THE CONCEPT OF RISK IN TUBERCULOSIS POLICY: AN EXPLORATION OF SOME ASPECTS OF THE TUBERCULOSIS PROGRAMME

Dissertation submitted to the Jawaharlal Nehru University
in partial fulfillment of the requirements
for the award of the degree of

MASTER OF PHILOSOPHY

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2009

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NEW DELHI - 110 067

July 29, 2008

DECLARATION

This dissertation titled **The Concept of Risk in Tuberculosis Policy: An Exploration of Some Aspects of the Tuberculosis Programme** is submitted for the award of the degree of Master of Philosophy of this university. This dissertation has not been submitted, in part or in full, for any other degree of this or any other university, and is my original work.

Lakshmi Kutty

CERTIFICATE

We recommend that this dissertation be placed before the examiners for evaluation.

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Acknowledgements

Heartfelt gratitude to my supervisors Prof. Mohan Rao and Dr. Ramila Bisht for enabling me to successfully finish this work! They have facilitated my entry into many arenas, which have helped this work come this far. They have given me the space to work freely while also being careful to see that I did not lose my way entirely.

I also wish to thank every faculty member for their patience and support, especially during the coursework year, and for always enquiring with care about the chapter-writing.

Many friends have helped me with resources of various kinds. Thanks to Ruchi, Thakur, Lata for material from their university libraries, and to Kamalini for material from VHAI. Thanks to Prachin for providing me a space to work undisturbed. Thanks to Tony, Miko and Amrita for enabling me to literally 'work on the move'!

Friends and colleagues at Anveshi Research Centre for Women's Studies, Hyderabad, have nurtured my earlier explorations in the field of public health; that space and time has contributed immensely to my growth. I wish to especially thank the CMC (Vellore)—Anveshi Book project team.

Thanks are especially due to Library staff at National Tuberculosis Institute, Bangalore and Community Health Cell, Bangalore. Interviews with Thelma Narayan and Dr A. K. Chakraborty helped me clarify many doubts and provided further leads for work. Vijay, a former student of Dr. Bisht's, provided timely help, with his audio recording equipment.

Friends at CSMCH, JNU have helped me deal with the nitty-gritties of writing a dissertation – on a daily basis! Thanks especially to Susrita!

Many thanks to Dinesh and Dorai of the CSMCH Documentation Unit, and to the office staff. To Sanjay Photostat, and the Library Canteen staff too.

With deep fondness and love, I thank my mum and dad and Jomo.

Contents

Abbreviations and acronyms

ARI/ ARTI	Annual Risk of Infection/ Annual Risk of Tuberculosis Infection
BCG	Bacillus Calmette Guerin
BMRC	British Medical Research Council
CDC	Centers for Disease Control
GBD	Global Burden of Disease
GoI	Government of India
ICMR	Indian Council of Medical Research
ICORCI	Institute of Communication, Operations Research And Community Involvement
INH	Isoniazid
ITC	International Tuberculosis Campaign
IUAT	International Union Against Tuberculosis
IUATLD	International Union Against Tuberculosis and Lung Disease
KNCV	Royal Netherlands Tuberculosis Association
NDTBC	New Delhi Tuberculosis Centre
NSS	National Sample Survey
NTI	National Tuberculosis Institute
NTP	National Tuberculosis Programme
PAS	Para amino salicylic acid
RNTCP	Revised National Tuberculosis Control Programme
SCC	Short Course Chemotherapy
SIDA	Swedish International Development Agency
SM	Streptomycin
TAI	Tuberculosis Association of India
TB	Tuberculosis
TCC	Tuberculosis Chemotherapy Centre
TRC	Tuberculosis Research Centre
TSRU	Tuberculosis Surveillance Research Unit
UMTS	United Mission Tuberculosis Sanatorium
UNICEF	United Nations International Children's Emergency Fund (old name). Now called United Nations Children's Fund.

USA/ US	United States of America
WB	World Bank
WHO	World Health Organization

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Introduction

The idea for this dissertation stemmed from an interest in understanding the pervasive influence of the concept of 'risk' in frameworks of modern epidemiology. Epidemiology is widely regarded as the basic science of public health. In contrast to clinical medicine, which focuses on the study of health and disease at the individual level, epidemiological tools are employed to study the determinants and distribution of patterns of health and disease in populations. Epidemiology's focus on populations has the potential to reflect *multiple levels of interconnections* between individuals and the structures and systems around them, all of which contribute to states of health and disease. As a discipline, it thus holds that wider processes and structures, and not individual level analysis, enable a holistic understanding of health and disease.

However, this interest in populations is a feature of another kind of knowledge system too – one whose disciplinary frameworks and conceptual tools are invested in knowing the population and all its characteristics, in order to discipline it towards well-being. Within what Michel Foucault has termed a *governmentality* framework, he argues that "the demographic expansion of the eighteenth century" was instrumental in the "emergence of the *problem of population*" (Foucault 2003: 240, italics added). He argues that the domain of statistics, among other domains such as economics and medicine, converged to consolidate 'population' as a *new scientific object.* Statistics shows that

> the domain of population involves a range of intrinsic, aggregate effects [...] such as epidemics, endemic levels of mortality, ascending spirals of labour and wealth; finally, it shows that, through its shifts, customs, activities, and so on, *population has specific economic effects* (Foucault 2003: 241, italics added).

This then, enabled an understanding of 'population' as a social category which needed to be administered, managed, *govern*-ed.

Within this disciplinary-administrative regime, *govern*-ment was effected via building a knowledge database and categorization and classification of various characteristics of the population, e.g., information about births, deaths, illness, migration. The development of statistical indices to represent these characteristics served as the

methodological apparatus of this administrative-governmental framing of populations. Foucault takes care to point out that "government has as its purpose not the act of government itself, but the welfare of the population, the *improvement of its condition*, the increase of its wealth, longevity, health, and so on" (Foucault 2003: 242, italics added), and it is this "intervention in the field of economy and population" (Foucault, 2003: 242), for providing well-being to more people at less cost, that is characteristic of *govern*-ment.

This, then, leads to what Foucault terms the *governmentalization of the state* – that is, a general field of apparatuses enacted by the state/ authorities "to conduct the conduct of their human charges towards certain ends" (Rabinow and Rose 2003: x). These would include, for instance, the development of the disciplines of administration and the civil service, the rise of professionals, the creation of plans, projects and practices by religious, medical, commercial, therapeutic authorities – all towards inculcating/ disseminating the arts of existence (*how to be*) among the population (Rabinow and Rose 2003). Governmentality – a combination of 'governing' and 'mentality', implying a rationality/ sensibility/ mode which renders a society *govern*-able – is thus effected by the formation of a whole series of specific governmental apparatuses, and alongside it, the development of a whole complex of knowledges (Foucault 2003: 244).

This brief gloss on the concept of governmentality shows how the discipline of epidemiology displays multiple continuities with the administrative-governmental framing of populations – epidemiology focuses on populations as the unit of study; it employs statistical indices to classify, categorize and study aggregate groups; its aim is to enable public health management of the population; this is effected through the domain of governmental policy; and finally, it is an epidemiological rationale that underlies welfare provisioning in a cost-effectiveness framework. Given these overlaps, it is pertinent to explore the various conceptual categories and precepts underlying modern epidemiology, with a view to delineate whether the concept of 'risk' builds or does not build a bridge between epidemiology/ public health/ welfare policy and a governmentality approach.

The relevance of the concept of governmentality to a wide range of studies of society can be explained by the fact that

> governmentality is not limited to administrative action but includes also knowledge and information (as in the policy-oriented social sciences, statistics, other disciplines), expertise (applied sciences), individual conduct (discipline, ethics, citizenly subjectivity) and aesthetics (narrative, taste, sensibility) necessary for government (Tharu 2008: 24).

Located within such an understanding, the exploration of the concept of risk in this dissertation traverses multiple fields such as epidemiology (dominant paradigms and precepts), statistical framing of knowledge, scientific expertise and legitimacy, and the creation of a 'responsible' self.

The main attempt of this dissertation is to understand how risk is constructed and legitimated by expert discourses, expert knowledges – those of scientists, public health officials and activists, policy makers, government as well as non-governmental agencies, and how this terminates ultimately in the call for individuals to live an 'appropriate' life, to be motivated, self-maximizing and responsible. In trying to map the way in which risk functions as an important conceptual principle in our contemporary world, I use the arena of tuberculosis policy and planning for programme management, looking at the Indian scenario in conjunction with the global one. This enables us to see the complexities that arise when risk is used as the common metric[1] of governmental programmes for protecting societal health and safety (Hornstein 1992).

A useful idea in this discussion is Foucault's concept of 'political technologies' – instruments/ apparatuses of power for shaping individuals. Among several scholars studying aspects of society within a governmentality framework, Keeley and Scoones note that the domain of policy can be seen as an instance of 'political technologies', as policy is enmeshed in the relations of power between citizens, experts and political authorities (Foucault 1991, cited in Keeley and Scoones 1999: 5) and seeks to manage and maintain social order. They also discuss Dreyfus and Rabinow, who, working ahead from Foucault, note,

> political technologies advance by taking what is essentially a political problem, *removing it from the realm of political discourse, and recasting it in the neutral language of science* (Dreyfus and Rabinow 1982: 196, cited in Keeley and Scoones 1999: 5; italics added).

[1] 'Metric' [noun] – a system of related measures that facilitates the quantification of some particular characteristic. Synonyms: system of measurement. http://www.elook.org/dictionary/metric.html. Accessed on 25 February 2009.

In this view, by mobilizing a legitimizing discourse and associated symbols of scientific authority, support is granted to 'official' policies. This power of expertise enables certain assumptions to become normalized and subsequently internalized (Shore and Wright 1997, cited in Keeley and Scoones 1999: 5).

In the four chapters that follow, mapping the construction of 'risk discourse' in the domain of TB policy and programme management shows it to be an exercise in governmentality, in the manner delineated above. The state's requirement to gather knowledge about its population, to section it into categories, and emphasize the maintenance of social order and productivity will be illustrated in the discussions on the epidemiological tools of Annual Risk of Infection (ARI) and default. The concluding chapter discusses the implications of this for larger questions of democratic citizenship.

Outline of the dissertation

The following excerpt from a central government publication titled *Tuberculosis Control in India* offers a useful entry point for discussing tuberculosis policy discourse in this dissertation. Given the emphasis of tuberculosis policy discourse on epidemiological tools, a critical review of this emphasis forms the main part of this dissertation. This critical analysis, from the first chapter onwards, begins its exploration by mapping some of the paradigms in epidemiology and associated knowledge systems and by showing their relevance to an exploration of risk discourse in tuberculosis policy.

The first chapter of this government publication, 'Epidemiology of Tuberculosis', lists statistics detailing the global burden of TB and the seriousness of the Indian situation as "India accounts for one-third of the global TB burden, with 1.8 million developing the disease each year and nearly 0.4 million dying due to TB annually" (Roy and Chauhan 2005: 1). It highlights three epidemiological approaches to the study of tuberculosis.

Figure 1: Epidemiology of Tuberculosis

The epidemiology of TB can be considered the model of web causation of disease with the agent, host and environment playing their respective parts. Traditionally, there have been three approaches to the epidemiology of tuberculosis, namely:

a. The Etiologic Approach (analytic epidemiology): mainly dealing with the risk factors associated with the agent – *M tuberculosis;*

b. The Descriptive Approach: dealing with the traditional incidence and prevalence of tubercular infection; and

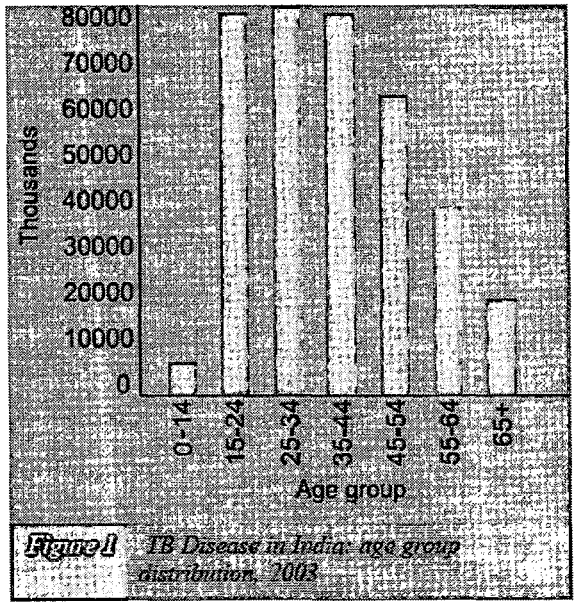


Figure 1 TB Disease in India: age group distribution, 2003

Source: RNTCP, 2003

c. The Predictive Approach: dealing with what happens next – forecasting the tubercular epidemic.

Epidemiology is essential for the successful implementation of a national tuberculosis control programme. For a basic understanding of the epidemiological basis of tuberculosis control, a model that follows the pathogenesis of tuberculosis from exposure to death is useful. The model should be simple enough to explain the dynamics of the disease but complex enough to allow the distinction between the major determinants of epidemiology of TB. Such a model is proposed in Figure 2 [4].

According to this model, four distinct steps in the pathogenesis of tuberculosis can be identified: exposure, infection, disease and death.

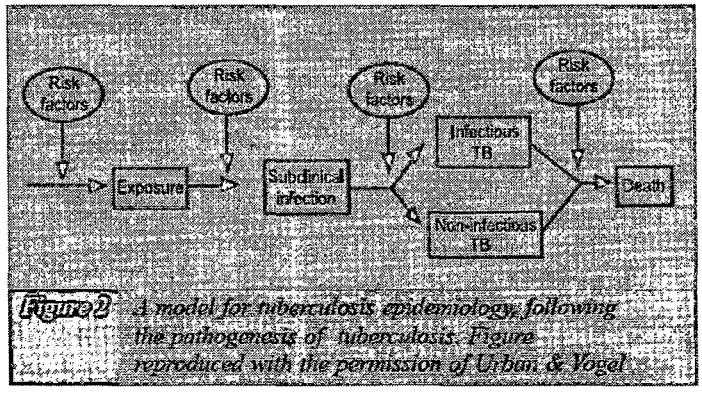


Figure 2 A model for tuberculosis epidemiology, following the pathogenesis of tuberculosis. Figure reproduced with the permission of Urban & Vogel

TB is an airborne infection. Thus exposure to an infectious case is a prerequisite to acquiring the infection. As noted earlier, an understanding of the risk factors leading to the TB infection from exposure is dealt with by *analytical or etiologic epidemiology. Descriptive epidemiology* deals with the frequency and distribution of the disease in a given community and *predictive epidemiology* with the modelling and forecasting of the epidemic, based on observations from the past. Understanding the risk factors for a given community provides the insight to develop effective tools for cure, whereas descriptive and predictive epidemiology are invaluable for an effective and efficient TB control programme.

From Agarwal, S.P. and Chauhan, L.S. (ed.) (2005) Tuberculosis Control in India Directorate General of Health Services, Ministry of Health and Family Welfare New Delhi

This book illustrates how today an analytical or etiologic approach to epidemiology means *the study of 'risk factors'*. That the pathogenesis of tuberculosis has been re-cast in terms of 'risk' factors, (which, as the figure in the excerpt warns us, exist at every stage – right from exposure till death), indicates less an understanding of the multifactorial nature of disease etiology in tuberculosis, and more the pervasive influence of risk factor epidemiology. An understanding of the multifactorial determinants of tuberculosis infection and disease would include an investigation of not just social, economic, cultural and political parameters – which are entirely absent in this book – but also other important factors such as nutritional, environmental, occupational, gender and age dimensions.

While a book such as this, located within a biomedical perspective and oriented towards tuberculosis control, might see these factors as extraneous to the *epidemiological* domain of tuberculosis, these multiple factors are in fact *indistinguishable* from tuberculosis epidemiology. The reason for this is – what emerges as the biomedical entity called 'tuberculosis infection' or 'tuberculosis disease' results from these multiple factors coming together in varying combinations and displaying varying impacts on communities and individuals. Thus, when any epidemiological study of tuberculosis is undertaken – whether it be related to studying the distribution and determinants, trends over a long period of time, or related to future predictions and modeling – *the epidemiological information that emerges is a function of the interplay between these multifactorial determinants.*

Studying multifactorial determinants of disease is not only extremely complicated, but is a managerial nightmare, especially from the point of view of policy and programme planning. 'Risk factor' terminology, drawing from the history of risk factor epidemiology, identifies aspects of disease etiology that are amenable to intervention and programme management; these are often linked to individual level factors. When the excerpt notes that studying risk factors enables the development of tools for cure, it becomes clear that *it is because of the utility of the risk factor approach for programme management* that the risk factor approach occupies such an important place in contemporary epidemiology. The discussion on the tool of 'default' (third chapter) and on the tool called 'Annual Risk of Infection' (ARI) (fourth chapter) illustrate that by constructing *compliance* as one important tool for programme management and

calculative techniques as another, the risk factor approach has cemented its place in epidemiology.

Chapters

Following the Introduction, the four chapters of this dissertation are structured as follows:

Chapter One, titled *A Biography of Risk*, begins as a literature review of the concept of risk as it is employed in social/ health policy and in epidemiological discourses. It then proceeds on a broader exploration of the way in which risk has become a *defining mentality of the modern period*, and the transformations it has effected in social life and conceptions of selfhood. It explores how the idea of risk can serve as a form of social control, creating the 'dangerous'/ 'risky' other, while at the same time urging the importance of becoming a 'prudential'/ 'responsible' self. Such practices, in effect, display elements of what Foucault has called disciplinary power. This chapter forms the conceptual framework of this dissertation, located within which I attempt a reading of how public health risks are constructed and legitimated by expert discourses – those of national and international scientists, public health officials, activists and policy makers at government as well as non-governmental levels.

Chapter Two, titled *The Tuberculosis Programme: An International 'Indigenous' Effort*, reviews some of the prominent developments in research, technology, chemotherapy and medical/ scientific thought and practice that have contributed to shifts in the management of pulmonary tuberculosis through the decades. The chapter discusses the Indian as well as the global scenario, the role of international health agencies in national level research, programme planning or management, and prominent governmental and non-governmental actors in these national-international networks. It explores the wider contexts of collaborative enterprises, and the politics behind the choice and action of certain policy, programme and collaborative initiatives.

Chapter Three, titled *Global Languages of Risk?: 'Default'*, explores the processes and contexts behind the construction of default/ non compliance as a conceptual epidemiological tool. Chapter Four, titled *Global Methodologies of Risk?: Annual Risk*

of Infection, explores the processes and contexts underlying knowledge building of a methodological epidemiological tool called Annual Risk of Infection (ARI).These two chapters analyze various levels of scientific and technical research towards legitimizing these two tools, ostensibly undertaken within a core 'rational' approach. These chapters focus mainly on the role that specific international organizations have played in constructing and promoting scientific knowledge and related policies/ programmes, and the ways in which specific policies become adopted and promoted as global policies/ practices.

I draw together the main themes emerging from the wider discussion in this dissertation in the Summary.

Methodology

This dissertation has employed the method of a literature review, pertaining to policy and public health debates related to the idea of risk, in health generally, and in tuberculosis specifically. I have used two kinds of sources – primary literature and secondary literature, and have accessed mostly printed material available in libraries of Jawaharlal Nehru University, New Delhi; National Medical Library, New Delhi, National Tuberculosis Institute, Bangalore; Centre for Public Health and Equity, Bangalore; and Community Health Cell, Bangalore.

This has included literature from the field of community health/ medicine on – epidemiology, treatment, chemotherapy, patient compliance, programme management, research studies, at global and Indian levels. I have focused special attention on reviewing literature from the Indian Journal of Tuberculosis, the NTI Newsletter and the Bulletin of the International Union Against Tuberculosis. It has also included critical commentaries on TB under the following broad themes – policy/ planning/ programme, international funding/ research, debates about welfare/ welfare state. Literature on risk from the fields of environment, health, welfare and social policy has also been explored.

A Biography of Risk

Section One – Definitions and Disciplinary Paradigms

1. 'Risk' – A concept birthed in the domains of insurance and statistics

The term 'risk' appears to have entered the English language in the seventeenth century, with various writers suggesting that it journeyed through the French, the Italian, the Greek, the Arabic, and the Latin before that. In its travel from the Arabic to the Greek in the twelfth century the term seems to have been value-neutral and indicated chance outcomes in general which could have either positive or negative outcomes, possibilities of gain or loss. In the Latin it originally had a nautical association and was used to indicate an action which gained an advantage by taking a chance (Alaszewski et al 1998).

The nautical connection stayed till the eighteenth century when risk was associated with marine insurance, the calculation of the chances of a ship returning safely to port or not and the notion of insuring against such loss. Such insurance-based calculations of risk were initially underpinned by personal knowledge and market forces. 'Prudential insurance' of this kind gradually led to the development of a probability approach to risk and formal mathematical models of risk assessment came into use. This was supported by an expansion in numerical information and the mathematical identification of frequencies and averages within the population: in effect, the birth of statistics, essential for the risk calculations used by today's insurance actuaries (Hacking 1987; Douglas 1992 cited in Kemshall 2002).

The era of actuarial or insurance risk is thus rooted in probability thinking and the rise of science and mathematics. The language of probability has contributed much to the field of risk, where, by the nineteenth century the term conveyed a strong emphasis on negative consequences, and this gradually facilitated the twentieth century framing of risk within engineering, scientific and technical discourse as a *statistically calculable hazard*. The vagaries of nature were recast as statistical probability. This is the era labeled by historian Ian Hacking as the 'taming of chance' (Hacking 1990).

During the nineteenth and twentieth centuries the probability and statistical calculations of actuarial risk were applied to many aspects of social life and public policy – the extension of commercial insurance to almost every aspect of social life is one example, and in social policy the application of a publicly funded insurance system for health and unemployment, especially in some industrialized nations of the west, is another (Rowe 1977, cited in Kemshall 2002).

The interface between risk and social/ public policy derives largely from the fact that risk research has mostly been the preserve of engineers and natural scientists concerned with technological risks and natural hazards. Specialist or technical applications intended to guard against possible negative outcomes of these hazards were eventually derived, such as risk assessment/ analysis, risk communication, risk perception, risk management or risk taking. Such research tended to adopt an 'artefact' approach to risk, framing risk as a static objective reality amenable to measurement and probabilistic calculation (Horlick-Jones 1998 cited in Kemshall 2002).

Scientific and technical disciplines such as epidemiology, engineering, operational research, management studies and the social sciences also derive many of their fundamental concepts and methodologies from this probabilistic/ statistical framing of risk. Assessing risk is one of the key elements of the discipline of public health, for instance, as epidemiologists calculate the 'relative risk' of a population developing an illness when exposed to a 'risk factor', compared with a similar population which has not suffered such exposure (Gabe 1995). Given this, it is important to understand more clearly the relationship between statistical rationality and epidemiological rationality. The following sections elaborate this relationship, in a manner pertinent to the exploration of this dissertation as laid out in the Introduction.

2. Quantitative reasoning and statistics – an inherent aspect of early epidemiologic thought

Epidemiology is widely considered to be the basic science of public health, "because it is the health science which describes health and disease in populations rather than individuals, information essential to the formulation of effective public health

initiatives, to prevent disease and promote health in communities" (Detels 1994: 122, cited in Smith, 1996: 1). Given that early nineteenth century ideas about disease causation were informed by the miasma theory, and there was little evidence supporting or negating this disease etiology, Smith notes that this was the context in which the *systematic epidemiological study* was first developed. This was the earliest attempt to identify the causes of infectious disease which were the primary public health problems of the time.

As to what led to the emergence of the epidemiological study at this point in time, Smith notes that even though it is not all very clear, the desire for knowledge about disease causality could not be, by itself, an adequate explanation. He argues that much more important was the emergence of the precepts of epidemiological reasoning.

> The systematic epidemiological study could not have emerged in the first few decades of the nineteenth century unless the early investigators were aware of and accepted, two essential precepts; that environmental factors have an important influence on the occurrence of disease (Dubos 1970, cited in Smith 1996: 1) and that statistical reasoning can contribute greatly to our understanding of disease through population level analysis (Cole 1994, cited in Smith 1996: 1-2).

In a series of articles documenting the emergence, development and pioneers of the science of epidemiology during the mid-1800s, Lilienfeld and Lilienfeld emphasize that

> the use of quantitative reasoning and statistics is an inherent aspect of epidemiologic thought. The progress of epidemiology has been closely allied to the development and availability of statistical data and quantitative reasoning (Lilienfeld and Lilienfeld 1977: 174).

They point out that an understanding of the "general growth of statistical-biometrical ideas" starting from the 1800s is vital for comprehending later developments in epidemiology (Lilienfeld 1978: 504). Hacking's extensive work on the history of statistics has shown that the calculus of probabilities was being developed during the first decade of the 1800s; he records the work of French mathematician Pierre Simon de Laplace on the theory of probabilities and that Laplace stated that the statistical analysis could be applied to results in medicine (Hacking, 1975 cited in Lilienfeld and Lilienfeld 1977).

Lilienfeld and Lilienfeld point out that many of these early scholars[1] who went on to become important public health personalities, were members or founders of various

kinds of institutions and associations devoted to statistical studies.[2] Founding members of the Statistical Society for London, for instance, included personalities who would go on to leave an indelible mark in several fields of the human sciences and societal development – Charles Babbage, inventor of the first mechanical calculating machine, which opened the pathway to modern-day computers; Edwin Chadwick, sanitary reformer; J.R. McCulloch, author of *Statistical Account of the British Empire*; M. Adolphe Quetelet, Belgian statistician; and T.R. Malthus, demographer (Lilienfeld 1978).[3] It is thus clear that statistical reasoning began to occupy a central place in studying society, and this period saw several scholars engaged in efforts and debates towards establishing the scientific credentials of statistical reasoning for understanding the nature of disease through population level analysis.

Among the early pioneers who conceived and applied a 'numerical method' to develop new insights into disease etiology through the population perspective was French physician, Pierre-Charles Alexandre Louis, who "was not the first to use statistics; rather, he was the first to make them the basis of medicine" (Lilienfeld 1978: 507).[4] He is known to have conducted early statistical studies of tuberculosis (Lilienfeld and Lilienfeld 1977). Another important personality was Adolphe Quetelet, a Belgian meteorologist, mathematician and philosopher. Quetelet had studied in Paris and corresponded with many of the French researchers, including the hygienist Louis-Rene Villerme and the inventor of judicial statistics A. M. Guerry (Cole 1994). Noting that Quetelet's conceptualization of the 'average man' is based on a combination of probability theory and the measurement of the characteristics of populations, Smith suggests that his work signaled the great potential of statistics for understanding the social context.

In the mid-1800s in England, scholars like William Augustus Guy and William Farr, both students of Louis, built on the basic aggregate level analysis of earlier pioneers by using the new range of numerical methods to study disease phenomenon at the population level. Their influence was due, in no small measure, to the important academic positions they held, in addition to their membership of the Statistical Society of London. Farr, for instance, did much to lay the foundations of the discipline of biostatistics, emphasizing the need for classification and nomenclature of diseases.

Continuing from Guy's pioneering work in modern biostatistics, Farr's efforts led to shifting the Statistical Society of London's "orientation from matters of political arithmetic to those of medical and vital statistics" (Lilienfeld 1978: 516). Other noted pioneers include Louis-Rene Villerme, John Snow and John Simon, each with different approaches to the study of disease as linked to the social environment. Early architects of the epidemiological method, Susser notes that these scholars "not only enumerated and quantified their data but also studied communities and populations especially selected to illuminate such areas as the effects of drainage, housing, occupation, and nutrition" (Susser 1985: 148).

That the head of the London Epidemiological Society, B.G. Babington, acknowledged in 1950 the debt that epidemiology owed to statistics by noting that

> Statistics [has] supplied us with a new and powerful means of testing medical truth, and we learn from the labours of the accurate Louis how appropriately they may be brought to bear upon the subject of epidemic diseases (Babington 1850, cited in Lilienfeld and Lilienfeld 1977: 176-177).

is testimony to the fact that the value of the numerical method to etiologic research, and the close relationship between vital statistics and biostatistics were well recognized by this time (Susser 1985: 172, cited in Smith 1996). Indeed, it is also argued that it was only "during the late 1840s [that] epidemiology had begun to emerge as a separate discipline, distinct from biostatistics" (Lilienfeld 1978: 516-517).

Reading this literature, Smith argues,

> the main reason that systematic epidemiologic studies did not emerge till the early nineteenth century is that it was only then that the two fundamental precepts of epidemiologic reasoning, a recognition of the influence of the environment and the utility of a population level of analysis, were both in place (Smith 1996: 5-6).

We also see that till about the 1840s the public health science of 'epidemiology' was essentially 'statistical methodology', and was indistinguishable from biostatistics. However, looking beyond this neat description of the development of epidemiology and biostatistics, there is other literature which suggests that the application of the precepts of statistical reasoning and aggregate analysis in medicine generated several debates and went through several epistemological shifts (Cole 1994).

Labeling histories of the field of statistics which concentrate primarily on technical developments and methodological or conceptual breakthroughs as a purely utilitarian recounting, Cole notes that such a narrative of quantitative knowledge

> makes no attempt to understand *how* the knowledge of the 'population expert' *achieved its legitimacy*. The institutionalization of this knowledge disrupted and transformed pre-existing social relations, challenged established conceptions of the state's responsibility to protect the public welfare, and *brought newly emergent corporate groups, such as public functionaries and doctors, to levels of power and prominence that they had never before possessed* (Cole 1994: 2, italics added).

In an article examining "how statistics were *staged* by their proponents, how they were *presented and represented as figures for a new knowledge of society*" (Cole 1994: 4, italics added) Cole notes that "in the 19th century, statisticians were phenomenally successful in *minimizing the problem of representing society*, by *reducing it* to a series of more or less verifiable technical procedures" (Cole 1994: 3, italics added). He points out that the utility and success of social statistics at this time "was based on their ability to render the complexity of the social world in a *neat and orderly fashion*, easily grasped by the educated reader" (Cole 1994: 3, italics added).

Cole points to rigid deterministic positions in the work of early theorists of probability who laid the mathematical foundation for statistical reasoning, for instance, Laplace, and argues that it was not until the emergence of Quetelet's idea of *aggregate statistics* that some of this determinism loosened. Not completely doing away with the deterministic paradigm, however, for Quetelet, an understanding of universal laws could be had only through studying the "agglomeration of individuals into collective bodies" (Cole 1994: 9). This system of calculation would average out 'accidental' differences and individual particularities. Hacking points out that the beginnings of the erosion of determinism was not envisioned as making room for disorder and chaos, however; it was rather the attempt to *tame* chance, to transform contingency into meaning, to bring "apparently chance or irregular events... under the control of natural or social law" (Hacking 1990: 10).

Pertinent for the discussion, however, is Cole's observation that Quetelet saw his formulations fit to go even further – just as a population's physical attributes could be worked out, so too "a population's intellectual and moral capacity could be calculated,"

and Quetelet intended that "the average be used as a normative standard for the measurement of progress." Cole effectively shows us how, through Quetelet's work,

> [t]he 'average', at first a methodological expedient for eliminating the confusion of accidental influence, *thus became incorporated into a political ideal*, where the source of society's ills and the obstacles to its progress were located in the existence of social and physical differences among individuals (Cole 1994: 11)

While it is true that by jettisoning the "reliance upon an absolute determinism [... and by] insisting that 'man' could be understood only as a collective body and not in the uniqueness of particular examples, Quetelet transformed the abstract individual of liberal political theory into a 'social' being," (Cole 1994: 11) it is also important to note that his epistemological insight "had a profound message for politics." Quetelet's work called upon the government to "focus its attention on the influences which acted upon the collective, *to act upon the 'milieu' as opposed to the individual*" (Cole 1994: 11). Drawing from Francois Ewald's work on Quetelet, however, we can see that at a time when taking action upon social causalities was the task of politics, studies of society were in fact a conversion of a *governmental rationality*. Elaborating Ewald's views Cole notes,

> Quetelet *tied the fortunes of his science to his vision of government*; both were concerned with the elaboration of a science of social causality, the former in the pursuit of enlightenment, the latter *in the interest of 'social' improvement* (Ewald 1986, cited in Cole 1994: 11).

That Quetelet could link his biostatistical view of epidemiology with his vision of government, and that for him government signified social improvement, enables us to see that societal studies of health and disease during the early epidemiological era were located within a governmentality framework, as hinted at in the Introduction. Within such a framework, all methodologies, knowledge systems, realms of activity effected by the state are undertaken to know/ document, to administer/ steer, to govern/ order its population – its health, wealth and happiness – towards 'improvement'. Foucault stresses that government in this sense "will have to ensure that the greatest quantity of wealth is produced, that the people are provided with sufficient means of subsistence, that the population is enabled to multiply, and so on" (Foucault 2003: 237).

Given that governmentality is not about the state enacting hierarchical coercive power on populations through the force of law, but is about social control enacted through a

multitude of organized practices (mentalities, rationalities, and techniques) through which subjects are governed, this discussion has shown how science and *govern*-ment were conjoined in the techniques of biostatistics and epidemiology. The following discussion will show how epidemiology's 'return to a multifactorial approach' – mediated through risk factor epidemiology – served as a pathway to a highly individualized, behavioural, paradigm of epidemiology, which in turn generated its own governmental/ disciplinary apparatuses.

3. Risk factors – epidemiology re-inscribes a multifactorial approach?

The discovery of the germ theory of disease in the 1870s created a major paradigm shift in knowledge systems and in the relationship between the population and scientific professionals/ experts. Smith notes that the germ theory of medicine, emphasizing the role of singular biologic agents – micro-organisms – in disease causation,

> promoted an approach to disease etiology which clearly prepared the ground for the later emergence of risk factor epidemiology. In this biologic approach to disease etiology the population based inferences of the pioneers of epidemiology were in effect displaced by a new set of laboratory based causal criteria, which we now know as the Henle-Koch postulates (Susser 1985, cited in Smith 1996: 14).

By the early decades of the 1900s, however, it started becoming clear that the single cause approach greatly oversimplified the complex realities of disease etiology, and this led to the return of a multifactorial approach to study disease by the mid-1900s.

Smith notes,

> [i]n retrospect there appear to have been three important triggers for the emergence of a new multifactorial approach within epidemiology (Susser 1985, cited in Smith 1996). First, the work by Ross and Frost during the 1930s to re-establish the role of multiple factors in the transmission of communicable diseases. Second, the emergence of a Social Medicine movement which was dissatisfied with the narrow approach of clinical medicine. Third, the recognition of the epidemiologic transition in developed countries. Of these, the epidemiological transition was perhaps the most significant because, at a time when secondary prevention was the only line of defence, chronic disease suddenly became the focus of attention (Smith 1996: 15)

This is an extremely important insight, and it shows that return of epidemiology to a multifactorial perspective occurred in the context of the new crisis faced by industrialized countries who had almost won their battles with infectious diseases, only to now be faced with the crisis of a rise in chronic diseases.

That the multifactorial perspective which emerged in this context in no way reflected the precepts of the early nineteenth century epidemiological paradigm, is explained by Smith's view that during the early decades of the 1900s there was a great anxiety among epidemiologists to prove the relevance of epidemiology to clinical peers and to the *clinical* profession. The two major epidemiological studies in the mid-1950s that carved out a respectable role for epidemiology were mediated by this context.[5] Even though these studies are said to have "provided the intellectual paradigm shift lever from an intrinsic to an environmental causal model in the discipline of epidemiology" (Susser 1985: 163, cited in Smith 1996: 18), Smith argues that *this new environmental causal model cannot really be viewed as a radical departure from the clinical model.* The new multifactorial approach still put a great deal of emphasis on "single etiologic agents and the quantification of their independent effects" (Loomis and Wing 1990: 2, cited in Smith 1996: 18), and did not take into account the broader determinants of health of the kind highlighted by the early pioneers of epidemiology.

Smith's lament that the return to a multifactorial approach to disease etiology in the mid-1900s did not reflect the precepts of the early nineteenth century epidemiological paradigm, is a sign of the abiding belief in the 'golden age' of early epidemiology. However, we have noted thus far that the close alignment of the early processes of epidemiology, statistics and biostatistics, in moving towards social improvement, functioned as apparatuses of a governmental rationality which works to render a population *governable*. In light of this, valourizing grand narratives which state that early epidemiology, in its observation of multifactorial population-level determinants of disease, put in place a singularly progressive practice of public health, are necessarily thrown into doubt. A closer look at the two major epidemiological studies of the 1950s will similarly show up several inconsistencies in the claim that these studies re-instated the importance of multifactorial, environmental analyses for exploring disease etiology, and upheld a progressive public health perspective.

In 1948, a state-sponsored longitudinal study of 'factors influencing the development of vascular disease' was started in the town of Framingham, Massachusetts, USA.[6] Smith points out that even though the Framingham study originally aimed to study all factors influencing the development of cardio-vascular disease by setting out a multicausal

environmental pathway, "this broad approach was soon changed to one which emphasized the much more limited goal of establishing the individual risks attached to particular behaviours" (Smith 1996: 18). By focusing primarily on individual risks, Smith holds the study guilty of choosing a highly selective definition of risk; he argues that this definition easily lent itself to the behavioural perspective on risk which went on to become the distinguishing feature of risk factor epidemiology. There is no dissent in the literature, however, on the fact that methodologically, the Framingham study was a key moment in the history of epidemiology as it firmly established the significance of the concept of risk factor (Rothstein 2003, cited in Moreira 2007).[7]

Literature exploring the conceptual and methodological precepts underlying the Framingham study suggests that the study was inventive on several counts. Pointing out that almost all the inhabitants of the town were of European ancestry, Moreira notes, "the Framingham study, like other studies on cardiovascular disease conducted around the same time, *drew on study designs used by life insurance companies*" (Moreira 2007). In several of these studies, the procedure was – medically examine a sample of persons and follow them up for a number of years; this would help determine personal characteristics associated with higher rates of disease. "*Upon this basis, the Framingham investigators were able to develop new techniques of cohort tracking, population selection and sampling that partly account for the success of the study*" (Moreira 2007).

Moreira also notes that one of the original investigators stated (Rothstein 2003, cited in Moreira 2007) that another important element borrowed from insurance companies,

> was *the concept of risk factor itself.* For insurance companies, risk factors were important decision making tools because they modelled the link between clients' contribution and likelihood of events. *They were most importantly a technique of regulating and reducing to a calculable figure the economic and financial risks taken by the company itself.* For these purposes, risk factors were most useful as gradients or continuous variables as these matched with monetary units of measurement (Moreira 2007).

The Framingham investigators, however, chose not to use such gradients and attempted to determine a risk threshold for healthy and non-healthy individuals.

Exploring the reason behind the choice of a risk threshold and not a gradient, Moreira examines a scientific debate on blood pressure that was occurring in the British medical community at the same time as the Framingham study. The controversy was about "whether blood pressure constituted a continuous variable or a graded one in which hypertension could be distinctly identified as a qualitative difference", with Roger Platt and George Pickering the main protagonists (Swales 1985, cited in Moreira 2007). This debate was extremely relevant for the investigators in the Framingham Study because

> the *different viewpoints embodied divergent forms of organizing public health systems.* Whereas a continuous variable would entail progressive, almost individualized forms of intervention, a graded, preferably dichotomous variable would identify a discrete population onto which attention should be focused. *In the decision to dichotomize blood pressure as a variable, Framingham adhered to an ideal of 'hypertension' as a discrete nosological entity mainly for political reasons, given that the debate cannot be said to be closed to this day* (Moreira 2007).

Analyzing the 'scientific' rationale behind the Framingham study, Moreira notes that even the investigators of the study saw it as "more than just 'a scientific study'" (Rothstein 2003, cited in Moreira 2007). That the main intention of the study was

> to establish the risk factor as a currency in public health and clinical practice [is] supported by the exclusion, as compared to the original study design, of any social or cultural factors that could be associated with disease, which reinforced an impression of homogeneity concerning the mostly white population under scrutiny. The persuasive strength of their results relied on the almost 'laboratorial' conditions that the choice of site and the methodological techniques delivered (Moreira 2007).

In spite of other writers echoing the view that the Framingham study moved away from its original study design, there is an overall consensus on the fact that the Framingham Study established a model for longitudinal studies beyond its own influence. This study set in motion a vast array of new studies on chronic diseases which sought to determine risk factors linked to such diseases, most of them being individual risk factors (Douglas 1992; Marmot 1993, cited in Smith 1996). Skolbekken's study of the increasing trend of articles on 'risk' in leading medical journals is a useful review. Analyzing this trend in several generalist as well as specialized journals from the Medline database over the period 1967-1991, Skolbekken found that the most rapid increase was found in epidemiological journals, and that in many of these journals epidemiology was increasingly viewed simply as the main tool for the identification and estimation of risks (Skolbekken 1995).

