

TB Surveillance and Programme Monitoring and Evaluation: Report of a Regional Workshop

*National Tuberculosis Institute, Bangalore
India, 20-24 July 2009*



**World Health
Organization**
Regional Office for South-East Asia

SEA-TB-325
Distribution: General

TB Surveillance and Programme Monitoring and Evaluation: Report of a Regional Workshop

*National Tuberculosis Institute, Bangalore
India, 20-24 July 2009*



© **World Health Organization 2010**

All rights reserved.

Requests for publications, or for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – can be obtained from Publishing and Sales, World Health Organization, Regional Office for South-East Asia, Indraprastha Estate, Mahatma Gandhi Marg, New Delhi 110 002, India (fax: +91 11 23370197; e-mail: publications@searo.who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

This publication does not necessarily represent the decisions or policies of the World Health Organization.

Printed in India

Contents

	<i>Page</i>
Abbreviations	v
1. Introduction	1
2. Inaugural session	2
3. Update on the Global and Regional Tuberculosis Burden	3
4. TB Impact Measurement	3
4.1 Global task force on TB impact measurement.....	4
4.2 Framework for impact measurement.....	6
5. Understanding the causal model for TB programme performance.....	7
6. Experiences from countries on surveys carried out to measure TB prevalence, incidence and mortality	7
7. Assessing the reliability and completeness of notification data.....	11
7.1 Estimating missing cases	11
7.2 Do changes in notifications over time reflect TB incidence?.....	17
8. Methods and assumptions used by WHO for estimating TB prevalence, incidence and mortality	23
9. Country plans to improve TB surveillance and programme monitoring and evaluation system	23
10. Conclusions and recommendations	26
10.1 Conclusions	26
10.2 Recommendations for National Tuberculosis Programmes	27
10.3 Recommendations for WHO and partners	28
Annexes	
1. Agenda.....	29
2. List of participants.....	30

Abbreviations

ACSM	advocacy, communication and social mobilization activities
AIDS	acquired immune deficiency syndrome
ARTI	annual risk of tuberculosis infection
CDR	case detection rate
COD	cause of death
DOTS	internationally recommended strategy for tuberculosis control
DTO	district TB officer
EPICENTRE	epi-info-based software to create and evaluate national tuberculosis reports
EPTB	extra pulmonary tuberculosis
HIV	Human immune deficiency virus
MDG	Millennium Development Goal
MDR-TB	multidrug-resistant tuberculosis
M&E	monitoring and evaluation
MO	medical officer
NSP	new sputum smear positive
NTI	national tuberculosis institute
NTP	national tuberculosis programme
PTB	pulmonary tuberculosis
NGO	nongovernmental organization
RNTCP	Revised National Tuberculosis Control Programme of India
SEAR	WHO South-East Asia Region
SEARO	Regional Office for South-East Asia
TB	tuberculosis
VR	vital registration
WHO	World Health Organization

1. Introduction

Substantial progress has been made during the last decade in capturing data on cases detected under the national tuberculosis programmes (NTPs) and their treatment outcomes. In the South-East Asia Region, population coverage with DOTS is complete and robust recording and reporting systems are in place in all Member States. Reporting by different health agencies involved in NTPs at different administrative levels generally tends to be complete and timely. The programme performance of Member countries is being regularly disseminated through annual /quarterly reports. However, there is need to continue strengthening the routine surveillance components under NTPs not only for efficient programme management but also to draw meaningful inferences on the epidemiological trends of tuberculosis (TB). This requires assimilation of data; and to build up the capacity to compile, analyse and interpret what has been assimilated. Community-based surveys (to estimate prevalence of TB disease, prevalence of TB infection and TB mortality rates for monitoring the progress towards Millennium Development Goals (MDGs) continue to remain relevant in the South-East Asia Region (SEAR) which carries a high burden of TB disease in terms of incidence and mortality. In this context, a regional workshop on Tuberculosis Surveillance and Programme Monitoring and Evaluation was held during 20-24 July 2009 at the National Tuberculosis Institute, (NTI) Bangalore, India with the following objectives:-

- To review current approaches to TB surveillance, monitoring and evaluation;
- To share the status and outcomes from surveillance, monitoring and evaluation activities in countries of the Region;
- To discuss plans for the implementation of the most appropriate TB surveillance, monitoring, evaluation and research methodology for each country, and
- To identify technical support as required by Member States to strengthen TB surveillance, monitoring and evaluation.

2. Inaugural session

The workshop was inaugurated by Dr Prahlad Kumar, Director, NTI, who emphasized the importance of effective surveillance systems not only to evaluate the performance of TB control programmes but also to monitor the epidemiological trends of TB. Following this, Dr Md Khurshid Alam Hyder, Medical Officer-TB, WHO/SEARO, delivered the message from Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia Region.

The message highlighted that TB continues to be a major public health problem in the Region with an incidence of about 2.7 million cases and half a million deaths due to TB each year. Poverty, urbanization, migration and the spread of HIV/AIDS are some of the socio-economic factors that continue to hamper TB control efforts. The application of newer methodologies to evaluate socioeconomic and cultural determinants that affect TB control are estimated to enhance the efficiency of NTPs to develop interventions to mitigate such factors. In addition, it is necessary to monitor the impact of these interventions on TB incidence, prevalence and mortality through improved surveillance and programme monitoring systems. Several national programmes have been assisted to plan and implement annual risk of tuberculous infection, disease prevalence and mortality surveys since the previous workshop on strengthening TB surveillance and monitoring held in 2006. This workshop is being convened as a part of WHO's overall support to Member States to further strengthen routine surveillance and assist to plan and implement appropriate studies and surveys which conform to internationally recommended guidelines, to accurately determine epidemiological trends in TB and progress towards the MDGs. The Regional Director stressed that the recommendations and plans developed during the workshop would help to provide more reliable information on the TB situation, on which future plans and interventions for better TB control in the Region could be based.

Dr Hyder then briefed participants from Member States, regional experts in the field of TB surveillance and staff from WHO headquarters, regional Office and country offices, on the objectives of the workshop. The inaugural session concluded with the introduction of all participants.

3. Update on the Global and Regional Tuberculosis Burden

Globally, there were an estimated 9.3 million incident cases of TB in 2007, about 29% of which occurred in SEAR alone. About 1.7 million people are estimated to have died due to TB in 2007, of which nearly 41% were in the SEA Region. About 80% of all TB cases in the Region belonged to the economically most active age group of 15-54 years. Globally, about 15% of all incident TB cases were HIV positive. In the Region, the estimated HIV prevalence among the adult cases of TB varied from 0.3% in Bangladesh to 17% in Thailand. Though only about 3% of the incident cases in the Region are estimated to be multi-drug resistant (MDR), this translates into a fairly high number of patients.

