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National Tuberculosis Control Programme Bhutan

Report of the External Review
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Annexes

Abbreviations

ACSM	advocacy, communication and social mobilization
AFB	acid-fast bacillus
ARTI	annual risk of tuberculosis infection
BCG	Bacillus Calmette-Guérin
BHU	basic health unit
DHSO	district health supervisory officer
DOT	directly-observed treatment
DOTS	internationally-recommended strategy for tuberculosis control
DST	drug-susceptibility testing
DVED	drugs, vaccines and equipment division
E	ethambutol
EQA	external quality assessment
Eto	ethionamide
FDC	fixed-dose combination
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
H	isoniazid
HIV	human immunodeficiency virus
HMIS	health management information system
JDWNRH	Jigme Dorji Wangchuck National Referral Hospital
Km	kanamycin
MDGs	Millennium Development Goals
MDR-TB	multidrug-resistant tuberculosis

MoH	Ministry of Health
MSD	medical supplies depot
NTCP	National Tuberculosis Control Programme
Ofx	ofloxacin
OPD	out-patient department
ORC	outreach clinic
PAL	practical approach to lung health
R	rifampicin
RGoB	Royal Government of Bhutan
RIHS	Royal Institute of Health Sciences
S	streptomycin
SAARC	South Asian Association for Regional Cooperation
SEA Region	WHO South-East Asia Region
SEARO	WHO South-East Asia Regional Office (New Delhi)
TB	tuberculosis
TDR	Unicef-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases
THPA	Tala Hydroelectric Project Authority
UNAIDS	Joint United Nations Programme on HIV/AIDS
US$	United States dollar
VCT	voluntary counselling and testing
VHW	village health worker
WHO	World Health Organization
Z	pyrazinamide

Executive Summary

An external review of the Bhutan National Tuberculosis Control Programme (NTCP) was conducted from 22 to 31 May 2006. This was the first external review of its kind in 10 years. Previous reviews were undertaken by Dr Philippe Sudre, WHO Short-term Consultant, in 1992 and from 4-11 November 1996.

Considerable progress has been achieved in the initiative to control tuberculosis on many fronts as compared to the situation described in the 1996 (draft) review report. Most of the recommendations made then have since been implemented. However, there were some important recommendations that have been inadequately addressed while others have become redundant over time.

There has also been a remarkable improvement in overall tuberculosis (TB) programme management. The laboratory situation has further been bolstered with regular provision of sputum containers, slides, diamond pencil loops and good immersion oil. Good-quality microscopes are available throughout the country. The organisation and logistics seem much better than they were 10 years ago. A considerable number of staff have been trained and health-care providers are widely adhering to the national guidelines.

Since the adoption of the DOTS[1] (directly-observed treatment, short course) strategy, the programme has expanded nationwide while maintaining its quality standard. Since 1999 Bhutan has exceeded the global targets of both 70% case detection and 85% treatment success. The proportion of smear-positive cases has steadily increased over the years, highlighting the increased attention for infectious cases and improved diagnostic quality.

[1] DOTS: Internationally recommended strategy for TB control consisting of the following elements: political commitment, diagnosis based on smear microscopy, uninterrupted drug supply, directly-observed treatment and standardized recording and reporting.

The political commitment of the Royal Government of Bhutan (RGoB) is manifested in the provision of the revised national guidelines and in the major financial contributions made towards salaries, infrastructure, drugs (including second-line drugs) and food during hospitalization. The annual messages by the honourable Minister for Health and the participation of high-level officials in activities organised to observe World TB Day also illustrate this commitment.

Financing has been secured for the medium term through a successful grant in Round 4 of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), as well as through increased domestic funding. Technical assistance has contributed to a more firm technically-sound base for the programme.

The collaboration between NTCP and the Public Health Laboratory has been scaled up in recent years. With support from the Public Health Laboratory, the laboratory network has been expanded to cover all hospitals and grade-I basic health units (BHUs) and a system for monitoring quality of TB laboratory activities has been developed.

The NTCP also has a commendable collaboration with other partners: other units in the Ministry of Health (MoH); National HIV/AIDS Control Programme; and the Drugs, Vaccines and Equipments Division (DVED) as well as military and corporate health services.

Constraints include the uncertain TB burden baseline data (prevalence, incidence and mortality) against which to measure the impact of the TB control interventions as well as the discrepancy in global and national data due to the difference in population figures used by various agencies.

The capacity at the central level is also limited, particularly in view of planning and monitoring the DOTS activities and, more importantly, the expected additional activities linked to the expanded DOTS concept and new global Stop TB Strategy. Most *dzongkhags*[2] have a focal point assigned for TB control. These TB in-charges focus on programme implementation. The system lacks an official directing, advisory or reporting line between the central TB unit and the *dzongkhag* focal point.

[2] *Dzongkhag*: the Bhutanese equivalent of district.

There is considerable room for further improvement of the laboratory capacity for TB, including first-line services (direct quality-assured smear microscopy) as well as in setting up reliable culture and drug-susceptibility testing (DST) facilities at the Public Health Laboratory. The proposed plan to further decentralize TB laboratory services beyond the grade-I BHUs poses a serious risk of rendering these services unsustainable. The Public Health Laboratory is also not linked to a supranational TB reference laboratory.

The current policy includes hospitalization during the intensive phase of all patients receiving category 1 or 2 treatment. This policy facilitates the implementation of strict supervised treatment. Since a majority of smear-negative and extra-pulmonary TB cases are also treated with category 1, it poses a heavy burden on hospital capacity at a fairly high cost and with no guarantee of strictly supervised treatment. Treatment services (including the intensive phase) down to the community level have not been envisaged.

TB services are delivered by dedicated staff. However, not all of them have been trained. The programme does not have a comprehensive human resources plan nor are data available on past training activities. Supervision is taking place on an ad-hoc basis and not according to standard practices.

Suspected multidrug-resistant tuberculosis (MDR-TB) patients are treated with second-line TB drugs provided by RGoB. The unconfirmed diagnosis, lack of knowledge of local drug-resistance patterns with inherently linked difficult choice of treatment regimens and the difficult follow-up of patients let the reviewers conclude that this is a risky and costly undertaking that needs to be streamlined.

The most important recommendations include strengthening NTCP planning, implementation, monitoring and evaluation by enhancing the management capacity at the national and regional level and by supervising the lower tiers of the health system. Advice for ensuring financial sustainability include reprogramming of savings during the first year of the GFATM grant implementation, accelerating implementation of GFATM-funded activities, maintaining (or even further increasing) the RGoB contribution and including technical assistance needs, where required, in any donor proposal.

The review team recommends not to expand the laboratory network beyond the current laboratories but to ensure increased access to sputum smear microscopy by collecting sputum at the BHU or community level.

The treatment regimens should also be modified and simplified by offering a fully oral category 1 regimen to all new cases (smear-positive, negative and extra-pulmonary, adults and children, HIV-positive and negative) with fixed-dose combinations (FDCs). The introduction of FDCs allows for community-based treatment supervision. The hospital would be pivotal in indenting and distributing drugs to outpatient departments (OPDs), BHUs and village health workers (VHWs) for diagnosed and registered cases.

Supervision should be systematically undertaken, at regular intervals, with standardized checklists and feedback.

Human resources development for TB needs to be properly addressed. All staff taking part in TB control should be properly trained and periodically retrained.

Intersectoral collaboration should be further strengthened by including all health-care providers in the programme and by increasing community participation in service delivery together with advocacy and social mobilization. Integration of TB in broader structures (health or development committees) should be pursued.

The Public Health Laboratory should be linked to a supranational reference laboratory to ensure the development in a cost-effective and sustainable way of quality assurance schemes, culture and DST facilities. Similarly, to improve the management of MDR-TB and upgrade it to international standards, the Green Light Committee (GLC)[3] should be involved. Capacity building should be enhanced through technical assistance and international training programmes and study visits.

[3] GLC: Mechanism established by the WHO Working Group on DOTS-Plus for MDR-TB to provide technical assistance to DOTS programmes, promote rational use of second-line drugs and improve access to concessionally-priced, quality-assured second-line drugs.

HIV monitoring in TB patients should be continued through the annual sentinel surveys.

The team also recommended undertaking another external review after two or three years in order not to lose the momentum and to allow providing adequate advice on strategic new issues that are expected to emerge in the coming years.

1. Introduction

Bhutan is a landlocked mountainous country about 300 km in length and 150 km wide. According to the Population and Housing Census of Bhutan (2005), the total population was 672 425. One third of the population is below 15 years of age, 62% belong to the economically active age group (15-64 years old), while only 5% is older than 65. The majority of people (69%) live in rural areas; there is a net migration from rural to urban areas. There are 111 men for 100 women. The average population density in the country is 16 persons per sq. km. The crude birth rate is 20 per 1000 while the crude death rate is 7 per 1000, resulting in a natural population growth rate of 1.3% per year.

The overall majority of the population is engaged in subsistence farming with a minimal cash income. The per capita income in 2005 was US$ 1969. Bhutan exports electricity, agricultural products, wood products and cement.

At the national level, legislation is enacted by the National Assembly. The executive authority lies with the Council of Ministers, elected by the National Assembly. The country is administratively divided into three regions (West, Central and East) and 20 districts, also called *dzongkhags*. At the sub-district level, the administrative unit is called *geog* or block. Each *geog* has about 2000-4000 people and is headed by an elected *gup*. There are 202 *geogs* organised in village or block councils, known as *Geog Yargary Tshokgung* or GYTs.

Most villages in Bhutan have community or primary schools. There are 59 junior high schools, 26 high schools, one college and ten specialized training institutes. The Royal Institute for Health Sciences is one such institute that offers preservice training courses for paramedical and allied health workers. Free education is provided to all students. There is also an adult education programme. Radio is now available in most households while 10% of the population is covered by the television network.

Bhutan provides free health services to all residents. The child immunization coverage level is over 90%. Iodine deficiency has been

eliminated. The infant mortality rate – once the highest in the world at 142 per 1000 live births – has been reduced to 40.1 per 1000 live births. Half of all deliveries are attended by health professionals. Leprosy has been eliminated as a public health problem.

Healthcare is provided through a four-tiered network. The Jigme Dorji Wangchuck National Referral Hospital (JDWNRH), located in the capital Thimphu, serves also as the regional referral hospital for the western region. There are two more regional referral hospitals: in Gelephu (central region) and Mongar (eastern region). These referral hospitals provide specialist services. The next tier consists of 28 *dzongkhag* hospitals (including military and corporate hospitals and grade-I BHUs) where medical officers are posted. The peripheral tier consists of 166 BHUs. These BHUs typically have three paramedical staff and three in-patient beds. Some of them also have a small laboratory. The BHU staff provide health services to more distant villages through intermittent (usually monthly) outreach clinics (ORCs). At the community level, the health services are supplemented by VHWs. A VHW typically takes care of 20 households and attends the monthly ORCs. Non-financial incentives including participation in an annual five-day workshop motivate VHWs to provide services on an otherwise entirely voluntary basis.

Around 40% of adults and 27% of the total population in Bhutan are infected with *Mycobacterium tuberculosis*. The only tuberculin survey carried out in Bhutan in 1991 showed an annual risk of tuberculosis infection (ARTI) of 1.5%. In the absence of more recent estimates, NTCP uses this figure as the basis for estimating the incidence and prevalence. A 1.5% ARTI translates, using the Styblo conversion factor[4], in an incidence of 75 new smear-positive cases per 100 000 population or approximately 504 cases. An additional 620 smear-negative and extra-pulmonary are estimated to be added each year. The prevalence is estimated to be around 1932 cases. The TB mortality is pegged at 20 per 100 000 (around 135 for the entire country, of which 36 were reported in the 2004 DOTS cohort report. The estimated prevalence of HIV in adult (15–49 years) TB patients is less than 0.1%. The rate of multidrug-resistance is estimated to be 1.8% in new cases and 15% in previously treated cases, according to the WHO annual TB Country Profile.

[4] Styblo conversion factor: 1% ARTI corresponds to 50 new smear-positive cases per 100 000 population.

The NTCP has been fully integrated into the general health services in the *dzongkhags* since its inception in 1976. Replacement of long-course chemotherapy by short-course chemotherapy was initiated in 1988. Learning from the experience of running the programme and the recommendations from the 1992 review; and following the declaration by the World Health Assembly in 1993 of TB as a global emergency, Bhutan adopted the DOTS strategy. Nationwide coverage was achieved in 1997. The most recent external programme review took place in 1996.

