Tuberculosis epidemiological review in Sri Lanka

August 2020

Contents

List of figures

List of tables

List of maps

Abbreviations

APC	annual percent of change
ART	antiretroviral treatment
CI	confidence interval
DCC	district chest clinic
DST	drug susceptibility testing
DTCO	district tuberculosis officer
EP	Extrapulmonary
GDP	gross domestic product
HIV	human immunodeficiency virus
IQR	interquartile range
JMO	juridical medical officer
LTBI	latent tuberculosis infection
IPT	isoniazid preventive treatment
LPA	line probe assay
MDR-TB	multidrug-resistant tuberculosis
MOH	medical office of health
MoH	Ministry of health
M&E	monitoring and evaluation
NSACP	national STD/AIDS control program
N&R	new and relapsed
NHRD	national hospital of respiratory diseases
NRL	national reference laboratory
NPTCCD	national program of tuberculosis control and chest diseases
OOP	out-of-pocket
PHI	public health inspector
PHM	public health midwife
PLHIV	people living with HIV
PMIS	patient management information system
PTB	pulmonary tuberculosis
R&R	recording and reporting
RR	rifampicin-resistant
TB	Tuberculosis
VRS	vital registration system
WHO	World Health Organization

Summary

Purpose: The purpose of the epidemiological review Sri Lanka that took place in August/September2020 was to assess the completeness and accuracy of routine tuberculosis (TB) surveillance and vital registration (VR) to inform WHO estimated TB burden and to investigate the plausible 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 Vital Registration 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 by developing an M & E investment plan, which will be consisting of required interventions to address gaps and an indication of whether and if so, what kind of technical assistance or additional funding is required and characterize the proportion represented by vertical TB, TB/HIV, or integrated health M&E activities.
- To provide feedback to the WHO regional and country office and funding agencies such as Global Fund on recommendations and prioritization, following approval by the NPTCCD.
- 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.

Methods: 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 and levels; (3) a review of TB records, registers and electronic surveillance system at the institutions visited; and (4) an analysis of notification/surveillance data over time and geographically to identify trends in the disease burden and programmatic efforts.

Key Findings: Of the 11 WHO standards for TB surveillance that were applied, five were met, six were partially met, and two were not met (Table 1). More detailed information of checklist implementation is shown in Annex 1.

Table 1. 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 system. Data are recorded for all individual TB cases at the service delivery points, using standardized TB data collection forms, then are entered into case-based electronic system. All TB cases from all parts of the country are included in the national TB surveillance. Patient-level data are available at national level. Routine monitoring and some quality control procedures are in place.

Introduction of ePIMS and scale up across all region during the second year of implementation shows a remarkable progress allowing to have cases-based data at the national level. However, currently the use of ePIMS to generate automated national and subnational indicators and use of it for the data analysis and interpretation is limited and surveillance system relays on paper-based reporting.

TB notification rate between 2015 and 2019 has been decreasing in the country on average 3.7% per year. This decline was attributed to both the true reduction of TB burden in the population as well as change of clinical practice of diagnosing the paucibacillary forms of TB. The following findings in TB surveillance indicate a decline in true burden of TB in the population:

- Constant decline in sputum smear positive TB cases over the time (in context of low positivity),
- Faster decline in the age-specific notification rate among younger age groups compared to those of older age groups.
- The change in the age structure of TB patients towards older age groups;
- Internal consistency of routine notification data at national and subnational level,
- Consistent trend of decline across subnational area and when disaggregated by sex, site of disease.

While following findings suggest that some part of TB cases is either not detected by health systems or detected but are under-reported:

- Comparatively faster decline of paucibacillary forms of TB (clinically diagnosed TB) over the time compared to sputum smear positive TB cases are most likely due to changes in diagnostic practice;
- Implausibly high bacteriological confirmation in several districts and prison system combined with low Gene-Xpert testing coverage and high positivity of gene X pert testing,

- External inconsistency (low proportion of child TB cases), and
- Observed initial lost to follow-up cases in facilities visited, which were not addressed by health systems

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

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

Major recommendations

- Address under-reporting through ensuring that all people with TB are registered, despite of initiation of treatment.
- Introduce automated connectivity solutions of data generated by Gene Xpert machines to ensure data transmission, and remote monitoring of performance.
- Develop a plan to optimize and upgrade ePIMS to enable generate reports on program key indicators including asses the notification rates conduct time series analysis of key indicators across the geographic areas and national level. Introduce and regularly implement data validation algorithms.

Introduction

Sri Lanka is pear-shaped island-country located in the Indian ocean, with a population of approximately 20 million people. Despite of being among middle-income country with GDP per capita reaching only 3,850 Sri Lanka has impressive health statistics, with infant mortality rate of 7.4 per 1,000 live births and universal free health care system that has brought the country's health indicators up to the level of high industrialized countries in the world. An initial epidemiological review was conducted in 2014.Before the present National Strategic Plan (NSP) the second epi-review was implemented in late 2017, along with mid-term review. Current review was initiated to support the end term review and NSP revision.

