Mid Term Review of the National TB Programme of Sri Lanka

17-28 July 2017

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Acknowledgements

The consultants must thank Dr Jayasundara Bandara, Director-General of Health, Ministry of Health, Nutrition and Indigenous Medicine, and Dr Sarath Amunugama, Deputy Director General (Public Health Services) for permission to carry out the mid-term review

We would like to acknowledge all the preparatory, logistics and administrative work carried out in preparation for the review mission by the staff of the National Programme for Tuberculosis Control and Chest Diseases. Its Director, Dr Kanthi Ariyarathne, is to be commended for her openness and willingness to discuss difficult issues.

Abbreviations

ACF	active case finding
ARTI	annual risk of tuberculosis infection
CNAPT	Ceylon National Association for the Prevention of TB
DCC	District Chest Clinic
DHS	demographic health survey
DDG	Deputy Director General
DGHS	Director General Health Services
DOT	directly observed treatment
DOTS	internationally recommended strategy for TB control
DRS	drug resistance survey
DR TB	drug resistant tuberculosis
DST	drug sensitivity (susceptibility) testing
DTCO	District TB Control Officer
GDP	gross domestic product
GLC	Green Light Committee
HIV	human immunodeficiency virus
ISTC	International Standards for TB care
JMM	joint monitoring mission
KAP	knowledge, attitudes and practices
LIMS	laboratory information and management system
M & E	monitoring and evaluation
MC	microscopy centre
MDR-TB	multidrug-resistant tuberculosis
MLT	Medical Laboratory Technologist
MoH	Ministry of Health
MOH	Medical Officers of Health
NCD	non communicable disease
NGO	nongovernmental organization
NPTCCD	National Programme for Tuberculosis Control and Chest Diseases
NRDH	National Respiratory Disease Hospital
NSACP	National STD/AIDS control programme
NSP	national strategic plan
NTRL	National TB Reference Laboratory
OPD	outpatient department
OR	operational research
PHI	Public Health Inspector
PHLT	Public Health Laboratory Technician

PHM	Public Health Midwife
PHW	Primary Health Care worker
PIMS	patient information management system
PLHIV	people living with HIV
PMDT	programmatic management of drug-resistant TB
PPD	purified protein derivative
PPM	public-private mix
PR	principal recipient
QA	quality assurance
RDHS	Regional Director of Health Services
RMO	Registered Medical Officer
SOP	standard operating procedure
SRL	supra-national TB reference laboratory
TB	tuberculosis
WHO	World Health Organization
WHO-SEARO	WHO South East Asia Regional Office

Executive summary

Introduction

Although the TB burden in Sri Lanka is not high, compared to neighbouring countries, there is little evidence of a decline in the last 20 years. Sri Lanka is a lower middle income country with a well-organised health system, providing health care to the general public, free at the point of need. It has rapidly expanding, private health care, whose growth is supported (and regulated) by the government.

Sri Lanka currently has a Global Fund TB grant for the period, 2015-2020. The Review Team was asked to assess the present status of the National Programme for TB (NPT), and progress made in the implementation of the National Strategic Plan (NSP) for TB control, 2015-2020. Successes and gaps or barriers to implementation were to be identified and recommendations made for improvement of the NPT. After completion of this work, the team is mandated to propose revisions to the NSP.

Sri Lanka has committed to the WHO's End TB Strategy at the World Health Assembly, 2014. At WHO's South East Asia Regional Office (SEARO) Ministerial Meeting to End TB in March 2017 in New Delhi, the Minister of Health of Sri Lanka signed up to a Call to Action to reduce TB deaths by 90%, and TB incidence by 80%, by 2030. The first milestone is a 35% reduction in TB deaths, and a 20% reduction in incidence rate, and elimination of catastrophic costs due to the disease, by 2020.

In November, 2017, Sri Lanka will attend the Global Ministerial Conference on Ending TB in Moscow, and, in September 2018, the High Level Meeting on TB at the UN General Assembly, the first meeting of its kind. **Sri Lanka will be in the spotlight.**

Burden

Following the Epidemiological Review carried out in June, 2017, the Review Team concludes that the priority issue for TB control in Sri Lanka is the worrying gap of some 4,000 cases between the estimated incidence of 13,000 cases and the numbers of patients notified with TB. Since 2011, this gap has widened as notifications have dropped from 10,329 (51.4 per 100,000 population) to 8,886 (42/100,000) in 2016. Children may be disproportionately under-diagnosed.

A partial explanation for falling notifications is that the smear testing rate fell in 2015, compared to 2011, in five districts, although it increased in all other districts.

Twice as many males as females are notified with TB in Sri Lanka. The proportion of pulmonary TB cases that occurred at age 45, or more, increased from 39% in 2014, to 43% in 2016. The population is ageing, which will put upward pressure on TB rates. TB is becoming an old person's disease.

Two thirds of the pulmonary cases are smear positive, suggesting that too few cases are diagnosed on clinical grounds - and hence miss out on treatment that might prevent them from becoming smear positive and transmitting the disease.

Each year about 1,200 people die from TB. Treatment success has remained below the 85% target of WHO since 2012. The End TB strategy now targets a success rate of 90%. The comparatively high fatality rate (6.8% in the 2015 cohort) may reflect the advanced age of cases, or their co-morbidities.

HIV-associated TB and multi-drug resistant (MDR) TB remain relatively small problems in Sri Lanka: over 90% of TB patients were tested for HIV in 2016, and 12 of the 19 cases found in 2014 were treated successfully for their TB. However, of an estimated 4,200 people living with HIV (PLHIV) in Sri Lanka only 18% is on anti-retroviral treatment. There were 17 cases of rifampicin resistant (RR)

or MDR-TB detected in Sri Lanka in 2016. However, this represents only 40% of the total number of 43 RR/MDR-TB cases that are estimated to be among the notified cases.

A very high prevalence rate of TB has been found among prisoners (1.68%), and two studies among diabetics have, unfortunately, given contradictory results. Malnutrition is likely to be a contributory factor: stunting rates in the under 5s (10% in 2015) are lower than other countries in the region, but significant. Tobacco smoking doubles the rate of TB and 29% of Sri Lankan men smoke.

Achievements

Sri Lanka has a low burden of TB compared to its neighbours and in comparison with its level of economic performance. This is likely due to the widespread availability of free health care throughout the country. Universal health care has been achieved, and at a comparatively low cost - approximately 4.2% of GDP (or USD$70 per capita) goes on health expenditure.

The under-5 mortality rate, which is often viewed as an indicator of the general level of health services, has halved since 1990 and in 2015 was 10 per 1,000 live births.

For many years Sri Lanka has had a National TB Programme which has succeeded in raising funds from the Global Fund, the World Bank and WHO, as well as from the Government. The Global Fund has allocated a further US$3 million to TB control for 2019 to 2021. Anti TB drug resistance has been kept low, according to a 2007 survey – a repeat survey is currently underway. Programmatic management of drug resistance has been successfully introduced, and 10 GeneXpert machines have been installed around the country – although some (eg Batticaloa) lack manpower to run them.

Challenges

Case finding is only about 70% of the estimated incidence, which means about 4,000 cases remain un-notified each year. This probably represents both under-diagnosis and under-reporting. The Review Team focused on the possible causes and solutions.

First, there are significant weaknesses in the TB surveillance system: of the 13 WHO Benchmark standards for monitoring and evaluation, 5 were met in 2017, 4 were partially met, 3 were not met and 1 was not applicable. The exact scale of the problem of missing cases is therefore uncertain.

Second, there is an urgent need to screen systematically the patients attending the out-patient departments (OPD). The team was informed that medical officers in OPD receive little or no in-service training on TB, are reluctant to attend training when provided, provide mainly symptomatic treatment, do not write records, and focus on “crowd clearance”. Registers to ensure presumptive TB cases receive a sputum test are not properly maintained. We heard reports of patients attending OPDs multiple times before being diagnosed with TB, sometimes with fatal results.

Thirdly, many large hospitals do not have a facility for microscopy of sputum for out-patients. This is not up to international standards. Among the 3 teaching hospitals in Colombo, only Colombo South has a Microscopy Centre. There is a serious lack of laboratory technicians to carry out microscopy, e.g. until recently, 3 out of 12 microscopy centres run by DCC, Colombo, were closed due to lack of a PHLT.

Fourthly, contact tracing is not always carried out for each case diagnosed (on average 2 contacts are reviewed per case, while average household size in Sri Lanka is 3.9). It is performed by public health inspectors who have little or no training on TB, and only refer patients to hospital for investigations if the contact has classical symptoms. Experience elsewhere in Asia has shown that

30-50% of cases of TB do not admit to a cough of more than 2 weeks – and hence will require chest X-ray or sputum examination to make a diagnosis.

Fifthly, active case finding (ACF) has been carried out, but has been done haphazardly among high risk populations. In 2016, over 32,000 people were included in ACF, and 6,400 were screened. Only 17 cases were found, all of whom were prisoners. WHO recommends ACF only in populations with at least 1% prevalence of TB, but the prevalence has not been established in most populations included in ACF in Sri Lanka. International studies strongly suggest that TB is likely to be a major comorbidity among diabetes patients, but this population has not yet been systematically addressed in Sri Lanka.

Lastly, half of all OPD attendances in Sri Lanka are in the private sector. We received credible reports that TB is being treated in the private sector with drugs from abroad. Experience in other countries suggests we should be concerned about the quality of care in the private market. There is an urgent need for more information on the services for TB provided in the private sector.

The consequence of obstacles to case-finding is delay in diagnosis, extensive disease when patients are finally diagnosed, and a higher risk of death.

With respect to treatment, Category II is still provided to patients who require retreatment. WHO has recommended in 2017 that: *"In patients who require TB retreatment, the category II regimen should no longer be prescribed and drug-susceptibility testing should be conducted to inform the choice of treatment regimen."*

Of the activities under the NSP 2015-2020, only 35% have been completed, while 36% have not been started and 29% were only partially completed. Activities not started were especially high (77%) under the objective of engaging the private sector, and 56% in the area of decentralisation to divisional hospitals. Progress made under the NSP indicators revealed similar results. The DDGHS requested a new "End TB" strategy after a SEARO meeting in 2016, and a further plan was prepared, which is substantially different from the NSP. The Programme appears to be focusing on routine activities and postponing adoption of any new initiatives.

The staff of the NPTCCD central unit has serious limitations with significant numbers inadequately trained. Motivation is low. Not all essential functions of a central unit are properly carried out: no annual report has been published since 2014 and policy development is slow.

Unless case finding and programme performance can be substantially improved, Sri Lanka will miss the WHO End TB Strategy targets for 2030. **Furthermore, if radical steps are not taken to address these challenges, no substantial progress will be made. Business as usual is not an option.**

Opportunities

Sri Lanka is fortunate in having easy access to health facilities in most of the country. Many of the hospitals are very well equipped. There is a cadre of highly -trained respiratory physicians. Social support is available for all patients with TB, although at a very low level of LKR 500 monthly. There is a well-established public health network with Public Health Midwives, Inspectors (PHI) and Nurses headed by the Medical Officer of Health and covering every household. PHIs are dedicated for disease prevention and are responsible for contact tracing. Under-used microscopy facilities are available in former malaria endemic zones. Microscopy for TB could piggy back on this system. Media awareness campaigns were successful in the past, and 80% households have television.

There is a real opportunity to eliminate tuberculosis from Sri Lanka, which should not be missed.

Major recommendations

Programme Management

1. **MOH should urgently strengthen the NPTCCD Central Unit** with 2 appropriately trained and committed community physicians and 4 medical officers with at least post-graduate qualifications in community medicine, including a full-time epidemiologist to support M&E and surveillance. The Director should clarify the policy directions of the NPT and the planning approach used.

2. **There should be one policy, one plan and one surveillance system**.

Case finding

3. **The NPT Central Unit should set up 2-3 pilot districts, in collaboration with provincial and regional health directors. The aim is to prove that addressing the challenges above can significantly increase case finding within one year, and improve treatment outcome.** Remaining districts will learn from these pilots and will eventually follow themselves. Criteria for selection should be developed, and a priority list of activities defined for each district, based on the analysis in this report. Meetings of all stakeholders, focused workshops and training of key staff will all be required.

4. **The DGHS and NPT should ensure patient-centred services are provided. It should become MOH policy that all hospitals without microscopy facilities in OPD should set them up, diagnose TB cases, register them (through a telephone call to the DTCO) and initiate treatment on bacteriologically confirmed cases.** DTCOs should provide constant supportive supervision. NPT staff will need to supervise weekly in the first instance.

5. **The DGHS and NPT should urgently strengthen contact tracing activities** by setting targets for the PHIs and DTCO to find all contacts, and refer them to the DTCO for examination. Increase the sensitivity of contact screening by performing chest X-rays on all.

6. **The NPTCCD should stop, with immediate effect, all active case finding in populations where a 1% prevalence rate of TB has not been demonstrated**, with the exception of household contacts and PLHIV. Resources thus saved should be used elsewhere.