2. Review of the National Tuberculosis Control Programme

2.1 Goal and Objectives

The overall goal was to undertake an in-depth review of the Bhutan NTCP against the set goals of the ninth Five-Year Plan (2002-2007).

The specific objectives were:

- To review the present policies, organizational structure, planning and financing of NTCP;
- To evaluate the progress of implementation of NTCP activities in:
  - Increasing access to DOTS, including the involvement of other sectors such as workplaces, prisons and the army; and measures to reach mobile populations;
  - Supervision, recording, reporting, monitoring and evaluation;
  - Improvement of quality assurance for mycobacteriology laboratories;
  - Drug procurement and distribution;
  - Advocacy, communication and social mobilization;
  - Management of MDR-TB;
  - HIV-related intervention status, and
- To make recommendations based on the findings during the field visits in the above-mentioned programme areas.

2.2 Methodology

The programme review was conducted with the full support of the MoH, RGoB. WHO has provided technical assistance for undertaking the review in cooperation with national and international reviewers.

A national task force was formed to guide and facilitate the review/planning process. The task force members were from various units, divisions and organisations, and included the following people:

- Dr Gado Tshering, Secretary, MoH.
- Dr Ei Kubota, WHO Representative.
- Dr Sonam Ugen, Joint Director, Department of Public Health, MoH.
- Mr Nado Dukpa, Deputy Secretary, Administration and Finance Division, MoH.
- Mr Thinley Dorji, Deputy Secretary, Policy and Planning Division, MoH.
- Dr Ugen Dophu, Medical Director, JDWNRH.
- Mr Sonam Wangchuk, Director-General, Department of Aid and Debt Management, Ministry of Finance, PCM[5] member.

The terms of reference of the task force were: (i) to review and endorse the proposal to conduct the external NTCP review; (ii) to provide policy guidelines and necessary support to conduct the NTCP review; (iii) to ensure collaboration with all relevant sectors and (iv) to oversee the overall implementation of the review process.

The NTCP Manager, Dr Lungten Z. Wangchuk, and WHO National Professional Officer Dr Norbu Wangchuk were appointed overall coordinators.

The review team consisted of three international experts from WHO/SEARO, WHO/Bangladesh and from the supranational reference laboratory in Gauting, Germany as well as seven national staff from NTCP, other MoH departments and doctors from different *dzongkhag* hospitals. The review team was led by Dr Erwin Cooreman, Medical Officer (TB), WHO/SEARO. The list of reviewers is provided in Annex 1.

[5] PCM: Partners Coordinating Mechanism, the local variant of the Country Coordinating Mechanism set up for the Global Fund to Fight AIDS, Tuberculosis and Malaria.

A briefing meeting was held on Monday 22 May 2006 to review the developments of NTCP and the TB situation in Bhutan as well as to discuss the review process and the schedule of the field visits. The MoH Secretary (and officiating minister) met the review team leader and was briefed on the planned activities.

The review team was divided into three sub-teams which visited different parts of the country from 23 to 28 May 2006. The following places were visited by the three sub-teams:

- Sub-team 1: Central-level institutions and the western part of the country;
- Sub-team 2: Central-level institutions and the central part of the country; and
- Sub-team 3: Central and eastern parts of the country.

The different sub-teams assessed the TB control services in selected referral hospitals, *dzongkhag* hospitals and BHUs. Interviews were conducted with the national and *dzongkhag* health authorities, TB in-charges at *dzongkhag* levels and in hospitals, health workers, VHWs and patients. Standard questionnaires and data collection forms were used by the sub-teams and in-depth analyses of specific areas were conducted by them.

Each sub-team prepared a presentation and a written summary report of their field visit, which was discussed during the plenary session of the review team on 29 May 2006. Following discussions among team members, a summary of the main findings, conclusions and recommendations was prepared. This was presented and discussed during a debriefing session with the Secretary and senior MoH staff and partner agencies. The list of people present during the debriefing is at Annex 3

3. Epidemiology of tuberculosis and case detection

3.1 Estimates

It is difficult to assess the current burden of tuberculosis in Bhutan in the absence of recent representative epidemiological studies. Only one tuberculin survey has taken place so far, in 1991. Based on this, ARTI was

estimated to be 1.5% per year. Although the case-notification shows a downward trend, this figure is still used by NTCP to estimate the incidence and prevalence.

As the ARTI survey was conducted a long time ago, NTCP has expressed the need for a better estimate of the tuberculosis infection and disease prevalence to evaluate the implementation and impact of TB control activities in Bhutan. A repeat tuberculin survey is planned for 2007 and funds to conduct this survey have been partially identified.

The estimated burden of tuberculosis, as published in the annual WHO Global TB Reports, differs significantly from the figures used by NTCP. This is explained by the difference in population figures obtained from the United Nations Population Division and used by WHO (2.1 million) and the recent census (0.7 million). Table 1 shows the different indicators as published in the WHO Country Profile and figures used by NTCP.

Table 1: *Tuberculosis burden*

	WHO (2004 estimates)		**NTCP**	
	% or rate per 100 000	**Number of cases**	**% or rate per 100 000**	**Number of cases**
Annual incidence (all cases)	107	2264	167	1124
Change in annual incidence	- 4.6%	-104	0	0
Annual incidence (new ss+ cases)	48	1016	75	504
Prevalence (all cases)	184	3893	288	1932
Mortality	20	423	20	134
HIV prevalence in adult TB patients	0.1%			
MDR-TB in new cases	1.8%			
MDR-TB in previously treated cases	15.0%			

According to the Global TB Report (2006), Bhutan has made considerable progress towards reaching the TB-related Millennium Development Goals (MDGs). The MDG targets include halving the prevalence and mortality and beginning to reduce the incidence by 2015, with 1990 as baseline. While the published rates per 100 000 may be affected by the population denominator, the decrease in rates should not. The report shows a decline, between 1990 and 2004, in overall estimated prevalence from 371 to 184 per 100 000 (50%), in estimated mortality from 40 to 20 per 100 000 (50%), in overall estimated incidence from 204 to 107 (48%) and in estimated incidence of smear-positive TB from 92 to 48 (48%). With the exception of Maldives, the latter two parameters show the highest decrease in the WHO South-East Asia (SEA) Region[6].

3.2 DOTS coverage

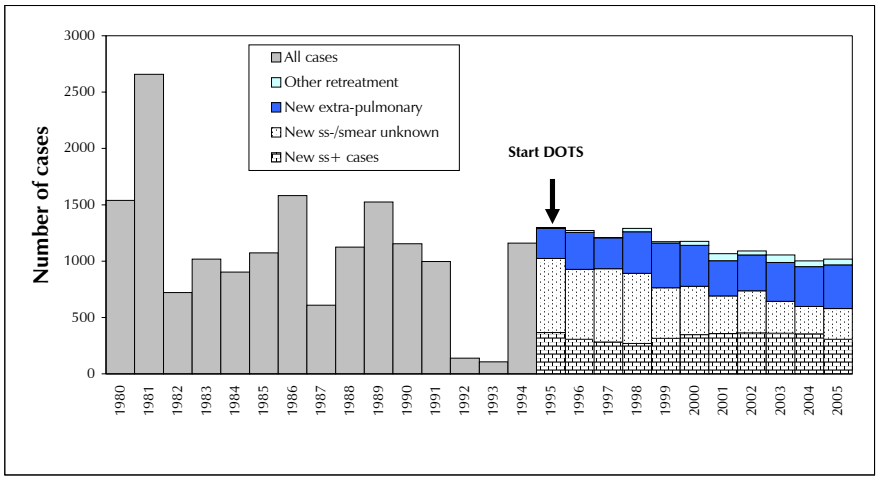
The DOTS programme was launched in 1997 and immediately rolled out all over the country. Coverage has been defined as providing diagnostic and treatment services at *dzongkhag* level (including hospitals and grade-I BHUs). Registration and reporting is done at this level.

3.3 Case notification

The overall case notification shows a downward trend (Fig.1). The notifications showed great variations in the 1980s and 1990s with a peak of an excess of 2600 cases in 1981. Since the second half of the 1990s the TB notifications show a more consistent trend, likely due to better adherence to case definitions and the introduction of standard reporting under the DOTS strategy. The reduction in overall case notification observed during the last 10 years is mainly attributable to a reduction in smear-negative cases while the number of smear-positive cases has remained fairly stable at around 330 cases per year. This may reflect an improved quality of diagnosis with a higher focus on smear-microscopy and a more careful consideration for smear-negative TB.

[6] SEA Region: WHO South-East Asia Region, which comprises the following countries: Bangladesh, Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste.

Figure 1: ***Trends in TB notifications (1980-2005)***



The distribution does not seem to be seems not uniform in the country. Table 2 shows the notification rates for the southern, northern and capital *dzongkhags*. The southern *dzongkhags* form the *terai* belt, a relatively plain land with a much higher population density and likely higher transmission. The capital *dzongkhag* Thimphu registers over a third of all cases. This should not be surprising as Thimphu *dzongkhag* also has the highest population of all *dzongkhags* and its referral centres (JDWNRH and Gidakom hospital) recruit patients from all over the country, particularly from the surrounding *dzongkhags*.

The age and sex breakdown for new smear-positive cases registered in 2005 is illustrated in Figure 2. Out of a total of 312 cases, 182 or 58% were male patients. The observed gender difference (female/male ratio 0.8/1) has not been investigated. It is, however, more balanced than in other countries in the Region (Nepal 0.5/1; India 0.4/1; Bangladesh 0.4/1; overall SEA Region 0.5/1). Research undertaken in different countries in the Region suggests that this observed gender difference is real and not due to any lesser accessibility of women to health services.

Table 2: *TB notifications and notification rates (2005)*

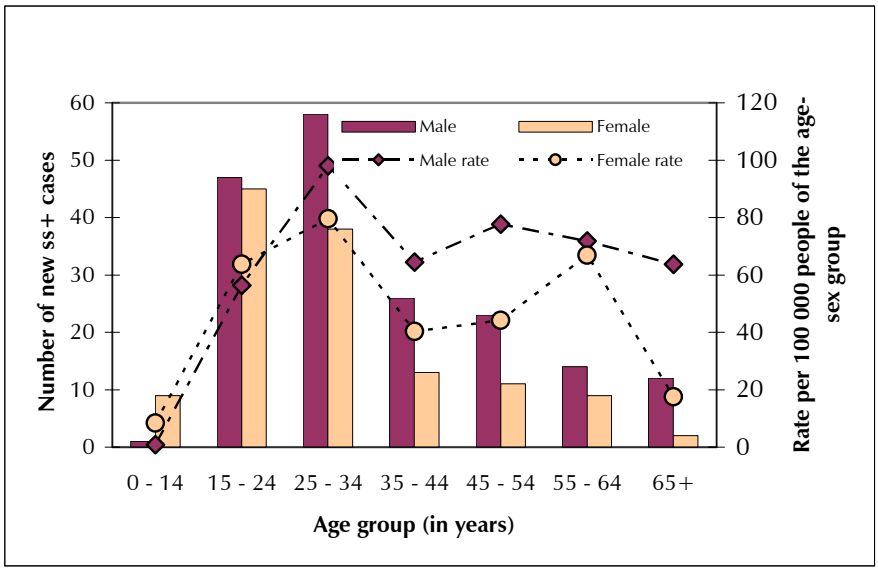
Area	New sm+ cases		All new and relapse cases	
	Number	Rate per 100 000	Number	Rate per 100 000
Northern *dzongkhags* *	45	28	80	49
Southern *dzongkhags* #	187	50	538	144
Thimphu *dzongkhag*	80	81	353	358
Total country ^	**312**	**46**	**971**	**144**

* Haa, Paro, Punakha, Gasa, Wangduephodrang, Trongsa, Bumthang, Lhuentse and Trashiyangtse.

\# Samtse, Chhukha, Dagana, Tsirang, Sarpang, Zhemgang, Mongar, Pemagatshel, Trashigang and Samdrub Jongkhar.

^ Rates calculated on total population, including floating population (not included in the *dzongkhag* figures).

Figure 2: ***Age- and sex-specific notification and notification rate, new ss+ cases (2005)***



With regard to age distribution, the highest number of female patients was reported in the 15–24-year age group while the highest TB rate in women is observed in the 25–34-year age group. For men, the absolute number and rate is highest in the 25–34-year age group. The total numbers of patients in the age groups above the peak show a steady decline for both men and women. However, a second peak can be observed for men in the 45–54-year age group and is even more pronounced in the 55–64-year age group in women. There were 10 times more girls diagnosed with smear-positive tuberculosis than boys, while there were as many male as female patients among adolescents (age group of 15–24 years). These two age groups also show a significant higher rate of tuberculosis among women. Analysing the age-specific data over the last five years, no real trend towards older people (TB in an ageing population) or young adults (possible co-infection with HIV) can be identified.