Purpose:

The purpose of the epidemiological review of Sri Lanka conducted in August/September 2020 was to assess the completeness and accuracy of routine tuberculosis (TB) surveillance and vital registration (VR) to inform WHO estimated TB burden and to investigate the plausible 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 Vital Registration 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 by developing an M & E investment plan, which will be consisting of required interventions to address gaps and an indication of whether and if so, what kind of technical assistance or additional funding is required and characterize the proportion represented by vertical TB, TB/HIV, or integrated health M&E activities.
- To provide feedback to the WHO regional and country office and funding agencies such as Global Fund on recommendations and prioritization, following approval by the NTP.
- To build capacity for epidemiological reviews in country by involving members of the NTP, DCCs and other in-country partners to actively participate in objectives 1-4.

Methods

Methods of data collection included: (1) desk review of available TB control-related policy papers, manuals, guidelines and forms; (2) interviews and discussions NPTCCD staff and health care providers at national and district chest clinics; (3) review and cross-check of TB records, laboratory registers and electronic surveillance systems at TB district chest clinics; (4) review of electronic databases to assess compliance of its architecture and functionality to WHO recommendations (5) analysis of notification/surveillance data over time and space to identify trends in disease burden and programmatic efforts.

Most of the TB control-related data were provided by National program of tuberculosis control and chest diseases. In addition, we used Global Tuberculosis database and other resources such as AIDS Info,

WHO Global Health Observatory, UNICEF, World Prison studies and the World Bank data repositories. All data sources are presented in the text and footnotes.

Analysis conducted includes plotting of annual data followed by visual observation; computation of slopes by linear regression to describe/compare the direction and speed of change of various indicators, and ecological analysis of TB case notification rates and trend of external factors.

The standard WHO-recommended assessment checklist and associated user guide, from S*tandards and benchmarks for tuberculosis surveillance and vital registration systems*[1], were applied. For analysis and interpretation of the influence of TB predictors and external factors, instructions from the handbook *Understanding and using tuberculosis data*[2] were followed.

Country shapefile was obtained from https://data.humdata.org/dataset/sri-lanka-administrative-levels-0-4-boundaries, on 30 July 2020.

[1] WHO Global Task Force on TB Impact Measurement. Standards and benchmarks for tuberculosis surveillance and vital registration systems: checklist and user guide. WHO/HTM/TB/2014.02. Geneva: World Health Organization; 2014 http://www.who.int/tb/publications/standardsandbenchmarks/en

[2] WHO Global Task Force on TB Impact Measurement. "Understanding and using Tuberculosis data" WHO/HTM/TB/2014.09, Geneva: World Health Organization 2014 https://www.who.int/tb/publications/understanding_and_using_tb_data/en/

1. Assessment of TB surveillance system and vital registration systems

1.1. Description of TB surveillance system

1.1.1. Structure

Oversight of overall TB surveillance system in Sri Lanka is implemented by National Program of Tuberculosis Control and Chest Diseases (NTPCCD) of the Ministry of Health. At district level TB diagnostic, treatment and preventive services are implemented by District Chest Clinics (DCC) manned by District Tuberculosis Control Officer (DTCO) who is the focal point for all TB control related activities within the district. Consultant respiratory physicians who are attached to hospitals visit DCC to provide expert guidance in management TB patients. In addition to the DTCO there are other Medical officers engaged in diagnosing and treating TB patients. The Public Health Inspector (PHI) attached to DCC is mainly responsible for DOTs allocation, tracing contacts, and tracing interrupters. In addition, there are nursing officers, radiographers, Medical/Public Health Laboratory technicians and the other supportive staff at the DCC. There are in total 26 DCCs serving all 25 districts of Sri Lanka. While preventive activities in Sri Lanka mainly are implemented by office of Medical officer of Health (MOH), manned by Medical officer of Health (MOH), Public Health Inspector (PHI), Public Health Midwives (PHM) etc. For each district there are 13-14 MOH offices. PHI attached to MOH office is responsible to make field visits, investigate the disease outbreak, doing the contact tracing and other activities related to control of communicable diseases in the respective area. However, DCC staff has the main responsibility in carrying out TB preventive and control activities within the district. In-patient care is provided at the National Hospital for Respiratory Diseases (NHRD) and chest wards situated in health institutions in some districts.

M & E Unit at NPTCCD is responsible for overall implementation, monitoring and evaluation of TB control activities and is manned by a medical officer, development officer and health assistant. Technical guidance is provided by the Consultant Community Physician (CCP)/NPTCCD.

Data are recorded for all individual TB cases at the service delivery points, using standardized TB data collection forms. All TB cases from all parts of the country are included in the national TB surveillance. Patient-level data are available at national level. The frequency of data transmission to the national level is in real time for the ePIMS, and quarterly for the paper based (aggregated) recording system.