Even though the lineage of today's risk factor epidemiology can be traced more directly to the Framingham study than the Doll and Hill study, Smith notes that the latter study also had several shortcomings. The Doll and Hill study was the first major case-control study on lung cancer, undertaken in England in the early 1950s (Doll and Hill 1956, cited in Smith 1996). Smith writes that this was "a fairly narrow study because it is based very much on a simple clinical hypothesis derived from clinical observation. The basic hypothesis was that smoking caused lung cancer; however, the nature of the study meant that *the environment was always likely to become reduced to a single risk factor, smoking tobacco products*" (Smith 1996: 18).

The emergence of risk factor epidemiology in the 1950s was thus the moment when the 'multifactorial approach' of epidemiology marked its comeback. However, the discussion so far has shown that wider social, cultural, economic factors were rarely investigated as determinants of health/ disease in the studies that inaugurated this era, and investigation of single risk factors, especially at the behavioural/ individual level, continued to hold sway. The fact that the notion of risk used in risk factor epidemiology emerged from within an actuarial/ insurance framework, that it was tied in with cost-benefit analyses, indicates that any methodological or conceptual fine-tuning of the precepts of the Framingham study was done keeping in mind the practicalities of public health provisioning (easier to cater to a discrete sub-population 'at risk', rather than the entire population).

The idea that risk was about medical probability, and it could be estimated by an epidemiologic study of the frequency of occurrence of an event in a particular population, thus owes a debt to the long and intertwined history of the governmental (managerial and cost-effective) imperatives of statistics and epidemiology. In contemporary society, the concept of risk appears to have become a central articulating principle of not just health discourse, but also many different aspects of general life. Sections two and three of this chapter will discuss this issue further.

4. Study of risk within different disciplinary frameworks

Social theories of risk emphasize the context within which decisions are made and locate individual risk decision-making within the social realm (Kemshall 2002). Social

analyses of risk, as they relate to health, can be divided into micro-level and macro-level studies. Micro-level studies are concerned with the meanings of risk and take an interpretive approach, focusing mostly on perceptions of risk and risk behaviour as well as on the relationship between expert and lay knowledge of risk. Macro-level work involves studying the role of social institutions and structures in the framing and legitimizing of risk – exploring the mass media's role on risk perception, would be a classic example (Gabe 1995).

In the arena of research that is psychological risk analysis, early work in the 1960s-70s adopted a behaviourist approach; during the 1970-80s this was replaced by cognitive psychology as the dominant research paradigm on risk perception; followed by social psychological approaches (Gabe 1995). The psychometric tradition has used the disciplines of cognitive psychology and decision theory to investigate *individual* risk decisions, choices and perceptions of risk, and why lay publics fail to act upon expert advice (Fischhoff et al 1982). Such a paradigm poses the risk assessor as "*Homo prudens*, epitomized by 'prudence, rationality and responsibility'" (Adams 1995: 16, cited in Kemshall 2002: 11), and the focus is upon *why expert risk information is disregarded, resulting in 'irrational' decision-making.*

The aim of such research is essentially corrective – focusing on *poor risk choices* such as drug taking, drink driving, alcohol abuse – and is undertaken in an effort to inform individual risk decisions and to improve the efficacy of public risk campaigns. Kemshall notes that Paul Slovic's work exemplifies this 'corrective' paradigm,[8] and that attention to the 'social' in these discussions is merely in passing. In this paradigm, subjective processes are seen as important, but the objective reality of risk is taken as the norm. These models have been critiqued primarily for treating individuals as independent, free agents in terms of their responses to risk, ignoring more complex social, cultural and institutional contexts which constrain choice (Denscombe 1993, cited in Gabe 1995).

Contrary to psychometric studies of risk as an objective phenomenon to be scientifically measured and explained, cultural theories of risk explored by anthropologists and sociologists state that risk is always a social product/ construct (Thompson and Wildavsky 1982, cited in Kemshall 2002). Mary Douglas's extensive

and influential work in this field has led to the understanding that risk attributes and types of differing risk can be identified "as a result of [people's] particular form of social organization and the nature of their interaction in the wider political culture" (Douglas and Wildavsky 1982, cited in Gabe 1995: 6).

In investigating the relationship between values, beliefs and risk perception, one of the key theoretical contributions of cultural theory has been the examination of *how risks are selected for concern and how these risks are legitimated for public attention* (Kemshall 2002). In essence, the argument is that risks are chosen for their usefulness to the social system and its order (Douglas 1992, cited in Kemshall 2002).

Social constructivism has similar concerns to cultural theory, and emphasizes that a multiplicity of meanings and perceptions on risk can exist. Research focuses on the context of risk decisions, and the knowledge and social processes that contribute to the formulation of risk concerns, their perception and their legitimacy. Disputes over risk levels or differences over the acceptability for risks (e.g. nuclear power or environmental risks) are understood as disputes of value and meaning, or as conflicts between differing *discourses* of risk.[9] It would be useful to record here Slovic's acknowledgement that risk could be seen as discourse,

> Whereas psychometric research implies that risk debates are not merely about risk statistics, some sociological and anthropological research implies that some of these debates *may not even be about risk*. Risk concerns may provide a rationale for actions taken on other grounds or they may be a surrogate for other social or ideological concerns. When this is the case, communication about risk is simply irrelevant to the discussion. Hidden agendas need to be brought to the surface for discussion (Slovic 1987: 285; italics added).

Drawing from this discussion, this dissertation investigates some of the processes underlying the formulation of risk concerns and their construction of legitimacy, with regard to certain epidemiological tools for tuberculosis programme management. As noted in Slovic's acknowledgement that risk could be regarded as discourse, 'hidden agendas need to be brought to the surface for discussion'.

Section Two – Risk as a Defining Mentality of the Modern Period

The fatalistic approach to risk pre-Renaissance outlined by was one example of a risk discourse (Green 1997, cited in Kemshall 2002). Hacking notes that the 'taming of chance' and the discourse of risk as 'probability' superseded this approach (Hacking 1987, 1990). Rationality and objective, scientific knowledge are endemic to modern thinking (Douglas 1992, cited in Kemshall 2002); and within this framing of risk the social as well as the natural world 'may be measured, calculated and therefore predicted' (Lupton 1999: 6, cited in Kemshall 2002: 4). Some writers have argued that late modernity, or postmodernity, has challenged this 'myth of calculability' (Reddy 1996, cited in Kemshall 2002).

A deeper investigation into risk as a concept of social-political-ideological bearing will show how risk has become a defining mentality of the modern period (Carter 1995). There are various perspectives from which this issue has been discussed in the literature

1. Beck and Giddens – 'risk society' and 'manufactured uncertainty'

Risk, modernity and uncertainty

Scholars such as Ulrich Beck and Anthony Giddens, important figures in studies of risk and society, have argued that postmodernity is largely characterized by indeterminate and contingent knowledge about the probability of risks, and uncertainty over future outcomes and impacts (Beck 1992a, 1992b, 1998; Giddens 1990, 1998a, 1998b).

Modernization-induced risks – manufactured uncertainty

Giddens notes these risks as the very products of advances in modernity, science and technology – internally produced risks (Giddens 1998a, 1999, cited in Kemshall 2002). Beck terms this a 'risk society', wherein the conditions of late modernity are producing risks as well as benefits, and often hazards and insecurities are induced and introduced *by modernization itself* (Beck 1992a: 21, cited in Kemshall 2002: 5-6). Giddens has termed this situation *manufactured uncertainty* (Giddens 1991, cited in Higgs 1998).

Risk leading to individualization, vulnerability, dislocation

Beck notes that the processes of industrialization have brought on ecological as well as social/ cultural disasters (Higgs 1998), and that modernization and the associated process of industrialism have given rise to intense individualization, resulting in the

dissolution of traditional norms, social bonds and securities (Beck 1992a, b; Giddens 1998a, b, cited in Kemshall 2002). This leaves the individual increasingly exposed to risk. Beck terms this 'risk society', where major levels of dislocation experienced by people (caused by socio-economic-technological advances and their associated hazards) have led to a growing sense of vulnerability, and for which there is no satisfactory care/protection.

Assessing evidence on risk; expert systems of knowledge

In order to deal with increasing exposure to risk, individuals must resort to calculative practices, make the 'right' type of choices, must self-monitor or be self-reflexive, and take a more "active and risk-infused orientation to their relationships and involvements" (Giddens 1998a: 28, cited in Kemshall 2002: 5). In such scenarios knowledge in modern society is intricately wound up in risk discourses – measurements and assessments of risk, insurance/ safety mechanisms against risk, and suchlike.

In such a scenario, however, there also arises "the problem of the interpretation of evidence of risk", which gives opportunities for many different groups to pronounce 'expert' opinions on risk (Higgs 1998). Beck's conception on risk society focuses special attention on the growth of technologies for identifying risk. From this perspective, risk is viewed as a technical matter relying on the *development and quantification of accurate scientific information* (Gabe 1995). This approach assumes that all risks are discoverable, measurable and, with the right expertise, controllable.

Risk and the re-configuration of welfare

Giddens notes that the inability to rely on expert systems (and this echoes Beck's point that these systems can themselves create risk) forces a re-conceptualization of the organization and conceptualization of social welfare. An implication of the uncertainty that characterizes risk society is that the available tools and solutions of social welfare and social policy fall short of the reality of emerging problems in risk society. This leads Giddens to argue that such a scenario leads to the concept of 'positive welfare' or the 'third way' – meaning that individuals should become active risk-takers, and actively negotiate with events on their own without looking for state support.

Giddens argues that the process by which people take responsibility for their own individual health and well-being creates 'self-respect'; such a self he labels the "autotelic self" (Higgs 1998).

> The autotelic self does not seek to neutralize risk or to suppose that 'someone else will take care of the problem'; risk is confronted as the active challenge which generates self-actualization. (Giddens 1994: 192, cited in Higgs 1998: 178)

As evidenced above, there are several commonalities in the perspectives of Giddens and Beck with regard to risk and modern society, and Higgs suggests that both are ultimately "positive about the benefits that can accrue to the individual as a result of accepting the challenges offered by risk" (Higgs 1998: 179).

2. The governmentality framework and self-surveillance

Exploring risk in this dissertation, I mark distance from the views of Beck and Giddens, joined in the view that modernization, technology and industrialization have broken traditional certainties and bonds, leading to risk. Such a perspective is congruent with the classic, and simplistic, Illichian view of bucolic/ natural security, the stripping away of which puts individuals and society at risk. Mainly, however, I take distance from their view that the way to deal with the dislocations and contingencies of contemporary postmodern society is to become an *active risk taker*, acting independently and responsibly to ensure one's own well-being.

Instead, drawing on the Foucauldian perspective elaborated earlier, I argue that the very construction of such a self-actualizing, motivated, risk-taking self epitomizes a governmentality framework – which deploys multiple 'technologies of the self' in order to effect the 'conduct of conduct'. This relates to the construction of an 'appropriate way of being', such that the larger social order is maintained and enabled to function smoothly.

Reviewing literature on risk in health discourse and policy, Moreira records the work of some scholars who suggest that this is "correlated with key transformations in the social and political order of contemporary societies" (Moreira 2007). Peter Conrad's work on medicalization (a process by which, increasingly, medical interpretations and solutions are offered for problems that were previously deemed to belong to the realm

of the social), for example, shows that the practices and policies that are associated with health correspond to a new form of social control (1992). The main consequence of this is that behaviours formerly seen as individual choices, such as smoking or drinking, "are invested with a *moral significance* because they demonstrate a *lack of care for the self, significant others and, increasingly, the community as a whole*" (Conrad 1992, cited in Moreira 2007; italics added).

Health risk management practices address future uncertainties through action based on calculations of the probability of developing disease. Armstrong's conceptualization of "surveillance medicine" is a concept tuned into precisely this aspect of health management; the concept entails a *problematization of the "normal"* in the expectation that it contains the *potential* ingredients for the *development of the pathological* (Armstrong 1995, cited in Moreira 2007). Individuals are expected to organize their present conduct with an eye on the possibility of future events; self-surveillance thus becomes a key mechanism in the production and maintenance of "health".

Moreira notes that drawing on Foucault's concept of governmentality (Foucault 1986), several sociological studies of risk in biomedicine have suggested that the emergence of the "risky self" is associated with neo-liberal modes of governance. These studies have pointed out that

> the intensification of epidemiological surveillance, screening and routine measurement of health indicators is intimately linked with a shift in the responsibility of care from professionals to collaborations across expertise lines and an emphasis on individual monitoring of lifestyle choices. (Moreira 2007)

Underlying the promotion of individual level choices is an assumptive conceptualization of "individuals as natural calculative subjects" (Moreira 2007).

Given that governmentality processes are reliant on "technologies of governance" (May et al 2005; Rose & Miller 1992; cited in Moreira 2007) that structure individuals' fields of action and operationalize governance systems, Moreira notes that Miller has recently called attention to how "calculative practices alter the capacities of agents, organizing the connections among them" and how they "enable new ways of acting upon and influencing the actions of individuals" (Miller 2001: 379, cited in Moreira 2007).

Miller's work draws deeply from Foucault's conceptualization of disciplinary power, which is distinguished from coercive/ authoritative power. The latter is an open direct form of control, oppression and violence, whereas the former is non-coercive, non-threatening and operates by "persuading its subjects that certain ways of behaving and thinking are appropriate for them" (Lupton 1997: 99). Elements of learning how to become this 'responsible', 'appropriately-behaving' self are constantly imparted to us in schools, workplaces, families, prisons, medical institutions – these sites of socialization symbolize some of the most potent locations of disciplinary power according to Foucault. The following section will discuss this further.

3. Risk, the prudential self, the calculable self

In the reframing of welfare provision as, noted above, the key issue is of value for money and efficiency – defined as a measure of whether society obtained the greatest success in achieving the objectives of welfare programmes (effectiveness) at the least possible cost (economy). This latter involves utilitarian judgements and cost-benefit analyses, measured in terms of price and outcome, not necessarily social justice or moral purpose. Such commoditization has resulted in a greater preoccupation with unit cost, targeting the most appropriate service at those *most in need*, and the reframing of need from social causes and collective responsibility to individual failings and individual responsibility (Kemshall 2002).

The notion of sifting through the 'deserving' and 'undeserving' poor is not new, nor is the concept of targeting; these have existed right from the time of the Poor Laws Commission of the 1830s. The concept of the 'deserving poor' during the Victorian age stressed *prudential behaviour* (Kemshall 2002). In the modern age, prudentialism has acquired a new edge – as Nikolas Rose puts it, prudentialism is the "construction of active citizenship in an active society" (1996: 60, cited in Kemshall 2002: 31). It requires the citizen to adopt a calculating attitude towards all her decisions, whether they be the traditional risks of the welfare state, or healthy lifestyle choices. Thus *the individual becomes the primary site of risk management*, not society, and *the 'good' citizen is the responsible prudential one.*

For Rose, following from Foucault, the hallmark of advanced liberal societies is that the technique of government is through the promotion of individual responsibility. He notes,

> Those 'excluded' from the benefits of a life of choice and self-fulfilling aspirations have been deformed by the dependency culture, whose efforts at self-advancement have been frustrated for so long that they suffer from 'learned helplessness', whose self-esteem has been destroyed... they are to be assisted... through their engagement in a whole array of programmes for their *ethical reconstruction as active citizens* – training to equip them with skills of self-promotion, counseling to restore their self-worth and self-esteem, programmes of empowerment to enable them to assume their rightful place as the *self actualizing and demanding subjects of an 'advanced' liberal democracy* (Rose 1996: 60, italics added).

In the Indian tuberculosis programme (right from the phase of the National Tuberculosis Programme (NTP) of the 1960s, and even more strongly during the Revised NTP phase and the DOTS strategy of the 1990s), this is exemplified by the persistent dilemma of *how to respond to those patients who fail to become 'self-actualizing'*. This dilemma is fundamental to the issue of default, and is a key factor in the evolution of techniques to 'motivate' patients to be compliant with drug regimens.

Petersen argues that health policy of the 'new public health' is characterized by reference to the citizen as a rational agent, the 'entrepreneurial' individual able to make informed, reflexive choices about his or her care, and consequently to self-regulate. In this context, health promotion can be seen as a mechanism for re-educating *irrational* citizens. This shift serves "the objective of privatizing health by distributing responsibility for managing risk throughout the social body while at the same time creating new possibilities for intervention in private lives" (Petersen 1997: 194, cited in Kemshall 2002: 45).

Foucault's theory of power, and his outlining of the relationship between the self and discipline, helps us in analyzing various facets of the modern state and its social policy. Expert knowledge, particularly within the social sciences, has played an important role in the controlling mechanisms of health and welfare. Lupton notes that such a system of governmentality (regulating conduct) is heavily dependent upon systems of expert knowledge which constitute and define the objects of their knowledge – the authority of the state is thus mediated through such welfare agencies, which set standards for

acceptable conduct and monitor compliance with societal norms. The surveillance net extends beyond the more obvious parameter of the police and the law (Foucault 1977).

Such a reading complicates the understanding of 'free will' – the hallmark of the liberal humanist paradigm – and how that is employed to make rational informed personal choices. 'Free will' can then be understood as a phenomenon that is shaped and constituted by particular discourses and knowledge forms, and not as something simply (or uncomplicatedly) dominated by the state. Following Foucault's work, one can argue that the rise of health promotion itself can be seen as the development of a surveillance net – the displacement of health risk management from the state to the individual and from illness response to prevention, along with an increased regulation of lifestyle regulation and management.

Bunton (1997, cited in Kemshall 2002) argues that key to the promotion of self-regulation is the power of risk both to individualize and to aggregate (there are *risky individuals* as well as *risky populations*). Group risks have the power to exclude, to marginalize. In health care, the idea of individual risk is epitomized by the emphasis upon citizens who are 'active and enterprising' in the maintenance of their own bodies and their own health (Bunton 1997: 241, cited in Kemshall 2002); the reward includes not only health benefits, but also moral worth and virtue as an enterprising citizen. This is central to the construction of a certain self as 'appropriate', 'normal', and not 'at-risk' – typified in respect of AIDS, or TB. This pursuit of 'normal' health often legitimizes the extension of regulatory practices, via health promotion mechanisms, to the entire population. This acts as a tool of social governance, as it labels certain individuals as 'dangerous' to the larger social body.

4. Risk factor epidemiology and the pre-eminence of 'individualism' in risk discourse

Winding up this discussion on risk as a defining mentality of the modern period, we briefly touch upon the field of risk factor epidemiology. The focus on the individual, a central feature of this paradigm of epidemiology, enables continuities with several of the conceptual precepts of a governmental framework discussed previously.

Noting that the fundamental weakness of risk factor epidemiology is that it is based on a "very narrow definition of risk which emphasizes only one aspect of risk, individual risk, [and therefore] tightly circumscribes the locus of the problem to risk factors which relate directly to individual behaviour" (McKinlay 1974, cited in Smith 1996: 20-21), Smith provides a glimpse of other literature concurring with this view. Califano writes,

> Of the ten leading causes of death at least seven could be substantially reduced if *persons at risk improved just five habits*; diet, smoking, lack of exercise, alcohol abuse and the use of hypertension medication (Califano 1979, cited in Smith 1996: 21; italics added).

Fuchs puts it rather more bluntly, "It is all about what people do and do not do for and to ourselves. *The choice is ours.*" (Fuchs 1974: 3, cited in Smith 1996: 21; italics added). The obvious consequence is that little attention is given to social and environmental factors. Mechanic observes,

> Much of the focus of public health action is on seeking solutions to major health risks by urging individual responsibility and personal health action as compared with social and environmental remedies that address key health risks at their source (Mechanic 1993: 97).

Thus, Smith shows how the conceptual basis for the risk factor approach to epidemiology is that *individuals are the cause of the problem*, and the basic causal reasoning determines that intervention strategies will be oriented to individuals. Risk factor epidemiology thus reduces epidemiology to the role of identifying, measuring, ranking and predicting *risk factors relating to individual behaviour*, a point noted even by Skolbekken's review of the 'risk epidemic' in medical journals (Skolbeken 1995). This strong emphasis on individual-level factors of risk gives risk factor epidemiology a considerable degree of congruence with clinical practice, which is based on the diagnosis and treatment of individuals in consulting rooms and hospitals.

Smith's viewpoint is underscored by the perspectives of Armstrong and Castel, both working from within a Foucauldian governmentality framework.

> The inevitable consequences of risk factor epidemiology are therefore an even increasing medicalisation of society. The widespread promotion of risk behaviour surveillance, risk prediction programmes and anticipatory health care in affluent countries is evidence that this is already very much underway. Castel believes that the spread of these programmes represents a new mode of medical surveillance in which the 'clinic of the subject' is being replaced by the 'epidemiologic clinic' which is based

> on the frequent risk profiling of populations and communities (Castel 1991). (Smith 1996: 22).

This attempt to identify new individual-level risk factors translates future patienthood into the present; *the repeated emphasis on secondary prevention (screening, monitoring and drug therapy regimes) protects the interests of existing medical institutions*, and does little to promote a population based public health which emphasizes primary prevention (Armstrong, 1995; Evans and Stoddart, 1990, cited in Smith, 1996). This approach is the foundation for today's 'lifestyle approach' to disease prevention and control – if individual risk behaviour is the problem then changing lifestyles is the solution.

Echoing the abovementioned perspectives in theories on risk, Smith's work finds that risk factor epidemiology, in failing to recognize that health behaviour is socially determined, echoes a perspective which reads lifestyle decisions as wholly voluntary behaviour and sees individuals as *free agents/ actors* when making decisions (Brown and Margo, 1978, Syme, 1988, cited in Smith, 1996). In this view of the world, "individuals are treated as health consumers in accordance with consumer capitalism" (Grace 1991: 334, cited in Smith 1996: 24). Viewing people as independent of their surroundings and unconstrained by social processes and events sets the ground for an approach to intervention known as *victim blaming* (Crawford 1977, cited in Smith 1996). This not only blames individuals for disease and illness, but also recommends that *individuals should take more responsibility for their own health.*

Smith points out that this perspective also leads to blame and moral outrage being directed at those *least able to adapt*, for their *individual failure* (Radley 1994, cited in Smith 1996). This gives rise to ideas about 'socially unacceptable' behaviours, and attaches moral judgements to *particular types of behaviour* by *particular groups of people.* As Lupton has observed, "risk discourse is often used to blame the victim, to displace the real reasons for ill-health upon the individual" (1993, cited in Smith 1996).

The combination of risk factor epidemiology and lifestyle discourse has led to a highly distorted view of the appropriate balance between personal and social responsibility for health – "risk factors are considered the cause while the whole complex of social and other environmental factors that create cause, and bring it into effective contact with the

host, tend to be ignored" (Terris 1983: 16, cited in Smith 1996). To acknowledge that risk behaviour is a feature not simply of individuals but of families, groups, communities, organizations and populations is to acknowledge that the determinants of health are wider than personal consumption issues, and are impacted by broader societal-level issues of production and distribution of resources.

However, since biomedical individualism – consistent with a positivist and empiricist perspective on disease etiology – is the underlying theoretical framework of risk factor epidemiology, the adoption of this narrow reductionist theoretical perspective is what leads risk factor epidemiology to be based on an individual rather than a population level of analysis. Epidemiologic models based on biomedical individualism see populations as simply the sum of individuals (Krieger 1994, cited in Smith 1996). Therefore etiologic explanations put forward by such models will exaggerate the importance of the biological determinants of disease, and their strategy for prevention will highlight individual-level aspects of prevention (Smith 1996), given that these are the very factors which are *most amenable to intervention* through the health care system.

This paradigm of epidemiology also depends on an empiricist mode of thinking, which exaggerates the importance of methods like statistical reasoning. As shown earlier, the statistical technique of reasoning and application is vital to epidemiology; this re-inscribes the practice of epidemiology as a quantitative science. This also underscores one of the enduring dilemmas of the discipline of epidemiology, which in an attempt to gain scientific respectability tends to veer close to the methods and rationales of the natural sciences. The next section discusses briefly the implications of this 'scientific', 'rational', 'statistically-oriented' perspective of epidemiology on the domain of policy making.

Section Three – The Relation between Risk and Policy Making

In this era of uncertainty and incalculability there is a defensive concern to be 'safe rather than sorry' and a pre-occupation with the 'precautionary principle', and therefore, as risks become increasingly unknowable and incalculable, formalized

systems for assessing and managing risks grow (Kemshall 2002). Individuals and organizations charged with getting risk right are required to defend these decisions, often from litigation, and formalized assessment methods are used to replace the vagaries of professional judgement (Kemshall 2002) This has been particularly acute in welfare, health, social care and criminal justice, as well as the more traditional risk arenas of science, engineering and new technologies. As Kemshall et al (1997) express it, audit, formalized assessment and bureaucratic risk management systems have become a key response to the uncertainty of risk.

To understand the relation between risk and social policy, as it will be explored in subsequent chapters of this dissertation, it is necessary to lay out a working understanding of social policy. Social policy is concerned with the state organization of social provision, although this provision may differ in its nature and extent, and in the type of state organization that provides it. As a practice, social policy has long been associated with social democratic societies and a commitment to meet social need outside of market forces, although development since the early 1980s have seen the rise of mixed economies of welfare and the increasing use of the market for social provision in social democratic societies.

Writers have noted the rise of the market and the mixed economy of welfare as a strategic tool in the reconfiguration of the health and personal social services (Mooney 1997, cited in Kemshall 2002). These developments have often been paralleled by increased attention to management objectives and style, epitomized by the new managerialism of 'key performance indicators'. Managerialism was promoted as a way to introduce sound business practices into the ailing and wasteful bureaucracies of the welfare state. While most of the literature discussed in this section focuses on the Western industrialized countries, it is pertinent to state for the record that it was this mode of managerialism that was at the core of 'structural adjustment policies' introduced by international development agencies in several developing countries starting from the 1970s.

There is an assumption that policymaking is a scientific, analytic enterprise, rather than a political, ideological one; that risk measured in terms of expected losses – mortality, morbidity, is the best way to conceptualize the existing problems; and that different

risks, once reduced to a common metric, can be compared, traded off or aggregated towards policy-making. Policy tends to emphasize the advantages of methodology over the less structured and less tangible/ measurable political processes that underlie these problems in the first place. However, other writers have also noted that social policy can also be central to policies of social control (Lavalette and Pratt 1997, cited in Kemshall 2002), and are driven by normative value judgements.

To aid policy making, risk has to be measured/ assessed – this is done through several kinds of risk research. There is literature on *risk perception*, which includes psychological research on lay people's perception of risk around them, faced as a consequence of varying activities, substances and technologies. Opinions, judgements of values, and what factors underlie those perceptions are investigated. Perceptions research seeks to uncover cognition, anxieties, biases/ prejudices, intuition, knowledge sources behind these behaviour/ actions while responding to risks.

There exists literature on *risk assessment*, which mainly discusses risk as effected by the domains of industry and management of hazardous outcomes – technology, engineering; chemical/ nuclear power, toxicology, science; the environment; or economic changes. Comparative risk analysis is the method adopted, wherein formal assessment techniques (a highly technical and quantitative/ statistical field) are used to assess how much 'risk' is posed by different types of problems, and a range is identified between problems that rank low on the risk index and those that rank high. Decisions about prioritizing these variously ranked risks, resources to be invested for these, budgetary allocations, etc., then drive policy making (Hornstein 1992).

And there is a field of *risk management*, where when risk assessment seeks to identify hazards and calculate their expected adverse effects, risk management seeks to structure decision-making on the acceptability of risks and on the measures society might employ against unacceptable risks (Hornstein 1992). The broad fields of *risk assessment* and *risk management* seek to pursue a 'scientific understanding' of risks, as opposed to 'public perceptions' of risk. Policy making within this framework of risk assessment/ management assesses 'population risk' and 'aggregate effects'.

However, it is important to note that population aggregates fail to account for equities and inequities in risk-bearing – they give us no indication about how these risks are distributed, who bears these risks, how disproportionately different populations/ people bear these risks, whether risk-bearing a function of merely technological/ industrial problems or is it located within other hierarchies, such as social, political, economic and cultural.

1. Risk assessment as 'rational'/ 'scientific'/ 'expert' knowledge – multiple trajectories

"The way in which expert knowledge about public health risks can serve as a form of social control and boundary production that constructs particular 'others' as dangerous" (Gabe 1995: 13) assumes a special significance in such a scenario. As hinted at earlier, quantitative risk analysis has often been used to make the case for expanded regulatory jurisdiction. As Hornstein informs us, "[i]t also provides a mechanism for officials to argue that *thorny political questions are being resolved 'scientifically,'* a position with a considerable heritage in the modem history of liberal democracies" (Hornstein 1992: 567). This then suggests that governmental policy/ programs (ostensibly created to protect human health and safety) themselves hold the possibilities of eroding democratic citizenship as they are situated within the boundaries of modern society's pervasive risk discourse.

Regarding the relation between the modern medical model, the state, and scientific, professional expert knowledge, Turner says,

> The growth of medical dominance under the auspices of the state, [is] associated with the development of a professional body of knowledge [...] The power of the professions depends, at least in part, on the ability to make claims successfully about the scientific value of their work and the way in which their professional knowledge is grounded in precise, accurate and reliable scientific information. (Turner 1987: 208)

Thus, the way in which disease categories are constructed is of critical importance to the status of medical professionals in contemporary society. Knowledge building, especially under the aegis of state institutions and practices, can thus be seen as part of a larger political exercise in power.

An instance is the earlier discussion on the Framingham study, where Moreira examined how *the establishment of hypertension as an object in public health was linked to the practices of calculation that were deployed* in the study. He noted how the legitimacy embodied in risk conditions such as hypertension derived specifically from the practices of calculation employed, which were themselves the

> effect of a contingent arrangement of the political and administrative stability and the ethnic and cultural homogeneity of Framingham, on the one hand, and the drawing together of methodological innovation and a political vision of public health [on the other] (Moreira 2007)

Critics have argued that given the unstable and dynamic nature of scientific judgements, these are "artifacts of the chosen methodologies rather than [...] representations of reality," (Hornstein 1992: 573) and have wondered how much of this is validated just because it is "backed up by an organizational infrastructure" (Hornstein 1992: 573-575). Suggesting that organizational backing will tend to "*emphasize those aspects of risk that its scientific bureaucracy has the tools to measure* (expected losses) at the expense of less easily measured, but not necessarily less important, aspects of risk-bearing" (Hornstein 1992: 575; italics added), the literature enables us to see that there is a coming together of two factors here, (i) backing of organizational infrastructure, and (ii) a management impetus, wherein decisions reflect the tools which the scientific bureaucracy has with it, to measure and to manage.

In light of the preceding discussions, it is plausible to argue that the impulse toward making choices according to universally standardized definitions (whether they be conceptual like "risk", or chemotherapeutic such as "treatment regimens", or methodological such as "Annual Risk of Infection (ARI)" in tuberculosis) is predominantly a utilitarian one – these must enable assessments that can weave into market-demands of cost-benefit analyses. Hornstein notes,

> The comparative risk analysts' conception of rational decision-making mimics (to a degree) the comparative methodology of expected utility theory, the dominant approach in economics and social science generally to making decisions under conditions of uncertainty or risk. At the core of expected utility theory is the maxim: 'In a given decision situation, the decision maker should choose the alternative with maximal expected utility...' This principle is accompanied by a number of conditions meant to assure the rationality of decisions. Prominent among these conditions are *the valuing of outcomes by numerical measurements* and *the maintenance of consistency in one's preferences among outcomes* (Hornstein 1992: 577; italics added).

He suggests that the emphasis on *outcomes* is a central feature not only of expected utility theory, but of "consequential utilitarianism in general and modern decision theory in particular" (Hornstein 1992: 578). To the comparative risk analyst, "rational policymaking must reduce risks to common units of measurement and then structure society's response in a way that directs relatively more resources to problems with high risk measurements than to problems with lower risk measurements" (Hornstein 1992: 579).

Such a system of narrowly focused management and regulatory initiatives – which directs limited resources on cases of *greatest risk*, by making rational and consistent choices based on *measurable outcomes* – can devise only single-problem "solutions" – it is unable to take into account the complex and layered nature of problems/hazards, the multi-faceted web of causation that stands behind these, and the wider interconnected/interdependent networks within which these are nested. Consequently, it is highly likely that such solutions will end up compounding several other existing problems, if not creating new ones entirely (Hornstein 1992).

This approach to risk involves a process of balancing the potential benefits of a decision or course of action against the possible harmful consequences; known more commonly today as 'cost-benefit analysis'. It is often on the basis of such risk assessments that governments/ states conduct health awareness and education campaigns or similar policies to warn the public, assuming that 'risky behaviour' will reduce as a result of dissemination of information (Gabe 1995).

2. Risk assessment is cost-benefit analysis/assessment

That discussions about risk are fundamentally discussions about cost-effectiveness has been established in several preceding discussions. When something or someone is labeled 'high-risk' it is precisely because the event/person poses a challenge to the balance that is aimed to be achieved between cost and benefit. When analyzing the *cost of inputs* and the *benefit of outcomes* the modern paradigm of thought is united in the expectation that outcomes should outweigh inputs, or at least that outcomes should be fairly commensurate with inputs. It is when the assessment shows that the outcomes are/ may be far lesser than the inputs that it leads to judgement/ discussion/ discourse

about risk. Risk – with regard to a certain event or person – arises because the costs that would have to be borne (to provide inputs) to address a/the problem that this event/person signifies far outweigh the benefits (of outcomes).

Costs, benefits, inputs, outcomes must all ultimately be reducible to *economically measurable entities*. A person's experience of ill health contains several dimensions, but of these only a few are picked for redressal at the level of policy. The dimensions that are picked for redressal are precisely those that can be broken down into disparate segments enabling a monetary valuation. So, for instance, while a person suffering from tuberculosis may experience chaos, fatigue and a deep sense of loss vis-à-vis her private and social world (especially if she belongs to the population which depends on care from the public healthcare system for serious ill health issues), these experiences rarely find their way into policy discussions for good/ relevant/ 'effective' tuberculosis treatment.

There is no attention paid to the fact that undergoing treatment for tuberculosis in a public health set-up effects significant changes in a person's sense of self. This is not just because her bodily practices undergo a change, but also because through accessing the public health care system she would have experienced a renewed reiteration of her vulnerable location as a disprivileged/ oppressed member of society. Tuberculosis treatment will thus reconfigure her engagement, commitments, responsibilities, status vis-à-vis other members of her family and community, which will have an impact on her life far beyond the therapy period of six months or twelve.

Dimensions of this experience of ill health that *do*, however, make it to policy discussions include:

- illness reduces the working capacity of the ill person as well as the carer/ family
- the monetary loss to the family, and to the larger economy, resulting from such debility
- the monetary cost of various aspects of treatment – to be borne by the ill person and family – such as availability, accessibility, time spent, diagnostic tests, drugs, outpatient or inpatient admission, additional support for food/ nutrition and caring

- the monetary cost of enabling people/ families to overcome obstacles in these various aspects of treatment and to utilize optimally the treatment options – to be borne by the state, various national and international bodies
- the monetary cost of one ill person causing other healthy persons to fall ill, and leading to the above noted costs being significantly multiplied at a population level – this is also to be borne by the state, and various national and international bodies.
- The monetary benefits from setting right all these wrongs/ problems

Such aspects of ill health as are reducible and measurable as economic entities then form the crux of any discussion on cost-benefit analysis for increasing the health of populations. And then degree of risk is derived from the limits that states/ national/ international bodies seek to impose upon spending for these aspects of ill health. Governments display their risk discourse in the framing of public policy, particularly in areas where resources are limited, as in health. Government response often adopts a calculated and probabilistic discourse of risk assessment, where an insurance approach to risk is used to aggregate and statistically calculate risks. In this, individuals are represented as 'instances of a population' and gain access to services on the basis of their 'risk level'.

3. Risk – re-configuring the discourses of welfare

Kemshall (2002) sets out the relationship between risk and the reconfiguration of welfare, and notes that contemporary social policy legislation is marked by how risk management procedures occupy a more established place in the *new management of welfare*. She agrees with Jessop's view that the new global economy is marked by *flexibility* in labour markets and production; technological *innovation*; economic regulation based upon an *enterprise culture* and the *reward of flexible technological skills* rather than traditional collective bargaining; leaner organizational forms designed to deliver *flexible supply systems* (Jessop 1993, cited in Kemshall 2002).

Leonard, taking distance from an economistic perspective on the 'retreat of the welfare state' locates the Keynesian welfare state itself as an enterprise of modernity – emphasizing the Golden Age of progress, reason and knowledge as the foundations of

'rational' interventions for the individual and public good, social reform through enlightened social policy and professional expertise (Leonard 1997, cited in Kemshall 2002). One of the key facets of his analysis is his position that the *social control function of welfare provision is both recognized and questioned.* This perspective on welfare draws considerably from the trajectory of Foucault's work on governmentality, which has drawn considerable attention to 'apparatuses of discipline' that the state enacts in monitoring and controlling populations to protect existing sites of power.[10]

This chapter has traversed various facets of risk and its relationship with aspects of society. It has shown that the rationale of modern society underscores a risk approach, which poses the individual as responsible for her own risk management – self-surveillance must be effected with regard to personal choices, 'risky' lifestyles, health choices, insurance and personal conduct which avoids risk. This approach stresses the notion of prevention via techniques of early identification and intervention in order to avoid undesirable risks, an approach epitomized by health promotion and Information, Education, Communication (IEC) campaigns. Such a social policy of prevention would serve a number of key purposes, in particular the *management* rather than the *elimination* of social problems, maintenance of the status quo and protection of vested interest, and the *reconstruction* of *social problems* as *individual choices and responsibilities* (Freeman 1992, cited in Kemshall 2002). The 'entrepreneurial self' must exercise informed choice and self-care to avoid risks (Castel 1991; Petersen 1996, cited in Kemshall 2002).

This chapter's discussions form the conceptual frame for the following three chapters. The following chapter, on the role of national and international bodies in the development of tuberculosis research and programme planning, does not forge a direct continuity with this chapter, but brings into focus a parallel thread of argument – regarding the politics of collaborative processes in 'scientific' research – which combined with this chapter on risk will enable an entry point into the Third Chapter's analysis of default and the Fourth chapter's analysis of Annual Risk of Infection (ARI).

End Notes

[1] Lilienfeld terms these nineteenth century counterparts of modern day epidemiologists 'sanitary physicians' due to the fact that in the absence of financial support for such endeavors they had to earn their livelihoods through clinical practice. Lilienfeld, D. E. (1978) '"The Greening of Epidemiology": Sanitary Physicians and the London Epidemiological Society (1830-1870)' *Bulletin of the History of Medicine*, 52: 4, pp 503-528.

[2] The American Statistical Association is discussed in Lilienfeld and Lilienfeld (1977) 'What Else Is New? An Historical Excursion', op. cit. The Statistical Society of London (predecessor to the Royal Statistical Society) and the London Epidemiological Society are discussed in Lilienfeld, D. E. (1978) '"The Greening of Epidemiology": Sanitary Physicians and the London Epidemiological Society' (1830-1870)', op. cit.

[3] Lilienfeld's article refers to 'Auguste Quetelet' as a founding member. However, in a 1984 article reviewing the history of the Statistical Society of London (SSL), I.D. Hill points out that Adolphe Quetelet was misnamed 'Auguste Quetelet' in the first two Fellows' Lists. Lilienfeld is only one instance of a common trend in literature about the SSL, which mistakenly refers to 'Auguste Quetelet' as a founding member. See, Hill, I.D. (1984) 'Statistical Society of London – Royal Statistical Society: The first 100 years, 1834-1934' *Journal of the Royal Statistical Society* Series A (General), Vol. 147, No. 2, The 150th Anniversary of the Royal Statistical Society, pp. 130-139.

[4] See Abraham M. Lilienfeld And David E. Lilienfeld (1977) 'What Else Is New? An Historical Excursion', op. cit., for a more thorough discussion on the influential impact of Louis on the development of statistics and epidemiology in the nineteenth century.

[5] The Framingham study, studying risk factors associated with cardiovascular disease, and the Doll and Hill study, studying the association between smoking and lung cancer.

[6] This study was conducted by a coalition of the National Health Institute of the U.S. Public Health Services, the Massachusetts Department of Public Health and the local Health Department. Framingham was chosen as the site of the study because it was deemed to be a cross-section of Americana. It also had a fairly stable population, with only one major hospital being used by almost all in the community, good archival records and practices and previous experience of community involvement with a tuberculosis study. The study involved 6,000 persons between the ages of 30 and 62 years of age from the same town. Recruited to participate in the study over a 20-year period, the study eventually spanned 30 years, during which medical tests were conducted with the participants. Moreira, 2007.

[7] *Forum: Qualitative Social Research* articles do not have page numbers.

[8] Kemshall notes Slovic, Paul (1992) 'Perception of risks: reflections on the psychometric paradigm' in Krimsky, S. and Golding, D. (ed.) *Social Theories of Risk* Westport, CT: Prager. See also, Slovic, Paul (1987) 'Perception of Risk' *Science*, New Series, 236 (4799): 280-285.