3.4 Case detection

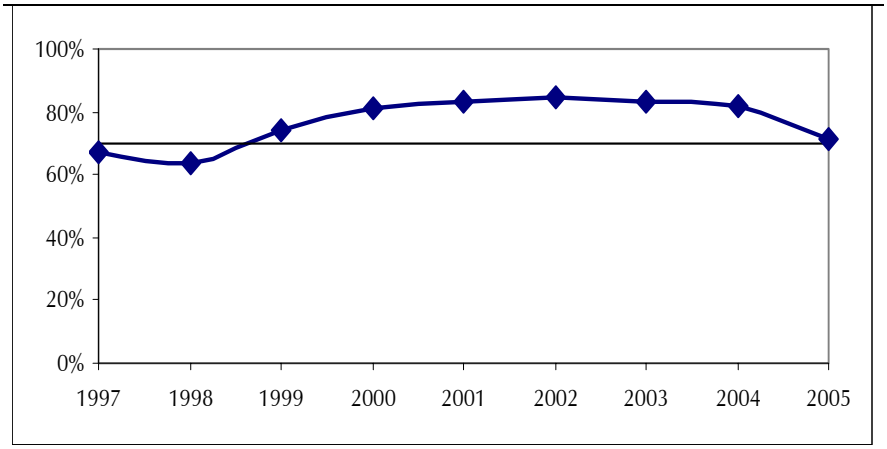
The case-detection rate, defined as the fraction of smear-positive cases detected over a one-year period out of all new smear-positive incident cases estimated to occur in the same period, is ambiguous due to the huge discrepancy in population figures adopted by the United Nations Population Division and the census report. As the census figures are closest to the real situation, case-detection rates are analysed in this report using these data.

The last (and only) ARTI survey, conducted in 1991, showed a 1.5% risk of being infected. Using the Styblo conversion factor, this translates into a smear-positivity rate of 75/100 000. Due to the lack of a better estimate of the current ARTI, a conservative assumption is made for a reduction in ARTI with one per cent per year. Population figures have been determined through back-calculation from the 2005 census, based on the assumption of a 1.3% annual population growth. The case-detection rate under DOTS has evolved as shown in Figure 3.

Based on the assumptions and data described above, the case-detection rate went up in the early years of DOTS implementation and decreased significantly in the last year. This may be due to mopping up of prevalent cases, a faster reduction in incidence than projected or to a

reduced performance of the programme, particularly with regard to identifying, registering and reporting smear-positive cases. Case-detection figures have remained above the global target of 70% since 1999.

Figure 3: ***DOTS case-detection rate***
New smear-positive cases (1997-2005)



The case-detection rate is one of the global targets and, despite the uncertainty of the estimate, can be a useful national indicator. It is, however, not appropriate to calculate case-detection rates at sub-national levels by simply applying the national estimate, for reasons of non-uniform distribution in TB incidence in different regions of the country. Differences in notification rates between *dzongkhags* may reflect excess inclusion of patients from neighbouring areas, different notification, case detection and/or underlying incidence.

In most cases, the main focus at the sub-national level should be directed at treatment outcomes and other measures of performance such as laboratory quality. Case-detection efforts can be monitored by studying trends in the number of notified cases, trends in the number of TB suspects and in the proportion of TB cases among TB suspects. Some caution, though, should be exercised while interpreting small numbers.

3.5 TB/HIV and MDR-TB

According to UNAIDS, the estimated HIV prevalence is less than 500 or < 0.1%. The estimated prevalence of HIV in adult TB patients (15-49 years) is also < 0.1%. On an average 250 TB patients are screened for TB during an annual sentinel survey. Only nine HIV-positive TB patients have been identified.

MDR-TB includes drug resistance to at least isoniazid and rifampicin. Anti-tuberculosis drug resistance has not been evaluated systematically. Patients are being treated with second-line drugs based on clinical, radiological and microscopy findings only. The MDR-TB rate is estimated to be 1.8% for new cases and 15% for retreatment cases, according to the WHO annual TB profile.

3.6 Recommendations

The following recommendations were made:

- Data obtained from the 2005 Population and Housing Census should be used as basis for determining estimates and rates;
- The planned ARTI survey should be conducted, including the obtaining of necessary technical assistance and sufficient funding.

4. Goals and objectives of NTCP

4.1 Goals of the National Tuberculosis Control Programme

The overall goal of NTCP are three-fold: (i) To reduce the morbidity and mortality of tuberculosis; (ii) to reduce the transmission of TB infection until it is no longer a public health problem; and (iii) to prevent the development of drug resistance.

4.2 Objectives of the National Tuberculosis Control Programme

The NTCP objectives are in line with the World Health Assembly targets (2005) and the Stop TB Partnership targets linked to the Millennium Development Goals (2015). They include:

- To detect at least 70% of the estimated new smear-positive cases;
- To cure at least 85% of the diagnosed new smear-positive cases;
- By 2015 to have halted and begun to reverse the TB incidence and
- To halve the prevalence and death rate of TB between 1990 and 2015.

More specifically, NTCP has formulated the following objectives and sub-objectives for the period 2005-2010:

- To increase the case-detection rate from 71% to 80%, through:
  - intensifying advocacy on TB disease, and
  - conducting training sessions targeting relevant staff.
- To increase the cure rate among new smear-positive detected cases above 85%, through:
  - developing policy and operational guidelines and training modules for improving diagnosis, and
  - conducting in-service training courses for improving case holding.
- To improve the quality of TB diagnosis and monitor and contain MDR-TB, through:
  - strengthening the laboratory capacity to carry out quality assurance, culture and DST, and
  - strengthening the quality of smear microscopy.
- To improve monitoring and evaluation of the programme, through:
  - improving the programme management and monitoring and evaluating the programme at national and dzongkhag level, and
  - reviewing the programme status at dzongkhag and community level.

4.3 Strategies of the National Tuberculosis Control Programme

The NTCP has adopted the DOTS strategy for implementation of TB control services. This strategy has been recommended by WHO and major partners since 1993. It has five components: (1) sustained political

commitment; (2) diagnosis based on quality-assured microscopy; (3) uninterrupted supply of drugs and logistics; (4) use of standardized regimens, including direct observation of treatment (DOT), and (5) standardized recording and reporting to monitor case detection and treatment outcome.

In addition, the strategy includes management of MDR-TB, including DST, and HIV sentinel testing in all TB patients during three months in a year. The strategy is being implemented through all health-care providers in the country. All TB patients are provided free diagnosis and treatment. The country's strategy is thus in line with the Regional Strategic Plan for TB Control (2006-2015) and the Stop TB Partnership's Global Plan to Stop TB (2006-2015). The review team leader briefed the Secretary on these two strategic documents.

The implementation of the different components of the strategy is ensured through the following mechanisms:

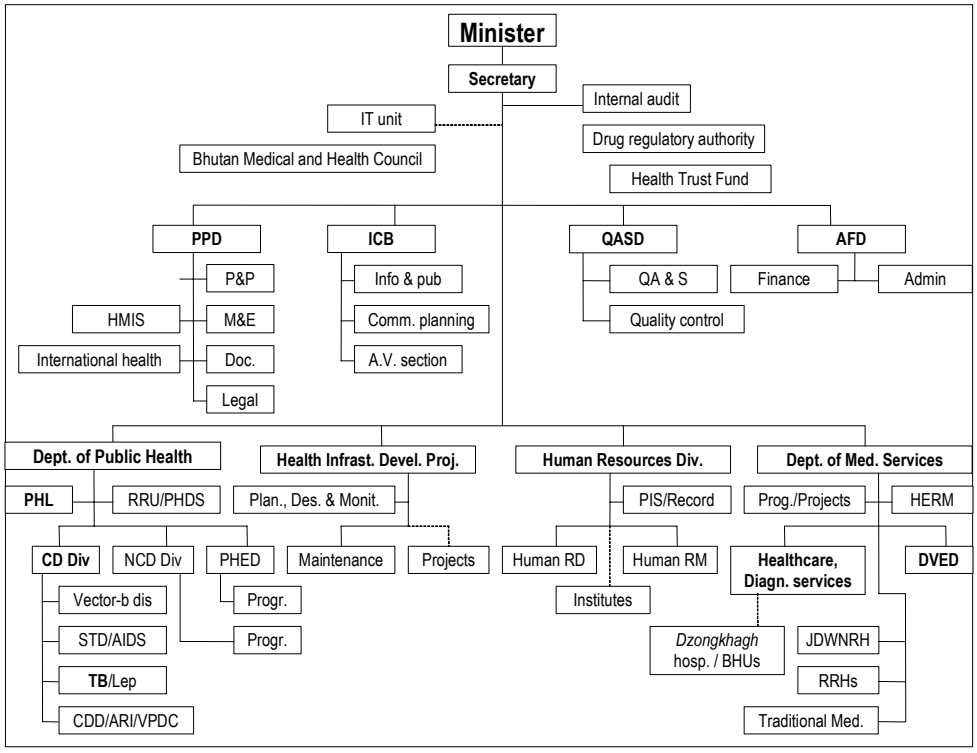
- Political commitment: Mobilization of adequate domestic and donor funds, provision of staffing, provision of drugs (including second-line drugs) and supplies, free-of-charge treatment for all patients;
- Quality-assured sputum smear microscopy: Priority is given to the diagnosis of infectious TB cases. Smear-negative and extra-pulmonary cases are given treatment after proper diagnosis by doctors. Laboratory services are provided through all hospitals, all grade-I BHUs and some grade-II BHUs (as part of an operational research activity). Some form of quality assurance is being done;
- Uninterrupted supply of drugs and logistics: Centralized procurement of all drugs, equipment, laboratory consumables and stationeries with annual distribution and six-monthly reporting; emergency supplies can be indented anytime;
- DOT: Hospitalization of all Category 1 and 2 cases during the intensive phase;
- Standardized recording and reporting system: All TB patients are recorded in the TB register, which is kept at the dzongkhag level; the standard internationally-recommended reports are generated on a quarterly basis and submitted to the central TB unit.

5. Structure of the national tuberculosis control programme

5.1 Findings

The NTCP falls within the Communicable Disease Division of the Department of Public Health of MoH. The MoH organogram is given in Figure 4.

Figure 4: ***Organogram of the Ministry of Health***



The NTCP has a part-time programme manager and two programme officers posted in the central unit. The responsibilities of the central level include:

- Policy formulation;
- Coordination with partners and donor agencies;
- Planning and budgeting;
- Human resources development for TB;
- Coordinating activities for improving the technical capacity of TB-related laboratory activities;
- Coordinating with DVED for the procurement and supply of TB drugs and other supplies;
- Coordinating implementation of TB control activities with other programmes and with dzongkhag health offices;
- Coordinating operational research for TB, and
- Monitoring and supervision of NTCP activities at all levels and reporting to MoH and related agencies.

The basic unit for diagnosis and initiation of anti-TB treatment is the hospital[7]. There are 29 hospitals in the country or at least one per *dzongkhag*. These 29 facilities have laboratories for sputum smear microscopy as well as X-ray facilities and have medical officers and laboratory technicians among their staff. Diagnosis and initiation of treatment as well as registration and quarterly reporting is done. Hospital admission is the norm for all patients receiving Category 1 and 2 regimens. The programme implementation at the *dzongkhag* or hospital level is overseen by the District Health Supervisory Officer (DHSO) and managed by the District Medical Officer (DMO)/superintendent/medical officer and TB in-charge. They also conduct outreach activities to BHUs.

The BHUs have a more limited role in TB control. They are staffed by medical assistants, general or auxiliary nurse midwives and basic health workers. They identify TB suspects, refer them for diagnosis and provide treatment during the continuation phase. They submit monthly reports, including TB, to the DHSO. The BHU-based staff conduct between one to five ORCs per month. The ORCs constitute the most peripheral health services. VHWs, selected from the community and engaged on a long-term voluntary basis, provide the link between the formal health services and the community since they attend the monthly ORCs.

[7] The term "hospital" used here and further in this report also includes grade-I BHU.

5.2 Recommendations

The review team formulated the following recommendations:

- The NTCP at the central level should be reinforced, either by assignment of a full-time programme manager or by assignment of an additional staff member;
- Individual staff at the central level unit should be made responsible for the coordination of the various sub-programmes, such as procurement, training, monitoring, laboratory, community involvement, etc;
- A full-time TB coordinator should be assigned for each region. They can be seconded from among the few TB/leprosy officers. In their own districts, another staff can be nominated TB in-charge, as in all other districts.