1.1.2. Tools and data flow

Sri Lanka TB surveillance system is in transition stage from paper to electronic case-based TB case recording and reporting. As of 2020 among 26 reporting units only Colombo fully has been transited to electronic forms, while in the remaining districts paper forms are still largely used in parallel to electronic system and national surveillance data still relays on aggregated quarterly data reporting system.

According to national manual of TB control, all presumptive TB patients should be recorded in "***Register of Tuberculosis suspects (TB 16)***" maintained at the outpatient department of the Health care institutions.

Once sputum smear/biological material is collected, ***Request form for bacteriological examination*** *(Form* ***TB05 &TB 06****)* is completed which accompanies the biological sample sent to a laboratory. TB 05 forms are used for microscopy examination and TB 06 for X pert, culture and DST. Laboratory results are communicated back to the requesting physician using the same TB 05 with completed results. In

addition to paper forms, in case of laboratory confirmation, laboratory test result are communicated back to requesting physician by phone to reduce turn-around time. In each laboratory, results are entered into "***Laboratory register (TB-04)***".

Following the confirmation of patient with TB disease, a triplicate *form H-**816 A "TB notification form"*** is completed by a medical officer from facility that confirmed TB diagnosis. If it is in the DCC one copy is sent to the MOH of the area of residence of the patient, second copy is sent to NPTCCD, while the third copy is retained at the clinic. When the patient is diagnosed at a hospital two copies should be sent to NPTCCD and one copy should be retained at the relevant health facility.

Detailed TB patients related data are captured in individual TB treatment card '***Form TB 01'*** which contains important administrative, demographic, and clinical details about the patient and his/her treatment. If DOT provision is not done at the chest clinic, TB card is filled in duplicate. The original card is retained in the clinic and the duplicate is sent to treatment center where patients is provided with DOT. At DCC all diagnosed TB patients are registered in "District *TB register" (Form TB 03*)" and regularly updated using TB treatment card. District TB registers are used to develop quarterly reports on case finding, sputum conversion and, treatment outcome.

H816 A form is sent to relevant MOH office by the DCC to ensure,

- Case investigation and patient follow-up
- Confirmation of the address of the patient
- contact screening, referral for in-depth examination if required and follow-up for two years. as they are at risk of getting the disease.

All patients notified by H816 A are entered in "***TB notification register (TB18)***" maintained at MOH office and handed over to the range PHI. Once household contacts are investigated and screened, the investigation outcome details are recorded in the TB investigation register (TB 19) maintained by the range PHI at his office. In addition, details of investigation of each index case are reported back to DCC using "***Response to notification H 816 B form***".

TB deaths are notified to the DCC using "***TB death notification form (H- 814***). Following in-depth investigation of the death event, a detailed report on deaths occurred among TB patients during the period of treatment - "***TB death investigation form /TB 17***" is filled by the DCC and forwards to NPTCCD.

Patients who are not adhering to the treatment are recorded in "***Interrupters register***", which aims to document the efforts of the heath facility directed to follow-up the patients who interrupted their treatment. "***Register of TB contacts***" is used to record the close contacts of all forms of TB.

