 (35)	18	8 (1.2-18.4)	7 (5)
Drug collection visits	27	2 (0-9.4)	135 (100)	1	0.6 (0.6-1.2)	118 (46)	5	4 (2.2-6.9)	128 (85)
Sum of sub-totals direct costs	**145**	**32**		**165**	**30**		**148**	**20**	
Sub-total indirect pre-/ diagnosis	**381**	**170 (43-340)**	**135 (100)**	**830**	**721 (478-1029)**	**51 (20)**	**1051**	**666 (275-1186)**	**112 (75)**
Inability to work	381	170 (43-340)	135 (100)	830	721 (478-1029)	51 (20)	1051	666 (275-1186)	112 (75)
Sub-total indirect treatment	**12**	**0 (0)**	**135 (100)**	**26**	**7 (3-12)**	**165 (64)**	**69**	**56 (20-79)**	**137 (91)**
Hospitalization	8	0 (0-4.4)	135 (100)	92	43 (15-123)	35 (14)	57	48 (21.2-78.2)	118 (79)
Drug collection visits	1	0 (0-0.4)	135 (100)	1	0.4 (0.2-0.8)	141 (55)	2	2 (1-4.6)	125 (84)
DOTS visits	3	0 (0-2.9)	135 (100)	3	3 (2-5)	165 (64)	6	3 (1.1-9.0)	117 (78)
Follow-up tests visits	0	0	130 (96)	5	2 (1-5)	82 (32)	2	2 (1-4.6)	126 (85)
Sum of sub-totals indirect costs	**393**	**170**		**856**	**728**		**1120**	**722**	
Total patient costs (direct + indirect totals)	**538**	**202**		**1021**	**758**		**1268**	**742**	

[8] In Viet Nam, some patients only provided (sub-)total direct costs without specifying individual cost items.

Table 5: Financial impact of TB on patients

	Ghana	Viet Nam	Dom Rep
% patients stopped working due to TB	70	27	60
% for more than 6 months	51	26	48
% patients hospitalized for TB	33	23	33
Time spent per drug collection visit	1 h 22 min	1 h 13 min	1 h 20 min
Coping costs			
% patients that sold property	37	5	19
- Land	2	21	8
- Livestock	44	57	3
- Other	54	22	89
% patients that took loan	47	17	45
- With interest >10%	8	7	37
- Without interest	84	84	8
Monthly individual income in USD			
Before onset of TB	62	79	0 (for 1%)[11]
After onset of TB	10	59	0 (for 54%)[12]
% income change due to TB	84	25	100 (for 54%)
Expenditures on healthcare as % of monthly household income	108	12	360[13]
Health insurance obtained by % patients	67	48	32
Reimbursements received by % patients	4	26	3

Factors related to the impact of TB on the welfare of individuals and their households are similar across the three countries. A substantial percentage of TB patients had to stop working due to TB (70% Ghana, 27% Viet Nam, 60% Dominican Republic) and therefore experienced reduced income (table 5). In all countries (table 5), nearly a third of all patients were hospitalized at some stage for TB, incurring enormous (mean) costs (table 4) equivalent to 67% of monthly

[11] Data is only available in ranges: 0USD:1% of interviewed patients; <42USD:8% of interviewed patients; 42-83USD:14% of interviewed patients; 83-166USD:27% of interviewed patients; >166USD:50% of interviewed patients

[12] Data is only available in ranges: 0USD:54% of interviewed patients; <42USD:2%; 42-83USD:6%; 83-166 USD:16%; >166USD:26% of interviewed patients

[13] Only applies to lowest income group (data is only available in ranges of income groups, see previous footnotes)

individual income in Ghana, 149% in Viet Nam and 34% in Dominican Republic[14]. Also, many interviewed patients sold property (37% Ghana, 5% Viet Nam, 19% Dominican Republic) or borrowed money (47% Ghana, 17% Viet Nam, 45% Dominican Republic) affecting future welfare and socio-economic status.

Main direct cost items before and during TB diagnosis in all three countries are drugs and tests which are not directly related to TB diagnosis and treatment (table 4). Hospitalization costs and additional food items form the largest part of direct costs during treatment.

Health-care seeking behavior

In all three countries, more than 40% visited hospitals during care-seeking and a considerable number in Viet Nam and Ghana visited private clinics (table 3). In Viet Nam and Dominican Republic, those patients who visited facilities other than public were asked for reasons. In Viet Nam, 21% cited distance as the main reason and 29% mentioned waiting time. Forty-six percent reported other reasons such as habits or convenience. In Dominican Republic, 27% cited mistrust of public services as the main reason, while 23% mentioned obtaining private health insurance. Sixteen percent mentioned distance as the main reason. Men prolonged health care seeking for the same symptoms on average one more week than women. In Ghana and Dominican Republic the mean delay of patients from experiencing symptoms to seeking care at a facility offering TB services was quite similar (7 and 6 weeks, respectively). In Viet Nam, data on this is not available, as the question was not well understood by the interviewers, and the non-response was very high.

Co-morbidities

In Dominican Republic 26% of TB patients had chronic co-morbidities other than HIV such as diabetes, high blood pressure, arthritis. In Viet Nam, 40 TB patients

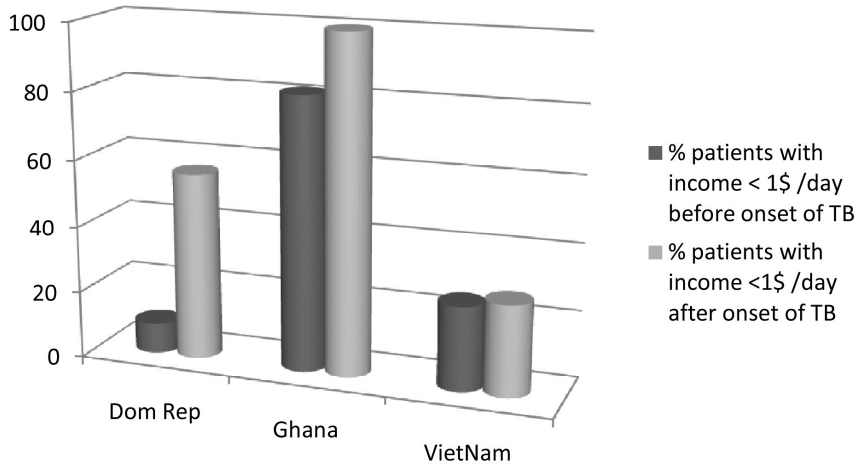
[14] Applicable to individuals with >166 USD monthly income before onset of disease, please see also table 5.

(15.5%) were also treated for other diseases, of which 4% were HIV positive. Patients treated for other diseases in addition to TB incurred a mean additional cost of USD 37. In Dominican Republic, 30% of HIV-positive TB patients were on ART. HIV-positive TB patients in the Dominican Republic had more direct (+USD 2) and indirect (+USD 600) costs than HIV-negative patients related to more health facility visits. However, HIV-negative patients had comparatively higher costs because of hospitalization (USD 127 vs USD 51). Costs during diagnosis and treatment in Ghana were lower for HIV-positive TB patients when compared to HIV-negative patients (USD 393 vs.793).

Impact of TB

In Dominican Republic, the percentage of patients with zero income increased from 1 to 54 due to TB (table 5). The lowest income group with < USD 42 per month, spent 360% of its monthly household income on healthcare. In Ghana, individual mean monthly income dropped by 79% due to TB. The change was particularly acute for women whose mean monthly individual income changed from USD 57 to 3 (men USD 67 to 16). Here, TB patients spent 108% of monthly household income on healthcare. In Viet Nam, household expenditures on food and healthcare increased by almost 50% due to TB. Expenditures on healthcare amounted to 12% of monthly household income due to TB. TB patients in Ghana and Dominican Republic face catastrophic health expenditures, defined by WHO[24] as equal or greater than 40% of non-subsistence household income. Moreover, the percentage of interviewed TB patients with incomes below the poverty line of $1 per day increased in all three countries due to TB (figure 1).

Figure 1 Patients below $1/day poverty line before and after onset of TB



In all countries, costs were incurred for a treatment supporter or family member (guardian). These were in Ghana USD median 26 direct and 0 indirect costs; in Viet Nam USD median 85 direct and 0 indirect costs; and in Dominican Republic USD median 51 direct and 66 indirect costs.

DISCUSSION

Mean total direct costs as a percentage of total patient costs are higher in Ghana (27%) compared to Viet Nam (16%) and Dominican Republic (12%), because of higher costs for health facility visits for DOTS and drug collection. The increase of patients with incomes less than USD 1 per day due to TB is high in the Dominican Republic while it is comparatively low in Viet Nam. The latter confirms the findings of van Doorslaer and O'Donnell [25] (page 10) that Viet Nam relies heavily on out-of-pocket payments but is comparatively "more successful in limiting their impoverishing effect". Total patient costs (including direct and indirect costs) in all countries are equivalent to approximately one year of individual income (table 5). The differences in guardian costs across countries are probably related to the circumstance, that health care facilities in Ghana are relatively far from the patients' homes resulting in higher transport costs and more time investment.

Recommendations based on the studies in all three countries were similar: bringing services closer to patients, reducing expenditures on transport and invested time, increasing efforts to find cases early to reduce indirect costs related to inability to work, informing health care workers and the public about TB diagnosis and treatment to reduce costs unrelated to TB, and including TB related outpatient costs in social protection schemes.

Following the presentation of results, each country took action to improve identified bottlenecks. In Ghana, the NTP presented the study findings to the Ministry of Health. As a result, policy makers agreed to include TB care interventions as part of its pro-poor strategies in the delivery of health care. The Nutrition Department of the Ministry has since developed nutrition guidelines to address the specific needs of TB patients. Secondly, the evidence generated from the study findings was key in informing and developing the successful Global Fund Round 10 TB proposal. Given the identified high burden on female TB patients in Ghana, presently the NTP is focused on addressing gender sensitive challenges of poor TB patients. Thirdly, the parliamentary sub-committee on health has considerably advanced insurance coverage for all TB patients for health related costs other than (free) TB treatment. Lastly, the study findings were presented at the Union conferences in Lille France, and Abuja, Nigeria.

As a result of the study, the NTP in Viet Nam is working toward increased involvement of the private sector in Public-Private-Mix projects focusing on reducing travel, accommodation and hospitalization costs for TB patients and guardians. Secondly, the study contributed to the decision to change from the eight-month to the six-month treatment regimen, which will help reduce the time of treatment and travel costs for follow-up tests. Thirdly, the NTP is working on the expansion of its NTP network to provide TB services at provincial general hospitals, all major public non-MOH and private hospitals. Fourthly, the NTP has started planning for a way to provide social and economic support to TB patients in each district. Last, the NTP has been mobilizing support for TB patients by organizations such as farmers and women unions.

In Dominican Republic the Ministry of Health evaluated the study findings in depth and explored the possibilities for implementing the recommendations. In 2011, the Ministry of Health then moved forward with increased efforts to allocate public funds for food supplements for TB patients and for the inclusion of in- and outpatient TB services in the national health insurance schemes.

In summary, using the tool[21] provided results pointing towards similar patterns and challenges across the three countries. These triggered similar conclusions and recommendations. TB patients are in danger of spiraling into (deeper) poverty around the world. As this effect is not limited to individual TB programs, it requires global action. Together with other research evidence [9-14, 26], our results strongly suggest that it is time for global institutions to improve social protection for TB patients. In the mean-time, NTPs need to minimize costs for patients by providing completely free services, decentralizing care with appropriate supervision and quality-assurance, and improving access to care.

Limitations

All study teams reported difficulties with recall bias and conveying cost and payment concepts to patients. In Viet Nam, several patients could only provide (sub-)total direct costs without specifying individual cost items (table 4). Although absolute costs in USD are difficult to compare, the relative burden and impact of TB on the welfare of the individual and the household can nevertheless be demonstrated. The costs incurred by TB patients as described here do not directly account for costs of co-morbidities, although these additional costs are reflected in the indirect costs and coping strategies. Free TB care is only partly helpful, if patients incur additional substantial costs due to co-morbidities. We did not investigate whether the financial burden affected treatment completion. We do not intend to closely compare results across countries with very different cultural settings, values, norms, health systems and purchasing power parities; however the results still indicate that TB patients on different continents face similar catastrophic events unmediated by existing health systems and social protection schemes.

