End-of-term Review Report of the National TB Programme of Sri Lanka

5 -19 October 2020

National Programme for Tuberculosis Control and Chest Diseases

End-of-term Review Report of the National TB Programme of Sri Lanka

5th-19th October 2020

Aindralal Balasuriya

Vineet Bhatia

Shirani Chandrasiri

Neranjan Dissanayake

Vithal P Myneedu

Paul Nunn*

Shamini Prathapan

Holger Sawert

*Team Leader and lead author

First submission: 30th October

Second submission: 13th November

Final submission: 18th November 2020

Acknowledgements

The review team would like to thank all the members of the NPTCCD who took part in the Review, and Dr Nirupa Pallewatte, Deputy Director, in particular, for their ready willingness to answer questions, and to find data when the questions could not be immediately answered.

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
FSW	Female sex workers
GDP	Gross domestic product
GLC	Green Light Committee
GOSL	Government of Sri Lanka
HIV	Human immunodeficiency virus
INAH	Isoniazid
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
MSM	Men who have sex with men
NCD	Non-communicable disease
NGO	Non-governmental organization
NNP	National Nutrition Policy (NNP)
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
PPA	Patient pathway analysis
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
STRL	Supra-national TB reference laboratory
TB	Tuberculosis
WHO	World Health Organization
WHO-SEARO	WHO South East Asia Regional Office

Executive Summary

This review, organised by the National Programme for Tuberculosis Control and Chest Diseases (NPTCCD), was carried out by NPT staff and four national consultants, able to visit facilities in and around Colombo, and by four external consultants[1], working remotely because of the COVID-19 pandemic.

The NPTCCD's predecessors brought down the burden of TB from a prevalence of 740 per 100,000 people in 1964 to an estimated incidence of 66/100,000 by the year 2000. However, there has been no significant progress since then. A golden opportunity to progress to TB elimination from 2000 has, thus far, been missed. This must not continue. Yet, with the current level of commitment, Sri Lanka is not on track to achieve the World Health Assembly End TB targets (95% and 90% reductions in mortality and incidence, respectively) for 2035, much less by 2025. Nor is it on track to reach the 2025 End TB milestones. In addition, the United Nations has set challenging targets for cases to be treated for TB, and for people to receive preventive treatment (TPT). This review aims to make recommendations that - if implemented - will get Sri Lanka back on track for the End TB targets.

Achievements

Sri Lanka has long been known for its "extensive health care infrastructure, low mortality rates, high life expectancy and literacy rates…." The network of district chest clinics (DCCs) maintains basic TB control functions in the field and is largely responsible for Sri Lanka having the second lowest burden of TB in the Region. They diagnose 77% of all new cases within two visits (but only 9% of all patients first attends the DCCs). Well-trained consultant respiratory physicians are increasingly engaged in managing the more difficult cases, approving the diagnosis of bacteriologically negative cases, and starting treatment for drug-resistant TB and latent infection.

Sri Lanka has attracted US$ 23 million in support from the Global Fund since 2002, and also receives grants from SAARC, the World Bank and WHO.

A new diagnostic algorithm including chest X-ray as a first-line test, and GeneXpert for sputum smear negative cases has been distributed (but poorly implemented). The country has adopted recent WHO updates on treatment of drug-resistant TB (though they are not yet in the guidelines). The ePIMS electronic case-based register has been initiated in almost all districts since 2017.

Since 2017, operational research and improved surveillance have improved understanding of deaths while on treatment for TB, the burden of TB among cases of diabetes, and the pathway taken by patients to get a diagnosis, including the role of the private sector. A drug-resistance survey, completed in 2018, showed low levels of drug resistance. Active case finding is established for contacts of cases, people living with HIV (PLHIV), and prisoners.

Burden

Of the estimated 14,000 cases that occurred in 2019, only 8,434 were notified. Notifications have been declining by 3.7% annually. The review felt that, on balance, the evidence suggests

[1] Drs Myneedu, Nunn and Sawert were contracted by NPTCCD for this review. Dr Bhatia, from WHO, was the Regional Green Light Committee mission consultant.

the burden of TB is gradually declining, and the incidence has been over-estimated in recent years. Diagnostic technologies and clinical care have been improving, but, nevertheless, a significant number of cases was not diagnosed, or not reported.

Gratifyingly, neither HIV-associated TB, nor multi-drug resistant TB, is a large problem in Sri Lanka. HIV testing occurred in 91% of TB cases in 2019, but systematic screening of PLHIV for TB is less often carried out by the National Sexually Transmitted Disease and AIDS Control Programme (NSACP). Of the enrolled TB cases, 77% of previously treated and 25% of new cases were screened for drug resistance in 2019.

The population of Sri Lanka is getting older, increasing the vulnerability to TB due to waning immunity and increasing co-morbidities, of which diabetes mellitus is one of the commonest, and the most associated with fatal outcomes. Case fatality is high, at 6.4-7.0% in the last 3 years, and associated with old age and comorbidities.

Very few children were notified with TB in 2019 (2.9% of all cases, compared to 3.3% in 2013) and a new, more sensitive, diagnostic algorithm is yet to be endorsed and distributed.

Challenges

Sri Lanka is failing to diagnose thousands of cases quickly enough. Still, too many people die unnecessarily from the disease.

The recommendations of the 2017 mid-term review have been insufficiently implemented. Weak human resource management and leadership are seriously impeding progress. The NPTCCD staff has not been reinforced as recommended, and the situation now is worse than in 2017. The Director has two other substantive positions, including Coordinator of National Disaster Preparedness and Response Unit, and Acting Deputy Director General (DDG) - Public Health 1, and was unable to meet with the external reviewers due to the current pandemic. None of the 3 consultant community physician posts, and only one of two consultant microbiologist posts is currently filled, while the Programme lacks 10 MOs, 2MLTs, 2 PHLTs and 2 pharmacists. Below the Deputy Director, no staff has been adequately trained in programmatic TB control. The MO transfer scheme prevents selection on the basis of competence or qualifications. It is difficult to hold on to, and train up, good staff. The Deputy Director is overloaded, having to compensate for the total lack of senior technical staff, as well as carry out her administrative duties. The absence of a full-time accountant and Administrative Officer adds to her administrative workload.

Only three of the five objectives of the National Strategic Plan (NSP), 2015-2020, have been partially achieved. Of the 175 activities in the NSP, 40% will not be complete by the end of 2020. Those activities aimed at engaging the private sector and community-based organisations were least implemented.

While 3 districts were nominated as pilot districts, as recommended by the 2017 Review, the interventions prescribed were only partially implemented, if at all, because of obstacles within the health system, including HR deficiencies, as well as issues outside the health sector, curfews and elections, and these districts have not observed any increase in case notifications. One DCC visited was operating in a crumbling building with rain pouring through the roof, inadequately supported by the regional authorities.

Active case finding in contacts and prisoners is done differently in different places: the diagnostic algorithm used is not optimally sensitive, and there are no standard operating

procedures for ACF. About 50% of household contacts were screened in 2019, but less than 3% (268) of those identified were provided TPT. A further 659 of other categories (PLHIV etc) also received TPT. However, WHO recommends, to significantly reduce the incidence, a massive expansion of TPT, including those greater than 5 years of age, which would amount to about 11,500 cases to be treated annually by 2022 and beyond.

The patient pathway analysis shows that 39% of patients goes to the private sector initially, and 70% of these to private part-time practitioners who have no direct access to diagnostic tools and give out pills without any diagnostic tests to 70% of those who have TB at their first visit.

Only 69% of the MDR-TB cases detected in 2017 were enrolled on treatment. Unsatisfactory outcomes of MDR-TB treatment are rising. This threatens Sri Lanka's historically low rates of drug resistance.

Although there is, on paper, a multi-sectoral National Advisory Committee on TB, its deliberations do not extend beyond health. The NPTCCD has engaged the private health sector and NGOs only in a most limited way, although the Review has concerns about the capacity of the NGOs.

Major recommendations - *These are the most strategic recommendations. More technical recommendations can be found in the body of the report.*

While recognising the demands made by COVID-19, a step change is required in the management of anti-TB activities which requires far greater attention paid to TB by Ministry of Health decision makers at both central and provincial levels. Without stronger leadership from both the Ministry and the Programme, there is no chance of reaching the End TB targets in Sri Lanka. Therefore, this Review recommends that:

1. The Minister of Health (MOH) should establish a *National TB Commission*, chaired by the Minister, to raise the priority of TB, and ensure an urgent response to bring down the burden of TB in Sri Lanka, with clear targets and mechanisms to hold Ministry decision-makers accountable.

2. In addition, the Minister should ensure that:
    a) The vacant CCP and other positions in NPTCCD are filled by the end of Quarter 1, 2021. These appointments are essential to better collaborate with regional authorities, undertake expansion of programmes such as preventive treatment, engagement of the private sector and NGOs, maintaining the programmatic management of drug resistant TB cases, and working with teaching hospitals to ensure there is no large OPD in Sri Lanka that does not have capacity to diagnose TB within a few hours.
    b) Staff should be adequately trained, abroad if necessary, in public health aspects of TB control, preferably <u>before</u> joining the Programme.
    c) Staff vacancies in the districts must be filled by end of Quarter 1, 2021.

3. The Minister of Health must ensure that the Director of NPTCCD has no substantive positions other than the Directorship of NPTCCD.

4. Case finding efforts should be urgently intensified through greater use of chest X-ray screening for symptomatic patients. The planned phased roll-out of GeneXpert as the

first-line diagnostic test should continue, supported by the establishment of an adequate specimen transport system. The Programme should also focus on increasing referrals to DCCs from all the initial points of contact, especially base hospitals, and private practitioners. A plan should be developed for post-COVID catch up of lost notifications in consultation with all stakeholders. Active case finding (ACF) should only be undertaken with chest X-rays and GeneXpert, and Standard Operating Procedures should be developed for ACF, and their implementation monitored. Operational research should be conducted in other high-risk groups, e.g., estate workers, in order to identify further groups for routine ACF. At least one additional mobile unit, and 2 portable X-ray machines should be purchased. Drug-sensitivity testing should be done before the start of treatment.

5. To decrease death rates, respiratory wards should be designated, established, or constructed in all districts that do not have them, and high-risk patients (with extensive disease, advanced age and/or comorbidities) should be identified and admitted for specialised care in collaboration with other specialists.

6. The laboratory network should urgently (by mid-2021) set up a laboratory information management system, in conjunction with the ePIMS, or separately, as long as the two systems are interoperable.

Contents

List of Tables

List of Figures

1. Introduction

This review was organised by the National Programme for Tuberculosis Control and Chest Diseases (NPTCCD) as Sri Lanka comes to the end of its current National Strategic Plan (NSP), and of the present grant for tuberculosis (TB) from the Global Fund. A review of the TB situation and of recent progress in curtailing the epidemic is recommended at such a time by the World Health Organisation (WHO)[2], and strongly supported by the Global Fund. The findings of the review will feed into the preparations for the next NSP, which have already begun.

1.1 Background and TB context

Tuberculosis was endemic in South Asia in the 19th and early 20th centuries, probably transmitted by European colonisers. However, unlike many other countries in the Region, Sri Lanka had, by the mid-1960s, an extensive health care infrastructure, low mortality rates, and high life expectancy and literacy rates for a low-income country[3]. The NPTCCD's predecessors brought down the burden of TB from a prevalence of 740 per 100,000 people in the Ceylon of 1964, to an estimated incidence of 66/100,000 by the year 2000 in Sri Lanka. In 2019 the incidence was estimated at 64/100,000, the second lowest in the Region (Table 1), but, as the population has continued to expand since 2000, the reduction in TB incidence is minimal, and estimated annual case numbers stand at around 14,000.

The opportunity to progress to TB elimination from 2000 has therefore, so far, been missed, which is a source of ongoing morbidity and mortality in Sri Lanka. Furthermore - with the current level of commitment - Sri Lanka is not on track to achieve the World Health Assembly End TB targets (95% and 90% reductions in mortality and incidence, respectively) for 2035, much less by 2025 (which has been mooted as a target by a previous Minister of Health). Nor is it on track to reach the 2025 End TB milestones. The significant amount of internal and external investment - the Global Fund has provided US$ 23 million for TB control efforts since 2002 – appears just to have maintained tuberculosis at this relatively low level through health interventions, while social determinants continue to play a key role in driving the epidemic.

*Table 1: South East Asian Region (SEAR) countries by estimated incidence level and absolute number of cases. High incidence, >300 /100,000 population (**red**); medium incidence, 100-300 /100,000 (**brown**), and low incidence, <100 /100,000 (**green**)*

Country	BAN	BHU	KRD	IND	INO	MAL	MYN	NEP	SRL	THA	TLS
Estimated incidence level											
Estimated incidence (per 100,000)	221	165	513	193	312	33	322	238	64	150	498
Estimated number of cases, (000)	361	1.3	132	2,640	845	0.17	174	68	14	105	6.4

Source, WHO Global TB Report 2020

[2] WHO. Framework for conducting reviews of tuberculosis programmes. 2014. WHO, Geneva.
[3] Jones M. Policy innovation and policy pathways: TB control in Sri Lanka, 1948-1990. Medical History (2016), vol. 60(4), pp. 514–533.

The pressures created by this rather static epidemiological situation are increased further by international targets. The United Nations High Level Meeting on TB (UNHLM-TB) in 2018 laid out a number of commitments, to which Sri Lanka, accompanied by 192 other countries, signed up[4]. These include targets for cases to be treated for TB, and, especially challenging for Sri Lanka, for people to receive TB preventive treatment (TPT).

With the challenges come opportunities. Recent technological advances have enabled greater effectiveness in TB control, and these include new drugs which are shortening the duration of treatment for drug-resistant TB almost monthly (see Objective 7 below); new, shorter regimens for TPT (Objective 9), and more sensitive, faster diagnostic tools (Objective 4).

After the challenges and opportunities, this review also assesses the effectiveness of the organisation and management of Sri Lanka's response to TB. We look particularly at the financial and human resources available to TB control efforts (Objective 12) in the light of the 2017 mid-term review[5] in which it was "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." An assessment of whether these improvements to the human resource situation have been made is clearly important. Effective leadership is needed in Sri Lanka to address the challenges, exploit the opportunities, and make a difference.

This review aims to make recommendations that - if implemented - will get Sri Lanka back on track for the End TB and other international targets.

1.2 Objectives

The objectives of the review were drafted following internal discussion among staff of the Ministry of Health (MOH) and the NPTCCD, and they were sent for comments to the WHO and the Global Fund. They were then revised accordingly.

1. To assess the present status of the National TB Programme and progress in the implementation of recommendations of the previous missions and reviews.
2. To assess the implementation status of the National Strategic Plan concerning its objectives for TB control for 2015-2020 in Sri Lanka and to identify successes and gaps/barriers for implementation.
3. Review progress in development and implementation of Multisectoral accountability Framework (MAF-TB)
4. To analyse achievements and constraints for the efficient delivery of all diagnostic services (Microscopy, Culture and DST for 1st and 2nd line drugs, Liquid Culture, GeneXpert, Digital X-ray) and efficiency of diagnostic algorithm for various forms of TB in different age groups
5. Evaluate treatment delivery mechanisms for people friendly case management of all forms of TB

[4] Stop TB Partnership. United Nations High Level Meeting on TB. Key targets and commitments until 2022. http://www.stoptb.org/assets/documents/global/advocacy/unhlm/UNHLM_Targets&Commitments.pdf Accessed 27th October 2020.

[5] Nunn P, Perera D, Senanayake S. Mid Term Review of the National TB Programme of Sri Lanka, 17-28 July 2017

6. Review implementation of collaborative activities with other programmes like HIV and diabetes
7. Review programmatic management of drug resistant TB in relation to adoption and implementation of updated WHO guidelines and infection control in health facilities, community, and congregate settings
8. Evaluate programme approach in reaching out to high-risk groups and those which do not have easy access to health systems like children, tea-estates and migrant workers
9. Review the current policies and strategies for TB preventive treatment including their alignment with updated WHO guidelines, coverage and plans for expansion.
10. Evaluate procurement, supply chain and stock management of first and second-line TB drugs, and other consumables
11. Review monitoring and evaluation system including data quality, and robustness of observed time trends based on epi-review findings
12. Review the funding and human resources availability considering the ambitious goal of programme to end TB by 2025
13. Review the TB research and innovation needs and country plans.
14. To make recommendations/ activities to be carried out for the improvement of the National Tuberculosis Programme.

In preparatory meetings between the Programme and the consultants the Review team decided that the final report would address these objectives directly, one-by-one, rather than the approach normally taken by TB Programme Reviews of having separate technical sections. The Programme, however, helpfully listed the 20 technical areas it expected the consultants would cover, and these are all covered by the 14 objectives.

1.3 Format and organisation of the Review

Because of the ongoing COVID-19 pandemic, the review, on the ground, was carried out by NPT staff and four national consultants (see Annex 1), who had to act as the “eyes and ears” of the four international consultants who worked remotely. The international consultants were selected following a request for proposals sent out through WHO, South East Asia Regional Office (SEARO). The national consultants were selected by the NPTCCD.

In August and September 2020 an epidemiological review was carried out by one of the international consultants, Dr Arax Hovhannesyan, an epidemiologist from Armenia with experience in national epidemiological analyses for TB, and Dr AIP Samarasinghe, Consultant Community Physician. The report of the epidemiological analysis was completed and in advance draft by the time the review began and was finalised during the Review with relatively small additions[6]. The results of this work were, therefore, available to the consultants for the Review. NPTCCD prepared a detailed draft agenda.

The consultant team organised pre-meetings between September 28th and 2nd October 2020, with the NPTCCD, and among themselves, to establish the ways of working and to modify the draft agenda prepared by the Programme. The NPTCCD staff involved, and all consultants,

[6] Hovhannesyan A and Samarasinghe A. Tuberculosis epidemiological review in Sri Lanka, August 2020. Available from the NPTCCD.

divided themselves into teams to address each of the objectives. A Google-drive repository of documents was set up by the Programme.

From October 5, when the Review started officially, to October 14, the local team was able to visit only the districts of Colombo, Galle and Kegalle, and Ministry of Health Departments. COVID-related lockdowns prevented a visit to the TB facilities in Gampaha District. The four external consultants were meanwhile working remotely, reviewing Programme reports, Sri Lankan health and TB statistics and reports, the 2016 National Manual for Tuberculosis Control, TB guidelines, reports of missions from 2017 onwards, etc. (see Annex 4 for the complete list of documents made available in the Google-drive.)

In the first 8 days of the Review, 5 remote meetings were held with the international consultants for two purposes: discussions with groups of major stakeholders, the District TB Control Officers (DTCOs), the Consultant Respiratory Physicians (CRPs) and other consultants, members of the Technical Support Group (TSG) and non-governmental and community-based organisations (NGOs and CBOs) involved in TB service provision, with some private providers. The second purpose was to present and discuss the findings of the national consultants from their visits to districts and health offices. Individual remote meetings of the teams working on separate objectives were also arranged as necessary.

The Review's conclusions were derived from presentation of the findings, by objective, which were held on October 15th and 16th, and from the subsequent discussion. Between October 17 and 19, multiple successive drafts of the debriefing summary, originally drafted by Paul Nunn, were circulated among all consultants and NPTCCD staff for inputs and revisions. The debriefing presentation was made to the Director, NPTCCD on October 19th.

The objective teams, led by the international consultants, each submitted drafts of the reports by objective, which were reviewed and commented on by the entire group of consultants. Almost complete drafts were submitted to Dr Nunn between October 21st and 27th for collation into the final report.

Comments on the remote format

This review was of "hybrid-remote" type, meaning that a part of the review team, namely the international consultants, were unable to be on the ground. Some further limitations were imposed on the review by local lockdowns. The remote way of working for the international part of the team does restrict the activities that would normally be performed during a physical review, especially a lack of direct observation of facilities and records, and of face-to-face interactions with NPT staff, clinicians, patients and policymakers.

Working and relaxing together for most of the time in a physical 12-day review facilitates a great deal of discussion and engagement on the issues, that is not compensated for by 3-4 hour teleconferences every other day or so. The reduced interaction between team members likely resulted in the generation of less ideas than in a physical review.

Another purpose of a Review that is minimized by the remote approach is advocacy - senior international figures on a Review are normally able to meet with the Minister, or above, and advocate for TB control resources, in a way that is usually impossible for a National Programme Manager or Director.

In summary, however, the consultants believe that sufficient was achieved to be able to draw conclusions that are valid and make recommendations that are useful to the Ministry.