6. Financial resources

6.1 Findings

The NTCP directly obtains funding from the Government, WHO and GFATM through a Round-4 grant. The Government bears the costs for salaries of all staff, health-care facilities, admission of TB patients, drugs and laboratory consumables, and some other operational costs.

The estimated government contributions for first-line anti-TB drugs and laboratory consumables for the period 2005-2009 are provided in Table 3. No data could be obtained on the budget or expenditures for salaries, health-care facilities, admission of patients and second-line drugs. The RGoB contribution is thus substantially underestimated.

WHO's contribution has a ceiling of US$ 5000 under the tuberculosis workplan during the current biennium (2006-2007) plus US$ 10 000 earmarked for TB-related multi-country activities. The TB budget provided through WHO is mainly to cover for training and meeting expenses.

Table 3: *RGoB contributions to the TB programme, 2005-2009 (Amounts in US$)*

Item	2005-06	2006-07	2007-08	2008-09	2009-10	Total
Anti-TB drugs	30 196	34 122	38 557	43 570	49 234	195 679
Laboratory consumables	12 713	13 136	13 614	14 085	14 614	68 162
Total	**42 909**	**47 258**	**52 171**	**57 655**	**63 848**	**263 841**

The GFATM grant for the first two years (first phase, April 2005-March 2007) includes funding of activities related to the four major NTCP objectives as shown in Table 4.

Table 4: *Activities supported by GFATM (first phase)*

Objective and main activities	1st year	2nd year
To increase the case-detection rate to 80%		
• Activities to intensify advocacy	√	√
• Activities to increase social mobilization		√
To increase the cure rate among detected cases to 85%		
• Preparation of training modules	√	
• Conducting training courses for medical and paramedical staff and village health workers		√
• Assessing sputum conversion in districts with decentralized TB services		√
To improve the quality of TB diagnosis and monitor and contain MDR-TB		
• Activities to strengthen laboratory capacity	√	√
• Training for strengthening sputum smear microscopy		√
To improve monitoring and evaluation		
• District and regional review meetings	√	√
• External programme review	√	
• Computerization of national data	√	
• Audio-visual aids	√	
• Supervision	√	√

The total GFATM proposal amounts to US$ 994 298 over five years. Phase 1 has been approved for US$ 560 568, of which US$ 322 453 is allocated for the first year and US$ 238 115 for the second year. The second phase will be approved subject to the performance during the first 16-18 months and availability of funds with GFATM, as per GFATM rules. At the time of the review US$ 503 954 had been disbursed, being the grant for the first year and part for the second year. The first and second disbursements for the first year cumulatively amounted to US$ 307 738. Until March 2006, expenditures incurred amounted to approximately US$ 170 000, which translates into a financial implementation rate of 71%. The financial implementation will need to be enhanced in order to obtain the maximum ceiling during the second phase. Substantial savings are already identified, especially in the printing budgets.

6.2 Recommendations

The following were the key recommendations:

- Urgently negotiate with the GFATM Fund Portfolio Manager a reprogramming of balance funds from the first-year GFATM grant in favour of underfunded but priority activities (supervision, training and advocacy, communication and social mobilization or ACSM);
- Prepare a fine-tuned budgeted activity plan for the first year of the second phase of the GFATM grant and realistic cost-based activity plans for the second and third year of the second phase. Special focus should be on human resource development (including training and supervision).
- Identify needs for technical assistance; include technical assistance in proposals to funding agencies where relevant.

7. Diagnostic and laboratory services

7.1 Diagnostic protocol

Suspect pulmonary TB patients are identified among those presenting with relevant signs and symptoms at the hospital OPDs or in BHUs. The BHUs

refer these patients to the hospital, through the hospital OPD, for sputum examination. BHUs do not keep a record of patients referred for smear microscopy. All OPD staff of the hospitals select suspect patients and send them to the hospital laboratory for smear microscopy. All staff interviewed in the various health facilities could list the signs/symptoms of patients suspect of pulmonary TB. Persistent cough for three or more weeks was generally mentioned as the most important symptom. The sputum examination request form is filled by the laboratory staff and sputum containers are marked properly for identification.

The hospitals visited reported between 100-200 out-patients per day; the average number of TB suspects identified amongst these out-patients was between seven and 23 per month during the last 6-12 months. One regional referral hospital, with 100-120 out-patients per day, identified on average 50 TB suspects per month. This hospital diagnosed 68 pulmonary TB patients during 2005 as compared to less than 15 at the other hospitals. This observation suggests that there is need to increase awareness amongst the OPD staff for signs and symptoms suspect of pulmonary TB.

Three sputum samples are generally collected for diagnosis: spot, morning, spot. Patients who live far from the hospital can be admitted while the investigations take place.

It was reported that in some areas additional and sometimes unnecessary diagnostic tests (including X-ray and different blood examinations) are conducted. While X-ray has a role in assessing complicated cases or in diagnosing smear-negative disease, it need not be routinely performed in smear-positive cases. The additional tests were sometimes justified in ruling out other conditions while awaiting the AFB results. Laboratory results, however, were usually available on the same day. In the Tala Hydroelectric Project Authority (THPA) Hospital many diagnoses of TB are based on X-ray alone.

7.2 Laboratory services

There are 29 hospital laboratories in the country with operational AFB services. A laboratory is usually staffed by 2-4 multipurpose personnel. In a few centres visited, AFB microscopy is allocated to one laboratory staff only. Supplementary laboratories are being made operational in selected grade-II BHUs. One laboratory on an average caters to a population of

approximately 24 000 in area of 1500 sq. km or within a radius of less than 25 km. This means that the number of laboratories is already far above the recommended one laboratory per 100 000 population (or one laboratory for every 50 000 people in remote areas).

Factors to consider for reliable laboratory services include workload and proficiency along with accessibility and infrastructure. During the last five years, the positivity rate (i.e. the number of positive slides among all slides examined) in the Public Health Laboratory varied between 5.5% and 7.2%, with an average of 6.6%. Box 1 projects a model for estimating the workload for the country as a whole based on identifying 60 smear-positive cases per 100 000 population. Ten slides per day constitute 40% of a daily workload but are considered sufficient to maintain the required levels of skill. The maximum workload should not exceed 25-30 slides per day per person, or about 8000 per year. An absolute minimum of 500 slides per year needs to be processed by each laboratory technician to maintain a minimal standard of quality and routine. About 6300 slides were prepared in Bhutan in 2005 – much less than the expected maximum of 21 000 – of which 1400 were done at the Public Health Laboratory. The current workload therefore would justify not more than 10 laboratories in the country. Based on those technical facts, the review team expressed strong reservations for further decentralization of microscopy services.

***Box 1**: Model for estimating workload in AFB laboratories*

Positivity rate: 6.6%
Number of smears examined for diagnosis: 3
Number of smears examined for each follow-up: 2
Total number of smears examined for each diagnosed smear-positive patient: (3/0.066 + 6) or 52
Number of smear-positive patients expected to be diagnosed: 60 per 100 000 or 403 for the entire country
Total country workload (maximum): 52 * 403 or 21 000
Average workload for one AFB laboratory: 21 000/29 or 725 slides per year or 2-3 per working day

Smear preparation and even sputum collection is only practised in laboratory settings. Sputum is usually collected in open air, although it was reported that the same was also collected in a toilet. The latter practice

should be abandoned as it favours transmission. The team was not apprised of any distribution of sputum containers in BHUs, outreach clinics or even with VHWs. This could contribute much to earlier case detection and the saving of one or two days for confirming a diagnosis and minimize hospitalization while awaiting the results.

A "Training Module in Sputum Microscopy for Laboratory Technicians" as well as a "Standard Manual for Laboratory Technicians on Sputum Microscopy" were available. These guidelines follow international recommendations, with the exception of the omission of internal quality control. They are generally well respected. From the laboratory register though, it appeared that up to 20%-50% of the suspects had less than three smear results reported. Follow-up smears were collected at appropriate intervals. In several instances, three smears were collected for each follow-up. The national guidelines do not specify how many samples need to be examined while the laboratory register provides room for two results for each follow-up. There was also no uniformity in entering test results in the laboratory register, with follow-up results either recorded next to the diagnostic (first) results or on a new line according to the date. The latter option is the preferred one and is practised in all other countries. Red marker pens were also not being systematically used to indicate positive results.

Binocular microscopes are used in all laboratories. The microscopes seen were recently procured and kept in good condition. In one laboratory a "malaria microscope" with 60x objectives had been used, leading to several false-negative slides. Standard operating procedures could not always be provided but the new Standard Manual contains all information. Solutions, normally in quantities of 500 ml, are usually prepared in the laboratory. In some cases, they were provided from the Public Health Laboratory and also bought ready made from India. Solutions for use are often stored in a plastic bottle with a nozzle spout. Although the bottles were not properly labelled stating content, concentration or date of first use and expiry, they contained no visible crystals and looked appropriate. The standard recording forms are used, provided by NTCP. One hospital had even printed its own forms.

Laboratory technicians were properly trained and displayed good knowledge and understanding. In-service training seemed to be done irregularly due to lack of planning. The supervision also was erratic.

The laboratory infrastructure was not uniform. In some cases, the rooms are too small. They are sometimes also poorly ventilated, leading to real and present risk for staff. The work benches were sometimes found to be disorganized and furniture not appropriate for laboratories where infectious materials are handled. Leg space was insufficient in several instances and damage to the chair covers (covers not always suited for or resistant to disinfectants) resulted in protrusion of foam rubber. Floors were sometimes in wood. Staff were also seen to consume food inside the laboratory premises, a practice not acceptable for an infectious zone.

Smearing was generally of good quality though a little inhomogeneous due to using a loop. Filtration of stains was mostly practised for each smear. In some laboratories the solutions were filtered once a week. The quality of staining was generally good.

Judging from the laboratory registers, the quality of examinations was on an average good, as suggested by the high consistency between the two or three results from cases and the proportion of high grading in positives.

Transmission of results was quite good as shown by the rarity of patients not registered for treatment. Patients residing in India but diagnosed in Bhutan are not registered for treatment.

7.3 Quality assurance

Quality assurance has three main components: (1) Internal quality control; (2) external quality assessment (EQA) and (3) quality improvement.

Internal quality control is said to be practised in most centres visited. Only the check with one positive and one negative slide for inspection of newly prepared solutions is reported. BCG vaccines were even used as positive controls in one centre. There is no further inspection for older staining solutions. Internal quality control per working day is missing.

Countrywide EQA for smear microscopy is organized by the Public Health Laboratory. Panel tests are sent to all laboratories performing AFB microscopy. Until the end of 2004, these panels consisted of 25 stained slides and were sent out quarterly. Since 2005, the number of stained slides was reduced to 10 and sent out twice a year. The results were “strange” for scanty slides due to the facts that slides were prepared as direct smears

without any prior homogenization. This method is highly sensitive to inhomogeneities in the specimens used. The preparation of good quality panels is very labour-intensive and does not yield the desired results since it does not measure routine performance. It is a good method though to discover major trouble spots. Feedback is provided through a "Quality Assurance Report on Sputum Microscopy" with laboratory scoring and overall agreement in examination of the 10 slides.

Since 2005, all slides from every laboratory are sent on a quarterly basis and rechecked at the Public Health Laboratory. Although there should not be a selection bias, it could not be confirmed if 100% of the slides were sent. In fact, some laboratories did not send slides at all. It was not clear if the peripheral test results were also provided. The Lot Quality Assurance Sampling (LQAS) method, although known, has not been used to select slides for rechecking. Rechecking was done in a blinded way. No restaining was done, even not for the false-negative slides. Table 4 shows the EQA results during the last round of blinded rechecking, covering a six-month period.

Table 4: *EQA Results (blinded rechecking and panel testing)*

Results of peripheral laboratories	No. of slides	% discordant results
Blinded rechecking		
positive	141	6.4%
negative	1 262	0.2%
Panel testing		
positive	162	0.6%
negative	108	37.0%*

* High discordant figure likely due to supposed scanty slides, which were in reality negative because of inhomogeneities in the specimen.

Feedback on discordant results has not always been communicated to laboratory staff concerned, although the Public Health Laboratory did send reports to all laboratories. Corrective actions were not systematically taken. Quarterly reporting on EQA to NTCP is not yet established.

On-site supervision, the third EQA component, had not been done in 2005.