CONCLUSIONS

Results from Dominican Republic, Ghana and Viet Nam show that patients face very high direct and indirect costs before and during TB diagnosis and treatment, which often translate into catastrophic financial events and increased poverty. It is time for the international community to come together and address the need for greater social protection of TB patients.

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CHAPTER 7

Unsustainable funding of high-burden tuberculosis control programmes: who is responsible?

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Chapter 7 Unsustainable funding of high-burden tuberculosis control programmes: who is responsible?

ABSTRACT

The literature suggests crowding out effects of government funding for health happen in low income, high HIV burden countries. In a survey, we investigated the hypothesis that domestic funding for TB control has decreased in eleven low income, high TB burden countries in the context of changes in GDP, development assistance inflows, and national health expenditures. We found that despite increases in GDP per capita between 2003 and 2009, health expenditure as percent of GDP decreased or stayed the same for the majority of these countries. Although TB control budgets increased for all eleven countries in absolute terms, six countries decreased government contribution to TB control. In the long run for health programs to become sustainable, we suggest increases in donor funding for health to be accompanied by requirements to increase domestic funding for health. We thereby attribute responsibility to avoid crowding-out effects to donors and governments alike. Moreover, it is the responsibility of both to ensure for essential items to be funded by government sources to avoid a collapse of programs once aid is withdrawn.

Introduction

In the past ten years, funding for tuberculosis (TB) control has substantially increased, mainly due to the establishment of The Global Fund and increasing financial commitment to TB by large donors such as USAID and the Gates Foundation. After a first hurray welcoming the influx of funding into previously largely neglected programs running on tiny budgets, questions about the sustainability of these inflows quickly arose within the TB community. Soon, TB program managers and project administrators sighed about pressures to spend large amounts in short periods of time. In 2010, Lu et al[1] demonstrated wide-spread crowding out effects of government funding for health, with the greatest reductions in government spending in sub-Saharan countries with large HIV

epidemics and comparatively large contributions of development aid for health to governments. In an accompanying article, Ooms et al [2] suggested the reductions of domestic funding on health despite increases in Gross Domestic Product (GDP) and development assistance to be deliberate policy choices. With World TB Day just passed and the Global Fund's announcement to cancel a new round of grants [3], we asked ourselves how this picture would look like specifically for low income countries facing a high TB burden. Since HIV and TB epidemics go hand in hand due to co-infection, we expect a similar picture in the high TB burden countries. Specifically, our question was whether domestic funding for TB has increased in the past years in context of changes in GDP, development assistance inflows, and national health expenditures.

Methods

For this purpose, we conducted a survey of World Bank [4] data from 2003 to 2009 (later data was not available) and WHO data from 2003 to 2011 for countries that fulfill all of the following criteria: high TB burden country as defined by WHO [5, 6], listed as least developed country by the OECD Development Assistance Committee [7] and listed by the World Bank as low income country [8]. This yielded a list of 11 countries: Afghanistan, Bangladesh, Cambodia, DR Congo, Ethiopia, Kenya, Mozambique, Myanmar, Tanzania, Uganda, and Zimbabwe. To answer our question, we chose to review the following indicators for each country: GDP per capita, net ODA and official aid inflows, net ODA as percent of Gross National Income (GNI), government health expenditure per capita, government health expenditure as percent of GDP, TB control program budget in million USD, and percent of TB budget funded by domestic sources.

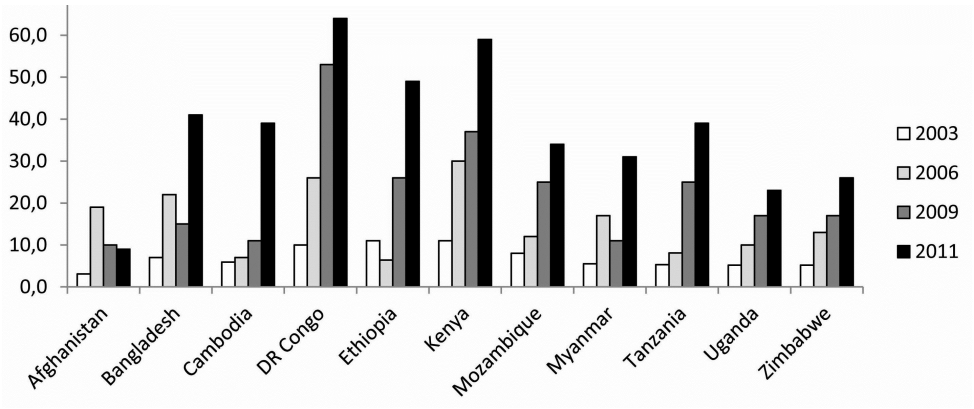
Results

Among the eleven countries, four are listed by the World Bank [9] as fragile situations: Afghanistan, DR Congo, Myanmar and Zimbabwe. Data for these countries was not always available for the selected indicators and as they are in conflict, difficulties in collecting quality data are to be expected. Our findings for

the high TB burden countries support Lu et al's [1] findings for the wider health sector. Although GDP per capita increased in all eleven countries in the years 2003-2009, health expenditure as proportion of GDP decreased or stayed the same (defined as an increase <1%) in all but one of the eleven countries. Contrary to Lu et al's trend of increasing aid flows, the high TB burden countries almost all experienced a decrease of development aid inflows as proportion of GNI, although development aid inflows in absolute numbers increased in all countries. Kenya is the only country that experienced an increase in net development aid inflows (+2,6% of GNI), but did not increase its health expenditure as proportion of GDP (zero), despite the largest increase in GDP/capita (+350 USD) compared to the other ten countries.

As far as data was available for TB control budgets over time, we found increases in TB budgets in absolute terms (Mln USD) in almost all countries (figure 1, numbers include budget gaps). However, domestic funding spent on TB control decreased or stayed the same for all countries except for Ethiopia, Kenya, Mozambique and Tanzania. The largest reductions happened in Bangladesh and Zimbabwe. Moreover, the percentage of National TB Program budgets funded by government sources decreased or stayed the same in six out of eleven countries, with the greatest reductions in Bangladesh, DR Congo and Cambodia (figure 2). A substantial drop of government contribution happened between 2003 and 2006 in eight countries. Thereafter, government contribution increased again in five countries. The only country that increased its domestic funding for TB control between 2003 and 2011 steadily and substantially was Tanzania (+15%).

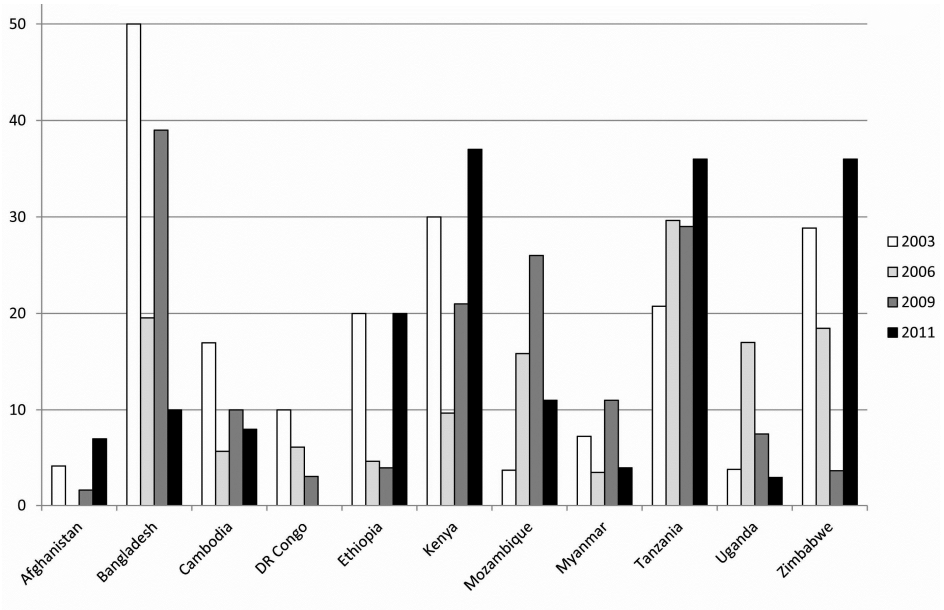
Figure 1: National TB Control Program Budgets (USD Mln)



Source [5, 6]

Zimbabwe data for 2003 was not available, instead data for 2004 was used.

Figure 2: Government Contribution to National TB Control Program Budget (%)



Source [5, 6]

Zimbabwe data for 2003 was not available, instead data for 2004 was used.

Discussion

Our survey confirms the hypothesis that domestic funding for most NTPs decreased in the past years. These findings are not surprising in the context of Lu et al's detailed analysis, however we wonder about the implications and future outlook for these programs, as many of them seem to be built on sand in the long run. We did not investigate on which items domestic and external funding were spent by the programs. It would be desirable for essential items such as drugs and laboratory supplies to be funded by domestic sources to guard the program's stability from external changes in funding. The worst case scenario is for programs to collapse once aid is withdrawn. This could be already witnessed to some extent with the advent of the financial crisis when global funding for development decreased suddenly [10] with resulting financial gaps [11]. The situation might worsen with the final year of the Millennium Development Goals to come in 2015 and a potential decrease in aid funding thereafter due to a possible shift in global attention to other urgent topics.

Conclusion

Flooding programs with money without securing sufficient parallel domestic funding sets wrong incentives and may be counterproductive in the long run. Increases in donor funding for health need to come with requirements to increase domestic funding for health. This would set national TB control programs under pressure to face their own governments instead of looking for outside sources to fill gaps. In this respect, donors are just as responsible to avoid fungibility of funding as national governments.

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CHAPTER 8

Discussion and Conclusion

Chapter 8 Discussion and conclusion

The following discussion will be structured according to the chapters. The findings of each chapter (except for chapter 2 – literature review) will be related to the conceptual framework of the WHO health system building blocks as explained in the introduction of this thesis. Thereby, a conclusion will be drawn for each health system building block. These are summarized by six primary policy recommendations.

In Chapter 2, existing knowledge on patient costs at the start of our studies was presented in a comprehensive literature review. It formed the basis for the development of the Tool to Estimate Patients' Costs (Annex 1). The advantages of the Tool have been explained in chapter 4. Its design allows simple and extended analyses of patient costs as a basis to identify bottlenecks in access to care and their removal. The main disadvantage of the Tool is its limitation to only reach those who in the end reached a health facility offering TB services. It does not reach those who have not sought help or defaulted from treatment due to barriers in accessing care. Unless defaulters are specifically targeted and interviewed, the Tool is biased towards those who have somehow been able to afford treatment and all that is related. Plus, the results of the Tool are heavily dependent on the areas and facilities where patients are interviewed.
After using the Tool in several countries some lessons learned have emerged: A) a more detailed disaggregation of costs would make it easier for patients to estimate expenditures thereby reducing recall bias and allowing for a distinction between turn-over and income; however it would extend the time of the interview which ranged in our studies already between 45 minutes and 1 hour 30 minutes. B) A weighted asset index to assess socio-economic status as a proxy for income would be more precise but would also require advanced knowledge in methods and statistics limiting the usage of the Tool to organizations and individuals experienced in research. C) We used changes in food expenditure instead of changes in food consumption; using food consumption might yield

other results in behavior change due to health care related costs and might be (more) useful as a proxy for income. D) Testing the robustness of income data is useful to put results from the questionnaire in perspective. This can be done by comparing income-related results to data from large population-based surveys such as national demographic and health surveys where available. E) The question on willingness to pay to estimate the cost of pain and suffering was difficult to explain to patients and was therefore largely omitted when the questionnaire was adapted to local circumstances. F) Thorough and comprehensive training of interviewers is paramount for obtaining quality results and must not be compromised in favour of saving time or resources.