2. Tuberculosis in Sri Lanka

2.1 Structure and function of the NPTCCD and DCCs

National TB control efforts are directed by the National Programme for Tuberculosis Control and Chest Diseases (NPTCCD), which is a control programme of the Ministry of Health, often referred to as "The Campaign". It has a national level directorate, technical and general support staff, as well as project staff to manage the Global Fund support. The organogram can be found in the JMM, 2014, and has not altered since.

The national directorate implements its activities through a network of DTCOs and District Chest Clinics (DCC) which carry out TB control functions in the field, as well as the follow up of other chest conditions. Except in Colombo and Gampaha where the Central Chest Clinic (CCC) and DCC Gampaha come directly under the NPTCCD, the DCCs report to the RDHS. The DTCO is responsible for implementation of all tuberculosis control activities of his/her district and, depending on the size of the district, is supported by a team of medical officers (MOs), Public Health Inspectors (PHI), nurses, pharmacist or pharmacy assistant, Public Health Laboratory Technician (PHLT) and/or Tuberculosis Assistant, Data Entry Officer and other general staff to run the clinic and investigations in the district. With this team, he/she is responsible for the diagnosis of TB patients, screening contacts, examining referred patients from other hospitals and the private sector, attending monthly conferences of the Medical Officer of Health (MOH), and training of other MOs and public health staff.

The DTCOs outside Colombo and Gampaha are therefore responsible for the programmatic, public health-related TB activities and report to the regional (district) and provincial authorities, and not directly to the NPTCCD, although they are accountable to the NPT for sending reports and records. Correspondingly, much of the resources - staff, buildings, maintenance etc - needed for their work are provided by local authorities. The NPTCCD organises the procurement and distribution of the necessary commodities - diagnostic material, Xpert cartridges, drugs - for all institutions under their administrative purview and for many other institutions as well, e.g., DCCs — and requires surveillance data to be reported quarterly to the Programme. DTCOs also regularly notify patients with TB to the Medical Officers of Health for contact tracing.

The Review identified a number of concerns with the organisation and management of DTCOs and DCCs: DTCO positions are left vacant for too long, their teams are understaffed, and the facilities in which they operate are not always in good condition. DTCO appointments are made by the Ministry of Health following advertisement in the annual transfers list, a system which introduces significant delay. DTCOs may also be appointed without any qualifications in chest disease, while holders of the Diploma in Tuberculosis and Chest Diseases are working in unrelated areas. The team observed water pouring through the roof of the DCC in Galle, with risks to paper records and drugs, not to mention the discomfort of the patients and staff.

Increasingly, the clinical work at the DCCs is carried out by well-trained consultant respiratory physicians who manage the more difficult cases, approve the diagnosis of bacteriologically negative cases prior to registration and treatment, initiate treatment of drug-resistant TB, and exclude active TB in contacts or others who are being assessed for TB preventive treatment (TPT) in doubtful situations. The consultants therefore act as gatekeepers for the provision of key TB services. On the other hand, some DTCOs engage too much in clinical work, to the detriment of their public health duties. There are also problems of management with some duties (both preventive and curative) not being properly delegated to the MOs at the DCC,

and insufficient support from other staff in some places to carry out their delegated activities. MOs often do not work all the hours for which they are contracted owing to other, unofficial, demands on their time. For some, this includes their private practices.

The network of DCCs is supported by a countrywide network of teaching hospitals, provincial general hospitals, district general hospitals, base hospitals, and district hospitals. Base hospitals and above are equipped with X-ray facilities, microscopy, bacteriology (in hospitals with a consultant microbiologist), and other laboratory facilities, while divisional hospitals usually have microscopy facilities. The Programme is further supported by the dedicated National Hospital for Respiratory Diseases (NHRD) at Welisara, Gampaha and separate tuberculosis and/or isolation wards in some, but not all, of the larger hospitals listed above. Whenever a TB patient is diagnosed, he or she will be referred to the DCC for treatment, regardless of the type of hospital. This is even the case in many private facilities, since the provision of anti-TB drugs is solely through the NPTCCD.

2.2 Preliminary results of the patient pathway analysis

One major achievement of the NPTCCD is to have carried out the patient pathway analysis (PPA) in the past year and almost completed its analysis[7]. This work contains important original data and yields essential insights for the Programme, including, as was intended, observations on the role of the private sector in TB control activities.

First, the analysis of the pathways of 743 patients shows that 39% of patients goes to the private sector initially (Figure 1). This is less than the previous "rule of thumb" that 50% of out-patients goes to the private sector, but is nevertheless, a significant amount. Vitally, 70% of those attending the private sector, go to private part-time practitioners (PPPs). Moreover, the single most popular first point of contact in both public and private sectors, is the PPP, accounting for fully 27% of initial consultations. And the PPP has no direct access to diagnostic tools. As a result, 70% of their patients were, initially, given medicines without further investigations, resulting in significant diagnostic delay.

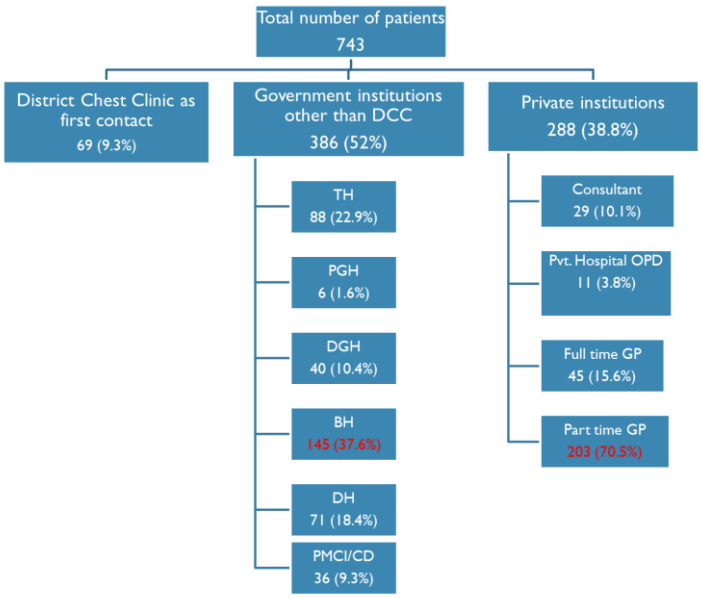


Figure 1: Pathway analysis for 743 patients who eventually were diagnosed as TB, 2018-19
Source: reference 5

[7] Care pathways, care delays and correlates of care delays among pulmonary tuberculosis patients attending District Chest Clinics in Sri Lanka. Presentation provided by NPTCCD.

Second, 71% of patients attended government facilities, including DCCs, but only 9% of patients attended the DCCs initially. Thus, 52% of all the patients went to other government facilities, particularly base hospitals, where 36% were admitted to hospital, and 32% were given medicine without testing. The DCCs were the most efficient at making the diagnosis (77% of all cases within two visits) but only a small proportion went there first. This high rate of admission in order to make the diagnosis suggests a major inefficiency for the management of a disease that can normally be diagnosed as an outpatient. In addition, admission to hospital is a significant health risk for the elderly, and 42% of TB patients in Sri Lanka are 55 years of age or over.

The PPA also quantified diagnostic delay: it showed patient delays were very significant - a median 21 days (range, less than 1 week to 2 years), and mean health system delays of 4 days for DCCs, 13 for government hospitals, and 26 days for private providers (Table 2).

Table 2: Health system delays in making the diagnosis

First Contact Point	Mean (days)	Median (days)	Range (days)
DCC	4	2	1-60
Government Hospitals	13	7	1-180
Private Hospitals	26	14	1-360

Source: reference 5.

The study therefore is pointing out the areas where action is needed, including major managerial and clinical deficiencies especially in the private sector, but also in government institutions, except for DCCs. It highlights where new interventions need to be deployed in order to diagnose TB more rapidly, although it does not explicitly say what those interventions need to be. The study will be key in the design of the NSP for 2021-2025 and needs to be widely disseminated within the NPTCCD and discussed.

2.3 The epidemiological situation of TB

The epidemiology of TB in Sri Lanka is analysed in the report prepared by Dr Arax Hovhannesyan and Dr AIP Samarasinghe, and the reader is advised to refer to this document[6]. The results of that report will only be summarised here.

As discussed in the introduction, the estimated incidence rate of TB in Sri Lanka has decreased only slightly since 2000, and is now about 64 per 100,000, or 14,000 cases annually. Notifications of TB in 2019, reported to WHO, were 8,434, including re-treatment cases. The TB notification rate was therefore about 39 per 100,000 in 2019 and has been steadily decreasing at an average 3.7% per year between 2015 and 2019 (Figure 2). However, if the estimated incidence is accurate, 5,500 cases were either not diagnosed, or not reported, in 2019[8].

In favour of the decline in notifications being a true reduction of TB burden in the population are:

- A constant decline in sputum smear positive TB cases over time (while as many as 36 sputa need to be screened for one positive case);

[8] A simple estimate of 8.4% under-reporting was obtained in the epidemiological analysis by comparing laboratory and treatment registers.

- A faster decline in the age-specific notification rate among younger age groups compared to those of older age groups – the average patient is becoming older (see below);
- Routine notification data at national and subnational level are internally consistent;
- Trends of decline across subnational areas, and when disaggregated by sex, and site of disease are consistent.

However, the following observations indicate that some TB cases are either not detected by health systems, or are detected, but are not reported, that is that the decline in notifications may not be a true reflection of the decline in burden:

- Implausibly high bacteriological confirmation in several districts and the prison system combined with low Gene-Xpert testing coverage and high positivity of GeneXpert testing,
- A comparatively faster decline of paucibacillary forms of TB (clinically diagnosed TB) over time compared to sputum smear positive TB cases (Figure 3) most likely due to changes in diagnostic practice; (an alternative, more optimistic interpretation, is that given by the consultant physicians who claim that EPTB and clinically diagnosed cases are falling more steeply than smear positive cases because they are increasingly applying more modern diagnostic techniques (Xpert, broncho-alveolar lavage, etc) which increases the smear negative, Xpert or culture positive group, while correctly excluding those smear negative cases who do not have TB, but who would in previous years have been diagnosed as such);
- The low proportion of child TB cases is externally inconsistent;
- Initial loss to follow-up was observed in facilities visited, which were not addressed by health systems.

On balance, this Review believes that the evidence, including the assessment of the impact of ageing on TB (below), suggests that the current estimates of incidence over-estimate the burden, and in fact the burden of TB (incidence) is likely to have been gently falling. The extent of the over-estimation is impossible to measure.

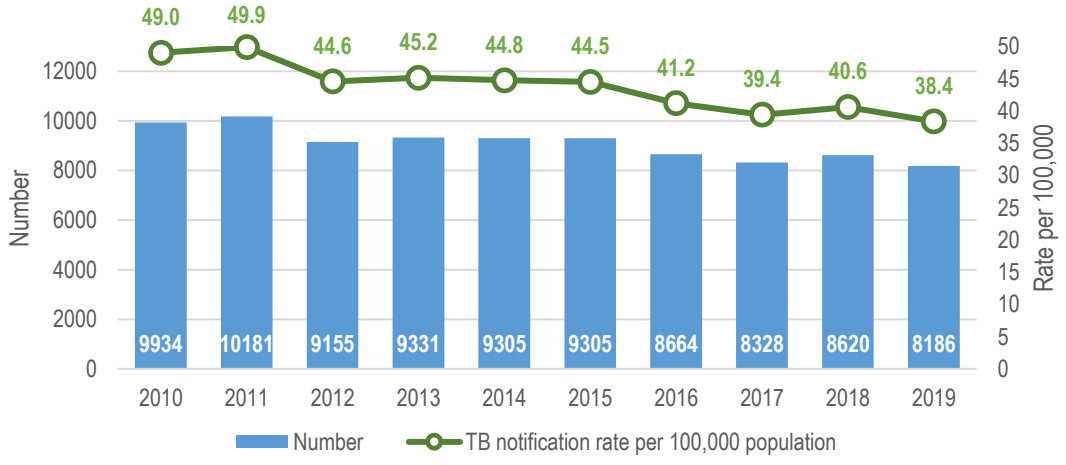
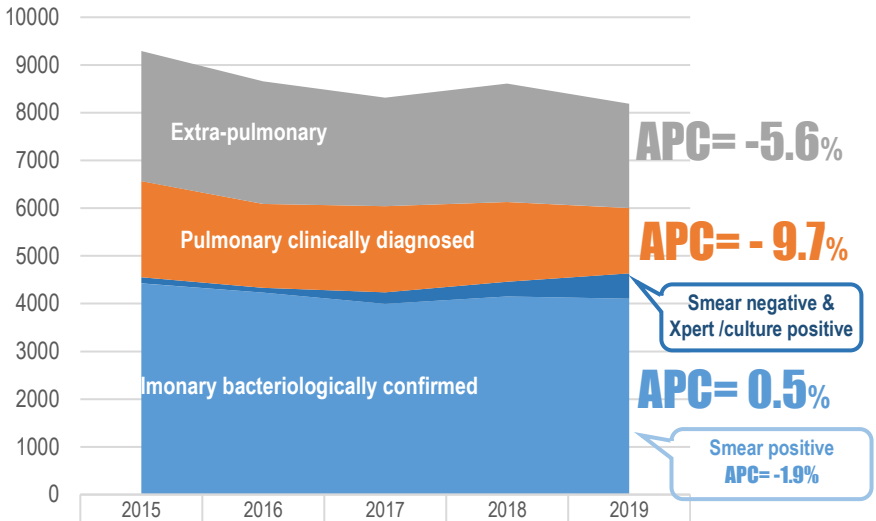


Figure 2: Trend of TB notification numbers and rates, 2010-2019 (new and relapse)

Source: NPTCCD data



	2015	2016	2017	2018	2019
Extrapulmonary	2725	2573	2270	2483	2182
Pulmonary clinically diagnosed	2016	1756	1808	1672	1369
Pulonary sm neg Xpert/cul positive	129	103	241	306	531
Pulmonary smear positive	4423	4228	3995	4152	4104

Figure 3: Notification of new and relapse TB by laboratory confirmation and localization, 2015–2019

Source: NPTCCD data and reference 5

District analysis showed a majority of districts consistent with the national picture of a gentle downward trend. The Epidemiological Review was, however, hampered by lack of data on the number of presumed cases and the number of diagnostic tests performed, nationally and by district. These data were made available to the ETR and national data are considered under Objective 4. Such data are crucial for telling if the performance of a district is most likely deteriorating (diagnostic testing is falling), and this is the reason for the decline in case notifications, or whether the district performance is good (diagnostic testing stable or increasing) and case notifications are falling in spite of increasing, or stable, amounts of diagnostic testing.

We also know from several observations that a significant percentage of presumed cases is not tested and there are initial defaulters. The diagnostic algorithm used in routine practice and in active case finding, is insufficiently sensitive, so for example, prisoners are inadequately screened even though there is evidence of high prevalence in the prisons.

The external factors that contributed to drive the TB epidemic downwards are addressed in detail in the epidemiological report and include health system strengthening (decrease in under-5 mortality); economic growth, improved nutrition of population, low HIV prevalence, access of population to health care.

The main factors that are likely to moderate the decline of TB burden in the population include: limited coverage with more sensitive diagnostic techniques (e.g., Gene Xpert, chest Xray, culture), modest coverage of contact tracing and TPT, suboptimal treatment success rates, as well as increases in diabetes and ageing of the population.

Age and TB in Sri Lanka

Because many low-income countries, including Sri Lanka, are experiencing an ageing of their populations, and yet are not specifically addressing TB in the elderly, we wish to emphasise

this issue in the Review. In addition, the analysis of TB by age and time yields further evidence for a real decline in TB burden.

In Sri Lanka both the absolute and relative number of TB notifications increase with as age increase, in a linear pattern (Figure 4). Among children and those aged "15-24 years" TB notification rates are comparable among males and females. Above the age of 25, the sexes diverge and the male to female disparity of TB burden gradually increases (M:F ratio=1.7) up to the elderly age group (M:F ratio=2.1).

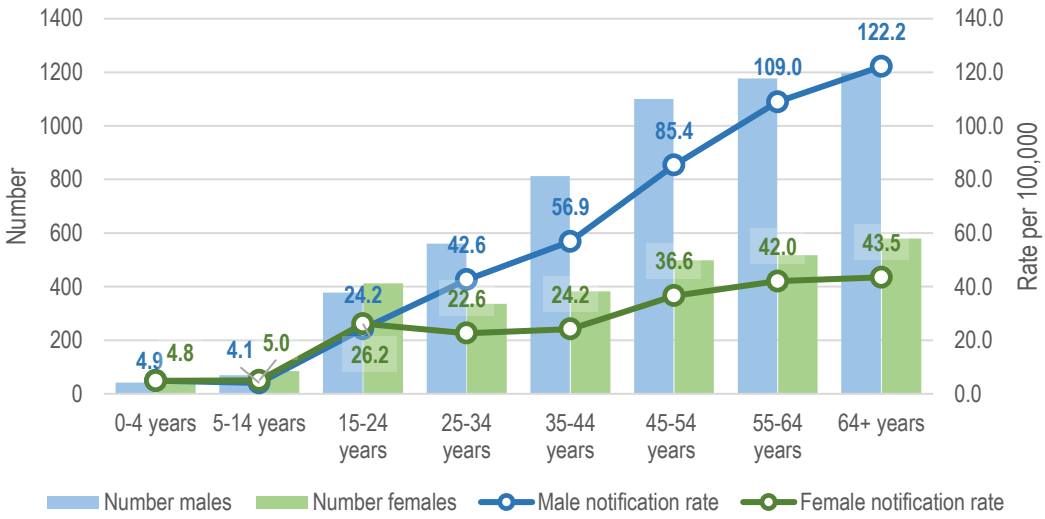


Figure 4: Notification of number and rates of new and relapse TB patients by age and sex, 2019

Source: NPTCCD and reference 5

Figure 5 shows the trends in notification rates for new and relapse TB cases disaggregated by age group. Between 2013 and 2019, the TB notification rate declined for all age groups but the magnitude of decline was less in the older age groups: thus, in adults the fastest decline was observed in the "25–34 years" (-5.3% annually) followed by "35–44 years" (-3.8% annually) and "15–24 years" (-3.7% annually) age groups, while the decline in notification rate of TB among those of older age was relatively slow, declining from -2.6% in "45-54 years" to -0.5% in the elderly (Figure 6). This pattern of temporal change is consistent with "ageing of the epidemic", which is generally held to be a sign of the decline of the TB burden in the population. Because TB in the elderly mostly results from the reactivation of latent infection, the decline in transmission rate has less of an effect on TB incidence in this age group. In contrast, TB in younger age groups is more the result of recent infection, and falling TB notifications in these groups suggests a decline in the annual risk of infection - falling transmission - which indicates a reduction in the TB burden.

Major recommendations – adapted from the Epidemiological Report[5]

1. Address under-reporting through ensuring that <u>all</u> people with TB are registered, whether or not they are treated, and conduct an inventory study (data audit) to quantify estimates of under-reporting of TB cases;
2. Introduce automated connectivity solutions of data generated by Gene Xpert machines to ensure data transmission, and remote monitoring of performance;

3. Develop a plan to optimize and upgrade ePIMS so that it can generate reports on programme key indicators, particularly notification rates, and time series analyses of key indicators across geographic areas as well as for national level. Introduce and regularly implement data validation algorithms;
4. Take the necessary steps in the new NSP to more fully understand the issue of TB and ageing, including how and where TB occurs in the elderly, the role of elderly care institutions in transmission or reactivation, the role of co-morbidities, and the impact of TB on older people and their families.