7. **The NPTCCD and National TB Reference Laboratory (NTRL) should urgently introduce a laboratory information system and an electronic case-based, web-based patient record system for TB patients.** Such a system could send text messages to health workers and patients, and link with contact tracing as well as with the NPTCCD surveillance system.

Treatment

8. The NPTCCD should urgently phase out Category II treatment in favour of drug susceptibility testing for all patients requiring re-treatment, with provision of a regimen that is appropriate for the resistance pattern found.

Operational Research

9. **The NPT, in discussion with academic groups, should prepare a list of research studies and projects that are urgently required in order to improve TB outcomes in Sri Lanka. Greater understanding of patients' pathways to TB care is essential and the performance and TB diagnostic and treatment practices of the private sector should be a priority area of study.**

External TA should be sought where necessary for the activities above.

1. Introduction

1.1 Background

Sri Lanka is a low middle income country with a well-organised health system, providing health care to the general public, inclusive of medication and diagnostic testing, free at the point of need. The services provided vary from out-patient consultations to open heart surgery. It also has a small, but expanding, private health care system, whose growth is encouraged, supported and regulated by government. Over 80% of admitted care and about 50% of the ambulatory services are provided by government health facilities.

Provision of preventive health services is a responsibility of the government, and the private health sector provides only a few preventive services, such as family planning and immunization, for those do not wish to attend government facilities.

Sri Lanka has a well-established strong preventive healthcare network with Public Health Midwives and Public Health Inspectors serving at village level. These workers provide community based maternal and child health services, family planning, immunization, health education, and epidemic prevention and control. Through widespread availability of services, malaria has been eradicated and filariasis and leprosy have reached elimination levels. Sri Lanka still has four vertical programmes to control tuberculosis and chest diseases, malaria, sexually transmitted diseases and HIV/AIDs, and human rabies.

For nearly 20 years there have been concerns that although the TB burden in Sri Lanka is not high, there is little evidence that it is improving. In particular, there is now a concerning gap of some 4,000 cases between the estimated incidence of 13,000 cases and the numbers of patients found to have TB[1]. Since 2012 this gap has widened as notifications have dropped from 10,329 (51.4 per 100,000) to 8,886 (42/100,000) in 2016. Unless case finding can be substantially improved, Sri Lanka is on track to miss the WHO End TB Strategy targets for the elimination of TB by 2050 – less than one case per million – and the 2030 targets. The gaps in case finding are well recognised at the highest policy-making levels[2].

Sri Lanka is currently using a Global Fund grant for the period, 2015-2020. This year, 2017, seemed an appropriate time to carry out a review and assess progress of the National Strategic Plan (NSP) for 2015-2020, and also to consider longer term constraints that might be inhibiting progress towards the End TB targets, with a view to recommending approaches to achieve both the 2020 and the longer term 2030/2035 and 2050 targets of the End TB Strategy.

As a middle income country, resources will always be constrained so this review has focused on recommendations which will maximise the efficient use of resources.

1.2 International context

At the 2014 World Health Assembly in Geneva, Sri Lanka committed to the End TB Strategy, which aims to end the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB. It sets interim milestones for 2020, 2025, and 2030 (Table 1).

Similarly, Sri Lanka is signed up to the United Nations' (UN) Sustainable Development Goals whose Goal 3 addresses health and aims by 2030, to end the epidemics of AIDS, tuberculosis, malaria and

[1] WHO. Global Tuberculosis Report 2016. WHO, Geneva, Switzerland.

[2] Interview of review team with Dr Sarath, Deputy Director-General Health Services (Public Health), July 17

neglected tropical diseases[3]. Sri Lanka also supported the Call for Action that concluded the New Delhi Regional Meeting towards Ending TB, March, 2017[4].

In November, 2017, Sri Lanka will likely attend the Moscow Ministerial Conference organised by WHO to increase commitment globally to reduce the burden of TB. This will be followed in 2018 by the unprecedented first UN High Level Meeting on TB, during the General Assembly. During both these upcoming meetings, **Sri Lanka will be in the spotlight.**

Table 1. Summary of the End TB Strategy targets and milestones. *Source Ref 4.*

Milestone/Target	2025 - Milestone	2030 - Milestone	2035 - Target
Incidence		80% reduction	90% reduction
Deaths		90% reduction	95% reduction
Those needing treatment	90% treated		
People in key populations	90% reached		
Treatment success	90%		

1.3 Objectives of the review

The following objectives were set by the management of the NPT and are copied verbatim from the Terms of Reference:

1. To assess the present status of the National TB Programme and progress of implementation.
2. To assess the implementation status of the National Strategic Plan for TB control for 2015-2020 in Sri Lanka and to identify successes and gaps / barriers for implementation.
3. To make recommendations for improvement of the National Tuberculosis Programme
4. To assess the progress of implementation of recommendations of the rGLC mission
5. To revise the NSP 2015-2020 in alignment with SDG and End TB strategy

1.4 Consultants

Paul Nunn, MA (Oxon), FRCP, Director, Global Infectious Diseases Consulting (GIDC), Ltd. Following a 20 year career in WHO, mostly as a Coordinator in the Stop TB Department responsible for development of key WHO strategies in the fields of TB/HIV, MDR-TB, laboratory strengthening, regional and country coordination, Paul left WHO in 2012, and has worked as an independent consultant since. In 2013 he founded GIDC and has gone on to lead national TB programme reviews in Cambodia, India, Indonesia, Iraq (and Iraqi Kurdistan)(x2), Myanmar (x2), North Korea, Tanzania, Thailand (x2),

[3] United Nations Sustainable Development Goals. http://www.un.org/sustainabledevelopment/health/ Accessed 31 July, 2017.
[4] WHO, SEARO. Ministerial Meeting towards Ending TB, New Delhi, March 16-17, 2017. http://www.searo.who.int/tb/call_for_action_signed_v_1.pdf?ua=1 Accessed 31 July, 2017.

as well as trouble-shooting missions elsewhere. He has authored over 100 peer-reviewed publications, and a recent book on Achievements and Challenges in Tuberculosis Control in Modern China.

Deepthi Perera (MB BS, MSc, MD Community Medicine), A Consultant Community Physician, with over 30 years' experience in the field of Public Health, she last served as the Provincial Director of Health Services, in Western Province, the largest Province of Sri Lanka. After obtaining postgraduate qualifications, as a Consultant Community Physician, she first served as the Deputy Director, Heath Education Bureau. She has also headed the National Programmes in the post of Director for Maternal and Child Health, and as the Director, Youth, Elderly, Disabled and Displaced Persons in the Ministry of Health for over two decades. Materials prepared by Dr Perera while at the Health Education Bureau are still being widely used in the country as health education material by the relevant target groups.

Sunil Senanayake, MBBS, MSc (Com Med), MD (Com Med),

Public Health and Health Systems Specialist. Following 25 years of service in Health Services, Sri Lanka, from grass root to national levels (17 years in Management Development and Planning Unit of the Ministry of Health and then serving as Director, Health Information) he served WHO over ten years as Vanuatu, Regional Adviser in Health Information at Western Pacific Regional Office, Regional Adviser- Health Situation and Trend Assessment, Regional Adviser – National Health Planning and Economics, Regional Adviser – Health Systems Management and Patient Safety, and retired end of April 2017. Dr Senanayake has wide local and international experience working in Cambodia, Laos PDR, Mongolia, Philippines, South Pacific Island countries (Fiji, Solomon Island, Tonga, Tuvalu, Vanuatu), Bangladesh, Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal, Thailand and Timor Leste. He has also contributed to many health systems evaluation missions including the "Fifth Joint Monitoring Mission of the Bangladesh National Tuberculosis Control Programme" in 2010.

1.5 Format of the review

The consultants reviewed relevant papers and data prior to the start of the mission on July 17, most notably the 2014 Joint Monitoring Mission Report, the NSP 2015-2020, including the Core, Monitoring and Evaluation and Budget Plans, the Operational Plan of the NSP concluded in early 2016, and the draft Epidemiological Review which was written by Drs Shamani Prathapan and Dr Vanessa Veronese. Annual Progress Reports, all proposals submitted for external funding, including GFATM approved plans, the Regional Green Light Committee (rGLC) report, June, 2017, and the 2016 KAP Survey Report were also scanned.

Economic data were obtained mostly from the World Bank, and demographic data from the World Population Review[5]. Health data were obtained from the WHO, Country Office[6] and TB data from the database of the Global TB Programme, WHO, Geneva[7].

[5] http://worldpopulationreview.com/countries/sri-lanka-population/ Accessed July 25, 2017.
[6] WHO, Sri Lanka. 2016 SDG Health Profile.
[7] https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=LK&LAN=EN&outtype=html Accessed July 12, 2017

The mission began on July 17, 2017 with a review of the current status of the National Programme for Tuberculosis Control and Chest Diseases (NPTCCD) presented by Dr Kanthi Ariyarathne, Director. Discussions at the Ministry of Health were followed by visits to the Colombo area, and the districts of Gampaha and Batticaloa (Figure 1). The National Hospital for Respiratory Diseases (NHRD), National Tuberculosis Reference Laboratory (NTRL), Central Drug Store (CDS) of the NTPCCD, Microscopy and DOT Centres, private sector hospitals and laboratories, teaching, general and base hospitals, offices of Medical Officers of Health (MOH), were all visited, and where possible patients were interviewed.

A consultation meeting between the consultants, NPTCCD staff and stakeholders of the Programme was called on July 20, and similarly with the District TB Control Officers (DTCOs) on July 24. The Review Team called for a meeting with a small group of consultant respiratory physicians (CRP) on July 26 in order to fill in gaps about the role of CRPs in TB control in the country. Discussions were held by telephone between Paul Nunn and the Global Fund portfolio team (Blanca Gil Antunano Vizcaino, the Portfolio Manager, and Ms Tsvetana Yakimova, M&E Specialist) and Dr Jacob Kumaresan, recently retired WR, Sri Lanka.

During the mission, quantitative analyses of progress compared to the activities in the NSP 2015-2020, and compared to the indicators and targets of the M&E Plan were prepared, based on levels of implementation reported by Programme staff.

A debrief summary was prepared by the consultants. Debriefing meetings to present the summary of the findings were held on July 28 with a selection of stakeholders at NPTCCD, with the WHO Representative (WR), Dr Razia Pendse, at the WHO Country Office, and, later, at the MOH with Dr Jayasundara Bandara, Director General of Health, and Dr Sarath Amunugama, Deputy Director General (Public Health Services). The summary document in Word and the presentation in Powerpoint were left with Programme staff.

This report was prepared through the sharing of iterative drafts between the three consultants and submitted on August 11, 2017.

Figure 1. Map of Sri Lanka

2. The present status of the National TB Programme

2.1 The epidemiological situation

2.1.1 Epidemiological analysis

A separate epidemiological analysis of the TB situation was conducted just prior to the mission by Dr Shamani Prathapan and Dr Vanessa Veronese, and has recently (November 2017) been published. Their report was in preparation by the time of the mission and a draft was made available to the Review Team. Comments on the draft were made by the Review Team to the authors. As well as the epidemiological analysis, the report included an assessment of the surveillance system carried out using the WHO standards and benchmarks, and should be read in conjunction with this report. In this report we will summarise just the main findings that are relevant to it.

2.1.2 The quality of surveillance for TB

The epidemiological analysis concluded that the surveillance, monitoring and evaluation system did not achieve the WHO standards (Table 2). Of the 13 benchmark standards, only 5 were met, 4 were partially met, 3 were not met and 1 was not applicable, since a national database of historical TB data had not yet been set up. In particular, there was evidence that a significant number of cases were registered in the district registers, but not reported in the NPT's statistics.