In Chapter 3, we demonstrated that TB control in fragile countries is possible and can be effective despite major challenges in coordination, management, security, logistics and funding. Partnerships play an important role among providers to bring services to the patients and guarantee continuity of care despite interruptions and collapse of infrastructure. Trust among partners plays a major role as well as the ability to plan in the long term (at least for 5 years). While internal and external NGOs often play a crucial role in making up for gaps in the human resources for health situation, their efforts can only make a wider impact, if they are coordinated and led by a central, national agency, usually the Ministry of Health. The leadership and governance function of the state is therefore a prerequisite for a functioning health system, whether it is still in the build-up phase, or already established and advanced. The leadership functions are: normative in providing and enforcing standards rules and guidelines; technical in how to implement rules and guidelines; and in building capacity for an educated workforce that is able to provide care according to the given standards; supervisory in enforcing the implementation and adherence to standards and guidelines; and coordinating as described above. **The policy recommendation for the health system building block on leadership and governance therefore here is that the national TB control program needs to exercise its leadership and**

stewardship functions (normative, technical, capacity-building, supervisory and coordinating).

Partnerships can also take up the traditional role of the state (in its absence) in providing leadership and coordinating partners. In Somalia, where a government was largely absent, this role was taken up by WHO, which guaranteed the continuation of TB care as much as possible by coordinating many non-governmental providers. Coordination is particularly important where (government employed) human resources are scarce and NGOs step in with their own human resources to fill gaps in the public sector. In Haiti, the leadership function of the NTP was weak which had negative consequences for the sustainability of investments and continued developments. It led to the development of parallel structures and to the development of capacity only within NGOs. **The policy recommendation for the human resources for health building block is that stable partnerships with and the coordination of donors, private providers, non-governmental, community- and faith-based organizations are necessary to cope with limited human resources for the provision of TB care in high TB burden and especially fragile countries.**

In Chapters 4 and 5 the hypothesized main barriers for accessible and equitable care were determined and confirmed again in chapter 6. These are charges for health services, costs for transport, accommodation and nutrition and lost income, productivity and time. The main cost burden consists of indirect costs resulting from inability to work due to the illness and time spent on the road to and from health facilities and waiting time. Inability to work is therefore a major cause of increased poverty and contributes to the worsening of individual economic situations. In the presented case in Kenya, individual incomes dropped to zero after onset of TB and household incomes dropped by 43%. In Ghana, monthly household income dropped by 40% due to TB, and individual mean monthly income dropped by 79%.

Direct costs for travel to and from health facilities during diagnosis and treatment, tests such as x-rays and administrative costs are major barriers in accessing health services. For example in Kenya, direct costs were equivalent to 7% of median annual individual income before the onset of TB. As a response, the lower income groups tend to reduce food expenditures. This is dramatic because especially during TB illness, nutrition is particularly important to convalesce and to make up for weight lost due to TB. In Dominican Republic, many patients suggested food coupons to alleviate their situation. However, *before* TB patients receive a TB diagnosis, they often spend already considerable amounts on seeking care in the private sector or with traditional healers. In Kenya, 25% of interviewed patients visited a private facility or laboratory, in Dominican Republic these were 23%. In all countries, about 1% visited a traditional healer. This is partly due to lack of information on TB and public services and partly a deliberate choice. In all sampled countries, patients who first went to a non-public facility were asked why. Waiting time, distance and mistrust of public services were often mentioned. These care-seeking episodes mean a delay in diagnosis (in the described countries between 4 and 7 weeks) and therefore high indirect costs due to the inability to work and a worsening health situation. It also means that additional costs are spent on medical products or traditional remedies prescribed by the facilities, administrative charges, and food supplements such as vitamins. Health insurance where available hardly covered the interviewed TB patients and when they were covered TB services were rarely included in the package. This was found across the board in all described countries (Kenya, Dominican Republic, Viet Nam, and Ghana).

It is therefore of major importance that the diagnostic delay is minimized by informing the general population about TB and availability of public services. This will help to reduce direct costs incurred until diagnosis, and to treat the patient early to improve prospects for cure and thereby limit indirect costs due to the inability to work. National TB control programs need to minimize direct and indirect costs for patients by providing completely free services, by decentralizing

care and by improving access to care. One possibility to improve access to care and limit unnecessary tests and medicines are public-private-mix (PPM) models. In the past years it was successfully shown in several countries, how PPM approaches could compliment public services and contribute to increased case finding [1-6].

Direct costs incurred by patients related to administrative services, x-rays, supplements and non-TB related drugs can be limited if TB care is included in social protection schemes. The health information system of a country plays thereby a pertinent role here in determining challenges in accessing care by the poor and vulnerable, costs incurred by patients, treatment outcomes and the extent of coverage of existing national health insurance schemes, particularly among the poor and vulnerable. For example, health insurance coverage among interviewed patients was 12% in Kenya, 67% in Ghana, 48% in Viet Nam and 32% in Dominican Republic. However, except for Viet Nam, only a small percentage actually received reimbursements. Therefore we could conclude that TB patients are not protected from financial shocks because of falling ill. So far, however, most health systems do not specifically investigate access to services and incurred costs. In this thesis, a pertinent need to do so has been demonstrated. **The policy recommendation for the building block on essential medicines and technical products is therefore that essential TB drugs and diagnosis should be free of charge. Non-TB related drugs and tests contribute to high direct costs of TB patients.**

Chapters 4-6 showed that the most vulnerable of society are most affected by a lack of social protection and barriers in accessing care. Moreover, chapter 5 shows that retreatment and MDR-TB patients are comparably worse off than new patients because of the severity of illness and related inability to work, costly tests and longevity of treatment. Compared to new patients, MDR-TB patients in the Dominican Republic incurred more than three times the pre-/diagnosis and treatment costs (908 USD vs. 3 557 USD). HIV infected TB patients are disadvantaged by a lack of TB/HIV integrated services necessitating additional

trips to health facilities to collect medicines, as well as severe combined disease leading to loss of work, and hospitalization. In Dominican Republic, HIV-positive patients spent 26% more than HIV-negative TB patients, in Kenya, HIV-positive patients experienced 16% higher costs during pre-/diagnosis and 48% higher costs during treatment. Chapter 6 also shows that these similar patterns and challenges in patient costs across countries triggered similar conclusions and recommendations: TB stands at a spiral into (deeper) poverty around the world unmediated by existing social protection schemes, which makes it a world-wide problem not limited to individual TB programs. Presented results strongly suggest that it is time for global institutions to take action and, most importantly, work together to improve social protection for TB patients. **The policy recommendation for the health system building block on health information systems is therefore that the poor and vulnerable and their challenges in seeking care need to be determined. TB care is to be included into affordable social protection schemes to prevent the impoverishment of TB patients due to high costs. Also, the policy recommendation for the building block on service delivery is that TB control needs to be integrated into the national health system and integrated TB/HIV services need to be provided.**

This can only be achieved if the necessary funding is available, particularly long-term and sustainable funding to allow for long-term planning and continuous build-up of infrastructure and know-how. Chapter 7 sadly confirms the hypothesis that domestic funding for most national TB control programs decreased in the past years. Among 11 poor, high TB burden countries, Bangladesh and Zimbabwe experienced the largest reductions in domestic funding for TB control between 2003 and 2011. Only one of the investigated countries could demonstrate continuous increases in domestic funding for TB control (Tanzania); it is perhaps no coincidence that Tanzania is the country, where the DOTS approach was piloted and proven effective by Karel Styblo, the father of modern TB control. Moreover, Tanzania has long been a model country for successful TB control. Some TB control programs are in real danger to collapse once aid funding is

withdrawn, because the programs are largely carried by external (donor) funding. The practical experience of the author suggests that unfortunately often important items, such as laboratory supplies, anti-TB drugs and human resources are completely funded by outside sources. If these basic components of a program are withdrawn, the program will collapse. If a patient cannot be diagnosed and treated, then what is left to call it a program? In 2010/2011, there were first signs that this has happened to some programs with the advent of the financial crisis and the Global Fund cancelling its new round of grants. In a survey of 19 African countries, Kirigia et al [7], presented data that seven countries reduced their budget for health due to the financial crisis and three countries were informed that partners would cut funding for health. Interestingly, as a reaction one of the strategies cited by these countries to overcome this situation was reinforcement of domestic resource mobilization[15]. The Abuja declaration [8] which specified the goal of allocating at least 15% of national budgets to health seems to be more relevant than ever – and so far largely neglected, apparently. With all its problems and disastrous consequences the global financial crisis carries at least a lesson-learned in this matter. **The policy recommendation according to the health system building block on health financing is therefore that domestic funding for health is paramount for sustainable services. External funding must not result in fungibility of funding.**

In summary, the six major policy recommendations resulting from this thesis are presented in figure 2 analogous to the overall concept of the WHO health system building blocks, previously presented in the introduction as figure 1:

[15] others were: improving efficiency in allocation and use of resources and improving planning, budgeting, monitoring & evaluation, and reinforcing external resource mobilization.

Figure 1: The health system building blocks

Figure 2: Policy recommendations according to the health system building blocks

How can accessible and sustainable TB control be achieved?

- The national TB control program needs to exercise its leadership and stewardship functions (normative, technical, capacity-building, supervisory and coordinating).
- The poor and vulnerable, and their challenges in seeking care need to be determined. TB care is to be included into affordable social protection schemes to prevent the impoverishment of TB patients due to high costs.
- Increasing domestic funding for health is paramount for sustainable services. External funding must not result in fungibility of funding.
- Stable partnerships with and the coordination of donors, private providers, non-governmental, community- and faith-based organizations are necessary to cope with limited human resources for the provision of TB care in high TB burden countries.
- Essential TB drugs and diagnosis should be free of charge. Non-TB related drugs and tests contribute to high direct costs of TB patients.
- TB control needs to be integrated into the national health system and integrated TB/HIV services need to be provided.

Remaining questions and future research agenda

There are several remaining questions that this thesis could not answer. These are mainly related to the interactions between disease-centered programs such as TB control and the national health system. Improvements in one disease area could benefit the whole health system and strengthen other public health programs but it is not clear, how this would work; that is, which screw to turn to make the wheel go round? In addition, health systems working with disease-focused programs sometimes forget that it is the same patient that is cared for by different programs. TB and HIV programs have been struggling with this issue continuously. Things have improved, but truly integrated care is still far away in most countries. This has mainly to do with the large case numbers of the three major diseases (HIV, TB, Malaria) in developing countries which have overwhelmed integrated health systems and therefore required separate, focused approaches. The patient – not the doctor – therefore often wears several hats, which puts a high burden on the patient in terms of time, money, and treatment adherence, because the knowledge of the disease and its treatment lies primarily with the doctors and nurses, not the patients. Accessible care can therefore only truly be achieved if each country finds its own balance between disease-oriented and integrated care. How this is to be done remains a challenge for each country. A 'one-size-fits-all' approach certainly cannot do the job.

Thus, a future research agenda could include the following four questions / topics:

1) How can TB control be integrated into national health systems without compromising its effectiveness?
   WHO [9] has started off in tackling this question, however the practical implementation remains a big question mark, as it is tried to square the circle: integrating TB care while keeping disease-oriented elements. Negative experiences with eliminating all vertical elements for a completely horizontal approach brought about consensus that some vertical elements must not be compromised for effective TB control [10].

At the moment, countries benefit monetarily from keeping disease-oriented structures, because funding is earmarked for specific diseases. These are often trends: for more than ten years the focus has been on HIV, TB, Malaria and ongoing discussions indicate that the future topics will be maternity and child health, and nutrition [11]. There are two approaches to incentivize countries for integrating TB/HIV care into the national health system: either through funding incentives, which deprives the country of its leadership and governance and to some extent, of its freedom of choice; and through active policy choices by the governments of affected countries; if they lead the policy discussions, the rest will follow. Leadership and governance of affected countries in its sum are therefore determining factors for shaping global health policies.