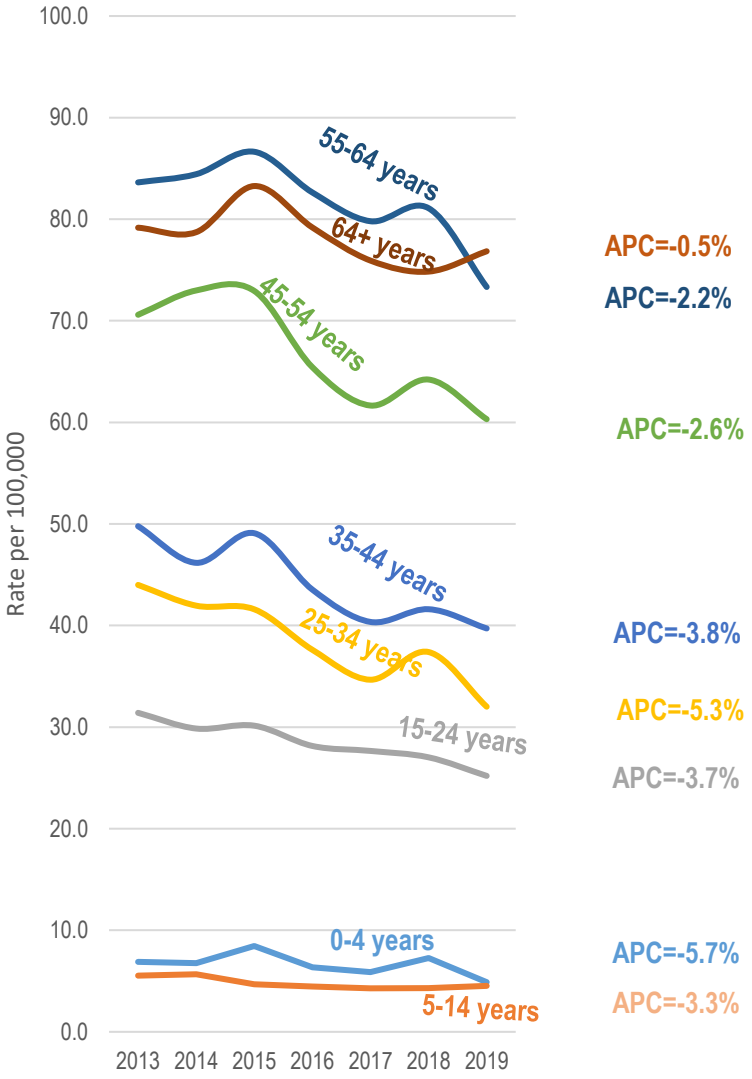


Figure 5: Trend in age-specific notification rate of new and relapse TB cases per 100,000

Source: NPTCCD and reference 5

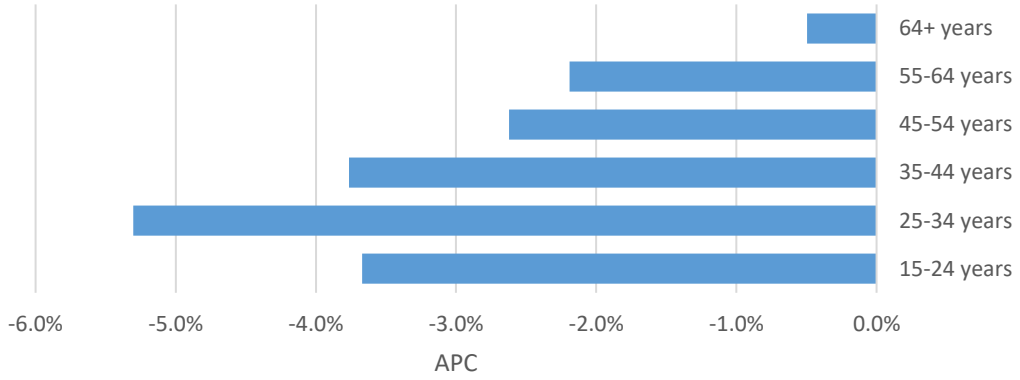


Figure 6: Average annual percent of change in TB notification by age group (2013-2019)

Source: NPTCCD and reference 5

3. Assessment of anti-TB efforts by objective

3.1 Objective 1

1. To assess the present status of the National TB Programme and progress in the implementation of recommendations of the previous missions and reviews.	What has been the response to the main recommendations in: a) the Executive Summary of the 2017 Mid-term review, b) the summaries of the International Technical Assistance reports in 2018 and 2019, and c) the Managerial Interventions of the End TB Mission, 2019? (r-GLC recommendations will be addressed in Obj. 6 below)

Findings

The mission considered the key recommendations made during the Mid-Term review 2017 and the subsequent follow-up visits in 2018 and 2019 (Table 3). The mission also reviewed progress towards the managerial recommendations made during the End-TB mission in 2019.

Table 3: Summary of progress made in response to the recommendations from the Mid-term Review in 2017

Recommendation	Status in 2020
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.**	The NPTCCD staff has not been reinforced as recommended, and the situation now is worse than in 2017. The Director has two other substantive positions, including Coordinator of National Disaster Preparedness and Response Unit, and Acting Deputy Director General (DDG) - Public Health 1, and was unable to meet with the external reviewers due to the current pandemic. None of the 3 consultant community physician posts, and only one of two consultant microbiologist posts is currently filled, while the Programme lacks 10 MOs, 2MLTs, 2 PHLTs and 2 pharmacists. Below the Deputy Director, no staff has been adequately trained in programmatic TB control. The MO transfer scheme prevents selection on the basis of competence or qualifications. It is difficult to hold on to, and train up, good staff. The Deputy Director is overloaded, having to compensate for the total lack of senior technical staff, as well as carry out her administrative duties. The absence of a full-time accountant and Administrative Officer adds to her administrative workload.

There should be one policy, one plan and one surveillance system	One single policy is available through the NPTCCD Manual, and there is one plan, the NSP 2015-2020, and one unified electronic surveillance system (ePIMS) has been developed. The previously co-existing NTB plan has been abandoned.
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. NPT staff will need to supervise weekly in the first instance.**	While 3 districts were nominated as pilot districts, the interventions prescribed were only partially implemented, if at all, because of obstacles within the health system, including HR deficiencies, as well as issues outside the health sector, curfews and elections, and these districts have not observed any increase in case notifications. One DCC visited was operating in a crumbling building with rain pouring through the roof, inadequately supported by the regional authorities.
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.**	Microscopy facilities are now available in 180 facilities and have been established considering case burden and other parameters including HR in the area. Some of the previous MC were converted to collection centres. Treatment, however, is not so widely available (see Objective 2).
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.**	National Policy is to screen all contacts of all TB patients. About 50% of household contacts were screened in 2019, but there is a variation in performance between districts.
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.**	Active TB screening is confined to Prisons, household contacts, PLHIV and other mass screening programs have ceased in 2020.
The NPTCCD and National TB Reference Laboratory (NTRL) should urgently introduce a laboratory information	An electronic, case-based, web-based surveillance system has been developed, ePIMS, and is used countrywide, but not all

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.**	its modalities are fully exploited (see Objective 11).
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.	The use of CAT II has stopped and patients requiring re-treatment receive drug susceptibility testing.
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.	Results of the study on TB in diabetics are available and the TB pathway survey is at the data analysis stage. Research agenda available, developed by research committee involving several partners also from research institutions

The End TB Mission, 2019 recommended the following key managerial interventions:

- To build confidence on the achievability of End TB Targets at leadership and managerial level through advocacy.
- Monitoring of End TB Mission by the highest political and administrative offices.
- Monitoring of District End TB Mission by Provincial and Regional Directors.
- Monitoring of MOH area End TB Mission activities by MOH.

Challenges

The review team noted that progress on advocacy and monitoring of End TB targets have remained weak. Although there is, on paper, a multi-sectoral National Advisory Committee on TB, its deliberations do not extend beyond health. Monitoring of the District End TB Mission by Provincial and Regional Directors did not happen properly since TB has not yet been identified as a priority by regions and provinces.

The review team concluded that five of the nine major recommendations of the 2017 mid-term review were fully implemented, while one, arguably the most important on human resources was not implemented at all, and the remaining three were partially addressed. The NPTCCD does not appear to have focused on the major recommendations or "managerial interventions" of the End TB Mission of Dr Shibu Balakrishnan in 2019. The key challenges remain weak human resource management and leadership (Objective 2).

Recommendations

Without stronger leadership from both the Ministry and the Programme, there is no chance of reaching the End TB targets in Sri Lanka, therefore this Review recommends that:

1. The Minister of Health (MOH) should establish a *National TB Commission*, chaired by the Minister, to raise the priority of TB, and ensure an urgent response to bring down the burden of TB in Sri Lanka, with clear targets and mechanisms to hold Ministry decision-makers accountable. The "managerial interventions" in the report of the End TB Mission of 2019 provide detailed guidance which should be followed.

Further key recommendations on human resources are made in Objective 12.

3.2 Objective 2

To assess the implementation status of the National Strategic Plan in relation to its objectives in TB control for 2015-2020 in Sri Lanka and to identify successes and gaps/barriers for implementation.	What is the achievement status of established targets and objectives in the NSP? What has been achieved in the interventions envisioned in the plan (semi-quantitative[9])?

Findings

1. We reviewed the achievements under the five objectives set in the NSP, 2015-2020:

NSP Objective 1: Detect at least 80% of incident TB cases (all forms) by 2017 and 90 % of incident cases by 2020

Incidence cannot be measured, but it is estimated by WHO, Geneva, at 14,000 cases annually, a rate of about 64/100,000 people. Notifications have been trending down since at least 2011, and case detection, or coverage, was recorded as 61% in 2019. For reasons addressed in the epidemiological section above, there are grounds for believing that incidence has been over-estimated, which would make case detection rather higher, but not so high as to reach the 2017 or the 2020 targets.

NSP Objective 2: Improve the outcome of enrolled TB patients

a) By achieving 90% treatment success in all forms of non-MDR-TB

b) By maintaining at least 75% of treatment success among MDR-TB cases by 2017

Treatment success for the last few years has been around 85% of notified cases that are known, or have been shown to be, at least rifampicin susceptible. Treatment success for MDR-TB cases was 68% for the 2017 cohort, although it did succeed once in exceeding 75%, in 2015.

Outcomes are discussed in Objective 5, but likely contributors to poor outcomes are old age, comorbidities and delays in obtaining treatment, which were, according to the patient pathway analysis, significantly more likely in the private sector.

NSP Objective 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

Diagnostic services, in the form of microscopy centres, have indeed been decentralised (see Objective 4) to about 180 sites, and GeneXpert access provided through sputum transport facilities to most large hospitals, although access is variable from base hospitals upwards. Furthermore, many large hospitals, especially teaching hospitals, still do not have the facilities to make a TB diagnosis from out-patients. In consequence, patients require to be admitted for investigations to be carried out, at considerable expense, and some risk to the patient (ref. 2).

Treatment services, on the other hand, have remained restricted to DCCs and the larger hospitals.

[9] Achieved (80-100% achieved); partially achieved (31-79% achieved); insufficient activity (0-30%): see Section 3 of the 2017 Mid-term Review

NSP Objective 4: Engage 40% of all private health care providers (hospitals and General Practitioners) in TB control by 2017, and 60% by 2020

Engagement of the private sector has not been systematically pursued by the NPTCCD, largely through lack of human resources. Given that the patient pathway analysis shows that 39% of patients ultimately found to have TB went first to a private facility or practitioner, with significant additional delays in diagnosis, this is a key finding that needs attention.

NSP 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

Quality TB services of the required standard are probably delivered at most DCCs, although not all DTCO posts are currently filled (four are vacant), which will lower standards. However, only 9% of TB patients first attends the DCCs and a significant number of MOs in other government facilities, and the majority of doctors seen in private facilities, simply provide medicines and discharge the suspected patient. This suggests that there are problems in the training, attitudes, practices and/or supervision of staff. WHO recommendations[10] are frequently not followed, e.g., presumptive case registers are not properly used and OPD staff are not specifically trained in TB. NPTCCD staff, prior to arrival in the Central Unit, are not trained in TB. Indeed, in the current health system, there is no provision to train doctors on any specific disease before being appointed to a specialized unit. The national appointment system, which does not appoint on merit and performance, is therefore at the centre of these problems.

In summary therefore, no objective of the NSP, 2015-2020 has been completely achieved. Objectives 3, and 5, and perhaps part of 2, have been partially achieved.

2. We next reviewed the implementation status of the 175 activities of the NSP, 2015-2020.

This analysis followed the methodology outlined in the 2017 Mid-Term Review Report, with the exception that, on this occasion, it was a self-assessment by NPTCCD staff. Results can be expected to cast the Programme in a positive light.

It should first be noted that there was a significant improvement in progress since 2017. However, still only 58% of activities had been completed or were on track to be so by end 2020; 30% were partially completed but would not be completed by end 2020; and 10% were not achieved, and possible not even started (Figure 7). The Programme has suggested that "the reasons maybe COVID-19 outbreak in the country in 2020, Easter bomb attack in 2019, and election."

The results varied significantly by NSP objective: in objective 3, 70% of activities were only partially achieved, in objective 4 (engaging the private sector) 38% were not done. In objective 5, 56% were only partially completed or not done.

[10] WHO. Compendium for WHO guidelines and associated standards: ensuring optimum delivery of the cascade of care for patients with tuberculosis. 2018, second edition, WHO, Geneva. https://apps.who.int/iris/bitstream/handle/10665/272644/9789241514101-eng.pdf?ua=1 Accessed 20 October, 2020.

In all objectives, there is a concentration on meetings, establishment of groups, preparation of papers, etc. rather than implementation of anti-TB activities in the field. As observed in 2017, routine activities or operations are generally performed and completed, while anything slightly innovative, or requiring collaboration with agencies or departments outside the Programme, risks being set aside and remaining incomplete.

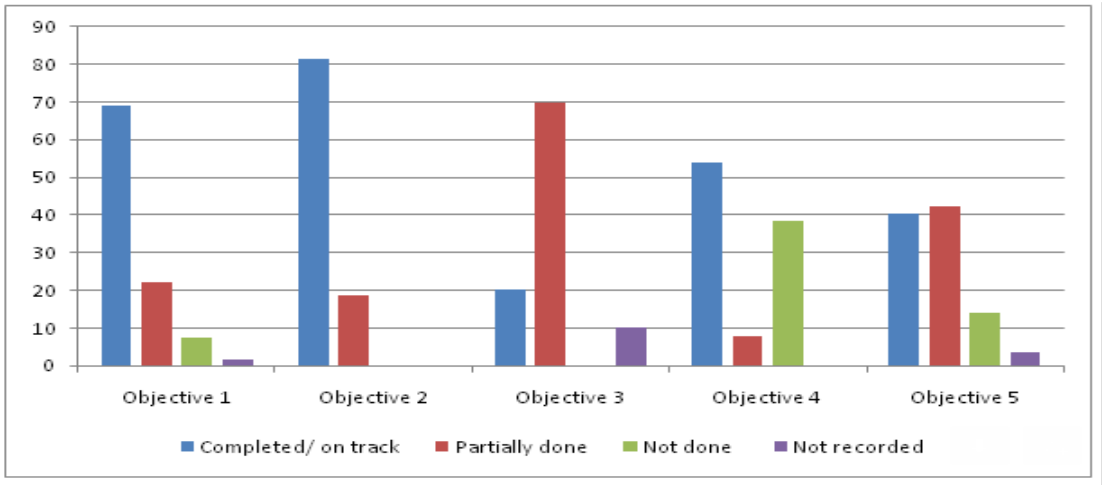


Figure 7: Status of the 175 activities of the NSP, 2015-2020, by percentage for each objective, October 2020

Challenges

The gaps identified include persistent inadequate NPTCCD staffing (see Objective 12), and attendant failures of management and organisation. It does not appear that these failures are due to a lack of funds (see Objective 12). The Programme has largely failed to address those recommendations that require thinking or moving outside the box, even those that have been repeatedly made since 2010, e.g., engaging the private sector.

Recommendations

1. The patient pathway analysis should be finalised, further analysed, published, discussed widely within the Programme, and put into practice.
2. The next NSP, 2021-2025 should be simpler, more focused, with less activities and indicators.

3.3 Objective 3

Review progress in development and implementation of Multisectoral Accountability Framework (MAF-TB)	If MAF not available, what is the progress of development? If MAF available, is it according to the WHO guidance? What is the contribution of civil society/community-based organisations/ private health sector/ non-health sectors in TB service provision?

Findings

The country has taken a few steps towards engagement of various departments within the Ministry of Health and beyond for their active engagement in TB control efforts. There is a multi-sectoral National Advisory Committee on TB that consists of representatives of, among others, the private health sector, GPs organisations, the Sri Lanka Medical Association, the Education Department, the armed forces and prisons, social welfare, planning etc. Additionally, the Country Coordination Mechanism (CCM) created for Global Fund projects is considered a mechanism for multi-sectoral oversight. Meetings of the minutes of the National Advisory Committee on TB disease were made available to the review team and it was evident that regular quarterly meetings of the committee were held in 2019. The meetings were mostly chaired by the Director/ DDG PHS-1, and only once by the DGHS. Most of the discussions in the meetings focussed on TB programme performance/ implementation challenges, and occasionally policy level issues were also discussed. However, there was little or no participation of other sectors in these meetings and hence multi-sectoral issues were not discussed in any of the meetings.

The MAF-TB checklist was also filled during the review and some of the key observations from the checklist include:

- The UN SDGs are mentioned only in the Annual Report of the Programme but not in the TORs of the Advisory Committee (which was set up before the SDGs, but there has been no revision since to incorporate this element) nor the existing NSP. However, the End-TB strategy targets are included in the NSP.
- Activities towards commitments made at Moscow declaration and in UNHLM need to be strengthened.
- Multi-sectoral coordination mechanisms exist for the defence/armed forces; education; foreign affairs/external affairs; social welfare; urban and estate health; private sector, but the mechanism of engagement is not formalized
- There is a need to additionally strengthen
    - TB legislation policies
    - Civil Society engagement and social mobilisation
    - Addressing the determinants of TB

The NPTCCD also organised regular meetings with key NGOs and some private sector representatives at national level. However, it appears that private sector engagement is mostly in Colombo and adjoining areas, although from the patient pathway analysis, nearly 40% of patients utilise the private sector as first point of contact, where there are significant problems with the quality of care.

At the private facility visited by the review team, the patients presenting to the OPD are screened using the algorithm provided by the NPTCCD. Presumptive TB patients are identified,

recorded and referred to DCCs. Facilities for sputum AFB examination (880 LKRS each) and chest X-rays (1500 + 500 (reporting) LKRS each) were available, but not for GeneXpert testing. All positive AFB reports are traced using the telephone number and anti-tuberculosis medication is not dispensed on site.

Challenges

- The current mechanisms for engagement of sectors beyond health are weak as there is no clear policy or mechanism on engagement. The roles are not specified and hence, potential partners are not aware how they can contribute.
- The accountability framework is not available.
- Only a limited number of NGOs is engaged with no identified priorities. The involvement of NGOs is mostly local, small-scale and ad-hoc.
- Private sector engagement is far from engagement of all major providers, and not at the points where the pathway analysis indicates serious problems.

Recommendations

1. Develop an accountability framework in consultation with all stakeholders identifying the person responsible for discharge of role and being accountable for the identified activity. Gaps identified in MAF checklist to be addressed by Q1 2021.

2. More active role for the Advisory Committee in tracking progress, ensuring accountability and reporting to the Honourable Health Minister.

3. Engage with sectors like prisons, estates, social services, immigration, and the private sector initially through individual dialogues, discuss possible contribution towards TB control, and develop a clear action plan to achieve defined objectives. This should lead to the highest level of representation from other sectors in meetings of the advisory committee to resolve policy issues.

4. Possible role of NGOs, seen in other countries in the Region, include:

    - Interface between private sector, estates and other NGOs for coordination. 1-2 central NGOs can lead and function like an ‘umbrella’ organisation for the purpose.
    - Awareness generation among community could be more focussed on areas like education and demand generation among community for appropriate management including TB preventive treatment.
    - Establishment and maintenance of half-way/ long stay home for homeless and economically challenged patients.
    - Development of a standardised package for treatment adherence and rehabilitation support through NGOs.

5. Recognise the contribution of the private sector and address the deficiencies through a working group which will include NPTCCD staff, General Practitioners, private part-time practitioners, and major private hospital representatives should be established, but only once an implementable plan is available.

6. The identified activities need to be made part of the NSP being developed in 2020.

3.4 Objective 4

To analyse achievements and constraints for the efficient delivery of all diagnostic services	How well are the lab diagnostic approaches working: microscopy, culture and DST for 1st and 2nd line drugs, liquid culture, GeneXpert? How well is the 2018 diagnostic algorithm adhered to, including chest (and where possible, digital) X-ray?

Findings

The tuberculosis laboratories form a well-developed health network in the country involving the National TB Reference Laboratory (NTRL) in Gampaha District, intermediate TB culture laboratories (ICLs) in Kandy, Ratanapura, Karapitiya and Jaffna, hospital microbiology laboratories, 26 district laboratories in each of the DCCs, 189 microscopy centres and 31 GeneXpert sites. A diagnostic algorithm is in place. The paediatric guideline developed in 2018 was distributed, but the new paediatric TB diagnostic algorithm developed in 2020 is yet to be distributed.