In order to achieve the TB-related Millennium Development Goals (MDGs), the main components of the Regional Strategic Plan to Control TB (2006-2015) include:-

- Sustaining and enhancing TB services to reach all TB patients and improving case detection and treatment success rates;
- Establishing interventions to address TB/HIV and drug-resistant TB; and other challenges
- Forging partnerships with all care providers and communities to ensure equitable access to an essential standard of care to all TB patients; and
- Contributing to strengthening of health systems.

4. TB Impact Measurement

With the introduction of the DOTS strategy in the mid-1990s, WHO began to systematically monitor progress in TB control by using the two global indicators and related targets for TB control established by the World Health Assembly (WHA) in 1991. The indicators are (i) the percentage of estimated new (incident) cases of smear-positive TB detected in DOTS programmes (case detection rate) and (ii) the percentage of detected cases successfully treated (successful treatment rate). The targets set were to reach

a 70% case detection rate and an 85% treatment success rate by 2000, a target year that was later reset to 2005. The notification data of the Member States in SEAR reveal that about 69% (case detection rate) of the estimated incident smear positive cases were detected in 2007 (compared to 62% at the global level). However, a third of cases continue to remain unregistered for treatment. This underlines the need for further improvements in the case detection rates. About 87% of the new smear positive (NSP) cases detected during 2006 were successfully treated.

The WHA targets have proved very useful for stimulating greater efforts to control TB in endemic countries. Case detection and treatment success rates are well-established indicators that are widely-used to measure the national TB programme (NTP) and to measure performance at global, regional and country levels. However, these targets only help to evaluate the outcomes of TB control programmes, and not their impact.

The 2015 impact targets for global TB control, set under the Millennium Development Goals (MDGs) and by the Stop TB Partnership, are to ensure that the TB incidence rates fall, and that TB prevalence and death rates are halved compared to their level in 1990. Achieving these targets is the focus of international and national efforts in TB control, and demonstrating whether or not they are being achieved is of major importance for individual countries, the UN and Stop TB Partnership, and a variety of technical, financial and development agencies. In addition, the Stop TB Partnership has set a goal of eliminating TB, to be reached by 2050, defined as less than one new case per million population.

4.1 Global task force on TB impact measurement

In response to the need for measuring progress towards the 2015 targets in terms of reduction in TB incidence, prevalence and mortality, WHO established a Global Task Force on TB Impact Measurement in June 2006. It includes experts in TB epidemiology, representatives from major technical and financial partners, and representatives from countries with a high burden of TB. The goal of the task force is to prepare a robust, rigorous, and widely-endorsed assessment on whether the targets set for TB control are being achieved at the global level and in each WHO Region, and to regularly report on progress towards these targets in the years leading up to 2015.

The task force at its meeting in 2008 made the following broad recommendations:

Prevalence surveys

Nationwide surveys for estimating prevalence of TB disease should be carried out in countries with high prevalence of TB, high burden of TB in terms of absolute numbers of incident cases each year, low CDR and high prevalence of HIV. There should also be a high motivation among NTPs to conduct these surveys. In countries where a prior survey has been carried out, a repeat survey would allow monitoring of trends. Some countries may need to conduct two surveys between 2009 and 2015. Of 21 global focus countries where prevalence surveys are recommended, four are in the South-East Asia Region, namely Bangladesh, Indonesia, Myanmar and Thailand.

Measuring TB incidence

Estimates of the absolute incidence and trends from the analysis of notification data can be better determined through:

- (1) Strengthening surveillance systems until TB notifications are a close proxy of TB incidence.
- (2) Periodically assessing TB incidence and trends by using standard framework and tools prepared for systematically analysing the reliability and coverage of TB notification data. The findings would lead to better estimates for TB incidence and CDR and to identify how TB surveillance can be strengthened and where TB control can be improved.
- (3) For those countries with TB notification data that meet specified standards/benchmarks the task force could certify that the data could be used as a direct measure of TB incidence.
- (4) Cross-verification of incidence estimates with reliable mortality data, if available.
- (5) It is suggested that ARTI surveys should not be used to measure TB incidence in most countries.

Strengthening surveillance

The capacity of individual countries may be systematically enhanced to analyze surveillance data.

4.2 Framework for impact measurement

The first step is to evaluate whether TB notification data can directly measure TB incidence (both its absolute value and trends). This should be followed by an analysis of the accuracy, completeness and timelines of reporting by all reporting units (for example, the number of expected reports can be compared with the number of reports actually received for a given period). An assessment of whether there is duplication and/or misclassification of data, exploration of variability geographically and over time (to check for internal consistency), and comparisons with values that are expected given existing knowledge of TB epidemiology (e.g. the fraction of pulmonary cases that are sputum smear-positive) would be very useful to determine the quality of data. This assessment should be used as a basis for reducing duplication and misclassification, recognize where data is missing, as the basis to identify where and how surveillance needs to be strengthened, and to make an initial assessment of the extent to which TB notifications account for all incident TB cases.

The second component of the framework relates to analysis of trends in notification data, with the aim of assessing the extent to which the data reflect trends in rates of TB incidence and the extent to which they reflect changes in other factors such as programmatic efforts to find and treat more cases. Distinguishing between changes due to incidence and those due to other factors is crucial when using notification data to estimate trends in the rates of TB incidence and case detection.

It must be understood that the true incidence of TB does not usually vary greatly across small geographic areas/regions or short time durations (<5 years). Larger geographic variations and large changes in notifications over short time periods indicate possible errors due to over or under-reporting of cases and fluctuations in reporting patterns rather than a true change in incidence.

5. Understanding the causal model for TB programme performance

The rationale of listing the causal factors and structuring them in a causal model, the methodology, strengths and bottlenecks of this approach were explained. The theoretical context was made clear through an example of the determinants of insufficient case detection. It was emphasized that the model could address a plethora of determinants. Therefore it is necessary to select the priority ones, and develop appropriate indicators for each, based also on the interrelationships between the causes.

A practical application of this methodology had taken place in Kerala, India, where the decreasing NSP notification rates were used as a proxy for the measurement of epidemiological impact of RNTCP on the disease incidence. The causal modelling approach was used to get a comprehensive view on the causes of the dynamics of NSP cases notified and then the exercise extended to all 14 districts of Kerala. The findings were independently assessed by another method that allowed obtaining a global score of the functioning of the RNTCP in the 14 districts of Kerala. It was finally shown that the five factors which had influenced RNTCP implementation the most were: the leadership capacity of the DTO, number of staff positions filled, the level of staff training, supportive supervision and effective feedback in place.