2) How can leadership and governance be strengthened in high TB burden countries?

   Recent scandals such as the cases of Zambia and Mali where officials embezzled Global Fund funding originally determined for ARVs and HIV-related projects [12, 13] point towards a general problem of countries with a weak democratic process and a lack of checks and balances.

3) What can be done to limit the brain drain from developing to developed countries? How can human resources be sustained given limited funding and career perspectives?

   The double moral standards of some western countries such as Great Britain and the United States have been criticized several times. On the one hand, development aid is provided to countries for capacity-building and at the same time, the very same countries provide employment opportunities, career perspectives and monetary incentives to the health workforce of developing countries to fill their own health system gaps [14-16]. Although this topic has been already addressed in international policy dialogues, the practice continues and needs to be stopped. Ghana

has fought this development by developing incentives to make it attractive for the diaspora to come back to Ghana [17].

4) How can the deadly bond between TB and HIV be broken to end the fuelling of TB by HIV?
   Here, many efforts are already undertaken by the *Tuberculosis Vaccine Initiative* and the *Global Alliance for TB Drug Development* for new vaccines and new anti-TB drugs to stop the problem where it starts. A successful candidate ("magic bullet") is not yet in sight, however. Prevention of TB cases is THE main challenge for the global elimination of TB.

Conclusion

Accessible, sustainable TB care can be achieved in high TB burden countries. It is determined by a) a national government exercising its leadership functions, b) the inclusion of TB care into affordable social protection schemes, c) sustainable financing of TB control, d) stable partnerships and coordination of partners to cope with limited human resources, e) free anti-TB drugs and diagnostic tests, and the abstention from prescribing unnecessary tests, drugs and supplements and f) the integration of the national TB control program into the national health system.

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ANNEX

The Tool to Estimate Patients' Costs

KNCV/Tuberculosis Control Assistance Program (TBCAP)

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and
http://www.tbcare1.org/publications/toolbox/access/

Annex The Tool to Estimate Patients' Costs

Introduction

The Tool to Estimate Patients' Costs has been developed by KNCV Tuberculosis Foundation, the World Health Organization and the Japan Anti-Tuberculosis Association from 1. October 2007 until 30.September 2008, coordinated by KNCV. Its development was funded by the Tuberculosis Control Assistance Program TBCAP www.tbcta.org. We aim to continuously improve the tool and will be therefore grateful for any suggestion or comment. In this case, please write to Verena Mauch vmauch@yahoo.de.

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Background and Context

Tuberculosis is a disease that disproportionately affects the poor. TB programs therefore need to ensure that the economically and socially disadvantaged groups do not face barriers that keep them from seeking treatment. In addition, TB

programs need to ensure that TB doesn't stand at the beginning of a spiral into (deeper) poverty.

By addressing barriers and reasons for delay to timely diagnosis and treatment by the NTP, costs to TB patients, particularly among the poor, can be effectively reduced. The Poverty Sub-Working Group of the Stop TB Partnership has therefore decided to develop a tool which can assist TB programs to estimate the costs of TB patients before and during diagnosis and during treatment by the NTP.

The aims of the tool are to:

a. To make economic constraints to individuals and households more apparent.
b. To provide means to assess the impoverishing impact of TB on patients and their families.
c. To establish an evidence-base upon which subsequent interventions can contribute to poverty reduction, increased equity in access to diagnosis and treatment, increased case detection, better treatment adherence

As a first step in developing the Tool, a literature review on studies dealing with patients' costs and methodologies employed was conducted. The objective of the review was to provide a detailed account of research findings at which stage what kinds of costs are incurred. The findings of the review formed the basis and context upon which the tool has been developed. The Tool to Estimate Patients' Costs integrates findings of the review with respect to types of costs, magnitude of costs, specific cost items and indicators to be measured.

The Tool and its parts – The tool consists of:

1. **Introduction** (this document)
2. **Detailed literature review on patient cost studies** (see chapter 2 of this thesis)
3. **Brief review of socioeconomic indicators**

   This short review of was prepared to identify the most important se indicators to ask for in the questionnaire. With the help of these

indicators, it will be easier to understand the se background of patients, their vulnerability and their ability to cover the costs they incur due to TB. The review also lists useful literature on se indicators and their usage.

4. **List of indicators to be measured**

   This list basically shows what we will know after analysing the results obtained from patient interviews with the questionnaire. It therefore gives you a quick overview what kind of information will be generated through application of the questionnaire.

5. **Generic questionnaire to be adapted to local circumstances**

   The questionnaire is the heart of the tool. It is designed to interview patients about their costs due to TB. It has been successfully tested in Kenya in 2008. It is a generic version which needs to be adapted to the respective country and setting. Please refer to the guidelines on adaptation and methods when adapting the questionnaire.

6. **Guidelines on adaptation to local circumstances** (see web-version for all guidelines)

   These guidelines give advice on translating the questionnaire and pretesting it, and it lists and explains all questions that need to be adapted to the local setting.

7. **Guidelines on methods, sampling and training of interviewers** (see web-version for all guidelines)

   These guidelines provide a step by step overview of the methodology that needs to be adhered to in order to produce replicable results. They highlight important points to be considered when the sample, sample size, the target group and in- and exclusion criteria are chosen, data is analyzed and the training of interviewers is planned; in addition, they provide examples of other patient cost survey methods and the coding of questions. It is recommended to refer to a qualitative and quantitative research methods book in addition to these guidelines; respective literature is listed and a quick guide and explanation to the Epi Info data entry template can be found here as well.

8. **Guidelines on interpretation of results generated by the questionnaire** (see web-version for all guidelines)

   These guidelines will help you to interpret your findings - what the results actually mean. The guidelines address each type of costs and related issues such as gender, socioeconomic questions, affordability, productivity etc that were measured by the questionnaire; in each section, the respective indicator and the questions that were used to measure the costs are listed - to guide you through each topic on a step-by-step basis. In addition, the guidelines provide an overview of income indicator usage and income data with links to databases and websites, so that you can compare your income data results with those of other sources.

9. **Guidelines on possible interventions** (see web-version for all guidelines)

   This table will help to think of measures to address the issues found through the analysis of the data generated by the patient interviews. It lists problems and related possible action points and therefore works in the sense of: if you found this, you could think of doing that. The conceivable action points and recommendations are based on the WHO guideline *Addressing Poverty in TB Control.*

10. **Epi Info template for data entry** (see web-version for all guidelines)

    In order to alleviate data entry after patient interviews, we have developed a template which is aligned with the generic questionnaire. The software Epi Info can be downloaded for free on the CDC website. The template needs to be still adapted in line with the adaptations made to the questionnaire according to the local setting.

11. **MS Excel template to summarize results** (see web-version for all guidelines)

    This Excel template lists all types of costs measured by the questionnaire. You can enter results and it will give you a nice overview of all costs incurred and it calculates for you aggregated costs and summaries. This will make it easier for you to report on the costs found by your study. It is

recommended to look at this template in the preparation stage of your study to get an idea what the end result should look like.

Types of costs

The three main types of costs are:

1. charges for health services,
2. transport, accommodation and subsistence and
3. lost income, productivity and time.[16]

Individuals suffering from TB are often ill in their most economically-productive age, which poses a significant economic burden on the household. Poor people have longer pathways to care and costs of accessing care are generally higher before than after diagnosis.[17] Relative costs for poor people as a percentage of their income is much higher than for non-poor patients, although aggregate real costs may be smaller.[18] Out-of-pocket costs for public and private healthcare services may stand at the beginning of a spiral into poverty for many families and exacerbate the poverty of the already-poor. This situation has been termed the "the medical poverty trap"[19].

Stratification of patients along several indicators (gender, geography, socioeconomic status) is therefore necessary to obtain an accurate picture of the economic situation facing TB patients.

Direct costs:

- ☐ Travel, food, accommodation during visits to care givers for seeking help in private and public sector including pharmacies, traditional healers etc. before diagnosis by the program
- ☐ Expenditures on medicines, special foods, tests before diagnosis by the program
- ☐ Travel forth and back for tests and receiving test results

[16] WHO 2005
[17] Nhlema et al 2003, Kamolratanakul 1999, Rajeswari et al 1999
[18] Nhlema et al 2003, Kemp et al 2007
[19] Dahlgren & Whithead 2006

- ☐ Food and “special foods”
- ☐ Guardian costs
- ☐ Diagnostic tests (if not provided for free)
- ☐ Additional informal payments
- ☐ Charges for drugs
- ☐ ‘Under the table’ fees
- ☐ Costs due to hospitalization
- ☐ Travel, food, accommodation for follow up tests
- ☐ Travel, food for DOT visits (if applicable)
- ☐ Travel, food for medicine collection visits (if applicable)
- ☐ Consultation / user fees (if applicable)
- ☐ Guardian costs (person accompanying the patient to health center)
- ☐ Informal payments (if applicable): additional diagnostic tests, drugs
- ☐ Additional costs due to (parallel) treatment sought by other providers
- ☐ Additional costs for TB-HIV co-infected patients
- ☐ health insurance up front payments to be reimbursed later (if applicable)

Indirect costs:

- ☐ Income reduction due to missed work days/hours, lost job, loss of time to seek job, uptake of less paid labor due to illness
- ☐ Reduced household activities (or cost of other household member replacing household work)
- ☐ Missed work for guardian/DOT supporter
- ☐ Decreased productivity
- ☐ Coping costs: use of savings, reduction of food intake, assets are sold, extra job, kids drop out of school to work, debt / loans

Limitations of the tool

The tool can only reach those who, in the end, reached a health facility which provides DOTS. It does not reach those who have not sought help or begun treatment or defaulted due to high costs. Unless specifically defaulters are

targeted and interviewed, the tool is biased towards those who have somehow been able to afford treatment and all that is related. Depending on the place of the interview, automatically a certain group of patients is excluded. The results of the tool will be heavily dependent on the districts and facilities where patients are interviewed; If the sampling strategy was purposive, the results will not be representative for all TB patients, but only for those considered poor or who live in the chosen districts; this needs to be taken into consideration when interpreting the results and designing interventions based on the results.

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Overview of Socioeconomic Indicators
to Measure Living Conditions & Impoverishment

Morris et al (2000) give a very good account on strengths and weaknesses of two approaches to measure wealth and income (which are theoretically different concepts with different trajectories to influence health and informed by different aspects of policymaking).

1) The asset-based approach as a proxy for **wealth**
   - Lists household assets (context-specific items) to elicit a weighted score which can be used to identify the poor from the non-poor.
   - Most countries have an LSMS (Living Standards Measurement Survey by the World Bank)[20], adjusted to local circumstances. Questionnaires can be downloaded from the web to identify a suitable list of assets.
   - Does not take into account the most valuable household items due to difficulty of measurement. This includes land, house, livestock, financial capital and human resources.

2) Total household expenditure as a proxy for **income**
   - Total household expenditure is an accepted alternative to household income in developing country settings.
   - Consumption/expenditure data provides a better proxy for socioeconomic status in low-resource settings than reported income (empirically proven) as it takes items into account which affect consumption but which would not appear if information on income was sought.
   - Where the majority of people are living from daily labor and agricultural work, consumption is easier to measure than income.
   - Includes a short list of key expenditures items.

[20] http://www.worldbank.org/LSMS/guide/select.html

- Key items can be taken from LSMS surveys (see above) or analysis of items most highly correlated with total income.
- Recall bias affecting reported income also affects reported expenditures.

Galobardes et al (2006) provide a good overview for widely used socioeconomic indicators, including their interpretation, meanings, values, strengths, weaknesses and measurements. For our purposes, their account of income and occupation is useful:

Income:

- Individual or household.
- If household: information on family size is needed for a weighted and comparable result.
- It can provide useful information about the poverty level when compared to the national poverty line.
- Disposable income is most useful, though difficult to discern from gross income.
- Income is age-specific. Retired and young people have lower incomes and income tends to grow over time.