There are staff shortages across all levels of the lab-network, notably 15 PHLTs in the DCCs, 52 PHLTs in the microscopy centres, and 1 of the two consultant microbiologists at the NPTCCD. Forty two out of the 90 microscopes at the DCCs are not functioning, and 18/132 in the microscopy centres.

From the PPA, 47% of the patients initially attend base hospitals and individual private care providers, which are not well-equipped to make the diagnosis, while 38% of the patients who attend big hospitals get admitted in order to get their diagnostic tests done. This is costly and entails the risk of nosocomial transmission but is also avoidable.

Sputum smear microscopy is the most frequent diagnostic performed by far. Both the DCCs and the microscopy centres (MCs) carry out nearly a quarter of a million tests per year, and the numbers show a slight increase from 2017 to 2018, and a smaller fall in 2019, which may be related to the political and security situations in that year (Table 4). Numbers of culture examinations, both diagnostic and total, show a steadier decrease 2017-2019, but there was a significant increase in cultures done at NTRL in 2017 due to the DRS. In addition, there were frequent breakdowns of the BSL3 lab and some of the critical equipment leading to interrupted services at NTRL. An engineer funded by the Global Fund at NTRL used to attend break downs promptly along with the local agent, but her services were terminated in 2018. Also, the intermediate laboratories have been set up in the same time and would have dome some of the tests previously performed at the NTRL (and we do not have data from them). GeneXpert testing has increased significantly from 11,350 tests in 2017 to over 28,000 in 2019. At the NTRL and 13 other sites, the proportion of samples tested by GeneXpert from smear negative cases is around double that from smear positive cases, suggesting that more GeneXpert tests were performed for diagnostic reasons than to determine rifampicin sensitivity in smear positive cases.

These figures do not suggest a significant fall-off in diagnostic testing such as might be seen in a deteriorating programme. Rather the falls that are seen, at national level, have explanations that are more in accord with events in society, staff changes, and shifts in diagnostic organisation and practices. At local level, this may not always be the case and further analyses should be done by district to help identify those districts that are performing less well.

Nearly three fourths of the total cultures (16,167/22,371 in 2019) carried out at NTRL are solid cultures. The remaining 1/4th (6204/22371) is done using liquid cultures (using an automated BD BACTEC machine procured in 2016). Currently, all culture-based drug susceptibility testing (DST) is performed only at NTRL using solid media for first line anti TB. NTRL has received a new BD BACTEC system and test kits for both first- and second-line liquid DST in September 2020. Thus, the NTRL is in the transition from solid DST to liquid DST.

The NTRL diagnoses most of the rifampicin resistance cases (58-80%). There are 29 other functional GeneXpert sites at various sites across the country, but these have been coming on stream.

NTRL has been using the Line Probe Assay (LPA) since 2013 to detect resistance to rifampicin and isoniazid. There are two LPA machines procured in 2013 and 2019 but both machines are currently out of service. Supplier (HAIN) has been informed several times but there is a long delay (several months) in getting the repair done. This has compromised rapid identification and detection of drug resistant TB. Test kits are available for both first and second line (fluoroquinolones and aminoglycosides) but will soon expire. ePIMS utilisation is poor except in the district of Colombo. Only patient registrations are done on ePIMS and other lab-related data is entered in various other registers. This may be one factor causing problems in the data flow and making analysis by the NTRL difficult.

Table 4: Trends in diagnostic tests from 2017 to 2019

Diagnostic test	2017	2018	2019
Diagnostic sputum smears - DCCs	239,781	249,303	241,813
Total sputum smears – MCs	225,287	247,902	232,731
GeneXpert	11,350	17,944	28,743
Diagnostic cultures – NTRL	19,712	18,936	18,723
Total cultures – NTRL	24,657	23,410	22,570

Source: NTRL

Supervisory activities to the laboratories, as required by the NPTCCD, are solely carried out by NTRL - ITLs do not contribute. An opportunity is thus lost for effective decentralisation and supervision within a 3-tiered lab network. HIV testing is being done as required and is well documented. Universal DST is adopted as a policy but not being implemented as per NTP guidelines.

Extra-pulmonary TB and paediatric TB testing with GeneXert and/or culture is happening but is limited to large hospitals. Very few children were notified with TB in 2019 (see Objective 8) and a new, more sensitive, diagnostic algorithm has been developed for children, but training is needed before implementation can occur.

Transportation of specimens is inadequate. Standard operating procedures (SOPs) are not in place. Currently, samples are transported from the DCC and the hospitals to culture laboratories (NTRL, ITLs) or GeneXpert sites by DCC vehicle or hospital ambulance or patients themselves or by their relatives. There is no formalized system for the transportation of specimens from those institutes (major hospitals and DCC) to culture laboratories and GeneXpert sites if needed at the moment.

Time taken from collection to delivery of the samples to the relevant laboratories ranges from 1 day to 10 days or more. Longer delays are mainly due to the unavailability of vehicles to transport specimens from the collection sites to the culture laboratories (NTRL and ITL) and GeneXpert sites. Further, there is no designated health care personnel who have been given the responsibility of transporting the samples to the laboratories

BSL3 laboratory at NTRL is the only fully functioning BSL3 laboratory under the MoH. However, frequent breakdown and long delay in repairing the bio-safety level (BSL) 3 laboratory was noted. There is no service agreement for the BSL3 laboratory, and no permanent biomedical engineer or technical officer onsite to maintain this system or other major laboratory equipment regularly. The BSL 3 laboratory also does not have a back-up Air Handling Unit (AHU).

Delay in transport of specimens to the culture laboratories or GeneXpert sites, and frequent break down of the BSL3 laboratory at NTRL, may have contributed to the high contamination rates of TB cultures at NTRL.

The new LPA machine has been broken for several months and the new BD BACTEC machine has not been installed two months after its receipt to NTRL. These machines have been procured through the GDF and local agents are unable to support these systems as there is no agreement between the supplier and a local agent.

Challenges

There is a human resource deficiency in certain areas, especially NTRL and some DCCs. Yet, the lab network is under-utilised in other places, especially several microscopy centres which do not have enough work. The average workload ranges from 0-4 slides per day in 82 of the microscopy centres.

There are fewer referrals from major hospitals than expected, given the size of their out-patient attendances.

The role of teaching hospitals and other major public hospitals in providing diagnostic services is sub-optimal. While 23% and 1.6% of initial contacts are made at the teaching hospitals and provincial hospitals[11], and over 77% achieve a diagnosis within the first visit, over 50% of patients (of the 77%) at the teaching hospitals requires admission to do so. The role of private hospitals and private laboratories is minimal, in spite of some of them carrying out TB cultures. Some laboratories do not perform drug susceptibility for positive cultures, which is a concern. Only one major private hospital laboratory submits data to the NTRL.

The utilisation of GeneXpert as the initial diagnostic test is yet to be initiated. It is largely still being used only after microscopy, and in presumptive DRTB cases and other defined cases. The utilisation of GeneXpert capacity is below 40% in centres with reasonable workload.

All programme related laboratory activities are managed only by NTRL at the moment. ITLs and other DGH and THs where qualified microbiologists are present, are not contributing to programmatic activities like monitoring and supervision of the TB laboratories. ITLs do not carry out supervisory activities to support the Programme.

All recording and reporting activity is by registers and forms developed by NPTCCD. Reports are also communicated by E mails etc. ePIMS is available, together with the laboratory

[11] Patient pathway analysis

manual, but it was often not being used in spite of training of all existing personnel. This was due to inherent flaws in the system such as no access to NTRL to monitor the data of other labs in the network, and no provision for generating regular reports from the data of different labs for monitoring purposes.

Most equipment at NTRL has service agreements except BSL 3 laboratory and the GeneXpert machines and there are no service contracts available for all the microscopes placed in the TB laboratories under the National TB laboratory network. There needs to be regular maintenance of BSL 3 through service contracts and the critical equipment like microscopes, GeneXpert. As there are no local agents for some of the machines at NTRL, repair of those machines takes longer, leading to an interrupted service, especially the diagnosis of MDR cases. All the machines procured therefore should have a local agent to enable rapid repairs.

The NTRL is doing solid culture for all TB patients for various tests including DST, which is technically intensive, and makes it difficult to meet all the demand, mainly due to HR issues.

Recommendations

1. Presumptive pulmonary cases of TB should be screened with CXR, wherever possible. The planned phased roll-out of GeneXpert as the first-line diagnostic test should continue. The Programme should also focus on increasing referrals to DCCs from all the initial points of contact, especially base hospitals and private practitioners. When lower cost rapid molecular tests become available, this recommendation should be reviewed.
2. The HR vacancies should be filled urgently at all levels, especially the consultant microbiologist post at NTRL, and the permanent on-site engineer or technical officer.
3. Because of the resources consumed by active case finding (ACF), its efficiency should be maximised by use of chest X-rays for screening and GeneXpert for diagnosis, and SOPs should be developed for ACF. More mobile units, with portable X-ray and GeneXpert machines should be deployed for ACF activities and their implementation monitored through the lab network.
4. Drug-sensitivity testing using should be done using GeneXpert before starting treatment for all smear positive patients. This will require revision of the guidelines for patient management and the request forms should be revised to include this information for monitoring purpose.
5. NTRL should shift to liquid culture and DST fully, as well as restart LPA, at the earliest possibility, to cut down the turnaround times of testing and reporting.
6. Results from automated tests like GeneXpert and Bactec machines should be automatically entered into the ePIMS and made immediately available to the requesting clinician. Use of SMS messages to the patients or caregivers should be considered.
7. The NTRL should work out an effective laboratory information management system (LIMS) within the ambit of ePIMS, or separately, with effective links to the existing systems, with controls for data management at all levels for effective communication.
8. Regular training (on commencing duties and annually thereafter) on specimen collection, transport, smear microscopy, culture techniques, molecular diagnostic methods and use of laboratory equipment should be provided to consultant microbiologists, medical officers, medical laboratory technologist, public health

technicians at ITLs, GeneXpert sites and microscopy centres. Training should be given by the trained staff at or trained international laboratory personnel. NTRL also should initiate proficiency testing for GeneXpert labs at the earliest.

9. All critical equipment should be on effective service contracts including GeneXpert machines and the BSL 3 laboratory. Annual servicing of all microscopes in the microscopy centres under national TB lab network should be arranged by NPTCCD

3.5 Objective 5

Evaluate treatment delivery mechanisms for people friendly case management of all forms of TB	What are the treatment outcomes in districts/regions visited and nationally? What are the reasons for the high death rates? Is treatment sufficiently patient-friendly?

Treatment supervision and outcomes

Findings

The review team noted that the most frequent form of providing DOT is through family members. Varying by district, about 60-80% of patients receive DOT in this way, with the remainder being supervised directly by clinic staff. NGOs are not utilized for providing DOT, apart from the CNAPT only in Kandy. In facilities visited during the review, patients reported that they were generally satisfied with the services they received, and DOT services generally appeared to be adequate. However, the proportion of patients successfully treated between 2014 and 2018 was below the global target of 90% treatment success rate (Figure 8). The main reason for unfavourable treatment outcomes is the relatively high death rate, which ranged between 6.4 and 7.0% over the past six years.

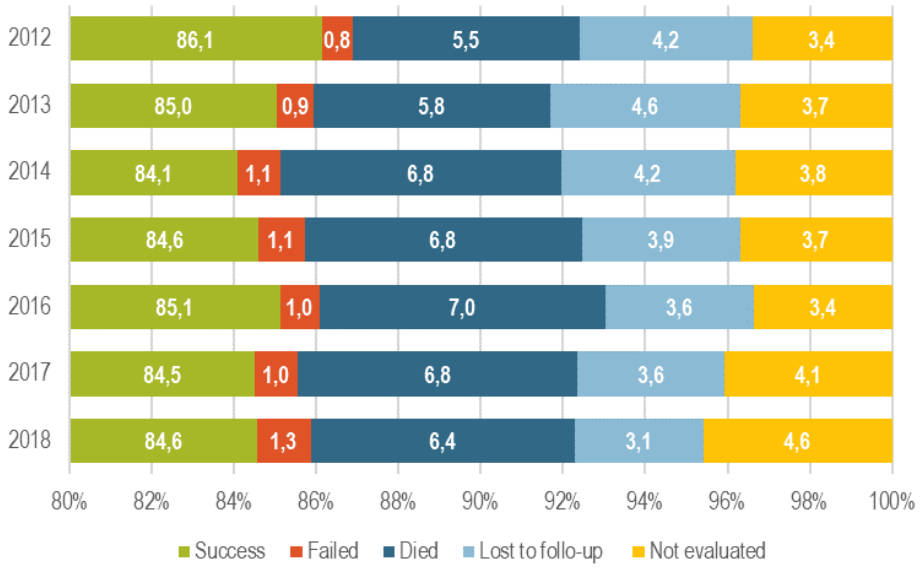


Figure 8: Treatment outcomes of new and relapsed TB patients, 2012-2018

Source: NPTCCD and reference 5.

Table 5: Attribution of cause of death in 198 patients in 2019

	Number	Percentage
Not Recorded	28	14.1
Death due to TB	**62**	**31.3**
Death not due to TB	61	30.8
Indeterminate	47	23.7

Source: NPTCCD

During the mission, a detailed analysis of the deaths from 2019, based on the Death Investigation TB-17 Forms, was made available. This included just 198 deaths on which information was reported by DTCOs, from a total of about 500. According to this analysis only 1/3 of deaths was directly attributed to TB (Table 5); in 1/3 the cause of death had been undetermined or not recorded and in the remaining one third the death was thought not attributable to TB. Half or more of the deaths may therefore not in fact be due to TB. Although the convention is to record a death during TB treatment as a death due to TB, if attribution of death is not recorded or analysed, the data will fail to give a true picture of the reality of TB deaths. Death due to causes other than TB is likely linked to the old age of the majority of patients that dies (Figure 9), which in turn is likely to be linked to the high number of comorbid conditions that these patients suffered (Table 6).

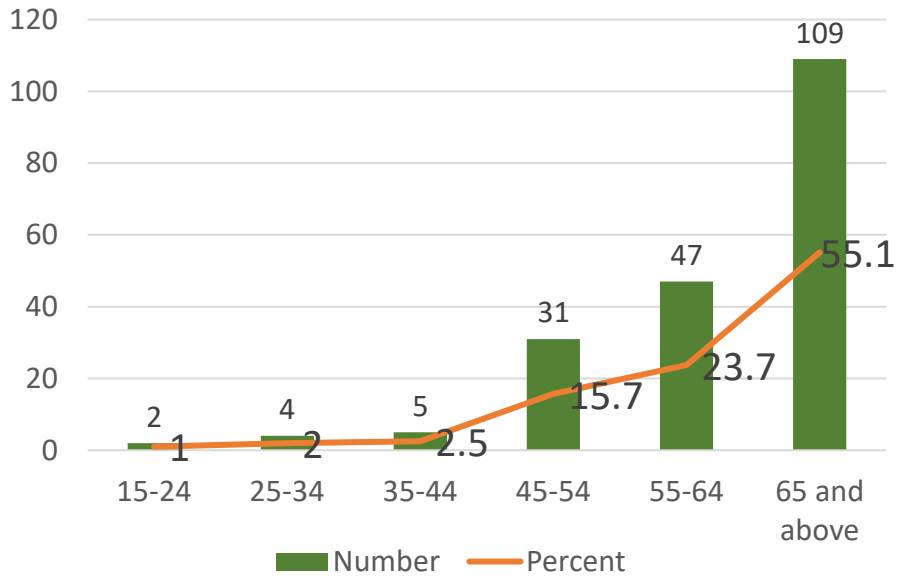


Figure 9: Deaths by age group from 2019 analysis of 198 deaths

70% of patients who died of TB had a co-morbid condition. About 50% had diabetes, much higher than the proportion in the normal population (10-15%). Chronic respiratory, renal and liver disease are also seen in higher proportions than the normal population. It is important that these diseases are identified as high-risk factors and patients with these co morbidities are monitored and followed up closely to prevent complications.

Eighty per cent of the deaths occurred in the first two months of commencing treatment, and half of the total deaths occurred during the first month. This may suggest that patients die due to advanced disease, some of which might not be amenable to treatment. Other causes of early death may be attributed to deterioration of the pre-existing comorbidities. Drug interactions, adverse effects and errors in clinical management cannot be excluded as causes of deterioration but could be analysed in future studies.

Table 6: Co-morbid conditions identified in 198 patients who died in 2019

Comorbid Condition	Number	Percentage
Chronic Liver Disease	**7**	**5.1**
Chronic Renal Disease	9	6.5
Diabetes	**66**	**47.8**
Epilepsy	1	0.7
HIV	3	2.2
HTN and Cardiac	**33**	**23.9**
Hypothyroidism	1	0.7
Psychiatric Illness	1	0.7
Renal Abscess	1	0.7
Respiratory Problems	**15**	**10.9**
Thyrotoxicosis	1	0.7

Source: NPTCCD. "Deaths in tuberculosis – an analysis" provided to the Review

Nutrition support

The NPTCCD had previously provided two packets of Triposha to patients. This has never been under a circular. The NPTCCD has been obtaining Triposha from the factory and providing it to patients. The Triposha programme is currently under threat as the corn that is needed was budgeted as Rs 55 per kg, whereas the farmers are asking for Rs 98. The importation policies are being reformulated and the import of corn is doubtful. In addition, the programme is now under the Ministry of Women and Child Affairs and Social Security's pre-school and primary education, school infrastructure and school services. This Ministry does not address those with diseases, and it is doubtful the Triposha supplementation can continue under this Ministry. The responsibility for nutrition support to patients will likely be shifted to the MOH, which has its own Nutrition Unit.

The MOH's National Nutrition Policy (NNP) 2010 is currently being revised and the NNP 2020-2030 is drafted. The guiding principles in the new NNP lead to six policy priority areas for actions. The fourth policy priority area 'Nutrition improvement throughout the life course' has 'Prevention and management of disease-related malnutrition' as its 10th key strategic direction, which is applicable to patients with acute or chronic diseases including TB. According to WHO, there is no good evidence that nutritional care improves TB-specific treatment outcomes, once proper treatment with TB medicines is provided. However, there is strong evidence that proper nutritional care improves nutritional recovery for people who are undernourished, and therefore helps reduce general health risks. This applies also to people with TB.

Challenges

The review team identified efforts to decrease the death rate due to co-morbidities during the initial treatment phase as the key challenge to the program to achieve the target treatment success rate of >90%. Also, a significant proportion of patients with TB has considerable social and economic problems. Some of them do not have a place to stay during treatment because they have no one to care for them, or the places that they stay do not have enough space. If not addressed properly these patients may default. In Colombo, 108 of 1916

(6%) patients were substance users in 2019, and 183/8251 (2%) nationwide. Many would benefit from institutionalised care for TB and substance abuse. The NSP 2015-2020 had described the establishment of respiratory wards in all districts as a key activity in this regard. However, the review team found that in many districts, facilities are still non-existent or inadequate. In Colombo, none of the hospitals including the National Hospital of Sri Lanka have designated respiratory or TB beds. The situation is similar in Galle, Karapitiya and Jaffna. In Rathnapura, the Teaching Hospital has only 4 beds in a medical ward to manage 1.5 million people. Other districts that have no designated respiratory beds in the whole District are Ampara, Vavuniya, Moneragala and Mannar.

Although not conclusive, some published studies do show a delay in sputum conversion among malnourished people and there are other studies that show poor outcome in malnourished patients[12].

Recommendations

1. To decrease death rates, respiratory wards should be constructed in all districts that are without them, preferably with isolation rooms for infectious patients, and high-risk patients (with advanced age and/or comorbidities) should be identified and admitted for intensified care in collaboration with other specialists.
2. To identify high-risk patients, a simple checklist should be developed by the NPTCCD for distribution to staff at all diagnostic facilities
3. The NPTCCD should conduct further analyses of causes of death to determine more accurately the cause of deaths with the ultimate aim of attributing a cause to each death.
4. Although not conclusive, some published studies do show a delay in sputum conversion among malnourished people and there are other studies that show poor outcome in malnourished patients. Necessary measures should be taken by the programme/ MoH for providing nutrition supplements like Triposha for malnourished TB patients through inclusion of the policy in the newly developed NNP.

[12] VS Maddumage, S.Gunasiri, N.Dinushika, R.Ayathilaka, P.Seneviratne, S.Prathapan, C.Undugodage. Factors influencing non-conversion of sputum smear at the end of two months of treatment in pulmonary tuberculosis patients at selected tertiary centers in Colombo District. Respire. 2019, 8 page 16-227.