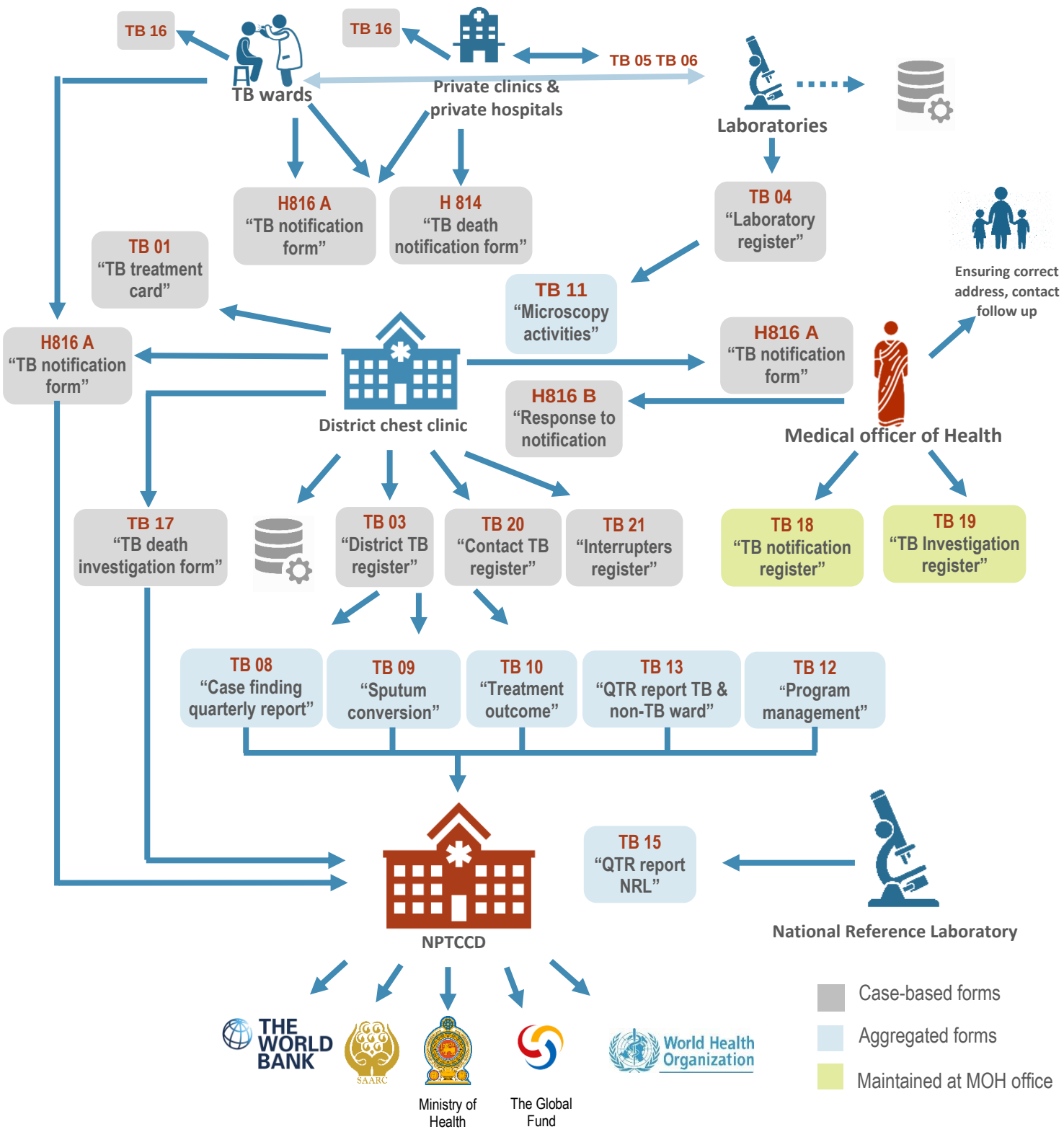
The paper forms usually are transmitted by post. While in Colombo, only electronic version of forms are used for reporting and information transmission.

Reporting of TB control related data from DCC to NPTCCD is implemented on quarterly basis using standard electronic spreadsheets and paper based RR forms. "Case finding quarterly report / TB 08" includes notification data per core variables of patients enrolled previous quarter, including data on HIV co-infection. "***Sputum conversion at the end of intensive phase of treatment / TB 09***" provides intermediate data on treatment effectiveness of the cohort enrolled 6 month before the report, while "***Quarterly report of TB treatment outcome TB-10 form***" summarizes final TB treatment outcome, of patients enrolled into treatment 12-15 months ago disaggregated by age group, sex, bacteriological

confirmation, site of disease, and history pf treatment. Summary of TB case finding, contact tracing activities, including number of OPD visits, people screened, including prisoners, drug addicts, number tested for microscopy, GeneXpert, data on available human resources during the reporting quarter are reported using "***Quarterly report on program management -TB 12***". This form is used to generate national statistical reports on TB and submit data to the Global TB database.

National surveillance statistics is generated by M&E unit/ NPTCCD following data validation process. Trainings for the surveillance staff are organized on regular basis – once a year, during the field supervisory visits as well whenever there is a revision in recording and reporting framework.