Table 2. Summary results of the assessment of the TB surveillance, monitoring and evaluation system of Sri Lanka. *Source: TB Epidemiological Review, 2017.*

CHECKLIST SUMMARY (Part B)				
STANDARD	MET	PARTIALLY MET	NOT MET	NA
B1.1: Case definitions consistent with WHO Guidelines	■			
B1.2 TB surveillance system is designed to capture a minimum set of variables for all reported TB cases	■			
B1.3 All scheduled periodic data submissions have been received and processed at the national level	■			
B1.4 Data in quarterly reports (or equivalent) are accurate, complete, and internally consistent		■		
B1.5 Data in the national database are accurate, complete, internally consistent, and free of duplicates				■
B1.6 TB surveillance data are externally consistent			■	
B1.7 TB surveillance data are internally consistent over time			■	
B1.8 All diagnosed cases of TB are reported		■		
B1.9 Population has good access to health care		■		
B1.10 Vital registration system has high national coverage and quality		■		
B2.1 Surveillance data provide a direct measure of drug-resistant TB in new cases	■			
B2.2 Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases	■			
B2.3 Surveillance data for children reported with TB are reliable and accurate, and all diagnosed childhood TB cases are reported			■	

2.1.3 Incidence and notifications

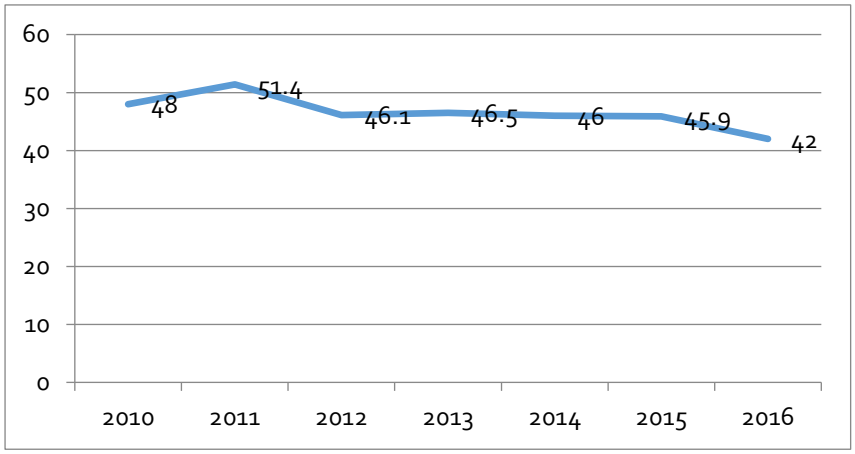
While the incidence of TB was estimated by WHO in 2016 to be 13,000 (65 cases of all forms of TB per 100,000 people), the notifications were 8,886 (42/100,000), a gap of over 4,000. Furthermore, the smear positive to clinically diagnosed ratio of 2.5 is high compared to other countries in the region, where clinically diagnosed cases are in the range of 36-61% of pulmonary cases, and suggests that too high a level of proof is demanded in order to make a diagnosis.

There were significant falls in notification in 2012 and 2016, which were so steep that they cannot be accounted for by concomitant falls in true incidence (Figure 2). A partial explanation for falling notifications is that the smear testing rate fell in 2015, compared to 2011, in the five districts of Matale, Galle, Mannar, Trincomalee and Kurunegela, although it increased in all other districts.

Because of the concerns about the capacity of the M&E system, the notification rate is uncertain. The same applies to the estimated incidence, since it relies to a large extent on data from Sri Lanka. The exact scale of the problem of missing cases is therefore uncertain. Nevertheless, there is clear evidence of under-reporting, not only from the public health system, but also from the private sector.

Taking into account the current status of the NPT which is further described below, the Review Team concluded that the problem of missing cases was the major priority for the Programme to focus on over the coming year or two. However, improvements to the surveillance system are also an urgent priority, and the epidemiological analysis includes several recommendations to achieve this.

Figure 2. Case notification rate for all forms of TB (2010 - 16)



2.1.4 The impact of age on TB

Sri Lankan citizens have a high life expectancy of 75.9 years. The population of Sri Lanka is ageing: 9.1% of the country's population is in the 54-65 year age bracket, while 8.1% of its population is above the age of 65[8]. Significant ageing was observed in the TB patient population: 39% of cases notified in 2014 were aged 45 years and older, while 43% of all notifications were in the same age

[8] Index Mundi. Sri Lanka age structure. 2017. http://www.indexmundi.com/sri_lanka/age_structure.html Accessed 31 July, 2017.

bracket in 2016. This ageing of the population is likely to lead to upward pressure on the notification rate in coming years.

There has been a dramatic fall in children diagnosed with TB in recent years: 345 (4.2%) cases in 2010, and only 46 (0.5%) in 2016. Again, this is unlikely to be accounted for by a concomitant fall in incidence of childhood TB. Although transmission of TB could be falling, the Epidemiological Review concluded that childhood TB was likely being underdiagnosed.

2.1.5 The drivers of TB

The major drivers of TB in Sri Lanka probably include imprisonment, HIV, diabetes mellitus, smoking and malnutrition. A 2013 study (unpublished) reported a very high burden of TB in prisoners - 1.68% prevalence of sputum smear positive TB[9].

While HIV testing among TB patients is high (89.5% in 2016), only 12 cases of HIV-associated TB were found. HIV is a negligible driver of TB incidence.

The exact burden of diabetes mellitus in Sri Lanka is unknown although more than 8% of women and 7% of males are thought to be living with diabetes[10] and, of these, over 60% of men and 70% of women are apparently receiving care for their diabetes[11]. Worldwide, diabetes is known to increase the risk of TB threefold. However, in a large study of 2,864 newly diagnosed patients with diabetes in diabetic clinics in Colombo and Kandy who completed a questionnaire, only 2 cases of TB were detected[12]. This is far lower than reported in many similar studies in neighbouring countries. Review of the unpublished paper suggests some methodological problems may have occurred – of 1,345 patients who received a chest X-ray, only 342 received a report and only one of these was abnormal. The data may not have been fully analysed.

The same study also investigated the prevalence of diabetes among TB patients: of 1,402 TB patients, 23 (2.2%) were found to have diabetes, which is not consistent with the diabetes prevalence given for Sri Lanka. However, in a smaller study of 112 patients with TB in Ampara, 10 (8.9%) were found to have diabetes[13].

Smoking approximately doubles the risk of TB[14] and is likely to be having a significant effect on TB in Sri Lanka: an estimated proportion of male tobacco use in 2012 was 29%[15].

Malnutrition and under-nutrition are thought to be significant risk factors for tuberculosis[16]. Malnutrition is still prevalent in Sri Lanka: 9.6% of children under 5 years of age were stunted, and

[9] A.K.S.B. De Alwis, S.D. Samaraweera, N.C. Pallewatte, T.M. Ambagahage. Prevalence of sputum positive tuberculosis among convicted prisoners in Sri Lankan prisons and its contributory factors. Unpublished abstract.

[10] WHO Diabetes Country Profile, 2016 http://www.searo.who.int/srilanka/lka_en.pdf?ua=1

[11] WHO, Sri Lanka. 2016 SDG Health Profile.

[12] S. Samaraweera. 2013. Piloting and scaling-up of TB and diabetes collaboration in Sri Lanka. Incomplete and unpublished.

[13] Rajapakshe W, Isaakidis P, Sagili K, et al. Screening patients with tuberculosis for diabetes mellitus in Ampara, Sri Lanka. Public Health Action, 2015; 5: 150-152.

[14] Gajalakshmi V, Peto R. Smoking, drinking and incident tuberculosis in rural India: population-based case-control study. Int J Epidemiol. 2009 Aug;38(4):1018-25. doi: 10.1093/ije/dyp225. Epub 2009 Jun 4.

[15] http://www.who.int/ncds/un-task-force/sri-lanka-mission-october-2015/en/

[16] J.P. Cegielski and D.N. McMurray. The relationship between malnutrition and tuberculosis: evidence from studies in humans and experimental animals. Int J Tuberc Lung Dis 2004: 8(3);286–298

12.2% wasted in 2015[17]. These levels of malnutrition would be expected to lead to an increased incidence of TB in those affected.

2.1.6 Treatment outcomes

Treatment success for all forms of TB fell below the 85% target of the old WHO Stop TB strategy in 2012, and has not exceeded that level since. The case fatality and default rates were 6.8% and 4.2%, respectively, in 2015. These are both quite high and may reflect, in the case of mortality, the relatively advanced age of the majority of patients and their likelihood of co-morbid conditions. The default rate, which is especially high in the Colombo Municipal Council area (9%), may reflect persistent problems with stigma (which informants regularly mentioned to the Review Team), as well as weaknesses of the Programme – doubtless among other factors.

2.1.7 Conclusions

The Epidemiological Review concluded that Sri Lanka needs a more accurate system for monitoring and evaluating performance in TB control and it provided prioritised recommendations to achieve it (see the Epidemiological Analysis). It also identified the following current needs in the NTP:

- to improve case finding,
    - to screen patients systematically in out-patient departments (OPD),
    - to introduce presumptive TB registers,
    - to improve the yield of contact tracing,
    - to increase smear microscopy rates especially in low-performing districts
    - to increase lab staff for smear microscopy
- to assess the role of the private sector in case management (including case finding)
- to address the low yield of active case finding among key populations,
- to improve treatment success rates
- to improve coordination with NCD programmes, notably with diabetic clinics.

These issues will all be addressed in this Review Team's observations below.

The most important conclusion of the Epidemiological Review, however, was that the current Programme does not possess the capacity to achieve the End TB Targets by 2035. To do so will require substantial and radical change. This mid-term review aims to lay out what such change looks like.

2.2 Management of the Programme

2.2.1 Background

The history of tuberculosis control activities in Sri Lanka goes back to 1910. A vertical TB control programme was established in 1945, linking several chest hospitals and district chest clinics. In 1980, the programme was renamed the Respiratory Disease Control Programme (RDCP). The national plan for prevention of tuberculosis was implemented from1988 to 2000, and the DOTS strategy was introduced in 1996.

The name of the RDCP was changed again in 2001, to the National Programme for Tuberculosis Control and Chest Diseases (NPTCCD), with a wider scope of controlling all chest diseases. Several medium-term plans were implemented by NPTCCD and the National Strategic Plan for Tuberculosis Control 2015-2020 was developed and implementation has been ongoing for the last two and a half years.

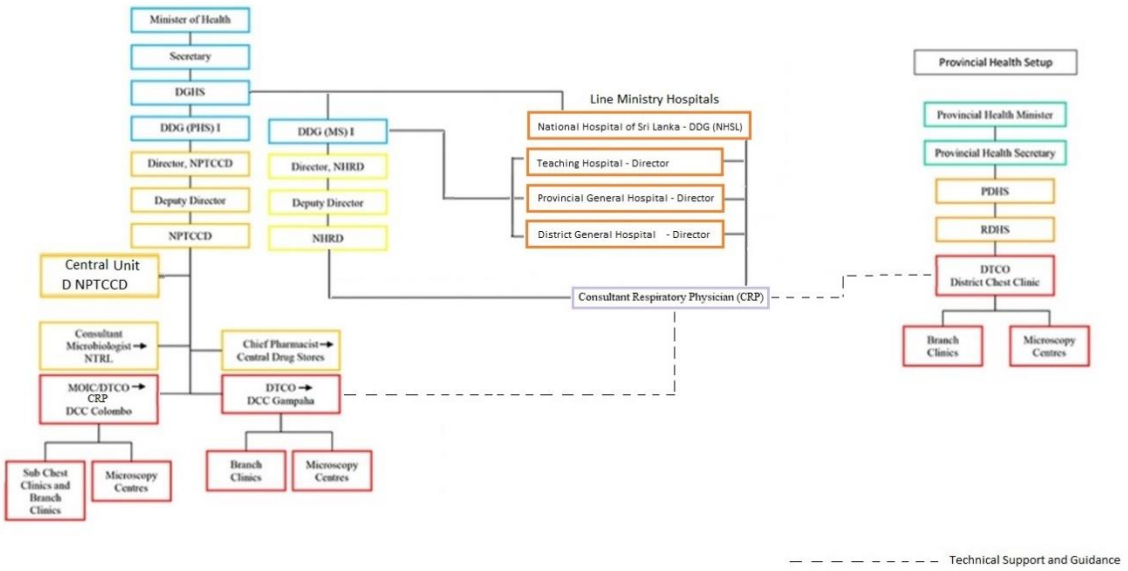
[17] Ibid. WHO Sri Lanka.

2.2.2 Structure of the NPTCCD

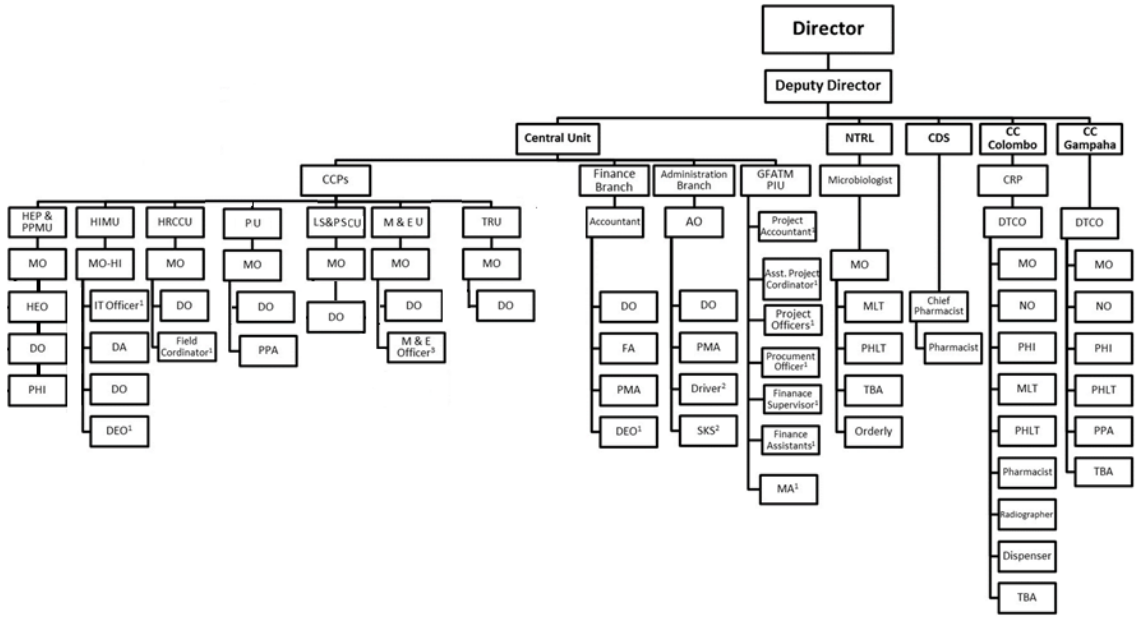
The National Programme for Tuberculosis Control and Chest Diseases (NPTCCD) is a decentralized control programme of the Ministry of Health and has a national level directorate, technical and general support staff, as well as project staff to implement special funded projects. The national directorate implement their activities through DTCOs and District Chest Clinics (DCC). This network is supported by a countrywide network of teaching hospitals (20), provincial general hospitals (4), district general hospitals (19) and district base hospitals, type A (27), and type B (44). All these hospitals are equipped with X-ray facilities, microscopy, bacteriology, including culture, and other laboratory facilities. The Programme is also supported by the dedicated hospital for tuberculosis and chest diseases (NHRD) at Welisara, Gampaha and separate tuberculosis and/or isolation wards in all the above mentioned large hospitals. All the above hospitals down to district base hospitals Type A, have consultant respiratory physicians (CRPs) who conduct daily chest clinics, visit the DCC periodically, and provide technical support to the DTCOs. Whenever they diagnose tuberculosis cases they are referred to the DTCO for treatment.