Occupation:

- Gives information about the social status of an individual and related income.
- Provides information about working conditions and hazards.
- Information on occupation is available in many routine data collections
- Not useful with unpaid, household, informal and illegal work; the unemployed, retired and students.

Not all poverty is alike. There are different kinds of poverty stratification, for example migrants, single mothers, refugees, unemployed persons, slum dwellers, and rural farmers. They all have different socioeconomic characteristics. There are however a set of indicators which are widely used and have empirically shown to adequately capture socioeconomic status among the various poverty sub-groups.

Wide applicability:

- ☐ literacy
- ☐ level of education
- ☐ place of residence
- ☐ work status
- ☐ type of employment
- ☐ occupation
- ☐ type of work
- ☐ schooling of children
- ☐ income (household, individual)
- ☐ food availability
- ☐ food vs non-food expenditures

Context specific:

- ☐ housing tenure (rented, owned)
- ☐ housing conditions (type of building, materials, crowding)
- ☐ household amenities (water, toilet, electricity)
- ☐ assets, i.e. electric appliances, furniture
- ☐ health insurance
- ☐ land ownership
- ☐ productive assets
- ☐ school-aged children working
- ☐ adult man in household
- ☐ occupation of household head
- ☐ clothing
- ☐ social involvement
- ☐ cooking fuel source

Conclusion

The above provides list of widely used se indicators can serve as a checklist for questionnaires stratifying patients according to socioeconomic status. The interpretation of these indicators is always context-specific, though there are indicators used globally and are proven and popular measures to assess socioeconomic status. The literature sources below provide ample information on the correct interpretation and usage of socioeconomic indicators and can guide

Income

It is useful to include measures of household consumption on food and non-food items as well as individual and household reported income for reasons given above. Asset-based approaches are useful tools, but context specific. If assets are included, questionnaires need to be adapted to local circumstances. This can be done by using data/questions from World Bank LSMS studies. Information on assets can be collected through interviews away from the patient's home, but it is better to assess them directly in the patient's home.

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Nhlema et al (2007). **Developing a socio-economic measure to monitor access to tuberculosis services in urban Lilongwe, Malawi.** *Int J tuberc Lung Dis 11*(1): 65-71.

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Indicators to be measured with questionnaire

Please refer to the guidelines on interpretation to see which questions cover each indicator.

We recommend to analyze the median and mean values (if applicable).

1. Direct costs to patient before and during diagnosis

- Direct costs before and during TB diagnosis
- The type of provider that was consulted before the patient reached the public facility

2. Patient and Health System Delays

- Patient delay (time gap between onset of symptoms and first visit at public clinic)
- Diagnostic delay (time gap between onset of symptoms and diagnosis by the NTP)
- Health system delay (doctor delay and treatment delay)
- Total delay (patient + health system)
- The type of provider consulted before patient reached public facility
- Health-seeking behavior of patient

3. Indirect costs before & during diagnosis

- Indirect costs before and during TB diagnosis

4. Direct costs of patients during treatment

- Direct costs during TB treatment
- Total direct costs due to TB
- Costs of hospitalization for TB patient

5. Indirect costs during treatment

- Indirect costs during TB treatment

6. Total costs of TB patients

- Total direct costs of TB patients (pre-diagnostic, diagnostic, treatment)
- Total indirect costs of TB patients (pre-diagnostic, diagnostic, treatment)

- Total costs of TB patients (indirect + direct before diagnosis, during diagnosis, during treatment)
- Cost of TB including pain and suffering (willingness to pay)

7. Productivity

- % reduction of productivity due to TB

8. Coping costs

- % of patients who take out loan
- Costs due to interest on loan
- % of patients who sell assets
- Type of assets sold
- % reduction of household income spent on food due to TB
- Extent of reduction in food consumption
- % of patients whose children miss school to help finance costs due to TB

9. Guardian costs

- Direct costs of guardians
- Indirect costs of guardians
- Total costs of guardians

10. Additional healthcare costs (including HIV)

- Additional costs due to other diseases

11. Willingness and ability to pay

- Cost of TB including pain and suffering

12. Income and affordability of TB and healthcare

- % of household income spent on food
- % of household income spent on TB (pre-diagnostic and diagnostic costs)
- % of household income spent on TB treatment
- % of household income spent on TB (prediagnostic, diagnostic, treatment)
- % of per capita income spent on TB pre-diagnostic and diagnostic costs
- % of per capita income spent on TB treatment
- % of per capita income spent on TB (pre-diagnostic, diagnostic, treatment)
- % of household income contributed by TB patient
- % reduction of household income due to TB illness of household member
- % reduction of personal income due to TB

13. Health Insurance

- % of patients covered by any kind of health insurance
- % of costs due to TB reimbursed by health insurance

14. Gender / social costs of TB

- % of women who cannot seek care by themselves
- % of women who are financially independent
- % of TB patients whose private or social life was affected by TB
- Type of effect on private or social life
- % of patients where daughters don't attend school regularly due to TB case in family
- % of patients where daughters replaced work due to TB case in family
- Difference in direct costs between men and women
- Difference in indirect costs between men and women
- Difference in patient delays between men and women
- Difference in health system delays between men and women
- Difference in reduction of productivity due to TB between men and women
- Difference in reduction of personal income due to TB between men and women

15. Socioeconomic questions

- % of literate and illiterate patients
- Educational level of patients, head of household, spouse of head of household, primary income earner
- Type of Occupation of patients
- Type of employment status of patients
- Level of impoverishment of household
- % of patients belonging to lowest income quartile/quintile of country
- % of patients belonging to poorest socioeconomic group
- % of patients belonging to minority (tribe/ethnic group/religion)

Questionnaire

Questionnaire Number:

Patient registration Number :

Date of Interview (dd/mm/yy)	Name of Province	Name of District	Place of interview (household / facility name)	Interviewer Name
Category of Facility	**1. Dispensary 2. Health Centre 3. District Hospital 4. Mission Hospital**			

Introduction to the patient:

My name is (name). The organization I am working for, (name of organization), is interested in the costs that people face when they are seeking health care. Therefore, we would like to inquire how much people spend on healthcare, and more specifically on Tuberculosis before and during diagnosis and during treatment.

It is important for you to understand that your participation in this study is completely voluntary. We would be really grateful if you would agree to participate in this study, but do feel free to refuse. If you refuse, there will be no consequence for you and you will receive whatever care and treatment you need at the health facility as usual. If you decline to participate you will not lose any benefit that you are entitled to such as receiving care and support that is provided at the clinic.

If you choose to participate in this study you need to know that you may withdraw from the study at any stage without giving any explanation for your withdrawal. Your answers will be kept confidential. At some point I will ask you about your personal income and the income of your household. We will NOT provide this information to any tax or welfare authorities, also not after the end of the study.
This survey will take ca 30 minutes.

Do you have any questions? Do you want to participate? (circle) **Yes / No**

If Yes: Thank you!

If No: Is there a reason why not?

1. *Language* not good enough 2. Time constraint

3. Not comfortable 4. Unspecified

Patient Information ***(to be filled in by Interviewer with the help of patient card; fill in also if interview is refused for non-response analysis)***	
1. Gender **1. male 2. female**	Age of patient:
2. Type of TB **(circle)**	**1. pulmonary smear + 2. pulmonary smear - 3. Extra-pulmonary**
3. Total duration of planned treatment **(circle)**	**1. (6 months) 2. (8 months) 3. Other**
4. Treatment Regimen **(circle)**	**1. Cat I (new Pulmonary) 2. Cat II (retreatment)** **3. Cat III (new ss- or Extra-Pulmonary) 4. Cat IV (chronic, MDR)**
5. Currently in intensive or continuation phase?	**1. Intensive 2. Continuation**
6. Interviewee	**1. Same as patient 2. DOT supporter / guardian 3. Other**
7. HIV status **(only if indicated on card!)**	**1. positive 2. negative 3. not tested 4. unknown 5. declined**

Proceed according to inclusion/exclusion criteria previously defined!

8. Date of Investigation **(first sputum or xray dd/mm/yy)**	Date of starting Treatment **(dd/mm/yy)**

Minimum treatment duration should be defined – proceed if in agreement with inclusion criteria.

Previous Treatment	
9. a) Have you ever had TB treatment before? ***Cross-check with patient card; If No, go to 10.***	**1. Yes (mm/yy treatment ended) ……. …….** **2. No**
b) **If yes:** Have you completed your previous TB treatment?	**1. Yes 2. No**
c) **If No:** why not? **1. Lack of money for treatment costs 2. Drug side effects 3. Moved 4. distance to facility** **5. Other (specify):**	

Delay, Prediagnostic & Diagnostic Costs

10. What symptoms did you experience that led you to seek treatment for your current illness? How long did you experience these symptoms before you went to seek treatment?

1. Cough yes □ no □_____ months 2. Night sweats yes □ no □ _____ months

3. Coughing up blood yes □ no □_____ months 4. Weight loss yes □ no □ _____ months

5. Other (specify) yes □ no □ _____ months

11. Did you seek treatment or advice for these symptoms at any of the following? *Check all that apply*

Where did you go first? *Circle first place of treatment*

1. District hospital yes ☐ no ☐ 2. Dispensary yes ☐ no ☐

3. Health Centre yes ☐ no ☐ 4. Mission hospital yes ☐ no ☐

5. Pharmacy, drug & grocery store yes ☐ no ☐ 6. Herbalist yes ☐ no ☐

7. Private hospital/clinic yes ☐ no ☐ 8. Other (specify): ☐_____

b) Have you visited a traditional healer? yes ☐ no ☐

If other than public provider was chosen in 11):

12. Why did you not go to the public health facility, such as government clinic or hospital when you first realized you were sick? *Circle most applicable.*

1. distance to facility 2. too expensive 3. time consuming to wait 4. lack of available facilities
5. mistrust of government health services provision 6. Belief system 7. No drugs available
8. other (specify)

13. How far is the nearest government facility for **a) diagnosis and treatment**	____ hours walking _____ hours with transport other:_____
b) treatment only	____ hours walking _____ hours with transport other:_____

14.

14. About how much did you spend for each of these visits before you were diagnosed with TB, including the visit when you actually received your diagnosis?
For all that don't apply, mark N/A; Fill one line per visit

	Provider (copy from question xy providers where patient sought treatment or advice)	**Total Time spent per visit** (in hours, includes travel time)	**Administrative Costs** (consultative , registration)	**Test costs** (for sputum or other except xray)	**Xray costs** (includes sending xrays to radiologist, travel & fees)	**Drug costs** (all kinds total)	**Travel Costs** (return total)	**Food costs** (total)	**Accomo-dation Costs** (total)	**Sub-Total costs per visit**	**Insurance Reimburse-ment** *If yes: amount, if no n/a*
Visit 1											
Visit 2											
Visit 3											
Visit 4											
Visit 5											
Visit 6											
Visit 7											
Visit 8											
Visit 9											
TOTAL	----------										

Total Direct Prediagnostic & Diagnostic costs (sum sub-totals) minus insurance = ***Name of currency***

Treatment Costs		
Costs related to DOT		
15. Where do you currently take your TB drugs? *If the patient has visited two different DOT places, tick the current place and report costs only for that place.* *If DOT at home, go to 19.* 1. Health facility / hospital 2. Home 3. Community 4. Workplace 5. Dispensary **15 b) How many times per week do you go there place to take your drugs?** ☐ 3 times ☐ 5 times ☐ 6 times ☐other		
16. How long does it take you to get there (one way)	____ hours walking _____ hours with transport other:_____	
17. How long does one of these visits take on average, including time on the road and waiting time (total turnaround time)**?**		Hours
18. From your home to the DOT place, how much does it cost if you take transport? (both ways)		
19. How much do you spend on food on the road, while waiting, for lunch?		