3.6 Objective 6

Review implementation of collaborative activities with other programmes like HIV and diabetes	Are the TB/HIV collaborative activities recommended by WHO adequately addressed? What is the extent of TB/diabetes collaboration?

Findings

The team reviewed the most recent available data on the size of the HIV problem. At the end of 2017, the estimated numbers of people living with HIV (PLHIV) was 3,500 (3,000-4,200) while the total reported PLHIV was 2391. In 2017, 285 new cases were identified most of whom were men who have sex with men (MSM) and bisexual men, followed by males with non-regular partners. The number of PLHIV represented by MSM/bisexual men has been gradually rising since 2010. Most cases are concentrated in the Western Province as in earlier years and the proportion of young people affected (15-24 years) has remained static around 10%, since the last eight years. Modelling of the epidemic over the years clearly show that the HIV infection among female sex workers (FSW) and their clients will decline but the worrying factor is increasing trends of the infection among MSM and bisexuals and female partners of and vulnerable populations. Vulnerable populations with the highest numbers are:

- Female sex workers (FSW) - 30,000 (20,000 – 35,000)
- Males who have sex with males (MSM) – 40,000 (30,000 – 50,000)
- Male sex workers - 6,000 (4,000 – 8,400)
- People who inject drugs (PWID) - 900 (650 – 1,200)
- Transwomen - 2,200 (2,000 – 3,500)
- Beach Boys – 4,500 (3,000 – 6,000)

The review team found that collaboration between the NPTCCD and the National Sexually Transmitted Diseases and AIDS Control Programme (NSACP) programs started in 2013 and a common policy has been included in the NSP of the NSCAP published in 2018. A high proportion of TB patients is screened for HIV (>90% nationwide). However, screening of HIV patients for TB was lower. It is currently 80% in Colombo, but the national level is not available in the recent annual reports of the NSACP[13]. In Colombo the policy is to start PLHIV on TPT after excluding active tuberculosis, however, coverage is low (57% in Colombo, no nationwide data). The NSACP report, which is more qualitative than quantitative, seems to appreciate the collaboration of CCC MOs attending the STD clinic, and states that "District STD clinics are interested to issue INAH with ART to improve adherence to treatment. This service needs to be established in district clinics in 2020."

Reported ART coverage among identified TB/HIV patients was usually high, ranging between 58.3 and 100% in different districts. Reported treatment success of TB/HIV co-infected patients is comparatively low when compared with the non-HIV TB patients, within the range

[13] Annual report of the National STD/AIDS campaign Programme 2019, National STD/AIDS Control Programme, Ministry of Health, Sri Lanka. https://www.aidscontrol.gov.lk/images/pdfs/publications/NSACP_Annual-Report_2019.pdf Accessed 18th November, 2020. And: HIV, TB year end data for TB, National STD/AIDS Control Programme, Ministry of Health, Sri Lanka.

of 63 to 83% during the recent four years. The main reason of unfavourable treatment outcome was "not evaluated". HIV status is not recorded in district TB registers, due to confidentiality issues as the register is handled by several people, so the current TB registration system doesn't include treatment outcome reports of TB/HIV cases. Treatment success in these patients could therefore actually be higher than is reported.

The rapport between the HIV and TB services was generally observed to be good. There were no concerns raised by the DCCs regarding the screening process of PLHIV, in spite of the risk entailed by immunosuppressed patients attending facilities with patients with active TB, and no concerns raised by the STD clinics regarding sending the patients for screening to the DCCs, as the screening is performed in separate chambers. However, some patients were concerned about the maintenance of their privacy and the need for increased number of visits to different places for investigations such as chest X-ray and treatment.

The review team noted the results of the recently concluded study on TB in diabetic patients. Of the 4548 study participants, 13 (0.3%) were already taking treatment for pulmonary TB (PTB) at the time of recruitment to the study. Of all 4,548 study participants, six (6) patients were newly detected with PTB as a result of active screening by the study itself giving a proportion of PTB among diabetes clinic attendees as 0.001 (6/4,548). The incidence of 6/4,548 or 132/100,000 is twice the estimated national level. As there are a large number of diabetic patients among the patients who died with TB, disproportionate to the number in the community, there appears to be scope for enhancing care of diabetes in those who are already diagnosed to have both conditions by collaborating with the endocrinologists and physicians.

Challenges

Countrywide collaboration between TB and HIV programmes has not yet been achieved, especially with respect to ensuring complete referral of HIV patients for TB screening and ensure complete coverage with IPT for HIV patients.

The study on TB in diabetic patients showed large differences in prevalence of TB between sub-groups, with the highest prevalence observed in older males. These observations could be used to improve the efficiency of the screening algorithm.

Recommendations

1. To ensure effective collaboration between the two programs, regular coordination meetings between TB and HIV programs at appropriate levels should be organized;
2. All staff working in the HIV program should be trained on the importance of TB screening and IPT;
3. The programs should explore mechanisms to provide "one-stop services" for TB/HIV patients, where they would receive care for both diseases and there would be common data monitoring, without exposing PLHIV to risk of TB infection;
4. The NPTCCD should consider restricting TB screening to high-risk groups among diabetics, such as older male patients.

3.7 Objective 7

Review programmatic management of drug resistant TB in relation to adoption and implementation of updated WHO guidelines and infection control in health facilities, community, and congregate settings	What has been the response to the r-GLC recommendations, 2017-2020?

Findings

Sri Lanka has a low burden of drug-resistant TB with an estimated 27 rifampicin-resistant (RR) or multidrug-resistant (MDR) TB cases appearing each year which translates into an incidence rate of only 0.13/100 000 population. It is also estimated that only 0.1% of the new cases and 3.3% of the previously treated cases have RR/MDR-TB[14].

As per the information provided to the review team, 16 districts are currently implementing universal drug-susceptibility testing (UDST), which is supposed to be expanded to 26 districts by 2021. The priority list for susceptibility testing in districts not implementing UDST is

a. Contacts of MDRTB patients
b. Previously treated patients
c. Non/delayed sputum converters
d. Repeated treatment interrupters
e. TB- treated outside the Programme
f. TB-HIV co-infection
g. Prison/drug addicts/barrack settings
h. Health care workers
i. Return from abroad with active TB
j. Other high-risk groups

As per the report available from WHO, the susceptibility testing for drug resistance has varied over the years, being 25% for new cases and 77% for retreatment cases in 2019. This is less than the 30% and 91%, respectively, from the previous year (Figure 10).

[14] Source: WHO Global TB Report 2020

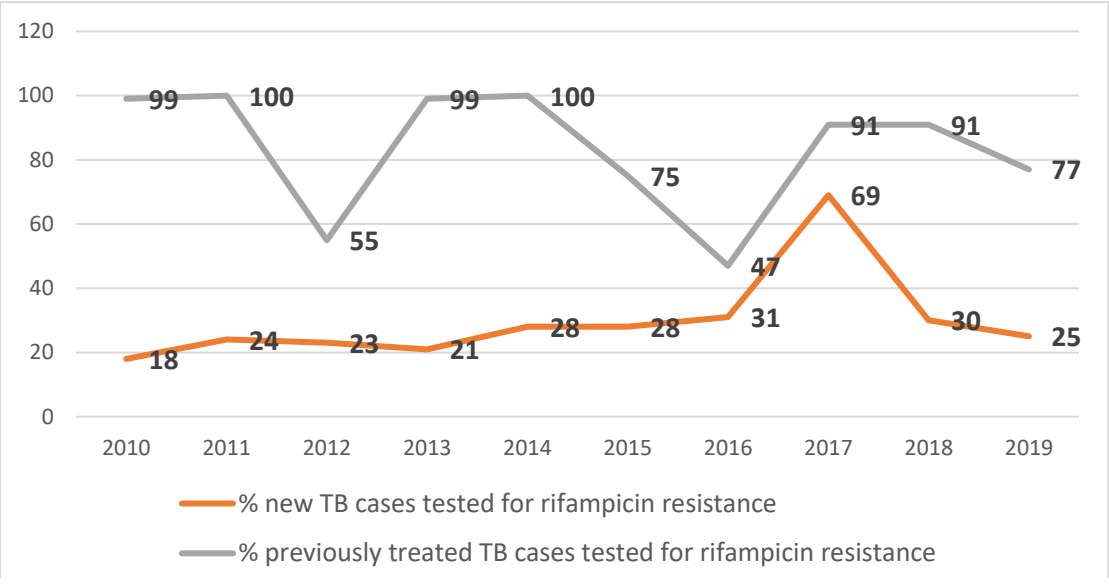


Figure 10: Trends of susceptibility testing for rifampicin resistance

Source: NPTCCD submission to WHO

In 2019, 20 RR/MDR-TB cases were diagnosed and 21 were initiated on second-line treatment in the same year (Table 7). The one additional case initiated on treatment was clinically diagnosed and hence not reported as a laboratory confirmed case. However, in 2017 and 2018, there was a wide gap between those diagnosed with RR/MDR-TB and those initiated on treatment (Figure 11). As per the information provided by the NTP, the discrepancy is because not all cases diagnosed as RR/MDR-TB were initiated on second-line treatment. Hence there is a separate number for those 'registered' under NTP. Further investigation of reasons for not starting the diagnosed patients revealed that most of these patients had either low risk (new TB cases), low bacillary load and/or a repeat test not detecting rifampicin resistance. Although it must also be noted that 3 out of 10 such patients in 2017 died while on treatment.

The cohort of those patients for whom outcome is reported excludes patients who died before the start of the treatment, after being registered and those who were lost to follow-up (Table 8).

Table 7: Drug-resistant TB Care, 2019

% of bacteriologically confirmed TB cases tested for rifampicin resistance- New Cases	25%
% of bacteriologically confirmed TB cases tested for rifampicin resistance- Previously treated cases	77%
Laboratory-confirmed cases- MDR/RR-TB	20
Patients started on treatment MDR/RR-TB	21
Laboratory-confirmed cases-XDR-TB	0
Patients started on treatment-XDR-TB	0

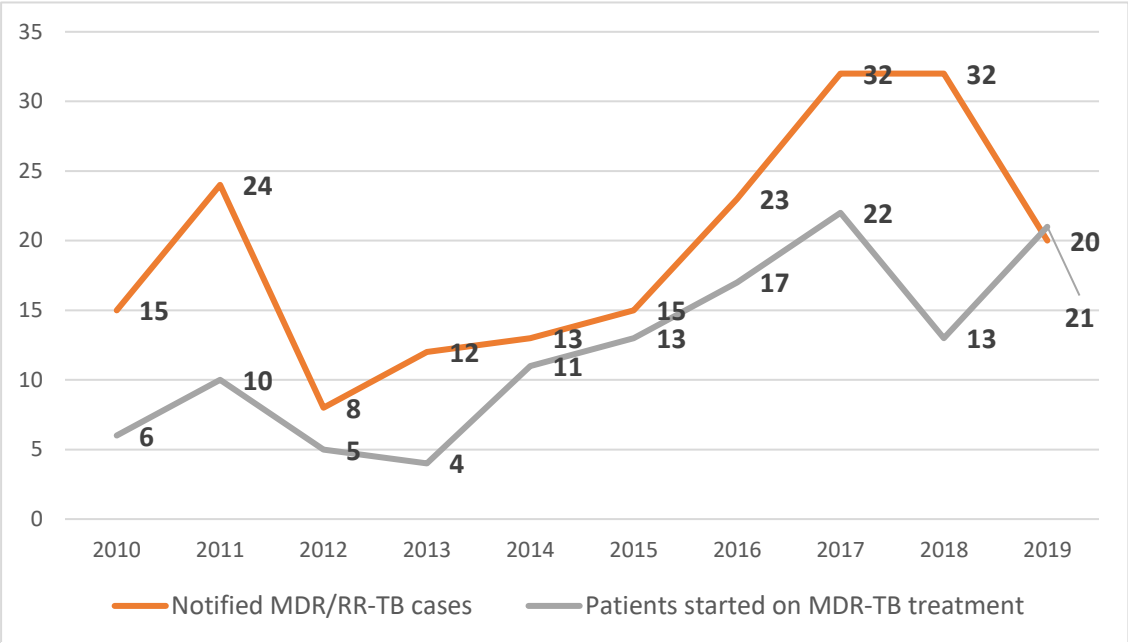


Figure 11: Trends in RR/MDR-TB case diagnosis and enrolment on treatment

Source: NPTCCD

Table 8: Annual RR/MDR-TB patient registration and treatment outcomes

Year	Patients Registered	Cured	Lost to Follow-up	Deaths	Still on Treatment	Diagnosis Changed
2016	18	11	00	06	01	
2017	25	17	02	06		
2018	12	12	00	00		
2019	21	01	01	05	12	02
2020 (Upto Q3)	14	-	01	02	07*	01

Source: NTP presentation on MDR-TB patient outcomes

All patients, except one, enrolled in 2020 were reported to be receiving all-oral bedaquiline containing regimens though this is not formalized into the guideline yet. The guideline shared with review team was quite old. The MDR/RR-TB treatment success rate for 2017 cohort is 68%.

It was also reported that supervisory visits from central level were held as per schedule in 2019. Active drug-safety monitoring and management (aDSM) could also not be assessed in detail because of the lockdown in Gampaha, which limited our access to the NHRD at Welisara, but limited information shows that treatment monitoring is happening on a regular basis. The limited review also revealed that there is an adverse event monitoring form and regular check-ups recorded e.g., hearing test.

Follow-up actions on recommendations from rGLC 2019 mission are placed in Annex 5 for reference.

Infection control

All DCC staff have been trained on infection control and triaging of patients, we were informed, but the same may not be true for bigger/ tertiary care hospitals. However, recently, because of the COVID-19 outbreak, triaging is happening in all major hospitals. The Infection Control guidelines available are from 2005. These were supposed to be updated in 2020 but it hadn't been done because of the COVID-19 outbreak. However, it is expected that this will be taken up soon through remote work. Guidelines for screening of health workers for TB have not yet been prepared.

The review team also noted that presumptive tuberculosis patients, when admitted for inward care, are often kept with other patients who may have multiple comorbidities. Confirmed TB cases are managed in an isolation ward, when possible but may be managed in open wards with other patients due to lack of isolation areas. This raised the possibility of nosocomial spread of tuberculosis to the patients as well as the staff.

While there was not much direct observation of infection control in hospitals and congregate settings, it appeared that COVID-19 provided opportunity for infection control in OPDs because of distancing being followed and masks being used.

Challenges

- The PMDT guidelines shared with review team are from 2015 and do not incorporate the updates since then. We were told that this is because the guidelines are updated only after 4-5 years and any interim changes are conveyed through an internal circular.
- The PMDT coordinator also functions as DTCO Gampaha, which is among the most populous districts, and is therefore overloaded with work.
- No children (<15 yrs) have been diagnosed with MDR-TB since 2016. While this could be due to low DR-TB incidence in the country, insufficient contact investigation may also be a contributing factor.
- A declining proportion of new and retreatment cases are being screened for drug-resistance.
- Data on case diagnosis and those enrolled on treatment for previous years does not match between what was submitted to WHO and that available in NTP records.
- MDR/RR-TB treatment success rate for 2017 cohort is 68% - less than the target of 75% established in previous NSP.
- Mixing of presumptive TB patients with bacteriologically confirmed cases increases the chance of cross-infection

Recommendations

1. Update PMDT guidelines, including treatment regimen for adults and children, as well as guidelines for health staff screening for TB, by end of Q4 2020.
2. Universal DST should be promoted and implemented in all districts by end-2021.
3. Decentralisation of MDR-TB care to at least two more centres. This should be included in the NSP 2021-2025.
4. Intensify contact investigations for MDR-TB patients. One of the indicators will be to monitor the numbers of contacts investigated per diagnosed patient.
5. Advocate with MoH to provide for sufficient support to the DTCO in Gampaha and separate the functions of the PMDT Coordinator and DTCO Gampaha.

6. If admission is required, all patients should be triaged and identified as presumptive or diagnosed bacteriologically confirmed, and, wherever possible, managed separately from other patients with proper infection control measures (see recommendation 1 of objective 5). All bacteriologically confirmed pulmonary TB patients, if requiring admission, should be managed in isolation units where regular monitoring is available, with training and facilities to the staff to maintain proper infection control measures.
7. Collate lessons learnt on infection control during COVID-19 outbreak to be adopted as a practice for future – Q4 2020.

3.8 Objective 8

Evaluate programme approach in reaching out to high-risk groups and those which do not have easy access to health systems like children, tea-estates, and migrant workers	What are the high-risk groups? (include prisoners, and household contacts, but PLHIV are addressed in Obj. 5) What active case-finding activities (policies, strategies, guidance for staff, implementation etc) have been performed? How effective were these? How can they be improved?

Findings

The review team observed that between 2013 and 2019 there was a decline of the proportion of child TB cases from 3.3% to 2.9% (Figure 12).

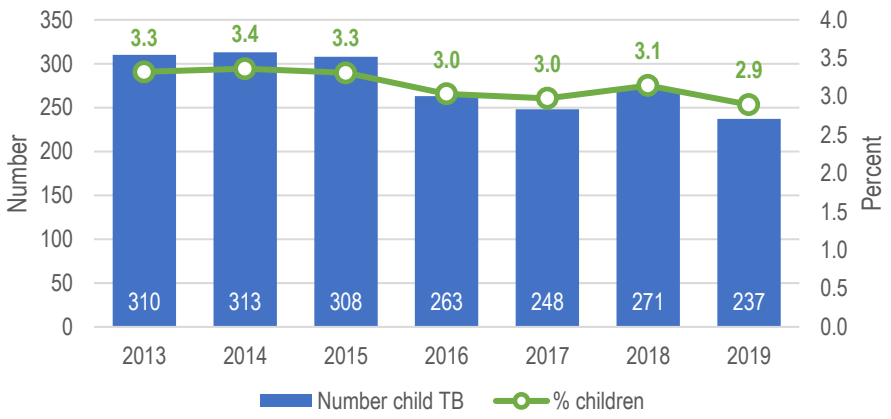


Figure 12: Trend notification of new and relapse cases by child TB cases

Source: NPTCCD

Evidence suggests that in low- and middle-income countries, like Sri Lanka, the expected proportion of children should be around 5 to 15%. A proportion below 5% suggest under-diagnosis or under-reporting of child-TB cases. A Child TB policy has been developed in 2018, but implementation has remained insufficient. Staff at peripheral facilities showed interest in childhood TB diagnosis during the review, but often had no training. A new diagnostic algorithm for TB in children has been developed (Figure 13) but has not yet been officially distributed.

Concerns have been expressed that the use of this algorithm should be restricted to specialists. i.e., paediatricians or chest physicians at the DCCs, because diagnosis of TB in children is difficult, and usually relies on clinical experience. However, the guideline is important to raise awareness of the issue of childhood TB and encourage more suspicion of the problem in the field, both of which are needed. The algorithm does provide multiple points for staff with less experience and/or facilities to refer presumptive cases to more experienced staff.

The child TB guideline refers to some tissue samples (*bloodstained samples, urine, faeces, and pleural fluids)* being unsuitable for Xpert MTB/RIF. This is inconsistent with WHO guidance[15].

[15] WHO. WHO operational handbook on tuberculosis, module 3: diagnosis - rapid diagnostics for tuberculosis detection. Page 4. Geneva: World Health Organization, 2020.