[9] Deborah Lupton has often used discourse to mean 'a bounded body of knowledge and associated practices, a particular identifiable way of giving meaning to reality via words or imagery'. Lupton, D. (1999) Risk London: Routledge.

[10] Foucault, Michel, (1991) 'Governmentality', in Burchell, Graham, Gordon, Colin and Miller, Peter (ed.) *The Foucault Effect: Studies in Governmentality* Chicago, IL: University of Chicago Press; Foucault, Michel (2000a) 'The Politics of Health in the Eighteenth Century' in Faubion, James D. (ed.) *The Essential Works of Foucault, Volume 3: Power* New York: The New Press; Foucault, Michel (2000b) 'The Birth of Social Medicine' in Faubion, James D. (ed.) *The Essential Works of Foucault, Volume 3: Power* New York: The New Press; Foucault, Michel (2007) 'Security, Territory, Population: Lectures at the Collège de France 1977–78' (trans.) Graham Burchell. London: Palgrave; Rabinow, Paul and Rose Nicholas (2003) 'Introduction: Foucault today' in *The Essential Foucault: Selections from The Essential Works of Foucault 1954-1984* New York and London: The New Press.

The Tuberculosis Programme: An International 'Indigenous' Effort

This chapter will conduct a critical review of the 'grand narrative' of the modern management and therapy of pulmonary tuberculosis, the period ranging from the late 1800s to the end of the 1990s. It will explore various developments in research, technology, chemotherapy and medical/ scientific thought and practice that have contributed to shifts in the management of pulmonary TB through the decades.

Section One of this chapter will present a brief timeline of major events and institutions relating to the trajectory of tuberculosis management efforts in India from the 1950s till the mid-1990s – this is broadly the transition from the National Tuberculosis Programme (NTP) to the Revised National Tuberculosis Control Programme (RNTCP).This draws from widely disseminated and well recognized scientific and technical literature on TB programme management and implementation. This can be called a 'straight history,' an attempt to answer the 'what' question – *what is the history of the management and control of TB?*

Section Two will draw a broader picture behind some of the developments that occurred in the global as well as Indian scenario. Discussing events as located in the wider contexts of collaborative enterprises, Section Two addresses the 'how' question – *how has this history of TB management and control been created?*

Section One – A straight history of tuberculosis management

Establishment of Sanatoria

The earliest phase of institutional management of tuberculosis in India began with the establishment of sanatoria – to control the transmission of infection by way of isolation. This sanatorium movement originated in Europe in the mid-1800s and, in the absence of chemotherapy, rested fundamentally on a balanced diet, fresh air and regulated exercise, preferably in an environment of unspoiled nature. Literature cites the first open-air sanatorium of India at Tilounia in Ajmer, founded in 1906, and another at Almora in 1908, both built by Christian missionaries. Notable among the many more sanatoria that developed are the first non-missionary sanatorium built in 1909 near

Shimla, and the United Mission Tuberculosis Sanatorium (UMTS, also called 'Aarogyavaram') built in 1912 at Madanapalle, Andhra Pradesh (Agarwal et al 2005; Annals of NTI 2000). The UMTS, under C. Frimodt Moller and later his son J. Frimodt Moller, continued to occupy an important place in the development of TB research and management initiatives in the coming decades.

Efforts of voluntary and non-governmental organizations

The early management of TB included isolation in sanatoria and a few surgical methods. Robert Philip, a Scottish medical scientist widely regarded as a pioneer in the management of TB is noted as "among the first to recognize that preventive aspects must form an important component of therapy and an *organized effort* was needed to tackle a contagious disease like TB" (Annals of NTI 2000: 8, italics in original). He set up the world's first dispensary for ambulatory care of consumption in Edinburgh in 1887, which eventually developed into a larger set of institutions including a sanatorium for the isolation and monitoring of infected individuals (Dubovsky 1973).

Following this a number of TB dispensaries and private anti-TB societies started developing in various countries and regions. After the First World War, from 1921, a Paris-based international anti-TB association called the International Union Against Tuberculosis (IUAT) started playing a prominent role in setting up national TB associations in different countries. The stated rationale for this was, "[a]s governments alone could not effectively take steps, voluntary agencies began to assume responsibility for providing relief" (Annals of NTI 2000: 8). The British Government of India joined efforts with voluntary societies emerging in India around this time (e.g., the Bengal TB Association started in 1929) to launch a wider campaign for health education about the cause and prevention of TB (Agarwal et al 2005; Annals of NTI 2000). In 1929 India signed membership into the IUAT, on Roger Lankaster's suggestion that it was important to join efforts with non-governmental initiatives in TB control (Annals of NTI 2000).

In the early 1900s, the Marchioness of Linlithgow, Vicereine of India issued a public appeal for anti-TB funds on behalf of the British government. A majority of the Rs. 1 crore collection was distributed for anti-TB efforts to the provinces and regions. A part

of this money was added to another fund, the King George V Thanksgiving (Anti-TB) Fund (which was used through the Indian Red Cross Society for preventive and educational activities, establishment of clinics, training of health visitors and preparation of health education material), and went into the setting up of the Indian chapter of the IUAT – the Tuberculosis Association of India (TAI) in 1939 (Annals of NTI 2000; Benjamin 1953).

The TAI was established with the objective of providing expert advice towards evolving standardization of methods of diagnosis and treatment to deal with the disease; setting up model institutions for training doctors, TB workers and health visitors; education of the public regarding preventive measures; and for organizing meetings and conferences for scientific discussions (Agarwal et al 2005; Benjamin 1953). The Marchioness of Linlithgow became the first President of the TAI, Frimodt Moller of UMTS became its Medical Commissioner, and Dr. B.K. Sikand its Secretary. The provinces and states which received money from the Linlithgow public fund started their TB associations.

The line of treatment advocated by TAI in this pre-chemotherapy, rudimentary diagnostics era continued to be as in the sanatoriums – balanced diet, fresh air, and mild exercise. However, the TAI saw domiciliary application of this treatment as the most practical option and in 1939 itself "recommended the Organised Home Treatment Scheme as the best compromise under the prevailing circumstances" (Annals of NTI 2000: 11).[1] The Association set up a model TB Clinic to demonstrate the feasibility of home treatment, establishing the New Delhi TB Clinic in 1940 (TAI Annual Report 1984), now called the New Delhi TB Centre, and the Lady Linlithgow Sanatoria in Kasouli. Research was also taken up in collaboration with the Indian Research Fund Association, now known as the Indian Council of Medical Research (ICMR). The New Delhi TB Centre and the ICMR grew to occupy very important positions in the future of TB management and control in India.

Earliest governmental level efforts

The Joseph Bhore headed Health Survey and Development Committee, set up by the Central Government of British India in 1943, outlined an organized domiciliary service

at the forefront of TB management efforts – setting up TB clinics in the districts and mobile TB clinics in rural areas. The Committee's recording of the abysmal health conditions of the Indian people necessitated governmental action in initiating measures to address the spread of the disease. A TB Division was established in the Directorate General of Health Services, with the Advisor in TB as its head.[2] This Division inaugurated the earliest governmental involvement in planning and execution of anti-TB activities.

BCG as a tool of prevention

As information about morbidity and mortality of TB started becoming known from small surveys conducted by TB workers in various locations during the 1930s-40s, the disparity between the needs of TB patients and the cost of care in institutions directed attention towards prevention efforts – by way of BCG vaccination. This was considered an operationally and economically feasible option, first introduced in 1921 in Paris.

The IUAT provided assistance to the BCG vaccination programme in India as part of its wider International Tuberculosis Campaign (ITC) in several countries;[3] WHO and UNICEF also supported the programme as part of their post-war assistance to developing countries. TB demonstration and training centres were set up for training required personnel. The BCG campaign was introduced on a small scale in Madanapalle in 1948 with Director of the Madanapalle institute J. Frimodt Moller in the lead, and was extended on a mass scale in 1951. This was the first organized nation-wide campaign against TB in independent India. In addition to the 65 million children vaccinated, 165 million tuberculin tests were administered. This campaign gave the first indications that the TB problem in rural areas could be as large as that found in the urban areas; that the disease was a public health, rather than a purely clinical, problem; and that the prevalence of TB infection was high in most parts of the country (Agarwal et al 2005).

The Annals of NTI inform us that during the mid-1960s there arose a worldwide debate and controversy regarding the protective effect of BCG.

> "The controversy regarding the protective effect of BCG, which came out of the findings of studies conducted in a number of different countries, was being debated at

this time. In 1968, GoI took the decision to carry out a meticulously designed clinical trial to test the efficacy of BCG vaccination in Chingleput district of Tamil Nadu. The results of this study, which revealed that BCG did not offer protection against pulmonary TB, had wider implications as the mass BCG campaign had already been established. After an in-depth review, it was decided, however, to continue BCG vaccination in children as a part of the Expanded Programme of Immunisation (EPI) to provide protection against the serious childhood forms of TB" (Agarwal et al 2005: 18).

Advances in chemotherapy, leading to further research

The period of the 1940s-50s saw the discovery of several effective drugs against TB – Streptomycin in 1944, Para amino salicylic acid in 1946, Thiacetazone in 1950, Isoniazid in 1952 and Rifampicin in 1966. Following this, the decade starting from the late 1940s saw researchers conduct various experiments and studies on effective dosages, duration and combination of drugs to be used for treatment. Some of the following are the most celebrated in the Indian literature as pioneering work.

In 1951, Dr. B.K. Sikand, the Director of the New Delhi TB Centre presented a study on the organized home treatment scheme in Delhi. He focused on the organized scientific diagnosis, modern scientific treatment and economic relief to patients. In 1952, Dr N.N .Sen presented a paper in the IX TB workers conference on the use of antibiotics and Dr E Nassau on the determination of sensitivity of the tubercle bacilli to SM and PAS. In 1953, Frimodt Moller and others presented the paper 'The effect of SM and INH, single and combined, in the treatment of pulmonary TB in Indian patients'. In 1956, Drs. Sikand and Pamra presented a paper on the 'Effect of SM, PAS and INH in 703 cases of pulmonary TB, diagnosed and treated during 1951-53'. They found that the results of domiciliary treatment were encouraging enough to warrant a shift of emphasis from hospitals and sanatoria to clinics without waiting for any further trials. These studies would, in time, revolutionize the management of TB all over the world (Annals of NTI 2000).

Establishment of the TCC, Madras, and its impact on research into TB management

It was in order to further research the possibilities of mass application of domiciliary treatment for pulmonary TB that the TB Chemotherapy Centre (TCC), now known as the TB Research Centre (TRC), was established in Madras in 1956 (Tuberculosis Chemotherapy Centre 1959). It was under the auspices of the ICMR that the

Government of India collaborated with the World Health Organization (WHO) and the British Medical Research Council (BMRC).

TCC demonstrated that the

> time-honoured virtues of sanatorium treatment such as bed rest, a well balanced diet and other sanatoria-based measures, were unimportant – provided adequate chemotherapy was prescribed and fully taken. Further, there was no evidence that close family contacts of patients treated at home, incurred an increased risk of contracting TB. Therefore, it would be appropriate to treat infectious patients in their own homes (Annals of NTI 2000: 15).

The study showed that recovery of patients treated at home (domiciliary treatment) was as good as hospital/sanatorium treatment. The discovery of specific, potent, and readily available anti-TB drugs and the efficacy of domiciliary treatment as shown by New Delhi TB Centre and TCC Madras, completely changed the outlook for TB patients (Agarwal et al 2005; TCC, 1959), and since then chemotherapy has become the mainstay of TB treatment (Bhagi 2001). These developments increased the probability of formulating a comprehensive TB programme to combat the disease on a community-wide basis.

National Sample Survey, and its impact on research into TB management

In the post-independence period, the high idealism, commitment and nascent ambitions of the ruling and planning establishment translated into a strong belief in the power of the available scientific methods and technological tools to address problems like TB. A combination of several 'scientifically spirited' minds – Prime Minister Jawaharlal Nehru, Rajkumari Amrit Kaur the Health Minister, K.C.K.E. Raja the D.G.H.S., followed by Lt Col C.K. Lakshmanan, and the recently created TB Division headed by P.V. Benjamin – harnessed the eager support of UNICEF and the WHO for epidemiological research activities on TB.

Towards this end, a special committee of the ICMR was set up to expeditiously collect detailed information through a systematic countrywide survey on the magnitude and extent of the disease in the various cross-sections of the population. India's decision to host the Fourteenth International TB Conference of the IUAT in New Delhi in 1957, with P.V. Benjamin designated the President of the Conference, is widely regarded as

the prime impetus which spurred the drive for gathering Indian epidemiological data (Annals of NTI, 2000); thus the National Sample Survey (NSS) was initiated, in preparation for the conference, in 1955.

The NSS of TB was conducted in 6 zones of India during 1955-58, and was the largest ever epidemiological survey on TB (ICMR, 1959). The study was trying to draw up information on TB prevalence (including prevalence in urban-rural areas), and focused attention on many methodological issues so that the information collected could be generalizable for the purposes of national planning to combat TB. Much thinking went into methodological issues like how to do sampling, what is the existing state of diagnostic facilities and how to use them effectively, the difficulties of diagnosing TB and the use of multiple X-ray readers to overcome biases/errors, and the organizational structure required to do such a survey.

The NSS showed that TB was not restricted only to urban areas, but was equally prevalent in rural areas too. It was also learnt that not all TB cases were equally infectious; the sputum smear positive cases were the most infectious and needed top priority for case-finding and treatment. The report acknowledged that TB was a public health problem because "conditions favourable to the spread to the disease such as poverty, inadequate or unbalanced nutrition, and overcrowding are only too common" (ICMR, 1959: 1). The links with increasing industrialization, seasonal rural unemployment leading to rural-urban migration were also acknowledged.

Some of the survey results showed –

1. Around 1.3% to 2.8% (Average 1.8%) of the population above the age of 5 years was suffering from radiologically active disease, of which 0.2% to 0.8% (Average 0.4%) were sputum positive. (This means that among 1000 persons there were 2-8 persons bacteriologically positive, i.e., persons in whose sputa TB bacilli were demonstrable; and among 1000 persons, 13-25 showed active or probably active disease, indicating that they were suffering from the moderately advanced disease, requiring treatment)
2. The disease was more or less equally prevalent in cities, towns and villages.
3. The disease prevalence was lower for females than for males, especially in the age group above 35 years.

4. Prevalence was more in the elderly and aged people
5. Higher prevalence was seen in over-crowded slums and in poor socio-economic conditions but there was no difference among those living in *kutcha* houses compared with those in *pucca* houses

NSS was a pioneering effort and the findings led to a fund of ideas about the public health aspects of the disease in the country-in terms of the size, age-sex and rural-urban distribution. The survey confirmed the impression of high prevalence of TB morbidity in the rural areas that had earlier been suggested by large-scale tuberculin testing; it was estimated that of the 8 million suffering from TB, about 80% were in the rural areas. With this revelation, the need for the development of a nationally applicable TB programme to tackle the problem was strongly felt.

> The NSS also provided the springboard for more detailed epidemiological studies concerning measurement of infection, the important role of non-specific allergy, and reliability and validity of tuberculin test and radiographic diagnosis, which culminated in determining a definition of a tuberculosis case. An even more ambitious study was the launching of a longitudinal epidemiological survey in Bangalore rural district in the 1960s. Apart from estimating the incidence of infection and disease, it provided valuable insight into the natural history of tuberculin positive individuals and of persons with radiologically or bacteriologically active disease. Another ambitious study in experimental epidemiology was the inquiry into the protective value of vaccines prepared from some of the common strains of BCG (Banerji, 1993: 63).

Establishment of NTI, Bangalore, and its impact on research into TB management

The findings of NSS and TRC revealed that the management of TB would require a totally new approach (Agarwal et al, 2005). The focus should be on the preventive aspects: to find and deal effectively with potential cases. Such work must be done on a community basis, especially in the hitherto neglected rural areas. Towards this end, the idea of setting up an institute to chart out a national programme of action for TB control for India was mooted. Halfdan Mahler and Stig Andersen of the WHO, already closely connected with the BCG campaign in India, were instrumental in establishing the National Tuberculosis Institute at Bangalore. With P.V. Benjamin, Advisor in TB to the GoI, as the driving force, the necessary support was garnered from the WHO and the UNICEF, and in 1959 an agreement was signed between WHO, UNICEF and Government of India towards setting up the institute.

The available tools for the control of TB consisted of BCG vaccination for prevention, chest radiography and sputum microscopy for case finding, and ambulatory domiciliary chemotherapy for treatment. NTI was expected to plan the National Tuberculosis Programme (NTP) to be operationally feasible, applicable to both rural and urban areas, economically affordable and promise substantial benefits to the community in the foreseeable future. NTI was expected to initiate research for the development of such a programme, create infrastructure, and train large numbers of key personnel from different states of the country, who in turn would implement and practice the methodologies developed.

Its national director was to be in charge of all operations, would represent the GoI and would execute the objectives as envisioned in the plan of operations. The key scientific team consisted of an epidemiologist, for studying the disease dynamics of TB as it existed in the community; a control officer to devise the means to seek out patients; a bacteriologist to head the research oriented needs of a national laboratory. Training was to be the responsibility of the control officer, assisted by all the concerned sections. "The director would also be assisted by a sociologist, so that the social ramifications would be understood and if feasible, woven into the strategy. This proved to be "the most radical inclusion of all" (Annals of NTI, 2000: 21).

National Tuberculosis Programme (NTP), launched in 1962

The development of the NTP was based on chemotherapeutic studies conducted by the TCC, and operational research studies conducted by the NTI related especially to the epidemiological, sociological, operational, technical and administrative aspects of TB control in India. Epidemiological information emerging from the NSS also formed the backdrop to several studies on epidemiological and sociological aspects. The two main studies that enabled the planning of NTP in 1962 were, the TCC study that demonstrated that domiciliary chemotherapeutic treatment of TB patients is as efficacious as sanatorium treatment, without increase in the possibility of contacts becoming infected; and the NTI study which demonstrated that the concept of 'suffering' and of 'felt need' should be the main criteria for case finding, and if priority is given to those symptom-aware sputum positive patients who are approaching health

institutions it will form a strong public health foundation for a successful TB management programme (TCC, 1959; Banerji and Andersen, 1963).

Consideration of tuberculosis as a problem of suffering, and of the availability, accessibility and affordability of general health services for TB patients, provided the basis for integration of NTP with general health services. The NTP was planned as an integrated programme, which would 'sink or sail' along with the general health services (Banerji, 1993). This community dimension of the programme diverted attention away from the TB sanatoria and rehabilitation centres, towards providing reliable diagnosis, domiciliary treatment and prevention services for the entire population. The NTP was pilot-tested in Ananthpur district of Andhra Pradesh in 1961, and thereafter launched in a phased manner throughout the country (Agarwal et al, 2005).

By 1978, the NTP, which had the district level as its basic unit, had covered 81% of the total districts in the country. Conventional treatment regimens of 12-18 months were developed through chemotherapy trials, and used in the programme. It was initially monitored on a regional basis, after which the NTI took up the monitoring of the entire country (Agarwal et al 2005). However, as revealed by programme monitoring reports and observational studies conducted in field conditions, the problem of treatment compliance in the programme was a significant one. Issues of irregularity, drop-out in drug intake and relapse provided the impetus for studies and trials on intermittent as well as supervised chemotherapy.

The availability of Rifampicin and the reintroduction of Pyrazinamide led to studies for the development of six-month short-course chemotherapy (SCC) regimens. Positive results from clinical trials of the BMRC in East African, Hong Kong and Singapore study sites made it possible to reduce treatment duration from 12 down to 6 months (Raviglione and Pio, 2002). With the introduction of SCC regimens, a new era had started in the fight against TB. In 1983, the Tuberculosis Research Centre (formerly, the Tuberculosis Chemotherapy Centre) which was conducting SCC trials on a small basis, pilot tested the SCC regimen in 18 districts of the country to assess the feasibility of SCC implementation on a larger scale. Subsequently, in 1986, following successful SCC field trials by TRC and NTI, GoI agreed to the introduction of SCC and its coverage was scaled up to cover 252 districts (Agarwal et al, 2005).

However, treatment compliance, even with the introduction of SCC regimens, showed only a marginal improvement. Between 1975 and 1992, the programme was evaluated by three independent agencies: the ICMR in 1975; the Institute of Communication, Operations Research and Community Involvement (ICORCI) in 1988; and by GoI, WHO, and the Swedish International Development Agency (SIDA) in 1992. These evaluations documented the already widely known facts of the wide gap between expected and actual achievements of the programme (Agarwal et al, 2005). Factors recognized widely by scholars and workers in the field of TB as responsible for NTP failure include, inadequate funding at the central and state levels, managerial weaknesses, over-reliance on X-ray as a diagnostic tool, the use of non-standard treatment regimens, severe shortages of drugs in the conventional chemotherapy regimens, poor administration, unmotivated and unevenly trained staff, poor quality of sputum smear microscopy, and lack of systematic information and recording/ documentation of treatment outcomes (WHO, 1992).

The Revised National Tuberculosis Control Programme (RNTCP), piloted in 1993, phased up in 1997

Despite the NTP being in existence since 1962, no appreciable change in the epidemiological situation of TB in the country had been observed. The HIV-AIDS epidemic and the spread of multi-drug resistance TB were threatening to further worsen the situation (Agarwal et al, 2005). In 1992, however, as tuberculosis was rapidly rising on the international health agenda, the NTP came under external audit (WHO, 1992).

The evaluation team, which included international tuberculosis experts from the World Health Organization (WHO), the International Union Against Tuberculosis and Lung Disease (IUATLD) and the Swedish International Development Agency (SIDA), as well as Indian members, found that the NTP was not performing well. They found that too few people were being cured, drug supplies were erratic, and the quality of the laboratory diagnosis techniques was not uniformly good (Ogden and Porter, 2000). A consequence of managerial weakness, inadequate funding, over reliance on X-ray, non-standard treatment regimens, low rates of treatment completion, and lack of systematic

information on treatment outcomes was that only 30% of patients were diagnosed out of which only 30% were treated successfully (Khatri, 2003).

This led to India revising its national programme in accordance with WHO guidelines for TB control. Most of the funding came from a World Bank loan to the government of India, with bilateral donors (notably ODA and DANIDA, the Danish International Development Agency) supporting the process in a number of specified sites (Ogden and Porter, 2000). The Revised National TB Control Programme (RNTCP) thus formulated, adopted the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, as the most systematic and cost-effective approach to revitalize the TB control programme in India.

Political and administrative commitment to ensure the provision of organized and comprehensive TB control services; reliable and early diagnosis through smear microscopy of self reporting chest symptomatics in the general health services; an uninterrupted supply of good quality anti-TB drugs; effective and patient-friendly treatment with SCC given under direct observation; and accountability through proper recording and reporting, and effective supervision were emphasized. The objectives of the RNTCP are to achieve at least 85 percent cure rate among the new smear-positive cases initiated on treatment, and thereafter a case detection rate of at least 70 percent of such cases (Agarwal 2005).

Section Two – A genealogical reading of tuberculosis management

While attempting to understand the modern management and therapy of pulmonary tuberculosis, it is important to read the Indian and global settings together. This is not only because knowledge is enriched by learning about Indian developments alongside what was happening in other parts of the world at the same time, but because the literature shows us that Indian developments are deeply intertwined with Western scientific thought, practices and developments. Contrary to claims of 'indigenous' developments, the review of literature constantly reiterates the 'international' nature of Indian scientific developments. This section is guided by an interest in understanding

the politics of the choice and action of certain policy, programme and collaborative initiatives.

In order to understand this deeper context, I extend my range beyond scientific, technical and programme-related literature to critical commentaries at global and Indian levels. This includes literature on TB policy processes; on important national & international players in TB research, operationalization and funding; on analyses of some of these organizational structures and changes in them through the decades; on the politics of collaborative initiatives, especially with regard to location in the international 'development' hierarchy (North v/s South, regional v/s global, developed nations v/s developing or underdeveloped nations).

This is a re-telling from a critical political perspective, to interrupt the smooth linear narrative of the history of TB management, in which contradiction and politics are completely erased from the picture. This is also an attempt at a *genealogical* reading in the sense that Foucault uses this term – to mean not the search for an original 'past'/ 'truth', linear in its progression, but to explore the multiple settings that have contributed to the specific shape and structure of the field of TB management in India, or globally, *as we know these to exist today.* Attempting to show the influence power has on what we understand as 'truth' (here, scientific truth), this section addresses the 'how' question, *how has this history of TB management and control been created?*

Sanatoria

Set up mostly by missionary, philanthropic and voluntary efforts, sanatoria were the earliest institutions for TB care set up in undivided India. Christian missionary presence and activity varied in the several regions and princely states that made up this territory, and they established the first sanatorium in 1906 in Tilaunia in today's Rajasthan,[4] "intended primarily for treating girls from mission schools and orphanages connected with this mission" (Prasad and Raju 2008: 53-54). This was followed by one in Almora in the Kumaon region of the Himalayas in 1908, and in 1915 the Union Mission Tuberculosis Sanatorium (UMTS, also called 'Aarogyavaram') in Madanapalle, Chittoor district, Andhra Pradesh was established. The first non-missionary sanatorium,

Hardinge Sanatorium at Dharampore near Shimla, established in 1909, saw the contribution of Bombay-based philanthropists, mainly Parsees, towards its construction.

Analyzing the spread of the sanatorium method of therapy Prasad and Raju write, "[i]t was the terror of infection, the high fatality rate and the desperate search for cure that saw the first sanatoriums come up in Europe" (Prasad and Raju 2008: 53). Avoiding the crowded towns and cities that were seen as unhealthy and the sources of infection and epidemics, the preferred locations for sanatoriums were the hills; the sanatorium line of treatment demanded fresh air-sunshine-rest-high protein diet-mild exercise. Describing the sanatoriums' wide appeal in the United States in the pre-chemotherapy era they quote social historian Shiela M Rotham writing about TB,

> [a] generation of physicians, social reformers and philanthropists were convinced that confining the tubercular in these facilities would promote not only societal well-being by isolating those with the disease, but also individual well-being by implementing a therapeutic regimen. *The sanatorium satisfied both the drive to coerce and cure* (Rotham 1994, cited in Prasad and Raju 2008: 53; italics added).

In India there seemed to be an additional impetus behind setting up sanatoria, apart from the by-now-established desire to keep the sick from compromising the health of the general population.

> Moller, the physician-in-charge of UMTS said in his 1915 address on the opening of UMTS, 'A sanatorium in India affords many possibilities, not to be observed to such an extent in other medical institutions in India, *for doing some research work*, because in a sanatorium the patients are under daily observation for a much longer period than they usually are in general hospitals in India' [UMTS Annual Report 1916-1917: 8]. It was argued that the relevance of the sanatorium was far greater in India than in the west, due to higher poverty and poor hygiene in the former (Prasad and Raju 2008: 59).

Clearly then, high poverty, poor hygiene and large numbers of the sick did not invoke as much a sense of suffering as it did a sense of the potential and opportunity it afforded for research work.

Efforts of voluntary and non-governmental organizations – the International Union Against Tuberculosis (IUAT) and the Tuberculosis Association of India (TAI)

In the early 1900s therapy for TB implied isolation in sanatoria and a few surgical methods. Robert Philip, a Scottish medical scientist widely regarded as a pioneer in the

management of TB, set up the world's first dispensary for ambulatory care of consumption in Edinburgh in 1887, which eventually developed into a larger set of institutions including a sanatorium for the isolation and monitoring of infected individuals. His revolutionary treatment, known as the Edinburgh Scheme, included putting measures in place to ensure tracing of all known contacts of a diagnosed patient, whereby the illness could be tracked and measures taken to avoid further contamination (Dubovsky 1973).

His efforts and his involvement of laymen in the scheme is considered an early prototype of private, voluntary, charitable initiatives in tuberculosis control and led to the subsequent idea of a national movement for the prevention of TB by encouraging the wide formation of Tuberculosis Associations (Dubovsky 1973). This anticipated modern TB control, crystallized by the setting up of the National Association for the Prevention of Tuberculosis in Edinburgh in 1898, and the Central Bureau for the Campaign Against TB in Berlin in 1900. This latter organization was the forerunner of the International Union Against Tuberculosis (IUAT), a specialized non-governmental organization for advocacy and scientific research in TB, which was set up in 1921 in Paris (Annals of NTI 2000).

After the First World War, the IUAT started playing a prominent role from 1922 in setting up national TB associations in different countries. The stated rationale for this was, "[a]s governments alone could not effectively take steps, voluntary agencies began to assume responsibility for providing relief" (Annals of NTI 2000: 8). The main efforts of these voluntary associations concentrated on educating the public regarding TB, its prevention and therapy – what in today's parlance is called Information, Education, Communication (IEC) activities – in addition to providing some treatment support for patients who needed assistance. IUAT saw government bodies as bound within certain structures which prevented them from taking all the necessary steps that were needed to combat the threat of TB, and it set itself a very important mandate – *stepping beyond the mandate that government bodies were bound by.*

It felt that even though the official health authorities could conduct programmes of health education, such government conducted programmes are known to be less successful and effective than those conducted by voluntary efforts.

> The personal contact of, and influence on, people reluctant to report for an examination even if they have the symptoms suspect of tuberculosis, cannot, of course, be arranged for by any governmental efforts short of legal compulsion, which, in any programme, has been a failure. Voluntary efforts, organized in local tuberculosis associations can have a great effect in bringing people for examination, who have infectious pulmonary tuberculosis with symptoms characteristic of the disease (The Mutual Assistance Programme of the International Union Against Tuberculosis 1963: 125).[5]

Further, it felt,

> The establishment of case-finding and treatment centres, the training of qualified personnel, the provision of drugs free of charge, all this must be backed at each stage by a parallel action in health education, propaganda, supervision and encouragement. No administration can undertake this without running the risk of making itself objectionable and sometimes even absurd. Such action must necessarily spring from private and voluntary associations. These associations have already shown their worth in the industrialized countries forty or fifty years ago.
> Spring spontaneously... perhaps that is not exactly true – at least, not in the beginning. Just as the role of big inter-governmental organizations is to assist governments, so our role is to help national associations to carry out the tasks which have fallen to them. (Editorial *T* 1962: 3).[6]

Affiliated to the IUAT (Benjamin, 1953), the TAI was formed in 1939, largely by official blessings. It was started "on account of some highly placed persons in the government, including the vicereine, the Marchioness of Linlithgow, and many more in public life. *The Association had been conceived as the national level non-official organization to become the motor for the fledgling anti-tuberculosis movement in India*" (Nagpaul 2003: 1, italics added). It was suggested that the movement could be on the lines of the National Association for Prevention of Tuberculosis, established in the United Kingdom in 1908 (Nagpaul 2003). State governments along with voluntary organizations in the country were expected to play different but complementary roles in the fight against tuberculosis; given that such associations would not just 'spring spontaneously', it was the IUAT's responsibility to help by guiding and shaping the directions, roles and responsibilities these bodies were to undertake for each country's TB management efforts.

However, the role of the voluntary associations under the aegis of the IUAT was not envisaged merely as a passive, supportive role to governmental efforts. These associations, in each country, and further down at state and district levels, had a mandate to act as a surveillance mechanism for governmental efforts, influence public opinion, and most importantly, assist in planning the TB management or control aspects

of the programme in any country. These associations were very closely involved with all levels of governmental efforts, given that an important part of their mandate was also to exert pressure to influence political decision-making. This close cooperation between the government machinery and the voluntary associations, and at various programme levels, has often been a function of the close interaction and traffic of scientific/ medical personnel between the government and the associations.

In India this close association started right from post-independence governmental efforts to combat TB, with P.V. Benjamin, widely regarded as the 'father' of the anti-tuberculosis movement in India, who was first the Medical Commissioner of the TAI in 1941 and became its Technical Adviser in 1944. M.M. Singh, Vice Chairman (Operational Research), TAI, elaborates on this early inter-linkage between TAI and the government structure, "The proposal that the Government of India should have a full time Adviser in the Ministry of Health, materialized in 1948 and consequently the Technical Adviser of TAI was also appointed as Adviser to Government of India" (Singh 2006). At the time of being called to Delhi, Benjamin was head of the Union Mission Tuberculosis Sanatorium (Aarogyavaram) at Madanapalle (Andersen and Benjamin 1962). Benjamin's appointment to this post is noted to have been linked to his close association with the Nehru family; Nehru had visited the UMTS on account of Kamala Nehru's protracted battle with TB, where he met Benjamin and grew to develop a rapport and sense of confidence in him (Narayan 2009).[7]

Benjamin continued functioning as Technical Adviser to the TAI, and remained so till 1964, even after retiring from his government post in 1963. He was a member of its Technical Committee from its inception in 1948 up to 1964. He was also the Editor of TAI's official publication, the *Indian Journal of Tuberculosis* from its inception in 1953 to 1964 (Obituary *IJT* 1973). As Adviser in TB to the government of India (GoI) he championed the cause of voluntary work and did his best to promote the work of the TAI, often advocating, at national as well as international fora, that voluntary associations like TAI could and should play a very important role in governmental TB management efforts (Benjamin 1953). For many years he was a member of the IUAT Executive Committee, and was President of the IUAT from 1956-58 (Andersen and Benjamin 1962).[8] An enduring legacy of his tenure is that he brought the Fourteenth International TB Conference of the IUAT to Delhi in 1957; this was the first time the

Conference moved outside Western Europe and the Americas. India's decision to host this important event, with Benjamin designated President of the Conference, is widely regarded as the prime impetus which spurred the drive for gathering Indian epidemiological data (Annals of NTI, 2000); it was in preparation for this conference that the National Sample Survey (NSS) was initiated in 1955. Benjamin also served as the President of the Eastern Regional Committee of the IUAT from 1957-64 (Obituary *IJT* 1973).

His position at the cusp of governmental and non-governmental bodies "was an important development and the fact that the Health Minister [then Rajkumari Amrit Kaur] was the President and the Director General of Health Services [then KCKE Raja] its ex-officio Chairman made it possible for the TAI to move in a concerted and systematic manner in close cooperation with Government to supplement and complement the Government activities" (Singh 2006) Singh recounts in his 2006 article,

> in keeping with the policy originally outlined, *expert advice was made available through the Technical Adviser to State Governments and Associations*. From 1948 onwards the Association has a Standing *Technical Committee consisting of prominent tuberculosis workers in the country*. This *Committee recommends steps to be taken in regard to various problems connected with tuberculosis*. The introduction of BCG vaccination in India as a preventive measure against tuberculosis, and other schemes for tuberculosis control included in the Five Year Plans of the Government were some of the recommendations made by the Committee in past and *this Committee also made recommendations on all technical matters referred by DGHS to Tuberculosis Association of India* (Singh 2006, italics added).

As just one illustration of the active support and encouragement shown to TAI by the Ministry of Health and Family Welfare, a look at TAI's 1984 Annual Report is informative. It notes that various suggestions and reports submitted by TAI's Technical Committee to the Ministry, for instance, regarding the role of TB associations and voluntary organizations in the implementation of the NTP, and regarding supply of anti-TB drugs and setting up of an Expert Committee to review drug regimens, have been noted by the ministry (TAI 1984). The Report notes, "It is a matter of great satisfaction that the Health Ministry at the Centre has *taken the representative of the Tuberculosis Association of India on practically all important committees concerned with the planning and performance of the National Tuberculosis Programme* (TAI 1984: 14)." Further, the "Committee noted that the D.G.H.S. had *invited suggestions*

from the Committee for consideration of the Working Group set up by the government in connection with the 7th Five Year Plan" (TAI 1984: 15).

Pointing out that "the Association continues to work in close collaboration with the International Union Against Tuberculosis, Paris" (TAI 1984), the Report informs that the President and Chairman of the TAI (this latter, the DGHS, GoI)

> continued to represent India on the Union's Council during 1984. In addition, the Association enrolled 29 TB workers from India as Individual Members of the Union. The Association also contributed a sum of Rs. 20,940.40 to the funds of the Union in 1984. This amount is made up of subscriptions received from individual members and a grant from the Association's funds towards the budget of the Union for 1984. Dr. S.P. Pamra, Honorary Technical Adviser of the Association, continued to represent the Eastern Region of the IUAT on the Executive Committee of the Union. He is also a member of the Union's Committee for 'Honorary Awards' and of its Scientific Committee on 'Treatment' (TAI 1984: 36-37).[9]

Pamra was also Editor of the Eastern Region's "Bulletin" (TAI 1984), and part of several landmark studies done by the New Delhi Tuberculosis Centre (NDTBC) in the 1950s-60s which played an influential role in revolutionizing TB management across the world (Annals 2000). Further, the report notes with thanks the opportunity afforded to some TAI staff by IUAT sponsored work trips "to some of the technically advanced countries for studying the activities of their National TB Associations" (TAI 1984).[10]

These various levels of interconnections hold up faithfully to the IUAT's vision for strengthening national tuberculosis programmes across the world. The IUAT holds that where voluntary tuberculosis associations exist,

> there is a close contact and working relationship between this association and the voluntary (non-governmental) society of tuberculosis doctors. *In several countries the society of tuberculosis doctors forms a part of the national tuberculosis association. This, of course, endows a special strength to the national tuberculosis association.*" (The Extended Programme of the International Union Against Tuberculosis 1963: 100).[11]

Further, one of the modalities of its "assistance to the official health authority in the planning, execution and evaluation of the national programme" is evident in its urging that the programme

> must be based on a well defined technical policy which will include recommendations for procedures, methods and techniques to be used in the programme. This involves, in the main, medical questions which should be handled by the specialists. *Through its medical tuberculosis society or medical advisory committees, the national tuberculosis*

> *association is well placed to assist the governmental authorities in handling such questions. The medical group will collect all the necessary knowledge and experience before making recommendations on a given measure, method or technique. While the national tuberculosis association may formulate a specific technical recommendation, such a recommendation should, before it is issued, be presented to and discussed with the governmental authority. A close collaboration between the association and the governmental authority in formulating and issuing technical recommendations is necessary to avoid conflicting recommendations for the same problem* (The Extended Programme of the International Union Against Tuberculosis 1963: 101, italics added).

Another modality of the IUAT mandate involves surveillance of the governmental programme

> "in order to exercise its function as the 'critical auditor' of all aspects of the national tuberculosis programme, the national tuberculosis associations must be familiar with all the activities of the programme. This means that there *must be a close and constant collaboration between the secretariat of the national tuberculosis association and the tuberculosis unit in the national health administration.* (The Extended Programme of the International Union Against Tuberculosis 1963: 102, italics added).

As mentioned earlier, this is also evident in India, where the DGHS, GoI is the ex-officio Chairman of TAI. Further, several medical/ scientific members of the central and state government structures as well as governmental TB institutions often serve as members of the TAI's Central Committee, Executive Committee and Technical Committee – for instance, in the mid-2000s Deputy Director General (TB), Government of India; Director, NTI; Director, TRC occupied important positions in these committees of TAI (TAI 2006). This is apart from the fact that several government officials have, after retirement, gone on to hold important positions in TAI, and both TAI members and government officials have gone on to join international development agencies in scientific, technical and advisory positions towards policy-making.

Thus, Benjamin's comment of the early 1950s on this intertwining only reiterates the wider framework within which IUAT and TAI were meant to operate – "Most of the Associations in India have on their committees officials and non-officials and in most cases important office bearers are ex-officio Government officials. There are advantages and disadvantages in this arrangement. In India at present *very few Associations can function properly without the active cooperation of Government servants*" (Benjamin 1953: 5). One of the stated advantages of having such voluntary, non-governmental bodies in the TB management structure of every country was that they had the *flexibility and freedom that governmental bodies do not enjoy*[12], and thus

they have a freer hand in taking on certain tasks of TB programme management – especially those, which, governmental bodies would not be able to undertake without running the risk of *making themselves objectionable.*

As regards financial connection between TAI and the government, curiously, donation forms of the TAI published in 2001-2002 claim that TAI "does not receive any grant from the government" (TAI, Adm.30/2001-2002).[13] However, a cursory look at statements of accounts from earlier annual reports of the TAI and the New Delhi TB Centre, an institution of the TAI, show that government grants formed the largest part of their income. For instance, the 1984 report states that TAI receipts in 1984 amounted to Rs. 45,83,100, including an opening balance of Rs 2,69, 624; the largest amount in this is "Rs. 28,50,000 representing grants from Government of India for our institutions" (TAI 1984: 43).[14] Annual NDTBC accounts presented in TAI's 48th Annual General Meeting in 1987, showed that out of the receipts of Rs. 19,58,542 in 1985-86, the recurring grant to NDTBC from the GoI was Rs. 18,20,000 (TAI 1987: 9);[15] further, in NDTBC's Annual Report 1992-93, apart from Rs. 34,75,000 given as the annual recurring grant, an additional amount of Rs. 5,22,000 was given by the MOHFW, GoI as an Ad-hoc grant to meet the deficit of the earlier year (NDTBC 1992-93: 22).[16]

Finally, a word about the *Indian Journal of Tuberculosis*, which is the official TAI publication, not only publishing original research in TB but also disseminating papers and discussions from TAI's annual National Conferences of Tuberculosis and Chest Diseases.[17] The most influential personalities in the field of TB, from the official to the voluntary and international arenas, constitute this scientific community of the journal and the conferences, which is closely intertwined with the Indian policy making community on TB programme and research. Banerji has noted that "[the] proceedings of the annual Tuberculosis and Chest Diseases Workers' Conferences reveal that proposals for reverting to the specialized tuberculosis programme had been made, from time to time, and from influential quarters" (Banerji 1993: 74).