7.4 National Reference Laboratory

The Public Health Laboratory, currently located in the premises of JDWNRH, is the National Reference Laboratory. While it has no formal link with one of the certified supranational reference laboratories for tuberculosis, it has been engaging at the international level with laboratories in India, Thailand and Australia as well as with the SAARC[8] TB Centre in Kathmandu, Nepal. The Public Health Laboratory performs tests to diagnose HIV and tuberculosis. Additionally, food and water is analysed. The Public Health Laboratory functions administratively under the Department of Public Health.

The Public Health Laboratory is headed by a microbiologist and has three staff involved in TB laboratory activities.

The infrastructure of the Public Health Laboratory is not adequate for TB diagnostic services. All tests, including media preparation, are performed in one room, which is definitely too small. The current set-up is in many aspects not suited to perform the work to be done in terms of workload, space equipment and bio-safety. There is one old bio-safety cabinet, about 1.5 m broad, which got a change of filters in November 2004. A hole had been drilled in to its left side as an inlet for the gas tube. The Bunsen burner was continually operational with a huge flame. The bio-safety cabinet had no air duct out. The influx of air seemed minimal. It was apparent that there had been no proper installation, introduction and hand-over. The capacity of the two incubators (Memmert™) is sufficient for the present workload.

A binocular microscope (Olympus CH20i™) is used. Earlier, fluorescence microscopy was also performed. The fluorescence microscope was found to be non-functional. More than 10 kg of Auramine O stain is still available, though.

The Public Health Laboratory activities consist of case detection for JDWNRH, providing training for students from the Royal Institute of Health Sciences (RIHS) as well as in-service training on a periodic basis (except for BHU staff who are trained in the regional referral or *dzongkhag* hospital).

[8] SAARC: South Asian Association for Regional Cooperation, that groups seven countries: Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka

From October 2005 till January 2006, 643 TB suspects were examined, of which 519 (81%) had three sputa examined, 64 (10%) two sputa and 60 (9%) only one sputum. The laboratory also organises the quality assurance for AFB microscopy as described above (panel testing and rechecking). Rechecking of 100% of the peripheral slides is very labour-intensive and not cost-effective at all.

Cultures are performed only in this laboratory. These use Löwenstein-Jensen medium with glycerol and a modified Petroff method for liquefying and decontaminating the sputum specimens. In 2005, 757 cultures had been performed for diagnosis with a decontamination rate below the 5% international standard. The number of positive cultures was reported to be 58. The NTCP policy on culture was to follow the purpose of routine diagnosis, special diagnostic needs and for DST. The Public Health Laboratory has only partial DST facilities. In 2005, 19 isolates were tested and 8 resistant results were reported. There was no quality-assurance system implemented for culture or for DST.

A new TB laboratory for culture, identification and DST is planned. The construction should be completed within 18 months. The plan was discussed with the head of the Public Health Laboratory and recommendations were formulated to improve this to allow a more efficient work flow.

7.5 Recommendations

The following were among the key recommendations made regarding the TB laboratory activities:

- The number of laboratories should not be further increased. The current initiative of expanding laboratory services should be considered as an operation research activity. Extension should be conditional, subject to overall positive evaluation.
- Accessibility to laboratory services should be further increased by making sputum containers available at the BHU or community level.

- Conducting additional tests, including X-ray, when diagnosis can be established through sputum examination and when no complication is present, should be discouraged.
- Strict adherence to infection control measures in the laboratory should be ensured; some laboratories should be refurbished taking into consideration infection control requirements; sputum should always be collected in open air.
- The Public Health Laboratory should be formally linked to a supranational TB reference laboratory.
- Stringent quality assurance in all laboratories including internal quality control, external quality assessment and quality improvement should be introduced or further improved.
- Routine quarterly or six-monthly panel testing should be discouraged. If panel testing is done, slides should be prepared from homogenised positive specimens with serial dilutions into negative homogenised sputum.
- Capacity should be built for quality-controlled culture services.
- An algorithm for selecting patients for whom cultures are needed (e.g. treatment failures) should be developed.
- Capacity for quality-controlled DST should be built; during the interim period, samples could be sent abroad for DST.
- The plan for the new Public Health Laboratory should be adjusted in order to obtain a more efficient work flow.

8. Treatment services

8.1 Treatment regimens and indications

Short-course chemotherapy was introduced in 1988. Through DOTS implementation, treatment regimens and indications have been standardized. The currently used treatment regimens last for eight months with only the intensive phase containing rifampicin. Table 6 gives an overview of the different treatment regimens and their indications.

Table 6: *Treatment regimens and indication*

Category	Regimen [9]	Indication
1	2 (3) SHRZ / 6 EH	New smear-positive New smear-negative and extra-pulmonary, seriously ill
2	2 SEHRZ / 1(2) EHRZ / 5 EHR	Relapse Treatment after failure of Category 1 Treatment after interruption Smear-negative and extra-pulmonary retreatment forms
3	2 HRZ / 6 EH	New smear-negative and extra-pulmonary, not seriously ill

While Table 6 provides the main regimens, some modifications on these regimens do occur, either in special situations and clarified in the NTCP guidelines or in defiance of the national guidelines. The modifications, as per the NTCP manual, include a continuation phase with rifampicin throughout (HR) for paediatric cases as well as all cases with TB meningitis; the substitution of streptomycin by ethambutol for pregnant women; the substitution of ethambutol by rifampicin and streptomycin by ethambutol during the intensive phase and an extended continuation phase (seven months) with HR for TB/HIV co-infected patients.

While some of those modifications are appropriate, the rationale of others is not always clear. This multitude of regimens poses also an additional burden on peripheral health staff and on drug management.

Tuberculosis treatment is initiated by medical officers in hospitals. All category 1 patients are admitted in hospital as long as streptomycin is required, i.e. two months. The category 3 regimen does not seem to be very popular as up to 40% of smear-negative and extra-pulmonary cases are treated with category 1, while not more than 10% of those cases are expected to be "seriously ill". Although category 3 is a valid and efficacious regimen, category 1 is probably safer in view of potential primary drug resistance and false-negative sputum test results. All retreatment cases receive category 2, including smear-negative or extra-pulmonary retreatment cases. The latter patient categories appear to be more

[9] First-line TB drugs: streptomycin (S), isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E)

numerous than the expected "rare" cases and may point towards a tendency of overdiagnosing those difficult cases.

The proportion of retreatment cases is fairly low, around 5%. Within the group of retreatment cases, relapses dominate. In view of the good treatment results in the past years and the absence of a private sector, the number of non-relapse retreatments is expected to be low. The number of relapses may be exaggerated with inclusion of smear-negative or extra-pulmonary retreatments. These should be classified as "other". Taking an accurate history though remains of utmost importance in TB control.

8.2 Directly-observed treatment

Hospitalization for directly-observed treatment (DOT) – one component of the DOTS strategy – is the general policy of NTCP, at least for the intensive phase of category 1 and 2. The current streptomycin-containing regimen also supports this policy. Hospitalization has the advantage of providing a chance to detect side-effects early, guaranteed rest and improved diet. It also offers a straightforward option for implementing the DOT component, particularly for patients living in remote areas.

A small number of patients, i.e. those living close to a hospital or BHU and wish to be treated as out-patient, are treated ambulatory. These patients attend the health facility daily for the streptomycin injection. They, however, swallow the other drugs unsupervised at home.

The review team also concluded from interviews with different patients that hospitalization does not ensure observation of drug intake. In several cases, the drugs are collected by patients during the nurse's round of the wards but no one monitors the actual intake of the same.

Since the proportion of smear-negative and extra-pulmonary cases receiving category 1 is fairly high, these patients impose a heavy burden on hospital beds. Some of them though, particularly those living in the vicinity of the hospital or a BHU, are reported to be released from hospital after a few weeks of treatment and continue ambulatory treatment.

Other options for strengthening DOT have not been explored sufficiently. The provision of DOT on an ambulatory basis in hospital OPDs, TB units, BHUs or through community involvement has not been made. Preliminary results from an operational research study conducted by a researcher from RIHS indicate that there are considerable delays in case

detection, particularly from the patient side. The policy of compulsory hospitalization may work as a deterrent for TB patients seeking medical advice.

8.3 Treatment follow-up

After the initial two months of treatment, and if the smears have become negative, patients are referred to the OPD or BHU for continuation of the treatment. Upon discharge from hospital, the patient is provided with anti-TB drugs for one month, after which they are expected to present themselves at the nearest BHU. During the rest of the continuation phase, the patient attends the health service fortnightly or monthly and is referred to the hospital for sputum follow-up examination after a period of five months and at the end of treatment. The five-month follow-up is, however, often ignored. There were also instances where relatives of patients collected drugs without justifiable reason.

The referral/transfer procedure seems complex at first sight, particularly if a patient is referred directly from a referral hospital to the BHU bypassing the *dzongkhag* hospital. However, the forms linked with this are well designed and adhered to.

The treatment card is retained in the hospital while no specific treatment card is used at the BHU. The treatment often continues beyond the 180-day continuation phase. Treatment cards are quite well maintained, but there is room for improving accuracy (e.g. eliminating the ticking-off of non-existent days such as 30 February or 31 April). Side-effects or actions taken during interruptions are also not mentioned in the "remarks" area.

The continuation phase in category 2 appears to be monitored on a fortnightly or monthly basis only with no DOT routinely provided although rifampicin is provided.

Irregular patients are traced after three to ten days of absence from their expected visit. Not all patients can be traced though, due to reasons such as incorrect address, shifting to other *dzongkhags* or their living too far away from the health facility. There is no system of verification of address at the time of diagnosis or during hospitalization. Other means of tracing a patient such as by telephone are rarely used. As most patients can be retrieved within less than two weeks, there is rarely a need to extend or restart the treatment or collect additional sputa.

The treatment result is determined by the medical officer in the hospital mainly on the basis of sputum examination (for smear-positive patients) and clinical or radiological findings.

8.4 Treatment results

The Bhutan NTCP is characterised by commendable treatment results. The treatment success has been consistently high since DOTS was introduced. Most smear-positive patients are cured, i.e. the final sputum has been collected and examined.

Tables 7 and 8 show the treatment results of the smear-positive and smear-negative and extra-pulmonary patients registered in 2004, respectively.

Table 7: *Treatment results of new and retreatment pulmonary smear-positive cases (2004 cohort)*

Patient type	Total registered	Cured	Com-pleted	Died	Failed	Default	Transfer out
New smear-positive	375	294 78%	19 5%	17 5%	14 4%	5 1%	0
Retreatment smear-positive	45	32 71%	5 11%	1 2%	4 9%	0	3 7%

Table 8: *Treatment results of pulmonary smear-negative and extra-pulmonary cases (2004 cohort)*

Patient type	Total registered	Com-pleted	Died	Failed	Default	Transfer out
New smear-negative	246	201 82%	10 4%	1 0%	7 3%	27 11%
Extra-pulmonary	351	285 81%	8 2%	2 1%	7 2%	46 13%

The treatment success rate in new smear-positive cases was 83% while it was 82% in retreatment cases. The completion rate for smear-negative and extra-pulmonary cases was 82% and 81% respectively. Not shown in the tables above, but of significant importance for the new smear-positive cases

in particular is the number of patients not evaluated: 26 new smear-positive cases (or 7%) and 3 extra-pulmonary cases. Not only do these bring down the cure and success rates but they also reflect poorly maintained records.

There were no major differences between the northern and southern *dzongkhags*. In Thimphu *dzongkhag*, however, the confirmation of cure could not be demonstrated in 10% of patients who completed the treatment. The treatment results were significantly lower in the central part of the country. Table 9 highlights the regional differences. There was a high variation between individual *dzongkhags*, often due to the evaluation of small numbers. Only one hospital (Gelephu Regional Referral Hospital) had cure (52%) and completion rates (55%) that could be considered real outliers.

Table 9: *Regional treatment results in new smear-positive patients (2004 cohort)*

	Total registered	Cured	Com-pleted	Died	Failed	Default	Transfer out
Thimphu *dzongkhag*	71	50 71%	7 10%	2 3%	3 4%	2 3%	6 9%
Western Region*	101	83 82%	8 8%	5 5%	1 1%	1 1%	2 2%
Central Region#	106	75 71%	2 2%	4 4%	9 8%	0	15 14%
Eastern Region^	98	86 88%	2 2%	6 6%	1 1%	1 1%	2 2%
Entire country	**376**	**294** **78%**	**19** **5%**	**17** **5%**	**14** **4%**	**4** **1%**	**25** **7%**

* Samtse, Haa, Paro and Chhukha.
\# Gasa, Punakha, Wangduephodrang, Trongsa, Bumthang, Dagana, Tsirang, Sarpang and Zhemgang.
^ Lhuentse, Trashiyangtse, Mongar, Pemagatshel, Trashigang and Samdrub Jongkhar.