The DTCO is responsible for all tuberculosis control activities of his/her district and is supported by a Public Health Inspector (PHI), Nurses, Pharmacist/Pharmacy Assistant, Public Health Laboratory Technician and/or Tuberculosis Assistant, Data Entry Officer and other general staff to run the clinic and investigations in the district. In some districts the DTCO also has Medical Officers (MO) working with them. The main cities like Colombo, Gampaha, Kalutara, Kandy, Galle, Rathnapura, and Jaffna have more than one MO, whereas some small cities have none. The Programme has requested an increase of the MO cadre. The DTCO is responsible for ensuring the diagnosis of TB patients, screening of contacts, examination of referred patients from other hospitals and the private sector, attending monthly conferences of the MOH, and training of medical officers (MO) and public health staff.

Organizational Structure of the National Tuberculosis Control Programme of Sri Lanka



Organizational Structure of National Programme for Tuberculosis Control and Chest Diseases(NPTCCD)



2.2.3 Central Unit planning and coordination

There appears to have been a very partial response, at best, to the recommendations made by the Joint Monitoring Mission (JMM) of 2010. As a result, many of the 2010 recommendations were repeated in the JMM of 2014. In addition, international developments, such as the development of the End TB Strategy, the increased emphasis on childhood TB and collaboration with the private sector, meant that there were significantly more recommendations in 2014.

The JMM 2014 recommendations were largely captured in the NSP 2015-2020 (drafted by a consultant) but only partially implemented (see 3.3). Concerns about how the NSP, 2015-2020, was going to be implemented led to another consultant being asked to prepare a more detailed Operational Plan (an Operational Plan is recommended by WHO), which multiplied the 175 activities of the NSP into a list of 286 sub-activities (with several activities still marked as requiring further discussion before sub-activities could be identified). This Operational Plan was not discussed with NPT staff sufficiently to get their buy-in and has therefore not been fully implemented. In any case, just preparing another plan did not address the major problem, which was that the NPT had insufficient motivated staff with the right training to carry out the activities.

More energy is spent in the NPT on planning and reporting, than on doing. There are multiple plans developed by NPTCCD for different purposes. The National Strategic Plan has 5 objectives, 56 interventions and 175 activities to be implemented between 2015 and 2020. The Global Fund Implementation Plan, prepared in 2015, has 370 activities and sub-activities distributed under the 5 objectives of the NSP. Table 3 shows a mapping of the activities/sub-activities of the Global Fund plan to the NSP objectives. Most of the activities are linked to objectives 1, 2 and 5 which are case detection, treatment and programme monitoring. A third plan, the “End TB 2020 – Strategic Plan” was developed in 2016 under three strategic directions which consists of only 42 activities. The DDGHS requested this strategy after a SEARO meeting in 2016. It differs substantially from the NSP, and is much weaker as a planning tool since many of the activities described are wishes, rather than precise actions, eg “2.2.7.2. Ensure notification and investigation of all TB cases at all levels”.

Table 3. Activities and sub-activities of Global Fund proposal mapped to National Strategic Plan 2015-2020

Objective	No of Activities	Percentage %
Objective 1: To improve the TB control by detecting at least 80% of incident TB cases …….	153	41
Objective 2: To improve the outcome of enrolled TB patients ……	53	14
Objective 3: To integrate TB control activities in to general healthcare system …….	18	5
Objective 4: To improve the accessibility to TB treatment and care by engaging 40% of all private health care providers ……..	26	7
Objective 5: Ensure that quality TB services in line with current international standards are provided by qualified and regularly supervised personnel ……..	87	24
Other*	33	9
Total	370	100%

Other* = Activities are not coming/related to any of the 5 objectives of NSP.

The NPTCCD has developed a Monitoring and Evaluation plan (M&E plan) as an element of the GF Implementation plan. This M&E plan has 96 indicators covering input, process, output and outcome indicators. The process of monitoring is through quarterly DTCO review meetings, but monitoring is incomplete (see 3.3).

Coordination with other key stakeholders needs to be improved. The coordination between private sector, professional and clinical colleges, medical, nursing and "Professions Supplementary to Medicine" (PSM), which includes pharmacists, physiotherapists, radiography technicians etc) needs to be strengthened. Engagement of the NPT with consultant respiratory physicians (CRPs), general physicians, paediatricians and MOs in OPDs also needs improvement. The leadership given by the Provincial Directors of Health Services (PDHS), provincial health chiefs, Deputy Provincial Directors of Health Services (DPDHS), and district health chiefs to tuberculosis control is not prominent. The NPTCCD needs to get them actively involved in the process of ending TB in Sri Lanka. The NPT appears to lack the staff with the skills, motivation, training, and perhaps time, to establish cooperative and productive relationships with these different groups in the health sector. The Director cannot and should not be expected to be the sole person responsible for these activities.

The NPTCCD Central Unit structure, and many of their activities, are more aligned with administrative and reporting needs than with what needs to be done, as expressed in the NSP, 2015-2020.

2.2.4 District level management

A DCC should be equipped with an adequate number of Medical Officers and Public Health Inspectors. It was reported to the Review Team that, in some places, one DTCO was doing all the clinical and preventive work in the district. In Kalmune, Killinochchi and Mulathivu, for example, there are no CRPs. One DTCO and one PHI cannot perform all the work required at the DCC, while also conducting effective contact tracing and screening (see 2.3.2), as well as recording and reporting, and attending MOH Conferences for monitoring and updating knowledge of public health staff.

The provincial and regional authorities appear largely uninvolved in TB control activities, leaving the DTCO the main responsible person in the periphery. The DPDHS could take more leadership of

conducting monthly review meetings to measure the progress of achieving targets in the district and support logistic requirements.

2.2.5 Training

Nurses' training on TB was described as "out of date". Doctors have some, but relatively little exposure to TB as undergraduates, with a lot of variability between the colleges. One week's exposure to the NPT is included. TB is already merged into modules of training for respiratory diseases. However, there is no follow-up once the doctors have been trained, and very little in-service training.

2.2.6 Financial resources and flows

TB control in Sri Lanka is supported by the Government of Sri Lanka (GOSL), The Global Fund, WHO, the World Bank, and until recently, the South Asian Association for Regional Cooperation (SAARC). In 2016, the total allocation was about US$ 6 million, with a significant budget gap, according to data submitted by the NPTCCD to WHO. The most significant source is the Global Fund, followed by the GOSL (Table 4a,b,c). For other sources of funds please see Annex 1. The proportion of the allocated funds that has been spent has varied considerably by year, but there have been significant underspends in recent years. In 2016, 39% of the allocated Global Fund budget was disbursed. There is also the suggestion of a trend towards lower spending more recently, which may relate to management limitations at central level. Expenditure of Global Fund support in 2017, seems set to exceed the proportion spent in 2016. This may, though, be related to the lower level of allocation on the part of GOSL for 2017, with more rapid use of Global Fund monies in order to compensate.

Table 4a. GFATM (USD)

Year	Allocation	Expenditure	Percentage (%)
2012	1,680,259.00	1,238,967.17	73.74
2013	1,893,515.00	573,944.97	30.31
2014	1,006,203.00	596,058.64	59.24
2015	927,220.00	754,435.51	81.37
2016	3,863,223.72	1,522,400.03	39.41
2017*	2,140,511.55	765,987.96	35.79
Total	11,510,932.30	5,451,794.28	47.36

Table 4b. Allocations and expenditures, 2012-2017, of funds from the Ministry of Health for GFATM Local Component (USD) (Vote 17).

Year	Allocation	Expenditure	Percentage (%)
2012	---	38,837.78	---
2013	38,726.70	33,042.55	85.32
2014	50,474.65	6,843.89	13.56
2015	110,344.59	23,012.36	20.85
2016	115,039.92	11,008.30	9.57
2017*	461,924.24	66,575.74	14.41
Total	776,510.10	179,320.63	23.09

Table 4c. Funding Source: Ministry of Health (Govt) Allocation (LKR) (Welisara Chest Hospital not included)

Year	Allocation	Expenditure	Percentage (%)
2012	96,125,000	101,438,883.35	105.34
2013	153,454,006.99	158,583,757.92	103.34
2014	220,927,245.23	213,715,748.91	96.74
2015	243,798,125.13	214,312,230.71	87.91
2016	317,247,058.56	264,725,623.44	83.44
2017*	173,304,640.00	91746,157.95	52.94
Total	1,204,856,075.91	1,044,522,402.28	86.69

*= Expenditure up to June only

Expenditures of Global Fund allocations rose significantly in 2016, but this is almost entirely accounted for by a nearly 50% increase in staff costs (Table 5) compared to 2015.

Table 5. Expenditures of Global Fund allocations by expenditure component, 2013-2016

Component	2013	2014	2015	2016
Human Resources	319,166.00	318,153.00	287,940.00	422,559.00
Travel Related	---	---	---	88,739.00
External Professional Services	---	---	---	62,378.00
Non Health Equipment	---	---	---	17,573.00
Technical Assistance	1,006.00	20,277.00	2,249.00	---
Training	20,473.00	66,713.00	20,089.00	---
Health Products and Health Equipment	22,851.00	15,970.00	65,991.00	1,601.00
Medicine and pharmaceutical Products	13,496.00	---	---	---
Procurement and Supply Management	2,582.00	3,425.00	2,296.00	4,681.00
Infrastructure and Other Materials	45,670.00	12,908.00	447.00	48,449.00
Communication and Other materials	14,243.00	23,838.00	---	---
Monitoring and Evaluation	12,789.00	2,544.00	1,430.00	---
Planning and Administration	2,808.00	214.00	3,938.00	18,900.00
Overheads	46,212.00	55,004.00	11,792.00	---
Depreciation -property, Plant & Equipment	---	---	128,643.00	66,277.00
Gratuity Expenditure	---	---	8,965.00	40,542.00
Other	5,200.00			
Total	506,496.00	519,073.00	533,779.00	771,640.00

2.2.7 Priority recommendations

1. **DGHS/MOH should urgently strengthen the NPTCCD Central Unit** with 2 appropriately trained and committed community physicians and 4 medical officers with at least post-graduate qualifications in community medicine, including a full-time epidemiologist to

support M&E and surveillance. The Director should clarify the policy directions of the NPT and the planning approach used.

2. **Director, NPTCCD, should make sure there is only one policy, one plan and one surveillance system. The Director needs to lead a change in culture at the NPT Central Unit which should focus more on carrying out TB control activities, and less on planning and reporting.**

2.3 Case-finding

Following the Epidemiological Review carried out in June, 2017, the Review Team concludes that the priority issue for TB control in Sri Lanka is the worrying gap of some 4,000 cases between the estimated incidence of 13,000 cases and the numbers of patients notified with TB. A lower than expected level of case notifications can be due to under-reporting (of cases diagnosed, but not reported in either the public or private systems), or under-diagnosis. The former is largely addressed in the epidemiological review and assessment of the surveillance system. Here we will focus on under-diagnosis, and will address under-reporting only in association with the private sector.

2.3.1 TB detection in out-patient departments (OPD)

Lack of microscopy facilities in hospitals

Among the 20 teaching hospitals in Sri Lanka, only two have a microscopy service in the OPD (Colombo South and Kandy Teaching Hospital). It is inefficient (and negligent) for such hospitals to be unable to carry out such a simple test in-house, when thousands of patients attend each day. The National Hospital, Sri Lanka, is reported to see 4-5,000 out-patients per day. A large proportion of presumptive TB patients is likely to attend these hospitals. For patients to be told to go to a DCC to have their sputum checked risks having them default on the way to the Clinic, or going instead to the private sector. The reason behind this unusual situation appears to be stigma, and the apparent desire to dispatch out of the hospital any person suspected of TB as rapidly as possible.