Figure 1.Schematic presentation of Data Flow to the NPTCCD



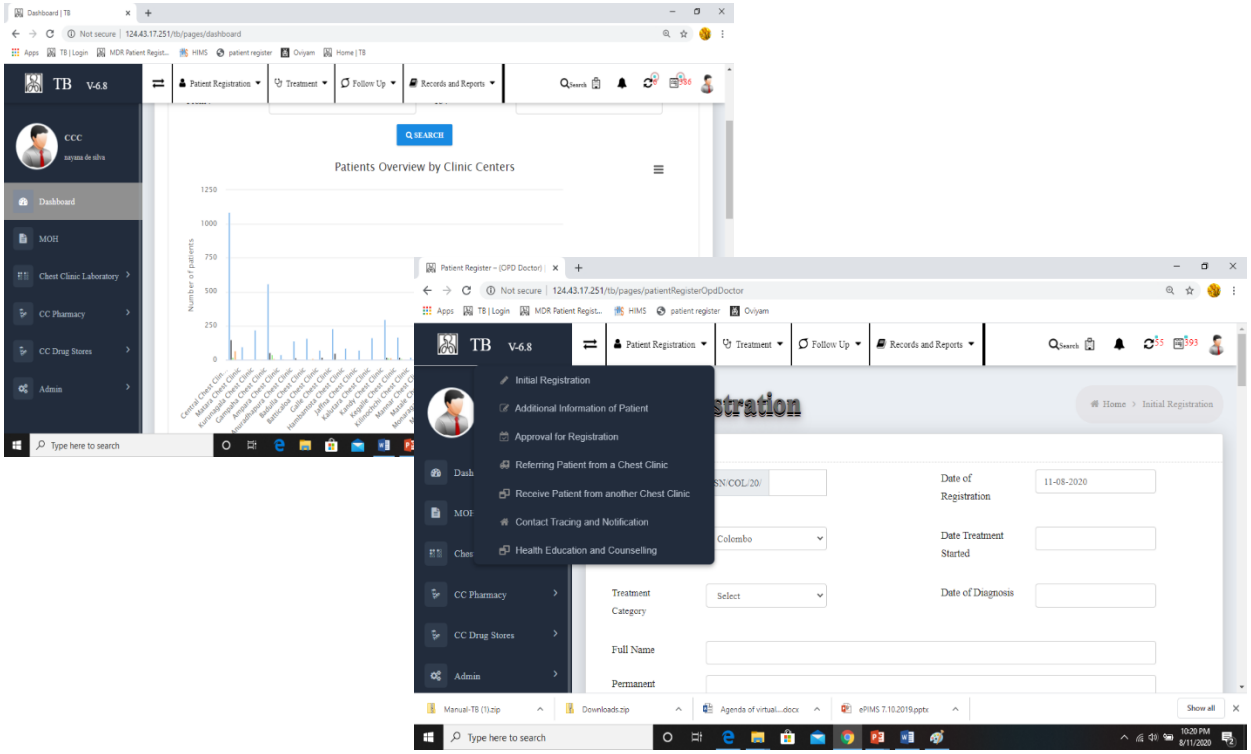
TB 05 – The Laboratory form request for sputum examination
TB 06 – Request for BT culture and drug susceptibility test
TB 10 - Quarterly report on the results of treatment of patients registered 12-15 months earlier.
TB 11 – Quarterly report on Microscopy activities and Logistics
TB 12 - Quarterly report of programme management

1.1.3. Electronic Programme Information Management System (ePIMS)

ePIMS is real time case based electronic surveillance system developed locally with support of Global Fund. With access via standard web browsers. Data and back-up server are located at the Colombo chest clinic premises. System consists from the following modules:

- Dashboard
- Aggregate and case based electronic recording and reporting system, including the following sections
    - Patient registration
    - Treatment
    - Follow-up
    - Record and reports
- Laboratory investigation module
- Drug stock information module
- MOH (medical officer of health) module
- MDR-TB Patient Information module
- GIS Mapping
- Admin

Figure 2.Screenshot of dashboard and Recording and reporting of PMIS



The system was designed by a committee comprised of specialists in health informatics and technical staff of NPTCCD, after assessing paper-based R&R system, clinicians' needs as well as information needed for the international agencies.

The system contains much more data elements than paper-based standard recording forms. The "Registration" section of recording and reporting module contains about 40 variables on patient demographic, social and clinical characteristics. "Treatment" section captures data on complains at the initiation of the treatment, prescription as well allows to order investigations, assign DOT center, record contacts, information about health education and counselling and record adverse drug events. The "follow-up" section of R&R module captures information on complains, weight, height, laboratory test results, chest radiography, adherence, contacts during the follow-up visits, save digital file of the x ray. ePIMS allows assign the appointment and in case of no show the system shows alert about potential lost to follow-up. Unit of recording is the case, to each record a system generated ID is assigned along with district TB ID, however, because National Identify Card number (NIC) and passport number are entered, therefore, a person with multiple episodes also could be identified. NIC are compulsory for all Sri Lankan citizens who are 16 years of age and older.

MOH module was designed to receive on-line H816 A notification forms, complete outcomes of contact tracing, tracing of treatment interrupters, death investigation and back referral of H816B.

The system generates following registers (line listing of records with key characteristics): central and district TB register, notification register (MOH area), contact tracing register, treatment interruption register (district level), central and district death register. in addition, it generates quarterly standard reports of case finding, treatment, smear conversion and treatment outcome (TB 08, TB 09, TB 10) by district.

Laboratory module is designed to enter data at three levels: DCC laboratory (microscopy and Xpert), intermediate laboratory (microscopy, Xpert, culture) and NTRL (microscopy, Xpert, culture and DST). However, at the time of epi-review laboratory module was used in CCC – Colombo and while drug store module was used only in 3 districts (i.e. Colombo, Anuradhapura and Polonnaruwa)

ePIMS in 2019 was piloted in three districts, including Colombo, Kurungela, Matara and then as of 2020 all 26 districts were engaged into the system gradually and function in different levels. Table 2 shows the utilization of ePIMS specific modules by districts. As it is shown Colombo is the only DCC utilizing all modules (except "MDR module"). All districts complete at least "registration module".