Evidence of such attempts can be seen, for instance, in the 1975 ICMR Expert Committee's Report of the first ever evaluation of the Indian NTP. Titled *A Review of the National Tuberculosis Programme*, the first few pages of the Expert Committee's

report are a foreword by the Technical Committee of the TAI – which will not seem out of place at all if one notes that it was the TAI that pushed then Union Health Minister Karan Singh to conduct an evaluation of the NTP, which according to several of TAI's own observations had not been functioning satisfactorily. While commending all the findings of the Expert Committee which echoed its own observations, TAI wonders why the Expert committee falls shy of making certain strong recommendations to revive the failing NTP – most urgent of which according to TAI is to have a vertical structure for the TB programme, "by having workers exclusively for tuberculosis control" (Indian Council of Medical Research 1975: 1).

In sum, the literature makes it evident that the role of the voluntary TB associations, here the TAI, was never envisaged as merely supplementary, but had the mandate to actively intervene in and give direction to governmental TB management efforts. This close association has only strengthened through the decades with several members of the central and state government structures as well as governmental TB institutions having close research scientific and programme-related associations with TAI. With TAI having close links with various arms of the government machinery, for instance, health, medical education and training, the railways, the armed forces medical services, it performs an influential and directing role in the structure of Indian TB programme planning and implementation.

The troubled life of the BCG vaccine

Mass vaccination with BCG has been one of the major WHO-promoted tools for the management of TB. Although the BCG vaccine is one of the most widely used vaccines worldwide, there has been a long standing controversy regarding its protective effect.[18] In an expansively researched article on the history behind the BCG vaccination strategy, historian Niels Brimnes points out that even

> "[i]n the 1940s there was no clear evidence to fully support or entirely reject BCG. As Bryder has argued the adoption of BCG was not simply based on medical evidence. Rather, it was contingent upon 'the social setting in which the researchers and assessors worked and lived' and the debates were 'underpinned by ideological difference' (Bryder, 1999, p1158). Whether the vaccine should be adopted was a matter of interpretation, policy preference and sense of urgency (Bryder 1999: 1158, cited in Brimnes 2008: 865).

This sense of urgency was positioned in respect to the developing countries with their large burden of TB infection and disease, and less so for the countries of Western Europe and North America.

Given this ambiguity, Brimnes writes that early debates on BCG "were about the *degree of protection* conferred by successful vaccination. Advocates of BCG claimed a protective effect of up to 80% for the vaccine, while its adversaries held that the vaccine offered no or little protection" (Brimnes 2008: 864, italics in original). Further, debates about degree of protection often hinged around the idea of *successful vaccination* – bacteriological characteristics of the BCG vaccine, as well as its implementation modalities in various settings, enabled the detractors of BCG to attack it, while at the same time enabling proponents of the vaccine to explain (away) the unsatisfactory results of BCG trials (Brimnes 2008: 864).

Brimnes informs us that from the time that BCG vaccination was introduced on a mass scale in India in 1951 till the middle of the 1960s, the WHO supported BCG vaccination in TB control programmes across the developing countries not on the basis of any large-scale scientific assessments, trials, studies in any of *these locations*, but on the basis of its firm belief in the protective effect of the vaccine in developed nations. Setting aside the demand for conducting studies on BCG in underdeveloped areas before large scale application in their programmes, WHO held that "such studies would be both expensive, highly complicated and might not provide a clear answer" (Holm 1956, cited in Brimnes 2008: 867).[19]

In the 1960s WHO's assessment of 4 controlled trials on the protective value of BCG – where two showed very high protection and the other two showed just the opposite – led to the admission that the actual value of BCG was not clear; however, the 'low protective effect' studies were almost dismissed by pointing out faults in those two trials. WHO adopted a similar response in the case of a 1960 study from Madanapalle in Andhra Pradesh which pointed to inconclusive evidence regarding the protective effect of BCG; all the while continuing to recommend BCG use in mass programmes in developing countries.

In 1968, a large scale BCG trial was begun at Chingleput, near Madras, in order to obtain "accurate empirical estimates of the protective value of BCG vaccination under the specific conditions prevailing in India" and to extrapolate the results as far as permissible to other tropical areas of the world (Brimnes 2008: 869). The methodology and design of the trial met all the scientific criteria by WHO's standards, in spite of which, when the data showed no protective effect of BCG WHO decided to vet the results through two more of its scientific committees.

Brimnes points out that the committees stated that the result "should not be regarded as applying automatically to other parts of the world" (WHO 1980a, cited in Brimnes 2008: 869), that the lack of protection may be related to "specific epidemiological, environmental and immunological characteristics of the population studied", that "no trial was generally valid", that the failure of this trial may be due to "lack of vaccine potency and the prevalence of low grade sensitivity in the area", that "different ethnic groups have different responses", and finally, that the trial had been set up to study the protective effect of BCG in adults, which meant that BCG could still protect against severe forms of TB in infants (WHO 1980b, cited in Brimnes 2008: 869-870). Struck by how the principle of *universality* of BCG trials suddenly disappeared, Brimnes writes, "Since the 1950s WHO and UNICEF had vaccinated millions with BCG, because it apparently worked in Europe. Now, however, the disturbing results from the Chingleput study were explained – if not entirely dismissed – simply as *local*" (Brimnes 2008: 870).

Drawing on his analysis of the role of the WHO in supporting and promoting BCG vaccination, we can see that from the very beginning, WHO was not unaware of the ambiguity regarding the protective effect of BCG. What it constantly did, however, was to selectively privilege certain parts of this inconclusive information in order to continue justifying its policy decisions. WHO's inability to abandon the BCG strategy had to do with the fact that massive investment had been made in it, "in terms of money as well as of medical prestige" (Brimnes 2008: 867). When finally faced with conclusive scientific evidence from the Chingleput trial the vaccine was again defended, though now with a newly discovered argument – that the vaccine protected against specific forms of childhood TB.

Some of the issues that continue till date to contribute to ambivalence in tuberculin testing and interpretation, which has implications for BCG vaccination as well as Annual Risk of Infection (ARI) estimation, especially for India, include, (i) the phenomenon of 'non-specific reaction' or 'low grade sensitivity' – when tuberculin testing is done to find out prior sensitization to *M. tuberculosis* (whether a person carried mycobacterium tuberculosis in her body), the test could not always be interpreted clearly in tropical areas like India because of the presence of other kinds of mycobacteria in the environment. A weak reaction to tuberculin thus often indicated cross-reacting sensitivity to non-tuberculous mycobacteria; (ii) the tuberculin test's positive result is also complicated to interpret in areas/countries with a history of prior BCG vaccination; (iii) nutritional status of the children tested, and presence of malnutrition among them, interfering with the test reading (Chakraborty *et al* 1980; Chadha *et al* 1997). This has implications for the application of tools such as ARI, which will be discussed at length in the following chapter.

NTP to RNTCP: paradigm shift or rearrangement?

Available reviews of the tuberculosis programme in India, especially its long sweep including the shift from the NTP to RNTCP phases, often stress that the earlier phase, i.e., NTP was structured to address the problem of tuberculosis in India in a holistic manner, and the therapy of TB patients keeping in mind their perceptions, needs and context. This was because the programme was evolved keeping in mind the epidemiological situation of TB in India, the sociological context and needs of the Indian people, an interdisciplinary approach towards operational research, and it was integrated with the general health services of the country (Banerji 1997). It was thus "a technically sound, economically feasible & operationally acceptable programme integrated with the general health services for the entire population services" (Ranga Rao 2003: 65).

Some of the important factors which drew from a social science perspective and influenced the planning and research background of the NTP, can be summarized thus,

- People rather than technology were at the forefront; there was a social orientation of the technology which was applied only after studying the ground situation thoroughly.

- The disease was sought to be tackled under the general health services system, ensuring that investment of efforts into one disease does not deprive the overall growth of the health services system, and the entire infrastructure grows simultaneously as more funds are received.
- The questions of how to diagnose and treat tuberculosis patients in remote rural areas was given considerable attention in the methodology.
- How people perceive the problem, what are their reactions to the illness, understanding the people concerned and their perceptions, people's responses in rural areas, the degree of worry they experienced – these aspects of learning from the affected people formed a significant part of the research methods.

Given that all these factors had been taken into account, such reviews highlight that the failure of the NTP was due to improper implementation and service delivery of the NTP to the people, mainly due to the *severe lacunae in the general health services* (ICORCI 1988; Banerji 1982; Qadeer 1994; Bordia 1978; Narasimha Rao 1972; Naganna 1975). Factors recognized widely by scholars and workers in the field of TB as responsible for NTP failure include, inadequate funding at the central and state levels, managerial weaknesses, over-reliance on X-ray as a diagnostic tool, the use of non-standard treatment regimens, severe shortages of drugs in the conventional chemotherapy regimens, poor administration, unmotivated and unevenly trained staff, poor quality of sputum smear microscopy, and lack of systematic information and recording/ documentation of treatment outcomes (WHO 1992).

Further, literature also suggests that the large and unregulated private sector remained uninformed and alienated from NTP, but because large numbers of patients visited it the detrimental effects of their incorrect treatment, diagnosis and case management practices impacted patients negatively (Banerji 1997; Mankodi and Van der Vaen 1985). Private clinicians tackling TB tended to view it as a purely medical problem without appreciating the epidemiological and social-economic-political realities and contexts from which TB arises and that its effects on impoverished and vulnerable populations were more severe than on others. Reviews also record problems with the bureaucratic behaviour of health administrators and attitude and knowledge of teachers of tuberculosis and chest diseases in medical institutions (Banerji 1993, 1997).

Other reviews identify the failure of the political leadership as a central factor of this failure, as decline in quality of key public health institutions, research, education, personnel, was compounded by the increasing influence and rise of physicians and medical specialists as well as generalist administrators who had little public health expertise (Banerji 1997; Fox 1989).[20] The literature notes that the leadership did not invest enough resources, attention and willpower as was required for strengthening and maintaining the TB programme, while investing far more in several specialized mass campaigns against other major communicable diseases like malaria, smallpox, leprosy and filariasis, with consequences which have proved to be catastrophic to the development of the general health services in the country (Banerji 1993; Qadeer 1994). Compounding this was the massively funded Family Planning programme, with built in pressures and incentives for target-achievement, as also the Universal Immunisation Programme, again, with built-in strong pressures for target achievement (Banerji 1993). The situation created by such neglect, Banerji writes, has often left the field "open to consultants from foreign countries/agencies to influence health policies and programmes of the country to subserve the interests of their organizations" (VHAI 1997).

Given this background, the Revised National Tuberculosis Control Programme (RNTCP) is criticized because not only does it completely ignore the deep and wide ranging epidemiological, sociological and socio-economic features of TB in India, but ignoring such key variables as maintenance of supply of drugs, or a strengthening of the referral system, or the orientation of the PHC physicians and teams, the revised programme singularly focuses on the issue of patient default and non-compliance, which is considered a major factor in creating drug resistance and poor rates of 'cure' (Banerji 1997; WHO 1995). It was the discovery of the re-emergence of TB and its linkage with HIV infection, as well as the increasing prospect of multi drug resistant TB in Western nations during the mid-1980s, that made TB control a point of pressure for the government of India during the late '80-early '90s.

This is the direct context in which the RNTCP took shape, where experts from the World Bank, the WHO and IUATLD, ignoring the history of the NTP in India, along with Indian government health officials, formulated an entirely new programme in the early 1990s (Banerji 1997). "RNTCP, according to DGHS, emphasizes on the cure of

infectious and seriously ill patients through administration of *supervised short course chemotherapy* (Directly Observed Treatment – DOTS in WHO terminology), to achieve a cure rate of at least 85 percent and to augment case finding activities to detect 70 percent of the cases only after having achieved the desired cure rate" (VHAI 1997).

The DOTS strategy was launched under the RNTCP during 1993/ 1997, where, in the backdrop of a collapsing general health service system, TB patients were made to visit DOTS clinics every alternate day during the intensive phase of treatment (the first 2-3 months of a 6-8 month course duration), and undergo monitored/observed treatment – geared to control treatment default. The perspective of DOTS and the kinds of treatment protocols it set up gradually gave rise to a scenario where timings of DOTS centres are not always geared to the work timings of people who need to use them; there is reluctance to register for treatment under DOTS those kinds of patients who may not complete the entire treatment, or do not show enough motivation at the outset; the existing eligibility criteria for registration cause a large number of people who need relief to fall out of the net, for instance, the requirement of proof of stable residence excludes various kinds of labouring classes, many of who have migratory cycles of work and life. There have emerged severe criticisms of the system of numerous clinic visits, which is very problematic for patients and totally disregards their lives and circumstances of work/ seasonal changes.

Inadequate primary health care infrastructure, drug availability problems, inaccessible and insensitive health personnel – all the bottlenecks that the NTP faced continue to exist (Jhunjhunwala 1994). The current phase of RNTCP is going ahead from roping in community actors to act as DOTS providers, to looking to involve NGOs and private healthcare service providers for providing treatment under DOTS. These seem to be steps in the gradual shifting of state-sponsored role and responsibility of providing public healthcare to various other players in the society – an underhanded way of putting 'people's health in the people's hands'. This move to the private sector spells further doom for TB patients who have minimal people-oriented, affordable and accessible care available to them.

Porter and Ogden note that the RNTCP has marked a significant shift away from social science issues in TB treatment and reiterates the biomedical aspect of TB as an illness.

It is no longer concerned with looking at the overall conditions of people's lives which foster illness. It is concerned with disciplining people's behaviours, wherein patients are subjected to 'directly observed treatment'. The underlying assumption being that patients are given to defaulting behaviour which then causes more problems for the country's overall health indices (Porter and Ogden 1999).[21] This perspective of the RNTCP is in direct contrast to Banerji's statement of how the NTP was conceptualized "principally to alleviate the suffering caused to the people due to pulmonary tuberculosis: *it was not visualized as a control programme – a programme meant to reduce the pool of infectors and infection*" (Banerji 1997: 9, italics added).

Two issues emerge strongly in the literature – (i) conceptualization, planning and structuring of the NTP catered to the needs, contexts and suffering of the patient, and thus upheld a public health perspective on health, illness and regarding the people who were impacted, and, (ii) the RNTCP obliterates the public health principles of the NTP because the former's singular emphasis is on controlling compliance failures among patients, regarding infectious patients as the most risky category needing priority attention, whereas the latter emphasized alleviation of suffering, viewing default as a function of the socio-economic-cultural and health service system constraints that patients faced.

While investigating these claims, I will attempt to show that the emergence of the revised programme was not a complete break from the existing ideas and rationales. I would hesitate to call the NTP to RNTCP shift a 'paradigm shift'; instead, I would label it 'repositioning', 'realignment', 'rearrangement'. These terms signify that even as the RNTCP brought certain aspects of tuberculosis epidemiology, diagnosis and treatment into the limelight and presented them as defining features of the new strategy, these, however, were constituents of the NTP policy and programme discussions too. The literature illustrates that these aspects were not *merely constitutive* elements, but they were *at the core* of a deep sense of dissatisfaction and frustration amongst the scientific community, which constantly debated the need for, and manners of, improving the potential success of the programmatic interventions.

These central aspects of dissatisfaction (some of which include, default, non-compliance, the need for motivating patients, long treatment duration, lack of

standardized chemotherapy regimens, cost-effectivity) drove the impetus for further research, programmatic innovations, alternative strategies in the field, trial studies, etc., all during the NTP itself. Elements of these very aspects can be identified in the turnaround in the TB treatment and control strategy between the 1980s and 1990s. The existing public health literature thus enables us to see that the principles and rationale behind RNTCP have an organic link with the NTP.

Default – compliance

One of the critiques of the RNTCP is that it is singularly focused on the issue of patient default; however, a survey of the NTI Newsletter shows that the issue of patient default was germane to the NTP too. True, studies at NTI like the Banerji-Andersen study were a radical departure from the norm, in that they questioned the traditional definition of a treatment defaulter as one who does not continue the treatment prescribed by doctors for at least twelve months as too technocentric, arbitrary and value-loaded. Instead, Banerji writes that their study

> offered a more realistic definition: a defaulter is one whose actions cause suffering to him/her or other members of the community, over a time span. Field studies revealed that health administrators were by far the worst defaulters. [...] some patients [however, existed,] who indeed inflict suffering on themselves, as on others in the community, because they fail to take their treatment. This, therefore, became an issue for a sociological study – why is it that some patients adopt such an obviously destructive or even suicidal attitude? (Banerji 1993).

However, even as the Banerji-Andersen study provided sociological insights into why patients were unable to maintain prolonged drug regimens, it *did not shift attention away from 'patient default' as a central issue* of programme management. On the contrary, one of the sociological insights which stated that it was organizational and administrative lacunae that created default, led to an instrumental approach towards patient default within the programme domain. A reading of the NTI Newsletter from its inception in 1964 till the mid-1970s – the decade on which the public health framework from which the NTP emerged would have had most impact – shows that the sociological and public health rationale and approach outlined by the Banerji-Andersen study could not always be translated into the demands of programmatic management in the field. The Newsletter, a forum for the exchange of views of tuberculosis workers in the field and those in the scientific research domains, is replete with articles lamenting

patient default, referring to the Banerji-Andersen study as a useful source of information that would help to *better the management and administration of risky patients.*

The scientific and programme-oriented literature from NTI Newsletter, IJT and also WHO documents during this period shows how sociology was a means for medical administration; the socio-political-economic contexts of patients were seen only in terms of how they affected the willingness and ability of patients to comply with therapy. Other considerations of these contexts which constrained patients from accessing and utilizing health services had a brief life in the subsequent volumes of the NTI NL, with most of the TB workers and programme planners writing on default adopting the instrumental approach – less visibly in the 1960s, but more clearly from the 1970s onwards. This instrumental approach to default laid the seed for later articles on the importance of motivation of patients before and during treatment, on various means and ways of conducting retrieval actions for defaulters, on the need for behavior change among patients,

In the very first volume, M. Piot identifies irregularity in treatment as a serious cause for concern (Piot 1964). Proper motivation of the patient before start of treatment and defaulter retrieval after that is emphasized as a main method of countering the problem of irregularity, which along with drug resistance is identified as 'the two important snags' of modern TB treatment (Nagpaul 1968). Some of the problems faced in "control of tuberculosis include, (i) incomplete investigations due to non-cooperation of patients, (ii) irregularity in drug collection, (iii) irregularity in attendance for check up, (iv) refusal to continue treatment, (v) non-cooperation in contact examination, (vi) sputum disposal and isolation of bacillary cases, (vii) lack of nutritious food and rest specially during fertile stage" (Nath 1968: 111). In spite of identifying fear of social and economic insecurities which befall a TB patient as one of the factors responsible for irregular drug intake, patients are still blamed for defaulting (Nath 1968).

Articles show that defaulter actions can cause the status of TB patient to be known to others in the community, and so one must be careful in doing defaulter retrieval. Setting this caution aside, there are other studies showing that home visiting is much better than sending a reminder letter because the impact on regularity is greater, even though

visiting has a higher cost (Seetha and Aneja 1977).What needs to be remembered is, "for effective results in the programme, a certain amount of modification of the day to day behaviour of the patient has to be brought about. This modification is necessary for the control of any disease" (Sudarsanam 1977: 91). Articles discuss the various facets and benefits of the psychological tool of 'motivation' for sustaining regularity in drug intake over long periods among TB patients.

> A motive is defined in psychological literature, as an impelling power which prompts or induces an action. Hence to motivate would mean to provide this urge to act, *assuming that the individual by himself does not have the motive or that the motive is not strong enough for the desired action.* [...] To the extent motives can be studied through a person's behaviour, verbalization or action, *it is possible to understand, control, direct or change (including addition and cummulation) motives to suit the type of action desired* (Narayan and Pramila 1972: 21).

The issues of irregular drug intake over the prescribed period of TB treatment, default from treatment, and recovery of defaulters thus were enduring themes in the articles, letters and editorials on the NTI Newsletter, showing that default and compliance were perpetual factors causing anxiety among NTP programme workers and planners. And one of the major reasons that were identified in the field conditions of the NTP as to why patients didn't take drugs or stopped them prematurely was the prolonged period of 12-18 month regimens of conventional therapy. This was understood as leading to treatment failure and also to drug resistance. It was thus the desire to address this lacuna – of default linked to prolonged treatment duration – that drove the impetus "for exploring the possibilities of evolving an effectively and operationally feasible short course therapy which, because of their short duration might enable better case-holding and contribute to a more successful outcome of chemotherapy in National Tuberculosis Programme (NTP)" (Aneja 1977: 46).[22]

'Control' programme – reduce the 'pool of infectors'

Another critique of the RNTCP is that it is a 'control' programme geared singularly towards the sputum smear positive tuberculosis case, i.e., the most infectious category. Banerji has argued that, contrary to this, the NTP was conceptualized "principally to alleviate the suffering caused to the people due to pulmonary tuberculosis: *it was not visualized as a control programme – a programme meant to reduce the pool of infectors and infection*" (Banerji 1997: 9, italics added).

The NTI NL literature shows the NTP being regularly addressed as a control programme, and often in military idioms. Writers note that the emergence of this programme "was made possible through the use of the modern Operations Research technique which so far has been applied mainly in fighting wars and increasing production in factories" (Nagpaul 1968: 14). Further, "the aim of treatment of tuberculosis should be three-pronged, to relieve the suffering, to stop transmission of bacilli and prevent emergence of drug resistant organisms" (Gothi 1968: 74). And this was also a cost effective technique,

> limitations of resources and the requirements of community control of the disease also emphasized that the really infectious cases should be given priority in both casefinding and treatment. Sooner this new strategy is implemented throughout the country, the greater will be the conservation of resources for a more effective attack on the disease leading to control of tuberculosis (Gothi 1968: 75).

Epidemiologists illustrating the dynamics of TB with diagrams note that "Class D [in the diagram] constitutes the important group being capable of spreading infection. This class must be first identified and appropriate measures should be taken to prevent transmission of infection by treating them effectively." More important information follows in the same article,

> the information on the rates of excretors of drug resistant organisms in the country and their infectivity is of paramount importance for planning tuberculosis programme. If it could be proved that the infectivity of the drug resistant organisms is poor or low, *then the public health workers need not become panicky even if the rates of drug resistant excretors among treated groups of patients increase.* On the other hand, *if they are as infectious as the excretor of drug sensitive organisms, then adequate preventive and curative steps will have to be taken to prevent transmission of infection by them* [....] Lastly, the most important aspect of formulation of the tuberculosis programme is that of the distribution of available resources so that *not only felt-need of the society is satisfied, but also the epidemiological returns of the investment are maximized* (Gothi 1970: 12, italics added).

Among the main programme principles outlined by the NTI in an article in its Newsletter in 1970, is to "concentrate first upon the epidemiologically important group of infectors (in order to break the chain of infection)" (NTI 1970: 14). The main diagnostic tool to be employed for this is sputum microscopy, which "is cheap, easy and can be done by nonspecialised personnel, but we diagnose only cases and not suspect cases. Moreover, the epidemiologically important group of cases is diagnosed" (Narang *et al* 1971). And highlighting the fact that the Banerji-Andersen study showed

that of the sputum smear positive patients 95% were aware of one of the four symptoms, meaning that "sputum positive cases not only suffer more but also the depth of their suffering is motivation enough to make them seek medical relief," writers have shown that those who have highest awareness and highest felt need must be addressed first (Jagota and Aneja 1977: 116). Using the Banerji-Andersen study's insights to urge prioritization of the most infectious cases is, thus, only the most epidemiologically watertight way of clubbing together 'risk infectious cases pose to others' with 'their suffering is highest'!

Finally, it needs to be acknowledged that in the phase of NTP the Indian programme did not always echo all the elements of the global stage. Indeed, in studies emerging from the NTI there was a difference of tone and approach between the global scenario and Indian scenario of TB management. The Banerji-Andersen study brought to the fore several issues which enabled the introduction of several new concepts into programmatic and management discussions.

> Since NTP purposely subordinates technology to the people rather than the other way round, the programme formulators took special care to ensure that technology used in the programme was based on consideration of (a) limitation of the resources, (b) knowledge about cultural meaning and cultural perception of the problem, and (c) the health behaviour generated by the cultural factors and access of people to technology. The people-oriented approach to technology enabled NTP to withstand pressures for inclusion of the then emerging technical advances such as tomography, mass radiography, advanced thoracic surgical techniques and large scale use of expensive second line drugs in NTP (Banerji 1993: 66).

By the period of the 1980s, however, the chemotherapeutic and technical aspects of TB management, that had first been delineated in the TCC domiciliary study, regained ascendancy and the work and approach of the NTI started becoming sidelined.

Literature suggests that the Indian NTP, especially elements inspired from the NTI studies, challenged the conventional global understanding of TB, and provided a model for new ways of thinking about TB management during the 1960s-70s.

> There were also workers from abroad, like Halfdan Mahler, Stig Andersen and Wallace Fox, who joined their Indian counterparts in this challenging venture. Many of them might have been in favour of a specialized tuberculosis programme, as it was then practiced in Western countries. However, they were open minded enough to subject their ideas to scientific test. When the NTP presented a better alternative, after some initial hesitation, they strongly supported it, including the then nascent sociological orientations. They took the ideas to the WHO Expert Committee on Tuberculosis and

> could convince them to bring about fundamental changes in the WHO programmes (Banerji 1993: 69).

This, however, seems to be true only in the case of certain things – case detection through 'passive' case finding (sputum smear microscopy for chest symptomatics presenting at a health facility), case definition, sputum diagnosis, domiciliary treatment, integration of case-finding and service delivery within general health services, to name a few.

In the case of several other ideas/ concepts, the global and WHO literature continued to hold the same perspectives as they did before NTI/ NTP. While writing about WHO-NTI collaboration, Banerji's articles stress the social science-inspired multidisciplinary approach to the creation of the NTP. But from Mahler's ideas, as expressed in IUAT meetings (Discussion of the Eighth Report of the WHO Expert Committee on Tuberculosis) and elsewhere, and WHO's ideas expressed in the WHO 1949-64 document, for instance, it appears that all the social science components were not taken on board seriously. The idea of stopping transmission of tubercle bacilli, of making sure that patients take their drugs for the full recommended period, the need for supervision to ensure that they do this, the importance of mathematical modeling – all these are constantly reiterated in the literature before as well as after the Indian NTP emerged on the scene.

Another kind of disjuncture that is evident in the literature is that in the case of many other concepts, the literature stated one kind of perspective, which was tuned into socio-economic-cultural-political contexts, but operationalization in the field continued to be guided by a biomedical, management-oriented perspective. So, for instance, while it is true that the Banerji-Andersen study's non-biomedical and sociological perspective focused on patient perspective and experience, it is also clear that its translation on the field meant that this got transformed from sociology into medical administration and got utilized instrumentally. On this point, historian Sunil Amrith writes that attention taken away from conventional definitions of default led instead to the foregrounding of organizational-administrative problems which meant that success lay in setting right the administrative-organizational-management of TB, setting aside any further discussions on socio-economic-political questions (Amrith 2004).

This then spawned a series of studies within the NTP, focusing on eliminating/ minimizing these organizational-administrative factors. These included,

- Studies on relationships between various human actors as part of the medical encounter – doctor-patient relationships, relationships of patients with other health personnel or para-medical staff, etc.
- Organizational studies of various health institutions, their functioning, accessibility, infrastructure, service delivery, administrative set ups, recording/ reporting and referral system, training, supervision, communication, distances, characteristics of the population and area (Venkateshaiah 1969).
- Studies on education and training of health personnel, medical and training institutions and institutional cultures, etc. Need to change the approach by which medical sciences are employed to bring about social change; need to re-orient existing notions about epidemiology of the disease; need to give equal importance to understanding the non-medical (social science and interdisciplinary) perspectives regarding health issues (Banerji 1971).

This then makes us pause and ask, is it only a case of good design being wrongly implemented, or does it force us to re-look at the design as well? On doing so, we can see that the B-A study did reflect a deep and abiding influence of an administrative-managerial perspective. But alongside saying this, we also have to remember that this is only a reflection of the wider mandate of public health – which, as an applied field of health, demands operationalizable solutions that will have a positive impact on the maximum number of people within cost effective means. Thus we can see that public health perspectives cannot always be translated into the demands of programme management. Not only that, programme management demands may often conflict with and reduce the possibly political edge of public health perspectives. This discussion will be elaborated further in the following chapter.

Governmental & non-governmental action, international collaborations, indigenous science, global public health

Indian scientific institutes of the immediate post-independence period were set up under the auspices of the international scientific community, mostly WHO and BMRC. The British Medical Research Council's (BMRC) Tuberculosis Research Unit

conceived and set up in 1956 the Tuberculosis Chemotherapy Centre, Madras, playing the main role of scientific advisor with WHO providing administrative and equipment support for several years. As part of the scientific and technical expertise that WHO was committed to providing to developing countries in the post-war period it helped conceive and set up the National Tuberculosis Institute (NTI) at Bangalore in India in 1958-59. Leading scientific and technical positions in both institutions were occupied for several years by WHO/ BMRC experts.

These two institutions were at the core of all TB-related scientific developments in India for the next few decades. Controlled trials, chemotherapy studies, epidemiological surveys, etc., were all conceived, planned and carried out in patient populations accessing, or identified by, these institutes. In the early years many of the scientific, technical and advisory positions in these institutions were held by WHO/ BMRC experts. The power to conceptualize and set the research agenda was in their hands (more so in the case of TCC than NTI), even though the research was conducted to address pressing demands and issues arising from the Indian context.

What exactly were these pressing demands and issues arising from the Indian context? The literature shows that lack of adequate resources – fewer sanatoriums and hospital beds as compared to the large numbers requiring TB treatment, and expensive and prolonged therapy regimens in these facilities which were out of reach of the majority of patients – was the main problem in the Indian scenario. This problem attracted scientific expertise and assistance from the wider international community, some of whom had been doing research in alternative modes of therapy such as ambulatory treatment in other locations of the world. This problem can be identified as one of the main issues that inaugurated the era of international collaborative research in TB in India.

Research conducted in these two premier Indian institutes are celebrated in the Indian TB literature as indigenous efforts carried out in spite of several constraints characteristic of a newly independent country. The non-Indian TB literature also acknowledges the important role played by these institutes and their research studies towards the global application of several TB control and management apparatuses. However, a close reading of the existing literature on TB policy and planning in the

Indian as well as global domain suggests that to read this as *indigenous Indian research* is more than slightly disingenuous. In order to better understand the role and functioning of these institutes in the development of initiatives for TB management and control a more multifaceted investigation into the *larger frame of collaborative research within which they were established* is therefore needed.

Exploring the dynamics of collaborative research by looking at the background story of ideas/ rationales, actors, context-specific processes of the knowledge paradigms that constituted them is only one of the ways of studying policy processes and subsequent planning and implementation of programmes. Social policy analysts associated with the London School of Hygiene and Tropical Medicine such as Gill Walt, Jessiga Ogden, Louisiana Lush and others have made significant contributions to this field of enquiry. The following discussion of collaborative research, showing up the fuzzy boundary lines between Indian and global research developments owes much to their framework of studying the processes behind policy transfer and policy formulation.

The nature and importance of these collaborative relationships, and the processes of their interlinkages, will throw further light on the development of two initiatives for TB management and control, which I will discuss in the following chapter. These are, (i) the issue of handling patient default/ non-compliance in drug intake, and (ii) the issue of estimating the risk that a person in a given community faces of becoming infected with mycobacterium tuberculosis, measured as Annual Risk of Infection.

BMRC-TCC

Starting from the mid-1940s, the British Medical Research Council's Tuberculosis Research Unit (known simply as BMRC in the TB literature) occupied a very important place in the international scientific community in the area of TB research. Among its several research units in different parts of the world, its collaborative site in Hong Kong had opened the first ever clinic for mass ambulatory care for TB in 1950, eight years before the reports of the Madras trials (Bayer and Wilkinson 1995). Thus, given the disparity between needs (of large number of patients) and resources (fewer number of beds) in the developing countries of Africa and Asia, BMRC had begun studying

alternative modes of therapy, such as clinic-based, ambulatory therapy right from the 1950s.

The Tuberculosis Chemotherapy Centre at Madras was established in 1956 under agreements between the Indian Central Government, the Madras State Government and the WHO, and between the WHO and the British Medical Research Council, in order to study the applicability of ambulatory therapy in mass programme settings (Fox et al 1999). BMRC research in its Indian unit at TCC reflected its wider research agenda, of finding solutions for the TB-related problems of the developing world marked by lack of resources, high cost of drug regimens that were being used in developed countries, and lack of technical know-how, among other things. As in the BMRC-TCC collaboration, its activities in its sites in Hong Kong, Singapore, East and Central Africa were similarly led by its experts in all leading scientific and decision-making positions.

Recounting the birth of the TRC, Wallace Fox writes,

> I became the Unit's first Director, under secondment to the WHO, and had the task of *implementing the scientific direction of the project which was the responsibility of the BMRC.* This entailed *establishing and training a research group* and *setting up an outpatient clinic and a domiciliary service from scratch* as well as *supervising the Tuberculosis Chemotherapy Centre's* (subsequently named the Tuberculosis Research Centre) (TRC) *patients in Tambaram Sanatorium* just outside Madras *where 100 beds had been put at our disposal.* Professor D.A. Mitchison came out to Madras in 1956 for a year and *built up the bacteriological and biochemical laboratory, essential for the controlled clinical trials, set up other important research studies and became a long-term consultant and collaborator* (Fox 1990: 175-176, italics added).

Writing about the development of the NTI close on the heels of the TRC, he writes,

> Thus, there were 2 institutes in South India 220 miles apart, *Madras with the remit of the intensive study of chemotherapy and its scientific basis as well as epidemiology*, for example the risk of contact infection from domiciliary therapy of index cases and the level of drug resistance in new cases of tuberculosis, *and the NTI concentrating essentially on training district teams, the operational problems of programme application and on epidemiology.* (Fox 1990: 176, italics added).

Apart from the epidemiological and training mandates, Fox et al emphasize the technical mandate of the BMRC Units across the developing world thus, "[a]n equally important aspect of their work was the *introduction of scientific method into the development programme.* They undertook one of the first randomised clinical trials

ever done in medicine, *and continued to use the controlled trial to develop effective regimens of treatment and to study control policies*" (Fox et al 1999: S232, italics added).[23] In the absence of notification procedures in the developing countries, Fox also credits BMRC with developing standardized tools and techniques for conducting surveys to collect information on chemotherapy-related pre-treatment and treatment characteristics of patients.

Fox writes,

> It was possible to do [representative] surveys because Dr Pierce Kent (subsequently Director of the East African Tuberculosis Investigation Centre) had established in the mid-1950s a treatment register in each district and every patient brought under treatment in the district had their identification details recorded in the register. The same district register system was specifically introduced in Tanzania by Dr R Doyle so that it would be possible to conduct the first representative survey in 1969, and a second one in 1978/80 at a time when the National Programme was in a state of reorganisational upheaval and the registers were not properly kept. As with Kenya, the central laboratory used BMRC methods, and was supervised by a seconded senior technician from Professor Mitchison's Unit. *This district register approach has been adopted in other countries, becoming, for example, in the last decade a standard and central feature of the International Union Against Tuberculosis and Lung Disease mutual assistance programmes* (Fox 1990: 201-202, italics added).

Explaining the purpose behind BMRC collaborations in various sites, Fox et al write,

> Collaborations outside Britain were established partly *because large numbers of patients were available in these countries*, but also because the needs of the countries differed widely in terms of the type of drug treatment that they could afford, in the organization of their tuberculosis services, for instance in availability of out-patient clinics and sanatorium beds, and in their social attitudes to the disease (Fox et al 1999: S232, italics added).

The *presence* of a large number of patients in these countries usually translated into *availability* of these large numbers for research purposes; thus, the importance of the Tambaram Sanatorium near Madras was not least because it made available *study subjects* for the early research studies. That such large numbers of study subjects would be *put at their disposal* was a very attractive proposition for organizers of chemotherapy trials.[24]

Thus, not only were these institutions set up, headed and directed in the beginning by WHO/ BMRC experts, but the literature enables us to see that new research in these new institutions represented further trials of research trends already charted out – (i)

conducting research on *two issues already identified as potentially important* from other BMRC and WHO researches in Hong Kong, British and African sites (Fox et al 1999; WHO 1965): the risk of contact infection from domiciliary therapy of index cases, and the level of drug resistance in new cases of tuberculosis; (ii) setting up and *training research groups to conduct research according to these identified themes*; and (iii) of *establishing standard scientific methods* to conduct these studies. The aim of further international research was to search for the best and most fruitful sites to set up more institutions, so that the kind of research solutions that had begun to be envisaged in these study sites – in the era when newly available antibiotics were being put to the test in mass programmes in these countries – could be further fine tuned, and tried and tested in different kinds of developing country populations.

And even though BMRC recognized that different countries had different needs, the offered programmatic/ chemotherapeutic solutions did not always speak directly to the specific shape, structure and complexity of the TB problem in each country. A scientific response to the problem of TB was not necessarily tuned into the context of *each specific* region/ country, its social, political and economic history, its status in the contemporary world, in terms of resources and constraints, etc. What was being termed 'needs of the developing nations' was often a broad and extremely apolitical understanding of the lack of resources and high presence of disease in these nations. Thus, even as India needed support to tackle its massive TB problem, the format/mode of the solutions expected from research studies in these new national institutions set up by international scientific expertise was structured by broad and sweeping generalizations about developing countries as a *singular, undifferentiated whole.*

Sunil Amrith helpfully points out that the search for global level policy and programme ideas during this time necessitated the ability to make generalizations – *research had to be universalizable.* That results emerging from any of the developing country sites must be amenable to replication and adaptation to all and any other developing country locations was of paramount importance; of necessity, this would lead to overlooking the specificities of countries and their populations. Providing us with a glimpse of the underlying tensions resulting from a divergence of thought on this matter in the WHO-BMRC collaboration as it played out in TCC, he writes, "the tension between scientific research [...] and the practicalities of public policy, was present from the early stages

of the research in Madras. The conflict focused on the balance between the necessary complexity of such a trial, and the need for results that could be put into practice as policy" (Amrith 2004: 124).

Discussing correspondence between Wallace Fox and Johannes Holm, WHO's chief advisor on TB at the time, Amrith writes,

> Holm was of the impression that Wallace Fox and his team wanted to 'do everything possible for each one of your patients, including those who have deteriorated after the treatment in the trial to which they have been allocated; that is *those patients who, for the purposes of the trial, can be described as failures and thereafter can be of little or no scientific interest.* I realize that this is from humanitarian or, if you prefer it, clinical considerations and feelings.' For Holm, however: 'The objectives of the project as I see them – and I think WHO in general – are somewhat different. They are to study the effect, in terms of rendering infectious patients non-infectious and keeping them so, of treatment that is inexpensive and which consists of self-administration of drugs with no close clinical supervision by experts and with no complicated laboratory tests.' (Amrith 2004: 124, italics added).

Amrith also points out that the collaboration between BMRC and the Indian actors was not exactly smooth either. Noting that the BMRC-TCC collaboration was a fundamentally hierarchical enterprise marked by conflict and contradiction, he writes,

> From the outset, there was a degree of institutional manoeuvring for control over the project. Internal memoranda within the BMRC expressed concern that 'a local Indian director is envisaged if a suitable candidate is available', and *insisted in negotiations that the 'WHO/ MRC leader has full scientific control of the research unit'.* Archival sources point to lingering tensions between the WHO and the BMRC, as well as between the WHO's regional office in Delhi and the organization's headquarters in Geneva. Administration of the project also rested on an ambiguous relationship between the central Indian health ministry, and the state government of Madras: both the BMRC and WHO were under the impression that 'the Madras authorities have decided to retain as much administrative control as possible' (Amrith 2004: 115, italics added).

A keen archivist of the social history of medicine in India, Amrith has interpreted such an outlook to mean that the decade of the 1950s-60s saw urban South India serve as a "global 'laboratory' for the study of tuberculosis" (Amrith 2004: 113). He notes that this enterprise of collaboration in TB between the Western and Indian scientific community enables "an interesting study in the relationship between knowledge, technological change and policy" (Amrith 2004: 113), whose ultimate result he writes was a policy paradigm "focused almost exclusively on the distribution of anti-TB drugs around the world, as a commodity to be supplied" (Amrith 2004: 115).