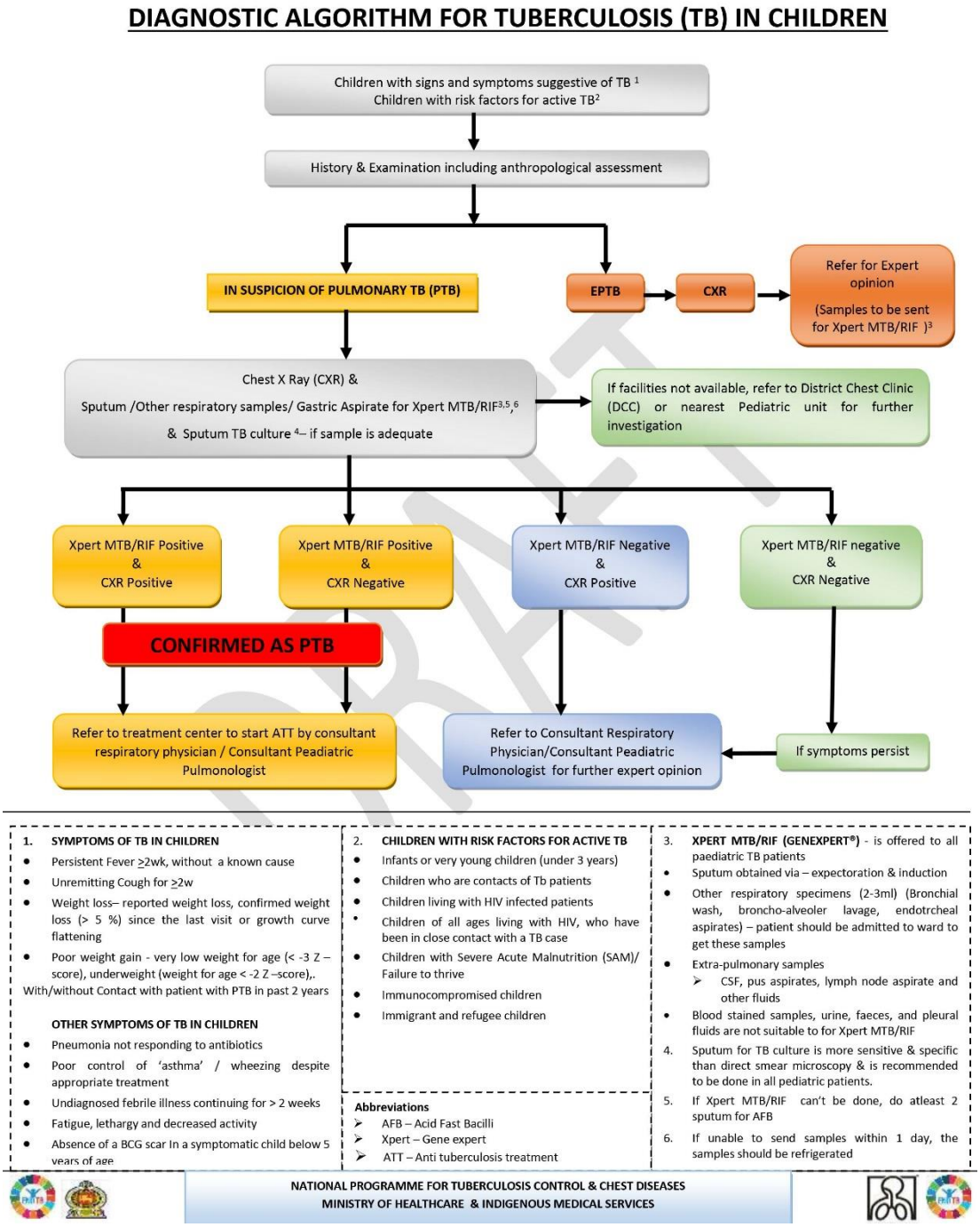


Figure 13: Diagnostic algorithm for children (not yet distributed)

Source: NPTCCD

In general, Maternal and Child Health (MCH) statistics in Sri Lanka are remarkable e.g. maternal mortality, infant deaths, MCH service provision and use, immunisation etc. As a summary indicator, under-five mortality is commonly used as a proxy indicator of overall population health and therefore for access to health services. The estimated under-five mortality is steadily declining (Figure 14). The observed spike in 2004 was due to the Indian Ocean tsunami on December 26, 2004, which killed 35,322 people in the country of which about one third were children. Between 2008 and 2018, the annual average decline of child

mortality was -5.2%, indicating a remarkable and fast improvement of population health and reasonable access to health care.

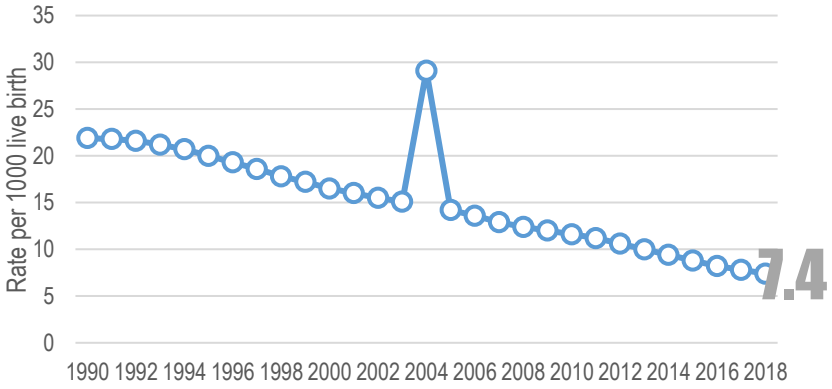


Figure 14: Trend in Under-five mortality rate per 1000 live births, 1990–2018

Data source https://data.worldbank.org/indicator/SH.DYN.MORT

Compared to other countries with the similar income U5MR in Sri Lanka was remarkably lower in 2018 than would be expected from the size of the economy expressed in GDP per capita. There is a well organised, systematic programme delivery, with management, supervision, monitoring and evaluation from national to divisional (MOH) level supported by a time-tested Information System. Training the primary healthcare (PHC) staff up to Public Health Midwifes is done through a cascade system using Training of Trainers, and which contains a component on TB, which was not prepared by the NPTCCD, but with their inputs.

An interview with the Director, Estate and Urban Health, showed that TB services in the estates remain poor. There is only one consultant community physician for the estate sector, and he finds it difficult to run the programme. Any patient who is having symptoms and signs will visit the nearest estate medical assistant (whose basic degree is either in pharmacy or some other allied health degree). He would usually give paracetamol and antibiotics and only after repeated visits when the patient feels that the symptoms are not improving, would they go to the District Medical Officer (DMO). As the DMO cannot do chest Xrays (CXR) he would also start on the same treatment. The nearest place that these patients would get a CXR would be a Base Hospital. There are some areas in Badulla (the ray berry estate) where the patient's closest hospital is the Badulla General Hospital which is 5 hours away. As a result, there is a minimum of 4 days of travel (5 hours one way), and loss of wages, for getting a diagnosis of TB.

Recent (post-review) data on ACF among the estate population found no cases in Galle or Kegalle (out of 48 and 379 people tested, respectively), but did find 8 cases out of 932 (0.85%) in Kalutara. This ACF was most likely performed using relatively insensitive algorithms (symptoms followed by sputum smear examination). An awareness campaign on TB and stigma management was implemented for 400 Child Development Officers (CDO). These CDOs work in crèches which are childcare centers in the estates. This was taken up well by the management. However, the outcome of the awareness programme was not measured. Transport of patients would be problematic even if the CDOs want to refer the symptom positive patients.

Screening of migrants for TB is currently done under a contract with IOM. From June 2019 to January 2020, 20,737 migrants were screened of which 15 were confirmed as TB. The IOM is reported to follow the national screening algorithm described in the national guidelines.

In prisoners, previous mass screening was also done using relatively insensitive algorithms, as in the estates, and yielded a low prevalence. Recent screenings have yielded rates well in excess of the population incidence by both mass screening, and also by routine programmes run by local DTCOs (Table 9). The algorithms used are unclear, however, but there were some data showing CXR and GeneXpert were used, but not on all presumptive cases. Currently, due to COVID-19 restrictions, there is only routine diagnosis of symptomatics in regular clinics. In symptomatics, the recent prevalence figure was >1.8%.

Table 9:Prison screening, 1st and 2nd quarters, 2020, by type of screening

Activity	No of Programs held during Quarter	No of persons screened	No. of suspects identified	Detected with TB	
				No.	%
Mass screening programmes	20	857	857	04	0.47
Routing screening clinics /programmes conducted by chest clinic staff	142	2406	2406	43	-1.78
Routine screening carried out by prison medical staff	-	-	-	-	-

Challenges

It is clear that some of the low prevalence figures in risk groups such as estate workers or prisoners was due to relatively insensitive algorithms, which indicates opportunities for operational research.

Recommendations

1. ACF should only be undertaken with chest X-rays and GeneXpert, and Standard Operating Procedures should be developed for ACF, and their implementation monitored. This applies especially to prisons which should be screened at least every two years, are recently if there are reasons to expect an outbreak.
2. The new diagnostic algorithm for children is sensitive and comprehensive and should be distributed and implemented. Staff at peripheral facilities (outside Colombo) should receive awareness training on it and simple education material about signs and symptoms.
3. Operational research should be conducted in other high-risk groups, eg estate workers, in order to identify further groups for routine ACF. One additional mobile unit, and 2 portable X-ray machines should be purchased.
4. The sectors (urban / rural /estate) should be included into the e-PIMS and the routine reporting system

3.9 Objective 9

Review the current policies and strategies for TB preventive treatment (TPT) including their alignment with updated WHO guidelines, coverage and plans for expansion.	What are the current plans for expansion of TPT?

Findings

The current guidelines enable TB preventive treatment (TPT) with isoniazid for 6 months to child contacts less than 5 years of age (U5s) of bacteriologically confirmed cases, and to PLHIV, as well as specific clinical groups with high risk, such as those receiving organ transplants, or anti-TNF blockers. For all groups active TB must first be excluded. Guidelines which would expand these treatment groups significantly have been in preparation for about one year and their implementation would create uniformity in TB prophylaxis and its monitoring processes.

The stimulus for the new guidelines was the 2018 UNHLM on TB which committed to "… at least 30 million people, including 4 million children under five years of age, 20 million other household contacts of people affected by tuberculosis, and 6 million people living with HIV, receiving preventive treatment by 2022."[16] The treatment targets for Sri Lanka, prepared by WHO, SEARO, are 10,500 adults and 1100 children annually by 2022.

The new guidelines aim to provide TPT first to PLHIV, both adults and adolescents, including those who have previously been treated for TB, pregnant women, infants aged < 12 months who are in contact with a case of TB, and children aged ≥12 months irrespective of their contact history.

HIV-negative close contacts of a person with pulmonary TB, both bacteriologically confirmed and clinically diagnosed, are also targeted. Infants and children under 5 years of age will be provided TPT after excluding active TB disease, while children above 5 years of age, adolescents and adults who are household contacts of a patient with pulmonary TB will be tested for latent TB infection (LTBI, and, if positive, will receive TPT only after excluding active TB disease, while non-household close contacts will be tested and treated after a positive risk assessment. The clinical risk groups consist of patients initiating anti-TNF treatment, receiving dialysis, preparing for organ transplants and patients with silicosis. For contacts of patients with MDR-TB, preventive treatment may be considered based on individualized risk assessment and a sound clinical justification.

The new guidelines also include "socially vulnerable" groups such as prisoners and drug users, and those who are "occupationally vulnerable" such as health care workers (HCW) if they are shown to have LTBI. Scale up of LTBI testing for these groups will be based on "programmatic factors" and "assurance of treatment completion (prisoners)".

Challenges

The UNHLM-based national target is put into stark relief by the fact that in 2019 only 268 children were treated (243 U5s), and 181 PLHIV. There are about 3,600 PLHIV in Sri Lanka.

[16] Stop TB Partnership. UNHLM – TB: Key targets and commitments for 2022. United Nations. http://stoptb.org/assets/documents/global/advocacy/unhlm/UNHLM_Targets&Commitments.pdf Accessed 20/10/2020.

Some others may have received TPT but the data are unclear. About 50% of all household contacts were screened in 2019, but less than 3% (268) of those identified were provided TPT, while those under 5 years form 9% of the population. There was no uniformity by district, or by target group, in provision of TPT.

This raises the question of whether the necessary resources are available for this level of scale up. The guidelines recognize this problem and plan for a gradual escalation (Figure 15). However, the lack of human resources at both central and district level is the major bottleneck for the expansion of TPT provision, followed by the challenge of procuring and distributing the infection testing tools to the treatment providers. The NPTCCD Central Unit, which lacks the staff to plan, coordinate and implement a TPT Programme of the scale demanded by the new targets. In addition, the DCCs visited on the review were struggling to cope with the current patient numbers, let alone those just with TB infection, and there were significant shortages particularly of radiographers and MLTs (see Objective 12 for further analysis of the human resource issues).

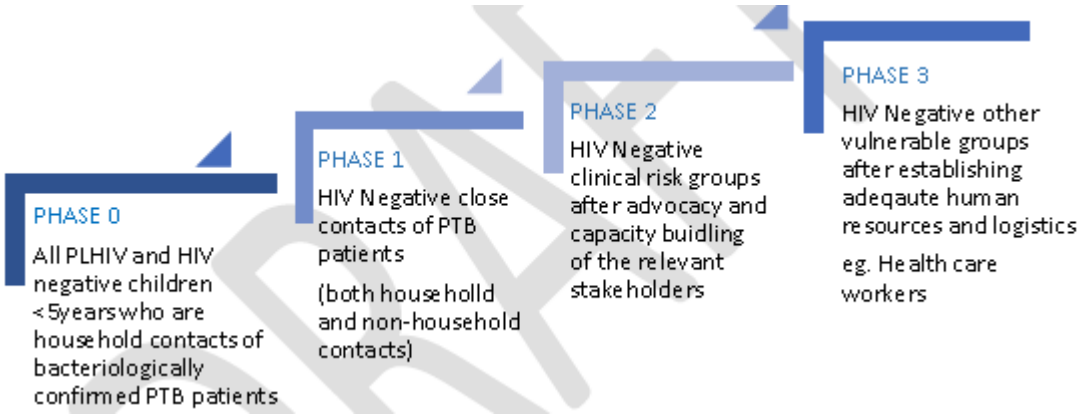


Figure 15: Schematic representation of scaling up of LTBI screening programme

Source: New guidelines for TPT, Ref.[17]

Recommendations

1. Finalize the new guidelines but hold off on publishing and disseminating them until there is at least 1 consultant community physician to lead a TPT expansion programme, with 1-2 MOs to support, and sufficient staff in at least some districts which can be used to pilot the new guidelines.
2. The TPT expansion plan, which should be included in the NSP 2021-2025, should include a review and revision of the process of contact identification, contact screening, LTBI testing, provision of TPT and its monitoring, dissemination of information to TB patients[18], and the distribution of clear standard operating procedures and training materials covering all these areas. Indicators should be defined, and targets set, with mechanisms in place to hold those responsible accountable.
3. Once contact tracing and provision of TPT are expanded for contacts and PLHIV, plans can be put in place for the identification of the socially and occupationally vulnerable groups, especially the elderly, and management of the provision of TPT to them.

[17] NPTCCD and the Sri Lanka College of Pulmonologists. Guidelines for programmatic management of latent TB infection in Sri Lanka. In preparation.

[18] Which could include an adaptation of the WHO, SEARO and the Global Coalition of Activists' brochure on *How to Protect Ourselves from TB: About TB Preventive Treatment.*

3.10 Objective 10

Evaluate procurement, supply chain and stock management of first and second-line TB drugs, and other consumables	What are the main procurement problems? What has been the response to these problems? What changes, if any, should be made to procurement

Findings

All first- and second line drug FDCs had been procured through GDF up to 2019, funded by the Global Fund. From 2019 onwards, funding for first-line drug FDCs has been provided from Government of Sri Lanka (GOSL) funds, while second line drugs continue to be funded by the Global Funds and are procured through the GDF/GLC mechanism. Individual Drugs have previously been procured through the Medical Supplies division following govt. tender procedure. Since 2019 they are procured through GDF using GOSL funds. All anti-TB drugs are available only in DCCs and are issued only for registered patients. After the shift of the funding for first-line drug FDCs to GOSL funds there had been initial quality problems due to procurement from local sources. To ensure the supply of quality ATT, ministry approval was obtained to purchase drugs through GDF following recommendation by the TB Advisory Committee. During the last year, some other initial problems with GOSL drug funding have been solved. For instance, the GDF needed pre-payment along with the order, however, according to SL govt. regulations, payments can only be made once the invoices are received. The NPTCCD negotiated with the GDF to be able to make the payment once invoices are received. Also, according to SL govt. regulations there is a maximum limit to send money abroad. The NPTCCD negotiated with the GDF to be able to make payments in instalments. As a result of these adaptation, the review team did not observe any stockouts of TB drugs during the last year, with the exception of INAH 100 mg tablets, which were out of stock for a few months last year. During this period INAH 300 was used (broken to adjust the dosage).

For drug distribution, the CDS had previously used their own vehicles, however, these have recently broken down and could not be replaced, so that DTCOs used to send their vehicles to CDS for the drugs. With respect to drug warehouses, the mission team observed that they are generally clean and organized and maintain orderly stock records. Warehouses are generally equipped with AC, but in some places this was not functioning. In one facility visited during the review, there was a shortage of racks and some boxes were on the floor. There was also a flooding risk due to a leaking roof. The NTP has a system of paying supervisory visits to all district drug stores funded through GF. The supervision mechanism for drug distribution facilities appears insufficient.

Challenges

The NPTCCD needs to ensure the continuous supply of high quality first- and second line drugs. A robust system of drug distribution and storage needs to be established at all levels.

Recommendations

1. The NPTCCD should continue to ensure sufficient first-line drug FDCs and individual drugs are available at point of need;
2. All drug procurement should be continued through GDF to ensure a high quality of all drugs
3. The NPTCCD should review the requirements for the distribution chain (vehicles etc.) through an inventory assessment and explore funding through the GOSL and the

Global Fund to replace non-functioning essential components of the distribution chain;

4. The NPTCCD already keeps a national database on warehouse conditions. To address the recorded deficiencies, the program should seek GF funding for repair/maintenance

3.11 Objective 11

Review monitoring and evaluation system including data quality, and robustness of observed time trends based on epi-review findings	This work has already been completed and the results are in the Epidemiological Review. Here we report a summary of the main points and chief recommendations.

Findings

The purpose of the epidemiological review was to assess the completeness and accuracy of routine TB surveillance and vital registration (VR), to provide more details around the TB burden estimated by WHO, and to investigate the drivers of the TB epidemic in the country. The specific objectives of the epidemiological review were:

- to describe and assess the current national TB surveillance and VR systems, with particular attention on their capacity to measure the level of, and trends in, the TB disease burden (incidence and mortality), using a TB surveillance checklist;
- to assess the level of, and trends in, the TB disease burden (incidence and mortality) using available surveillance, survey, programmatic and other data;
- to assess whether recent trends in TB disease burden indicators are plausibly related to changes in TB-specific interventions, taking into account external factors such as economic or demographic trends;
- To define the actions and investments needed to directly measure trends in TB disease burden in Sri Lanka in the future, and other recommendations for improvement in TB surveillance, case finding and treatment success;
- To build capacity for epidemiological reviews in country by involving members of the NPTCCD, DCCs and other in-country partners to actively participate in objectives 1-4.

The checklist and associated user guide from S*tandards and benchmarks for tuberculosis surveillance and vital registration systems* were applied for the assessment. Methods of data collection included: (1) a desk review of available TB control-related policy papers, decrees, guidelines and forms; (2) interviews and discussions with programme staff at national and district levels; (3) a review of TB records, registers and electronic surveillance system at the facilities visited; and (4) an analysis of notification/surveillance data over time and geographically to identify trends in the disease burden and programmatic efforts.

Of the 11 WHO standards for TB surveillance that were applied, five were met, six were partially met, and two were not met (Table 10).

Table 10: Checklist results in 2017 and 2020

Standard	2017	2020
B1.1 Case definitions consistent with WHO guidelines		
B1.2 TB surveillance system captures minimum set of variables for reported TB cases		
B1.3 All scheduled periodic data received and processed at the national level		
B1.4 Data in quarterly reports are accurate, complete, and internally consistent		
B1.5 Data in national database are accurate, complete, consistent, and free of duplicates		
B1.6 TB surveillance data are externally consistent		
B1.7 Number of reported TB cases is internally consistent		
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 in TB cases		
B2.3 Surveillance data for children reported with TB are reliable and accurate		

Green – met; orange – partially met; red – not met

Sri Lanka operates both paper and electronic, case-based, real-time electronic surveillance systems. Data are recorded for all individual TB cases at the service delivery points, using standardized TB data collection forms which are then entered into the case-based electronic system. All TB cases from all parts of the country are included. Patient-level data are thus available at national level. Routine monitoring and some quality control procedures are in place. Introduction of ePIMS and scale up across all regions during the second year of implementation was remarkable progress and enabled case-based data at the national level.

Challenges

However, currently, ePIMS is not being sufficiently used to generate automated national and subnational indicators to facilitate data analysis and interpretation, and the surveillance system relies still on paper-based reporting - the opportunities of a real-time case-based system are not being sufficiently exploited.

Overall, routine notification data collection, aggregation, and generation of reports at national level are good enough, but data collection from prisons, and especially the laboratory network, is not. There are skilled personnel at the national level to work with data, but there is nobody at DCC, or at NPTCCD, to oversee the quality of data collected through ePIMS, including cleaning, providing feedback, identifying system bugs etc.