6. Experiences from countries on surveys carried out to measure TB prevalence, incidence and mortality

During the workshop, results of surveys carried out by different countries to estimate the prevalence, incidence, and mortality due to TB were presented by country participants. Since the baseline year for MDGs is 1990, the surveys (national, sub-national level) carried out in the Region since 1990 to estimate the prevalence of bacteriologically positive pulmonary TB (PTB) and to estimate the annual risk of tuberculous infection (ARTI) were reviewed. These are presented in Tables 1 and 2 respectively.

National level surveys to estimate prevalence of PTB are currently in progress in Bangladesh and Myanmar; while sub-national surveys are being conducted in seven sites (district/sub-district levels) in India. These surveys along with the national level survey of Indonesia in 2004, would provide the baseline estimates for the study of trends in prevalence of TB by means of another repeat survey before 2015.

Three rounds of disease prevalence surveys in Thiruvallur district in South India between 1999-2006 revealed a decline of about 12% per year in the prevalence of smear-positive as well as culture-positive PTB. The overall decline over this period of DOTS implementation was 50%. In this area, no statistically significant decline was observed during several rounds of surveys carried out during the pre-DOTS period of 1968-1986. No trends are yet available from any other areas of the Region. Two sub-national surveys in Bangladesh were carried out adopting different methodologies in different areas and were thus not comparable.

Baseline national level tuberculin surveys are in progress in Sri Lanka and Bhutan. In Thiruvallur district, South India, three rounds of tuberculin surveys between 1999-2003 revealed a decline in ARTI at the rate of about 6% per year. To estimate the trends in ARTI in different parts of India since the first zonal level surveys during 2000-03, repeat zonal level tuberculin surveys are presently in progress.

A national level study to find out the cause of death (COD) for 1 million events of death has been completed in India under the auspices of the office of the Registrar General and Census Commissioner. Similar studies have also been carried out in two states of India in and selected provinces of Indonesia. All these studies are based on investigating COD by verbal autopsy and their results are awaited.

It was also re-iterated during the workshop that the ARTI rates may no longer be used for estimating incidence of TB. The tuberculin surveys may be carried out for the study of trends in ARTI only in such areas where the survey data are likely to be interpretable.

Though surveys to find out the proportion of multi-drug resistant cases among all new and retreatment cases are being carried out in many countries of the Region, these require to be augmented.

Table 1: Prevalence of Pulmonary TB per 100 000 population

State & District	Study period	Age (yrs)	Sample Size	Screening Method	Prevalence of PTB cases/ 100,000 population		
					Culture + ve	Smear + ve	culture &/or smear + ve
Morena (M. P)India	1991-92	>14	11 097	Symptoms	-	-	1270
Delhi India	1991	>4	27 838	MMR	-	-	330
Car Nicobar (A & N), India	2000-2001	>14	10 570	Symptoms	-	729	-
Thiruvallur (T. N), India	1999-2001	>14	83 425	MMR + symptoms	609	326	
	2001-2003		85474		451	257	
	2004-2006		89413		311	169	
74 Sub districts, Bangladesh	2001	>11	266189	Symptoms	24		
Matlab rural area, Bangladesh	2004-05	>14	59395	Symptoms	95		
Indonesia-National level	2004	>14	50134	Symptoms	104 (66-142)		
Yangon division, Myanmar	2006				279 (193-364)		537 (421-653)

J& K: Jammu & Kashmir, T.N: Tamil Nadu, Mah.: Maharashtra, Kar.: Karnataka, M.P: Madhya Pradesh; -: Not available – CI: Confidence Interval

Table 2: Tuberculin surveys

	Area	Year	Sample size	Age group (Years)	Estimated ARTI (%)
Indonesia Provincial Level surveys	West Sumatra	2006	5653	6-9	1-1.3 ^s
	Nusa Tenggara	2007	5479		1
	Central Java	2007	6943		0.9
	North Sulawesi	2008	6557		1.9-2.5 ^s
	South Kalimantan	2008	6359		1.8
Nepal	Sub-national surveys in 17 selected areas	1985-95	-	6-10	2.1
	National Level	2006-07	17260	5-7	0.9(0.5-1.2)
Bhutan	Thimphu, Mongar and Bumthang dsitriacts	1991	1736	6-14	1.9
India	Bangalore	1998	4936	5-8	2.2
		2006	3354	5-8	1.5
	Thiruvallur	1999-01	12854	0-9	1.6
		2004-05	8668	0-9	1.4
		2001-03	8329	0-9	1.2
	Orissa	2002	10626	1-9	1.7
	Andhra Pradesh	2005-06	3636	5-9	1.4
	Khammam	2001-02		5-7	1.5
	Zonal level surveys (4 zones)	2000-03	N. Zone-51380 W. Zone-51733 E. Zone-42836 S. Zone-52300	0-9	N. Zone-1.9 W. Zone-1.6 E. Zone-1.3 S. Zone-1.0
DPR Korea	National level	2007	11182	7-8	3.0

^sEstimates very depending upon statistical method of estimation, ():95% CI

7. Assessing the reliability and completeness of notification data

7.1 Estimating missing cases

An analysis of available TB notification data is an essential component of assessing TB incidence and its trends. However, this data alone does not provide alternate information on which to base estimates of TB incidence in absolute terms. This is because of a significant number of TB cases that exist, but which are not counted in TB notification data. To estimate the real numbers of incidence cases, two approaches could be used:-

(a) Onion model:

The “Onion Model” is a framework that can be used to understand where and why incident TB cases might not be accounted for in routine programme notification data, to investigate and quantify the proportion of incident TB cases that are actually captured in TB notification data, and to identify the kind of programmatic or health system interventions that might be required to increase the fraction of incident TB cases being recorded through programme data on case notifications.

This framework was first presented to the international TB community in 2002, and has been termed as “Onion Model”. In the onion model, only TB cases in the first inner layer are found in TB notification data. The relative size of the layers 2 to 6, determines the proportion of TB incident cases not being accounted for in TB notification data. The major reasons why cases are missed from programme notification data include laboratory errors, lack of notification of cases by public and private providers, failure of cases accessing health services to be identified as TB suspects or a complete lack of access to health services.

Estimating the proportion of TB cases that might be missed in each layer of the onion model for one specific year in terms of lowest possible value (%) was used as the means to provide a preliminary assessment of completeness of data and reliability.