We observed that sputum collection areas are sometimes off-putting (mere gaps between buildings), and properly designed cough booths are not always present. Their absence is sometimes used as an excuse for the lack of microscopy.

Staff deficiencies and organisation of patient flows in OPD (triage)

Insufficient laboratory staff undoubtedly underlie this gap in capacity to some extent, especially in smaller hospitals, such as base hospitals, as the Team observed in Batticaloa district. The same problem may be responsible for the fact that none of the 17 government hospitals in the plantation sector has microscopy facilities for TB. Until recently, 3 out of 12 microscopy centres in hospitals and clinics run by DCC, Colombo, were closed through lack of a Public Health Laboratory Technician (PHLT). Moreover, lack of staff also affects more modern technology: at least one GeneXpert machine (TH Batticaloa) was out of use during the mission because of lack of a technician.

Many OPDs request sputum examination for TB on only a tiny proportion of OPD attendances (0.1% in some cases). While the proposed 2% target for requesting sputum microscopy may be excessive, and the data do not make clear what the right figure should be, below about 1% seems insufficient. It appears that MOs and registered medical officers (RMO) working in OPD rarely suspect TB or request sputum microscopy themselves.

Few MOs or RMOs are specifically trained in respiratory diseases. Of the 60 or so doctors trained each year in the Post Graduate Institute of Medicine's course for the Diploma in Tuberculosis and Chest Diseases (DTCD), very few go on to work in that specialty. However, this provides an

opportunity: if more of them were posted to work in OPD, and patients were triaged on the basis of cough, then appropriate diagnostic procedures and care could be provided to out-patients with respiratory symptoms. The respiratory-trained MOs (or the nurses working with them) could keep the Presumptive TB Register, and so ensure that patients sent for tests came back with their results. There is a precedent for such an approach. During the current dengue epidemic, patients in OPD are being triaged on the basis of fever and sent for lab tests.

In some instances, eg Castle Street – there are low levels of referrals (0.5%), yet high rates of sputum positivity (6.3%), which suggests that more referrals would likely yield more cases.

Demarcation disputes, closed shops and special interests also limit efficient use of staff for microscopy. For example, Medical Laboratory Technicians (MLT) and public health laboratory technicians (PHLT) working for the Malaria Programme, although trained in microscopy are reluctant to do sputum smears for TB. The TB Assistants, a cadre hired through support from the Global Fund, have been used to overcome this problem in some areas. They are due to be phased out in 2018, which will only exacerbate the current problem unless solutions are found.

2.3.2 Contact tracing

Household contact screening is not carried out in all cases, even in well-run districts. In Q4, 2016 for example, 3,429 contacts were screened, out of 4,118 contacts that were identified. On the face of it, this is 83% of contacts screened. In reality however, from the > 2,000 cases diagnosed in that quarter, there should have been around 6,000 contacts to be screened, given that the average household size is 3.9 people per household[18]. Thus, half as many again of contacts should have been screened, if the Programme Manual recommendations had been followed[19].

When contact tracing is performed, it is done mostly by the PHIs. While some of the PHIs working in the DCC have some training in this activity, some do not, and in any case much of the tracing is referred to the "range PHIs" in the office of the Medical Officer of Health (MOH), who generally are not so trained. The Programme Manual advises that only contacts with symptoms should be investigated, apart from children under five, who should be examined and receive a chest X-ray. "Symptoms" is usually interpreted as a cough lasting 2 weeks or more. Tuberculin skin test (TST, usually it is the Mantoux test that is performed) is not routinely done and hence isoniazid prophylaxis is rarely given, although data on this were unavailable. Thus, only a small minority of the identified contacts is fully investigated. The sensitivity of the process is thus low.

Moreover, in prevalence surveys in several Asian countries, the percentage of sputum positive cases that did not screen positive on reported TB symptoms ranged from 34% in Lao to 68% in Vietnam. Among bacteriologically positive cases, the proportion that did not screen positive based on reported TB symptoms was even higher, ranging from 40% in Pakistan to 79% in Myanmar[20]. If the same situation pertains among contacts in Sri Lanka (and there is no reason to suppose that it would not), the procedure of contact tracing is seriously flawed.

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18 ArcGIS. Sri Lanka Average Household Size.
www.arcgis.com/home/item.html?id=b899ee4d428c45328dfc0b9f27ba6a3f Accessed 20 July 2017

[19] Ministry of Health, Nutrition and Indigenous Medicine/NPTCCD. National manual for tuberculosis control (p. 93). 2016.

[20] Onozaki I, Law I, Sismanidis C, Zignol M, Glaziou P, Floyd K. National tuberculosis prevalence surveys in Asia, 1990-2012: an overview of results and lessons learnt. Tropical Medicine and International Health, 2015; 20: 1128-1145.

2.3.3 The role of consultant respiratory physicians (CRP)

In the last 5 years, the proportion of clinically diagnosed pulmonary cases (the smear negative) among the total number of pulmonary cases ranged from 29.8% to 31.7%. This is low compared to other countries in the region where clinically diagnosed cases are in the range of 36-61% of pulmonary cases. A low proportion of clinically diagnosed cases means that smear negative cases are being missed. Their condition will worsen before the diagnosis is eventually made (if at all), become smear positive and be more likely to transmit the disease to their contacts. Linked to the fact that many DTCOs appear to refer many, if not all, smear negative, presumed cases to the CRPs, these figures suggest that CRPs are reluctant to diagnose TB clinically.

From discussions with some CRPs, they agreed that medical staff too readily see tests for TB as exclusionary – that is, if they are negative, the staff assumes that the patient cannot have TB. This even happens with sputum smears. They agreed that too few chest X-rays were performed on presumed TB cases. (Some patients are being charged LKR 200 for a chest X-ray, as a step to limit demand on insufficient radiological facilities). They complained of the lack of knowledge about TB among the MOs. However, they did not appear to feel responsible for correcting these situations and ensure proper training of the MOs, even though they recognized that patients in Sri Lanka have extensive disease when they are finally diagnosed, which is additional evidence that the national health system is not efficiently diagnosing TB.

In Batticaloa, 50% of cases referred to the DCC had already seen a CRP, and 50% of cases arrived with a diagnosis. It would be more efficient to start treatment on these cases in the hospital clinics where they were diagnosed rather than referring them. In Batticaloa the distance between the Teaching Hospital OPD and the DCC is only about 200 metres. In other places, however, it may be considerably further, thus increasing the risk of patients defaulting.

2.3.4 Coordination with other Health Programmes

Cadres of staff that could relatively easily assist in finding cases are not involved in TB care, in spite of recommendations to do so in the 2014 JMM. For example, the Public Health Midwives (PHM) who carry out maternal and child health duties principally through house to house visits, could easily and rapidly enquire if anyone within the household has a cough lasting more than 2 weeks, or is losing weight.

Around the world, most NTPs collaborate more or less closely with the local national AIDS Programme. There is some collaboration in Sri Lanka, but in spite of the tiny number of cases of HIV-associated TB, there are still significant discrepancies in the reported figures coming from the two programmes, suggesting there is something still to do to improve coordination.

Likewise, most NTPs collaborate with NGOs or community based or civil society organisations. Such collaboration seems to be confined to work with the National Association for the Prevention of TB (NAPT)

Other than the two research projects on TB and diabetes mentioned above, no systematic overtures have been made to the diabeticians to establish an effective collaboration. We did not explore childhood TB in much detail, but saw little evidence of constructive collaboration with the paediatricians in spite of the fact that childhood TB is recognized as being under-reported, and the 2014 JMM recommended more collaboration.

2.3.5 Organization of DCCs

At present, the majority of patients suspected of having TB are still referred to the local DCC. In many places, including Colombo, this may entail a journey of several kilometers. This happens even

in large hospitals that should have the capacity to diagnose TB. It results in out-of-pocket costs for patients and may well be a cause for loss to follow-up. These negative effects impact most on the poor, some of whom "do not have the money to go even a kilometer." There is no available source of financial support to provide funds for transport for patients. The very good, and available, primary and secondary health care network in Sri Lanka is being underutilized, at the expense of patients and of the public health.

The policy of decentralization, recommended by the 2014 JMM, and with initial attempts to carry out a pilot in 13 districts, has not worked. The "Guidelines for the integration of TB care facilities into general health care institutions" were detailed and accurate, but were too cautious, placed too much responsibility on the DTCO, and approached the issue as a pilot study. Adequate high level support was necessary in order to make the required change, especially among hospital directors, but was not consistently provided by the Central Unit. Poor support for the changes on the part of peripheral staff were also reported.

A lesser form of decentralization - branch clinics - involve the staff of the DCC translocating to a peripheral facility to carry out review of presumed cases and follow-up of DOTS patients. This typically involves one MO, one PHLT and one dispenser and is thus a resource-intensive approach. Further, if this effort acts as a disincentive to install laboratory facilities in hospitals and dispensaries, or set up a sputum collection point, it is even more inefficient.

The Review Team frequently encountered the statement "Decentralisation has not worked". Lest it be concluded that decentralisation has failed, it has not, in reality, been tried. It has been neither properly designed, nor implemented.

2.3.6 Active case-finding among key populations

Active case finding (ACF) efforts are poorly targeted and at risk of wasting resources. NPTCCD's ACF efforts screened over 32,000 people in 2016, and resulted in only 17 cases – all of whom were prisoners[21]. The groups screened included several in whom an increased prevalence of TB would not be predicted, such as medical students, government officers, PHIs in training, "hospital staff and patients", "community", army recruits, school children etc., as well as the elderly, drug users, and prisoners, in whom a higher prevalence is more likely, based on studies in Sri Lanka and elsewhere. Estate workers, returning refugees, and nurses are groups in whom the prevalence in Sri Lanka is unknown and who may be at higher risk. The groups appear to have been selected largely on the grounds of convenience.

In Colombo the DCC conducts ACF in the general population every two weeks in high TB rate areas. About 200 cases are screened each trip, amounting to some 5,000 cases annually, from which only 4 cases have been found in over 18 months of operation. WHO recommends ACF only in populations in which the prevalence is known to be about 1% or greater[22]. In Sri Lanka this applies at present only to prisoners. (Household contacts and PLHIV are automatically included as high risk groups since among children and the immunosuppressed the risk of poor outcomes if TB is not diagnosed on time is high.)

[21] NPTCCD. Feedback on screening awareness and advocacy programmes, 2016 (Excel file).

[22] WHO. Systematic screening for active tuberculosis: principles and recommendations. WHO, Geneva, 2013. And WHO. Systematic screening for active tuberculosis: an operational guide. WHO, Geneva, 2015.

The situation with diabetics is confusing in Sri Lanka (see 2.1.5), and requires urgent clarification, either through careful re-evaluation of the data in the unfinished large study from Colombo and Kandy, or through new studies, or both.

Meanwhile, entry screening is not being routinely carried out in prisons, which is a basic measure to protect public health in prisons[23].

2.3.7 The private sector

Cases are found in the private sector and referred to local DCCs. At Colombo DCC, 12% of patients were referred by private hospitals in 2016. Surprisingly, few patients appear to be referred by private general practitioners (GP): less than 1% in Colombo DCC. This may reflect the fact that most private doctors work also in the public sector and, instead of seeing presumed cases of TB privately, might simply have referred them to the DCC.

The recommendations from the 2014 JMM that advised the NPTCCD to address the private sector, and involve NGOs in TB control, have, for the most part, not been followed. In particular, a Working Group on Private-Public-Mix (PPM) activities has not been set up. Some reassurance appears to have been derived from the fact that anti-TB drugs are not generally available in private pharmacies. It has been assumed therefore that any patients diagnosed in the private sector would be notified in the public sector in order to be able to obtain drugs. However, drugs are obtainable through India and via the internet, and at least two physicians working in the private sector assured us that treatment was taking place there. To what extent is unknown, but to the extent that it is happening, it appears that there is no reporting of these cases to the NPTCCD. This raises the question of how private practitioners could be persuaded to report these cases. The End TB Strategy 2016 has only two activities relating to the private sector:
"1.1.2.2.a. Conducting training programms for staff in private health care facilities to improve the case detection. [and]1.1.2.2.b. Orientation programms for Hospital management, staff and individual GPs" How these programmes are to be put together, what content they will have, who will provide the training, how their effectiveness will be ensured, and how the private sector's collaboration will be obtained are not addressed.

What is surprising about the Sri Lankan private sector is how little appears to be known about its TB-related practices. However, it should be assumed that some of the missing cases will be in the private sector.