Recommendations

1. **Strengthen coverage of the TB surveillance system ("missed" TB cases)**
   a) Ensure that presumptive TB registers are consistently used in all facilities engaged in TB care and referral (urgent)
   b) Introduce standard recording forms for patients enrolled into second-line treatment (urgent)
   c) Transition from treatment register into register of people with TB. The district TB register should include not only patients who are started on treatment, but all patients diagnosed with TB which are also primary lost-to-follow-up cases (those not started on treatment) and those that die prior to starting TB treatment. (urgent)
   d) Ensure that all prison TB cases are included in the quarterly report in programmatic management (TB 12). Strengthen on-site/remote supervision, analysis of prison TB data, followed by interpretation and provision of the feedback to prison health staff and authorities (urgent)
   e) Improve routine household source contact tracing and contact tracing of adult index cases focusing on potentially exposed children (urgent)
   f) The TB diagnostic algorithm should be further revised, so that more sensitive methods of screening and diagnosis are deployed to avoid missing cases among those tested for TB. Increase Gene-Xpert testing coverage with aim to reach universal testing coverage among diagnosed TB cases in line with Top 10 TB indicators of End-TB strategy. All GeneXpert laboratories should be integrated with ePIMS with appropriate connectivity solutions (e.g., GxAlert) to facilitate reporting to requesting clinicians for faster patient follow-up, and ensure remote monitoring of key performance indicators (mid-term)
   g) Advocate to improve the quality of the VR system by systematic registration of cause of death by health care providers (long-term)
2. **Strengthen quality of the TB surveillance system**
   a) Aim for automatic integration or importation of data generated by other electronic systems (such as laboratory systems, digital X-ray) into ePIMS without manual data re-entry. This will reduce staff time and the chance of transcription errors. Furthermore, remote monitoring via data connectivity solutions should be used to monitor key performance indicators of all Gene Xpert sites, which may highlight a need for troubleshooting, device repairs, targeted on- site supervision, or retraining of technicians[19] (urgent)
   b) NPTCCD might consider to simplify the ePIMS structure by removing variables that are not used for analysis or decision-making (e.g. presenting complaint and duration, contact history of TB, Mantoux, ESR, civil status, living, occupation, education, complaints, investigations) or have a high "missing" rate (not feasible to complete). Develop a plan to optimize and upgrade ePIMS with clear actions, budget, timeline, indicators and targets in line with WHO requirements[20] for electronic surveillance systems. The system should be enhanced with dashboards to allow automated generation of key standard programmatic indicators. WHO has a recommended set of dashboards for programmatic management of TB control program described in "Guidance for TB programme managers" accessible

[19] Global Laboratory Initiative. (2016) GLI quick guide to TB diagnostic connectivity. http://www.stoptb.org/wg/gli/assets/documents/gli_connectivity_guide.pdf

[20] World Health Organization. (2012). Electronic recording and reporting for tuberculosis care and control. WHO. http://www.who.int/tb/publications/electronic_recording_reporting/en/

from https://www.who.int/healthinfo/FacilityAnalysisGuide_TB.pdf?ua=1 (mid-term)

c) Introduce data validation algorithm to be run by designated staff at different levels, at defined frequencies, with defined clean-up processes and full documentation of the results and provision of feedback to users. Introduce algorithms at least for: missing items, suspected duplicate records, assessing completeness. Introduce regular checks against samples of original paper documents. Introduce reports on performance indicators, such as data completeness rates, available to all users so that staff within districts can compare their performance with others. Parallel runs using paper and electronic systems may be necessary until districts achieve high coverage and consistency of electronic system (mid-term).

d) Organise more frequent, but targeted, central staff supervisory visits, following-up the implementation of the recommendations during the subsequent supervisory visits (mid-term).

e) Consider simplifying case finding and treatment outcome reporting forms. Unnecessary dis-aggregation could be removed from TB notification and treatment outcome reports (both electronic and paper forms) (mid-term).

f) Improve collaboration with STD/AIDS control program (NSACP) by regular exchange of case-based data on TB/HIV cases at national level to ensure accurate surveillance and quality care.

3. Use of data and informed decision making

a) The national surveillance and monitoring annual report on TB must include data on laboratory activities which are key in analysis of trends of TB burden, such as number of diagnostic sputum smear microscopy testing and results, total number of Xpert tests and positivity, number of patients with Xpert test results. In addition, the trends of TB (APC) by type and geographic area should be analysed to assess unusual, sudden changes, or outbreaks, for timely investigation (urgent).

b) Conduct a national-level data quality audit to assess data validity, reliability and identify sources and magnitude of under-reporting. Audit should include cross-check between laboratory register and TB registers (both paper and ePIMS) to assess under-reporting, and initial loss to follow-up (long-term).

c) Conduct operational research using ePIMS to assess the predictors of unfavourable outcome, particularly death, and design targeted. This will also identify ePIMS data quality issues and boost the improvement of ePiMS data quality (long-term)

d) Conduct catastrophic cost survey to monitor progress towards the target to eliminate catastrophic cost and help design interventions toward the social protection of people affected with TB (long-term).

3.12 Objective 12

Review the funding and human resources availability considering the ambitious goal of programme to end TB by 2025	What are the main funding streams, and future projections, for NPTCCD and regional and district anti-TB activities? What are the HR policies, strategies and guidance for all levels? What happens in practice?

3.12.1 Main funding streams and future projections

Findings

From the financial data submitted to WHO for the 2020 Global Control Report (Figure 16) there are three observations. First, the overall budget amount has declined from 2015 to 2020. The explanation that was given was that provincial and regional (district) budgets were excluded from 2018 onwards, so that the budget figures since 2018 represent those for the NPTCCD alone. Second, the overall domestic contribution has fallen, very markedly from 2015 to 2016, and again in 2018. We cannot tell from these figures whether this fall has been compensated, after 2018, by increases to the provinces or regions. Third, the budget gap – the unfunded component – grew significantly in 2017, and almost disappeared in 2018, at the same time that provincial and regional budgets were excluded, implying that the budget gaps were largely for spending in the provinces and regions.

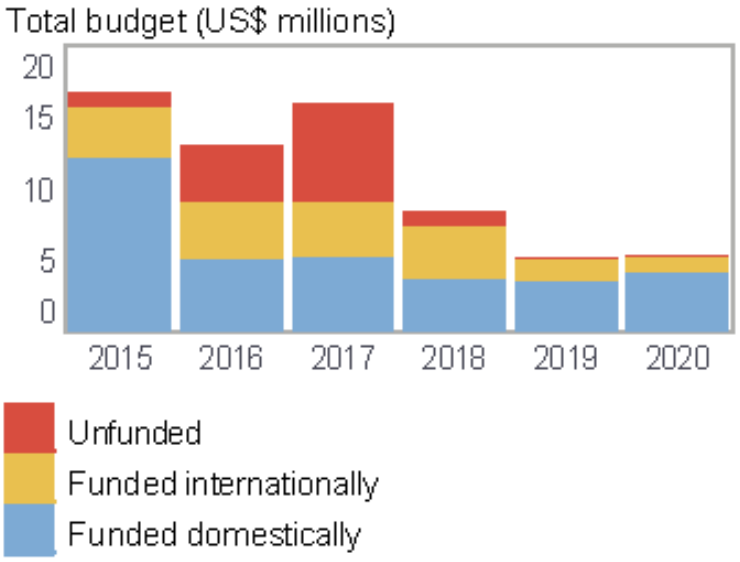


Figure 16: Total budget (US$ millions)

Source: WHO, Global TB Control Report, 2020

Table 11: GoSL allocations for NPTCCD and b. Global Fund contributions, in LKR and US$, 2019-2020, and estimates for 2021

	Conversion rate as per orginal Budget	156.45						
GFATM	**USD**	**LKR**	**USD**	**LKR**	**USD**	**USD**	**USD**	**LKR**
1.0 Human Resources (HR)	85,910.13	13,440,639.40	89,116.75	13,942,315.54	85,910.13	89,116.75	93,380.61	14,609,396.70
2.0 Travel related costs (TRC)	220,821.33	34,547,496.34	237,407.23	37,142,361.13	220,821.33	237,407.23	244,779.10	38,295,690.39
3.0 External Professional services (EPS)		-		-			-	-
4.0 Health Products - Pharmaceutical Products (HPPP)	170,497.77	26,674,375.40	196,719.76	30,776,806.45	170,497.77	196,719.76	204,014.65	31,918,091.83
5.0 Health Products - Non-Pharmaceuticals (HPNP)	23,416.20	3,663,465.23	19,658.75	3,075,611.44	23,416.20	19,658.75	15,008.43	2,348,068.22
6.0 Health Products - Equipment (HPE)	551,781.88	86,326,275.51	355,182.53	55,568,306.82	551,781.88	355,182.53	203,650.15	31,861,066.17
7.0 Procurement and Supply-Chain Management costs (PSM)	44,425.11	6,950,307.98	44,689.90	6,991,734.86	44,425.11	44,689.90	44,931.48	7,029,529.37
8.0 Infrastructure (INF)	2,818.85	441,009.30	2,818.85	441,009.30	2,818.85	2,818.85	2,818.85	441,009.30
9.0 Non-health equipment (NHP)	14,347.22	2,244,623.35	14,347.22	2,244,623.35	14,347.22	14,347.22	20,426.46	3,195,719.41
10.0 Communication Material and Publications (CMP)	19,962.71	3,123,165.88	-	-	19,962.71	-	-	-
11.0 Programme Administration costs (PA)		-		-			-	-
12.0 Living support to client/ target population (LSCTP)	7,670.34	1,200,025.31	9,587.93	1,500,031.65	7,670.34	9,587.93	10,546.72	1,650,034.80
		-		-			2,950,736.92	461,642,790.42
	1,141,651.54	**178,611,383.70**	**969,528.93**	**151,682,800.53**	**1,141,651.54**	**969,528.93**	**839,556.45**	**131,348,606.19**

Funding Source	**Allocation**				**Received**		**Estimates**	
	2019		**2020**		**2019**	**2020**	**2021**	
GOSL	**USD**	**LKR**	**USD**	**LKR**	**USD**	**USD**	**USD**	**LKR**
1. Reccurent								
1.1 salary /overtime/oth	1,466,819.36	229,483,889.00	1,540,902.97	241,074,269.52	1,466,819.36	1,540,902.97	1,732,517.48	271,052,359.00
1.2 travelling	17,737.30	2,775,000.00	17,342.35	2,713,210.00	17,737.30	17,342.35	22,371.36	3,500,000.00
1.3 supplies	42,186.00	6,600,000.00	34,994.57	5,474,900.14	42,186.00	34,994.57	1,334,292.11	208,750,000.00
1.4 maintenance	36,273.57	5,675,000.00	37,577.64	5,879,022.51	36,273.57	37,577.64	48,577.82	7,600,000.00
1.5 Contractual Services	142,889.10	22,355,000.00	136,165.02	21,303,017.16	142,889.10	136,165.02	147,011.82	23,000,000.00
1.6 Transfers	5,560.88	870,000.00	6,033.27	943,905.60	5,560.88	6,033.27	13,422.82	2,100,000.00
1.7 Medical supply(Reage	488,974.11	76,500,000.00	147,869.12	23,134,124.50	488,974.11	147,869.12	1,273,569.83	199,250,000.00
2. Capital					-	-		
2.1 Furniture	6,391.82	1,000,000.00	-	-	6,391.82	-		
2.2 Machinary	4,250.56	665,000.00	-	-	4,250.56	-		
2.3 Other(GOSL)	95,877.28	15,000,000.00	-	-	95,877.28	-		
2.4 Vehicle	5,950.85	931,010.00	-	-	5,950.85	-		
2.5 Infrastructure			6,391.82	1,000,000.00		6,391.82		
2.6 Research and Develop ment			6,391.82	1,000,000.00		6,391.82		
3. World Bank(PSSP)					-	-		
3.1 Building(World BANI	63,918.18	10,000,000.00	-	-	63,918.18	-		
3.2 Training(World BANI	6,391.82	1,000,000.00	-	-	6,391.82	-		
3.3 Plant,Machinary, and	-	-	31,959.09	5,000,000.00	-	31,959.09		
4. WHO								
	9,874.27	1,544,830.29	890.82	139,369.31	9,874.27	890.82		
5. SAARC					-	-		
	35,806.99	5,602,004.05	-	-	35,806.99	-		
	2,428,902.10	**380,001,733.34**	**1,966,518.50**	**307,661,818.74**	**2,428,902.10**	**1,966,518.50**	**4,571,763.24**	**715,252,359.00**

Challenges

First, the overall budget appears to be declining, partly due to a change in the way data are presented. This decline may therefore not be real, but, without the data, we cannot tell, and TB specific financial allocations in the provinces and regions are difficult to obtain. Budgets should not decline while the TB burden remains almost the same. Second, there was a serious fall in the government contribution in 2016, and, in the absence of provincial or district data to the contrary, appears to have stayed low. Third, the data from 2019 and 2020 (Table 11) show allocations and received monies as being identical, which is unusual. However, fourthly, the budgets for 2021 show an 88% increase in the government's planned contribution compared to 2020, largely due to supplies and procurements, especially GeneXpert cartridges.

A fifth challenge is that the Programme is not disbursing funds on time and over US$1 million remains unspent, since March 2020 (Table 12). The reasons given for the slow disbursement were curfews and restrictions on movement due to elections and to the Easter Bombings, as well as to slow procurement processes. This was added to more recently by restrictions due to the COVID pandemic. Programme records[21] indicate that only 60% of 2020 revenues are

[21] NPTCCD. Minutes of Teleconference 30th September.

expected to be disbursed by the end of 2020. While these monies can be rolled into 2021, any unspent funds at the end of 2021 will be lost to the country.

Table 12: Cash balances in March, June and September of the Global Fund TB grant

Cash Balance as at 30th September 2020						
Grant	Balance in new USD Accounts (at CBSL)	Balance at Treasury GOSL (LKR)	PR Cash Book Balance in LKR	Treasury + PR Cash book balance in USD	Total Cash Balance in USD (at CBSL + Treasury + PR cash book)	Total Cash Balance in LKR (at CBSL + Treasury + PR cash book)
TB	908,058.91	2,207,339.35	22,422,133.75	132,757.41	1,040,816.32	193,094,741.42

Cash Balance as at 30th June 2020						
Grant	Balance in new USD Accounts (at CBSL)	Balance at Treasury GOSL (LKR)	PR Cash Book Balance in LKR	Treasury + PR Cash book balance in USD	Total Cash Balance in USD (at CBSL + Treasury + PR cash book)	Total Cash Balance in LKR (at CBSL + Treasury + PR cash book)
TB	$ 1,008,058.91	12,207,539.35	8,017,043.00	$ 108,600.49	$ 1,116,659.40	203,016,607.18

Cash Balance as at 31st March 2020						
Grant	Balance in new USD Accounts (at CBSL)	Balance at Treasury GOSL (LKR)	PR Cash Book Balance in LKR	Treasury + PR Cash book balance in USD	Total Cash Balance in USD (at CBSL + Treasury + PR cash book)	Total Cash Balance in LKR (at CBSL + Treasury + PR cash book)
TB	$ 1,108,058.91	2,207,339.35	4,351,732.80	$ 34,773.34	$ 1,142,832.25	207,775,016.75

Source: Global Fund portfolio manager

3.12.2 Human resources

Findings

The Review concluded that there are major problems with the human resources in the Programme. These include insufficient leadership, unfilled positions at all levels, especially consultant community physicians, and a lack of training and experience in programmatic TB work. With respect to leadership, the review noted that the Director, NPTCCD is also National Coordinator of Disaster Preparedness and Response and the Acting Deputy Director General – PHS1. He attended none of the 7 remote meetings. However, he did meet with one national consultant for a few minutes and attended the final debriefing. We should emphasize that during the COVID epidemic this is not the fault of the Director but is due to appointing one individual to so many senior positions. The NPT needs a full-time, undistracted, Director. The posts vacant in the NPTCCD include all three consultant community physicians (CCP) (with a fourth previously approved, but not listed by the Ministry), one of two consultant microbiologists, 10 MOs, 2MLTs, 2 PHLTs and 2 pharmacists.

The review also observed that the Deputy Director is overloaded, having to compensate for the total lack of senior technical staff, as well as carry out her administrative duties. The absence of a full-time accountant and Administrative Officer adds to her administrative workload.

With respect to training and experience, the MOs at Central Unit had no specific training in TB when they were appointed, other than basic undergraduate training, which is unusual for a national Central Unit in a country of the size of Sri Lanka. MoH policy that MOs receive only

undergraduate training on TB prior to joining the Central Unit makes little sense when there are holders of the Diploma in Control of TB and Chest Diseases working elsewhere.

The Review recognised that the Programme faces severe constraints with the MO transfer scheme, which prevents selection on the basis of competence or qualifications. Selection on the basis of the lottery of the MO transfer system is not appropriate for a specialised unit like the Central Unit. The scheme also makes it difficult to hold on to, and train up, good staff. The path for a young staff to establish her/himself in the public health aspects of TB is difficult.

The 2017 mid-term review recommendations to strengthen HR in the Central Unit were only very partially addressed. One CCP came for just over a year, contributed significantly to the Programme, but has left for a better career opportunity. One Senior Registrar arrived but is due for training abroad as soon as pandemic restrictions are lifted. Overall, there are now less senior staff than there were in 2017, while numbers of middle grade technical staff are unchanged.

In the districts, four are without DTCOs, a PMDT Coordinator is required in Gampaha to support the DTCO there and the vacant posts include 6 MOs, 1 pharmacist, 1 dispenser, 9 PHIs, 5 radiographers, 2 nursing officers, 5 PHLTs, 2 MLTs. Other observations include that district staff report to their institutions, rather than to the needs of the NPTCCD, MOs do not utilize the full working time dedicated for patient care at the chest clinics, and there have been demarcation disputes involving MLTs, PHLTs and Public Health Laboratory Assistants, sometimes with involvement of the Unions.

Programme staff voiced their opinion that the DTCOs are neglected by the provincial and regional authorities, in part because of the vertical history of the Programme, where resources came from the Central Unit, in spite of the fact that changed decades ago. Some DTCOs are keener on the clinical than the public health work, are often physically housed in a building away from the regional teams, and are not asked to prepare monthly plans in advance as other programmes do. TB is rarely on the agenda of the provincial and regional review meetings of, although regional and provincial directors of health services are supposed to attend. As a result, DTCOs are felt to be unaccountable.

It will, though, be impossible to implement successfully those components of the Programme that need to be expanded, such as TPT, with the current human resources and infra- structure.

Recommendations

Although ending TB by 2025 is virtually impossible, responding rapidly to the Review's recommendations would make the WHO's End TB target of 2035 (6.7% average annual decline) achievable. A step change is required in the management of anti-TB activities which requires far greater attention paid to TB by Ministry of Health decision makers at both central and provincial levels. Therefore, this Review recommends that:

1. The Minister of Health (MOH) should establish a *National TB Commission*, chaired by the Minister, to raise the priority of TB, and ensure an urgent response to bring down the burden of TB in Sri Lanka, with clear targets and mechanisms to hold Ministry, provincial, and regional decision-makers accountable for providing at least basic support structure for district TB activities.

2. MOH should ensure the Director of NPTCCD has only one job, and is committed to implementing the recommendations of the review, and the objectives of the new NSP, and h/she should be held accountable;

3. The MOH should urgently fill the vacant posts at NPTCCD, with priority given to the three CCP posts. These new CCPs should direct teams to address the major responsibilities of the Programme;

4. The MOH should fund TB activities at, or above, the level it did so in 2015. NPTCCD staff should be held accountable by an external Steering Committee of technical, programme and financial experts, to ensure all future TB funds are disbursed on priority activities. This should be included in the new NSP.
5. Each institute carrying out TB related activities should appoint a designated officer who can be held accountable - at least in centres where there is a GeneXpert is available and certainly in centres where cultures are done.

6. DTCOs should be selected on the basis of having the Diploma in TB and Chest Diseases, or the equivalent. With the mandatory transfer system, the regular training of the MOs appointed to the DCC should be strengthened (mid-term).

3.13 Objective 13

Review the TB research and innovation needs and country plans	Has data been used to generate hypotheses? Have those hypotheses been appropriately addressed? What are the future plans and budgets?

Findings

The NPTCCD has a comprehensive research agenda developed by NPTCCD that encompasses all TB related areas. The areas covered under the agenda range from burden of TB, diagnosis, management, TPT, DR-TB, paediatric TB to Information Systems and others. However, it is not clear if this agenda has been circulated widely enough for adoption by other research and academic institutes and whether any discussions on the subject are being regularly organized between NPTCCD and research institutes. The focal point for research in NPTCCD has started working on establishing a research repository, collecting information on research related to TB and formally requesting different bodies to disseminate information on research conducted related to TB under their purview in 2019.