Figure 1. The “onion” model: a framework for assessing the fraction of TB cases accounted for in TB notification data, and how this fraction can be increased

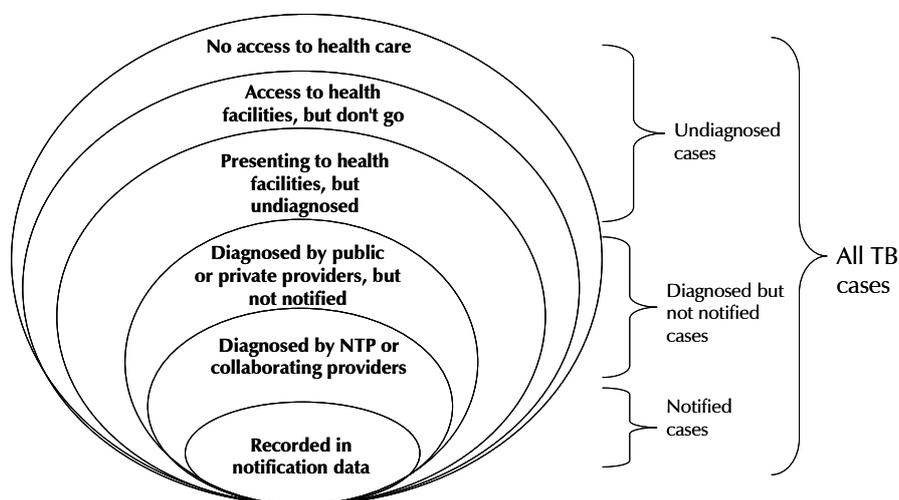


Table 3: Examples of data and methods that could be used to assess how many TB cases are missing from TB notification data

Possible reason for cases to be missing from TB notification data	Examples of methods that could be used to directly measure how many TB cases are missing from TB notification data	Examples of published studies	Examples of analysis and supporting evidence that could be used
Cases recorded in TB notification data (Ring 1)	Analysis of available TB notification data and trends could provide indirect evidence of its completeness, timeliness and validity. Analysis of trends in notification data could be used to assess the extent to which they reflect trends in rates of	Suarez et al (Peru) ¹ Dye et al (Morocco) ² Mansour et al (Kenya) ³ Vree et al (Viet Nam) ⁴	The number of notification data reports expected to arrive from reporting health care units or lower level administrative levels can be compared with the number of reports actually received for a given period. Assessment of whether

Possible reason for cases to be missing from TB notification data	Examples of methods that could be used to directly measure how many TB cases are missing from TB notification data	Examples of published studies	Examples of analysis and supporting evidence that could be used
	TB incidence (which may be influenced by HIV prevalence, for example) and the extent to which they reflect changes in other factors (such as programmatic efforts to find and treat more cases).		there is duplication or misclassification of data, exploration of variability geographically and over time (to check for internal consistency). HIV prevalence in the general population. HIV prevalence among TB cases. Changes in diagnostic efforts over time: number of mycobacterial labs, number of trained clinical and lab staff, number of sputum smear slides performed per TB suspects.
Cases diagnosed by NTP but not recorded in notification data (Ring 2)	Operational research can be used to study the number of cases that are missing from TB notification data. These studies typically	Botha E et al (S. Africa) ⁵	
Cases diagnosed by non-NTP providers that are not notified (Ring 3)	involve prospectively collecting data from places where TB cases may be (i) diagnosed but not notified (ii) seeking care but not being diagnosed and (iii) experiencing symptoms but not seeking care.	Miglioiri et al (Italy), Maung et al, (Myanmar), Lonroth et al (Viet Nam), Ambe et al (India), Arora et al (India), Dewan et al (India) ⁶⁻¹³	Drugs sales in the private sector. Health expenditures in private/NGO sectors, out-of-pocket expenditures. Number of health facilities/private practitioners and proportion that are not collaborating with the

Possible reason for cases to be missing from TB notification data	Examples of methods that could be used to directly measure how many TB cases are missing from TB notification data	Examples of published studies	Examples of analysis and supporting evidence that could be used
	To assess the number of cases whose diagnosis is being missed at health care facilities and to assess the number of cases that are being correctly diagnosed and treated but not notified, a common approach is to introduce study registers at health		NTP. Prescriptions in pharmacies. Regulations regarding prescribing and availability of drugs and their application in practice. Knowledge and use of the international standards for TB care.
Cases presenting to health facilities that are not diagnosed (Ring 4)	facilities (including laboratories), in which TB suspects and TB cases are listed. These lists can then be compared with lists of notified cases. If 3 or more lists can be generated, it may be possible to use capture-recapture methods ¹⁷⁻²⁰		Knowledge/attitudes/practices of health staff. Suspect management practices. Slides examined per TB suspect. % laboratories with satisfactory performance (based on EQA).
Cases that have access to health services but do not seek care (Ring 5)	to estimate total incident cases (i.e. to estimate not only cases that are missing from notifications, but also to estimate the number of cases that are missing from all lists i.e. cases that are not in contact with health facilities at all).	Gasana et al (Rwanda), Espinal et al (Dominican Republic), Lee et al (Hong Kong) ¹⁴⁻¹⁶	Data on population knowledge, attitudes and practice (KAP) from TB-related KAP surveys.
Cases that do not have access to health services (Ring 6)	Since it is not possible to study all health care	Van Hest et al (the Netherlands), Baussano et al, Crofts et al (UK) ¹⁷⁻²⁰	Population access to health services e.g. % population living within a certain distance of a health facility. Number of laboratories doing smear microscopy per 100 000 population.

Possible reason for cases to be missing from TB notification data	Examples of methods that could be used to directly measure how many TB cases are missing from TB notification data	Examples of published studies	Examples of analysis and supporting evidence that could be used
	facilities, a critical issue in study design is the sampling of facilities to make sure that results are representative of the population as a whole. Convincing non-NTP providers to participate in such studies may also be challenging.		Number of nurses and doctors per 100 000 population compared with international norms of what is required. Data from major household/demographic surveys. Vital registration data showing what proportion of TB deaths never accessed TB diagnosis and treatment.
All reasons listed above		Prevalence survey from Myanmar	Prevalence of TB disease survey in which questions about health-seeking behaviour and contact with health services are asked.