In an article reviewing its four decade history in addressing TB, BMRC applauds the role it has played in helping to provide all the solutions that could be needed world over for TB control; needless to add, the development of techno-scientific tools has been at the centre of their work.

> When the units were closed in 1986, all of the measures necessary for successful programmes for the control of tuberculosis had been delineated, particularly the regimens of treatment to be used, the need for full supervision of drug-taking (DOT) and the use of surveys to measure the extent to which national programmes were finding and treating infectious disease. These tools were then available to national organisations and to international organisations such as the World Health Organisation (WHO) and the International Union Against Tuberculosis and Lung Disease (IUATLD), to implement in control programmes (Fox et al 1999: S231).

WHO-IUAT

While the primary role and mandate of the WHO-BMRC research was the development of *chemotherapeutic and technical tools* for TB therapy and management, the defining feature of the IUAT was the development of *models for national tuberculosis programmes* across the world. Often, BMRC tools were available for use by WHO-IUAT, and WHO-IUAT support for global NTP development proceeded on the basis of tools developed by BMRC.

Since its inception WHO has had a close collaborator in the International Union Against Tuberculosis (IUAT), a specialized non-governmental organization based in Paris doing advocacy and scientific research in TB through its own units in several countries. While the WHO functions at the inter-governmental level in countries across the globe, the IUAT functions at the non-governmental level; this connection deriving from the "WHO's acceptance of the Union into official relationship in November 1948, in accordance with WHO's rules for co-operating with non-governmental organizations. *The Union is the only organization in the field of tuberculosis which has such a relationship*" (The Extended Programme of the International Union Against Tuberculosis 1963: 106, italics added). Bound by the fact that the constitutions of the two organizations do not allow formal and official co-ordination of activity, "it is the desire of the Union that there be the *closest possible unofficial co-operation between the two bodies*" (ibid., italics added).

In the context of scientific advancements in diagnosis, treatment and prevention of chemotherapy for TB during the 1950s, the IUAT embarked on a change of course, crystallizing an Extended Programme in its Fifteenth International Conference at Istanbul in 1959. This Extended Programme meant that,

> considerably more emphasis should now be placed upon certain functions which have not in the past had such emphasis. This means particularly: a far broader programme of health education on tuberculosis; considerably more contact with and assistance to national tuberculosis associations; and *pioneering work to collect knowledge and experience which will assist in planning tuberculosis eradication programmes* (ibid., 107, italics added).

Towards this end, the IUAT pledged to "provide WHO with full information for that Organization's comments and suggestions," enable each "national tuberculosis association [to] exercise a function of public surveillance of the official government programme in its country", "assist in creating well-informed public opinion and support" for WHO's programmes, and also "utilize its influence, through its Constituent Members, to obtain the necessary support for WHO tuberculosis activities" (ibid., 107).

Starting from the 1960s then, one of the IUAT's main roles was in ensuring that there be "authoritative technical recommendations widely available and widely accepted (*ibid.*, 111)."[25] The reasons for setting up such international technical recommendations were, firstly, "to make the latest knowledge and experience available in *suitably digested and understandable form* to the personnel engaged in the planning, execution and evaluation of national tuberculosis programmes"; and, secondly, "to make possible the useful exchange of knowledge and experience among different countries, the *results of the tuberculosis programmes must be comparable.* For comparable results it is not sufficient to employ the same terminology; it is essential that the same methodology and techniques should have been employed" (ibid., italics added).

The IUAT asserts that

> *[b]ecause of the close collaboration with the Union, constantly demonstrated by the medical profession, research workers and research institutions in all parts of the world, the Union is in a particularly strategic position to formulate technical recommendations. Through its own channels and through the Constituent Members, the Union is further able to achieve wide distribution of such recommendations, and wide acceptance*"(ibid.112, italics added).

Taking care to avoid conflicting recommendations by the various participants in the international TB programme, the IUAT suggests that,

> before publication of the Technical Committee's recommendations, the Technical Unit at WHO headquarters in Geneva should be given an opportunity to *express an opinion. It is understood that this will be done on an unofficial basis* and that the recommendation will be published wholly on the responsibility of the Union without any reference in the final text of such publication to WHO's agreement or disagreement (ibid.113, italics added).

The WHO has reciprocally attested this important role of the IUAT in global TB control activities, treating it as at par with WHO and its partner organization UNICEF. The WHO Expert Committee on Tuberculosis' Eighth Report, 1964 – which, adopting the epidemiological paradigm emerging from the Indian research sites set the benchmark for future TB management in national programmes – included apart from members from WHO, BMRC, current and retired heads of governmental TB departments from USSR, India, Chile and Australia, a Professor of Medicine from Yugoslavia and the head of the National Tuberculosis Association of the USA, a representative from IUAT (WHO 1964). Another member, the Chief of Laboratories of the Parisian Pasteur Institute, later went on to join the IUAT. Endorsing a statement made by the IUAT which said "although the chief responsibility for control lies with governments and public health authorities, these same authorities cannot do everything," and the "effectiveness of the official programmes can be considerably increased if the action of the public health authorities is supplemented by that of voluntary associations," WHO urged that "*the closest co-ordination should be maintained between the official and voluntary tuberculosis agencies* in order to eliminate competition and duplication" (WHO 1964: 24).

The shift that Johannes Holm made, from being Head of the TB Unit at WHO in 1959 to becoming the Executive Director of the IUAT in the next few years, is testimony to the traffic of personnel between these two organizations. Further, in the case of apprehensions of disagreement between positions of WHO and IUAT, as happened after the 1964 WHO Expert Committee's Eighth Report, meetings and consultations were held between these two organizations in order to smooth out the differences and speak in one voice to the global TB management community (Discussion of the Eighth Report of the WHO Expert Committee on Tuberculosis 1965). Joint consultations and

meetings between the two organizations have impacted TB policy and planning, as in the case of the Joint IUAT/WHO Study Group on Tuberculosis Control in 1981 (WHO 1982) – which was labeled "the meeting of the century" by some Indian officials (Rao 1984: 48).[26]

In a 1965 review document *International Work in Tuberculosis 1949-1964*, on the prefatory page itself, WHO is at pains to point out "The title of this review does not imply that all international work in tuberculosis control is carried out by WHO. The valuable work against tuberculosis of the International Union against Tuberculosis and other governmental or private organizations is well known and has been the subject of many other publications" (WHO 1965: 4). The text of the document further elucidates the close relationship between WHO and IUAT, "[t]he International Union against Tuberculosis (IUAT) gives valuable support to WHO's tuberculosis work in many ways, e.g., through research activities undertaken *on behalf of or in co-ordination with WHO*, the dissemination of information about WHO-assisted activities in its publications, and the encouragement of national tuberculosis associations" (WHO 1965: 21). Having given the IUAT due credit, the document proceeds to chart out global TB control efforts; with no other organizations finding mention in the document. The fact that after WHO's partner organization UNICEF, a single voluntary and non-governmental body, the IUAT, is accorded the same platform as WHO, is an indication of the phenomenal role that IUAT played in global TB management efforts of that era.

Since the 1980s on, WHO's collaboration with IUAT has to be located in the larger context of the shifting power and influence of various international organizations in the global health arena. Writing about the WHO's declining role and influence in this period Walt et al note that "[a]lthough the organization had traditionally enjoyed considerable authority within the UN, in the late 1980s and 1990s its legitimacy as an international agency was challenged" (Walt et al 2003).[28] Charting the shifts in the field of global TB policy and planning during this period, they point out that WHO were "*reactive* rather than *proactive*" in getting TB on the health policy agenda, with other agencies taking the lead in agenda setting (Ogden et al 2003: 183, italics in original).

In the mid-1980s, the World Bank undertook a cost-effectiveness study of different health interventions as part of a health sector priorities review, and highlighted the need

to address TB (Ogden et al 2003). Further, it was an independent *ad hoc* Commission on Health Research for Development, set up in 1987 at Harvard University, that drew attention to tuberculosis as the most common preventable cause of death among adults in developing countries, yet neglected and with little research devoted to it (Walt et al, 2003; Ogden et al 2003). Walt et al write that this Commission "was a body of high-level international public health elites – independent scientists, academics and members of non-government organisations – linked to international organisations such as the World Bank and WHO. Key individuals working with the Commission included an economist then based at Harvard, but working closely with the World Bank on a burden of disease study" (Walt et al, 2003).

Analyzing the connections between WHO-IUATLD[29] in TB in this context they point out that, "[m]embers of the Commission met [Karel] Styblo, one of the few in public health doing operational research, and based on [his] work in Tanzania, did 'a very crude benefit/cost calculation' (Interview WHO, 2000) of Styblo's approach, which indicated that his use of short-course regimens, even in these poor country settings, was cost-effective" (Ogden et al 2003: 183). In the economist's words, "as part of the background work we did, there was a very simplistic assessment that I did for the Commission on the size of the health problems – very crude, back of the envelope, potential years of life lost. Whenever you do something like that, tuberculosis comes top [Interview WHO, 2000]" (Walt et al, 2003). This was a "startling finding" which provided a crucial link between field-based, small scale trials and large scale programme implementation, and

> led WHO to organise an evaluation of three countries where the IUATLD had set up sites to pilot Styblo's strategy: Tanzania, Malawi and Mozambique. An article published as a result of this work declared that '*in terms of costs per death averted and per year of life saved, chemotherapy for smear positive TB is the cheapest health intervention available in developing countries*' (Murray et al., 1991, p. 1307). The outcome of this evaluation was to establish for the first time the legitimacy of using short-course regimens in developing countries (Ogden et al 2003: 183, italics in original).

In sum, even a cursory look at WHO's early research studies, publications and committees related to TB reveals constant traffic between WHO and IUAT. This reflects a traffic of experts, ideas, ideologies and practices, where the literature shows IUAT-conducted researches paving the way for WHO-directed global policy for TB

management and control. WHO's early role at the forefront of global TB management efforts was largely supported by the advocacy as well as technical operations that the IUAT undertook in several countries, as an equal partner of WHO. Often this complementary role was enabled by the fact that IUAT had the "flexibility of approach and action of a non-governmental agency, [which] can be useful in promoting joint programme activities" (WHO 1974: 40). In the period after the 1980s, however, the connections between WHO-IUAT were crystallized in a new form by the World Bank's emerging presence in international health, marked most notably by its ability to insert cost effectiveness discourse into health sector analysis.

The World Bank's influential role in global health, especially TB, was also sealed during this time by the fact that following the Commission's report in 1990 and Murray et al's study in 1991, WHO and the World Bank worked together to get the Chinese government to introduce a DOTS programme, "essentially testing the implementation of Styblo's approach there with a World Bank loan of US$50 million" (Ogden et al 2003: 183). "Considerable pressure was put on the Chinese government to agree to the implementation of such a programme (Interview with ex-WHO official, 2000), and the introduction of a DOTS programme in China was seen as a major coup – the chance to demonstrate that DOTS would work in a large, highly populated, high tuberculosis burden country" (Walt et al, 2003). In spite of such a thickly intertwined relationship between the WHO and IUAT, the latter is discussed/ written about much less than WHO in the wider TB literature; this hidden face is surprising (and misleading) given the highly influential position it occupies in the global TB research, advocacy and policy making arenas.

End Notes

[1] See also K. N. Rao (1966) 'Tuberculosis Problem in India' *Ind. J. Tub.*, 13 (3): 85-93.

[2] This appears an instance of contested history. The Annals of the NTI note, "However, after the War, even though India was being ruled by the British, it is to the credit of the government that they recognized TB as a major problem. They established a TB Division in the DGHS in 1946, with the Adviser in TB as its head. TB was also given a prominent place in the planning" (p 11). The book *Tuberculosis Control in India* (Agarwal and Chauhan 2005), however, notes, "The first step taken by the Central Government in independent India was to establish a TB Division in 1947 in the Directorate General of Health Services of the Ministry of Health, with an advisor in TB as the head. Planning and execution of anti-TB activities were greatly facilitated by this Division" (p 16).

[3] Niels Brimnes notes that the ITC was initiated as a Scandinavian effort, inaugurated by Denmark. See Brimnes, Niels (2007) 'Vikings against Tuberculosis: The International Tuberculosis Campaign in India, 1948–1951' *Bulletin of the History of Medicine* 81 (2): 407–430.

[4] While writing the history of 'Indian TB management efforts' we must not lose sight of the fact that in the early decades of the 1900s 'India' was not only a conglomerate of provinces and princely states under British rule, but also included the territories that are today's Pakistan and Bangladesh; it was thus not a *national* entity like we recognize in today's territorial, citizen-ly or social-cultural sense. Curiously, in the process of recording a broad sweep of history, references in the Indian TB literature to the period before Indian decolonization gloss over this fact.

[5] 'The Mutual Assistance Programme of the International Union Against Tuberculosis' (1963) *Bulletin of the International Union Against Tuberculosis* 33 (2): 116-135. This is a document prepared by the Executive Director of the Union, presented as Annexure 6, at a meeting 'How can the voluntary bodies best assist in the global attack on Tuberculosis: A Panel Discussion'.

[6] Editorial (1962) *T* No. 3, July. *T* was an auxiliary magazine of the IUAT, in addition to the existing *Bulletin of the International Union Against Tuberculosis*

[7] Interview with Thelma Narayan, Centre for Public Health and Equity, 2009. See also, Narayan Thelma (1998) *A Study of Policy Process and Implementation of the National Tuberculosis Control Programme in India* Unpublished PhD Thesis, London University.

[8] There is a lack of clarity on this point, though, because the *IJT* records his term as IUAT President from 1955-57. See Obituary *Indian Journal of Tuberculosis* (1973) 'Dr. P.V. Benjamin no more' *Indian Journal of Tuberculosis* 20 (1): p 33-34.

[9] TAI's contribution to the Union is the largest sum of the 5 grants and contributions made by TAI in 1984 – Rs. 15,000 to New Delhi Tuberculosis Centre; Rs. 1000 to Eastern Region of IUAT; Rs. 2573 to New Delhi TB Centre for medicines to indigent patients; Rs 5040 as contributions to institutions. 'Statement of Income and Expenditure Account for the year ended December 31, 1984' p 56. TAI Annual Report 1984.

[10] These were all Western European, mostly Scandinavian, countries.

[11] 'The Extended Programme of the International Union Against Tuberculosis' (1963) *Bulletin of the International Union Against Tuberculosis* 33 (2): 94-115. This is a document prepared by the Executive Director of the Union, presented as Annexure 5, at a meeting 'How can the voluntary bodies best assist in the global attack on Tuberculosis: A Panel Discussion'.

[12] See for instance, WHO (1974) Expert Committee on Tuberculosis Ninth Report, *WHO Technical Report Series* 552, where the WHO notes that one of the advantages of working jointly with IUAT is that it has the "flexibility of approach and action of a non-governmental agency" (p 40).

[13] TAI (2001-2002) Donation form, Adm.30/2001-2002. See Annexure 1.

[14] Tuberculosis Association of India (1984) Forty-Sixth Annual Report 'Association Accounts', p 43. New Delhi.

[15] Tuberculosis Association of India (1987) Proceedings of the Forty Eighth Annual General Meeting, 22nd April 1987, 'New Delhi TB Centre Accounts', p 9. New Delhi.

[16] New Delhi Tuberculosis Centre (1992-93) Annual Report, p22.

[17] This earlier name was changed to 'National Conference on Tuberculosis and Chest Diseases' after 1968.

[18] This section draws largely from Brimnes, Niels (2008) 'BCG vaccination and the WHO's global strategy for tuberculosis control, 1948-1983' *Social Science and Medicine*, 67: 863-873.

[19] This view was expressed by Johannes Holm during a 1956 meeting of the UNICEF-WHO Joint Committee on Health Policy. Brimnes writes, "another representative of WHO, Dr. Suarez, concluded that although the degree of protection was not known, the committee had 'every reason to believe that BCG vaccination was useful in underdeveloped countries' (UN Archives, 24 October 1956, p.12)."

Brimnes thus shows how the value of BCG was "advocated with reference to the *absence* of evidence that pointed to the contrary." Italics in original.

[20] Fox notes that the NTI has had a long-standing problem of recruitment of senior key scientific staff members, and discusses how this affects its role as a premier institute in TB management. But while recording Fox's views, it also needs to be kept in mind that Fox's vision of the TB programme was closely tied in with the scientific mandate and development of the TCC, Madras, and the NTI's purpose and vision was charted out slightly differently from this. Between NTI and TCC, Fox would have seen the kinds of studies that emerged fm TCC as having better uptake and value for the programme, especially its SCC and intermittent regimen studies. He would have been less favourably inclined to the vision and functioning of the NTI.

[21] Porter, J. and Ogden, J. (1999) allude to the ethical issues in the debate on the DOTS strategy in their paper, 'Public health, ethics, and tuberculosis: Is DOTs a breakthrough or inappropriate strategy in the Indian context?' *Indian Journal of Medical Ethics* 7 (3): 79-84.

[22] See also 'Editorial' of this issue, NTI NL V14, N2

[23] Referring to the TCC, Madras study.

[24] Refer also to Prasad and Raju,,'Magic Mountain' op cit. Moller of the UMTS also saw sanatoria in India as affording good research opportunities due to many patients being under daily observation for long periods.

[25] By technical recommendations they meant, "the translation made by an international group of experts, in a particular field of tuberculosis, of the results of available scientific investigations and practical experience, into a procedure, method or technique for use in a tuberculosis programme" (ibid.).

[26] Rao, K.N. (1984) 'Outlook for tuberculosis control: 2000 A.D.' *Ind. J. Tub.* 31(2): 47-52. Rao was DGHS, GoI, at the time.

[27] See the following for a more detailed discussion on the changing international context in the domain of health during this period – Theodore M. Brown, Marcos Cueto, Elizabeth Fee 'The World Health Organization and the Transition From "International" to "Global" Public Health' *Am J Public Health* 2006 96: 1, pp 62–72.

[28] This article, accessed from http://www.hull.ac.uk/futgov/Papers/PubPapers/WaltPaper16.pdf on May 28 2009, does not have page numbers.

[29] The International Union Against Tuberculosis (IUAT) expanded its mandate to include other lung diseases, and changed its name to International Union Against Tuberculosis and Lung Disease (IUATLD) in 1986.

Global Languages of Risk?: 'Default'

Section One – Scientific mediation of risk discourse

On the relation between the modern biomedical model and scientific, professional expert knowledge, Turner says, "The growth of medical dominance under the auspices of the state, [is] associated with the development of a professional body of knowledge [...] The *power of the professions depends, at least in part, on the ability to make claims successfully about the scientific value of their work and the way in which their professional knowledge is grounded in precise, accurate and reliable scientific information*" (Turner 1987: 208). Knowledge building is thus part of a larger political exercise in power.

This often translates into the application of a core 'rational' approach to scientific and technical research, and utilizing this purely 'rational' scientific/ technical model for decision making about policy eliminates any considerations of a wider social-political context. Discussing the broad perspectives dominating health policy research Porter and Kielmann write, "The current international perspective in tuberculosis control is one that predominates in the biomedical scientific model of infectious disease control. It is based on a structure and system that has as its core a rational approach to policy making. Programmes are based on a biomedical approach with the use of rational processes to design, implement and evaluate information. This is the 'normal' perspective of the 'technical advisors'" (Porter and Kielmann 2003: 144).

Among the range of existing technical tools "for identifying the optimum policy proposals for reforming the health system [are] burden of disease assessments; evaluation of the evidence on the effectiveness and cost effectiveness of interventions; analyses of health systems performance and available finances" (Frenk 1995, Brugha and Varvasovszky 2000, cited in Porter and Kielmann 2003: 146). Asserting that "[h]ealth policy [...] is a part of *frameworks, structures and systems*," they state, "[p]olicy decision-making [is] an inherently political process, one that must be historically situated and grounded in a particular social context. In order to link the technical with the political, it is therefore appropriate that we interrogate our

approaches to the creation of TB programmes and their implementation with perspectives that *go beyond the rational model of decision-making.*" (Porter and Kielmann 2003: 144-145).

In trying to explore the role international organizations play in constructing, reviewing, and promoting scientific knowledge and related policies/ programmes, and the way in which specific policies become adopted and promoted to various constituencies as international scientific 'best practice', Gill Walt, Jessica Ogden and others from the London School of Hygiene and Tropical Medicine, working in the area of public policy, have conducted an in-depth study of the policy process behind the Directly Observed Therapy, Short course (DOTS) strategy. They suggest that "the development of international best practice is best analyzed by looking at the processes of interaction between *international and national jurisdictions*" (Walt et al 2003).[1] They use the concept of iterative loops (Walt et al 2003), as well the interactions between the TB problem, policy and politics streams (Ogden et al 2003) to study global-level TB policy making between the 1960s and 1990s, and point out that the development, adoption and adaptation of *best practice* policies in the case of DOTS took place through the intermingling of several processes beyond plain scientific.

Walt et al have also discussed how a techno-scientific framing of knowledge and its consequent legitimacy is enabled, and in no small way, by the presence of strong and closely knit 'epistemic communities' of scientists or of policy makers. As editorials in the NTI Newsletter from the early 1970s testify, communities of scientists would do well to converge their technical skills with those required by the advancement of 'industry', and apply insights and tools from the fields of statistics, mathematical reasoning and management to the health of the nation.

> Today the role that statistics plays both in research in medicine and in the day-to-day management of health services is well appreciated. Since medical care is coming to be viewed as a right rather than as a privilege, positive health is essential to nation building, and further, because of the rapid progress in medical technology, health care is becoming one of the largest undertakings in many countries. Consequently, medical care is being viewed as an 'industry' and sciences that are invoked for the advancement of industry, are being invoked for the advancement of medical care as well: to name a few, cost-benefit analyses, cost effectiveness, network analyses and operations research in its various forms. Needless to mention, mathematical reasoning and especially the science of statistics have greatly helped in these applications. Even certain social

> factors till very recently considered as non-quantifiable are being made amenable to mathematical reasoning (Editorial *NTI Newsletter* 1973).

At the time, recent developments in the field of health included the application of management frameworks to health, and "newer concepts of improvement of health services such as measurement of health demands and needs, utilization analysis and review, programme assessment" and others emerged (ibid.). Further, the editorial notes, "Even the science of epidemiology, till very recently limited to measurement of morbidity and mortality, today is applied also to the measurement of other social indicators of health viz., availability of medical care, amount of disability, availability of resources etc." (ibid.). In conclusion, it says,

> The need today appears to be to develop health services in consonance with the development of other services. This seems possible when pursued objectively through the application of various management sciences to decision making. Mathematical reasoning is one of the pillars on which such applications stand, and when the methods are used – without merely trumpeting and bellowing and thus reducing them to jargons – they will most likely yield lasting results (ibid.).

Another point that has been touched upon previously, is that the broad fields of risk assessment and risk management seek to pursue a scientific understanding of risk, *as opposed to public perceptions of risk.* Critics have also argued that quantitative risk analysis has often been used to make the case for expanded regulatory jurisdiction, and that this "also provides a mechanism for officials to argue that *thorny political questions are being resolved 'scientifically,' a position with a considerable heritage in the modern history of liberal democracies*" (Hornstein 1992: 567).

When thinking of these 'thorny political questions' which are being resolved scientifically, being recast into a techno-scientific frame whereby the realm of politics is being undermined, global development hierarchies between the countries of the North and those of the South are most central. The historical, socio-political and economic context of the 'developing' countries and the countries of the South has resulted from being locked in an inequitable relationship with the countries of the industrialized North, which have variously subjected the former countries to colonial and imperial trade and rule since centuries. The contemporary inadequacies and constraints that are considered 'characteristic' features of India, for instance, – lack of resources being the most evident; linked to this, a large population – have to be located within this history.

It has also to be remembered that the contemporary global system, and the dominant paradigms governing it, continue to perpetuate these hierarchies and inequalities in renewed and re-arranged modes. International concern and assistance from the powerful countries of the industrialized North, to enable the countries of the South to overcome their various constraints and develop adequate systems and structures to meet the needs of their huge populations, in fields such as health and healthcare especially, holds immense potential to act as a potent site for reiterating these established hierarchies.

The zealous and almost messianic enthusiasm of such efforts, rather than being read as benevolent global assistance has been critiqued as a merely instrumental response to the threat that countries of the North perceive from what they perceive as over-populated, resource-lacking – and by consequence, 'illness-breeding', 'resource-consuming', 'productivity-stymieing' – countries of the South. This issue of threat perception connects the global development hierarchy to scientific policy making, because a central feature of the development of *universalizable scientific policy* is the ability to harness a *universal perception of risk* – that is, the ability to generate substantial discourse that something/ someone poses great risk to everyone else. In the arena of global tuberculosis policy development the combination of 'lack of resources' and 'large population' has functioned as a handy rational/ technical/ scientific terminology codifying the fear, risk and threat that the industrialized North perceives from the countries of the South.

An illustration is a 1998 WHO document which announces, "*Everyone who breathes air, from Wall Street to the Great Wall of China, needs to worry about the risk.* Once multi-drug resistance TB is unleashed, we may never be able to stop it. We will face a deadly infectious disease that spreads through air, *yet is virtually as incurable as AIDS or Ebola. This frightening prospect must be avoided at any cost*!" (WHO 1998, cited in Basu __: 43-44). For WHO to justify universal policy formulations on TB, it needs to generate a universal threat perception regarding TB, and there can be few more successful ways of achieving this than aligning TB with AIDS and Ebola. For the West, AIDS and Ebola are catchphrases associated overwhelmingly with the diseased and

decaying countries of Africa and Haiti, considered the geographical origins of these diseases.

Finally, Foucault's concept of 'political technologies', as discussed in the Introduction, is a useful entry point to this chapter and the next – which are combined at the level of ideas, but are discussing two different tools. As noted earlier, the term implies

> policies removed from the realm of political discourse and recast within a scientific frame. Thus they appear as technical responses to particular problems, *which fall within the mandate or objectives for which an international organization has been established* (Dreyfus and Rabinow 1982: 196, cited in Keeley and Scoones 1999: 5; italics added).

Having shown the powerful organizational backing that has underlain TB research and programme management, the second chapter has laid the basis for arguing that policy decisions of a scientific nature cannot be separated from the organizational contexts within which they are located and from whose authority they draw legitimacy. By showing that risk is mediated not only through the backing of organizational infrastructure but also through a *techno-scientific framing* and the legitimacy claims of scientific/ technical *expertise*, this chapter and the next discuss some important elements that may provide a more in-depth answer to the question '*How is a scientific understanding/ perception/ discourse of risk mediated?*'

Section Two – Two specific apparatuses of risk discourse

Banerji writes that for formulating the NTP the problem of tuberculosis in India was defined both in the conventional epidemiological terms as well as in social terms (Banerji 1993). Keeping this frame in mind, and looking at the epidemiological framework from which programme and policy directions for TB emerged, I am looking simultaneously at the conceptual tools or categories which enable policy making and programme planning (default), and at the operational and programmatic tools arising from this for TB control (ARI).

And both these are epidemiological apparatuses – that the issue of default/ non compliance is a centrally significant epidemiological tool can be gauged by the fact that it has single-handedly steered the direction of epidemiological research and programme planning for TB since the time it was 'discovered'; and, ARI is a technical/

methodological epidemiological tool, used for epidemiological estimation of infection risk among the population so that reliable data and information gathering can lead to more efficient and cost-effective programme planning for TB. While the attempt of this dissertation is to critically analyze the multiple constituents of the NTP and its rearrangement as the RNTCP in India, since it has been shown in the previous chapter that the nature of TB policy and programme planning in India is inextricably intertwined and coeval with that of international TB policy and programme planning, this chapter dwells more on the international contexts behind these two tools.

While investigating the conceptual tools or categories that have driven research and programme planning for TB, it is clear that the concepts of 'default' and 'non compliance' play a foundational role in this process. Reading discussions around default, compliance and non-compliance in the Indian and global TB literature, the defining frame is one of danger – *danger that individuals pose to others* (to the larger community) because of their irregularity in treatment completion, non-compliance, defaulting behaviour, lack of motivation and self-control in adhering to regimens. These individuals are constructed as being "*at high risk for non compliance*" (Bayer and Wilkinson 1995: 1547). This danger posed by individual default leads to construction of categories for programme purposes, such as 'risky behaviour,' or 'high risk groups.'

When speaking of operational and programmatic tools, I focus on "Annual Risk of (Tuberculosis) Infection" (ARI or ARTI), an epidemiological tool that emerged during the mid-1930s. The construction of risk here is a statistical estimate derived from the prevalence of infection in a community, which in turn is drawn from the results of tuberculin testing in that community. The ARTI is defined as the probability of an individual acquiring new tuberculous infection or reinfection over a period of 1 year (Rao et al 2008). This epidemiological measure aims to alert communities to the risk/danger that all individuals within that community face given that a certain amount of mycobacterium tuberculosis infection is present in that community. It aims to state that the community and individuals within it are *vulnerable*, are *at risk of getting infected* to a given extent.

Even though ostensibly these two aspects of risk – dangerousness and vulnerability– are combined in the rationale and imagination behind the programme, the focus of programmatic responses is centred on the risk that errant, non compliant individuals pose to the larger society. Programme structures, diagnostic and therapeutic procedures, clinical and research practices, all emerge from the need to control and minimize this risk. However, I am not reading risk in TB policy and programme literature by investigating the 'vulnerability' or 'dangerousness' aspects of risk; this would be a simplistic, external and conventional way of understanding risk.

Instead, drawing on the conceptual discussion in the first chapter, and as detailed above, the purpose of this chapter and the next is to explore risk as a *paradigmatic construct.* By this term I mean that 'risk' is the dominant frame, the defining mentality, the governing paradigm within which knowledge building processes in the TB programme and policy domains have been carried out. As discussed in several preceding sections, such an exploration identifies risk as operating via the techno-scientific framing of knowledge, and its derivation of authority from its location within powerful organizational sites. This is the perspective from which these two chapters will investigate the construction of two epidemiological tools assessing risk in TB management and control (one conceptual – default, and the other operational – ARI), and how they are legitimized globally as *best practice.*

Some of the questions that will be taken up in these two chapters are: What are the specific research structures, actors, initiatives that enable the creation of certain kinds of tools and methodologies? How are certain apparatuses chosen or given priority over others? What kinds of infrastructural backing and/ or institutional/ organizational support structures enable such processes and apparatuses? As regards epidemiological tools – How are these epidemiological tools highlighted and structured to aid policy making? As regards conceptual categories/ knowledge tools – How have these conceptual categories emerged? In what contexts have they been highlighted, constructed and shaped to meet the ends of policy making?

Conceptual tool – Default

I Default and non compliance

It is difficult to delineate the exact trajectory from which default emerged as an epidemiological concept for TB management and control. The literature suggests that as far as international institutional initiatives go, both the BMRC and the IUATLD played definitive roles in identifying and centering the concepts of irregularity in drug intake and default for research as well as programme management. Not only this, but as important constituents of the narrow scientific community each institution was also aware of, and engaging with, the contemporary research developments emerging from the other.

Literature from as well as on the BMRC credits this institution with original research on supervised therapy, intermittent therapy and finally short course chemotherapy which was supervised and also intermittent. There also exists a credible body of literature which shows that it was the IUATLD, through its Mutual Assistance Programme, that pioneered the practice and assessment of these modalities of supervised, short course, intermittent therapy under actual field conditions. This chapter will provide an in-depth picture of the multiple sources and contexts behind the development of default as a central problem and the importance of supervised therapy as an important solution for non compliance.

1.1 BMRC research on supervised therapy

As noted earlier, in developing countries in the post Second World War period the disparity between the prevalence of tuberculosis and the availability of hospital beds made ambulatory care the only viable option. Studies carried out in TCC under the directorship of Wallace Fox (who, incidentally, underscored during an IUAT conference that the TCC "is under the scientific direction of the Tuberculosis Research Unit of the Medical Research Council" (Fox 1962: 309)), aimed to assess how well ambulatory care compared with sanatorium-based care. Writing about the results, Fox lamented in as early as 1958 that compliance to drug regimens was a problem among

ambulatory patients – "Irregularity [had] been a problem throughout the course of treatments" (Fox 1958, cited in Bayer and Wilkinson 1995: 1545). He also urged that while the issue of which oral medications to use was important, it was "less fundamental" than the regularity with which patients would self-administer treatment over the long term (ibid.). Subsequently, Fox started research on the potential efficacy of supervised therapy in TCC (TCC 1964). In spite of many hurdles that patients had to face to undergo such treatment (Bayer and Wilkinson 1995; Fox 1962),[2] by the early 1960s Fox advocated that long term supervised therapy could be organized in special circumstances, even in developing countries (Fox 1962; TCC 1964).

This gave rise to research studies in various parts of the world with the aim of improving compliance in drug taking. There were broadly two areas of research developing at this time –first, studies on supervised therapy, and second, studies on intermittent therapy. The second area of research emerged directly from the first; gradually, studies on supervised chemotherapy started exploring "the development of intermittent regimens, *since these would ease the task of supervision*" (Fox et al 1999: S237, italics added). These BMRC researches culminated in the WHO Expert Committee on Tuberculosis' Ninth Report recommendation in 1974 that twice weekly regimens containing Streptomycin and Isoniazid were to be the standard regimen for programme application, as they were therapeutically effective, had lower toxicity and cost, overcame undetected irregularity inherent in long-term self-administration, and enabled quick defaulter identification and subsequent action (WHO 1974: 19-20).

The era of short course chemotherapy emerged only by the 1970s, "primarily because of the failure of regimens of standard duration (minimum of 12 or more months), both daily and intermittent, to achieve their potential, particularly in developing countries, because such regimens were beyond the organizational and financial resources of the health services of nearly all these countries" (Fox 1983). This lack of organizational and financial resources of the developing countries arose because apart from severe drug shortages, these countries were not in any position to set up the infrastructural and personnel requirements for supervised treatment. When short course regimens were combined with the principle of intermittence this represented the highest advance in fully supervised chemotherapy (Fox et al 1999).

Detailing the kinds of efforts taken to ensure compliance to therapy at TCC Fox writes,

> In 1956 we developed in the then Tuberculosis Chemotherapy Centre, Madras, a coordinated approach to patients under ambulatory domiciliary treatment for pulmonary tuberculosis. This included (1) the involvement of the family as well as the patient during the pre-treatment diagnosis and assessment period, (2) frequently repeating during therapy the need to take the medicaments regularly and emphasizing the family's or a neighbour's role in supervision, (3) a policy of restricting the medication to antituberculosis chemotherapy whenever possible, (4) surprise visits to the home to (a) check the patient's stock of pills and (b) to collect a urine specimen to test for antituberculosis drugs, and (5) taking speedy absconder action if a patient failed to attend when due (Fox 1990: 188).

He elaborates the exact modalities of this last point further in a footnote in the same article,

> For every patient admitted to treatment a full list of addresses was obtained, namely 1) the patient's home address, 2) the addresses of his relatives and friends in Madras city, and 3) how often he visited them, 4) if employed, the place of work, 5) if children were at school, its address, 6) the address of his native place. If a patient failed to attend and the home was locked and the neighbours did not know where the patient or the family was, *a systematic approach to the above alternatives was made until the patient was traced.* (Adequate transport and devoted trained home visitors for this purpose were available.) (Fox 1990: 188, footnote, italics added).

Apart from India, these areas of research were also being advanced through studies conducted by BMRC units in their other collaborative sites including Hong Kong and Singapore (Fox 1977; Fox et al 1999). However, BMRC research in Hong Kong had begun much earlier than in Madras, with the first clinic for ambulatory care opened in Hong Kong in 1950, much before the Madras trials. "The introduction of fully supervised chemotherapy in the Hong Kong government tuberculosis service and at the Tuberculosis Chemotherapy Centre, Madras, provided opportunities for exploring the practical problems involved and the benefits gained" (Fox et al 1999: S237). By the early 1960s treatment regimens there entailed, in addition to streptomycin injections, direct supervision of oral medications; this latter aspect was introduced into the Hong Kong programme on the advice of Fox (Bayer and Wilkinson 1995: 1546).

Thus,

> it was the patient compliance problem which had led us in the BMRC to explore both short-course chemotherapy and then intermittency combined with short-course chemotherapy studying regimens based on isoniazid and rifampicin. Also, pyrazinamide was reintroduced into primary chemotherapy in the very first study which was conducted with our collaborators in East Africa. (Fox 1990: 188).[3]

While BMRC involvement in Africa started in 1952 in a series of controlled chemotherapy trials in the three territories of East Africa – Uganda, Tanganyika and Kenya (d'Arcy Hart, 1961) –BMRC's first foray into short course chemotherapy research started in these regions by the end of the 1960s. The results started emerging by the early 1970s, and these studies were foundational for the development of future SCC regimens (East African/ BMRC 1973; East African/ BMRC 1974).

BMRC research at the Hammersmith Clinic, London, also experimented with supervised therapy during this period.[4] Here, however, the results were less encouraging than at the other sites, with only half the patients completing the daily supervised treatment. The limits of daily attendance faced by this research team reinforced the case for development of intermittent regimens. Literature thus shows that by the end of the 1960s-early 1970s BMRC research in tuberculosis control in various locations of the world had concluded that "effective treatment required direct supervision of therapy and that only such an approach could interrupt a general tendency [...] on the part of patients to cease taking medications when they no longer felt ill" (Bayer and Wilkinson 1995: 1546). Intermittent regimens, short course regimens, and short course intermittent regimens thus all grew out of the singular and overwhelming desire to arrest patient default and non-compliance with TB treatment.

1.2 Supervised therapy in the USA

The BMRC studies greatly influenced John Sbarbaro and S. Johnson in the United States of America (USA), who, despite the trend prevalent in the USA during the 1960s – to initiate supervised therapy only for defaulting or potentially non-compliant patients – pushed for universal supervised therapy for all patients. Tracing this history Bayer and Wilkinson write,

> Beginning in the late 1970s, Sbarbaro began a lonely but persistent campaign to transform the practice of outpatient care of tuberculosis patients. Central to his mission was an effort to characterize the problem of compliance with medical regimens as one that extended beyond the narrow class of 'unreliable' patients. Taking a dim view of human nature and echoing the observations made by Fox almost two decades earlier, he asserted, 'Unfortunately the health behavior of most people is unpredictable and does not conform with our expectation that patients will follow what their physicians recommend' (Sbarbaro 1980, cited in Bayer and Wilkinson 1995: 1546).

Bayer and Wilkinson write that breaking with the practice of identifying characteristics predictive of non compliance among patients, Sbarbaro noted that *for increasing compliance a shift from daily regimens to intermittent therapy had to be made.* He pointed out, "there have been no reports of successful outpatient programs in which long term daily supervised treatment was the keystone of the therapeutic programme" (Sbarbaro 1980, cited in Bayer and Wilkinson 1995: 1546). Following this line of reasoning, B-W write,

> Sbarbaro's arguments for and claims on behalf of supervised therapy formed the basis of the case for universal application of such care. To the obvious challenge that such an approach would impose unacceptable costs on local tuberculosis control programmes, *he responded by presenting cost-benefit analyses that were the hallmark of his efforts. Against the costs associated with supervised treatment he compared the costs linked to the treatment of relapses and failures that might be anticipated with self-administration*" (Bayer and Wilkinson 1995: 1546, italics added).[5]

Accounting for these shifts in US TB management practices, Bayer and Wilkinson lament that in spite of Sbarbaro's efforts, US policy during the first half of the 1980s, emerging mainly from the Centers for Disease Control (CDC) and the American Thoracic Society, continued to emphasize supervised therapy only for 'problem' patients, such as the unemployed or alcoholic patients. They go on to list evidence showing that in the mid-1980s "at least 20-30% of patients throughout the USA failed to complete treatment within 24 months" (Bayer and Wilkinson 1995: 1547) – reasons included among other things "frequently missed appointments, drug resistance, mental incompetence, chronic alcoholism, failure to respond to therapy, two hospital admissions for treatment of tuberculosis, and living conditions unconducive to compliance with ambulatory care" (Bayer and Wilkinson 1995: 1546).

Questioning policy makers' reluctance to push for universal supervision of therapy during this time, they surmise that health departments tended to be cautious about assuming that individuals were required to take their medication in the presence of a responsible party. Some departments felt this would entail "unacceptable assumptions about the prospect of the future behaviour of those under care" (Bayer and Wilkinson 1995: 1547). They note that there were also arguments that emerged later stating that "widespread application of directly observed therapy entailed an inversion of a basic human right by treating tuberculosis patients as guilty until proven innocent" (Bayer and Wilkinson 1995: 1547). Setting aside these uncomfortable doubts and questions

posed from a 'human rights perspective', they feel, however, that the most important limiting factor was

> the assumption that the widescale use of supervised therapy would entail an extraordinary and unjustifiable expense. Certainly questions of cost and severe limitations on available resources were among the factors that played a part in the failure of the CDC to press publicly for the wider adoption of directly observed therapy as a practice even when some believed such a move would have salutory consequences (Bayer and Wilkinson 1995: 1547).