Costs related to picking up the TB drugs – where drugs are <u>currently</u> picked up		
20. How often do you travel to the health facility / hospital for picking up your TB drugs?		Times / month
21. How long does it take you to get there (one way)	____ hours walking _____ hours with transport _____ other	
22. How long does one of these visits take on average, including time on the road and waiting time (total turnaround time) ?		hours
23. From your home to the facility, how much does it cost if you take transport? (both ways)		
24. If you go to a facility to pick up your drugs, how much do you spend on food on that day? (on the road, while waiting, lunch etc.)		
25. a) Do you have to pay administration fees when picking up your TB drugs? *If No, go to 26.* **b)** If YES, **how much?**		1. Yes 2. No
26. a) Do you have any accommodation costs when picking up your TB drugs? *If No, go to 27.* **b)** If YES**: how much?**		1. Yes 2. No

Costs related to follow up tests	
27. a) Did you ever have to go to the health facility in addition to your regular visits for follow up tests since the beginning of treatment? *If No, go to 28.* **b) If yes, how many times?** **c) If yes, did you have to pay any additional costs any time during the entire period?** **d) If so, what kind of costs and how much?** Fees_____ sputum test _____Xray_____ TB Drugs _____ Other Drugs_____ Other_____	1. Yes 2. No Times 1. Yes 2. No Total:
e) How long does one of these follow-up visits take on average, including time on the road, waiting time and tests (total turnaround time) **?**	Hours
Guardian Costs	
28. a) Does any family/friend/DOT supporter accompany you on any visits or go in your place to collect your TB drugs ? *If No, go to 29.*	1. Yes 2. No
b) *If YES,* **on how many visits has your family/friend/DOT supporter accompanied you or gone in your place?** *Record pre-diagnosis/diagnosis visits and treatment visits separately* Complete at data entry: Pre-diagnosis/diagnosis costs per visit: Transport _____ Food _____ Accommodation ____ Costs during treatment per visit: Transport _____ Food _____ Accommodation _____	_____ Diag. times _____Treatment times Total Diag: Total Treatm:
c) How much does your friend/family/DOT supporter earn per day?	1. 2. Doesn't earn
d) Why did someone accompany you? 1. Distance 2. Security 3. Administrative barriers 4. Too ill to travel alone 5. Was required for treatment 6. Other (specify)	

Hospitalization	
29. Have you been hospitalized before or during your TB treatment? *If No, go to question 38.*	1. Yes 2. No
30. If YES: **how many days in total did you stay at the hospital?**	days

31. How much did you pay in the hospital during your entire stay? Hospital administration fees: Sheets/Linnen: Food (not provided by hospital): Transport (return): Drugs: Tests: Others:	Total:
32. Did any family/friend <u>stay</u> with you while in hospital? *If No, go to question 38.*	1. Yes 2. No
33. If YES**: How many days did he/she stay with you (sleep there)?** **34. Were there any extra costs for your relative/friend for staying at the hospital?** Accommodation (hospital or other): Food: Transport: Other:	Days 1. Yes 2. No Total Costs:
35. How much does your friend/family normally earn per day?	1. 2. Doesn't earn
36. a) Did any <u>other</u> family/friend visit you while in hospital? *If No, go to 38.* **b) If yes, how many people visited you?** **c) how many times did they visit you?** Accommodation per person: Food per person: Transport per person: Other: **37. How long were the visits including traveling time?**	1. Yes 2. No Persons Times Total number of visits: Total Cost per person: Hours

Other Costs *Food Supplements*	
38. a) Do you buy any supplements for your diet because of the TB illness, for example vitamins, meat, energy drinks, soft drinks, fruits or medicines? *If No, go to 39.*	1. Yes 2. No
b) If YES: **What kind of items?** (specify) 1. Fruits 2. Drinks 3. Vitamins/Herbs 4. Meat 5. Other (specify):	
c) How much did you spend on these items in the last month approximately?	

Other Illnesses	
39. a) Do you have any chronic illness for which you are receiving treatment? *If No, go to 40.* **b)** If yes: **which?**	1. Yes 2. No
c) Are there any additional costs for you because of this other illness <u>besides</u> the costs that you have already mentioned? *If No, go to 40.*	1. Yes 2. No
d) If YES: **How much are these additional costs on average per month?** Tests: Drugs: Transport: Food: Other:	Total:
40. How much did you spend on healthcare on average per month BEFORE the TB illness?	
41. How much do you spend on healthcare on average per month NOW?	

Insurance	
42. a) Do you have any kind of private or government health/medical insurance scheme? *If No, go to 43.*	1. Yes 2. No
b) If YES: **What type?** 1. reimbursement scheme 2. monthly medical allowance 3. donor 4. family/community fund 5. Western scheme (contract) 6. Other (specify)	
c) Have you received reimbursement for any costs related to the TB illness? *Cross-check with question xy (table on prediagnostic & diagnostic costs)* *If No, go to 43.*	1. Yes 2. No
d) How much have you received as reimbursement?	

Coping Costs	
43. Did you borrow any money to cover costs due to the TB illness? *If No, go to question 45.*	1. Yes 2. No
44. a) If YES: **How much did you borrow?** **b) From whom did you borrow?** *Circle most appropriate* 1. Family 2. Neighbors/friends 3. Private bank 4. Cooperative	

5. Other (specify):	
c) What is the interest rate on the loan? (%) 1. less than xx 2. xx to xy 3. More than xy 4. I don't pay any interest 5. I am not expected to pay back the money	
45. a) Have you sold any of your property to finance the cost of the TB illness? *If No, go to 46.*	1. Yes 2. No
b) If YES**: What did you sell?** *Circle most appropriate* 1. Land 2. Livestock 3. Transport/vehicle 4. Household item 5. Farm produce 6. Other (specify):	
c) What is the estimated market value of the property you sold?	
d) How much did you earn from the sale of your property?	

Socioeconomic Information *Individual Situation and Income*
46. Who is the primary income earner in the household? ***Circle most appropriate*** **1. Patient 2. Wife/mother 3. Husband/father 4. Extended family 5. Son/daughter** **6. Other (specify)**
What is the highest level of education of ...? **47. The patient?** 1. Not attended/illiterate 2. primary 3. secondary 4.graduate/certificate 5. other **48. Primary income earner?** 1. Not attended/illiterate 2. primary 3. secondary 4.graduate/certificate 5. other **49. Head of household?** 1. Not attended/illiterate 2. primary 3. secondary 4.graduate/certificate 5. primary income earner = head of hh **50.** Spouse of head of household? ***If more than one spouse, choose highest level of education*** **1. Not attended/illiterate 2. primary 3. secondary 4. graduate/certificate 5. other**

51. Are you currently formally employed? ***Name all options first***	**1. Yes, formal work** ***(go to 54)*** **7. Combination (specify)** **2. No, informal work** ***(go to 54)***

	3. On sick leave ***(go to 52)*** **8. Other (specify)** **4. Retired** ***(go to 52)*** **5. School, university** ***(go to 58)*** **6. Housework** ***(go to 54)***	
52. Is the reason for Not Working related to the TB illness?		1. Yes 2. No
53. If Yes**: When was the last time you were working? (mm/yy)**		
54. How are you usually paid? **1. cash 2. in kind 3. cash and in kind 4. not paid 5. bank transferred salary 6. other**		
55. What was your estimated personal take home earning per month BEFORE the TB illness? **(includes welfare, disability, or other social support):** **1. Under xx per week 2. Xx to xy per week 3. Xy to xz per week 4. More than xz per week 5. Don't earn**		
56. What is your estimated personal take home earning per month NOW**? (includes welfare, disability, or other social support)** **1. Under xx per week 2. Xx to xy per week 3. Xy to xz per week 4. More than xz per week 5. Don't earn**		
If answer to 56 differs from 55: **57.** Is the change related to the TB illness?		1. Yes 2. No

58. a) Have you ever stopped working/going to school/doing housework due to TB? *If No, go to 59.*	1. Yes 2. No
b) If YES**: for how long?**	1. Less than 1 month 2. one month 3. 2-3 months 4. 4-5 months 5. more than 6 months
59. a) Does someone stay home <u>specifically</u> to take care of you? *If NO, go to 60* **b**) If YES: **for how long?** **c) Did they quit their income-earning job to stay home and care for you?**	1. Yes 2. No Weeks 1. Yes 2. No

60. How regularly did you work before you became ill with TB?	**1. Throughout the year 2. Seasonal/part of the year 3. Day labor 4. Other**
61. Did you have to change jobs when you became ill with TB?	**1. Yes 2. No**
62. What is your main occupation? ***Tick all that applies, cross-check with question 51.*** **1. Sales/Service 2. Agriculture 3. Household 4. Production/construction** **5. Combination (specify) 6.Other (specify)**	
63. How many hours did you work on average per day BEFORE you became ill with TB?	**Hours**
64. How many hours do you work on average NOW per day?	**Hours**
If answer to 64 differs from answer to 63: **65.** Is the change related to the TB illness?	1. Yes 2. No
If answer to 64 differs from answer to 63: **66.** a) Is someone doing the work that you used to do? **b)** 1. daughter 2. son 3. spouse 4. friend 5. nobody 6. other family	
67. a) Do you have children of or below school age? ***If No, go to 68.***	1. Yes 2. No
b) Do all of your children of school age attend school regularly? ***If YES, go to 67d)***	1. Yes 2. No
c) **If NO:** Why not? ***Circle most appropriate*** 1. Needs to help around the house 2. No money for school fees 3. Also sick 4. Has to work to earn income 5. Other (specify):	
d) Do any of your children of or below school age work to finance costs due to the TB illness?	1. Yes 2. No
68. If you employed someone to do the housework for your household, how much would you have to pay him/her per day? **a) While you are sick**	

b) While you are healthy	
69. Are you financially independent?	1. Yes 2. No
70. a) Has the TB illness affected your social or private life in any way? ***If No, go to 71.*** **1. No 2. Divorce 3. Loss of Job 4. Dropped out of school** **5. Separated from spouse/partner 6. disruption of sexual life 7. Sick child 8. Other (specify):**	
b) **If Yes:** Has this resulted in a financial burden?	**1. Yes 2. No**
71. *What is your tribe / ethnic group / religion?*	**1. 2. 3. 4. 5.**

Household Income and Spending	
72. How much do you estimate was the average income of your household per month BEFORE the TB illness ? **(for all persons in the house, including patient; includes welfare payments, government assistance or other social support)** **1. income patient: 2. income rest of household 3. welfare payments** **4. government assistance 5. Other: TOTAL:**	
73. How much do you estimate is the average income of your household per month NOW ? **1. income patient: 2. income rest of household 3. welfare payments** **4. government assistance 5. Other: TOTAL:**	
74. How many people regularly sleep in your house? **(including patient)** *If patient lives alone, go to question 77 and replace the word 'household' with 'you'*	
75. How many of the household members are paid for working? **(including patient) (*includes payment in kind or farm produce)***	
76. a) Besides yourself, does anyone else of your household receive treatment for TB? ***If No, go to 77.***	**1. Yes 2. No**
b) **If Yes:** How many?	
77. How much food did your household consume every month on average BEFORE the TB illness? ***Calculate value*** ***If home production:***	

If the food that you consumed per month before the TB illness was sold on the market: How much would it be worth? (plus how much you spent on average on food not produced at home?)	
78. How much food does your household consume NOW every month on average? ***Calculate value*** ***(for same number of people)*** ***If home production:*** If the food that you consume per month now was sold on the market: How much would it be worth? (plus how much you spent on average on food not produced at home?)	