(b) Recapture studies

No surveillance system captures ALL cases. Capture-recapture studies can be used to derive a better estimate on the real numbers of cases by finding out the proportion of under/over-estimation of the case notifications under NTP. A minimum of three sources of data are required for this purpose. The sources of data that can be used for such studies are: laboratory registrations, hospital registries, HIV notification data with TB diagnosis, data from prisons, pharmacies, and workplace and insurance agencies.

Capture-recapture studies may be utilized to estimate the number of TB cases that are diagnosed but not reported (Rings 2 & 3 of Figure 1).

These studies are however based on certain assumptions: (i) Closed population: i.e. no birth, death or migration i.e. (ii) Every case has the same chance of being captured (iii) sources of data are independent from each other.

Group work

Using the "Onion" model, the participants made the estimates of the proportion of cases missed by NTPs of respective countries. However, such estimates on the proportions of cases missed at each level (ring 2-6) were based on rough estimates. Thus, it was suggested that behavioural studies (accessibility of health services, knowledge attitude and care seeking practices, patient delay) and operational research (practices of diagnostic procedures, diagnostic delay, additional yield of cases through contact tracing and ACSM activities) may be carried out to arrive at better estimates of the missed cases at each of these levels.

Participants from most countries were of the view that most of the reporting units regularly reported to NTP. The reports are received on time from the lower to higher administrative levels and are delayed only rarely. The system for electronic transmission of NTP reports from district to national level is also in place in India and Indonesia. There was a possibility that notification reports may be missing some cases diagnosed at the lowest administrative levels and due to administrative errors. Also, a large proportion of public sector hospitals and non-NTP health providers have not yet been brought under the standardized diagnostic and treatment practices and recording and reporting system of the respective NTPs. In Indonesia, 38% of hospitals are involved in the DOTS programme but only a minority of them report regularly to NTP. Similarly, cases diagnosed in the private sector and other collaborating agencies such as prisons and workplaces might be missed from reporting in most of the countries. In Sri Lanka, there is only one sub-national reporting i.e. at the district level and there is no system to monitor the completeness of reporting from districts to national level.

The TB-HIV collaborative activities are part of the routine reporting systems in some countries like Thailand, Myanmar and India. Provider-initiated HIV testing and counselling of TB cases has been incorporated nationally in Thailand and Myanmar while it is being carried out in selected districts in India and in selected provinces of Indonesia. However, the

available data on HIV among TB cases is grossly insufficient and there is an urgent need to scale up TB-HIV surveillance in the Region to cover at least a representative sample of the cases. This would also facilitate refining the estimates of TB incidence.

7.2 Changes in notifications over time

It is important to note that changes in notification rates can occur due to technical/administrative reasons such as changes in efficiency of case finding effort, quality of notification data, coverage of reporting, TB case definitions etc. To understand whether the trends in TB case notification rates truly reflect the trends in TB incidence, the following questions need to be answered in the context of each country:

(a) Have TB notifications been increasing, decreasing or been stable over time?

These notification rates have to be analysed separately for new smear positive cases, new smear negative pulmonary cases, new extra-pulmonary cases and re-treatment cases. Attention needs to be paid to ensure that the data is consistent with known parameters, namely, the proportion of NSP cases out of all new pulmonary TB cases, the proportion of NSP cases detected out of all suspects examined, proportion of extra-pulmonary cases and the male- female ratio.

(b) Were there changes in case-finding effort and/or recording and reporting that might have affected notification rates over time?

The following factors that have an impact on case detection and are likely to affect notifications over time need to be considered:

- (1) The number of laboratories doing smear and/or culture
- (2) The number of NTP staff
- (3) Expenditure on TB control
- (4) Suspect evaluation rate (Number of people examined for TB per unit population)

- (5) Number of sputum slides examined per TB suspect
- (6) Proportion of population screened for TB through active case finding and pulmonary cases diagnosed
- (7) Proportion of all notified cases diagnosed and reported by non-NTP health providers.

The following systemic changes in recording and reporting systems which could affect notifications over time, but do not impact the true underlying incidence also need to be considered:

- (1) Expanding coverage of the recording and reporting mechanism
- (2) When the notifying of re-treatment cases began
- (3) When the notifying of smear negative cases began
- (4) When the notifying of extra-pulmonary cases began
- (5) When the notifying of smear positive cases in children began
- (6) When the notifying of smear negative/extra-pulmonary cases in children began
- (7) When the system was changed from paper-based to electronic systems, or electronic to internet-based systems
- (8) Whether the checked data has duplications and misclassifications and whether these have been corrected.

(c) Which factors influence TB incidence over time, and do they have an impact on underlying TB incidence as well?

These are some indicators that may affect or be affected by changing the underlying TB incidence, and therefore notifications, over time. The factors also need to be considered: HIV prevalence in the general population: as HIV prevalence increases an increase in TB incidence could be expected.

- (1) Gross Domestic Product (GDP) - as GDP increases, a decrease in TB incidence could be expected
- (2) Trends in age distribution of notified cases over time - in areas of persistently high TB transmission, incidence rates are known to peak among young adults; in areas of lower recent transmission (declining TB incidence), more cases would occur among older

individuals due to reactivation, which results in the mean age of cases tending to increase over time. However, wherever the reliable demographic information is not available, trends in the average age of TB cases should be interpreted with caution

- (3) Other risk factors for TB such as malnutrition, smoking, alcoholism, diabetes, indoor air pollution can also impact TB incidence and could be included in the analysis.

(d) Based on the analysis of the situation based on questions 1 through 3, what could be the true underlying change in incidence over time?

(e) Analyse how, in some years, notifications might have been closer to true incidence than in other years. How different (or similar) is the true underlying incidence from the actual notifications?

Group Work—Analysing country data

Participants analysed the notification data of their respective countries through the responses to the above questions to determine whether trends in TB notifications reflected the trends in TB incidence in their countries. The major observations made by the participants were as follows:

- The analysis of time trends in case notifications is confounded by the differences in the characteristics of implementing geographical areas within individual countries, as the countries were in a phase of expansion of services. The services delivered by NTPs have also been constantly evolving in this period to include intervention for TB-HIV collaborative activities, involvement of the private sector, etc. At the same time, there have been changes in trends of the different determinants that influence transmission of infection and development of TB disease.
- An increasing trend in notification rates among new smear positive cases was observed over the last decade in five countries of the Region, namely Bangladesh, DPR Korea, India, Indonesia

and Myanmar (Figure 2). This may largely be attributable to changes in case finding efforts and diagnostic capacity rather than any increase in incidence rates. The increasing trends in notification rates of NSP cases in these countries were generally in parallel with the increasing trends in suspect evaluation rate.