NPTCCD has a research steering committee that oversees proposal screening and monitoring progress. For capacity building on research, it was informed that there are some national and international trainings being conducted in the country. A training was planned by SAARC TB and HIV/AIDS Centre, Kathmandu, which will now be held virtually in November 2020.

There is a long list of ongoing and planned research activities (Annex 3) but occasionally the results of the research are not available to NPTCCD. This happens when the research is conducted by other institutes. The list of conducted research studies includes the two priority areas identified in the 2017 review:

1. Patient pathway analysis
2. Relation between TB and diabetes

It is learnt that the study on relation between TB and diabetes has been submitted for publication while a manuscript on pathway analysis will be developed for publication soon. However, these studies may still need further discussions on results and conclusions to understand their implications for the Programme.

Funding for research has been variable over the years (Table 13) and often tied to specific research areas. This allows less flexibility and leads to unutilized funds.

Table 13: Research budget and expenditure

Year	Total Budget LKR	Expenditure LKR	Source of Funding	Remarks
2018	2,500,000	0	Global Fund	Originally for Inventory survey but abandoned due to technical non-feasibility as advised by experts. Therefore, it was budgeted for pharmaceutical survey in 2019-2021 which was also abandoned due to data collection issues during COVID situation. Therefore, funds were identified as savings and reallocated.
2019	591,000	565,000	WHO	For Care pathways & Care Delays research.
2020	200,000	195,000	GOSL (Research & Development)	Assessment on gender and human rights issues.

Challenges

1. The research agenda is too broad and may not provide appropriate direction to a research student for priorities to be addressed.
2. There is limited funding available for research activities through NPTCCD.
3. Lack of coordination between NPTCCD and other institutes conducting research.
4. There has also been a reported delay in planned research cost-effectiveness and prisons because of COVID-19 outbreak.
5. Most technical staff at NPTCCD have limited experience and no formal training on operational research. Challenges with selection process of staff who are sent for such trainings in the past has been noted, leading to their low engagement in research activities post-training.

Recommendations

1. The research agenda needs to be prioritised, have specific research questions and linked to programmatic gaps. This agenda needs to be included in the new NSP being developed in Q4 2020.
2. The ongoing and planned research studies should be completed on priority and based on assessed needs, funding mobilized for the purpose.
3. Capacity building of key NPTCCD staff on research. This should be done after a proper selection procedure so that appropriate persons can get trained.
4. Some other suggested priority research areas for inclusion in the NSP are:
    a. To identify the current challenges with treatment delivery to the homeless and those facing economic challenges and evaluate the effectiveness of long stay shelters in making treatment more people centred.
    b. Detailed analysis of the data available[22] on previously treated cases to understand the reasons for interruption and risk of resistance. Consider prospective data collection if this first analysis is insufficient.

[22] Should include (but not limited to): the clinical and demographic features of these patients, drug discontinuation, combinations of drugs used, comorbidities, onset since the last TB treatment stopped, radiological/clinical features at the termination of TB and substance abuse.

c. Analysis of the socio-economic impact of TB starting with high-burden districts with a view to a complete picture of the major socio-economic factors in this group such as unemployment, lack of a permanent place to stay, overcrowding, malnutrition and substance abuse.
d. Detailed death investigations in selected districts by a confidential in-depth analysis of the feedback from field officers involved in TB control.

5. It is learnt that the MoH is procuring genome sequencing equipment for other departments that can be shared for analysis by TB department. This could be taken up as one of the activities in the country if this doesn't have significant financial implication for the programme.

3.13.1 Observations on social protection

1. The Department of Social Services offers provision of welfare facilities to low-income patients attending government hospitals. They carry out welfare activities through 331 Divisional Secretary Divisions of the island to ensure welfare, and for post treatment support of hospitalized low-income patients. Accordingly, they make direct interventions to provide facilities to secure medical assistance.

   Welfare support payments differ according to the Province, and the range is wide, starting from Rs.450 in the South to Rs 4000 in the North. Payments vary according to the disease. The diseases that are considered for support include thalassemia, tuberculosis, and chronic kidney disease. TB is the only disease that is given for a short term. The payment is provided at the local post office. A TB patient who is lost to follow up, could also be collecting the payment.

2. The Department of Social Services has more than 8,500 elderly people and more than 341 homes for the elderly under their care, of which five are under the central government and the others are under the governing councils or NGOs. Medical care is not provided at the homes, unless requested and brought in, and diseases like TB are never screened for. Although there is a law that an officer has to visit these facilities to ensure standards, there are no punishments in place for a facility that does not achieve the standards, nor a policy to enable the Department to take legal action.

3. The Department also has many vocational services, in which there are risk groups like mental retardation, substance abuse etc. The Director is also involved in the National Substance Abuse Prevention Programme at the Ministry of Health.

4. The Department does not receive monthly names and addresses of patients with TB.

Recommendations

1. Annual screening of the population in elderly care facilities could be considered, but an assessment of the burden in those facilities would be appropriate first, in order to see if it would be worthwhile. Consideration also needs to be given to identify and manage outbreaks of TB in facilities such as homes for the elderly.
2. Further thought and discussion of how best to manage the more difficult patients, such as people who use drugs (PWUD), is needed. This should take place as a part of

the NSP, 2021-2025 preparations, and should focus on treatment settings for such patients, perhaps shared with other programmes or campaigns, and linked with rehabilitation programmes such as those organised by the National Dangerous Drugs Advisory Board.

3. As part of the planned improvement of the e-PIMS, consideration should be given to ways of informing the Department of Social Security of patients who require their assistance.

4. Annexes

Annex 1. Members of the Review Team

National Consultants

Aindralal Balasuriya

Shirani Chandrasiri

Neranjan Dissanayake

Shamini Prathapan

International Consultants (working remotely)

Vineet Bhatia

Vithal P Myneedu

Paul Nunn (Team leader)

Holger Sawert

Activity coordinator

Dr Awanthi Senadheera - Medical Officer/ NPTCCD

NPTCCD Staff

Dr H D.B Herath – Director/ NPTCCD

Dr Nirupa Pallewatte – Deputy Director/ NPTCCD

Dr Dushani Jayawardene – Consultant Microbiologist/ NTRL

Dr Sumudu Hewage – Acting Consultant Community Physician

Dr Shashika Abeysekara - Medical Officer/ NPTCCD

Dr Kishan Suriyaaratchie - Medical Officer/ NPTCCD

Dr S Kajanan - Medical Officer/ NPTCCD

Dr Amali Senanayake - Medical Officer/ NPTCCD

Dr Kaushalya Rajapaksha – PMDT Coordinator

Dr Nadeeja Liyanage - Senior Registrar in Community Medicine

Dr Chathurani Wickramaarachchi - Senior Registrar in Community Medicine

Dr Pramil Liyanage – Senior Registrar in Health Informatics

Annex 2 - NPTCCD Central Unit staffing position, key staff positions only

Institution	Category of Staff	Approved cadre	In position	Remarks
Central Unit NPTCCD	Director	01	01	
	Deputy Director	01	01	
	Consultant Community Physician	03	00	We got cadre approval for another CCP post, but it's not indicated in the list provided by the Ministry
	Medical Officers		05	MO cadre 45 for all the institutions under NPTCCD and 35 at available at present MO/Health Informatics position is vacant
NTRL	Consultant Microbiologist	02	01	
	Medical Officers		04	MO cadre 45 for all the institutions under NPTCCD and 35 available at present
	Scientific officer	01	00	
	MLT		15	PHLT cadre 20 for all the institutions under NPTCCD and 19 available at present
	PHLT		03	PHLT cadre 20 for all the institutions under NPTCCD and 18 available at present
Central Drug Stores	Chief Pharmacist (Supra-grade)	01	00	
	Pharmacists	03	02	One acting as Chief pharmacist

Annex 3. Completed, ongoing and planned research activities

Completed

Topic	Status
1. Care pathways and Care delays of new pulmonary TB patients	Data entry and Analysis
2. Prevalence of Pulmonary Tuberculosis and associated factors among Prison inmates	Data entry and analysis Preliminary findings
3. Proportion of pulmonary tuberculosis among patients attending diabetes clinic	Completed

Ongoing

Topic	Status
4. Study on Knowledge, Attitude and practice about DOT and its side effects	Data collection ongoing
5. Quality of life among smear positive pulmonary tuberculosis patients	Data collection ongoing

Planned

Topic	Remarks
1. Automatic detection algorithm for Pulmonary TB on Digital chest radiographs"	Proposal stage
2. Mathematical model to analyze and forecasting infectious diseases in Sri Lanka	Proposal stage
3. Availability and use of anti-TB medicines outside State sector chest clinics	Draft of the proposal formed. Funding source not identified yet.
Challenges faced in diagnosis and management of Tuberculosis patients during COVID-19 pandemic	Qualitative study will be done in all the districts in SL.
4. study on Adverse drug reactions	Study done in a setting where services are provided for 25% of the total TB cases in SL.
5. Death Audit "Children dying with Respiratory illnesses	It is planned to conduct study in the only two specialized hospital for children in SL, to determine whether the children dying with severe respiratory illness are misdiagnosed TB patients.
6. Prevalence of Latent TB Infection among Health Care workers	The evidence in the study will aid in taking policy decisions preventive therapy

7. prevalence of presumptive tuberculosis symptoms, and the factors associated with presumptive tuberculosis symptoms among children under five years with acute malnutrition	Study done in a setting where acute malnutrition is high and where detection of paediatric cases are on rise (especially among contacts).

Annex 4. List of documents shared in the Google Drive

Surveys (folder)

1. Tuberculosis among Young People on Rise in Sri Lanka (An analysis of trend and associated factors)
2. ARTI_Survey
3. Proportion of pulmonary tuberculosis among patients attending diabetes clinic of National Hospital of Sri Lanka. A guide to inform the national policy on active screening for pulmonary tuberculosis
4. National Survey on Anti-mycobacterial Drug Resistance in M. tuberculosis, Sri Lanka, 2017 – summary
5. Survey on Knowledge Attitudes and Practices Related to Tuberculosis among General Public

Other Mission reports (folder)

6. 5th Joint Monitoring Mission of the National Programme for Tuberculosis control Sri Lanka 2 -13 June 2014
7. Mid Term Review of the National TB Programme of Sri Lanka 2017
8. Mission report to National TB Programme, Sri Lanka, 18-30 November 2017

Other Documents (folder)

9. 2015-2019 summarized TB data
10. Childhood TB in Sri Lanka_report
11. Ending Tuberculosis and AIDS in Sri Lanka: Urgent and immediate actions required to reach 2025 targets
12. National Manual for Tuberculosis Control 2016
13. Planning pilots in districts in Sri Lanka
14. Index of research studies on Tuberculosis in Sri Lanka

NSP and M&E (folder)

15. Gene xpert expansion plan as on 31 August 2018
16. Monitoring and Evaluation System for the National Tuberculosis Control Programme in Sri Lanka 2015-2020 (Amended according to End TB Targets)
17. National Strategic Plan for Tuberculosis Control 2015-2020
18. Reprioritized Activity Plan of National Strategic Plan for Tuberculosis Control
19. Revised Monitoring and Evaluation indicator framework

Guidelines (folder)

20. Guideline on using Rifampicin for indications other than mycobacterial infections
21. Guidelines for Mantoux Testing
22. Natonal-Guidelines-for-Management-of-tuberculosis-in-children-2018
23. PMDT Guidelines Final

GLC Mission reports (folder)

24. GLC mission report – 2011
25. GLC mission report – 2013
26. GLC mission report – 2015
27. GLC mission report – 2016
28. GLC mission report – 2017
29. GLC mission report – 2019
30. GLC mission report – 2019 presentation

GDF Mission reports (folder)

31. The Global Drug Facility Mission Report 2008

32. The Global Drug Facility Mission Report 2010
33. The Global Drug Facility Mission Report 2012
34. The Global Drug Facility Mission Report 2014
35. The Global Drug Facility Mission Report 2015
36. The Global Drug Facility Mission Report 2016

Epid review reports (folder)
37. TB Epidemiological Review and Impact Analysis of Tuberculosis in Sri Lanka, 2017
38. Tuberculosis in Sri Lanka: An epidemiological analysis December 2013

Circulars (folder)
39. Presumptive-TB
40. Screening of TB Patients for HIV-AIDS
41. Strengthening of TB Surveillance and Control
42. Tuberculosis Case Revisions 2013

Annual reports (folder)
43. Annual report 2012
44. Annual report 2013
45. Annual report 2014
46. Annual report 2015
47. Annual report 2016
48. Annual report 2017
49. Annual report 2018
50. Statistical-Data-Tables-2019

Algorithm (folder)
51. Diagnostic algorithm
52. Algorithm for the diagnosis of children who presents with Symptoms suggestive of TB

30-09-2020 (folder)
53. Report of the National Survey on Anti-mycobacterial Drug Resistance in M. tuberculosis Sri Lanka 2016-2018
54. PTB among DM_NPTCCD Final
55. Report of Consultant Revised 8 Jan 2020 (2019 mission report)

03-10-2020 (folder)
56. 2nd draft Report - Sri Lanka Epidemiological Review 2020
57. 2019 GLC monitoring report – implementation of recommendations
58. GXpert Utilization - Upto Aug 2020
59. Objective 08 End Term Review - High-Risk Groups pptx
60. Terms of Reference for the Advisory Committee on Tuberculosis Control
61. Terms of Reference for the Technical Support Group to National Progarmme for Tuberculosis Control and Chest Diseases
62. Terms of Reference - Central and Site Committees for Programmatic Management of Drug Resistant Tuberculosis (PMDT Central & Site Committees)

Infection Control Related (folder)
63. Guidelines on diagnosis and management of tb patients at district level during Current covid-19 pandemic situation
64. Hospital Infection Control Manual – 2005
65. Interim guidance for intermediate TB laboratories, GeneXpert laboratories and microscopy centers for handing patients' samples amid COVID pandemic.

IOM (folder)
66. Inbound health assessment programme Technical instructions for designated panel physicians
67. IHAC/ IHU Summary from June 2019 to date

LTBI (folder)
68. LTBI Guidelines 2020 – draft
69. LTBI pptx

Publications (folder)
70. Sustaining essential TB services in Sri Lanka amid COVID-19 pandemic: a brief report

Research Related (folder)
71. Terms of Reference for Research Committee
72. Selection Criteria of proposals
73. Priority areas for OR in TB – NPTCCD

Statistical reports (folder)
74. Central bank report 2018
75. Household Income and Expenditure Survey 2016 Final Report
76. Sri Lanka Socio Economic data 2018

04-10-2020 (folder)
77. Supply Chain Management

05-10-2020 (folder)
78. INAH data 2015-2019
79. Key Statistical Data trends and Charts 2019 for Anual Report
80. Statistical Data Tables – 2019

PPM (folder)
81. 2020 PPM TOR for PPM Working Group Central Level
82. 2020 PPM TOR guide for other provinces
83. PPM Related Activities pptx

06-10-2020 (folder)
84. Chest Clinic OPD - Case finding activities 2018-2019
85. INAH Data Charts 2019
86. OPDs in Hospitals with Microscopy Centers - Monthly Summary 2012-2019

08-10-2020 (folder)
87. Agrahara - National Insurance Trust Fund (NITF)
88. NGO/ CBO involvement
89. Social Services Sri Lanka
90. Utilization of Digital X-rays provided by Global Fund

11-10-2020 (folder)
PMDT (folder)
91. 2019 MDRTB summary
92. 2020 DRTB Summary
93. Implementation of recommendations GLC mission 2019
94. MDR Activities pptx

12-10-2020 (folder)
95. PPT care pathway
96. Standards for TB Care for Gps & Private Health Care Institutions

13-10-2020 (folder)
97. Standard Operative Procedures for Community Awareness and Referral of suspects having tuberculosis
98. Revised Diagnostic Algorithm for Tuberculosis (TB) in children

CCM (folder)
99. Country Coordination Mechanism Sri Lanka Governance Manual October 2016
100. 131st CCM Meeting Minutes – CCM Sri Lanka
101. Terms of Reference of Oversight Committee 2018-2020

Mobile X-ray screening data (folder)
102. Combined summary data on mobile x-ray screening programmes 2019 - 09 programmes
103. Data on mobile x-ray screening programmes in prison - combined data

Operational plan and TA plan- submitted with previous NSP (folder)
104. Operational Plan
105. TA Plan
106. Target assumptions template 6Jul2018 V2

TB deaths (folder)
107. DTCO Review presentation 2019
108. TB death review

14-10-2020 (folder)
109. Not Evaluated 2018 pptx

15-10-2020 (folder)
110. Budget NPTCCD
111. Cadre - 2020.10.14
112. Cadre - Central Unit - 2020-10-14
113. Health care workers & Foreigners with TB 2018 and 2019
114. Not Evaluated Chart-2017 and 2018
115. Prioritized Activity Plan - Implementation status

TBACM minutes (folder)
116. Minute TBACM 10.03.2020
117. Minutes TBACM 17.05.2019
118. TBACM minute 10.12.2019
119. TBACM minute 10.09.2019

16-10-2020 (folder)
120. Patient Referral by the private sector, GPs and NGOs 2018 & 2019
121. WRD tests conducted for Smear positive and clinically diagnosed patients by district chest clinics – 2019
122. Status of SLD 09.10.2020
123. Thriposha requirement

Annex 5. Progress against the recommendations made during the rGLC mission in 2019

Sl. No.	Recommendation	Progress in 2020	Activities planned for 2021
1	Establish a PMDT unit at the national level to monitor all PMDT activities and ensure appropriate diagnosis, treatment, monitoring and relapse-free cure for all DR TB patients and fill all vacancies in programme staff (DTCO, MO, nurses, PHI, microbiologist, LT, etc.) on priority	Already unit is available with the PMDT coordinator	Supportive staff will be provided
2	Bridge the gap between reported and estimated TB by implementing universal DST for all TB cases; expand Gx to all confirmed and high-risk presumptive DR TB patients; ICF in high-risk populations	Universal DST for all TB cases is practiced in 16 pilot districts.	Universal DST for all TB cases will be expanded to all 26 districts by end of 2021.
3	Start initiating at least 80% of all eligible cases on the all oral bedaquiline-containing treatment regimen with strict drug safety monitoring and management practices	All MDR- TB patients getting oral bedaquiline regimen except one patient who had cardiac problems	Already in practice
4	Strengthen patient counseling to reduce diagnostic delays and engage partners (NGOs, Funding organizations, Private providers) in the provision of TB services such as ACF, DOT provision, IEC, contact evaluation, etc.	• Patient counseling for TB strengthened. • Capacity building of Staff on counseling skills carried out • Private sector collaborative activities are strengthened and engage in DOT provision patient referral. NGO involvement is improving	Planned to carry out more activities to further strengthen counseling of patients, Engagement of Private care providers and NGOs
5	Ensure DOT for DS and DR TB patients; continue to explore ICT models for treatment adherence. • Mobile phone DOT (99 DOTs model) • Video DOT • Medication Event Reminder Mechanisms (MERM) for MDR TB • Community based DOT	• Usage of ICT modalities for DOTS already planned and in the procurement process. • Provision of Community based DOTS already in practice with strict monitoring by DTCOs and PHIS	DOTS using mobile phones will be started at the end of 2021

6	Decentralize MDR TB care by expanding DR TB treatment initiation to two more centers - Kandy and in/around Jaffna. Redistrict Colombo to three sites (in progress).	Already discussions were made, and Funds need to be explored.	Already discussions were made and Funds need to be explored.
7	Consider shifting to an ambulatory care model for DR TB treatment as the all oral regimen is implemented after culture conversion in order to: • Improve patient quality of life • Decrease risk of transmission in hospital settings • Decrease cost to the system • Further decentralize PMDT services	Patients are provided ambulatory care after culture conversion. They will be followed up at respective chest clinics closer to their place of residence	same
8	Ensure adequate funding to sustain all TB activities and implement key recommendations to improve PMDT management.	GF and GOSL funds are available for sustaining all TB activities	GF and GOSL funds are available for sustaining all TB activities

National Programme for Tuberculosis Control and Chest Diseases
4th Floor, Public Health Complex, 555/5, Elvitigala Mawatha,
Narahenpita, Colombo 05
Tel: (94) 011-2368386 | Fax: (94) 011-2368386 | E-mail: dnptccd@gmail.com