2.3.8 Conclusions and recommendations

To reach the End TB targets on incidence, much earlier case finding must be achieved in order to limit the transmission of disease from each case. This is a major issue for the TB Programme. Failure to suspect TB at the point of presentation, and failure to request the correct tests, leads to delays in diagnosis. This increases transmission in the community and progression of disease in the individual. The result is, as consultant respiratory physicians report, that many patients present very late, with extensive disease. The review team heard reports of patients presenting up to 22 times before the diagnosis was made, unfortunately with fatal consequences in the most extreme cases. The solution to this problem is to train the front-line medical staff to request sputum examination in every patient with cough, and supervise and monitor until the result is obtained. Some consideration may

[23] Tuberculosis Coalition for Technical Assistance and International Committee of the Red Cross. Guidelines for TB Control in Prisons. 2009. USAID, Washington DC, USA.

also be given to awareness campaigns for the general population – as long as they clearly inform people that a cough lasting 2 weeks or more requires a sputum test for TB.

Some obvious recommendations follow, based on these findings. Hardly any of these recommendations is new. Almost all have been made before, in either the 2010 or 2014 JMM, or both. It is striking how little response there has been to many of them, which raises concerns about the management capacity of the NPT and the Ministry.

1. **The DGHS and NPT should ensure patient-centred services are provided. It should become MOH policy that all hospitals without microscopy facilities in OPD should set them up, diagnose TB cases, register them (through a telephone call to the DTCO) and initiate treatment on bacteriologically confirmed cases.** DTCOs should provide constant supportive supervision. NPT staff will need to drive this change and convince hospital directors to take appropriate action.

2. **The Director, NPTCCD, should make the case for increasing the sensitivity of the diagnostic process, by accelerating the availability of MTB/RIF testing and digital radiography for the diagnosis of TB (and not just for the diagnosis of MDR-TB) so that all districts and all patients have access to these tools. The Global Fund should support this process, by budget re-allocations if necessary, within the limits of the 2019-2021 allocation. This will also help achieve the End TB goal of universal drug susceptibility testing for all TB patients.**

3. **The DGHS should expand the cadres of laboratory technicians.** The plan to phase out TBAs in 2018 should be reconsidered in areas of high need. Underworked PHLTs/TBAs who are performing a small number of slides per day should be moved to facilities with a higher workload. The DGHS should also take steps to reduce the reluctance of MLTs to do sputum microscopy. Malaria and filariasis technicians should be brought in to assist in TB diagnoses (and vice versa where necessary). Performance incentives should be considered as a means to effect these changes.

4. **The DGHS and NPT should further increase the rate of referrals for sputum examination from OPDs by:**
    a. Organising in-service training of MOs and RMO in OPD including clear information on the screening criteria for TB;
    b. Promoting the triage of patients with cough and other respiratory symptoms to be seen by one MO with the Diploma in Tuberculosis and Respiratory Diseases. This has the added advantage of improving infection control in OPD.
    c. Ensuring the presumed case registers are properly kept – that is, put the lab results into the register when available, and if they do not come within an appropriate time, initiate tracing of the patient to ensure that her/his sputum has been examined.
    d. Defining a target of 2% to be applied to the proportion of all OPD patients referred for sputum examination. Consider some system of reward for those that meet the target.
    e. Making Hospital Directors responsible for achieving these targets and hold them accountable for the results.

5. **The DGHS, DDGHS (PHS) and NPT should urgently strengthen contact tracing activities** by setting targets for the PHIs and DTCO to find all contacts, and refer them to the DTCO for examination. Increase the sensitivity of contact screening by performing chest X-rays on all.

6. **The NPTCCD should stop, with immediate effect, all active case finding in populations where a 1% (approximately) prevalence rate of TB has not been demonstrated**, with the exception of household contacts and PLHIV. Resources thus saved should be used elsewhere.

7. **The NPTCCD should start a programme of work that aims to understand how the private sector deals with TB, and set up a Private-Public Mix Working Group (as recommended by the 2014 JMM) to engage the private sector in discussion on TB management, especially case-notification.** The questions about the private sector's activities in TB will be addressed in Section 5 on operational research.

8. **The NPT Central Unit should set up 2-3 pilot districts, in collaboration with provincial and regional health directors. The aim is to prove that addressing the challenges above can significantly increase case finding within one year, and improve treatment outcome.** Remaining districts will learn from these pilots and will eventually follow themselves. Criteria for selection should be developed, and a priority list of activities defined for each district, based on the analysis in this report.

2.3.9 What has not – yet – been recommended

As discussed above (2.1), it is not clear if the incidence of TB is falling, but sooner or later it will. This raises the question of what level of incidence would justify the integration of all activities of the DCC into the general health system, predominately the respiratory medicine departments – similar to what has happened in most high income countries. In such countries, integration has significantly reduced the costs of having two parallel systems (one for respiratory diseases, one for TB), when one would be enough. The current estimated incidence of 65/100,000 is close to the level at which this integration occurred in Western Europe.

Why then do we not recommend it now? Because it is not clear that the general health system would have the capacity to manage it, largely because of the problems in the OPD, but also because the CRP cadre, which would have to lead the process, is mostly concentrated on clinical care and not well attuned to the needs and demands of public health. CRPs are also too sensitive to the stigma surrounding TB, preferring to dispatch TB suspects or cases as quickly as possible to the DCCs, but that is something that could be addressed with training, and would likely improve through the integration process itself, and should not be seen as something that must be improved before integration can start. There would need to be a review of the roles and responsibilities of the CRP cadre, involving the CRPs themselves in discussions, bringing them on board, and making changes to their pre-service and in-service training content. Performance incentives may be required.

2.4 Treatment

2.4.1 Observations

The national treatment success rate (TSR) is below the WHO target of 90%, and since 2012 has even been below the old 85% target of the Stop TB strategy (see 2.1.6). Although the intensive phase was reported as largely observed by health workers, in the continuation phase, family DOT is widely used and even self-administered treatment.

In many parts of the country, although not in Colombo, 50% of patients are admitted for a few days as a routine. Unless clinically indicated, which is usually not the case, admission is contraindicated and not in line with WHO recommendations.

Category II treatment is still provided to patients who require retreatment. WHO recommended in 2017 that: *"In patients who require TB retreatment, the category II regimen should no longer be prescribed and drug-susceptibility testing should be conducted to inform the choice of treatment regimen.*[24]*"*

2.4.2 Conclusions and recommendations

The chief concerns are the low treatment success and high default and fatality rates. If the End TB mortality targets are to be reached, the follow-up of patients demands substantial improvement. (Case finding needs to be more efficient too, to avoid late presentation and concomitant poor outcomes - addressed in 2.3) A deeper understanding of the reasons for default and death is needed.

The Review Team was informed that a study of deaths had been made, but that the results were not available. Such studies are important and investigators should be held to account by the NPT management. Failure to do so reflects poorly on the management of the NPTCCD.

The Review Team recommends:

1. **The NPTCCD should urgently phase out Category II treatment in favour of drug susceptibility testing for all patients requiring re-treatment, with provision of a regimen that is appropriate for the resistance pattern found.**

2. **While fatality and default rates are so high, the NPTCCD should clarify the national policy on DOT and make it more, not less, stringent.**

3. **All data on the causes of, and reasons for, death among patients with TB should be pulled together and comprehensively reviewed by skilled TB staff, respiratory physicians and epidemiologists. Recommendations for action should be taken on the basis of the results of this review.**

2.4 Unexploited opportunities

Healthy lifestyle centres are being introduced for the screening and diagnosis of non-communicable diseases, including in some districts, the use of mobile clinics. This represents an opportunity for the inclusion of a simple TB screening question, and referral for sputum examination for all those with cough.

Non-governmental organizations (NGOs) and community service organizations (CSOs) are mostly uninvolved in TB diagnosis, treatment care or prevention. They may be especially useful as partners in TB management in isolated areas/areas with a high concentration of poor people who cannot afford easy access to local health facilities eg plantation sector. Recommendations from the JMMs of 2010 and 2014 to involve them in TB management have not been followed.

Electronic systems to enhance efficiency of TB management have not been properly pursued. The electronic case-based, patient information and management system (PIMS) has not been set up, and, in consequence (we were informed by the Head of the NTRL) the laboratory information and

[24] WHO. Guidelines for the treatment of drug-susceptible tuberculosis and patient care, 2017 update. WHO, Geneva.

management system (LIMS) has not been introduced. These failures represent a significant loss of opportunity – the existent of such systems can introduce significant efficiencies into patient management and into the administrative functions of an NTP. Both PIMS and LIMS systems could be used to send automatic text messages (SMS) to inform clinicians, DTCOs and even the patient of a positive test result, and the need to initiate action and they can help to remind patients to take their medicines. On the administrative side, a case based, web-based system can provide much more detailed data at central level than the current paper-based system which aggregates data from the districts (and introduces significant opportunities for errors) and can generate routinely required graphs and tables for all levels with minimal work. This would free up NPT staff from filling in forms and managing paper, and give them time to devote to managing the key elements of TB control that are currently ignored. It would also enable them to have a fuller, more accurate, understanding of the TB situation.

3. The status of implementation of the National Strategic Plan, 2015-2020

3.1 Assessment of progress against the NSP objectives

3.1.1 **Objective 1:**

To improve the TB control by detecting at least 80% of incident TB cases(all forms) by 2017 and 90% of incident cases by 2020

Incidence is, in fact, impossible to measure, but has been most recently estimated by WHO at 13,000 cases in 2015. If this objective were on track, by mid-2017, an increase in case detection compared to 2014 should have been observed. In fact, the total cases of all types of TB notified fell to 8,886 in 2016, from 9,473 in 2014, a reduction of 6%. It is unlikely, although conceivable, that the underlying incidence fell at the same rate. Progress thus needs to improve.

3.1.2 **Objective 2:**

To improve the outcome of enrolled TB patients

a) By achieving 90% treatment success rate of all forms of non MDR TB patients and;
b) To maintain at least 75% of treatment success rate among MDR TB cases by 2017

The treatment success rate fell below 85% in 2012, and although it has been rising slightly since, has not yet achieved 85%. In the meantime, WHO has recommended a target of 90% to be achieved by 2025. Sri Lanka appears now to be moving in the right direction, but has a way to go.

3.1.3 **Objective 3:**

To integrate TB control activities in to general healthcare system by establishing TB diagnostic and treatment services in 40% of all hospitals up to the level of Divisional Hospitals Type B or above by 2017 and in 80% -by 2020

Integration attempts in 13 districts have established some microscopy and DOT centres, but this activity has faltered (see 2.3.5). Insufficient progress.

3.1.4 **Objective 4:**

To improve the accessibility to TB treatment and care by engaging 40% of all private health care providers (hospitals and General Practitioners) in TB control by 2017, and 60% by 2020

This area of work has been insufficiently addressed and it is not known how many private health care providers there are, nor how many are engaged in TB control. Insufficient progress.

3.1.5 Objective 5:

Ensure that quality TB services in line with current international standards are provided by qualified and regularly supervised personnel at 100% of all implementation sites by 2017

With respect to "current international standards", WHO recommendations[25] are often not followed, e.g. engagement of all care providers, and WHO targets are often not met, e.g. the treatment success rate. "The International Standards of TB Care[26]" appear to be unknown in Sri Lanka. Many OPD staff seeing presumptive TB cases are not specifically trained in TB management, however, the DTCOs generally are. Supervision of the DTCOs and their work is regularly carried out, but does not usually include supervision of OPDs and their staff. Examination of progress of each of the strategic interventions under this objective is mixed – see 3.3 below. Mixed progress.

3.2 An assessment of progress against the strategic interventions and activities

The Review Team carried out a semi-quantitative analysis of the progress under each of the 175 activities that are in the NSP. Our classification is, in general, rather optimistic - that is it tends to conclude that any progress at all is at least partially done, and if most of an activity was done, we classified it as "Done". "Not done" therefore means only negligible, if any, actions were undertaken.

Overall, a positive 64/175 (37%) of activities were already done - the largest single category (Table 6). However, 62 (35.4%) were not addressed at all, while 47 (26.8%) were partially done, making 109 (63%) incomplete. For over a third of activities not to be addressed at all suggests that the NSP is not strongly guiding programme activities.

If we look at the different objectives - the issues come out more clearly (Figure 3). In objective 3 - decentralisation to divisional hospitals - over half (56%) of activities are not addressed at all. In objective 4 - engagement of the private sector - the "not done" category is a massive 77%.

Examining the individual activities, it is apparent that the routine activities essential to keeping the programme going are those that are completed or underway, while in general, anything innovative is either not done or only partially so. Another interpretation is that it is mostly the activities that require establishing programmes of collaboration with bodies or individuals outside the NPT (hospital directors, consultants, private practitioners, directors of associations of doctors) that are not being undertaken. This could be because NPT staff do not feel the need to do so – perhaps they do not feel ownership of the NSP – or do not have the confidence, or the abilities, to be outgoing and establish the necessary relationships with senior professionals outside the NPT.