The evolution of the treatment results over the last 10 years has not fluctuated much. It is illustrated in Figures 4 and 5 for treatment success and unfavourable outcomes, respectively. The success rate tends to decrease slightly, even dipping below the global target of 85% which had been achieved since the DOTS programme was introduced. The cure rate remains fairly stable, with most patients now confirmed as cured. As mentioned earlier, a big proportion of patients in the 2004 cohort has not been evaluated, which likely includes defaulters and transfer-out cases.

Figure 4: ***Treatment success (1995-2004)***

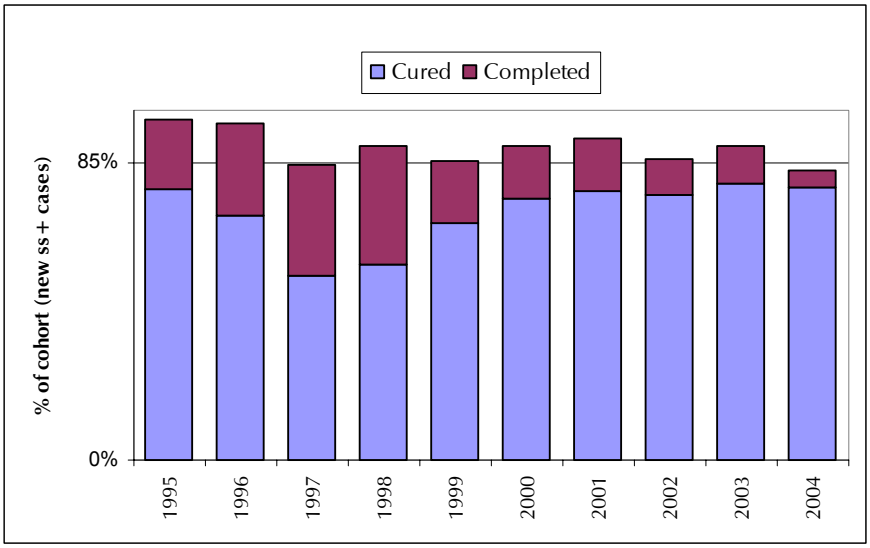
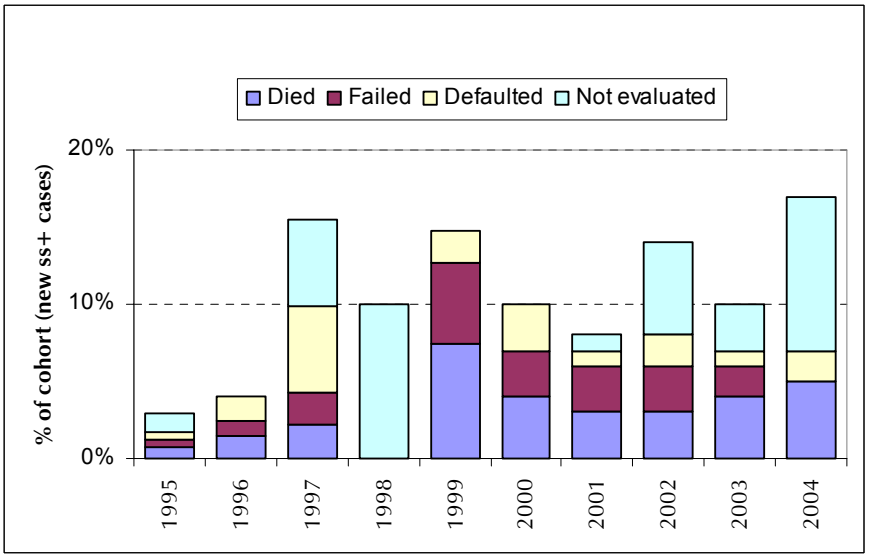


Figure 5: ***Unfavourable outcomes (1995-2004)***



8.5 Recommendations

The following recommendations were made:

- Only two treatment categories should be withheld, in line with more recent international recommendations: A fully oral category 1 regimen and category 2. This would allow introducing FDCs, which seem to produce less side-effects and improve drug management; and abolish the separate regimens for pregnant women, TB meningitis, TB/HIV and childhood TB. The proposed oral regimen would allow further decentralisation of treatment, ambulatory treatment and reduce the risk linked to daily injections (transmission of HIV and other infections, sores). It would be much cheaper too. The perceived less efficacy in terms of delayed sputum conversion is unreal after two months.
- The category 1 regimen should be changed to an entirely oral regimen: 2 (EHRZ) / 6 (EH) or 2 (EHRZ) / 4 (HR); drugs should be provided in FDCs.
- The category 3 regimen should be abolished; the proposed category 1 should be introduced for all new cases.
- Hospital admission criteria should be restricted to complicated cases, retreatment cases or patients living too far away; DOT should be strictly implemented within hospitals.
- Treatment and DOT should be further decentralized, also during the intensive phase, to BHUs and community level.
- The treatment cards (or duplicate of it) should be maintained at the health facility from where the patient is taking treatment.

9. Drugs and logistics

9.1 Drug procurement, storage and distribution

All drugs and laboratory consumables are procured by DVED under the Department of Medical Services.

Quantities of drugs and consumables are calculated based on consumption in the *dzongkhags*. The BHUs and hospitals submit twice a

year a consumption report with monthly breakdown through the *dzongkhag* health office to DVED. A 10% buffer stock for the *dzongkhags* and a 30% buffer stock for the central level are added to the estimated quantities.

There are no pharmaceutical companies in the country. In order to ensure quality of drugs the country relies on certification and guidance by WHO and has a list of reputable manufacturers. In case of new drugs samples are sent for quality testing to the Bureau of Drugs and Narcotics, Department of Medical Sciences, Ministry of Public Health, Bangkok, Thailand. If the quality fails the acceptable standards, no payment will be made and costs incurred will be deducted from the next order to the concerned company. The process of floating tenders for all listed manufacturers is taken up every year. The annual procurement cycle starts in the beginning of June and should be completed by the end of the year.

The Medical Supplies Depot (MSD), located in the border town of Phuentsholing, receives the supplies order from DVED. It is responsible for storage and distribution of the supplies to all hospitals and BHUs. Since 2006 the MoH has issued contracts for the transport of supplies to private firms. Supplies are transported to defined drop-off points (all hospitals and BHUs along motorable roads) from where they are collected for other health facilities. Drugs are supplied to health facilities only once a year. In case of anticipated shortages the hospital or BHU can request for additional supplies through DVED or alternatively drugs can also be redistributed internally within a *dzongkhag*.

The MSD consists of a main store and an additional store located in a rented private house. There are separate packing and delivery rooms. Five cars are available for transportation of supplies while bigger trucks are rented for delivery. The combined storage capacity appears to be inadequate. Some goods were piled in the open and covered against the rain with barely a plastic foil. The store is not air-conditioned and hence vaccines are not stored there. The annual TB drug supply for each health facility is repacked based on DVED quantification and dispatched to the health facilities within a month. The amount of TB drugs available was reasonable, except for a huge quantity of the second-line drug ethionamide (7000 tablets), which is very unlikely to be consumed before the expiry date.

The drug stores at the hospitals and BHUs were well organized. The first-expiry/first-out (FEFO) principle was reportedly adhered to. The stores maintained a register featuring amounts of drugs received, drugs distributed and balance left.

There were no stock-outs of drugs reported with very few exceptions. Shortage of sputum containers were reported at several facilities. Instead, sterilized penicillin bottles or streptomycin vials were used. This is potentially dangerous as it may spread infection through the handling of soiled containers. There were no reported shortages of laboratory supplies. The review team observed that in view of the decreasing notifications there might even be an oversupply with the accompanying risk of expiration of the drugs. The drug management becomes more difficult in smaller centres (including BHUs) with relatively higher fluctuations in case load. The team also calculated that to maintain a TB laboratory operational at the BHU level as per the planned decentralization a minimum of 80% of the reagents will unavoidably expire, another reason to reconsider this process.

9.2 Recommendations

The proposed new regimens with FDCs and ambulatory treatment will have repercussions on drug management and supply. It should finally lead to a simplified drug management. It is proposed to indent drugs only from places that diagnose and register the patients (i.e. hospitals) and provide supplies for those patients through introduction of "patient boxes" which can be locally assembled. All BHUs should be provided with a buffer stock of one treatment, to allow continuing the treatment after the patient reports back from hospital and while awaiting the patient box, which will substitute the buffer stock.

It was also recommended that:

- The NTCP should request WHO to provide a white list of FDC manufacturers;
- TB drugs (intensive and continuation phase) should be indented by hospitals only;
- A "patient box" containing all drugs for the entire treatment should be assembled when starting treatment and the balance of this box should be sent to the BHU or VHW that will provide DOT, and

- Wide-mouth sputum containers with screw cap should be provided in sufficient quantities to all health facilities that refer suspect patients including BHUs, ORCs and even to VHWs.

10. Supervision, monitoring and evaluation

10.1 Recording and reporting

The Bhutan NTCP has adapted the standard recording and reporting forms. There is no register for TB suspects. All TB suspects are referred to the laboratory with a hospital slip or simple note from the BHU. In the laboratory, the sputum request form is completed. The TB laboratory register is maintained by the laboratory staff (see section 7).

A treatment card is made for all diagnosed and registered patients. The treatment is initiated by the hospital medical officer. The treatment card is maintained by the hospital TB in-charge. While cards are generally well maintained and kept in neat condition, a number of inconsistencies with regard to correctness or completeness were observed by the review team (e.g. category 1 with omission of streptomycin, missing of laboratory results, inaccurate marking when drugs are supplied). Rarely were side-effects or special interventions (e.g. home visit) mentioned on the treatment card. This would facilitate a better case management, particularly if different staff are involved during the eight-month course.

A treatment register was available in each hospital as well as in the BHUs visited. As the BHUs do not report directly to the programme and as the number of cases is extremely low in a BHU, there is no real need to maintain a register. The treatment card (currently not provided to BHUs) should suffice. BHUs did correctly register the patient as "transfer in" so as not to double report one patient. The treatment register in the hospital is also maintained by the TB in-charge. Some information was missing or entries were delayed without justification. When cross-checking the laboratory with the treatment register the reviewers found all diagnosed smear-positive patients registered except in Phuentsholing, where all diagnosed patients who resided in India were neither registered nor treated.

A double system of reporting is in use, through the Health Management Information System (HMIS) and to the central TB unit. The BHUs report on a monthly basis to the DHSO. This is an integrated report which includes only the numbers of TB patients on treatment, added or deleted. Similar crude data are obtained from the hospitals. After compilation by the DHSO, the report is sent electronically to HMIS. The more detailed quarterly TB reports, as is practised in many other countries and in line with international recommendations, are generated from the TB treatment register. The reports are prepared manually by the TB in-charge, signed off by the medical officer, and directly submitted to the central TB unit. Some inconsistencies were observed in the reports, including differences in age or sex, or not corresponding cohorts.

The workload of the TB in-charge as well as insufficient training and the high turnover of various staff involved in TB control were reported as major bottlenecks.

At the central level, the quarterly *dzongkhag* reports are compiled by the Programme Officer (TB). Data are entered in a locally developed excel-based programme. An overview of TB control is provided in the annual health bulletin produced by MoH. This overview includes statistical data but is otherwise not very specific for the year concerned.

External reviews of the programme have been infrequently conducted. The last two reviews, supported by WHO, were conducted in 1992 and 1996.

10.2 Supervision

The sub-teams visiting different parts of the country received mixed information on levels of supervision. In the *dzongkhags* with more than one hospital, the hospitals have been supervised by the DHSO, sometimes once a year and sometimes more frequently. Only a few hospitals mentioned quarterly visits with feedback provided. Basic health units receive even less visits. This is compensated by the fact that the health assistant reports to the DHSO on a monthly basis and submits monthly reports.

A supervision plan was not in place and supervision checklists are not used. Laboratory visits are not always included in the supervisory visits.

The review team was also informed that transport for supervision is usually not a problem. When official transport is not available, central-level staff use their personal vehicle and claim reimbursement for mileage.

The review team acknowledges that disease-specific supervision is not cost-effective at the *dzongkhag* level or below. There are cross-cutting issues which can be covered through the supervision of other health programmes. The use of a checklist could be explained to staff from other disease control programmes who could then incorporate TB into their supervision visits and report upon completion of the same to the TB programme. The TB programme manager could similarly give attention to other programmes as well. This mode of integrated supervision appears not to occur except when the same person – usually the medical officer based in the *dzongkhag* hospital – is conducting a supervisory visit to a BHU.