Despite the lack of policy backing for universal application of directly observed therapy, however, they take care to point out that there were locations in the US where, starting from the late 1970s, directly observed therapy was a widely applied treatment modality for a majority of tuberculosis patients. These included Sbarbaro's home base of Denver, Colorado; Baltimore, Maryland, where the Commissioner of Health was greatly influenced by the work of the IUAT and by the BMRC studies in Hong Kong; the state of Mississippi, where universal supervision spread from one region to the entire state in the course of the 1980s; parts of Texas, where following an outbreak of multidrug-resistant tuberculosis in the mid-1980s the Director of Public Health in consultation with Sbarbaro started directly observed therapy for all patients treated in public institutions.

Bayer and Wilkinson suggest that given that many of these initiatives were undertaken without additional funds and in the absence of federal support, *resource constraints explained only a part of the resistance* in the USA to directly observed therapy. The most potent aspect of their history writing, as I see it, lies in the normality and the confidence with which they state,

> Where there was a political commitment to instituting such an approach to tuberculosis control it was possible to make substantial changes. Such commitment also required a cultural climate within which supervision of all, or nearly all, patients was not offensive. Certainly the cultural climate in Texas and Mississippi was very different from that in northern states, making possible tuberculosis-control initiatives that might otherwise have been viewed as unacceptably authoritarian (Bayer and Wilkinson 1995: 1547, italics added).

What might have been this cultural climate, allowing the states of Texas and Mississippi to experiment with what would otherwise have been rejected as 'unacceptably authoritarian' treatment regimens in the northern states? Unfortunately,

B &W shy away from providing further details of this, but some understanding of this will give us a fair idea of the myriad constituents that must come into alignment for the *creation of a widely applicable scientific/ technical practice* and the subsequent operationalizing of such practice into *legitimate public policy.*

One way to understand this '*certainly* different' cultural climate would be to delve a little into the historical socio-political context of the states of the South. The southern states of the USA, including Mississippi and Texas, were historically slave states.[6] During the period of the 1960s-80s these conservative and segregationist states gradually became a stronghold of the Republican Party, which cultivated the support of the religious right and attracted strong majorities from the evangelical Christian (mostly white and Protestant) vote here. Also termed 'the Bible states', societies in these states are characterized as being strongly influenced by authority structures such as the Church, tend to lean towards conservative social-political ideas, and societal structures and institutions in these states reflect this conservatism by often defending the status quo and being deferential to the power of authority.

In the light of Bayer and Wilkinson's comment – and placing it in a larger socio-political-historical context – we are able to read the cultural climate of the Southern states as being framed by societal frameworks wherein deference to authority is considered normal and acceptable, reinforced by various penalties imposed on those not exhibiting this deference. Combine this with the fact that health practices are fundamentally based on a hierarchical relationship between patient-doctor, and we have a clear sense of how in some of these sites local clinical procedures and practices that reiterate submitting to expert authority opinion only reflect the wider societal pattern. This helps us understand how policy measures are not enacted simply within techno-scientific spheres. The presence of a conducive socio-cultural climate is vitally significant for the *successful commingling* between science and public policy, and the reason why these experimental therapeutic regimens worked successfully in the South early on has a lot to do with the fact that these regions provided this climate.

A word about the immediate context in the USA from which DOT arose as a recommended universal format of TB therapy – some prominent states in the early 1990s saw a rising number of TB cases, especially linked with HIV infection; an

increase in drug resistant TB; and nosocomial outbreaks in several hospitals and prison systems; these three factors combined to heighten the public health threat of TB in the USA. Bayer and Wilkinson note,

> *As a result of the fear that what had been a treatable disease might become an untreatable danger to middleclass populations that had in recent years been spared the threat of tuberculosis, concern took hold about the rate at which patients failed to complete their tuberculosis therapy* in cities such as New York, Chicago, Newark, and Washington. Public concern and a demand for remedial action provoked Congress to greatly increase funding for tuberculosis-control efforts. In all, the money available to CDC for tuberculosis control rose from$25 million in 1991 to$104 million in 1993 (CDC, unpublished data). Central to the new commitment was *a striking determination to place directly observed therapy for most if not all patients* at the centre of public-health efforts (Bayer and Wilkinson 1995: 1547, italics added).

As a result of all these factors, in 1993 the Advisory Council on the Elimination of Tuberculosis (ACET) made DOT the standard of care (DeHovitz 1995). This was a federal policy shift from the decades-long "efforts to identify *individuals at high risk for non-compliance* and more recent attempts to *designate groups as being at high risk for failure to complete their tuberculosis treatment*" (Bayer and Wilkinson 1995: 1547, italics added). The ACET's position now stated, "Directly observed therapy should be considered *for all patients because of the difficulty in predicting which patients will adhere* to a prescribed regimen" (Bayer and Wilkinson 1995: 1547, italics added). Following this, the recommendations of the ACET were reflected in the CDC's standards for cooperative agreement applications from state and local health departments seeking funds for tuberculosis elimination; thus, the transformation of federal policy has been reflected at the local level as state, county, and municipal health departments shape their tuberculosis policies and practices accordingly (Bayer and Wilkinson 1995).

1.3 Supervised therapy research of the International Union Against Tuberculosis (IUAT)

The other organization involved in global TB research and programme management, the IUAT, was also doing research in these areas in several African countries. During the 1970s-80s, national tuberculosis programmes initiated under the Mutual Assistance Programme of the IUAT in Malawi, Mozambique and Tanzania (and three more countries later) were the sites for numerous experimental trials on chemotherapeutic

regimens and their implementation in mass programmes (Murray et al 1991; Enarson 1995). Tanzania was the IUAT's first experimental location in the developing world for carrying out research and programme management trials. It was under the aegis of the WHO-IUAT collaborative venture TSRU, directed by Karel Styblo (Rouillon 1998), that Tanzania eventually became the first country to implement, in collaboration with IUATLD, what is now known as the DOTS strategy (Enarson 1991, cited in Rieder 2005). It is also important to note that in 1979 Styblo became Director of Scientific Activities of the IUATLD.[7]

Walt et al have noted that during this period Styblo initiated a number of studies in these countries related to shortening the duration of the regimen. They write,

> He challenged conventional methods of treatment, by prescribing a shorter drug regimen (a six-month therapy), containing the drug rifampicin. *This course was administered in hospital for the first two months so that patients could be directly observed taking their medicines.* This was contrary to medical wisdom at the time, which said patients in poor countries should be treated in the community with traditional anti-tuberculosis drugs. It was feared that if patients did not complete their full course of medication, resistance to some of the more powerful anti-tuberculosis drugs – rifampicin in particular – would develop, thus threatening effective tuberculosis control in the West. *Styblo argued that by hospitalising patients so health workers could directly observe them taking drugs, and monitor their progress towards cure, resistance could be avoided* (Rouillon 1991, cited in Walt et al 2003).

The literature makes clear that Styblo's work put him at odds with the rest of the TB establishment, and that it was in the face of massive skepticism that "Dr Styblo fought to obtain enough money to start applying short-course chemotherapy (from 1983 onward) in the National Tuberculosis Programme of a low resource country, Tanzania" (Rouillon 1998: 9).

While speaking of IUAT (or BMRC) research conducted in Africa and medical wisdom relating to scientific practices there, it is important to not lose sight of the fact that it was only by the 1960s that the countries of Africa started becoming independent from colonial rule – for instance, Uganda gained independence from Britain in 1962, Kenya from Britain in 1963, Tanganyika from Britain/ Germany in 1961, Malawi from Britain in 1964, and Mozambique from Portugal in 1976. Scientific research conducted prior to this period is thus located in the context of colonial rule, conflict, exploitation and hierarchy, demolishing pretensions of a secular equitable search for global scientific progress. That economic, political, social, cultural distinctions between Anglophone

and Francophone regions are firmly entrenched in contemporary Africa is an example of the enduring impact of colonial rule by different European countries in Africa; the presentation of separate reports for 'English-speaking Africa' and 'French-speaking Africa' during the previously mentioned IUAT Seminar on Tuberculosis in Africa in Paris in 1960 needs to be read in the context of this colonial history.

IUAT literature of the time notes that this period of unrest and upheaval in these countries impacted their ability to cater to the health needs of their tuberculous populations, thus necessitating close cooperation and assistance between these countries and the IUAT. The main complaint in Africa is that in spite of the proven efficacy of domiciliary treatment, it is a

> formidable administrative task to translate the techniques and methods used in these carefully conducted trials to the treatment of large heterogeneous communities scattered over wide areas. Neglect in taking drugs and absconding from hospitals and clinic control are the main obstacles. *These are particularly evident in patients of a low standard of mentality and education.* Fox is correct in his conclusion that *unrelenting pressure and education* by health visitors and nurses is the only remedy (Fox 1958, cited in Heaf 1961: 8).

On the point of African patients having low mentality and education, John Crofton applauds the practice of a certain Dr. Gordon in Tanganyika, who

> began by inviting to his hospital all the tribal chiefs of his district and describing to them the struggle against tuberculosis and the part he hoped they would play in the control of the disease. After this his policy was to admit all new patients to the hospital for one month only: *during this month the main object was not only to start the combined chemotherapy, but chiefly propaganda to persuade the patients of the necessity of continuing their drugs* even after they had become quite well, and this propaganda was carried out by Dr Gordon's staff and by patients who had been cured by previous treatment. After one month the patient went back to his area, and in each of these areas there was an orderly; every week the patient came up to receive his cachets of P.A.S. and isoniazid, and his urine was tested for P.A.S. At least once every month the orderly had to visit the patient unexpectedly in his home, demand a specimen of urine and test it for P.A.S. If the urine proved to be negative for P.A.S., the patient was reported to his chief. If he continued to be a defaulter, to have negative urines, he was *readmitted in disgrace to hospital*. By this means 90% of the patients in this national study were made sputum negative by the end of a year and nearly all the failures were in one small area where the chief would not co-operate properly (Crofton 1961: 50-51).

Thus it is clear that in as early as 1960, the precise modalities of conducting supervised treatment to arrest patient default were well in place, and that contemporary regimes of DOT only mirror these previously established practices. Health education was propaganda, power and hierarchy were defining frameworks and most crucially,

disgrace and shame were the central weapons with which compliance was to be effected.

II The conceptual tool of default vis-à-vis a welfare perspective of public health

Research on intermittent supervised therapy and short course treatment regimens through the 1960s-1970s, with its attendant biases and ideologies arising from its socio-political-cultural-historical contexts, then went on to provide the basis for a managerial approach to control programmes by the end of the next decade. The need for management of irregularity, default and non compliance in treatment reached its most ambitious scale by the late 1980s-early 1990s, with the resurgence of TB alongside HIV infection; the methods/ strategies that emerged on the scene were now sought to be applied universally, with legitimacy granted by international health agencies such as WHO.

Relevant to the Indian context, as has been noted in the Second Chapter, the Banerji-Anderson study was a notable contrast from other kinds of studies done earlier related to TB, not just within India but also in other countries. This study was not only a departure from precedent, but also a sign of the ways in which context-specific perspectives could drive research studies. It focused attention on the experience of suffering caused by ill health, thus inserting the person into the patient. Positioning the patient as first and foremost a social entity, the study noted that patients' experiences are constituted by the social-structural space they occupy.

However, as Amrith has pointed out, and as has been noted in preceding sections, while proposing a new understanding of sociological factors underlying TB therapy the Banerji-Andersen study laid the blame on the organizational and administrative failures of the NTP – "the slippery slope of sloppy treatment organization" – thus suggesting that it would be a managerial, administrative overhauling that would ultimately provide success for the NTP (Amrith 2004: 121). Even though the Banerji-Andersen study identified socio-economic-political questions as central to the development of the people as well as the health service systems, 'sloppy treatment organization' was clearly more easily amenable to the management impetus which was growing steadily among Indian programme planners by the early 1970s; this has also been noted earlier.

The fact that the Banerji-Andersen study spawned a series of studies focusing solely on eliminating/ minimizing organizational-administrative factors, completely neglecting other social-economic-political questions, forces an acknowledgement that the Banerji-Andersen study in fact reflected a deep and abiding influence of an administrative-managerial perspective. Rather than thinking that the influence of such an administrative-managerial perspective in the Banerji-Andersen study was incongruent with the wider mandate of public health, it would do well to recall that the domain of public health, as an applied field of health, demands operationalizable solutions that can be used to manage large populations effectively (and that too, cost-effectively).

Literature on the historical contexts from which early public health and social welfare measures arose suggests that welfare measures for health were inaugurated with a view to minimize economic losses of the larger society that would inevitably result from illness causing lower productivity of labour, from the diseased status of indigent populations, and from the fear of the spread of illness from the depressed sections of society to the rest of society. Noting the historical-political moment in which legislative enactments relating to public health and sanitation measures were drafted in England as well as the United States of America, Rosen points out that there were adverse reactions to "the different way of life of the workers and the poor, a sense that there was something unknown, mysterious and dangerous about the lower orders of society", and that "[d]eath and disease seemed to lurk in the houses and haunts of the poor ready to emerge as epidemics to threaten the health and life of their betters" (Rosen 1971: 61-62).

This fear of how the working class's depressed conditions of life would impact the rest of society played no small role in the creation of the Public Health Act of 1848, the Nuisances Removal and Disease Prevention Acts of 1855, the Arsenic Act of 1857, the Act for Preventing the Adulteration of Articles of Food and Drink in 1860, and also the Act creating the Metropolitan Board of Health in New York in 1866 (ibid.). Also important to remember is the fact that Chadwick's sanitary reforms of 1842 were drafted in the backdrop of his work with the Poor Laws Commission in 1834, wherein the purpose was to save the British exchequer's expenditure on looking after its sick populations, especially the poor and indigent (Hutchinson 1973). Clearly, managing

and disciplining society by eliminating perceived threats to order, and ensuring that there were no obstacles to economic profit and productivity was the mandate of these public health legislations.

This literature suggests that the pointed focus on combating illness in society stemmed from a basic utilitarian need to minimize economic losses from ill health. The implication of this is that the development and stability of wider social-economic aspects warrants much more attention. There is, however, a convincing argument regarding the creation of the welfare state in Britain, which states that the *focus on growth and stability was also an effort at quelling potential working class revolts against the government* in the immediate post-war period (Doyal 1979; Kennet 2001). While discussing the Beveridge Report – best known for its articulation of a national health service for Britain – and its push for the provision of "a minimum income for all through an effective system of social security," Doyal, for instance, states that the conceptualization of the welfare state in Britain at this time cannot be read as a revolutionary move (Doyal 1979: 178). She insists that such proposals signifying "ruling class reformism," served mainly to maintain the status quo and ensure the stability of British capitalism (ibid.).

This discussion enables us to understand that given that public health perspectives have emerged from within the framework of welfare states as in the above mentioned contexts, public health cannot but be conjoined with a programmatic, administrative and managerial outlook vis-à-vis the population. This is evidenced in the Indian context by the fact that by the 1980s when SCC was introduced in the Indian NTP on a pilot basis in some districts, the sociological concepts and perspectives of the early literature were wholly absent, and the major focus was on *operational* studies to enhance and strengthen the organizational set-up of the NTP to ensure better patient compliance.[8]

Finally, even as several writers have often held that default and non-compliance arise not because the patient is being willfully deviant or recalcitrant, but because the circumstances around the patient made compliance difficult, the implication of this is that if convenient access for patients could be ensured, and there were no major drug resistance issues, then supervised therapy ought not to be a problem issue. When Fox writes

> I had not regarded full supervision as suitable for rural areas in developing countries except for patients near to treatment facilities, or until an effective primary health care infrastructure had been set up or existed (as was virtually the way supervision was organised in the Czechoslovakian study) and administrative problems such as whether peripheral health staff could distribute or supervise antituberculosis chemotherapy were resoled (Fox 1990: 188),

the unstated assumption behind this seems to be that where infrastructure is available supervised therapy can be organized without any qualms.

Viewing 'supervision of patients ingesting their drugs' as merely a technical matter and locating solutions for impediments in organizational re-arrangements, is a deeply problematic perspective. The mistrust attached to patients implies that they are rarely interested in their own health, and given that with a disease such as TB their indolence is highly risk-ridden patients and their therapy 'need to be supported' with adequate organizational and human resources. Such a perspective is unmindful of the fact that this construction and representation of patients reiterates their fragile status vis-à-vis the welfare system of public health. Further, there is a very thin line between such a public health perspective and a governmentality perspective, wherein a person is viewed as merely an instance of a population – a 'subject' – and various disciplining mechanisms, at the societal level, are put into place in order that this instance does not threaten the *order* of the larger system. The IUAT outlines this governmentality perspective most effectively when it identifies *individual responsibility* as the cornerstone for societal well being – "it is of critical importance that the *individual be taught to accept his responsibility to the community in health matters generally*, as well as *his specific responsibility in the control of a communicable disease like tuberculosis*" (The Extended Programme of the International Union Against Tuberculosis 1963: 98-99). The concluding chapter will elaborate this discussion further.

III 'Best practice' – knowledge re-cast in a scientific frame

The point that has emerged thus far has shown that the development of scientific policy is much less a process of delineating value-neutral, apolitical, objective, scientific and technical information, and more one of fulfilling wider political rationales and goals. As a fact, scientific information always emerges from within a specific, often narrow, context – which has its own historical-political rationale. The vital part is next – *its*

transformation from just context-specific information into wider generalizable (universalizable?) scientific policy depends crucially on the pulls and pushes of several other factors – geopolitical processes, national and international institutional power and authority, appropriate branding and advocacy/ marketing, identifying and/or generating policy-conducive perspectives within field practice as also within influential global networks, and mostly importantly, global development hierarchies.

As an illustration of the processes by which scientific information is re-cast into universal best practice, a discussion on the development of the DOTS strategy follows. This draws largely from the work of Walt et al, Ogden et al, and is corroborated by supplementing literature.

3.1 Field-level, context-specific genesis of policy; the international context; the relevant community – roughly the 1960s-mid 1980s.

Walt et al write that the first phase of the policy process was "knowledge generation and experimentation"; they identify the genesis of the later formulation of DOTS in the field trials in India in the 1960s, which demonstrated the applicability of domiciliary treatment according to standardized treatment protocols with 18 month treatment regimens (Walt et al 2003). As pointed out already, in the 1970s and '80s, Karel Styblo at the TSRU, under the auspices of the IUATLD, was undertaking what were then considered heretical steps in his experimental studies in field settings in several African countries.

> TB control experts generally felt that using short course regimens in developing countries (as Styblo was doing) was unsafe. This was because of the fear that *if health systems were not sufficiently strong, patients would not be adequately supported in completing their treatment, thus leading to the potential for an epidemic of multi-drug resistant disease*. Standard or 18-month regimens, being less likely to lead to resistance, were generally considered more appropriate in these settings (Ogden et al 2003: 182, italics added).

Responding to the fear

> that if patients did not complete their full course of medication, resistance to some of the more powerful anti-tuberculosis drugs – rifampicin in particular – would develop, thus threatening effective tuberculosis control in the West[,] Styblo argued that *by hospitalizing patients so health workers could directly observe them taking drugs, and*

> *monitor their progress towards cure, resistance could be avoided* (Rouillon 1991, cited in Walt et al 2003).

Even though they label this initial loop of the policy process as "bottom-up, field-oriented, context specific (taking into account the realities of the environment in which the policies were tested)," they point out that this 'knowledge generation and experimentation' with regard to Styblo's efforts, was, however, shared – and contested – within a narrow tuberculosis scientific and policy-making community (Walt et al 2003; Ogden et al 2003: 182). The above-mentioned technical concerns formed one part of the criticism; further, the international health policy context of the 1970s and '80s – primary health care and integration – also mitigated against support for the development of Styblo's more vertical approach to TB control.

"According to one informant, the neglect of TB at WHO was also partly a product of the personal interests of Mahler, whose own experience of TB control in India had been fraught with difficulties" (Ogden et al 2003: 182). The 1970s was also the period which witnessed failing national TB control programmes in developing countries because the general health services infrastructure had not developed enough to sustain TB control programmes. Lacunae were expressed at every level – case finding, treatment, sustainable drug supplies, and health manpower.

This low performance in TB control programmes everywhere led to a gradual waning of WHO's role/interest in global TB control by the late 1970s (Raviglione and Pio 2002). Late 1970s-mid 1980s was characterized by a significant decrease in the publication of scientific papers on TB; transformation of TB journals into respiratory disease journals, the wrapping up of TB conferences, TB units or regional offices, their shrinkage or transformation into respiratory and communicable disease units, and suchlike. During this period the existing TB programme was cut back to two professional staff in the Geneva headquarters, even fewer people in WHO's regional offices (Ogden et al 2003).

"The closure, in 1985–86, of the British Medical Research Council Tuberculosis Units, that had played a key part in the development and testing of modern tuberculosis control interventions, was yet another dramatic example of the loss of interest" (Raviglione and Pio 2002: 777). Arguably, the International Union Against

Tuberculosis expanding its attention towards other lung diseases (and changing its name to International Union Against Tuberculosis *and Lung Disease*) is another instance of this declining focus on tuberculosis. Commentators closely associated with WHO have acknowledged, "During this period, WHO, many international agencies, most ministries of health, and academic institutions were perceived to have lost interest in tuberculosis control" (Raviglione and Pio 2002: 777).

3.2 Global policy networks; re-emergence of TB on the international scene; relevant communities – roughly mid 1980s to 1990.

While the first loop was concentrated in developing countries at the local level, this second loop went global, wherein "the knowledge generated was then taken up at international level, and *attempts were made to consolidate these highly context-specific findings into standardized, global health policies*" (Walt et al 2003). This was enabled by individuals in international organizations acting as catalysts for the formation of global public policy networks. Citing the work of Reinicke (1999/ 2000) Walt et al write that "global public policy networks operate as alliances of government agencies, international organizations, corporations, and elements of civil society that join together 'to achieve what none can accomplish on their own'" (Walt et al 2003). A discussion in the following chapter will make this point more explicit by discussing the deep organizational interconnections between scientific/ technical policy making groups related to the WHO and the World Bank, which eventually led to the turnaround in international health during the late 1980s-early 1990s.

As noted earlier, Walt et al have pointed out that Styblo's work at the field level in Africa was taken up by members of the *Ad Hoc* Commission on Health Research for Development in the late 1980s, and then endorsed by a subsequent study by WHO. It has to be noted that the moment and setting of this *Ad Hoc* Commission were not benign; the period of the late 1980s was the defining period for a paradigm shift in TB management and control because of the resurgence of TB in locations where it had been thought to have been almost eliminated. It was becoming clear that the increasing numbers of cases, alarming rises in multi-drug resistant disease and in TB deaths were linked to HIV infection and the AIDS epidemic.

HIV was producing increases in TB notifications in the African countries; Western industrialized countries were seeing a resurgence of TB connected largely with HIV infection and previously declining trends in TB were reversed (Raviglione and Pio 2002). Walt et al point out, for instance, that in North America, tuberculosis had declined at an average rate of five per cent a year between 1953 and 1984, but between 1985 and 1991 the number of reported tuberculosis cases increased by 18 per cent and in some areas, such as New York City, by 99 per cent (Fujiwara 2000, cited in Walt et al 2003). The dissolution of the former USSR is also recorded as having led to economic and health services collapses, leading to a rise of TB incidence in those countries (Raviglione and Pio 2002).

Although TB had always been a serious public health problem in the developing countries, and in the impoverished regions of Western industrialized countries, as noted earlier, it was "as a result of *the fear that what had been a treatable disease might become an untreatable danger to middleclass populations that had in recent years been spared the threat of tuberculosis*" (Bayer and Wilkinson 1995: 1547), in this climate of serious alarm and threat of TB linked to HIV, that the WHO got reinvigorated. Arata Kochi was appointed Head of the WHO TB Unit at this time; he came to WHO from UNICEF, with a legacy of impressive field operations in the immunization programme and massive extra-budgetary support for WHO from the Japanese (Ogden et al 2003). Thus it was this changed epidemiological pattern – reversals of TB declines, as a result of HIV infection – that peaked the interest in and concern over TB, "created a new agenda for action among rich countries and triggered recognition of the ongoing problem in the developing world" (Walt et al 2003).

A product of this context, the *Ad Hoc* Commission was a body of international public health elites, and one of the key individuals working with the Commission was an economist then based at Harvard, but who was working closely with the World Bank on a burden of disease study (Walt et al 2003). Walt et al point out that while Styblo was trying out new ways of treatment for tuberculosis in the field, it was this economist with international contacts, who, with the urgency and authority behind the *Ad Hoc* Commission on Health Research and his influential position in the wider 'epistemic' community of the WB, translated the evidence from field level research and mobilized support to translate it into a broader, generalisable policy. In an interview he stated, "as

part of the background work we did, there was a very simplistic assessment that I did for the Commission on the size of the health problems – very crude, back of the envelope, potential years of life lost. Whenever you do something like that, tuberculosis comes top" (Interview, cited in Walt et al 2003).

They write that the process of policy formulation stemming from this crucial link between field-based, small scale trials and large scale programme implementation occurred

> largely behind closed doors in the corridors of power in Geneva and other Euro-American cities, and with considerable contestation. The broad issues network, which catalysed interest and funds, was composed of many organizations and policy communities, but rapidly divided into two: the technical group (academic, scientific, public health groups) and the advocacy/politics group.
>
> The imperative of this period was towards action and resource generation, and there was a *clear shift away from science and research, towards devising global best practice, public relations and marketing – getting DOTS accepted in countries*. For example, the WHO and the World Bank worked together to get the Chinese government to introduce a DOTS programme. Considerable pressure was put on the Chinese government to agree to the implementation of such a programme (Interview with ex-WHO official, 2000), and the introduction of a DOTS programme in China was seen as a major coup – the chance to demonstrate that DOTS would work in a large, highly populated, high tuberculosis burden country. A key individual played important broker and entrepreneurial roles in this network: seconded from the World Bank to WHO, with considerable experience in China, he brokered the agreement in China, *harnessing the national tuberculosis managers to support the policy, even while higher level Chinese policymakers remained equivocal* (Walt et al 2003, italics added).

3.3 Marketing and dissemination of 'one-size-fits-all' TB policy; contest between scientific and policy-making communities; early 1990s

Following the *Ad Hoc* Commission's report on Styblo's work, the WHO did an evaluation which established "for the first time the legitimacy of using short-course regimens in developing countries" (Ogden et al 2003: 183). Following this the WHO engaged in various studies, workshops and meetings to develop policy for TB based on Styblo's methods.

> DOTS was not mentioned at this point – the brand had not yet been conceived – but the components of the strategy discussed were: improvement of cure rates (85 per cent in developing countries, 95 per cent in developed); expansion of TB services (to be pursued only when first objective was reached) through the available health services networks, at least down to district level; detection of more sputum positive cases (i.e. to expand case finding); setting global targets (85 per cent cure rates of smear positive patients under treatment and 70 per cent case detection) (Ogden et al 2003: 183).

In 1991 WHO and the World Bank initiated the China TB Project, essentially testing the implementation of Styblo's approach there with a World Bank loan of US $ 50 million. Meanwhile, to combat criticism that WHO's Global TB Programme was moving too slowly, it hired an advocacy expert from the USA, and "within a few months of his arriving the whole tenor of the TB Programme shifted from a primarily technical focus to intensive advocacy" (Ogden et al 2003: 183-184).

During this time, members of international organizations who made up the advocacy/ politics coalition were more active while the scientists, academics, public health practitioners were marginalized. The advocacy coalition took on two main tasks:

> the first was to simplify the work of the epistemic community which had been built on local knowledge and conditions into *simple, 'one-size-fits-all' best practices, presented as easy to understand steps, which needed to be rigidly adhered to.* The tuberculosis programme team at WHO worked on a Framework for Effective Tuberculosis Control (WHO 1994), which distilled Styblo's complex 200-page tuberculosis "cookbook" (Interviews 2000) into more *manageable* elements, and then further simplified them into what became the five essential elements of DOTS (Ogden et al 2003). [...] The second task was to communicate and *disseminate this simplified strategy as new global 'best practice'* (Walt et al 2003, italics added).

In an interview with the expert responsible for the branding and dissemination strategy – who "likened DOTS to a brand such as Coca-cola" – Ogden et al note his sense of success,

> I look at the DOTS campaign as being a remarkable success in brand name dissemination around the world... DOTS is perhaps the best-ever public sector campaign... When you manage to get your brand name disseminated to the lowest possible level, then you've succeeded. This is an important mechanism of policy transfer—*you need to have a message that is simple enough to rally people around so that even if they don't understand it they can say that they want it* (Ogden et al 2003: 184).

And then, Walt et al point out, after DOTS was launched in 1995 it was "followed up by wide dissemination of tuberculosis emergency figures in 1996 (WHO 1996)" (Walt et al 2003).

They also point out, however, that the marketing and advocacy of DOTS through such a process of branding shocked and was contested by many in the tuberculosis community.[9] Some argued that marketing led to distortions, dogma and relatively coercive approaches to TB therapy, others demanded more research and support for

vaccine and drug developments, while some argued that DOTS programmes were being "imposed on countries, service providers and patients, and were out of touch with people's needs and health service realities on the ground" (Walt et al 2003). "While the WHO were pushing the use of conventional TB control methods, updated and repackaged as DOTS, *the scientific community was concerned that DOTS was going to be operationally difficult and that it was a dangerous over-simplification of an extremely complex problem*" (Ogden et al 2003: 184, italics added).

This lack of concern in the WHO regarding the over-simplification of the DOTS message, as well as its apparent lack of interest in research for new drugs fits with the explanation Ogden et al provide – that

> the main emphasis in the Organisation in the mid- to late 1990s was on *operations*, with a strong political approach that focused on advocacy and communications, and *targeted donors and policy makers* rather than academics and scientists. The Global TB Programme explicitly *intended to develop a policy package that was simple and marketable to policy makers and programme implementers*" (Interview, cited in Ogden et al 2003: 184, italics added).

Discussing the response among WHO to this dissent, they quote from one key player's interview,

> A lot of the allergies you have in the scientific community around the DOTS strategy are actually quite predictable given the difference between *how to sell something effectively* and how doctors learn things in medical school *and how academics operate. Advocacy is the exact opposite! You don't slowly and carefully build an argument in order to convince – you start with a simple clear message to grab attention*, and work down and start filling in the gaps and the explanations (Interview, cited in Walt et al 2003).

This illustration from Walt et al's work has analyzed how the combined power of the World Bank and the prevailing advocacy orientation at WHO led to the strong promotion and adoption of the DOTS strategy around the world. It has consolidated further the argument of the rest of this chapter, and that of the preceding one – that the tools and methodologies that aid the process of assessing risk in tuberculosis, which constitutes what I call the risk discourse in tuberculosis, are contingent on the myriad processes underlying technical/ scientific expertise and knowledge, and on the organizational contexts within which they are framed.

End Notes

[1] This article, accessed from http://www.hull.ac.uk/futgov/Papers/PubPapers/WaltPaper16.pdf on May 28 2009, does not have page numbers.

[2] See Amrith, Sunil (2004) 'In Search of a "Magic Bullet" for Tuberculosis: South India and Beyond, 1955-1965' Social History of Medicine 17 (1): 113-130, for a discussion on the intrusiveness of compliance checks on patients under self-administered domiciliary therapy.

[3] Pyrazinamide was a drug relegated to reserve regimen chemotherapy in the 1950s, notes Fox, W. in 'Whither Short Course Chemotherapy?' *Br J Dis Chest* (1981) 75, pp 331-357.

[4] Fox refers to Stradling, P. *Proceedings of the Royal Society of Medicine*, 1957, 50, 342 [name of article not mentioned], and Stradling P, Poole G. 'Self-medication in tuberculosis' *Lancet* 1958; ii: 1066-67.

[5] Bayer and Wilkinson refer to some of Sbarbaro's writings on this issue Sbarbaro, J.A. (1979) 'Compliance: inducements and enforcements' *Chest* 6 (suppl): 750-56; Sbarbaro J.A. (1981) 'The nature of man and physician' *Am Rev Respir Dis* 123: 247; Sbarbaro J.A. (1988) 'All patients should receive directly observed therapy in tuberculosis' *Am Rev Respir Dis* 138: 1075-76.

[6] Opposing attempts to end the system of slavery, these Confederate States of America (CSA) fought the northern states (the Union) in the American Civil War (1855-60). The Civil War culminated in abolishing slavery and set in place laws enabling civil rights for Africans freed from slavery. Through the century of the mid-1870s to the 1960s, however, successive Democrat governments in these former Confederate states passed segregation laws which continued severe discrimination against African-Americans in a bid to restore white supremacy. This gave rise to the American Civil Rights Movement in these very states in the mid-1950s which culminated in several civil rights laws outlawing segregation and discrimination against African-Americans by the late 1960s. Starting from this decade the Democratic Party started supporting the civil rights movement, in the process heavily losing its strong support base in these states.

[7] Award Citation of the American Lung Association President's Award to Karel Styblo (1990). Presented by Anne Davis at the 1990 World Conference on Lung Health, *Bull IUATLD* 65 (2-3): 12.

[8] Some examples of such studies are: Jagota, P. Xirasagar, Sudha, Parimala, N., and Chaudhuri, K. (1989) 'A Study of Operational Factors Influencing the Applicability of Two Regimens of Short Course Chemotherapy under Conditions of an Urban Tuberculosis Programme' *Ind. J. Tub.*, 36: 213; Mankodi, Kashyap (1982) 'Socio-Cultural Context of TB Treatment: A Case Study of Southern Gujarat' *Ind. J. Tub.*, Vol. 29(2); Gehani, S., Perumal, V.K. and Mathur, G.P. (1989) 'A Study to Determine the Reliability of Assessing the Regularity of Self-Administration of Drugs at Home by Patients' Attendance at the Clinic' *Ind. J. Tub.*, 31: 74; Aneja, K.S. and Samuel, G.E.R. (1982) 'Organizational Effort in a Clinical Trial and its Relevance to Applicability of Short-Course Chemotherapy in National Tuberculosis Programme *Ind. J. Tub.*, 29 (1); Satagopan, M.C., Radhakrishna, S., Krishnaswami, K.V., Somasundaram, P.R., Tripathy, S.P., and Fox, Wallace (1983) 'A Novel System to obtain Addresses of Out-Patients: Assessment in Routine Clinic Practice in Madras *Ind. J. Tub.*, 30: 93.

[9] Their citations on this literature include – Editorial (1994). Tuberculosis in HIV infection. Lancet, 344, 277–278; Brown, P. (1997). TB claims slammed as dangerous. New Scientist, 2078, 4; Rangan, S., & Ogden, J. (Eds.) (1997). Shifting the paradigm in tuberculosis control: a state-of-the-art review. Delhi: Department for International Development (UK) Health & Population Office.

Global Methodologies of Risk?: Annual Risk of Infection

Methodological tool – Annual Risk of Infection

I Annual risk of tuberculosis infection (ARTI)

1 Risk of infection – an outline

Annual risk of tuberculosis infection (ARTI, or just ARI) is defined as the probability of acquiring new infection or re-infection during the course of one year and is computed from the estimated prevalence of infection among younger children (Chadha et al 2005). Theoretically, 'risk of infection' has the potential to be informative about the extent of transmission of tubercle bacilli in a community (Rieder 2005), and, further, allows for a comparison of the extent of transmission in various populations (Rieder 1994). Information about risk of tuberculous infection is abstracted from tuberculin skin test surveys, conducted among children, measuring prevalence of infection among them. Set to a statistical calculation, this information indicates the risk of infection that the wider community is exposed to (Narain et al 1965: Bogen 1957). This concept of ARTI, developed by Karel Styblo and colleagues from the Tuberculosis Surveillance Research Unit in 1969 (Styblo et al 1969), is thus a calculated average from an observed prevalence of infection, approximating the incidence of infection (Rieder 2005).

The first infectious disease to be studied by means of the risk of infection was smallpox in the year 1760 (Sutherland 1981).[1] The use of the risk of infection to study tuberculosis is, by comparison, very recent; the earliest reference in the literature is to work by H. Muench in 1934.[2] In a paper summarizing the development of the risk of infection with *Mycobacterium tuberculosis* as a model, H Rieder of the IUATLD writes "in 1934, Muench proposed a means to derive average annual rates of infection incidence from observed infection prevalence using, among others, the example of infection with *M. tuberculosis*" (Rieder 2005: 181). Further, "in 1957, Nyboe formulated the simplest model to estimate expected prevalence (P) of infection from a known constant risk (R) by age and calendar year, i.e. $P = 1-(1-R)^a$, where a is the age at which the observed prevalence is expected. Solved for R, the following is obtained:

$R = 1-(1-P)^{1/a}$" (Rieder 2005: 181). This is the standard approach to derive the average annual risk from prevalence of infection under the assumption of no change over calendar time.

However, the true incidence of infection is likely to change over calendar time. Rieder writes that this issue was addressed in the work of the TSRU, which developed a model of the dynamics by taking calendar changes in the risk of infection into account from a *series* of tuberculin skin-test prevalence surveys (Rieder 2005). In a further study employing the same methodology, Murray, Styblo and Rouillon write, "If several tuberculin surveys of the same population have been made at different times (using similar techniques and testing a representative sample of non-BCG-vaccinated subjects of the same age) the level of and percentage decrease in the risk of infection can be estimated" (Murray et al 1990).[3] This way, "the risk of infection becomes a better approximation of the average annual incidence of infection in the community" (Rieder 2005: 182).

As regards early work in India on this, in the mid-1960s, Raj Narain and colleagues at the NTI worked to develop a suitable method to derive estimations of the risk of infection (Raj Narain et al 1965). They took into account the various limitations associated with epidemiological knowledge, programme issues in India, and earlier studies and methods estimating risk of infection indirectly (via age-specific rates of prevalence of infection using a mathematical method) as well as directly (by repeating the tuberculin test in the same population after an interval), and the problem of the influence of non-specific allergy. They used the method of repeat tuberculin test, and assessed the emerging information through two methods. First, by a simple method of conversion rates (wherein they regarded as newly infected those tuberculin 'negatives' of the first round who became 'positive' at the second round), and, second, by increase of allergy as evidence of new infection (wherein they noted that "if new infection causes a distinct rise in tuberculin allergy which is larger than the combined rise due to boosting and reader variation, the distribution of the differences in 1 TU reactions from the first to the second round should show the newly infected distinctly" (Raj Narain et al 1965: 9-12).

However, they noted that even though the second method of estimating the newly infected was a definite improvement over the first, both these methods were tentative and needed testing on larger populations and also on those from other areas. The problem with trying to estimate the risk of infection, they wrote, was

> to estimate the previously non-infected at the beginning of a specified period and to estimate the number among them who develop primary infection during the period. Both these groups, however, are difficult to determine as they are influenced by experimental errors associated with tuberculin testing and reading, prevalence of non-specific allergy, waning of allergy and chance variations. In addition, the results of a second tuberculin test are influenced by boosting effect and this creates further problems in the estimation of newly infected (Raj Narain et al 1965: 16).[4]

They write that the second method used by them eliminates the effect of all these factors, but "it is not possible to identify the newly infected persons by the method, except in age group (0-4)" (Raj Narain et al 1965: 16).

2 Tuberculin testing

The risk of infection index can be obtained by carrying out tuberculin testing on an appropriately representative population with the appropriate technique, either on the same age group tested repeatedly over certain time intervals or on different age groups at one point in time (Bogen 1957; Shimao 1983). Given that the aim of these surveys is to test current, or at least recent, risk of infection, globally, it is children who are tested (Dye et al 2008). The age range of children enrolled for tuberculin skin test usually ranges between 1-15 years, with the aim to test for prevalence of natural infection among them. In developing countries the age limit is lower, usually below 10 years (Chadha et al 1997).

In India, as elsewhere, different studies through the decades have used different age limits for tuberculin testing of children. In a comment on the WHO Expert Committee's Seventh Report's declaration (WHO 1959) that tuberculosis ceases to be a public health problem when the prevalence of natural reactors to tuberculin among children of age 14 years is less than 1%, S.S. Nair of the NTI pointed out that

> in countries where BCG vaccination is carried out, prevalence of natural infection at age 14 cannot be established by tuberculin testing. To overcome this difficulty, it has been suggested by some tuberculosis workers to withhold vaccination from some areas and/or to consider prevalence of infection in very young children (age 0-4 years). The

> former cannot be justified as a long-term arrangement. The latter presupposes vaccination through mass campaigns which take 5 years or more to cover the area and requires surveys of very large populations to get adequate number of children for examination (Nair 1977: 58).

The most recent large-scale effort to assess prevalence of infection in the Indian population is the NSS ARTI survey 2002-2003, which has tested children ranging from 1-9 years (Chadha et al 2005).