The declining trends in case notification rates of NSP cases have been observed in Bhutan, Nepal and Maldives, from 2002-2003 and 2005 respectively (Fig. 3). The declining trends of incidence of TB had also been predicted in these three countries by mathematical models.

The case notification rates remained stable in Sri Lanka (Fig. 3).

Fluctuating trends were seen in Thailand and Timor-Leste (Fig. 3). Such trends in Thailand are attributed to fluctuations in case finding efforts. Timor-Leste emerged as a new country in 2000 and the NTP is still in a phase of evolution. This coupled with changes in implementation and quality of reporting, particularly during periods of civil unrest may be responsible for the fluctuating trends in case notification rates.

The following issues were also discussed as key considerations in the analysis of notification data:

- Diagnosis of smear positive PTB is reliable and most of the reported smear positives cases are actual TB cases; this may not be true of smear negative cases. A few NGOs may also be misclassifying some cases.
- The proportion of new cases among all cases was found to be unexpectedly high in some countries of the Region. This could be due to misclassification of a proportion of 're-treatment cases' as 'new cases'. Overall, 86% of all cases (new + re-treatment) diagnosed in the Region were 'new cases'. Cases of PTB constituted 84% of all new cases. About 61% of new PTB cases were smear positive.
- In many Member States, the notifications of smear negative, extra-pulmonary relapse and other re-treatment cases and paediatric cases were introduced into the routine surveillance programme at different time periods.

- The recent trend of increase in the proportion of extra-pulmonary TB (EPTB) cases in some countries may be due to increased involvement of medical colleges and hospitals in the reporting system.
- Notification rates in countries like Myanmar and Thailand have run in parallel with the estimated HIV prevalence in the community.
- Over the years, there has been increased involvement of NGOs, the private sector, medical colleges and general hospitals.
- Increased efforts have also been made to reach inaccessible regions and prisons in some countries.

Figure 2 : Increasing trends in TB NSP case notification rates in five SEAR, Member States

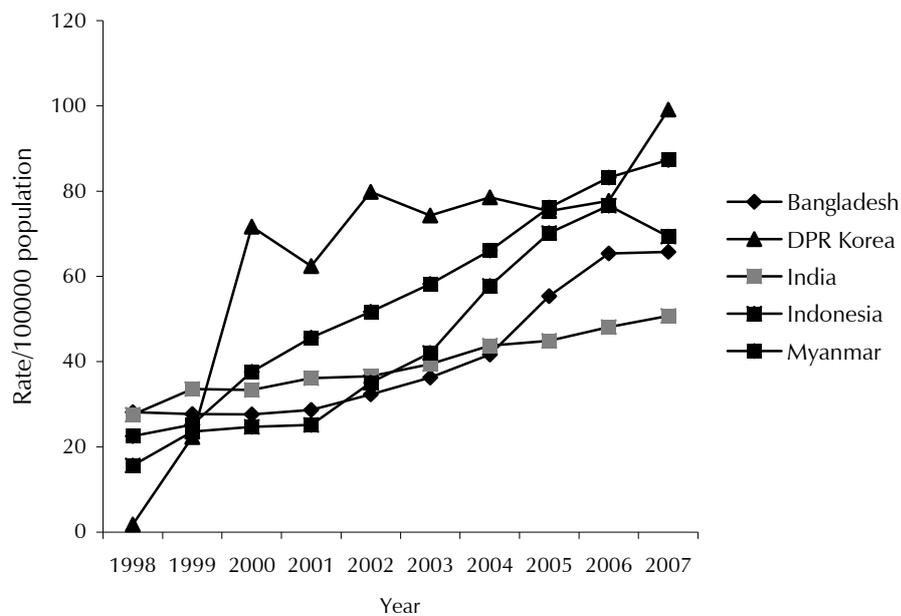
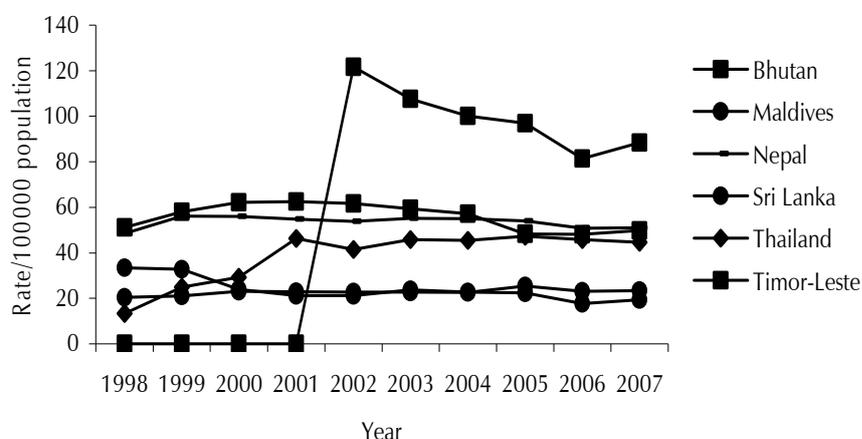


Figure 3: **Varying trends in TB NSP case notification rates in six SEAR Member States**



The following measures were suggested to strengthen routine surveillance under NTPs:

- Ensure accuracy in recording, completeness of reporting of data, and adherence to time schedules, all of which enhance reliability.
- Strengthen supervision of NTPs at various levels, including that of recording and reporting systems.
- Introduce reliable systems to capture data on cases detected by health agencies/ providers other than NTPs, under the ambit of NTP surveillance. Miss-diagnosis or miss-classification of types of TB cases could be reduced by training relevant staff or providers in other sectors.
- Avoid double counting of cases by using unique identifiers for each patient.
- Analyse routine surveillance data at the sub-national levels with the primary objective of gaining insight into diagnostic practices and for monitoring different programme components.
- Cross-validate mortality data generated through NTP reports using data from vital registration systems in order to accurately assign the cause of death occurring during the period of anti-TB

treatment (ATT) and to capture deaths due to TB occurring after completion of treatment. It is estimated that currently less than 1% of all deaths estimated to occur in the Region are captured by national vital registration systems.

8. Methods and assumptions used by WHO for estimating TB prevalence, incidence and mortality

Specific methods for estimating the incidence and prevalence of TB and TB deaths in each country, and the statistical methods used to estimate their trends in time used by WHO were presented in the workshop. These methods take into account the proportion of HIV positives among smear positive and smear negative incidence TB cases and the variability in disease duration and case fatality rates by HIV status, type of TB case (smear positive/negative) and treatment status (DOTS, non-DOTS, untreated). However, the impact of anti-retro-viral therapy on the estimates of incidence, prevalence and mortality due to TB has not yet been determined, and has not therefore been factored in.