The recommendations of the JMM 2014 are thus not being followed, and the NSP is not leading positive change. Rather, judging from the discussions with staff, it is mostly ignored, while the country's End TB Strategy is taking up staff time. It seems to be the reporting tools, which are based on the Global Fund modules, that are most motivating NPT staff to action and expenditure. These reporting tools do contain mostly activities that are in the NSP, but are not presented in any

[25] WHO. Compendium for WHO guidelines and associated standards: ensuring optimum delivery of the cascade of care for patients with tuberculosis. 2017, WHO, Geneva. http://apps.who.int/iris/bitstream/10665/259180/1/9789241512572-eng.pdf?ua=1 Accessed 15 November 2017.

[26] WHO. The international standards for tuberculosis care. 3rd edition. 2014, WHO, Geneva.

systematic way that allows one to see at a glance the progress that is being made in each strategic intervention.

3.3 An assessment of progress against the monitoring and evaluation (M&E) indicators

Of the impact indicators in the monitoring and evaluation system for the NTP (which is derived from the M&E Plan of the NSP), the incidence, prevalence and mortality rates are estimated to have fallen slightly since the baseline in 2014. These are estimated by WHO each year and are influenced by the fall in notification figures.

Of the remaining 93 indicators, 26 (27%) were on track to achieve or come close to the 2017 target, and a further 7 (7.5%) were headed in the right direction, although they would not hit the target. Therefore, 33 (35%) were "positive". The same number, 33 (35%) were heading in the wrong direction, while for 27 indicators the data were not reported, or could not be assessed for other reasons. If one excludes the indicators that could not be reported, then those heading in the right direction are exactly matched (50%:50%) by those heading in the wrong direction.

Leaving aside the indicators that could not be reported, objective 1 had 13/21 (62%) indicators on track or moving in the right direction, objective 2, 11/19 (58%) and objective 5 had 9/18 (50%). Objectives 3 and 4, on the other hand had no indicators that were on track or heading in the right direction. This tends to confirm the observations on the NSP activities, namely, that movement towards integration/decentralisation (objective 3) or towards the development of a public:private collaboration were stalled during the first half of the NSP period.

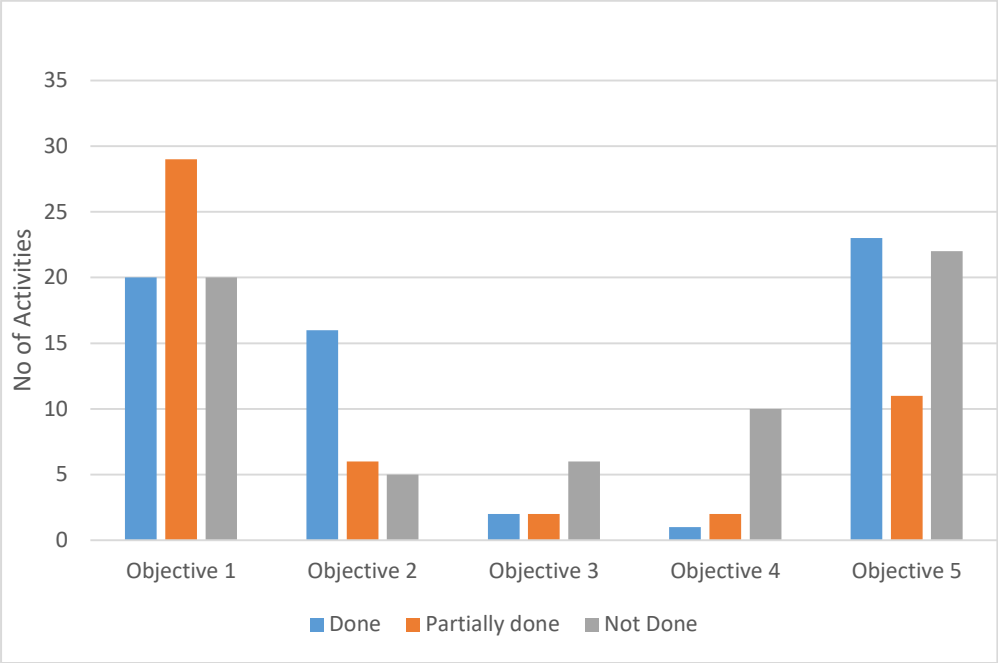
This analysis also showed that multiple indicators effectively measure the same thing, eg the outcome of MDR-TB treatment. Add these to the number that could not be reported, and it would seem wise to cut the number of indicators and reduce the time and energy spent on this work.

Monitoring of progress under these indicators is mostly done at quarterly DTCO review meetings. This process does not appear to work well. The DTCOs focus on case finding and treatment results, and do not appear to have sufficient ownership of the NSP to report on some of the other indicators. The NPT needs a more robust monitoring system, which should be simpler, fully discussed with DTCOs and supported by them. This would improve the quality of data collection, which could still be quarterly.

Table 6. Summary of the assessment of implementation of the NSP, 2015-2020, as of July 23 2017.

Objective	No. of Strategic Interventions	Activities						
		No.	No. completed	%	No. partially completed	%	No. not started	%
1. Detect at least 80% of incident TB cases (all forms) by 2017 and 90 % of incident cases by 2020	17	69	20	29%	29	42%	20	29%
2. To improve the outcome of enrolled TB patients a) By achieving 90% treatment success rate of all forms of non MDR TB patients and; b) To maintain at least 75% of treatment success rate among MDR TB cases by 2017	12	27	16	59%	6	22%	5	19%
3. Decentralize TB diagnostic- and treatment services to include 50% of all Divisional Hospitals (up to Type B) by 2017 and 100% of all Divisional Hospitals (up to Type B) by 2020	4	10	2	20%	2	20%	6	60%
4. Engage 40% of all private health care providers (hospitals and General Practitioners) in TB control by 2017, and 60% by 2020	5	13	1	8%	2	15%	10	77%
5. Ensure that quality TB services in line with current international standards are provided by qualified and regularly supervised personnel at 100% of all implementation sites by 2017	18	56	23	41%	11	20%	22	39%
Total	**56**	**175**	**62**	**35%**	**50**	**29%**	**63**	**36%**

Figure 3. Status of the 175 activities of the NSP, 2015-2020, by objective, at 23 July 2017



3.4 Missing elements of the NSP, 2015 - 2020

Pillar 2 of the End TB strategy includes "bold policies and supportive systems"[27]. The Pillar

- *Strengthens health and social sector policies and systems to prevent and end TB*
- *Supports implementation of universal health coverage, social protection, and strengthened regulatory frameworks.*
- *Addresses the social determinants of TB and tackles TB among vulnerable groups such as the very poor, people living with HIV, migrants, refugees and prisoners.*

These elements are almost completely missing from the NSP, 2015 – 2020, and include the following key components:

A. Political commitment with adequate resources for TB care and prevention
B. Engagement of communities, civil society organizations, and all public and private care providers
C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
D. Social protection, poverty alleviation and actions on other determinants of TB

3.5 Recommendation

The NPT needs to debate and engage in the issues covered by Pillar 2 of the End TB Strategy, and revise its NSP by end 2018. Although very important, the revitalisation of the Central Unit and recovery of sense of purpose in the NPT are higher priority at present, but as progress is made in these areas, Pillar 2 of the End TB Strategy will become increasingly relevant. One of the most pressing issues may be the linking of poorer TB patients with the social protection mechanisms that

[27] WHO. The End TB Strategy. End TB Brochure, 2016, WHO, Geneva. http://www.who.int/tb/End_TB_brochure.pdf?ua=1 Accessed 15 November, 2017.

already exist in Sri Lanka, so that financial and other support can be provided for families that might otherwise fall into catastrophic expenditure when one of their members contracts TB.

4. Progress of implementation of the Programmatic Management of Drug Resistant TB (PMDT)

Progress in implementation of the Programmatic Management of Drug Resistant TB (PMDT) can be judged through the twice-yearly assessments of Sri Lanka's progress provided by the regional Green Light Committee (rGLC). The most recent assessment was conducted by Dr Vineet Bhatia in June 2017 in preparation for the Mid-Term Review. His report was rapidly made available to the Review Team and his findings are summarised here, with particular respect to the assessment of progress in response to previous recommendations. The aims of the rGLC mission were to:

- Review the performance of PMDT including status of implementation of DR-TB diagnostic and treatment services
- Review the status of implementation of recommendations from previous review mission (2016)
- Technical discussions on shorter regimen and use of new drugs for DR-TB
- Planning way forward with support needed for roll-out of shorter regimen and new drugs

WHO estimates that there are 43 cases of MDR/Rifampicin resistant (RR)-TB occurring each year among the notified cases. The target for detection in 2016 was less than half this total, at 20 cases (Table 7). This was partially met – 17/20 (85% of the arbitrary target, but only 39% of the estimated total burden).

Table 7. Implementation status of PMDT compared to targets in NSP, 2010-2016. Status of implementation of Global Fund supported activities

	2010	2011	2012	2013	2014	2015	2016	2017 up to date
Target	14	14	14	10	14	15	20	28
RR /MDR TB patients detected	8	12	5	4	13	13	17	9
Enrolled in the same year	4	5	4	4	11	13	17	9
Enrolled in the next year	1	4	1	-	-	-	-	-
Total no. and % put on treatment	**5 63%**	**9 75%**	**5 100%**	**4 100%**	**11 85%**	**13 100%**	**17 100%**	**9 100%**

Significant achievements since November, 2016, included 9 new (additional) GeneXpert machines, including one 16 module machine, and 3 more were in the pipeline. Nutritional support (Thriposha) had been approved for all TB patients through government funding. In those districts visited, at least, contact investigations were becoming increasingly systematic. Orders for drugs for the shorter regimen and new drugs had been placed.

Key challenges identified included:

a) Low notifications of retreatment cases leading to lower screening for drug-resistance
b) Sputum transportation network remained weak
c) Lab quality assurance supervisory visits were not always possible
d) Suboptimal use of available GeneXpert machines

e) Treatment initiation of MDR-TB continued to be centralized to a single centre
f) Infection control at visited facilities continued to be sub-optimal
g) Treatment success rates were declining with increasing number of deaths among those started on second-line treatment
h) DOT was generally only family based (both for DS and DR-TB)
i) There was a need to develop standard operating procedures (SoPs) for the shorter regimen and newer drugs including strengthening of mechanisms for monitoring of adverse events

Review of the status of priority recommendations made during the previous mission reveal that of 7 sets of activities, one was completed, one had not started and 5 were partially addressed (Table 8). This is consistent with the previous analyses of performance in Section 3.

Table 8. Status of priority recommendations of the previous mission, November, 2016. Key:

Achieved	
Some progress/ ongoing	
No change	

Recommendations	Responsible agency/person	Status
Improve TB case notification • Focus on districts with low case notifications • Hiring and placement of lab staff for operationalising all microscopy centres • Monitor contact investigations • Improving communication channels with private sector and teaching hospitals	MoH, NPTCCD,	• District Coordinating committees were formulated to discuss the matters with RDHS & other health & non health sectors.
Strengthening laboratory network • Quick introduction and roll out of Laboratory Information Management System • Strengthening sputum transportation mechanism from remote areas • Rapid establishment of SL DST capacity	NPTCCD and NTRL	• LIMS - Still it is in process. Future uncertain • Strengthening sputum transportation mechanism is in process. But not completed. • SL DST capacity will be established with MGIT, in 2018.
Find missing DR-TB cases • Increased use and access of rapid diagnostics as per national guidelines • Expedite procurement of pending GeneXpert machines and their installation at identified sites • Supplement efforts by involvement of private sector laboratory • Screening criteria for drug resistance should be widely disseminated to all health facilities managing TB symptomatics or cases, in all sectors	NPTCCD and NTRL	• Increased use and access of rapid diagnostics as per national guidelines started & in process. • Eight 4 modular machines & one 16 modular machine received. • One private lab is having GeneXpert - monitored by NPTCCD. • Screening criteria for drug resistance dissemination in all sectors is done. Will be revised after DRS.