System users include doctors (230), nurses (53), PHLT (23), MLT (26), PHI (41), pharmacists (19), development officers (2) and users in office of the MOH (73). The system is accessed using individual user accounts (usernames and passwords); role-based permissions define which data items, screens and reports different types of users can see and which data items they can modify. Data users were trained on system use; brief written training modules are available. In addition, there is a training module via google classroom.
According to NPTCCD the system has good acceptance. It reduced workload, improved case notification and investigation at MOH level and improved contact tracing and timely tracing of those with treatment interruption.

Table 2. Completion of ePIMS modules by districts

District	Registration	Treat-ment & FU	Contact tracing	Default tracing	GIS	MoH	Pharm.	Lab	TB08 TB09 TB10	Death investig	Patient transfer	MDR
Colombo	●	●	●	●	●	●	●	●	●	●	●	●
Gampaha	●	●	●	●	●	●	●	●	●	●	●	●
Anuradhapura	●	●	●	●	●	●	●	●	●	●	●	●
Trincomalee	●	●	●	●	●	●	●	●	●	●	●	●
Galle	●	●	●	●	●	●	●	●	●	●	●	●
Nuwara Eliya	●	●	●	●	●	●	●	●	●	●	●	●
Matara	●	●	●	●	●	●	●	●	●	●	●	●
Kurunegala	●	●	●	●	●	●	●	●	●	●	●	●
Kegalle	●	●	●	●	●	●	●	●	●	●	●	●
Matale	●	●	●	●	●	●	●	●	●	●	●	●
Monaragala	●	●	●	●	●	●	●	●	●	●	●	●
Ampara	●	●	●	●	●	●	●	●	●	●	●	●
Kalutara	●	●	●	●	●	●	●	●	●	●	●	●
Kandy	●	●	●	●	●	●	●	●	●	●	●	●
Badulla	●	●	●	●	●	●	●	●	●	●	●	●
Batticaloa	●	●	●	●	●	●	●	●	●	●	●	●
Polonnaruwa	●	●	●	●	●	●	●	●	●	●	●	●
Mannar	●	●	●	●	●	●	●	●	●	●	●	●
Kilinochchi	●	●	●	●	●	●	●	●	●	●	●	●
Jaffna	●	●	●	●	●	●	●	●	●	●	●	●
Hambantota	●	●	●	●	●	●	●	●	●	●	●	●
Vavuniya	●	●	●	●	●	●	●	●	●	●	●	●
Puttalam	●	●	●	●	●	●	●	●	●	●	●	●
Colombo South Teaching Hospital	●	●	●	●	●	●	●	●	●	●	●	●
Ratnapura	●	●	●	●	●	●	●	●	●	●	●	●
Colombo East base hospital	●	●	●	●	●	●	●	●	●	●	●	●
Kalmunai	●	●	●	●	●	●	●	●	●	●	●	●
Mullaitivu	●	●	●	●	●	●	●	●	●	●	●	●

1.1.4. Quality assurance

Data quality control and verification is implemented at district and national levels. At district level quality control is implemented during the supervisory visits using standard check-list, which contains qualitative and quantitative measurement of data quality of the district, included cross-check between source documents and recounting of reports. In addition, quality control is implemented during the quarterly meeting as described above. And final data quality and verification is implemented at national level on quarterly basis – by comparing the reported data field. Feedback is provided to district staff if any problem is identified.