79. ***If answer to 78 differs from 77:*** Has the amount of food consumed per month changed due to the TB illness?	1. Yes 2.No

Socioeconomic Indicators				
80. What is your electricity supply?	1. Own connection 2. Shared connection 3. None			
81. What is your source of drinking water? 1. Rainwater 2. lake/pond/ dam/river 3. public well 4. private well/bore hole 5. piped water 6. bottled water				
82. What type of toilet facility is available? 1. no facility/bush/field 2. shared pit toilet/latrine 3. own pit toilet/latrine 4. flush toilet				
83. How many rooms are there in your house? 1. 1 room 2. 2 rooms 3. 3 rooms 4. 4 or more rooms				
84. Current place of residence?	**1.Urban (specify)**	**2. Urban Slum**	**3. Rural**	**4. Other**
85. Do you own the house or residence you live in?	1. Yes 2. No			
86. Do you own…. ***Include standard assets adapted to country Demographic and Health Survey (DHS)*** **1. mobile phone** **2. washing machine** **3. motorcycle** **4. bicycle** **5. land (quantify)** **6. etc…**				
87. If the government could provide you with some service to ease the burden of TB on you and your household, what would you prefer to have? ***State options, choose one*** 1. **Transport vouchers** **2. food vouchers** **3. More efficient service** **4. Other (specify):**				

We would like to know the cost of the TB illness on the welfare of your household; that is, we would like to put a value on the TB illness which includes pain and suffering.

Therefore, we would like to know how much it would be worth to you if you could avoid becoming ill with TB in the first place. Note that we don't ask what you actually can, but what you would be willing pay if you had an unlimited amount of money.

88. How much would you be willing to pay for not becoming ill with TB in the first place?			
1. Under xx	2. between xx and xy	3. over y	4. Other (specify)

Thank you for your cooperation!

Is there anything you would like to ask or say?

Comments by Interviewer:

Date, Signature by Interviewer:

SAMENVATTING

Samenvatting

Deze thesis onderzoekt hoe er een toegankelijke en duurzame beperking van tuberculose (tbc) kan worden opgezet in landen met een zware tbc-problematiek. Deze vraag wordt beantwoord aan de hand van vier deelvragen: 1. Hoe kan de beperking van tbc functioneren in fragiele staten, waarin sprake is van een beperkte mate van bestuur en mankracht? 2. Wat zijn de uitdagingen voor de zieken en zwakkeren bij de toegang tot gezondheidszorg, informatie en medische producten? 3. Met welke kosten hebben tbc-patiënten in landen met een zware tbc-problematiek voor of tijdens de diagnose en tijdens de behandeling te maken? 4. Worden de programma's voor zware tbc-problemen duurzaam gefinancierd? De zes bouwstenen van de Wereldgezondheidsorganisatie voor gezondheids-systemen vormen het begeleidende concept voor het beantwoorden van deze vragen. Het onderzoeksonderwerp, de deelvragen en het begeleidende concept worden geïntroduceerd in **hoofdstuk 1.** De vier onderzoeksvragen worden beantwoord in de hoofdstukken 3 t/m 7. **Hoofdstuk 2** bevat een overzicht van de literatuur over de bestaande kennis aan het begin van ons onderzoek over kosten van patiënten en concepten om de kosten van ziekte te meten. Het doel van dit overzicht is om een gedetailleerd overzicht weer te geven van onderzoeken die nagaan welke kosten op welk ogenblik worden gemaakt. Het is de basis voor de ontwikkeling van de "Tool to Estimate Patients' Costs" in bijlage 1.

Hoofdstuk 3 geeft antwoord op deelvraag 1 en onderzoekt het functioneren van tbc-bestrijding in vier fragiele staten. Gezondheidszorg is met name problematisch in fragiele staten die vaak te maken hebben met het vaker voorkomen van overdraagbare ziekten, zoals tuberculose. Om te bepalen welke thema's vaak voorkomen bij tbc-bestrijding in fragiele staten werd er een gestructureerde inventarisatie uitgevoerd onder twaalf aanbieders van technische hulp die hebben gewerkt in fragiele staten. Deze thema's hebben betrekking op de tbc-bestrijdingsprogramma's in Afghanistan, DR Congo, Haïti en Somalië in de jaren 2000 tot 2006. We hebben ontdekt dat het aantal meldingen en het aantal behandelingen sinds 2003 in alle vier de landen is gestegen. Toch is de toegang tot

de gezondheidszorg en het aantal diagnoses nog onvoldoende. We hebben vier lessen kunnen noteren die men heeft geleerd: 1. Tbc-bestrijdingsprogramma's kunnen in fragiele staten werken; 2. Voor de kwaliteit en de duurzaamheid van tbc-bestrijding is een landelijk programma essentieel, op bestuurlijk en op organisatorisch niveau; 3. Samenwerking met niet-gouvernementele aanbieders is cruciaal voor een consequente dienstverlening; 4. Tbc-bestrijdingsprogramma's in fragiele staten hebben voortdurende ondersteuning nodig van donoren. Onze conclusie is dat tbc-bestrijdingsprogramma's ondanks uitdagingen op het gebied van management, coördinatie, veiligheid, logistiek en financiering kunnen functioneren in fragiele staten, maar dat er aanzienlijke problemen zijn bij de toegang tot diagnose en behandeling en daarmee bij de herkenning van tbc.

Hoofdstuk 4 geeft antwoord op de deelvragen 2 en 3 en presenteert een tool om het soort hindernissen en kosten te bepalen dat tbc-patiënten, voor en tijdens de diagnose en tijdens de behandeling, tegenkomen. Ook worden de resultaten van de pilot van deze tool in Kenia gepresenteerd. De armen hebben bij de toegang tot tuberculosezorg te maken met hindernissen op het gebied van geografie, sociaal-culturele omstandigheden en het systeem van gezondheidszorg. Deze kunnen vertragingen veroorzaken bij een tijdige diagnose en behandeling die resulteren in verdere vorderingen van de ziekte en een verdere verspreiding van tbc. Door de hindernissen en de redenen voor de vertraging vast te stellen kunnen de kosten die tbc-patiënten maken effectief worden teruggebracht. Er is een "Tool to Estimate Patients' Costs" ontwikkeld. Deze kan tbc-bestrijdings-programma's helpen bij het vaststellen van zulke hindernissen. De tool is aangepast op lokale omstandigheden, vertaald in het Swahili en vooraf getest. In totaal zijn er in september 2008 208 patiënten ondervraagd. We ontdekten dat er voor de patiënten in de beide districten een aanzienlijke drempel van directe (uit eigen zak; USD 55,80) en indirecte (mogelijke; USD 294,20) kosten is dankzij tbc. De onmogelijkheid om te werken is een belangrijke reden van de verhoogde armoede. De resultaten bevestigen een 'medische armoedeval' in de twee districten: de uitgaven van personen gingen omhoog terwijl de inkomsten omlaag

gingen. Vervolgens werden de tbc-behandelingscentra gedecentraliseerd in 15 extra faciliteiten en werden andere gezondheidsprogramma's benaderd voor voedselhulp aan tbc-patiënten en voor het transport van sputummonsters. Op landelijk niveau werd er een tbc- en armoede-subcomité bijeengeroepen voor de ontwikkeling van een uitgebreide pro-armenbenadering. Onze conclusies waren dat de tool een waardevol instrument is gebleken om de gemaakte kosten van tbc-patiënten vast te stellen, evenals hun sociaal-economische situaties, de patronen van het zoeken naar zorg, gelijktijdige ziektes als hiv en sociale en gender-gerelateerde invloeden. De tool helpt om knelpunten bij de toegang tot tbc-zorg te bepalen en te verhelpen, met name voor de armen.

Na de pilot is de tool op bepaalde punten aangepast en verbeterd. **Hoofdstuk 5** beantwoordt de deelvragen 2 en 3 en beschrijft de implementatie van de verbeterde tool in de Dominicaanse Republiek in 2009. Hier werden de directe (uit eigen zak) en indirecte (mogelijke) kosten onderzocht van nieuwe, herbehandelde en multiresistente tbc-patiënten, voor en tijdens de diagnose en tijdens de behandeling. Het doel van de studie was het creëren van een feitelijke basis voor het doen van aanbevelingen en het voorstellen van interventies. De "Tool to Estimate Patients' Costs" werd aangepast aan de lokale omstandigheden, vertaald in het Spaans en vooraf getest. Er werden patiënten ondervraagd die een bezoek brachten aan 32 willekeurig gekozen gezondheidsfaciliteiten in zes geselecteerde onderzoeksgebieden op de dagen van het onderzoek. In totaal werden er 200 patiënten ondervraagd. Voor de meeste ondervraagden gingen de directe en indirecte kosten omhoog, terwijl de inkomsten omlaag gingen. Dit treft de meest kwetsbare groepen in de samenleving. De totale kosten (van pre-diagnose, diagnose en behandeling) waren USD 908 voor nieuwe patiënten, USD 432 voor patiënten in herbehandeling en USD 3.557 voor multiresistente tbc-patiënten. Voor de laagste inkomensgroep betekent dit respectievelijk 2215%, 1054% en 8676% van het mediaan maandelijks inkomen. Het percentage patiënten zonder regelmatig inkomen steeg van 1 naar 54 als gevolg van het krijgen van tbc. Het ministerie van gezondheid heeft vervolgens een poging gedaan om

overheidsmiddelen ter beschikking te stellen voor voedselsupplementen. Ook werd er geprobeerd om de dienstverlening aan patiënten met tbc, zowel in ziekenhuizen als in de ambulante zorgverlening, op te nemen in de nationale zorgverzekeringsstelsels. Onze conclusie was dat gratis tbc-diagnose en -behandeling niet genoeg is om de kwetsbare groepen te vrijwaren van financiële zorgen als gevolg van de ziekte. Zorgverzekeringen die de kosten van tbc dekken, zowel voor ambulante als voor klinische zorg, zijn absoluut cruciaal om tbc-gerelateerde financiële problemen in de Dominicaanse Republiek te voorkomen.

Als antwoord op de deelvragen 2 en 3 presenteert **hoofdstuk 6** vervolgens vergelijkende gegevens uit drie landen in drie continenten waarmee het mogelijk is om vergelijkbare patronen vast te stellen in verschillende landen, evenals algemene conclusies en beleidsaanbevelingen. De gegevens zijn afkomstig van de nationale tuberculoseprogramma's van Ghana, Vietnam en de Dominicaanse Republiek. Het doel van de studie was het vaststellen van de directe en indirecte kosten van tbc-diagnose en –behandeling voor patiënten en huishoudens in alle drie de landen. Elk land heeft de "Tool to Estimate Patients' Costs" vertaald en aangepast. Er werd in elk van de drie landen een willekeurige testgroep van volwassen, nieuwe patiënten ondervraagd met minimaal één maand behandeling. We ontdekten dat in deze landen 27 tot 70% van de patiënten is gestopt met werken en te maken heeft met een verlaging van het inkomen; 5 tot 37% heeft bezittingen moeten verkopen en/of geld moeten lenen als gevolg van tbc (17-47%). De opnemingskosten (USD 50-196) en extra voedsel vormen het grootste deel van de directe kosten tijdens de behandeling. De gemiddelde totale kosten per patiënt (USD 538-1268) waren het equivalent van ongeveer een jaarlijks individueel inkomen. Onze conclusies waren dat we vergelijkbare patronen en uitdagingen van tbc-gerelateerde kosten hebben waargenomen bij patiënten in de drie landen. We pleiten voor wereldwijde, gezamenlijke actie om tbc-patiënten onder te brengen in sociale beschermingsprogramma's en om een aanvaardbare toegang tot zorg binnen nationale tbc-programma's te verbeteren.