For tuberculin testing, a representative sample of children without BCG scar is injected intradermally with a standard dose of tuberculin; the test is administered usually on the mid-volar aspect of the left forearm. An induration develops at the point of injection; this is read/ interpreted by trained readers after 48-96 hours and the maximum diameter of induration is recorded. The prevalence of infection can be estimated by using three different methods to read the frequency distribution of reaction sizes that emerges – one is the cut off point method, the other is the mirror-image technique, and the third is a combination of the two, called mixture analysis. ARTI is then computed from the estimated prevalence of infection by using the above-mentioned statistical equation, $R = 1-(1- P)^{1/a}$, where 'R' is ARTI, 'P' is prevalence and 'a' is average age of the group of children tested.

3 Why study risk of infection

A repeated reason mentioned in the literature regarding the need for risk of infection information, is the paucity and absence of adequate information (globally, as well as within each country) on *relevant*, as well as *comparable*, parameters of TB epidemiology. Developed industrialized countries have had notification, surveillance and data gathering mechanisms and systems for health information since much earlier than developing countries, and the paucity of information has been noted as a customary feature of the developing countries.[5] Also, the "rate of new infection with Myco. tuberculosis [...] is of considerable importance in understanding the epidemiology of tuberculosis and in organizing control measures", as "the epidemiology of tuberculosis morbidity may differ between communities with high and low risks of infection" (Raj Narain et al 1965: 5). The high prevalence of disease in developing countries played no small part in the creation of a heightened sense of anxiety among the developed countries, who perceived this lack of relevant

epidemiological information as the biggest obstacle in planning future control programmes for tuberculosis in these countries.

Testimony to this is the institution of the Tuberculosis Surveillance Research Unit (TSRU), a collaborative enterprise between the WHO, the IUAT and the Royal Netherlands Tuberculosis Association (KNCV) (wherein Styblo conducted the pioneering Kolin study), set up in the mid-1960s in the Netherlands to "study tuberculosis epidemiology *relevant to tuberculosis control and surveillance*" (Rouillon 1998: 5, italics added). The legacy of TSRU lies in the fact that it is where Styblo, as Head of Scientific Activities, constructed the concept of risk of infection in 1969. TSRU's initial years were invested in the study of low prevalence countries to determine the means and procedures that helped these countries reach their current status, and though "it was understood from the beginning that the studies should be planned in such a way as to facilitate tuberculosis control in *high prevalence* countries as well", the TSRU started including the epidemiological issues of these high prevalence countries in their studies only by 1980 (Rouillon 1998: 5, italics in original).

Ian Sutherland's (of the BMRC, consultant to TSRU, and co-author of the seminal 1969 'Risk of Infection' paper along with Styblo and Meijer) discussion of the concept of risk of infection echoes the thinking within TSRU when he points out that the study of TB epidemiological parameters and tools like risk of infection is important because *it has decisive implications for population level strategies for the control of tuberculosis* (Sutherland 1981). Given the specificities of TB epidemiology, he contends that while attempting a comparison of the relative benefits of prevention-based policies and cure-based policies for population level TB management, seeing the outcome of these two kinds of policies on the risk of infection is what enables the most relevant assessment. In other words, the risk of infection/ the issue of transmission is positioned as *the* most important aspect of TB management and control, and all epidemiological investigations and strategies should be assessed in terms of their relative abilities to influence shifts (reductions) in this main aspect.

Literature suggests that the WHO also endorsed the concept of the risk of infection because of the benefits of enhanced information that it offered, which could bypass previous data-related shortcomings. Martien W. Borgdorff discusses a seminal WHO

document (Cauthen et al 1988), which, by using the risk of infection model to study global epidemiology of TB, legitimized its foundational role in future epidemiological analyses. Borgdorff writes,

> In 1977, before Cauthen et al.'s document, WHO identified high-burden areas for TB, separately for prevalence of infection, notification rates, and mortality. Since tuberculin surveys had been conducted in different age groups, a direct comparison of infection prevalences between areas was not possible. TB incidence and mortality were estimated from notification rates of countries reporting these and were extrapolated to other countries.
>
> The document of Cauthen et al. made two important contributions. It applied the concept of the annual risk of infection to data from a broad range of countries and it included an assessment of trend, rather than of current status only. The concept of annual risk of infection had been developed and applied to Dutch data by Styblo et al. *The attraction of this measure is that, contrary to notification data, it is independent of the quality and comprehensiveness of the notification system* (Borgdorff 2002: 501, italics added).

4 The Styblo Rule

In 1985, another seminal publication from TSRU and Styblo emerged, titled "The relationship between the risk of tuberculous infection and the risk of developing infectious tuberculosis," (Styblo 1985) which promptly became a "guiding rule" and the most "established and cherished part of the epidemiological canon" (Dye 2008: 4). The aim of this paper was to "study whether a uniform empirical relationship can be established between the annual risk of tuberculous infection in a community and the incidence of infectious (smear-positive) tuberculosis and, if so, to estimate this parameter" (Styblo 1985: 117). The paper stated that an ARTI of 1% corresponded to about 50 new cases of pulmonary TB disease for every 100,000 population.

Even though this paper (which analyzed data from 1950s-70s) was published in 1985, the conceptualization and methodology for this estimation were in place at least by the end of the 1970s, as Styblo and Rouillon published an article on data from this estimation in 1981 (Styblo and Rouillon 1981) and a report on this estimation was presented in the public domain at the 25th World Conference of the IUAT in Buenos Aires, Argentina in 1982. In the 1981 article, discussing the estimates of disease incidence from the risk of infection Styblo and Rouillon write,

> The Tuberculosis Unit of the World Health Organization has asked the TSRU to go further and to study whether there was an empirical relationship between the level of

> the risk of tuberculous infection in a community and the incidence of smear-positive pulmonary tuberculosis. It was felt that such information would be especially important for developing countries because it would enable them to estimate the incidence of smear-positive cases from the tuberculosis infection rate, without any further investigation, and hence plan more easily the efforts to be made to cope with the problem (Styblo and Rouillon 1981: 123).[6]

Apart from estimating disease incidence from ARTI, Styblo's 1985 paper also derived a fixed mathematical relationship between the risk of infection and prevalence of smear positive TB. In the data from 10 of the 13 developing countries, the ratio between the ARTI (expressed as a rate per 100,000 population) and the number of prevalent smear-positive TB cases (per 100,000) was about 10, i.e., each prevalent smear-positive case makes about ten contacts per year that lead to (new) established infections.

The estimation of disease incidence from risk of infection was derived in the following manner. Of the information needed to quantify the relationship between ARTI and disease incidence, information on infection prevalence (and thus on ARTI) was available in a number of developed and developing countries. But given the asymmetric state of global epidemiological information in relation to disease incidence, Styblo employed certain epidemiological assumptions in relation to this parameter. Assuming (i) incidence is twice the mortality, and (ii) incidence is half the prevalence (assuming duration of disease of two years), he derived estimates of the disease incidence of TB from three different sources. van Leth et al highlight that while *directly measured incidence in the general population was used only in the Netherlands*, data on TB mortality were used to estimate disease incidence in the Netherlands and Alaska, and data on measured prevalence of disease was used to estimate disease incidence for India and other developing countries, i.e., 13 African countries (van Leth et al 2008). The following table will provide a clearer picture.

Table 1: Data as reported by Karel Styblo

Source	Period	Disease parameter	ARTI (%)	Ratio between ARTI (%) and Mortality[a]	Incidence[a]	Prevalence[a]
Netherlands	1921–1928	Mortality	2.7–6.0	**19**	38 [19x2]	–
Netherlands	1951–1976	Incidence	0.038–0.4	–	**37**	–
Developing countries	1956–1961	Prevalence	2.0–8.0	–	40–60 [80/2; 120/2]	**80–120**
Alaska	1948–1951	Mortality	25	**26**	52 [26x2]	–
India	1961–1968	Prevalence	1.5	–	53 [106/2]	**106**
India	1969–1971	Prevalence	4.1	–	51 [102/2]	**102**

ARTI = annual risk of tuberculous infection
[a] = per 100 000 population
van Leth et al indicate in **bold figures** data from source documents used by Styblo; the other figures are the estimates that Styblo derived using his assumptions.
The figures in square brackets are added by me, signifying the assumptions Styblo employed.

Table adapted from van Leth, F, MJ van der Werf & MW Borgdorff (2008) 'Prevalence of tuberculous infection and incidence of tuberculosis; a re-assessment of the Styblo rule' *Bulletin of the World Health Organization* 2008; 86:20–26.

Thus, Styblo calculated that 50–60 new cases per 100,000 population per year of smear-positive TB corresponded to 1% ARTI. Since then, the usual method used to estimate the incidence of TB disease in the general population has been to assess the ARTI and apply the Styblo rule to it (van Leth et al 2008).

II Critiques and methodological shortcomings

The literature suggests that there are two broad kinds of critiques relating to the risk of infection – one relates to the *very computation of the risk of infection*, and the other relates to the *use that the risk of infection model is put to* in programme settings. The first kind of critique, constituted by technical issues noted in the literature since several decades, points out that the prior steps required for the gathering of accurate information, in order to then estimate risk of infection, are themselves limited by significant errors and shortcomings. The second kind of critique, which has evolved only during the last decade and half, re-assesses the applicability of the Styblo Rule, and pointing out several important technical limitations in this relationship questions the use of this relationship to estimate disease incidence for programme purposes.

1 Critique relating to the computation of the risk of infection – Methodological shortcomings of tuberculin skin testing

Even though tuberculin testing is one of the oldest and most central tools for gauging tuberculosis infection prevalence, it has since long been noted as an extremely ambiguous measure in certain epidemiological situations. Given that tuberculin testing is done to find out prior sensitization to *M. tuberculosis* (whether a person carries mycobacterium tuberculosis in her body) (Friedan 2004), two scenarios can complicate the validity of this assessment. As a large body of Indian and global literature has testified, the phenomenon of 'non-specific reaction' or 'low grade sensitivity' makes it difficult to interpret the test clearly in areas with a high presence of other kinds of mycobacteria in the environment. A weak reaction to tuberculin thus can often indicate cross-reacting sensitivity to non-tuberculous mycobacteria. "Tuberculin reactions become more unreliable in areas with nonspecific sensitivity. The distortion by the latter can be quite considerable even in younger age groups. Chakraborty et al, (1976) have reported a prevalence rate of 2.1 % for tuberculous infection in 0-4 year children and 12.9% (about 6 times) for infection by other mycobacteria giving rise to non-specific sensitivity" (Nair 1977: 58).

And, the second issue, which has also been addressed in the Indian literature, is that a positive reaction of the test is difficult to interpret clearly in areas with 'tuberculin sensitivity', i.e., a prior history of mass BCG vaccination. Thus, the

> major obstacle to determining the prevalence of infection, and, thus, deriving the risk of infection, is related to the *varying and unpredictable specificity* of the tuberculin skin test in various settings. Specificity is driven by the frequency of nonspecific sensitisation to environmental mycobacteria, as well as the type, policy and extent of BCG vaccination. In such settings, it often *becomes arbitrary to define a cut-off point that 'balances' errors resulting from a lack of sensitivity against errors from a lack of specificity*. Similarly, assuming a symmetric distribution around the true mean of the diameter of tuberculin skin-test reaction sizes from true tuberculous infection becomes a doubtful undertaking (Rieder 2005: 183).

Given that these 2 epidemiological scenarios dominate in several developing countries, the feasibility and usefulness of conducting tuberculin tests is questionable for large parts of the world because the results of the tests cannot be interpreted unambiguously.

However, Rieder points out that when the ARI estimation was evolved in TSRU, this issue of "[r]educed specificity of the tuberculin skin test in areas where cross-sensitisation is frequent was not addressed by the TSRU report, largely because *it was not of particular relevance in The Netherlands at the time* the data had been collected" (Rieder 2005: 182, italics added). Thus, the established global parameters regarding interpretation of the tuberculin test in relation to ARI were established in one specific epidemiological context, which then, was unproblematically transposed onto all other epidemiological contexts. This was done without any consideration of not only the differences, but also of the fact that these differences posed such fundamental questions for tuberculin test interpretation that they would almost render these parameters irrelevant for situations unlike the Netherlands.

The practical problems of embarking on tuberculin testing in such areas have been elaborated by Rieder with the example of Tanzania, the early experimental ground for the IUAT's and the TSRU's later forays into research in developing nations. Under the Mutual Assistance Programme of the IUAT large numbers of children in Tanzania had been BCG vaccinated, and there also existed a "staggering amount of nonspecific reactions" (Rieder 2005: 183), which effectively meant that any groups of unvaccinated children selected for tuberculin testing for ARI estimation would not be truly representative of the larger population. Interestingly, Rieder points out that even though "several major obstacles were encountered [...] the results of the tuberculin skin-test surveys were presented at TSRU meetings, *but were never published in the formal biomedical literature*" (Rieder 2005: 182).[7] Noting that the value of ARI is reduced in countries where these two scenarios exist, literature has often urged that "[t]he significance of the tuberculosis prevalence survey in estimating the prevalence of the disease and that of the repeated ones in estimating the trend of the disease should be investigated in detail in this connection" (Shimao 1983: 37).

Further, it is also important to note that variations with regard to each technical aspect of tuberculin testing exist in the literature, with different studies during various years and locations having incorporated different parameters in their research. For instance, there are variations in the dose and type of tuberculin used (1TU PPD RT23 with Tween 80 being the latest); of the specific location on the left (or right) forearm on which to administer the test; on the duration (number of hours) after which the test is to

be read; on whether the maximum longitudinal or the transverse diameter has to be read; whether it is at all necessary to distinguish between BCG-vaccinated and unvaccinated children prior to tuberculin testing; on the most appropriate method used for interpreting the frequency distribution; and several related issues. This raises some inevitable questions: one, can these myriad data sets be treated as if they are comparable across time, place and procedure, and, two, when the broad TB epidemiological literature provides judgements or estimates of infection/ disease prevalence or infection based on collated or comparative information arising from these myriad data sources of tuberculin test results, how reliable and epidemiologically sound are such judgements?

The problems of non specific reaction or prior sensitivity through mass BCG vaccination are just two of a wide range of methodological shortcomings related to the risk of infection model. Apart from this, two other issues mentioned in the literature are the problem of boosting, and the issue of terminal digit preference in tuberculin test interpretations. That repeated testing with tuberculin often results in "enhancing of tuberculin allergy" emerged out of the early studies done by Raj Narain et al at the NTI (Raj Narain et al 1965; 1966). Rieder points out that in boosting "the induration size tends to increase on repeat testing even if no infection was acquired in the interim between the two tests" (Snider and Cauthen 1984, cited in Rieder 2005: 182). He also writes that even though Raj Narain et al's 1966 study developed a methodology to address the boosting problem in incidence surveys, "it has never gained wide acceptance" (Narain et al 1966, cited in Rieder 2005: 182). As regards terminal digit preference, Rieder writes, "[t]erminal-digit preference refers to the readily observable fact that humans tend to exhibit preferences for certain digits, such as those ending in zero or five, or even numbers over odd numbers. This can create problems when cut-off points containing such digits are being used to determine the proportion of individuals who are infected with M. tuberculosis" (Rieder 2005: 183).

2 Critique relating to the relationship of risk of infection to burden of disease – Condition of 'absence of control measures' no longer fulfilled

Even though most critiques against Styblo's estimated relationship between risk of infection and burden of disease have emerged in the mid-1990s and in the mid-2000s, it

is important to point out that an understanding of the specific applicability of this statistical relationship to programme management in *developed* countries was recognized much earlier. For instance, Tadao Shimao of Japan's Anti-Tuberculosis Association noted in the early 1980s, "[t]he relation between the annual risk of infection and other epidemiological indices was analysed, and it was found that there was a good correlation between them *as far as* the Western European countries are concerned" (Shimao 1983: 37).

Writing in the mid-2000s, writers have pointed out that Styblo's equation showed a constant relationship between disease incidence and infection risk in the pre-chemotherapy era settings (Rieder 2005). Not only was Styblo's data from an era without established TB control programmes and TB treatment regimens, but it was also before the emergence of the HIV epidemic (van Let et al 2008). The scenario of TB therapy and programme management having changed since then, van Leth et al point out,

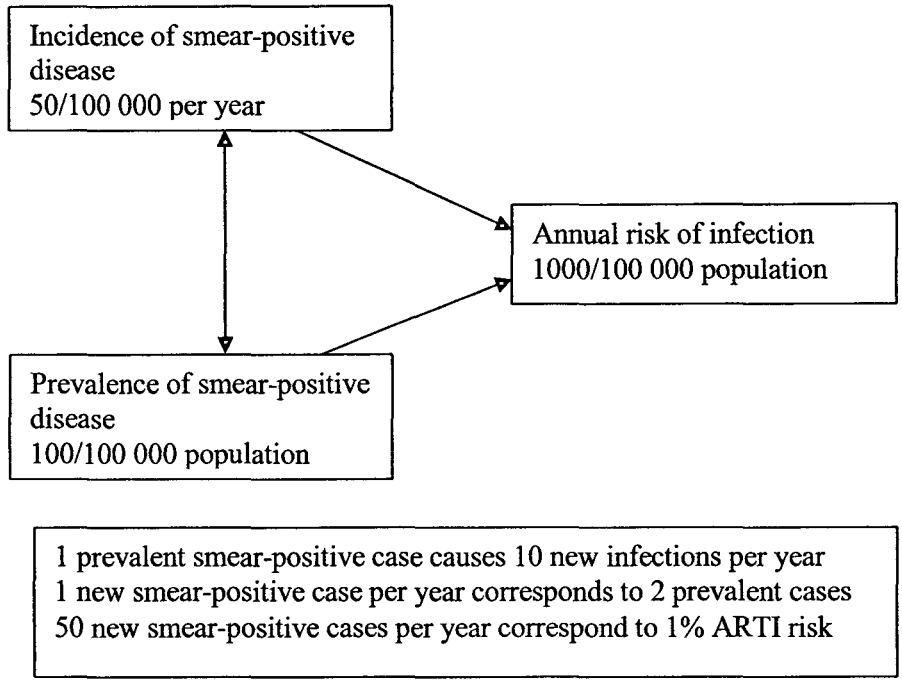
> it is likely that the fixed mathematical relationship does not hold. Identification of smear-positive TB cases through control programmes and treatment of the cases with effective drug regimens will *reduce the duration of infectiousness, and as a consequence interrupt ongoing transmission.* Furthermore, HIV-associated TB becomes symptomatic faster than TB in HIV-negative individuals, which may lead to earlier detection and treatment with interruption of transmission. *With any interruption in transmission, the number of new tuberculous infections per prevalent smear-positive TB case will be lower than originally reported by Styblo. As a consequence, the incidence of smear-positive TB must in these circumstances be higher to establish an ARTI of 1%. Therefore, using the Styblo rule for calculating the incidence of smear-positive TB might not be a valid approach in a situation where interventions that interrupt transmission are available* (van Let et al 2008: 21, italics added).

van Leth and other writers have built this line of reasoning drawing from the work of one of the earliest proponents of this argument, H.L. Rieder of the IUATLD, who in a 1995 article pointed out that,

> infection risk is intrinsically coupled to duration of undiagnosed, untreated transmissible tuberculosis, thus with person-time of infectiousness in the community. Intervention with chemotherapy has as its epidemiological aim to reduce the rate of transmission, and where this form of intervention encompasses effectively and efficiently a large proportion of the population, *the average duration of infectiousness connecting prevalence and incidence becomes fundamentally changed* (Rieder 1995: 120).

The following illustration from van Leth et al's study – whose main question was, "does the Styblo rule, with an estimated 8–12 new tuberculous infections per year per prevalent smear-positive case of TB disease, still hold?" (van Let et al 2008: 21) and through this to assess the validity of the Styblo Rule for estimating disease incidence from ARTI – will elaborate this point further.

Figure 2 Mathematical relationship between ARTI, and prevalence and incidence of smear-positive TB according to the Styblo rule. Figure adapted from van Leth et al (2008).



The ratio between risk of infection and disease incidence has an inextricable link with transmission rates, i.e., the number of infections generated per case, and if the established rule that '1 prevalent case causes about 10 new infections per year' no longer holds, then it will impact the validity of the Styblo Rule. Further, Rider has also questioned the validity of the assumption that for areas where information on disease incidence was lacking, the incidence could be derived by dividing prevalence by two (Rieder 1995) (based on another assumption that duration of disease was on average two years). Indeed, Murray, Styblo and Rouillon's own later expanded study on this relationship states that this was a "historical observation," in "communities without widespread institution of chemotherapy" (Murray et al 1990: 7). Thus, Rider finds this "somewhat circular argumentation" to be a major weakness of the Murray et al paper (Rieder 2005: 183).

Further, Borgdorff points out that even though "Cauthen et al themselves warned against the extrapolation of their results to countries which were not surveyed," in Murray et al's "estimates of TB incidence in developing countries [based on the former's prevalence of infection data...] results were extrapolated from countries covered by tuberculin surveys to countries not covered" (Borgdorff 2002: 501, italics added). In sum, with the introduction of TB therapy, management and control efforts the duration of illness and prevalence-to-incidence ratio are expected to be lowered, and "if β [contact rate] is less than ten or $P < 2I$, [prevalence is less than twice the incidence] then the ratio of smear-positive incidence to ARI exceeds 50" (Dye et al 2008: 240), i.e., to produce a 1% risk of infection a lager number of incident cases will be required (Rieder 1995).

Given these many critiques, several writers have urged that "we can no longer assume that the Styblo rule applies generally" (Dye et al 2008: 240). Murray, one of the prominent figures responsible for legitimizing the Styblo Rule, has also acknowledged in a 1996 publication that "[t]here is little or no evidence that ARI and incidence are correlated in the modern era where chemotherapy is used in nearly all populations to a greater or lesser extent" (Murray 1996: 10). Yet, even in 1998, "despite the apparent flaw in argumentation, the erroneous notion that information about the risk of infection allows the estimation of disease incidence stubbornly persist[ed], even in some prominent publications" (Rieder 2005: 183), such as the WHO TB handbook (WHO 1998). However, writing in 2008, van Leth et al report that "WHO's Strategic and Technical Advisory Group [...], in its meeting in June 2006 in Geneva, endorsed the recommendation of a WHO working group to no longer use the Styblo rule to estimate the incidence of smear-positive TB" (van Leth et al 2008: 24).

3 Other methodological issues in the literature

- The aforementioned problem of the lack of adequate epidemiological data and the questionable quality of tuberculosis notifications and data collection especially in developing countries.
- In spite of warnings in the 1988 Cauthen et al document, against the extrapolation of these results from countries covered by tuberculin surveys to

countries which were not surveyed, epidemiological analyses that have used this important document as a base for further work have made such generalized estimates (Borgdorff 2002, referring to Murray et al 1993).

- Styblo's rule for estimating disease incidence from ARI was based on a relatively small database (Borgdorff 2002).
- In countries with a high prevalence of HIV infection, the relationship between risk of TB infection and the incidence of TB will definitely be altered, depending on the infectiousness of HIV-infected TB cases (Borgdorff 2002).
- In countries like India, where BCG vaccination has been a long term policy and its success is measured in terms of its coverage, not only is finding unvaccinated children for ARI surveys difficult, but studies done on unvaccinated children pose uncomfortable questions either about the claimed 'coverage success' of BCG programmes, or about the ethical implications of purposively leaving some areas devoid of vaccination services.
- The serious problem of malnutrition and under-nutrition among Indian children, and its impact on the value of tuberculin skin tests.
- There are serious technical, logistical and financial issues associated with carrying out representative tuberculin skin test surveys, especially in resource-constrained settings.

4 Epidemiological indices and their role in programme management – more dilemmas

In order to understand ARI, it is also important to have a sense of the complex inter-connections between the main epidemiological indices related to TB, i.e., prevalence of disease, incidence of disease, prevalence of infection, incidence of infection and tuberculosis mortality. These indices are discussed in the literature primarily in terms of the implications these indices have on *programme planning for TB management and control.* The literature suggests that two things form the crux of the definitions as well as applications of many epidemiological concepts and tools as related to programme assessment – (i) *the inability to conduct routine surveillance in, and gather comparable data from, the developing countries*, due to the inadequacy and unreliability of tuberculosis data emerging from them, and, (ii) the need to *prioritize factors that respond visibly and substantially to control efforts and interventions*, such as chemotherapy.

Based on this, a further analysis of the different viewpoints in the literature suggests that the indices which provide information about progress towards the goal of *control/ elimination are prioritized and utilized more enthusiastically in the scientific and programme planning literature* than those contributing to information on trends assessment and surveillance. Further, though there are important limitations with regard to each index, limitations of the indices providing information on control efforts are treated more casually and continue to be legitimized as compared to limitations of the other indices.

Thus, for instance, in the late 1970s, considering that the WHO Expert Committee's Seventh Report established *reduction in prevalence of infection* as the main indicator for TB ceasing to be a public health problem, S. S. Nair of the NTI wrote that out of the main epidemiological indices,

> It could be inferred that the three other epidemiological indices for measuring the problem (or the reduction thereof) viz., prevalence and incidence of disease and incidence of infection have not been considered to be as suitable as prevalence of infection. One reason for this could be that prevalence or incidence of disease can be established only by expensive epidemiological surveys in countries where notification of tuberculosis cases is incomplete. To establish incidence of infection, repeated tuberculin testing may be necessary and their interpretation poses many difficulties e.g., the enhancing effect of repeated testing (Nair 1977: 58).[8]

He goes on to point out,

> Prevalence of infection is the least sensitive index for measuring *changes* in the tuberculosis problem. This is understandable because the incidence of infection is only a small fraction of the prevalence of infection (e.g., one-ninth for children of age 0-14 years; NT1, 1974). Even a complete absence of incidence of infection (i.e., 100% reduction) can bring down the prevalence rate only by a small extent (say 11% in age group 0-14 years and much less for all ages combined) (Nair 1977: 59, italics added).

Viewed in this context,

> The criterion suggested by WHO was not intended to be an index of change and its use for that purpose may not be justified. This criterion was intended to assess *whether the goal of control has been reached* and could be applied without reservation *only after a period of about 30 to 40 years after full implementation of the programme when control of the disease could be expected.*
> On the other hand, *prevalence of disease and incidence of infection show the fastest decline* and any assessment in the early periods on the basis of these two indices alone *may lead to overoptimism because the rate of decline noted in the first 5 or 10 years is followed by a much slower rate thereafter. Incidence of disease which declines more*

> *steadily than the other indices is probably the most suitable index from technical point of view. [...] This index is readily available in developed countries. However, for practical reasons, it is difficult to get figures for incidences of disease in developing countries and the real choice has to be made between prevalence of infection and prevalence of disease, for surveillance and/or assessment.* (Nair 1977: 59-60).

Other writers, separated by time, distance, perspective, have echoed this point of having to settle for an assessment index on the basis of the limitations of data gathering. Rieder writes,

> If the primary interest is in assessing the incidence of infection with *M. tuberculosis* in a community, a legitimate question is why a detour has to be made to derive the risk of infection from prevalence, rather than directly measuring the incidence of infection. There are several impediments to doing that. Most important is that even where the incidence of infection is relatively large, i.e. typically 1–3% [4, 5], the change is nevertheless so small as to require repeated tests of a large population. The small prevalence entails a poor predictive value of a positive test result. Repeat testing of low-grade reactors entails the risk of boosting, so called because the induration size tends to increase on repeat testing even if no infection was acquired in the interim between the two tests (Rieder 2005: 182).

As one viewpoint holds that **disease incidence** is probably the most suitable index of change and trends assessment (which is a *long term* assessment), the other viewpoint centre-stages indices which respond *rapidly* to control efforts and interventions, such as case-finding and chemotherapy. According to the latter view, "[a] comparative disadvantage of incidence as an epidemiological indicator is that it *usually changes more slowly than prevalence or deaths in response to control efforts*" (Dye et al 2008: 233, italics added), and in the long term, information on this measure emerges following reductions in transmission, which occur very slowly, and so information on this index cannot be had very easily (ibid.). Considering that *trends assessment is a long range activity*, the dismissal of disease incidence as a useful measure of long-term trends because it *does not show rapid responses to control efforts* appears to be a misplaced argument, meriting deeper analysis.

Further, this point of view advocates those very indices which the first viewpoint urged caution against. So, while Nair acknowledges that because information on disease incidence is difficult to get in developing countries the next approximation that they have to settle for is information on prevalence of infection and on prevalence of disease, he warns that even though **disease prevalence** (as well as infection incidence) show rapid declines, "*any assessment in the early periods on the basis of these two indices alone may lead to overoptimism because the rate of decline noted in the first 5*

or 10 years is followed by a much slower rate thereafter" (Nair 1977: 59, italics added). However, Dye et al argue that even though prevalence surveys are logistically complex, they are useful in scenarios where routine surveillance data is poor. Further, "measures of [disease] prevalence are most useful as primary indicators of tuberculosis burden and trends", and, "in its dependence on the duration of illness, prevalence responds more rapidly than incidence to improved case finding and drug treatment (which shorten the duration)" (Dye et al 2008: 235).

Here too, ability to respond rapidly to control efforts is the defining criterion for disease prevalence being endorsed as a relevant epidemiological measure. Also, Nair's caution against over optimism from early declines in disease prevalence suggests that Dye et al's enthusiasm in disease prevalence stems more from this possibility of visible rapid declines soon, more than from its use as a measure of long term trends assessment. And finally, while measures of disease prevalence do have the potential to provide information on disease incidence, the literature suggests that this derivation is beset with several limitations and hence prevalence surveys are now arguably used only for prevalence and not for estimating incidence.

This leads us to discuss the next index which can fulfill the next best requirement in the balance between surveillance and control – **prevalence of infection**. Nair says that the prevalence of infection is the least sensitive index for doing trends assessment of the tuberculosis problem, and that it is intended as a measure of the progress towards the goal of control or elimination. He points out that this criterion (of assessing progress towards control) can "be applied without reservation *only after a period of about 30 to 40 years after full implementation of the programme when control of the disease could be expected*" (Nair 1977: 59). In direct contrast to this view, however, Dye et al's discussion of the prevalence of infection issues no such caveat about prevalence of infection data being relevant only if collected in epidemiological scenarios which have had long and successful programmes and are nearing the goal of control. They imply that because of the relationship between (i) ARI, (ii) prevalence of disease and (iii) contact rate (infectious contacts made by each case per person per year), prevalence of infection has the potential to be read as a *measure indicating response to control efforts in any scenario.*

They draw a correspondence between prevalence of infection and ARI in the following manner: first, "prevalence of infectious cases [...] determines how much transmission takes place in any population, because the annual risk of infection (ARI or λ) equals the number of infectious contacts made by each case per person per year (β) multiplied by the prevalence of infectious cases (P): $\lambda=\beta P$" (Dye et al 2008: 235), second, it is known that prevalence of disease responds rapidly to control efforts, and third, "[b]ecause $\lambda=\beta P$, programmes of drug treatment are expected to reduce the risk of infection (λ) at least as quickly as tuberculosis prevalence (P), and even more quickly if there are concomitant reductions in the contact rate (β)" (Dye et al: 238).

However, it is important to note that when Dye et al discuss prevalence of infection in this article, they do not discuss the epidemiological parameters of prevalence of infection, instead they discuss ARI (they do discuss the limitations of the tuberculin test, but that is because it has implications for ARI estimation. Technically, however, though ARI is *derived from* prevalence of infection, it is a measure *of* the index 'incidence of infection'). Following their use of 'prevalence of infection' coterminously with 'ARI', their discussion of prevalence of infection rests satisfactorily on the fact that even though *it* itself changes slowly, the two constituents of ARI respond rapidly to control efforts.

Their acknowledgement that prevalence of infection and ARI are not direct measures of disease burden and have limited value for monitoring variation and trends, does not stop them from also writing, "a tuberculin survey is not guaranteed to give interpretable results in [just] any setting, but is more likely to be useful for measuring time trends and geographical variation, in settings in which (1) the ARI is high (>1% per year), (2) there are data on infection prevalence from previous surveys, (3) there is capacity to ensure strict adherence to recommended procedures, and (4) there is an independent measure of the response of true positives" (Dye et al: 240).

This discussion has traversed various epidemiological indices, and has shown that the ability to have a substantial and visible (rapid) impact on control efforts is a more important and desirable quality of an index than its ability to detect long term trends in tuberculosis. This is in spite of the fact that (i) cases of TB that make up the 'pool of infection' can be affected "only when the case mopping operation continues for a long

period of time (10-20 years), and is of the order of TB incidence at least" (Qadeer), and (ii) tuberculosis is a disease acknowledged to be highly complex even today owing to the fact that it has no defined incubation period, and that the various stages from primary complex to primary disease to early post-primary disease to late post-primary disease can take an unspecified period of time and the progression from infection to disease depends on various biomedical, social, nutritional and environmental factors (Pamra 1991; Singh and Dhingra 2003; Gothi 1978).

This enables us to understand not only the myriad complexities behind gathering epidemiological information related to TB, but also the fact that methodological indices or tools are an outcome of jostling between (i) the need to gather universally comparable data, and (ii) the need to have data that would serve as a promising expression of the administrative, organizational and managerial imperatives of programme planning.

III Implications of ARI as a programme tool for India

During the 1970s, pioneering tuberculin surveys in various regions of Bangalore, Delhi and Madanapalle had been conducted by veteran workers such as Bogen, Ukil, Benjamin, Sikand, Pamra, Raj Narain, Frimodt-Moller, and also by the I.C.M.R. and the National Tuberculosis Institute, all of which estimated risk of infection as being between 1-2%. At this time there was no reference in the Indian TB literature, here surveyed through the IJT, to the ARI calculations by Styblo, and methods for estimating incidence rates of pulmonary TB often relied on the construction of various epidemetric models (Sivaraman and Umasankar 1979).

An epidemetric model is a

> mathematical representation of the epidemiological situation in a community. The model approach is based on the concept that the probabilities of occurrence of various events in the natural history of tuberculosis in any community, when environmental factors do not vary, are constant. In other words there is a fixed relationship between the number of source of infection in a community and the number of persons that will be infected in a year; between the number that will develop disease and the number of infected; and between the number of cures and deaths among the diseased. [However,] the models do not take into account the changes in environmental factors which influence the epidemiology of tuberculosis. This shortcoming could invalidate the predictions (Gothi 1978: 10-11).

Several of the other methodological problems noted earlier were acknowledged in these studies. It was also recognized that "repeated epidemiological surveys done at short intervals of 10-15 years may reveal little change in prevalence rates, which is but expected when tuberculosis is in endemic phase or on slow downward trend" (Gothi et al 1979: 134). The points in favour of a declining trend of the disease can be summarized as (a) descending prevalence of infection rate in paediatric age group (b) very few cases in younger age group upto 19 years of age, relative concentration of cases in higher age groups and higher mean age of the prevalence cases diagnosed in the later surveys (indirect evidence); (c) even the unchanged prevalence rates of the cases from survey to survey may indirectly indicate decline (Chakraborty et al 1982).

It was only by the early 1980s that Styblo's work started finding mention in the Indian literature. The "study of the risk of infection by converting data on the prevalence of infection into risk of infection through the method developed by the Tuberculosis Surveillance and Research Unit of the International Union against Tuberculosis, some more problems can be overcome. Thus, data on tuberculin sensitivity obtained at different times by different individuals are rendered comparable" (Baily 1983: 46).

Baily goes on to note the logistical problems with repeated surveys,

> Direct measurement of the reduction of the tuberculosis problem, based on the estimates of prevalence and incidence of disease in the community, is beset with difficulties. It involves repeated surveys, using X-ray and sputum examinations, of representative population samples. The samples will have to be very large because the prevalence and incidence indices are not only small in relation to the total population but also the difference from one time to the other, smaller. Such surveys are expensive and time-consuming. In the event that such direct measurements are not feasible, direct estimations of problems reduction can be made on the basis of the measurement of other indices such as the risk of infection as stressed earlier (Baily 1983: 54).

He points out that

> A downward trend will indicate that a 'policy of control' is in operation in the country. [...] Thus, at the present stage, *it is far more important to adopt a 'policy of control' rather than to offer an epidemiological definition of the problem of tuberculosis*. With the available evidence in India, about the inability of BCG as a measure for reducing the transmission of infection, such a policy of control can be adopted, at the present state of our knowledge, only through adequate chemotherapy of larger proportions of cases prevalent and occurring in the community (Baily 1983: 54).

This indicates that information about the lack of protective effect of BCG was an important influencing factor for the re-invigorated stress on chemotherapy as an indicator of effective *control* measures.

By the early 1990s, noted epidemiologist A.K. Chakraborty, a strong proponent of Styblo's method of estimating ARI and incidence from it, conducted several studies and published articles constructing epidemiological time trends and models for TB. In a 1992 article co-authored by him he notes,

> The annual reduction in the risk of infection about 3.5% observed by Chakraborty et al for 23 years was found to be in conformity with hypothetical decline seen in the model [presented]. [...] Styblo recommends that a continuous annual reduction of 5% in the risk of infection is likely to halve the problem of tuberculosis in 14 years. *The trend in the risk of infection derived from the studies may be used to forecast the period required to reduce the problem of tuberculosis to the level considered not to be a public health problem*, which is the ultimate goal of National Tuberculosis Programme (Balasangameshwara et al 1992: 97).

By the end of the 1990s-early 2000s there emerged many studies on the impact of malnutrition among children on ARI estimation (Chadha et al 1997), on the value of distinguishing between vaccinated and unvaccinated children for tuberculin testing for ARI estimation (in a scenario where it was becoming increasingly difficult to find populations of unvaccinated children for testing, and where unvaccinated children failed to be representative of the larger population) (Chadha et al 2000; Kumari Indira et al 2000).

Further, there was now increasing acknowledgement that in spite of several limited tuberculosis surveys carried out by interested workers and institutions to ascertain current prevalence rates, these could not provide a satisfactory answer to the basic question of effectiveness of NTP, and repeated demands continue for repetition of a 'national' tuberculosis survey, using uniform design and techniques.

> But, the demands have been turned down because besides being very expensive, it was felt it was too early to conduct such a survey. The programme actually implemented could not have made any dent on the problem since it did not diagnose even a majority of the prevalence cases and the number of cases diagnosed was less than the number of new cases added every year. It was also too early to expect any measurable improvement in the tuberculosis problem because of limited general socio-economic improvement. More than forty years after the ICMR survey, however, there is a need to ascertain current prevalence rates in different parts of the country. The fact that annual risk of infection has shown a declining trend: without an effective control programme,

> indicates that the prevalence has come down, to some extent, most probably due to socio-economic improvement. Confirming this reduction is very important.
>
> It is possible that a fairly satisfactory answer to the trend of tuberculosis can be had by calculating Annual Risk of Infection, if this information can be systematically obtained on a national scale. However, this possibility has not succeeded and most probably will not succeed in curbing the demand for a national tuberculosis survey, which seems to be still looming large in the minds of a sizeable number of tuberculosis workers in the country. Moreover, it is significant that *knowledge of the trend of tuberculosis alone will not suffice*. It is equally (or even more) important to have adequate information on epidemiological, social, economic and cultural factors and their interactions which not only influence the spread of tuberculosis but also ought to influence choice of methods of tuberculosis control and their effective implementation (Nair 2000: 53).

During this time the IJT witnessed heated debates about the continuing relevance of data generated through the NSS in 1955-58, and the reliability of Styblo's parametric relationship between ARI and incidence for India (Kant 2000; Chakraborty 2000; 'Editor Replies' 2000; Jagota and Chadha 2001; Chakraborty 2001); Chakraborty was a key participant in much of this discussion, and his work was also in line with WHO work on this issue.

> Under the auspices of the WHO, Chakraborty re-estimated the burden of disease in the country, updating the technique followed heretofore, by incorporating the findings of JPR [an X-ray technique called Joint Parallel Reading] and multiple sputum investigation studies as explained earlier. This was followed by the work by Christopher Dye et al in 1999, as a part of the global exercise and expressed as a consensus statement by the WHO Geneva.
> It was against this background, that the Government of India convened an 'Expert Committee' in 2000 and assigned them the task of estimating the burden of TB in the country. The Committee reviewed all the available data, including the estimates made by Chakraborty and Christopher Dye. It identified the various surveys carried out in the country which had followed similar investigation procedures. The average both sexes all ages rates from these surveys were standardized on the basis of the observed prevalence rates in different age and sex groups of each survey, with the projected population structure of 2000. A weightage was given for the size of the population covered in each survey to estimate the burden of disease in the country.
> Based on the above exercise, one has now access to a fresh set of estimates of the burden of tuberculosis in the country, as of today (Krishnamurthy 2001: 195-197).

However, this author also notes that the rates, as worked out by the Government of India expert group,

> suffer from the same lacuna of not considering the results of surveys on the basis of symptom elicitation and concluding on an equal average prevalence rate for the entire country. The latter had also erred in disregarding the overwhelming evidence of under-diagnosis of bacteriological cases in the surveys, related to the number of sputum specimens examined, as well as on the over-diagnosis inherent in the X-ray reading technique. Moreover, they had chosen to consider the proportion of smear positive cases to be over 60%, for which there is no support from the available data. Thus, the prevalence rates given above by different groups were different from each other, and

> each with obvious lacunae in estimating procedures. To be meaningful, these differences need to be resolved, as they are bound to influence the decision of health planners for allocation of funds and for monitoring of the programme (Krishnamurthy 2001: 199).