• Improving communication with private sector screening and managing DR-TB		• Awareness programmes are done.
Improving adherence • Decentralize treatment initiation to at least 2 more centres • Expedite the process of enhanced allowance for MDR-TB patients • Make access to allowance easy and streamlined • Provide access to Thriposha for patients on second line treatment • Strengthen counselling services for RR/MDR-TB patients • Early management of adverse events	NPTCCD, Provincial Director of Health Services (PDHS), DTCO	• It is decided to build two facilities in Jaffna & Kandy, when more patients detected. • It is requested from Social Service Ministry. Meeting is scheduled with Social Service officers in July. • "Thriposha" will be provided for all TB patients from June onwards. • Counselling is done by a trained nurse. Will arrange at district level by Social service Department. • Early management of adverse events is happening. ADRs are monitored continuously.
Adoption of shorter regimen • Include new chapter/ annexures to PMDT guidelines • Prepare a transition plan • Plan for aDSM mechanism • Aim to initiate at least 5-10 cases on shorter regimen in 2017 (based on targeted MDR-TB cases)	NPTCCD, NMRA, Pulmonologists, Microbiologist, DTCO	• It is to be disseminated as a new document as the PMDT Guideline was printed. • Selection criteria were prepared. Selection will be done by the site committee, where treatment is initiated. • Plan for aDSM mechanism is prepared. Format is being used for patients on SLD. • It is decided to start one to two patients in 2017. Drugs ordered for two patients.
Airborne infection control practices in general should be followed	NPTCCD and PDHS	• TOR was prepared. Guideline will be prepared by a National TA. Awareness programmes were done for infection prevention control, triage of patients, promoting cough etiquette, avoidance of over crowding

Role of NGOs needs to be strengthened with involvement of grassroots workers	NPTCCD	• CNAPT is the only active NGO in this regard, Very active in Kandy

Table 9. Priority recommendations of the July 2017 mission

Recommendation	Responsible persons/agency	Timeline	Support required to fulfill the recommendation
Monitor referrals from large hospitals specifically teaching hospitals	MoH, NPTCCD	Ongoing/ quarterly	
Purchase sputum transportation boxes and strengthen sputum transportation	NPTCCD and NTRL	Purchase by 4th quarter 2017	
Monitor the use of available GeneXpert machines and optimize their use	NPTCCD and NTRL	Ongoing/ quarterly	
Prepare guidelines and SoPs for introduction of shorter regimen	NPTCCD	BY 4th quarter 2017	External TA may be needed
Set up all elements of aDSM	NPTCCD	BY 4th quarter 2017	External TA may be needed
Prepare a PMDT monitoring framework for monitoring MDR-TB services including the use of shorter regimen and newer drugs in future	NPTCCD	BY 4th quarter 2017	External TA may be needed
Establish model centres for infection control and replicate	NPTCCD	By 1st quarter 2018	

5. Priority areas for operational research

5.1 Patient pathway analysis

A retrospective survey among existing TB patients of their diagnostic experience (patient pathway analysis) in order to assess the efficiency of health facilities in making the diagnosis of TB is urgently needed. This should include an assessment of the proportion of patients that first attends private facilities and the results obtained there. Similarly it will enable an assessment of the proportion of patients that starts seeking care in the public sector and then, because of perceptions of poor care, or for whatever reason, then moves to the private sector.

5.2 Understand the role of the private sector in diagnosing and managing TB

This area of activity could usefully start with a **literature review of the activities of the private sector in diagnosing and treating TB in India**. Of course, the situation in Sri Lanka is different, but the India data will generate hypotheses for investigating exactly what the Sri Lankan private doctors are doing with TB cases. Assuming it transpires from this activity and 5.1 that the private sector is involved in TB management, then studies that explore the motivations and needs of the private

sector in such activities will be needed in order to set the stage for better private:public collaboration on TB.

5.3 Improvements in case finding among household contacts

The clearest way of working out how to improve case-finding among household contacts would be to **compare existing practice with existing practice, plus additional training of PHIs, greater involvement of DTCOs in excluding TB, chest-radiology for every contact, GeneXpert and/or culture for any contact with symptoms, no matter how minimal.** The comparison could be historical (the case detection rate in contacts in the same place(s) over time), or simultaneously as a controlled trial.

5.4 Case-finding among groups that are suspected of being at high risk

While case finding in high risk, or vulnerable, groups has been unsuccessful in Sri Lanka in the recent past, other than in prisoners, this does not prove that such groups do not have a sufficiently high prevalence to make them potential targets for active case finding in the future in Sri Lanka. However, before any group is included for ACF, it needs to be established that they have a prevalence that makes it cost-effective for ACF. The best approach would be to **use the most sensitive diagnostic algorithm that is possible in Sri Lanka (see 5.3) and start with the groups most likely to have high prevalence of TB, eg diabetics currently attending diabetic clinics, TB laboratory workers, front-line health staff from emergency departments and medical assessment units, elderly people** (perhaps focusing initially on elderly, male smokers) in residential homes (if such exist), and then move on to groups with probably a lower prevalence, such as estate or plantation workers.

6. Conclusions and recommendations

If the End TB targets are to be achieved, business as usual is not an option. The Review Team has concluded that the most important (highest priority) step is to significantly strengthen the NPTCCD Central Unit. Without this it seems likely that the actions required elsewhere in order to improve TB control performance will not happen sufficiently to make enough difference. The Director's priority should be to elicit firm commitment from the DG that the NPTCCD will be significantly strengthened with appropriate staff appointments.

However, since a significant expertise still lies among the DTCOs, we have recommended that 2-3 pilot districts be set up in order to prove the principle that in modern day Sri Lanka, multiple efforts, including availability of GeneXpert diagnosis, can succeed at increasing case-finding. These pilot districts will need to be strongly supported and monitored very closely by NPT staff. They should be chosen on the basis of several criteria, including:

- Highly competent and experienced DTCO
- Support from RDHS, PDHS
- Support from key Hospital Directors (to ensure OPD-based microscopy and X-rays when necessary)
- Sufficient laboratory staff to carry out all smears and GeneXpert tests required
- Not too far from Colombo (for easier monitoring)

The TB surveillance and M&E system needs to be significantly improved, as laid out in the epidemiological analysis. A national-level inventory study to assess the proportion of TB cases reported to the national programme is essential. These two approaches constitute the only route in Sri Lanka to arrive at a more accurate understanding of the burden of TB, since the option of a

prevalence survey is excluded on grounds of cost. Employing the improving M&E system, regular, constructive and supportive monitoring of progress toward the milestones - particularly the 2020 targets - will be required.

Partners should be more strongly engaged by the NPTCCD. The WHO could provide support for advocating for the changes recommended in this report and could help significantly in beefing up quarterly surveillance. The Global Fund needs to maintain flexibility in fund disbursement, especially in re-orienting activities to focus just on the high priority activities identified in the next section. The operational research agenda will require academia and, possibly, NGOs, to show willingness. Civil society organisations (CSO) should also step up to the plate in order to carry out their watch dog role – but this will require the NPT to work with such organisations and support them.

In the future there needs to be a reconsideration of the role of the DTCO. He/she could be fully responsible for all the preventive activities in his district rather than doing mainly clinical work. The responsibility of screening and detecting tuberculosis cases could be mainly given to CRPs and MOs specialised in tuberculosis in chest clinics and in hospitals. Linked with decentralisation of DCC activities to hospitals (see 2.3.5) there could be substantial financial savings to be made by making this preventive:clinical split. However, as of now, the focus needs to be on improving the performance of the existing system, especially in case-finding, before embarking on a more fundamental re-organisation.

7. Revision of the NSP, 2015-2020 (in alignment with SDG and End TB strategy)

The current, understaffed state of the NPTCCD requires prioritisation of existing activities and focus in the immediate term (until the NPT is strengthened) just on the high priority activities. The important activities are already included in the NSP and thus a major revision is not required, rather an indication needs to be given as to which are the priority ones. We have done this in the Excel files that come with the final report.

Annexes

1. Financial data for the NPTCCD, 2012-2017

1.1 GFATM (USD)

Year	Allocation	Expenditure	Percentage (%)
2012	1,680,259.00	1,238,967.17	73.74
2013	1,893,515.00	573,944.97	30.31
2014	1,006,203.00	596,058.64	59.24
2015	927,220.00	754,435.51	81.37
2016	3,863,223.72	1,522,400.03	39.41
2017*	2,140,511.55	765,987.96	35.79
Total	11,510,932.30	5,451,794.28	47.36

1.2 Ministry of Health (Govt) Allocation for GFATM Local Component (USD)

Year	Allocation	Expenditure	Percentage (%)
2012	---	38,837.78	---
2013	38,726.70	33,042.55	85.32
2014	50,474.65	6,843.89	13.56
2015	110,344.59	23,012.36	20.85
2016	115,039.92	11,008.30	9.57
2017*	461,924.24	66,575.74	14.41
Total	776,510.10	179,320.63	23.09

1.3 World Bank (LKR) 2012-2017

Year	Allocation	Expenditure	Percentage (%)
2012	---	---	---
2013	---	---	---
2014	50,000,000.00	51,850,948.38	103.70
2015	75,000,000.00	18,179,156.58	24.24
2016	68,500,000.00	41,791,497.87	61.01
2017*	30,300,000.00	6,133,327.65	20.24
Total	223,800,000.00	117,954,930.48	52.71

1.4 Funding Source: WHO (USD) 2012-2017

Year	Allocation	Expenditure	Percentage (%)
2012-13	20,000.00	25,990.00	130.00
	---	---	---
2014-15	23,250.00	21,550.00	92.69
	---	---	---
2016-17*	104,000.00	74,475.00	71.61
	---	---	---
Total			

1.5 Funding Source: SAARC TB Fund (LKR) 2012-2017

Year	Allocation	Expenditure	Percentage (%)
2012	1,100,000.00	1,100,000.00	100.00
2013	2,917,599.00	2,917,599.00	100.00
2014	1,468,250.00	1,468,250.00	100.00
2015	1,500,000.00	485,441.00	32.36
2016			
2017	2,838,249.50	2,755,672.76	97

1.6 Funding Source: Ministry of Health (Govt) Allocation (LKR) 2012-2017 (Chest Hospital Welisara not included)

Year	Allocation	Expenditure	Percentage (%)
2012	96,125,000	101,438,883.35	105.34
2013	153,454,006.99	158,583,757.92	103.34
2014	220,927,245.23	213,715,748.91	96.74
2015	243,798,125.13	214,312,230.71	87.91
2016	317,247,058.56	264,725,623.44	83.44
2017*	173,304,640.00	91746,157.95	52.94
Total	1,204,856,075.91	1,044,522,402.28	86.69

*= Expenditure up to June only

1.7 Ministry of Health (Govt) Allocation (LKR) 2013-2016 (Chest Hospital Welisara not included)

Component	2013	2014	2015	2016
Capital Expenditure	42,090,591.00	68,922,444.40	39,915,634.55	186,218,703.74
Medical Supply	5,363,995.04	9,059,473.09	96,455,061.25	10,005,694.19
Personal Emoluments	94,408,638.65	111,993,708.60	141,631,214.98	152,209,399.12
Travelling	1,527,186.21	1,710,319.61	1,628,226.65	1,611,122.51
Supplies	4,209,146.50	4,672,097.58	4,199,668.80	3,655,696.55
Maintenance	4,873,447.85	5,581,187.44	5,800,222.70	4,270,943.36
Contractual Services	4,522,264.70	10,014,725.76	9,580,965.46	12,762,852.96
Transfers	1,588,487.42	1,761,797.46	1,911,236.32	1,702,995.05
Total	**158,583,757.92**	**213,715,748.91**	**301,122,230.71**	**372,437,407.48**

1.8 Funding Source: GFATM (USD) 2013-2016

Component	2013	2014	2015	2016
Human Resources	319,166.00	318,153.00	287,940.00	422,559.00
Travel Related	---	---	---	88,739.00
External Professional Services	---	---	---	62,378.00
Non Health Equipment	---	---	---	17,573.00
Technical Assistance	1,006.00	20,277.00	2,249.00	---
Training	20,473.00	66,713.00	20,089.00	---

Health Products and Health Equipment	22,851.00	15,970.00	65,991.00	1,601.00
Medicine and pharmaceutical Products	13,496.00	---	---	---
Procurement and Supply Management	2,582.00	3,425.00	2,296.00	4,681.00
Infrastructure and Other Materials	45,670.00	12,908.00	447.00	48,449.00
Communication and Other materials	14,243.00	23,838.00	---	---
Monitoring and Evaluation	12,789.00	2,544.00	1,430.00	---
Planning and Administration	2,808.00	214.00	3,938.00	18,900.00
Overheads	46,212.00	55,004.00	11,792.00	---
Depreciation -property, Plant & Equipment	---	---	128,643.00	66,277.00
Gratuity Expenditure	---	---	8,965.00	40,542.00
Other	5,200.00			
Total	506,496.00	519,073.00	533,779.00	771,640.00

HEP & PPMCU	Health Education and Promotion and Public Private Mix Coordination Unit
HIMU	Health Information Management Unit
LS & PS CU	Laboratory Services and Pediatric Services Coordination Unit
PMEU	Planning, Monitoring and Evaluation Unit
HRCCU	High Risk Category Coordination Unit
TRU	Training and Research Unit
NTRL	National Tuberculosis Reference Laboratory
CDS	Central Drug Stores
CC	Chest Clinic
CCP	Consultant Community Physician
AO	Administrative Officer
GFATM PIU	GFATM Project Implementation Unit
CRP	Consultant Respiratory Physician
DTCO	District Tuberculosis Control Officer
MOIC	Medical Officer In Charge
MO	Medical Officer
MO-HI	Medical Officer-Health Informatics
NO	Nursing Officer
PHI	Public Health Inspector
HEO	Health Education Officer
MLT	Medical Laboratory Technician
PHLT	Public Health Laboratory Technician
M & E Officer	Monitoring and Evaluation Officer
DA	Development Assistant
PPA	Planning and Program Assistant
DO	Development Officer
FA	Finance Assistant
PMA	Public Management Assistant
TBA	TB Assistants
SKS	Saukya Karya Sahayaka
IT Officer	Information Technology Officer