Supervision is important for managing setbacks normally occurring at the peripheral level. Problems may be reported to the central level for further action or may be solved locally. Supervision also provides an opportunity for on-the-spot refresher training.

10.3 Coordination

Coordination meetings are planned and do take place periodically. They are region-based, with participation from the national level. The *dzongkhag* TB in-charges convene the meetings, usually at the regional referral hospital. The review team could not offer an opinion on the quality or frequency of these meetings since the minutes of the same were not provided.

There is, however, a good degree of coordination among different implementers in the country for higher-level policy or strategy meetings. A workshop on updating the NTCP manual was attended by a fair selection of health staff from different parts of the country and from different levels and even different sectors. This increases the ownership of the national TB programme and is instrumental in having everybody adhering to the national guidelines.

10.4 Recommendations

The following were the salient recommendations:

- Since the equipment is available with DHSOs for electronic data transfer for HMIS reports, NTCP should also consider submission of quarterly TB reports from the dzongkhag to the central TB unit electronically.
- The NTCP should request WHO to provide technical assistance for streamlining the centrally used TB software so that compilations are computed automatically and standard feedback is provided routinely.
- Integrated supervision should be conducted below the dzongkhag level, making use of checklists to be submitted to the district TB in-charge.
- Quarterly supervision of all dzongkhag-level health facilities from the regional level should be performed according to a standard checklist; this type of supervision should also include routine laboratory activities.
- Six-monthly supervision should be conducted from the central level to the regions.
- Laboratory supervision should be institutionalized for specific technical issues at least once a year and within a month in case of major problems.
- Capacity should be built at the dzongkhag level to identify problems based on interpretation of quarterly reports that are locally generated.
- The TB chapter in the annual health bulletin should summarize the most crucial activities undertaken during the year.
- A coordinated external review involving different partners should be undertaken more frequently – at about 2 to 3-year intervals.

11. Human resources and training

11.1 Staffing

The central-level staffing and the advantage of seconding staff to regional TB coordinator positions on a full-time basis has been discussed in chapter 5 (structure of NTCP).

The hospitals have a TB in-charge who is responsible for recording, reporting, and follow-up of patients. The TB in-charge is not a specialized staff but rather a focal point who coordinates TB control activities. The scope for TB control includes not only the hospital but also the dependent BHUs and ORCs. In all hospitals visited this person is assigned part-time to TB activities and has other, often full-time, responsibilities. There is also no uniformity in qualification of staff. The following cadres were assigned as TB in-charge: pharmacist, health assistant, leprosy health worker and general or auxiliary nurse midwife. When the TB in-charge is absent, there is no replacement. Turnover among these staff is reportedly high.

At the hospital OPDs all staff, medical officers, clinical officers, health assistants, etc. have to identify TB suspects and refer them for examination.

Health assistants posted in BHUs have to refer TB suspects to a microscopy centre. Different health workers in BHUs (health assistant, auxiliary nurse midwife, basic health worker) are often made responsible for managing patients during the continuation phase of the treatment.

The hospital laboratories have one to three laboratory technicians. In most laboratories, the TB microscopy is shared among them according to a roster. While it is desirable to have multipurpose laboratory staff, it further reduces individual exposure and dilutes the opportunities for strengthening AFB microscopy skills.

The country has only one qualified chest physician who is employed by the Royal Bhutan Army. His services can be availed by NTCP.

11.2 Training

The development of skilled health staff in NTCP is a prerequisite for a successful programme. The NTCP is primarily responsible for training in TB. It plans all aspects of training.

As the country does not have a medical college, all doctors are trained in neighbouring countries, especially Bangladesh, India, Myanmar and Thailand. There is a varying degree of integration of national TB control programme policies in the curriculum in these countries. The TB policies are also not uniform across these countries. Upon their return, all medical

officers are briefed about Bhutan's health and disease control policies, including TB. This briefing is an intensive activity where the entire gamut of policies and strategies is discussed but disease-specific (including TB) issues may not be sufficiently elaborated.

The RIHS does not have TB/DOTS included in their official training curricula. However, TB is taught in various RIHS training programmes using the NTCP training modules and NTCP is also updating students on the latest developments in TB control.

The TB in-charges were trained in TB recording and recording in November 2005. BHU staff are trained at the *dzongkhag* or regional referral hospital. Laboratory technicians have attended training sessions/workshops annually during the last few years.

No formal reports are available from these workshops. The NTCP was not able to inform the reviewers on which staff were trained and when and where. Limited information could be obtained from the finance department.

Many staff involved in TB activities were not trained yet. These include medical officers, health assistants and other staff at the OPDs of hospitals, indoor nurses and health workers at BHUs.

The first and second editions of the NTCP guidelines were available in all hospitals visited but it appeared that the document is hardly or not at all used as reference material. The staff mentioned that training is required in order to use these guidelines appropriately. The DOTS modular manual (third edition of the NTCP guidelines) was developed in 2005 and overrides the previous editions. Contrary to the second edition these guidelines will only be distributed in connection with staff training. Training modules on TB microscopy have been prepared and printed.

Table 10 gives an overview of the staff members that participated in WHO regional or intercountry training courses and workshops or received international training in a WHO Collaborating Centre through the fellowship mechanism.

Table 10: *WHO-supported international trainings courses and workshops (2000-2005)*

Name	Designation	Training / Workshop	Place and dates
Mr Rinchen Namgyal	District Health Officer	SEARO/TDR Proposal Development Workshop	New Delhi, India 26-30/09/2005
Dr Nado Zango	Chief Medical Officer THPA Hospital, Gedu	TB Epidemiology and Surveillance for Public Heath Professionals	Geneva, Switzerland 27-30/06/2005
Dr Lungten Z. Wangchuk	Programme Manager	TB management course	Bangalore, India 20/06-29/07/2005
Ms Dechen Wangmo	Radiology technician	Laboratory diagnosis of TB	Bangalore, India 01/11-26/11/2004
Ms Pavitra Bhujel	Radiology technician	Laboratory diagnosis of TB	Bangalore, India 01-26/11/2004
Dr Tobgyel Wangchuk	Medical superintendent JDWNRH	Workshop on TB surveillance, monitoring and evaluation	New Delhi, India 21-24/09/2004
Dr Tashi Choden	Superintendent Gidakom hospital	Workshop on TB surveillance, monitoring and evaluation	New Delhi, India 21-24/09/2004
Dr Ritulal Sharma	Medical Officer	SEA Regional training course on TB control	Bangalore, India 16-28/08/2004
Mr Kinzang Namgyel	Programme Officer (TB&ARI)	SEA Leadership and strategic management for TB control	Bangalore, India 25/04-01/05/2004
Mr Kinzang Namgyel	Programme Officer (TB&ARI)	SEA Leadership and strategic management for TB control	Bangalore, India 10-21/03/2003
Dr Pema Tenzing	Chest physician	TB management course	Bangalore, India 03/03-11/04/2003
Dr T B Rana	District Medical officer	SEA Leadership and strategic management development for TB control	Bangalore, India 7-11/11/2001
Dr Tapas Gurung	Programme Manager	SEA Regional training course on TB control	Kathmandu, Nepal 11-22/09/2000
Ms Tchewang	Instructor RIHS	SEA Regional training course on TB control	Kathmandu, Nepal 11-22/09/2000

Training of a laboratory technician in quality assurance for smear microscopy as well as training of another laboratory technician in DST, both planned during the first year of the GFATM grant, have still to be done. The

decision is awaiting the outcome and recommendations of the NTCP review.

There is a need to combine or integrate TB training in bigger packages In order to increase the cost-effectiveness of training programmes. This is especially relevant for training programmes where only one or two days are required for TB. An advanced training course (e.g. TB management or laboratory) usually requires more time, in which case pros and cons of integration should be carefully evaluated.

While the need for sending staff abroad is obvious for the pre-service training of medical officers is obvious, it may not always be the most cost-effective option for other categories of staff. Particularly in the case of skills transfers, needed to further strengthen the Public Health Laboratory to strengthen or develop its culture and DST capacity, it is advisable to train a critical mass of laboratory staff in-country by a senior international laboratory expert. This can be followed by getting the work started and then selecting key staff for overseas exposure to allow further improvement of the country-specific services. Such an approach would avoid simply copying services that are designed for other settings or countries.

11.3 Recommendations

The following recommendations were made:

- The NTCP should advise hospitals to select TB in-charges from limited cadres of staff, preferably a health assistant or basic health worker. The need for a part-time or full-time TB in-charge should be evaluated based on the existing workload.
- All staff involved in TB control should be trained. This should include staff assigned to OPDs and responsible for examination of patients on DOTS principles and practices; indoor nurses responsible for infectious disease patients in the management of TB; BHU health workers in DOTS principles, management of patients, and recording and reporting where and when applicable.
- The NTCP policies and strategies should be emphasized in the briefing package for medical officers upon joining the health workforce.

- Records should be kept of newly assigned staff requiring training; such training courses should be organized periodically.
- A database should be developed on staff trained for TB throughout the country.
- Specific laboratory training courses should be organised in-country for staff from the Public Health Laboratory, followed by overseas exposure after gaining in-country experience.
- Integrated training programmes should be pursued as much as possible.
- TB/DOTS should be included in the formal RIHS curricula.

12. Partnerships and community involvement

12.1 Collaboration with non-MoH health-care providers

Almost all health-care facilities are under the MoH's jurisdiction. There are a few exceptions, though, including the army hospitals. With regard to TB, one national policy applies to all health-care providers, irrespective of the ministry under which they are placed. The ownership of the NTCP by all health-care providers is also supported by their inclusion in policy meetings and operational workshops.

The review sub-team 3 visited the army hospital in Wangdi, Wangduephodrang *dzongkhag*. The hospital is responsible for the health-care of approximately 3000 military staff and their families. It provides also services to the civilian population living in the neighbourhood. The hospital has an intricate working relationship with Bajo grade-I BHU, located 6 km away.

With regard to TB, all patients diagnosed are admitted and receive treatment. Complicated cases are referred to Lungtenphu Military Hospital, Thimphu, in case of military patients and to JDWNRH for civilian patients. The hospital has no TB outreach programme. This is not relevant for the military patients as the army barracks are located in the neighbourhood of the hospital. If civilian patients are irregular, then staff from Bajo BHU do the tracing. Reports are submitted to the DHSO as well as to the Army

Headquarters. Tuberculosis drugs are indented from DVED and supplied by MSD.

The close collaboration between the military and civilian health services reportedly applies to all military health facilities. The main problem identified was that military health workers are not included in the regular in-service training programmes, although they are fully involved in the execution of the programme.

Review sub-team 1 visited the THPA hospital in Gedu in Chhuka district. This corporate facility is a joint-venture between RGoB and the Government of India. The current population at the project site is approximately 3000. Problems with adhering to the NTCP rules have been reported, particularly for expatriate doctors. Although many diagnoses are based on X-ray, all components of the DOTS strategy are implemented. The drugs and reagents supply from DVED functions well but additional procurements do take place on the Indian market, albeit without any guarantee of quality. The Chief Medical Officer has no jurisdiction over the BHUs in the catchment area as these are under the DHSO. Therefore, the hospital is not in a position to conduct community outreach activities.

The planned visit to the prison health services could not take place due to time constraints. However, it was reported that the TB programme is implemented in the prisons in collaboration with the nearest health facility.

12.2 Public-private collaboration

The private health sector in Bhutan is in a rudimentary stage. There are no private practitioners. There is one private laboratory (in Phuentsholing) performing AFB microscopy. The workload is very low, although one smear-positive case was identified and subsequently referred to Phuentsholing Hospital for treatment. The laboratory technician is trained for sputum microscopy and sends all positive slides to the hospital for reconfirmation. The majority of patients attending this laboratory come from across the border.

A few private pharmacies were visited in Phuentsholing and Thimphu. One private pharmacy was selling ethambutol and pyrazinamide. There appears to be no regulation on the sale of these drugs.

12.3 Community involvement

The policy of hospitalizing all category 1 and 2 patients has limited the need to directly involve the community in the TB programme. The review team could identify several opportunities for further decentralization of the services.

An excellent system is in place to extend the health services beyond the BHU level through intermittent ORCs and the network of VHWs. These VHWs are selected by the community and provide very basic health services to approximately 20 households, all within walking distance. The turnover appears to be limited. One VHW who was already 19 years in the service was visited. The formal health services have a regular link with these VHWs as they attend the ORCs conducted by BHU staff. The volunteers also receive an annual one-week refresher course and some take part in the annual national health conference.