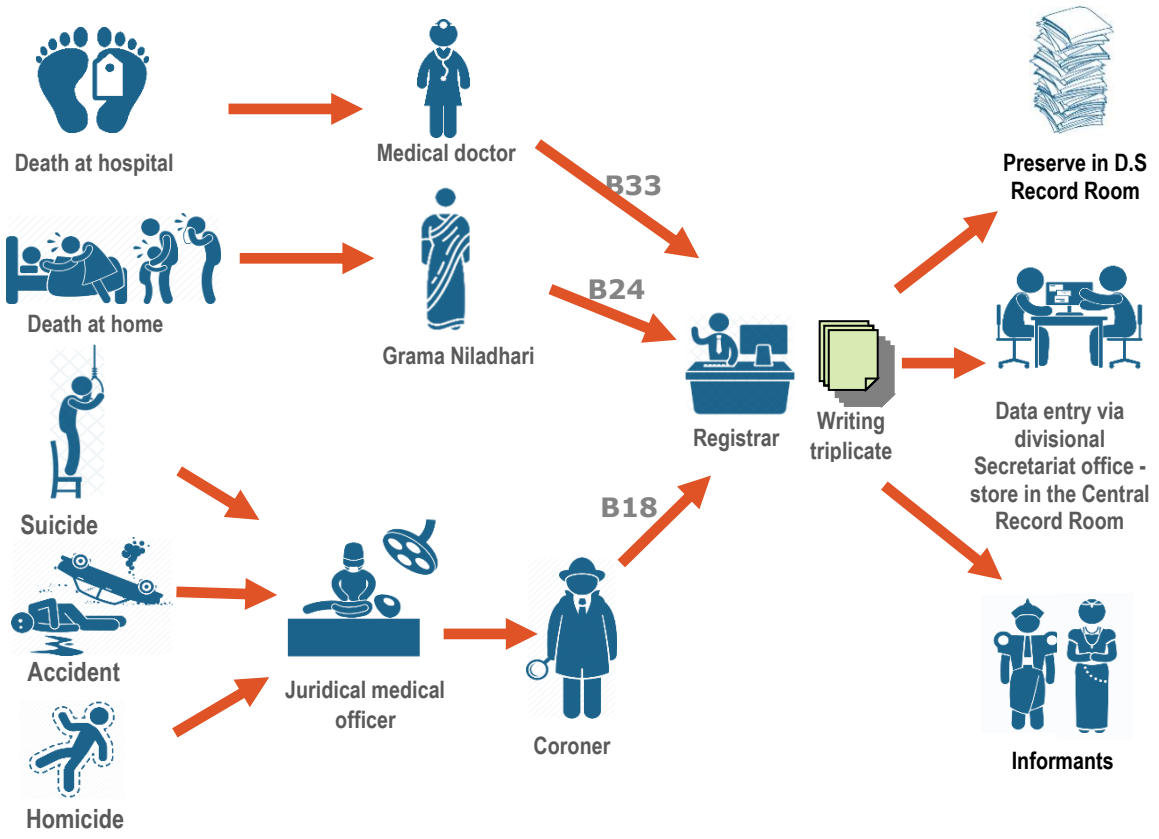
ePIMS is designed in a way that during the data entry process data validation checks are undertaken to prevent errors. For example, for most of the variables (sex, geographical location, anatomical site of disease, previous history, outcomes of treatment and other) only pre-defined options are allowed to enter that appear as a drop-down menu during the data entry. Fields are enhanced with the checks, so that only numbers are possible to enter in numeric fields and dates in date fields, however, there are no extended data quality controls in place for batch checking nor standard operating procedures.

1.2. Vital registration system

Sri Lanka has a well-established civil registration and vital statistics system and registration of births, deaths and marriages are established practice in the country. Civil registration system has high completeness rates for both births (97%) and deaths (100%)[3]. However, the quality of Sri Lanka's mortality statistics produced by the civil registration system is low, which compromises access to accurate and reliable cause of death data for informed, evidence-based health policy and planning purposes.

According to the Birth and Death Registration Act, the death registration in Sri Lanka is mandatory[4]. Families should provide with death certificate for cremation or burial.

Figure 3. Diagram of death registration



Source of diagram: Adapted from slides provided at the meeting at Registrar General's Department

[3] Sri Lanka Implementation Working Group. Sri Lanka: Strengthening the quality and availability of mortality statistics. CRVS country reports. Melbourne, Australia: Bloomberg Philanthropies Data for Health Initiative, Civil Registration and Vital Statistics Improvement, University of Melbourne; 2019.

[4] Registrar General's Department [online] http://www.rgd.gov.lk/web/index.php/en/services/civil-registration/death-registration.html#, accessed 29 August, 2020

Death registration in Sri Lanka is decentralized and under the control of district and divisional authorities. There are around 1700 Birth, Death and Marriage Registrars in Sri Lanka. During recruitment they were given a special training & annually on the job training. A Registrar acts as a focal point for registration of all births, deaths, and marriages that occur in that area. Families can obtain the death certificate from the Registrar in their administrative area upon provision of proof of death, in the form of a death declaration from the hospital for health facility deaths through Form B33, or a death notification completed by the Village Officer ("Grama Niladhari") through a verbal autopsy by using the available data sources for community deaths sends the data through Form B24. When death need some legal procedures, juridical medical officer will do the postmortem and submits his findings to the coroner. After that coroner notified the death through Form B18 (Figure 3).

Once he received the Death Declaration form, he sent it to the Vital Statistic Unit at Divisional Secretariat and then it sent to the national level. Once it received at the national level, coders at the national level review all forms. These coders are Diploma holders in Information and Communication Technology with special training on ICD coding at National Institute of Health Sciences.

All deaths that occur at the hospital are medically certified, while the deaths that occur outside of hospital settings (i.e. deaths that occur at home or in the community) are certified by non-medically trained staff (such as Gramaniladari) in most of the occasions. Considering that over half of all deaths in Sri Lanka occur outside of hospitals, the lack of medically certification of the deaths results poor quality of death registration. Moreover, an evaluation conducted in six hospital indicated accuracy of recording of cause of death was unsatisfactory: concordance between the underlying cause of death in the vital registration data and that from the medical records review diagnosis was 41.4% only[5]. Currently training is provided to undergraduate period for all doctors. Some doctors also receive in-service training. According to the verbal communication with the Registrar General Department around 50% were ill defined and unknown causes. Only the published data available up to 2014, the main problem was with the coding of data. There was no recent evaluation to assess completeness of death registration by Registrar General Department, but they are planning to put into the next census which will be on 2021. Regarding the quality assurance of the available data, they only manually checked for major errors.