Hoofdstuk 7 geeft antwoord op deelvraag 4 en neemt het perspectief in van het gezondheidssysteem voor de financiering van tbc-bestrijding. De literatuur suggereert dat er in landen met een laag inkomen en een zware hiv-problematiek verdringingseffecten plaatsvinden bij de overheidsfinanciering van zorg. In een korte enquête onderzochten we de hypothese dat binnenlandse financiering van tbc-bestrijding in elf landen met een laag inkomen en een zware tbc-problematiek is verminderd vanwege veranderingen in het BBP, de instroom van ontwikkelingshulp en nationale zorguitgaven. We ontdekten dat er in het merendeel van deze landen ondanks een gegroeid bbp per hoofd van de bevolking tussen 2003 en 2009 hetzelfde of minder werd besteed aan zorguitgaven als percentage van het bbp. Hoewel de budgetten voor tbc-bestrijding in absolute zin in alle elf landen stegen, verlaagden zes landen de overheidsbijdrage aan tbc-bestrijding. Om gezondheidsprogramma's op de lange termijn duurzaam te laten worden, pleiten we voor meer donorfinanciering van de gezondheidszorg, die moet samengaan met verplichtingen om de binnenlandse uitgaven voor de gezondheidszorg te verhogen. We maken daarbij zowel donoren als overheden verantwoordelijk voor het voorkomen van verdringingseffecten. Bovendien is het de verantwoordelijkheid van beiden om essentiële onderdelen van de programma's te laten financieren door overheidsinstanties; zo kan een ineenstorting van deze programma's worden voorkomen in het geval dat er hulp zou worden stopgezet.

Hoofdstuk 8 bespreekt de resultaten uit de hoofdstukken 3 t/m 7 en schetst de overgebleven vragen en de agenda voor toekomstig onderzoek. Samengevat kan toegankelijke en duurzame tbc-bestrijding worden gecreëerd door a) de nationale tbc-bestrijdingsprogramma's te integreren in het nationale systeem van gezondheidszorg, b) tbc-zorg te integreren in betaalbare sociale beschermingsprogramma's, c) de tbc-bestrijding duurzaam te financieren, d) de nationale overheid haar bestuurlijke functie naar behoren te laten uitoefenen, e) de partijen stabiel te laten samenwerken en deze samenwerking goed te coördineren om te kunnen omgaan met de personele beperkingen en f) gratis anti-tbc-medicatie en

diagnoses ter beschikking te stellen en het voorschrijven van onnodige tests, medicatie en supplementen te voorkomen.

De toekomstige onderzoeksagenda voor tbc-bestrijding moet de volgende vier vragen bevatten: hoe kan tbc-bestrijding worden geïntegreerd in nationale zorgsystemen zonder concessies te doen aan de effectiviteit? Hoe kunnen bestuur en organisatie worden versterkt in landen met zware tbc-problematiek? Wat kan er worden gedaan om de brain drain uit ontwikkelingslanden naar ontwikkelde landen te stoppen? Hoe kan het dodelijke verband tussen tbc en hiv worden doorbroken om de versterking van tbc door hiv te stoppen?

SUMMARY

Summary

This thesis inquires how accessible and sustainable tuberculosis (TB) control can be achieved in high TB burden countries. This question is answered by addressing four sub-questions: 1) how can TB control function in fragile states given a limited governance and human resource situation? 2) What are the challenges for the poor and vulnerable in accessing health services, information and medical products? 3) What kinds of costs do TB patients face before/during diagnosis and during treatment in high TB burden countries? 4) Are high TB burden programs sustainably funded? The six WHO health system building blocks provide the guiding concept to answer these questions. The research topic, sub-questions and the guiding concept are introduced in **Chapter 1.** The four research questions are answered in chapters 3-7. **Chapter 2** provides a literature review on existing knowledge at the start of our studies of patient costs and concepts to measure the cost of illness. The objective of this review is to provide a detailed account of research findings at which stage what kinds of costs are incurred. It forms the basis to develop the "Tool to Estimate Patients Costs" included in Annex 1.

Chapter 3 responds to sub-question 1 and investigates the functioning of TB control in four fragile states. Health care delivery is particularly problematic in fragile states often connected with increased incidence of communicable diseases, among them tuberculosis. A structured inventory to extract common themes specific for TB control in fragile states was conducted among twelve providers of technical assistance who have worked in fragile states. The themes were applied to the TB control programs of Afghanistan, DR Congo, Haiti and Somalia during the years 2000–2006. We found that case notifications and treatment outcomes have increased in all four countries since 2003. Access to care and case detection however has remained insufficient; we identified four lessons learned: 1. TB control programs can function in fragile states. 2. National program leadership and stewardship are essential for quality and sustained TB control. 3. Partnerships with nongovernmental providers are vital for continuous service delivery; 4. TB control programs in fragile states require consistent donor

support. Our conclusion is that despite challenges in management, coordination, security, logistics and funding, TB control programs can function in fragile states, but face considerable problems in access to diagnosis and treatment and therefore case detection.

Chapter 4 responds to sub-questions 2 and 3 and presents a tool and its pilot results in Kenya to determine the kinds of barriers and costs that TB patients face before/during diagnosis and treatment. The poor face geographical, socio-cultural and health system barriers in accessing tuberculosis care. These may cause delays to timely diagnosis and treatment resulting in more advanced disease and continued transmission of TB. By addressing barriers and reasons for delay, costs incurred by TB patients can be effectively reduced. A "Tool to Estimate Patients' Costs" has been developed. It can assist TB control programs in assessing such barriers. The Tool was adapted to the local setting, translated into Kiswahili and pretested. Nine public health facilities in two districts in Eastern Province were purposively sampled. A total of 208 patients were interviewed in September 2008. We found that TB patients in both districts have a substantial burden of direct (out of pocket; USD 55.8) and indirect (opportunity; USD 294.2) costs due to TB. Inability to work is a major cause of increased poverty. Results confirm a 'medical poverty trap' situation in the two districts: expenditures increased while incomes decreased. Subsequently, TB treatment services were decentralized to fifteen more facilities and other health programs were approached for nutritional support of TB patients and sputum sample transport. On the national level, a TB and poverty sub-committee was convened to develop a comprehensive pro-poor approach. Our conclusions were that the Tool proved a valuable instrument to assess the costs incurred by TB patients, their socioeconomic situations, health-seeking behavior patterns, concurrent illnesses such as HIV, and social and gender-related impacts. The Tool helps to identify and tackle bottlenecks in access to TB care, especially for the poor.

After the Tool's pilot and improvement, **Chapter 5** responds to sub-questions 2 and 3 and describes its implementation in the Dominican Republic in 2009. The direct (out of pocket) and indirect (opportunity) costs of new, retreatment and multi-drug resistant TB patients before and during diagnosis and during treatment were investigated. The aim of the study was an evidence base upon which recommendations and interventions could be formulated. The "Tool to Estimate Patients' Costs" was adapted to the local setting, translated into Spanish and pretested. Patients attending 32 randomly selected health facilities in six chosen study areas on the study days were interviewed. A total of 200 patients were interviewed. For most respondents, direct and indirect costs increased while income decreased. This affects the most vulnerable of society. Total costs (pre-diagnostic, diagnostic and treatment costs) amounted to USD 908 for new patients, USD 432 for retreatment patients and USD 3 557 for MDR-TB patients. For the lowest income group, these costs constitute 2215%, 1054% and 8676% of median monthly income, respectively. The percentage of patients without a regular income increased from 1 to 54 because of falling ill with TB. The Ministry of Health has subsequently been making an effort to allocate public funds for food supplements and to include in- and outpatient TB services in the national health insurance schemes. Our conclusion was that free TB diagnosis and treatment are not enough to alleviate the vulnerable from financial constraints due to the illness. Health insurances covering TB in- and outpatient costs are absolutely critical to prevent TB-related financial hardship in the Dominican Republic.

Responding to sub-questions 2 and 3, **Chapter 6** then presents comparative data on patient costs in three countries on three continents allowing the confirmation of similar patterns across countries, as well as overall conclusions and policy recommendations. The settings were the National Tuberculosis Programs of Ghana, Viet Nam and Dominican Republic. The objective of the study was to assess the direct and indirect costs of TB diagnosis and treatment for patients and households in all three countries. Each country translated and adapted the "Tool to Estimate Patients' Costs". A random sample of adult, new patients with at least

one month of treatment was interviewed in all three countries. We found that across the countries, 27-70% of patients stopped working and experienced reduced income; 5-37% sold property and/or borrowed money due to TB (17-47%). Hospitalization costs (USD 50-196) and additional food items form the largest part of direct costs during treatment. Average total patient costs (USD 538-1268) were equivalent to approximately one year of individual income. Our conclusions were that we observed similar patterns and challenges of TB related costs for patients across the three countries. We advocate for global, united action for TB patients to be included under social protection schemes and for national TB programs to improve equitable access to care.

Chapter 7 responds to sub-question 4 and takes the perspective of the health system for financing TB control. The literature suggests crowding-out effects of government funding for health happen in low-income, high HIV burden countries. In a short survey, we investigated the hypothesis that domestic funding for TB control has decreased in eleven low income, high TB burden countries in the context of changes in GDP, development assistance inflows, and national health expenditures. We found that despite increases in GDP per capita between 2003 and 2009, health expenditure as percent of GDP decreased or stayed the same for the majority of these countries. Although TB control budgets increased for all eleven countries in absolute terms, six countries decreased government contribution to TB control. In the long run for health programs to become sustainable, we suggest increases in donor funding for health to be accompanied by requirements to increase domestic funding for health. We thereby attribute responsibility to avoid crowding out effects to donors and governments alike. Moreover, it is the responsibility of both to ensure for essential items to be funded by government sources to avoid a collapse of programs once aid is withdrawn.

Chapter 8 discusses the results of chapters 3-7 and lines out remaining questions and a future research agenda. In summary, accessible and sustainable TB control

can be achieved by a) integrating the national TB control program into the national health system, b) including TB care into affordable social protection schemes c) sustainable financing of TB control, d) a national government exercising its leadership functions, e) stable partnerships and coordination of partners to cope with limited human resources, and f) free anti-TB drugs and diagnostic tests, and the abstention from prescribing unnecessary tests, drugs and supplements.

The future research agenda tuberculosis control should include the following four questions: How can TB control be integrated into national health systems without compromising its effectiveness? How can leadership and governance be strengthened high TB burden countries? What can be done to limit the brain drain from developing to developed countries? How can the deadly bond between TB and HIV be broken to end the fuelling of TB by HIV?

List of publications

Original articles related to this thesis

1. Mauch et al: **Structure and management of tuberculosis control programs in fragile states - Afghanistan, DR Congo, Haiti, Somalia**. *Health Policy* 2010, **96**:118–127.

2. Mauch et al: **Assessing access barriers to tuberculosis care with the Tool to Estimate Patients' Costs: pilot results from two districts in Kenya**. *BMC Public Health* 2011,**11**.

3. Mauch V, Baltussen R, van der Velden J: **Unsustainable funding of high-burden tuberculosis control programmes: who is responsible?** *Tropical Medicine and International Health* 2012,**17:** 1044-1046.

4. Mauch et al: **Free TB diagnosis and treatment are not enough – Patient cost evidence from three continents.** *International Journal of Tuberculosis and Lung Disease* **17**(3): 381–387.

5. Mauch et al: **Tuberculosis patients in the Dominican Republic face severe direct and indirect costs and need social protection**. *Journal of the Panamerican Health Organization (accepted, in press).*

6. Mann et al: **Engaging the rural health insurance scheme to reduce out-of pocket expenditure during health care seeking for TB in China**. *Submitted*.

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Curriculum Vitae

Verena Mauch was born in 1979 in Ravensburg, Southern Germany. After her German Abitur and a high-school exchange year in Montana, USA, she completed a professional training in publishing in Hamburg with a subsequent internship/scholarship in a French publishing house in Toulon, France. She then studied social sciences (political science, sociology, economics, and research methods) at Jacobs University Bremen, Germany and Mahidol University International College Bangkok, Thailand, followed by a Master's degree in public policy at the Hertie School of Governance in Berlin. Numerous internships in (political) institutions, among them the World Health Organization (WHO), took her to the field of tuberculosis control. She wrote her Master Thesis in collaboration with WHO's Stop TB Department and thereafter joined KNCV Tuberculosis Foundation in Den Haag, the Netherlands, first as a junior TB consultant and later as a senior TB consultant. This work took her to many countries in western, southern and eastern Africa and China always supporting the national TB programs of the Ministries of Health. After four years at KNCV, Verena moved back to Southern Germany and is working now for the Max Planck Society in Munich supporting the management of bio-medical Max Planck institutes in Germany and the USA.