Group work

The participants from individual countries debated and discussed the assumptions used by WHO for the estimates of TB prevalence incidence and mortality in their respective countries. By and large, the participants agreed with WHO assumptions though there was some difference in opinion regarding the proportions of untreated cases and those treated under non-DOTS.

9. Country plans to improve TB surveillance and programme monitoring and evaluation system

Proposals and plans for the period 2009-2011 to improve TB surveillance were made during the workshop by participants. These are as detailed in Table 4.

Table 4: Country plans for strengthening surveillance, monitoring and evaluation

List of activities	Country	Countries requiring technical assistance
1. Improve recording and reporting capacity:	i. Improve coverage of recording & reporting (R&R)	Indonesia, Myanmar, Timor-Leste
ii. Improve supervision of R&R activities, from data collection to data validation and transmission	Bhutan, Maldives, Myanmar, Timor-Leste,	Myanmar
iii. Progress from a paper-based to an electronic-based system	Bhutan, Indonesia, Maldives, Myanmar	Bhutan, Myanmar
iv. Progress to web-based system	Myanmar	
2. Improve capacity to analyse TB notification and other supporting data at national level	Bangladesh, Bhutan, Indonesia Myanmar, Thailand, Timor Leste	Bhutan, Thailand, Timor-Leste
3. Improve capacity to analyse TB notification and other supporting data at sub-national level	Maldives, Myanmar, Sri Lanka,Thailand	Maldives, Thailand
4. Improve feedback of data analysis and interpretation to TB staff and other health care workers at peripheral level	Indonesia, Myanmar, Timor-Leste	
5. Identify and eliminate duplicate and misclassified records at national level	Bangladesh, Myanmar	
6. Establish data quality assessment (e.g. using data quality assessment tool)	Bangladesh, Bhutan, Myanmar	Bhutan, Myanmar
7. Improve feedback of data analysis and interpretation to TB staff and other health care workers at peripheral level	Myanmar	Myanmar
8. Conduct sample studies of health care facilities, on the yield of patients:	i. by comparing number of TB cases with number of suspects	Bhutan, Myanmar, Thailand, Timor-

List of activities	Country	Countries requiring technical assistance
examined and/or number of suspects examined with number of chronic respiratory cases attending health care facilities	Leste	
ii. diagnosed through active case finding	Myanmar,	
iii. diagnosed through contact investigation	Maldives, Timor-Leste	
iv. diagnosed through PPM	Indonesia, Sri Lanka	
9. Perform cross-validation of TB notification data with other pre-existing sources of TB data	Indonesia	Indonesia
10. Perform cross-validation of TB notification data with other newly collected TB data (for example, introduce new registries to be completed by non-NTP providers)	Indonesia	Indonesia
11. Perform a national survey of TB drug resistance	Bangladesh, Bhutan, Sri Lanka, Thailand , Timor-Leste	Bangladesh , Bhutan, Sri Lanka, Thailand, Timor-Leste,
12. Perform a national survey of HIV prevalence among TB registered patients	Bangladesh, Bhutan, Maldives, Sri Lanka, Timor-Leste	Bhutan, Timor Leste
13. Perform a national survey of TB disease prevalence	Indonesia, Thailand	Indonesia, Thailand
14. Screening for TB in high risk populations	Bangladesh, Sri Lanka, Maldives	
15. Implement and intensify PAL	Indonesia	Indonesia

10. Conclusions and recommendations

10.1 Conclusions

- There has been steady progress in TB surveillance and control in countries of the South East Asia Region. Data from various sources indicate that the disease burden is stable in most countries in the Region, though there might be decreasing trends in some. A national prevalence survey of TB disease is almost complete in Bangladesh and underway in Myanmar. Methods to estimate the burden of TB were presented and discussed in detail.
- Limited data on changes in case finding efforts over time make it difficult to interpret time-changes in case notifications in several countries.
- Incompleteness of routine surveillance data was described in several countries where there is no systematic monitoring of data quality and completeness, including simple checks.
- There is over-reliance on tuberculin surveys to assess the burden of TB and its trends in several countries. Results from tuberculin surveys are often very difficult to interpret and use and the performance of such surveys is unpredictable.
- There is over-reliance on sub-national surveys as opposed to national surveys in most countries.
- Most countries in the Region lack a sound surveillance system for assessing and monitoring the burden of TBHIV and MDRTB.
- Extensive discussions during the workshop on changes over time in TB determinants and a thorough analysis of notification data have allowed for improvements in documentation of the performance of case finding and reporting. The analysis will be the basis for an extensive revision of estimates of TB incidence, prevalence and mortality.
- Country participants updated plans to strengthen national surveillance systems, improve the assessment of disease burden and the impact of TB control.

10.2 Recommendations for National Tuberculosis Programmes

- Ensure appropriate plans that comprehensively cover activities and budgets required to strengthen surveillance and undertake planned national survey of TB disease, HIV prevalence among TB registered patients and TB drug resistance for reducing the burden of TB, including the following:
- Conduct formal assessments of the quality of TB data e.g. using GF data quality assessment tools;
- Urgently plan for national surveys of TB drug resistance in countries where no representative data are available;
- Urgently strengthen surveillance of HIV/TB and consider nationwide surveys of HIV in new TB patients in countries with limited data;
- Undertake operational research and studies to identify and eliminate duplicate and misclassified records at national level and yield of patients that will help to further understand trends and support the development of targeted interventions;
- Strengthen capacity to improve the recording and reporting system, analyze TB notification and other supporting data at national and sub-national levels and improve feedback of data analysis and interpretation to TB staff and other health care workers at in the peripheral level;
- Develop systems to capture data on cases diagnosed in hospitals under other public sector units. Non-NTP health facilities like private health facilities and NGOs should also be made part of routine surveillance. It should, however, be ensured that the case definitions are followed accurately. Data from various sources can be linked to eliminate double counting by use of common identifiers and appropriate software;
- Institute appropriate actions for accurate diagnosis of TB among children and capturing the same under routine surveillance data;

10.3 Recommendations for WHO and partners

- A report of the analysis conducted during the workshop should be shared with countries for feedback and corrections prior to updating estimates of TB disease burden at WHO/HQ;
- WHO and partners should provide technical assistance for developing and strengthening the monitoring and evaluation components of GF applications;
- Standard protocols and guidelines should continue to be developed to assist Member States to undertake population-based representative surveys/studies, to establish sound baselines and measure trends in TB case detection, treatment success, incidence, prevalence and mortality;
- Continue developing guidelines and assist in building capacity through training and maintaining a roster of consultants to provide technical assistance to Member States;
- Assist in building national capacity in order to systematically analyze routinely collected programme data, to better understand emerging trends and to develop targeted programme interventions;
- Assist Member States on operational research priorities related to TB surveillance and monitoring and assist in promoting and implementing operational research activities, particularly those related to better analyzing and using data from routine surveillance.