Alongside these debates, the period of the early 2000s saw studies on ARI estimation in various regions of India, drawing from Styblo's work (Chadha 2001). The clamour for revising and updating the epidemiological data on status of TB in India was beset with further discussions on how best to do this, the actual need for this, the resources required, the specific methodologies and tools to use – underlying all this was the need for universalizable and comparable data.

This debate finally culminated in a nation-wide ARI survey which estimated the average ARI in the country to be 1.5% (southern Zone 1-1.1%; eastern zone 1.3%; western zone 1.6-1.8%; and north zone 1.9%). The literature suggests that the early phase of the RNTCP, and its appraisal and evaluation as per the joint reviews by the GOI-WHO expert committees (especially the earliest one, in 2000), had an important role to play in laying down the norms, guidelines and operational protocols for monitoring the overall performance of RNTCP in the long run. The plan to conduct a nation-wide survey to estimate ARI was part of this larger protocol (Kumar, 2005).

The relevance of this ARI survey is, however, questionable, and not only because of the several methodological shortcomings noted thus far. Literature also suggests that these surveys are valuable only in terms of long term trend assessment; ARI is not sensitive to short term changes because of its 'averaging' characteristic (Rieder 1995). Thus, this current stand alone survey will have limited relevance for making sense of India's TB situation. Further, "the common underlying technical problems will often undermine the precision in estimating the size of the tuberculosis problem in a community from a single survey," (Rieder 1995: 119) as has been elaborated already. The constraints with regard to following this survey up with serial tuberculin surveys, especially for countries like India, have also been detailed.

Another point relevant to the Indian situation is that even if there is information on tuberculin tests from regional surveys done across different time periods from which ARI can be derived, "[t]wo sequential surveys alone a few years apart will not

necessarily provide information on the change in infection risk because of the problems associated with the *comparison of cross-sectional data across time*" (ibid.). Also, this information from only one or two surveys will provide information about the extent of transmission *at some point in the past* (ibid.).

This then creates a serious epidemiological conundrum, evidenced by the fact that even though Indian programme and policy literature agrees on some of the points like the importance of trend assessment and serial surveys – e.g., "trends in the risk of getting infected are more important than a one-time assessment of the risk of infection in the course of the tuberculosis epidemic" (Roy and Chauhan 2005: 7) – it is deliberately silent on the crippling implications of this for its continued endorsement of ARI in Indian programme management. The confusing and insubstantial defense of ARI by an official GoI publication, in spite of acknowledging some glaring lacunae of the ARI tool, is worth noting –

> The net effect of an initial decline, followed by an increase in risk of infection, may be that a similar prevalence of infection is measured in the two surveys. Only serial estimates will allow the determination of a trend. Because tuberculin surveys are, by their very nature, not capable of identifying short-term changes in the risk of infection in a community, spacing of surveys should be sufficiently large to economise on resources (ibid.: 6).

Noting only the need for *spacing of surveys*, and that too, only for *economizing on resources*, is glaring evidence of how purposively the Indian epidemiological and policy making communities are ignoring the several technical, methodological and contextual problems evident in the literature.

The concluding section of this chapter is an attempt to analyze this enduring significance of ARI as an important and relevant tool to "*illustrate the continuing magnitude* of the tuberculosis problem" (Murray et al 1990: 8, italics added). In keeping with the perspective of previous analyses, the following section explores the construction of global legitimacy for ARI.

IV Artifacts of the chosen methodologies: backed up by organizational infrastructure

Through the discussion of risk as a conceptual category in the first chapter, as also in the opening section of the third chapter, I have argued that a construction of professional, expert judgement on risk is often contingent on a *techno-scientific framing of knowledge*. As noted in the first chapter, critics have argued that given the unstable and dynamic nature of scientific judgements, such judgements tend to be "*artifacts of the chosen methodologies rather than [...] representations of reality*" (Hornstein 1992: 573, italics added). Indeed, how much of this is validated just because it is "*backed up by an organizational infrastructure*" (ibid.: 573-574, italics added)? Suggesting that organizational backing will tend to "*emphasize those aspects of risk that its scientific bureaucracy has the tools to measure* (expected losses) at the expense of less easily measured, but not necessarily less important, aspects of risk-bearing" (ibid.: 575, italics added), the literature enables us to see that there is a coming together of two factors here, (i) backing of organizational infrastructure, and (ii) a management impetus, wherein decisions reflect the tools which the scientific bureaucracy has with it, to measure and to manage.

Other literature discussing similar issues of how scientific knowledge is legitimized has also pointed out that the approach of rational choice is in many respects close to economical considerations of decision making and rational action (Zinn 2006). The logics of political decision making in health care often become intertwined with the tools of health economics (Moreira 2007) and economists' attempts to combine rationality with pragmatic tool development enables calculating the relationship between costs and benefits. It has also been noted that

> "[t]he comparative risk analysts' conception of rational decision-making mimics (to a degree) the comparative methodology of expected utility theory, the dominant approach in economics and social science generally to making decisions under conditions of uncertainty or risk. At the core of expected utility theory is the maxim: 'In a given decision situation, the decision maker should choose the alternative with maximal expected utility...' This principle is accompanied by a number of conditions meant to assure the rationality of decisions. Prominent among these conditions are *the valuing of outcomes by numerical measurements* and *the maintenance of consistency in one's preferences among outcomes*." (Gardenfors and Sahlin 1988, cited in Hornstein 1992: 577).

Given that the emphasis on measuring and maximizing the value of outcomes is the central rational feature underlying utilitarianism, it is plausible to argue that the general impulse toward making rational choices might provide sustenance to a predominantly utilitarian perspective. Assessments of rational choice are expected to weave into the demands of cost-benefit analyses that the market dictates, and one way this is ably supported is by the demands for universally standardized definitions – whether they be conceptual like 'risk', or chemotherapeutic such as 'treatment regimens', or methodological such as 'ARI' in tuberculosis. Another such route of scientific/ technical innovation has been the development of cost effectiveness as a defining criterion for programme planning.

Using the preceding discussion on ARI as background, in this section I will attempt to identify *ARI as an artifact of the cost-effectiveness methodology* of the World Bank, which emerged strongly by the end of the 1980s. This discussion does not claim that the tool of ARI did not exist before this. Clearly, Styblo and TB institutions and programmes associated with him were employing this tool for epidemiological data gathering and assessment even during the 1970s. The literature, however, suggests that this tool was given a certain visibility, a certain life and status as a *globally relevant scientific tool* under the aegis of WB research on global health sector priorities, driven fundamentally by a cost effectiveness rationale. To understand the connections between the WB's research on and creation of a cost-effectiveness methodology and the tool of ARI we need to look closely at the various developments that were taking place during the period of the 1980s.

- 1985 – Paper expounding the Styblo Rule, relating risk of infection to disease incidence and considered a great advance in enabling epidemiological estimations especially for developing countries with inadequate data, was published.
- 1987 – *Ad Hoc* Commission on Health Research was set up, with a Secretariat at Harvard University. Constituted by international public health elites with close links to WB and WHO.
- 1987 – WB starts work on a global Health Sector Priorities Review (HSPR). (Paalman et al 1998). Publications resulting from this work emerge by 1991-

1993.[9] Working with a number of collaborators, this "Review is a series of studies on the public health significance of major clusters of disease in the developing world and on the costs and effectiveness of currently available technologies for their prevention and case management" (Murray et al 1990: 6).

- 1988 – WHO publishes a seminal document titled 'Annual risk of tuberculous infection' (Cauthen et al 1988), which, by using Styblo's 1969 *'risk of infection' model* to study global epidemiology of TB grants for the first time global legitimacy to Styblo's ARI method. This document, which looked at data from 1975 to about 1984, secures this model's foundational role in future epidemiological analyses. Though never formally released into the public domain (till it was published in a 'Public Health Classics' section of the Bull WHO in 2002) this internal technical document, however, turned out to be widely disseminated, and it set the parameters for several future global epidemiological analyses (Borgdorff 2002).
- The literature shows very close intermingling between work towards the HSPR and the other major WB initiative of this time – the Global Burden of Disease (GBD) study, sponsored jointly by WHO and WB.
- Further, these two knowledge sources formed the main background documents for the World Development Report 1993 titled *Investing in Health*.

While trying to explore and understand the implications of this international climate on ARI, it is important to investigate in some depth the linkages between the 1988 WHO document, the three WB exercises/ documents, and also between these and the *Ad Hoc* Commission.

Some writers note that the GBD exercise started in 1992 (Paalman et al 1998). However, two points make us re-consider this – first, Walt et al note that one of the key members of the 1987 *Ad Hoc* Commission on Health Research was a Harvard-based economist who was already assisting the WB on a burden of disease study.[10] And, second, starting from the late 1980s, several publications on the connections between global health problems, global burden of illness, and rational priority setting for health service efficiency start emerging, written by members of both these studies, and sometimes jointly.[11] That there are definite conceptual, operational and methodological

overlaps and interactions between the HSPR and the GBD study becomes clear by surveying some of this literature.

A 1994 article by leading figures of these two studies states,

> In 1987 the World Bank initiated a major analytical public health initiative, the Health Sector Priorities Review. This exercise, culminating in the publication of Disease Control Priorities for Developing Countries[12], has documented existing knowledge about the cost-effectiveness of health interventions in developing countries. With comparable information on the cost-effectiveness of nearly 50 interventions, interest in the allocative efficiency of the health sector has increased. The broadening analytical role for cost-effectiveness laid the foundation for the health policy message in the world development report for 1993. In order to use cost-effectiveness to develop an essential package of health services, it is useful to know the burden of disease.[13] The quantification reported here of the global and regional disease and injury burden to be addressed by the health services was thus a critical input to the World Development Report. The study has received financial aid and technical support from the World Bank, WHO, the Edna McConnell Clark Foundation, the Rockefeller Foundation, and the U.S. Centers for Disease Control and Prevention (Murray et al 1994: 496).[14]

Referring to work by Bobadilla et al, Murray et al state, "[w]ith the expanding role of cost-effectiveness in planning the health sector, the need for a more comprehensive measurement of the burden of disease has become more apparent and urgent" (Murray et al 1994: 496). Bobadilla et al go on to make clear in their article that the, "[e]stimates of the cost effectiveness of interventions, which were used to design the package come, with some modifications, from Jamison et al" (Bobadilla et al 1994: 654).[15] Other literature states that the GBD project

> was undertaken in a number of stages, with the first stage initiated by the World Bank in 1988. The initial aims were to assess the significance to public health of individual diseases (or related clusters of disease) and what was known about the cost and effectiveness of relevant interventions for their control. This first phase led to the introduction of a new common measure for examining diverse disease outcomes, the DALY or Disability Adjusted Life Years. Phase two extended the effort by attempting to provide a comprehensive set of estimates for total disease burden by including disability as well as number of deaths. The publication of the Global Burden of Disease and Injury series represents the third phase of the project (Pruss and Havelaar 2001: 44).

Relevant for TB, two methodological tools were constructed/ legitimized via the WB cost effectiveness framework being developed during this period – ARI is one, and the other is DALYs – Disability Adjusted Life Years. As for ARI, it was a 1990 article by Murray, Styblo and Rouillon on the burden, intervention and cost of TB in developing countries (Murray et al 1990) – one of the studies done for the HSPR – that outlined

how ARI was the central tool that enabled estimation of burden of disease, which then enabled a cost-effectiveness analysis for the HSPR. This article rests fundamentally on two things – one, Styblo's 1969 work on ARI as well as his 1985 relationship between risk ARI and disease incidence. It notes,

> Health information systems in developing countries are too incomplete to provide meaningful information on the incidence or mortality of tuberculosis (Styblo and Rouillon, 1981). We are forced to *estimate the burden of tuberculosis indirectly using several epidemiological parameters. These include the average annual risk of tuberculous infection and the incidence of smear positive pulmonary tuberculosis*, the proportion of all cases of tuberculosis that are smear positive and case fatality rates for smear-positive tuberculosis and other tuberculosis (Murray et al 1990: 6-7).

And the second base for the article is, cost effectiveness analysis based on DALYs. As regards DALYs, Paalman et al point to an interesting fact – that "[i]n the original research used for the HSPR, DALYs were not used as the effectiveness/ utility measure. Rather, DALYs were calculated *during the HSPR review and re-working of the original research*" (Paalman 1998: 20). Following this, DALYs made its grand debut as a methodology of the GBD study, where it was noted that "[t]wo major contributors to the potential DALY gain in low-income countries are the prenatal and delivery care cluster and the treatment of tuberculosis, both of which are largely neglected" (Bobadilla et al 1994: 656-657).

As regards continuities between the HSPR and the *Ad Hoc* Commission for Health Research – Murray was a key participant in both, and given that Walt et al credit the *Ad Hoc* Commission with discovering Styblo's work in Tanzania, it is highly likely that Murray facilitated the bridge between the Commission and the HSPR (in terms of ideas, people, knowledge frameworks and associated methodologies). Literature from the IUATLD provides different details though – "In 1989, this model [the IUATLD model for NTPs in developing countries, starting with Tanzania] was evaluated *within the Health Sectors Priority Review of the World Bank* and assessed as among the most cost-effective of any health intervention in developing countries" (Enarson 1995: 95). Responding to the Commission's study on Styblo's work (located within this cost-effectiveness framework) the WHO conducted a review of Styblo's IUATLD/ Tanzania work (Walt et al 2003). This time, under the aegis of the WHO review, Murray along with others co-authored an article published in 1991, legitimizing and endorsing SCC as the *most cost-effective* intervention for developing countries (Murray et al 1991).

This article draws from and refers a great deal to the 1990 article by Murray, Styblo and Rouillon detailing the TB study for the HSPR.

In this manner, developments in the late 1980s galvanized the widespread use and global legitimacy of the ARI tool, set in motion largely by WHO and WB initiatives such as the HSPR, the GBD study and the closely related *Ad Hoc* Commission for Health Research studies. It was essentially the 1987 initiated HSPR exercise which formed the fundamental ground from which several subsequent research developments of the World Bank emerged, spurred on by a rationale of cost-effectiveness. What began in 1987 culminated in 1993 with the publication of the highly controversial *WDR 1993: Investing in Health*, authored by, among others, Dean Jamison and Christopher Murray. This in turn proved to be the defining feature of the turnaround that the WB was to then effect in the field of global public health.

In the sense that the ARI was constructed/ showcased as a valuable tool, and was raised to a stature and legitimacy it did not enjoy prior to this – all within the ambit of WB research on cost effectiveness during the late 1980s – I argue that ARI as a methodological tool is a potent example of how scientific judgements posses a measure of *manufactured legitimacy*, and thus warrant being called "artifacts of the chosen methodologies rather than [...] representations of reality."

Bringing together the various points discussed in the previous chapters, in the concluding chapter I will briefly summarize the various issues emerging from this entire analysis for TB programme planning and management.

End Notes

[1] Daniel Bernoulli, a Swiss mathematician, is credited with this estimation. See also, Lilienfeld, Abraham M. and Lilienfeld, David E. (1977) discussing Bernoulli as an early pioneer of probability reasoning in health, 'What Else Is New? An Historical Excursion' *American Journal Of Epidemiology* 105 (3).

[2] Muench, H. 'Derivation of rates from summation data by the catalytic curve' *J Am Stat Assoc* 1934; 29: 25–38. cited in Sutherland, Ian 'The Epidemiology of Tuberculosis: Is Prevention Better Than Cure?' Bull IUAT V56, N3-4, Sept-Dec 1981

[3] Murray CJL, Styblo K, Rouillon A. 'Tuberculosis in developing countries: burden, intervention and cost' *Bull Int Union Tuberc Lung Dis* 1990; 65: 2–20.

[4] Data arising out of this and a related subsequent study provided very important information regarding the 'enhancing of tuberculin allergy' (called boosting) seen in repeat tuberculin tests. Raj Narain, Nair S.S., Ramanatha, Rao G., Chandrasekhar, P. & Pyare Lal: Enhancing of tuberculin allergy by previous tuberculin test(s). Indian J TB 1966, 13, 43-56.

[5] The following few important writings give a glimpse into the large body of literature on this point – P.V. Benjamin 'Incidence of Tuberculosis in Economically Underdeveloped Countries and the Methods for Evaluating it' (Summary of Principal Report presented to the IUAT's XIVth International Tuberculosis Conference, held in New Delhi from January 7-11, 1957) *Ind. J. Tub.*, Vol. IV, No. 2; Bulla, A. (1981) 'Worldwide review of reported tuberculosis morbidity and mortality (1967-1971-1977)' *Bull IUAT* 56: 111-117; Styblo, K and A Rouillon (1981) 'Estimated global incidence of smear-positive pulmonary tuberculosis: Unreliability of officially reported figures on tuberculosis' *Bull IUAT* 56: 118-126; Cauthen GM, Pio A, ten Dam HG 'Annual risk of tuberculous infection' Geneva: World Health Organization; 1988. Unpublished document WHO/TB/88.154; Murray CJL, Styblo K, Rouillon A. 'Tuberculosis in developing countries: burden, intervention and cost' *Bull Int Union Tuberc Lung Dis* 1990; 65: 2–20; C Dye, A Bassili, A L Bierrenbach, J F Broekmans, V K Chadha, P Glaziou, P G Gopi, M Hosseini, S J Kim, D Manissero, I Onozaki, H L Rieder, S Scheele, F van Leth, M van der Werf, B G Williams (2008) 'Measuring tuberculosis burden, trends, and the impact of control programmes' *Lancet Infect Dis* 8: 233–43

[6] See also, Styblo K. (1985) 'The Relationship between the risk of tuberculous infection and the risk of developing infectious tuberculosis'.

[7] This view further corroborates Walt et al's (2003) and Ogden et al's (2003) observations noted in the previous chapter that Styblo's work in IUAT/ TSRU was shared within a very narrow tuberculosis scientific and policy-making community.

[8] See also, Raj Narain et al 1965 and 1966.

[9] Jamison, D. T., & Mosley, W. H., (1991) 'Disease control priorities in developing countries: health policy responses to epidemiological change' *Am J Public Health* 81: 15-22; Jamison, D. T., & Mosley, W. H. (Eds.) (1991a). *Evolving health sector priorities in developing countries* Washington, DC: World Bank; Jamison, D. T., Mosley, W. H., Measham, A.R., Bobadilla, J.L. (Eds.) (1993) *Disease control priorities in developing countries* Oxford; Oxford University Press.

[10] It is evident from the literature that this is C.J.L. Murray from Center for Population Studies at Harvard University. Murray appears to be a very prominent and influential figure, participating simultaneously in several WB and related initiatives of the late 1980s-early 1990s.

[11] Some examples of this literature are: Feachem, R.G., Graham, W.J. and Timaeus, I.M. (1989) 'Identifying health problems and health research priorities in developing countries' *J Trop Med Hyg* 92: 133-191; Jamison, D.T. and Jardel, J.P. (1994) Foreword: Comparative health data and analyses in Murray, C.J.L. and Lopez, A.D. *Global comparative assessments in the health sector* Geneva: WHO: v-vii; Murray, C.J.L. (1990) 'Rational approaches to priority setting in international health' *J Trop Med Hyg* 93: 303-311.

[12] Referring to Jamison et al (Eds.) (1993) *Disease control priorities in developing countries*

[13] Referring to a then forthcoming study by J.-L. Bobadilla, P. Cowley, P. Musgrove, H. Saxenian 'Design, content and financing of an essential national package of health services'; discussed next in this section..

[14] Murray and Lopez were key authors of the GBD study, while Jamison was a key author of the HSPR. The HSPR document also contains articles by Murray and Lopez.

[15] The article is about identifying an essential national package of health services, the criteria to decide which are size of the burden caused by a particular disease, injury or risk factor, and the cost effectiveness of interventions to deal with it.

Summary

> Governmentality is "crucially reliant upon systems of expert knowledge which constitute and define the objects of their knowledge, mediate between individuals and authority, measure progress and set up the markers of compliance" (Higgs 1998: 185).

The idea for this dissertation stemmed from an interest in understanding the pervasive influence of the concept of 'risk' in frameworks of modern epidemiology, which holds that population level, and not individual level analysis, enables a holistic understanding of health and disease.

While discussing epidemiology's population-level focus, or the shift away from this approach, this dissertation has made use of Michel Foucault's governmentality framework in order to throw more light on the multiple facets, and implications, of epidemiology. Noting that a governmentality framework enacts a disciplinary and administrative regime through building a knowledge database and collecting, categorizing and classifying various characteristics of the population it governs, this dissertation has shown how certain disciplinary and methodological developments to represent these characteristics (for instance, statistical reasoning and indices) have, since long, served as the apparatuses/ tools of such an administrative-governmental framing of populations.

This formed the basis for the investigation carried out in the rest of the chapters, especially in the second, third and fourth. The attempt in these chapters was to investigate the general field of apparatuses enacted by the state/ authorities "to conduct the conduct of their human charges towards certain ends" (Rabinow and Rose 2003: x). This dissertation showed that this 'field of apparatuses' was enacted by (i) the *construction* and legitimization of 'risk', (ii) creating risk through a *techno-scientific framing* of 'rational', 'expert' and 'state' knowledges – those of scientists, public health officials and activists, policy makers, government as well as non-governmental agencies, and translating this into global, official 'best practice', (iii) and the location of these processes (labeled 'artefacts', to stress their *constructed* nature) in specific *methodological, ideological and organizational settings*.

This field of apparatuses, engaged in the 'conduct of conduct' of individuals terminates ultimately in the call for individuals to live an 'appropriate' life, to be self-actualizing, active, self-maximizing – in other words, responsible for themselves and their well-being. This overlaps with the managerial approach of maintaining social order as well as cost-efficiency, typified by the welfare state and related social policy – and especially, with the *re-configuration* of the welfare state which started around the 1980s in several western countries and gradually found its way to the developing countries of the South. A managerial approach matching outcomes to inputs results in a heightened encouragement of an entrepreneurial sensibility, and the application of a cost-benefit assessment to all aspects of social life.

The specific form this investigation took in this dissertation was a study of the contexts and processes of construction behind two influential scientific apparatuses/ tools in the domain of tuberculosis policy and programme management – Annual Risk of Infection (ARI) and default. An in-depth study of these two tools, having very high *utility* for programme management in tuberculosis, was undertaken from the standpoint that 'scientific', 'expert', 'professional', 'rational' knowledges were accorded widespread legitimacy and the status of 'truth claims' based on the backing of influential organizational and collaborative ideological contexts. Thus, the exploration of the concept of risk in this dissertation traverses multiple fields such as epidemiology (dominant paradigms and precepts), statistical framing of knowledge, scientific expertise and legitimacy, framing of rationality and scientificity, organizational backing, and the creation of a 'responsible' self.

The genealogical reading of tuberculosis management and control, as explored in the second chapter, has shown how policy planning at the national level in India is a function of multiple kinds of national and international collaborative influences. The beginnings of tuberculosis management in India, whether through sanatoria like UMTS/ Madanapalle, or voluntary associations, or BCG vaccination, were all closely entwined with Western institutions, personnel and scientific rationales. Further, the development and refinement of scientific practices, spearheaded in the early post-independence years by Western personnel in Indian institutions as part of various collaborative ventures, drew ample benefits from the possibilities for research in locations such as India, where a large majority of patients was available for testing and

fine-tuning recent developments in chemotherapy, treatment regimens, and related programme management issues.

Linking biostatistics-epidemiology to a vision of social improvement

The utility and success of social statistics "was based on their ability to render the complexity of the social world in a *neat and orderly fashion*, easily grasped by the educated reader" (Cole 1994: 3, italics added). That social statistics is not simply a methodology but a way of thinking about and organizing information is evidenced by the fact that the vision of the policy makers behind the DOTS strategy, also saw the need for "*simple, 'one-size-fits-all' best practices, presented as easy to understand steps, which needed to be rigidly adhered to*" (Walt et al, 2003).

This shows that linking a biostatistical view of epidemiology to a vision of government as social improvement has complex implications for citizenship – on the one hand, it necessarily strips information down to what is easily marketable and can be branded, creating the problem of asymmetry of information, while on the other hand, the very expectation that along with calculating neat sets of information about a population's physical attributes its intellectual and moral capacity could also be improved/ worked upon generates its own sets of disciplinary apparatuses.

An expectation of social improvement, tied in with the concept of governmentality, is heavily dependent on systems of expert knowledge which constitute and define the parameters and boundaries of this 'ideal self', the 'compliant patient', in other words, the objects of their knowledge. These expert knowledges set standards for *acceptable* conduct and monitor compliance with societal norms. This ends up creating practices of exclusion, of blaming those who cannot comply with social norms, and of marking differences between the 'normal' and the 'deviant' in societal terms.

The managerial-administrative mode of public health

Another issue that has been discussed in this dissertation is that of the managerial-administrative mode of public health, and how given its definitional boundaries, a public health mode cannot but be administrative and managerial in nature. This explains why early studies done for the NTP formulation from a sociological

perspective were treated as a means for medical administration, rather than as a means for re-thinking the practice of public health in the Indian context.

The ideas of default, non compliance and non adherence to drug regimens have plagued the Indian health administrators and research communities since the inception of the NTP, and these were constantly addressed from a behavioural psychology perspective, intent on the patient's behaviour change. Studies that were conducted to understand and analyse various facets of default, took a very instrumental approach to the issue. They explored primarily organizational and administrative lacunae that hindered default, and sought to 'fix' these. The socio-political-economic contexts of patients were seen only in terms of how they affected the willingness and ability of patients to comply.

This mode of public health tends to re-cast social, economic and political questions into a techno-scientific frame, making them amenable to managerial intervention, thereby cutting the radical edge off of what might otherwise have been strong arenas for political debate. Global development hierarchies also re-inscribe the fact that the developing countries are 'overburdened' with problems, which they lack resources to tackle; this threatens the stability of the larger world order, and pushes for developed industrialized countries to help the former countries 'manage' their problems such that they do not spill over to the rest of the world.

Legitimacy of scientific knowledge – from precepts of pure science or from organizational backing?

This dissertation has placed special emphasis on exploring the processes by which certain kinds of scientific information are legitimized and promoted on a wide scale, beyond the primary context, beyond boundaries. The discussions in the third and fourth chapter have shown clearly how the tools of default and ARI were translated from their specific local contexts into global 'best practice'. In the case of default, this translation was effected by events in a context completely different from where the concept had been practiced till then. It had to do with the sense of fear and threat perceived by Western industrialized countries as tuberculosis re-surfaced in some of them after having declined over several years, and this resurgence being associated with HIV infection.

In the case of ARI, an estimation technique that emerged from a developed Scandinavian country, with a declining trend in tuberculosis, and during the pre-chemotherapy era, was translated into a globally effective and relevant tool, for estimations in all and any kind of epidemiological situations. The meteoric rise in importance of the ARI as a tool occurred in the context of a steadily growing cost-effectiveness framework in World Bank research: ARI was to serve as the central tool to be utilized towards cost-effective programme management decision-making. Clearly, the way in which these two tools got constructed, selected, and *legitimated for public attention* reiterates the argument that both these tools garnered worldwide attention on the basis of their usefulness to the social system, as dictated by influential actors, and the maintenance of order.

Notwithstanding this global legitimacy, which lasted nearly two decades, there has emerged criticism of the shortcomings in the conceptualization of ARI and the use of ARI for disease incidence estimation. However, the scientific appeal of the concept has not waned yet, as evidenced by the many debates and discussions on the need for using ARI estimations in the Indian programme and planning domains. The epistemic community responsible for framing this as a techno-scientific tool was able to successfully claim for several years that their work held scientific value and was based on a rational approach to decision-making, in which cost-effectiveness was an important part.

This is also evidenced in the manner in which the WHO continued to promote the widespread use of the BCG vaccine in the developing countries, in spite of there having been no actual studies conducted on its relevance in these regions. After trying to downplay results of studies that proved there was no protective effect of the BCG vaccine, the WHO finally went ahead and justified the vaccine for infants based on the fact that there was *no evidence to the contrary.*

There is an assumption that the scientific enterprise is a methodological one, rather than a political, ideological one; that risk measured in terms of indices – mortality, morbidity – is the best way to conceptualize the existing problems; and that different risks, once reduced to a common metric, can be compared, traded off or aggregated

towards policy-making. Policy, similarly aligned with scientific practices, tends to emphasize the advantages of methodology over the less structured and less tangible/ measurable political processes that underlie these problems in the first place.

Information gathering within a cost-effectiveness framework

Information gathering in the post-HIV world serves a very distinct purpose – relevant information is that which is amenable to the management-oriented principles of 'increasing cost efficiency.' Tools of default and ARI are brought on board in order to fulfill the need for regulation and surveillance of individual behaviour alongside population characteristics. They are thus integral to the global strategy for TB control that was heralded by WHO's call in 1993 declaring TB a global emergency. Regulation and surveillance are evident not just at an idea level, but these are put into operation through reinvigorated mechanisms of data collection towards 'effective global management' of the TB problem. Issues in the estimation of burden of TB – prevalence, incidence (of disease, and of infection), different surveys, different regions, different methods and tools, different screening tools, differences in age-sex adjustments, etc., were always there.

Small studies on 'burden of TB' were conducted from the 1970s in India (and in other study locations too) but this information started to become significant only in the early 1990s when TB control efforts and rationales underwent a paradigm shift. Relevant information about the current status of TB from all countries started to be called upon – not just about treatment, but about 'case management'. Epidemiological studies, operational research, behavioural/ psychological and KAP surveys, risk-assessment studies, even statistical concepts and tools started being revived and refreshed with new sensibilities – all to serve the new purpose at hand.

Contemporary policy discourses urge 'public-private partnerships' in healthcare

The close association between the IUATLD and the TAI, and the TAI and the GoI, as noted in chapter two, are early examples of what is today called 'public-private partnerships'. Even though a stated rationale behind such a move is that the state needs all the assistance it can get, or that health is everybody's concern and therefore the onus should not be only on the state for provisioning and financing of healthcare, it is

possible to see from this dissertation that these ideas stem from a perception amongst private/ non-state/ voluntary bodies that the state is lacking in its ability, failing in its mandate, to control/ combat disorder in states of health. And because the ill-health of some can have a negative impact on the health of others, effectively reducing economic productivity of the larger society, there is a greater need to protect the healthy from the sick; thus, private institutions start getting involved in healthcare. A study such as this, which re-visits the early modes in which such collaborations have been carried out, urges the need to be cautious about contemporary policy discourses pushing for greater linkages between state bodies and voluntary bodies in health care.

The rationale and driving force behind the IUATLD consisted of going beyond what was perceived as the rather restricted mandate of the state. In this, we see an early example of the state being perceived, in a sense, as 'weak', of not capable of issuing a whip to control tuberculosis effectively. The state had to maintain its legitimacy and not take on activities that would render it oppressive in the popular imagination; however, voluntary bodies were not constrained by any such boundaries. The fact that IUAT, and TAI, are voluntary agencies is deemed a huge plus point, since it leaves them free to undertake slightly more aggressive advocacy activities than the state could have done, while at the same time they enjoy the status of remaining unregulated/ unaccountable, unlike state bodies.

That they are unregulated by state authorities is one thing; that they continue, nevertheless, to have close cooperation, linkages and collaborations with state bodies – at the level of technical/ scientific, programme-related research – is another thing altogether. TAI is an extremely influential medical community, and is closely connected with the official tuberculosis management and control programme in India. Drawing from the mandates, rationales and precepts of its parent body, the IUAT, TAI does not only work towards influencing patients through the activities of propaganda, supervision and encouragement, but also acts as a surveillance mechanism and pressure point for the activities of the state. Given that members of various state bodies are closely associated with TAI it is not unreasonable to argue that TAI plays a very important role in how state policies for tuberculosis are constructed and implemented in the field.

The role of the WHO in collaborative relationships

While discussing WHO's diminishing leadership and influence in international health, several writers suggest that the period of shift was the 1980s when other agencies like the World Bank started getting involved in issues of international health in a very visible and resource-rich manner. It would, however, be disingenuous to insist that the ambiguity in the influence and leadership role of the WHO started only since the 1980s. There is an equally persuasive range of literature, both of and focusing on the period from when the WHO was founded till the 1980s, that shows that even during this early period the WHO was constantly grappling with several internal and external uncertainties regarding its leadership role, and shifts of its power, position, and ideology in the wider socio-political context.

It may be a gesture of faith – but wholly incorrect – to argue that WHO as an independent UN agency has spearheaded the direction of global health initiatives and set agendas in its early days only to be jostled out of the ring recently by new players. Thus the assessment made by Walt et al in the context of WHO's response to TB in the 1990s – "WHO were *reactive* rather than *proactive* in getting TB on the health policy agenda. Other agencies were more influential in initiating the agenda setting process" – seems to hold true for several other periods and several other health initiatives also (Ogden et al 2003: 183). Often it is other powerful agencies, individuals, institutions and countries that set the direction on which WHO responds and then courses forward. Once WHO joins in and decides to support or promote certain initiatives, the legitimacy that these gain is multiplied manifold, smoothening the process of adoption and replication of these initiatives in nations across the globe.

This, then, signifies another of the internal contradictions of the organization, where in a bid to not be outdone or left lagging behind, or in order to be seen as responding to a call for WHO to act, the WHO gives its stamp of approval and provides legitimacy to initiatives that may be driven by agendas other than the betterment of all people's health and well-being. It is hard to say whether this means that WHO continues to have authority in efforts for global health, or that powerful agenda setters make mere instrumental use of WHO's stamp of legitimacy in order to counter the possibility of any controversy, and to facilitate the process of worldwide replication.

However, it needs to be said that the WHO is increasingly following the footsteps of the World Bank, which has, since the 1990s, emerged as the largest donor in the field of health. Alongside this, there has also occurred a transformation in the role of international non-governmental organizations (INGOs), which have come to play a more central role in decision-making within the WHO under the "imprimatur" of public-private partnerships (PPPs) (Rao forthcoming). Two recent outcomes of this can be seen in the Global Alliance for Vaccines and Immunization (GAVI) playing an increasing policy advocacy role in the arena of immunizations research and programme management, and in the Gates Foundation's role in global tuberculosis management.

Implications for policy formulation

Medicalization and surveillance are thus increasingly becoming the organizing principles for dealing with illness at the level of the individual body, the growth of institutional regulation, and the emergence of biopolitics of populations. Drawing from the idea of governmentality, biopolitics broadly indicates state agencies' constant intervention and supervision of the production and reproduction of life. This raises several questions, at a political level, and it also points to the fact that medical intervention is increasingly requiring the complicated backup of social workers, health visitors, social policy units – agencies/ actors that were regarded as belonging to the domain of the social and not necessarily medical world. And lastly, the critique of medicalization that has emerged – a critique of technocentric, profit-driven, individualistic biomedicine – pushes us to recommend other kinds of interventionist practices, like extensive preventive approaches. The field of public health is located at this cusp of the social and the medical encounter. Situated here, how do we account for the fact that "[p]reventive medicine is far more interventionist than curative medicine"?

Implications for citizenship

"Provision of citizenship tends to require the expansion of regulation, control and surveillance from the state" (Turner 1987: 217). This poses a paradox regarding the role of the state in the lives of citizens. On one hand is the expectation that the state should provide for health, while on the other we are faced with the increasing regulatory powers of the state in every sphere of citizens' lives. Thus, the greater the demand fo personal equality, the greater the requirement for surveillance; it seems as if it is ve

difficult to provide for equality of health outcomes without a serious invasion of personal liberties, privacy, and the rights of citizens to not be under constant surveillance.

This has serious implications for citizenship because it seems to suggest that "[p]rovision of citizenship tends to require the expansion of regulation, control and surveillance from the state" (Turner 1995: 217). This poses a paradox regarding the role of the state in the lives of citizens.

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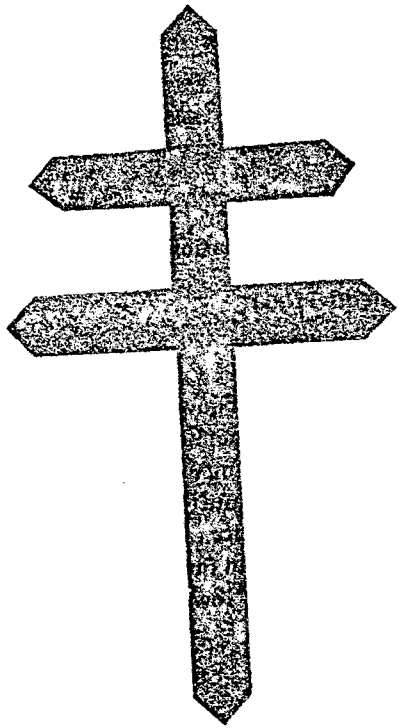
Annexure 1: Tuberculosis Association of India (2001-2002)
Donation form, Adm.30/2001-2002.



THE TUBERCULOSIS ASSOCIATION OF INDIA
3, Red Cross Road
New Delhi-110001
Tel. : 371-5217, 371-1303
Telegram : TUBERCLASS 110 001

DONATIONS TO THIS ASSOCIATION ARE EXEMPT FROM INCOME TAX

FOR DONORS AND WELL-WISHERS

DONATE GENEROUSLY AND SAVE THE PEOPLE FROM DYING

TB Can be cured if timely detected

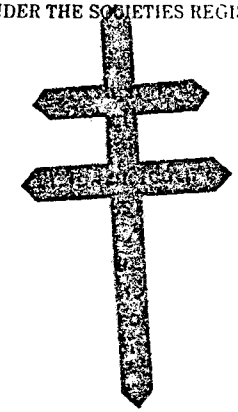
TB patients should take the drugs regularly and in prescribed dose and as long as the doctor advises. They should visit the doctor for check up and assessment as and when called.

Your kind gesture will be a great step in aid of furthering a great cause

- Make people aware of the disease.
- Get TB detected by sputum examination and X-ray of the chest.
- Get treated and cured at the earliest.
- Use handkerchief while coughing and sneezing.
- Do not spit here and there. TB is an air borne disease.
- TB can be cured.

Tuberculosis is a problem
It concerns all of us

THE TUBERCULOSIS ASSOCIATION OF INDIA
(REGISTERED UNDER THE SOCIETIES REGISTRATION ACT)



CONTROL TB NOW AND FOREVER TB IS THE LARGEST KILLER DISEASE

Contribute To a Noble Cause

THE TUBERCULOSIS ASSOCIATION OF INDIA
3, Red Cross Road
New Delhi-110001
Tel. : 371-5217, 371-1303
Telegram : TUBERCLASS 110 001

INTRODUCTION

Setup in 1939, the Tuberculosis Association of India is a voluntary organisation. The President of India is its patron. Its main objectives are prevention, control, treatment and relief from TB. It is dedicated to the promotion of health awareness in anti-tuberculosis work. The Association brings health education material like leaflets, flip charts, scrolls, panels & films etc. that are devoted to bringing about awareness on the problems of TB, its prevention & cure. It has been doing meaningful, useful and commendable anti-tuberculosis work in the country for the past six decades now, thereby supplementing and complementing the efforts of the Government in their National Tuberculosis Control Programme. It does not receive any grant from the Government.

Tuberculosis is Preventable and Curable

SOME STARTLING FACTS

Nearly 60 percent of the people are infected with tuberculosis. About 5 lakh persons die from TB every year. At present it is the single largest killer disease in the country. However, TB can be cured if timely detected.

AN APPEAL

The Association depends entirely on public support in this humanitarian work. The Tuberculosis Association of India is convince that the main reason for lack of success in controlling TB is inadequate awareness about the disease in the common man. Therefore, we are focussing our attention on health education to create proper awareness about TB and to remove misconceptions and superstitious beliefs. All these activities involve heavy expenditure and need the generous contribution from individuals and institutions.

We are therefore approaching you for a generous donation to a noble cause. Your kind contribution will help furthering this cause. Kindly mail your cheque and send your contribution to the **Tuberculosis Association of India, 3, Red Cross Road, New Delhi-110001.**

Donations given to the Tuberculosis Association of India for its various activities are exempted from Income-tax under Section 80-G of the Income Tax Act 1961.

PLEASE PARTICIPATE IN ALLEVIATING HUMAN SUFFERING

DONATION FORM

From :

.....

.....

.....

To :

The Vice-Chairman,
Tuberculosis Association of India,
3 Red Cross Road,
New Delhi-110001.

Dear Sir,

In response to your request vide Adm.30/2001-02 dated..... for donation to the Tuberculosis Association of India, I am/We are pleased to enclose herewith cheque/demand draft No..... dated.....for Rs..... drawn on ..... in favour of the Tuberculosis Association of India. New Delhi, as donation.

Please send us the official receipt and the exemption certificate at our above address.

Date..... Signature .....

Designation .....

Name & Address .....

.....

.....

You may use this donation form for your donation OR send your donation under your letter head.