A much more important role could be played by VHWs in TB control activities, particularly in the delivery of DOT. The fact that patients are personally known to VHWs will certainly help in motivating the VHW to support the patient for the entire duration of the treatment. The fortnightly or monthly attendance in ORCs provides a mechanism for regular feedback to the regular health services. Community involvement would reduce the hospitalization burden and would mean a major cost saving.

As part of the efforts at building closer links with the community at large the NTCP planned to set up DOTS committees at the village level. As TB is a rare disease at the village level, it may be difficult to create an effective and sustainable disease-specific committee. The review team opined that such a committee would be a very valuable initiative but that the same objectives could be reached by expanding the terms of reference of existing village health or development committees to include TB control.

12.4 Advocacy, communication and social mobilization

Advocacy, communication and social mobilization (ACSM) is a key component in reaching NTCP objectives and targets. In order for NTCP to have a maximum positive impact on the TB situation, all stakeholders and community members need to be aware of the national strategy and should understand the role they can play.

The NTCP ACSM activities have been commendable. Plans are in place to accelerate their implementation. Some posters and pamphlets were available at the hospitals and BHUs visited. The NTCP has recently developed advocacy materials on TB, including leaflets, pamphlets, posters and brochures. These have been distributed to few districts and are planned to be distributed countrywide within the next months. Advocacy through the national television and radio is done once weekly for three months. A cartoon for publication in newspapers has also been prepared.

World TB Day is observed every year in all districts and the event is covered extensively in the national newspapers, on radio and television.

The key to achieving wider communication is identifying the "catalysers" and targeting these actors. TB orientation modules for key community influencers as well as training modules for non-formal literacy instructors have been printed. The training of community influencers and non-formal literacy instructors has begun in four districts.

12.5 Recommendations

The following were the key recommendations made:

- The NTCP should provide training to staff of military health services, prisons and workplaces. These services should be included in the NTCP's regular planning, supervision and monitoring activities. Engagement of these service providers should be done through appropriate channels.
- The Government should prohibit the sale of TB drugs through private pharmacies.
- The Public Health Laboratory should include the private laboratory within the purview of its training and supervision activities and in its quality assurance programme.
- VHWs should be involved in TB treatment service delivery.
- Village health or development committees should also include supporting DOTS-related activities.
- A media plan should be developed to highlight regular and relevant features on TB/DOTS in all forms of mass media.

13. Operational research

13.1 Findings

Operational research conducted in-country is the best option for evaluating recommendations and guidelines about their feasibility in the country-specific context. It also increases country ownership of the programme. Policies based on evidence generated within the country will be best tailored to the country and are most likely to be adhered to.

Operational research for TB has been conducted on a very limited scale in Bhutan. There is currently one project partially implemented with support from TDR[10]. The review team could meet the principal investigator of this project. The study aims at identifying barriers for health-seeking behaviour among TB patients. Preliminary results indicate that delays are mainly patient-related. More accessible services, both for diagnosis and treatment, as well as increasing the knowledge of the community on TB, its signs and symptoms and management, are needed to reduce the identified barriers.

A second proposal on studying the migratory patterns of mobile population groups and their impact on TB control was drafted and the principal investigator was invited to a training workshop held at the WHO SEA Regional Office in 2005. However, the final proposal was never submitted to TDR.

The decentralization of sputum-smear microscopy to BHU level is still in the trial phase.

13.2 Recommendations

The following recommendations were enunciated:

- In order to conduct research most relevant to the programme, the NTCP should identify areas where operational research is needed and communicate this to potential researchers.

[10] TDR: Unicef-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases.

- The NTCP should request WHO to provide technical support for conducting operational research projects.
- Operational research on decentralization of sputum smear microscopy services to BHUs should determine whether it is feasible, cost-effective and also guarantees high-quality services in the long term.

14. TB/HIV

14.1 Findings

HIV infection is very limited in Bhutan. According to UNAIDS estimates, the total number of patients in the country is less than 500. A cumulative number of 83 HIV-positive patients have been diagnosed since 1993, of whom 19 have died. Five of them died of TB. Currently, four people are known to be living with HIV while at the same time receiving TB treatment.

The risk groups identified in other countries play a less dominant role in Bhutan. It is assumed that the spread is more likely happening through families after infected citizens return from abroad.

Mandatory screening is required for some people who are linked to visa applications for some countries or studying abroad. For police and army staff, screening is strongly recommended while annual testing is advocated for prisoners. Blood screening has yielded nine cases so far. There seems to be no bias as to overrepresentation of donors from high-risk groups.

Every year from April to June a nationwide sentinel survey takes place, which includes all TB patients. This survey is anonymous and unlinked. No TB/HIV patient was identified among 250 TB patients during the sentinel survey. Voluntary counselling and testing (VCT) is offered during other times of the year. The uptake of the test is universal in some centres. It was not clear to the review team as to how far the HIV tests are on a voluntary basis in view of the extremely high uptake and the lack of counsellors in many *dzongkhag* hospitals. It seemed that HIV is tested in blood taken during hospitalization for other reasons. To focus too hard on testing TB patients for HIV might prevent TB suspects from coming forward for TB screening.

Till date one rapid test system is used in *dzongkhag* hospitals. In future, three rapid test will become available in line with WHO guidelines. The Public Health Laboratory also conducts ELISA[11] tests for confirmation. Although desired, PCR[12] tests are not available.

14.2 Recommendations

It was recommended to:

- Continue the annual sentinel surveillance.
- Move to routine offer of HIV testing to all TB patients, with the right to opt out, where pre-test counselling is available.

15. Drug-resistant tuberculosis

15.1 Findings

The extent of TB drug resistance is not known. No national drug-resistance survey was undertaken. On a national scale, the treatment success rate in new smear-positive cases registered for treatment in 2004 was 83%. This indicates that MDR-TB should not be a problem in new cases. A slightly lower treatment success rate (82%) was reported in retreatment cases. The declining trend in treatment results is more worrisome, though.

Patients suspected of MDR-TB are referred to Gidakom Hospital. Diagnosis is done clinically based on patient history. At the time of the visit four patients were treated with second-line drugs. The following regimen was prescribed: An intensive phase of six months KmEtoOfxZE[13] followed by a continuation phase of 12-18 months of Eto, Ofx and Z or E. Drugs are procured using RGoB resources.

The patients treated with second-line drugs are not registered in the regular TB treatment register. Most patients are admitted in Gidakom Hospital for the entire treatment duration. The number of patients treated,

[11] ELISA: Enzyme-linked immunosorbent assay.
[12] PCR: Polymerase chain reaction.
[13] Km: Kanamycin; Eto: ethionamide; Ofx: ofloxacin.

cases referred to other hospitals and treatment outcomes were not well documented.

There are well-established DOTS-Plus projects in neighbouring countries. The Bhutan NTCP could benefit considerably from lessons learnt in the management of MDR-TB in these countries.

15.2 Recommendations

The following recommendations were made:

- A policy for the diagnosis and management of MDR-TB should be formulated.
- Technical assistance should be obtained for developing MDR-TB services and a GLC proposal.
- Study visits should be organized to DOTS-Plus projects in other countries.
- A protocol should be developed to conduct a drug-resistance survey.

Annex 1

List of reviewers

National reviewers

Dr Lungten Z. Wangchuk
NTCP Manager
MoH

Mr Kinzang Namgyel
Programme Officer (TB)
MoH

Mr Dorji Tshewang
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Dr Taka
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International reviewers

Dr Erwin Cooreman
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Dr Marijke Becx-Bleumink
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Professor Dr Knut Feldmann
Head, Supranational Reference Laboratory
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Annex 2

Places visited and people met

Ministry of Health

Dr Gado Tshering
Secretary and Officiating Minister

Mr Thinley Dorji
Deputy Secretary, Policy and Planning Division

Mr Nado Dukpa
Deputy Secretary, Administration and Finance Division

Dr Gembo Dorji
Programme Manager, National HIV/AIDS Programme

Mr Tshwang Ringzin
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Dr Ei Kubota
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Dr Norbu Wangchuk
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Dr Ugen Dophu
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Mr Tshewang Tenzin
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Dzongkhag Hospital, Tsimalakha, Chhuka

Mr Rinchen Namgay
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Ms Maya Thapa
Assistant Nurse Midwife, TB in-charge

Mr Som Kumar Namchu
Laboratory Technician

Phuentsholing General Hospital, Chhuka

Dr T.B. Rana
Superintendent

Ms Jigme Wangmo
Laboratory Technician

Mr Shekhar Nepal
Basic Health Worker, TB In-charge

MSD, Phuentsholing, Chhuka

Mr Chakchu Tshering
Welfare Officer

THPA Hospital, Gedu, Chhuka

Dr Nado Zangpo
Chief Medical Officer

Mr Harka Bhadur
Laboratory Technician

Mr Ghalley
Basic Health Worker, TB in-charge

Dawakha BHU, Paro

Mr Tashi Dhendup
Health Assistant

Ms Chencho Pem
Assistant Nurse Midwife

Mr Pema
Basic Health Worker

Military Hospital, Wangdi, Wangduephodrang

Dr (Maj.) Wangchuk Dorji
Chief Medical Officer

Mr (Drimpon) T. S. Rai
Nursing Assistant, TB in-charge

Mr Ugyen
Laboratory Technician

Mr Tashi Jangchuk
Laboratory Technician

Mr Mangal Singh Rai
Laboratory Technician

Dzongkhag Hospital, Jacar, Bumthang

Dr Nima Wangchuk
District Medical Officer

Mr Gopal Hingmang
District Health Supervision Officer

Mr Tshering Choeda
Non Medical Supervisor

Mr Dorjee
Assistant Administrative Officer

Ms Samten Wangmo
Pharmacy Technician

Ms Banita Sharma
Laboratory Technician

Ura BHU, Bumthang

Mr Lachuman Neopaney
Health Assistant

Ms Dhanmaya Tamang
Auxiliary Nurse Midwife

Mr Chador Tenzin
Basic Health Worker

Mr Sonam Gyelpo
sMenpa

Takar village, Chumey Geog, Bumthang

Ms Tshering Wangmo
Village Health Worker

Regional Referral Hospital, Mongar

Ms Khena Maya
District Health Supervisory Officer

Mr Pema Tshewang
Assistant District Health Supervisory Officer

Dr Ritulal Sharma
Medical Superintendent

Mr Kinley Penjor
TB in-charge

Mr Rigzin Jamtsho
Laboratory technologist

Ms Sonam Wangmo
Laboratory technician

Mr Tashi
X-ray technician

Ms Tek Bhahadur
Store in-charge

Yadi BHU, Mongar

Mr Yogya Narda Sharma
Health Assistant

Ms Genden Zangmo
Auxiliary Nurse Midwife

Thinangbi ORC, Mongar

Thinleygang BHU, Thimphu

Mr Ugyen Lhindup
Health Assistant

Ms Dhan Maya
Auxiliary Nurse Midwife

Mr Dhan Singh
Basic Health Worker

Dzongkhag Hospital, Punakha

Mr Peden Dorji
District Health Supervisory Officer

Ms Lhamo
Assistant Clinical Officer

Ms Tandin Pemo
Pharmacy Technician, TB In-charge

Mr Karma
Laboratory Technician

Dzongkhag Hospital, Sarpang

Dr Kunzang Wangdi
District Medical Officer

Mr Sonam Zangpo
District Health Supervisory Officer

Mr Dorji Gyeltshen
Health Assistant, TB In-charge

Mr Jambey Dorji
Laboratory Technician

Mr Pema Gyeltshen
Assistant Clinical Officer

Norbuling BHU, Sarpang

Mr Kencho Wangdi
Health Assistant

Mr Chabilal Darjee
Malaria Technician

Regional Referral Hospital, Gelephu, Sarpang

Dr Dupthop Sonam
Superintendent

Mr Karma Yeshi
Administrative Officer

Mr Sangay Dorji
Non-medical Supervisor, TB In-charge

Mr Tshewang Dorji
Laboratory Technician

Mr Sangay Wangchuk
Laboratory Technician

Damphu Hospital, Tsirang

Dr Tika Ram Adikari
District Medical Officer

Mr Pema Wangchuk
District Health Supervisory Officer

Ms Lungten Zangmo
General Nurse Midwife, TB In-charge

Ms Dil Maya Rai
Laboratory Technician

Mr Ugay Dukpa
Assistant Clinical Officer

Liaison Office of Denmark

Mr Tek B. Chhetri
Deputy Head, Programme Officer

Annex 3

Map of Bhutan indicating places visited