Annex 1

Agenda

- (1) Measuring TB incidence, prevalence and mortality: an overview of the recommendations of the WHO Global Task Force on TB Impact Measurement.
- (2) WHO framework for assessment of TB burden: Understanding the impact of disease control.
- (3) Causal model for TB performance: challenges for its development and usefulness for programme management.
- (4) Experiences from countries:
 - Bangladesh
 - India
 - Indonesia
 - Myanmar
 - Nepal
- (5) Assessing the reliability and completeness of notification data.
- (6) Methods and assumptions used by WHO for estimating TB prevalence, incidence and mortality.
- (7) Country plans to improve TB surveillance and programme monitoring and evaluation system.
- (8) Assessment of whether trends in TB notifications over time reflect trends in TB incidence.
- (9) Conclusions
- (10) Recommendations

Annex 1

List of participants

Country Participants

Bangladesh

Dr Md Nazrul Islam
Programme manager (TB)
National Tuberculosis Control Programme
DGHS, Dhaka

Mr Md Asadul Haque
Sr Health Education Officer
Civil Surgeon Office
Dinajpur

Md Abdul Ghani
Medical Officer
TB Clinic
Natore

Bhutan

Ms Pema Yudon
Assistant Laboratory Technician
Public Health Laboratory
Department of Public Health
Thimphu

Ms Choki Seldon
Health Assistant
Chamgang BHU
Thimphu

Dr Lungten Zangmo Wangchuk
Head
Research and Epidemiology Unit
Ministry of Health
Thimphu

Indonesia

Dr Eka Yusuf Singka
National TB Programme
Ministry of Health Republic of Indonesia
Jakarta

Dr Endang Lukitosari
National TB Programme
Ministry of Health Republic of Indonesia
Jakarta

Mr Sulistyono
SKM, M. Epid
National TB Programme
Ministry of Health Republic of Indonesia
Jakarta

Maldives

Ms Fatimath Reeza
Programme Officer
Centre for Community Health and
Disease Control
Ministry of Health and Family
Male

Myanmar

Dr Aye Thein (Mr)
Divisional TB Officer
Sagaing Divisional TB Centre
Monywa

Dr Hnin Wai Lwin (Ms)
Medical Officer
Divisional TB Centre
Yangon

Dr Thandar Lwin (Ms)
Assistant Director
National TB Control Programme
Department of Health
Nyapitaw

Nepal

Mr Mukunda Raj Gautam
Sr Public Health Administrator
Ministry of Health and Population
Kathmandu

Mr Sandip Chitrakar
Medical Record Officer
National Tuberculosis Centre
Kathmandu

Sri Lanka

Dr D.S.D. Samaraweera
Consultant Community Physician
National Programme for TB Control
and Chest Diseases
Colombo 5

Prof. A.J. Perera
Faculty of Medicine
University of Colombo
Colombo

Thailand

Dr Sompong Jaroongjittanusonti
Provincial Chief Medical Officer
Buriram Provincial Health Office
Office of the Permanent Secretary
Ministry of Public Health
Tivanond Road
Nonthaburi 11000

Dr Sriprapa Nateniyom
Deputy Director
Bureau of Tuberculosis
Department of Disease Control
Ministry of Public Health
Tivanond Road
Nonthaburi 11000

Ms Sumalee Amarinsangpen
Registered Nurse
Office of Disease Prevention and Control 10
Department of Disease Control
Ministry of Public Health
Chiang Mai Province

Timor-Leste

Mr Constantino Lopes
NTP Manager
Ministry of Health
Dili

Mr Domingos Pereira
Regional Supervisor
Ministry of Health
Dili

Temporary Advisors

Dr Prahlad Kumar
Director
National Tuberculosis Institute (NTI)
No. 8, Bellary Road
Bangalore, India

Dr Vineet K. Chadha
Sr Epidemiologist
National TB Institute
No 8, Bellary Road
Bangalore, India

Dr Thelma Narayan
Coordinator and Public Health Consultant
Centre for Public Health and Equity
SOCHARA
No.27, 1st Floor, 6th Cross
1st Main, 1st Block
Koramangala
Bangalore, India

Dr V.S. Salhotra
Deputy Director
SAARC TB Centre
Thimi, Bhaktapur
P.O. Box 9517
Kathmandu, Nepal

Dr Aime De Muyneck
37 Hof Ter Schrieklaan
B2600 Berchem, Belgium

Other Agencies/Observers

Dr Vishnuvardhan Kamineni
Technical Consultant
UNION
C-6 Qutub Institutional Area
New Delhi, India

Dr K. Zaman
Scientist, ICDDR
B 68 Shaheed Tajuddin Ahmed Sharani
Mohakhali
Dhaka, Bangladesh

WHO Country Staff

Dr D.F. Wares
Medical Officer –TB
WHO India

WHO HQ

Dr Philippe Glaziou
STB/TME

Dr Ana Bierrenbach
STB/TME

Dr Mehran Hosseini

WHO SEARO

Dr Md Khurshid Alam Hyder
MO-TB

A regional workshop on Tuberculosis Surveillance and Programme Monitoring and Evaluation was held during 20-24 July 2009 at the National Tuberculosis Institute, (NTI) Bangalore, India with the objectives to review current approaches to TB surveillance, monitoring and evaluation; to share the status and outcomes from surveillance, monitoring and evaluation activities in countries of the Region; to discuss plans for the implementation of the most appropriate TB surveillance, monitoring, evaluation and research methodology for each country, and to identify technical support as required by Member States to strengthen TB surveillance, monitoring and evaluation.

The key recommendations that were made in the workshop were: regular monitoring, analysis and provision of feedback on cohorts reports received from by NTPs; monitoring missions to review progress with TB data management and surveillance at national and sub-national level; assistance in planning and undertaking TB prevalence and mortality surveys/studies in countries; and documentation and dissemination of information on trends in TB morbidity and mortality through regular regional meetings and reports.



**World Health
Organization**

Regional Office for South-East Asia

World Health House
Indraprastha Estate,
Mahatma Gandhi Marg,
New Delhi-110002, India



SEA-TB-325