1.3. Strengths of surveillance system

Recording and reporting forms and case definitions are in line with WHO standards. During our review, the facilities that visited were maintaining appropriate TB treatment registers and forms. Data quality was high (although not perfect), and national TB data have good internal consistency for most key variables (with the exception of clinically diagnosed TB). Historical data disaggregated by age, sex, bacteriological confirmation and history of treatment are available. Data are verified at district and national level.

All types of TB patients are included in surveillance system across the country. Private sector and NGOs are not involved in TB treatment. TB notification is a legal requirement.

[5] Rampatige R, Gamage S, Peiris S, Lopez AD. Assessing the reliability of causes of death reported by the Vital Registration System in Sri Lanka: medical records review in Colombo. Health Inf Manag. 2013;42(3):20-8. doi: 10.1177/183335831304200302. PMID: 24067238

NPTCCD produces annual analytical surveillance and monitoring report which is posted on the web site.

Sri Lanka has also made outstanding progress introducing real time case based electronic surveillance system and gradually transiting from paper to electronic recording and reporting. HIV testing coverage among all TB patients is very high. The prevalence of MDR-TB among representative sample of TB patients is available from the country wide drug-resistance survey conducted in 2017. Gene Xpert roll-out is continuing, with 29 sites (31 machines) established as of 2020

1.4. Challenges of surveillance system

Despite of progress made still there were some challenges related to TB surveillance.

Presumptive TB register in general are not accurately maintained at the health institutions involved in TB detection and referral, therefore information about presumptive TB patients is not reliable at national level.

Reports and returns from the laboratories to DCC and NPTCCD (e.g. number of microscopy, GeneXpert test and results) are not received and processed regularly and those indicators are not included into annual surveillance and monitoring report.

Gene Xpert testing coverage is far below of End-TB strategy target of at least 90% level.

Discussion with health care providers, review and cross-check of laboratory and TB registers indicated that patients with initial lost to follow-up and those who die before the start of the treatment and most probably RR-TB cases are not registered in the TB register in most of the time and therefore are not included into case finding reports.

Reporting prison TB cases are not complete. In last two years only sputum-smear positive TB cases identified through active case finding are reported, while clinically diagnosed and Xpert positive case are not reported. TB screening in prison largely relies on symptom checks, suggesting high likelihood of underestimation of presumptive TB cases. Poor internal consistency over the time, high variability of presumptive TB cases and case detection across the prisons in the country suggest that significant number of TB cases in prisons are missed. On-site monitoring of TB program by NPTCCD is difficult to carry out in prison system within current legal system.

Currently used case finding and treatment outcome reporting forms incorporate numerous un-necessary dis-aggregations. This increases workload of providers to tally and tabulate the data. There are no standard forms for RR/MDR-TB recording (individual treatment card and register). Currently used excel spreadsheets to record the patients enrolled into second-line treatment is not in-line with WHO recommended standard RR/MDR-TB register.

The ePIMS design is more focused on clinical care of the patients and resource management rather than surveillance and monitoring of the trend of disease burden and programmatic indicators. Therefore, the use of ePIMS to generate national reports and use of it for the data analysis and interpretation is still limited. The system has no dashboard of key TB indicators, and there are no built-in features to produce time-series analysis, tables, figures, maps, no features to calculate rates. There are no automated checks to assess/alert duplicate, incomplete entries, and inconsistencies. To generate annual reports, the quarterly reports should be summarized manually.

NTRL and intermediate laboratories do not yet use ePIMS laboratory module, therefore the laboratory results remain largely incomplete. There are no automated connectivity with GeneXperts and it is required manually to re-enter GenXpert outputs. In addition to the increased workload such approach might lead to errors in data transmission.

No designated personnel at DCC and NPTCCD to oversight ePIMS data quality and provide feedback to users (position was vacant at the time of epi-review). No standard operating procedure/algorithm for data cleaning (de-duplication, checking missing values, inconsistencies)

Although vital registration system has, however, the proportion of deaths with ill-defined cause of death are high indicating poor data quality of VRS

Despite of high HIV testing coverage, however, about quarter of TB/HIV cases are missed by TB surveillance system (demonstrated by different number of newly diagnosed TB/HIV cases reported by NPTCCD and National STD/AIDS control program (NSACP)) and highlighting the need for more close collaboration between those two institutions.

1.5. Recommendations

Strengthen coverage of the TB surveillance system ("missed" TB cases)

- Ensure that presumptive TB register is consistently used in all facilities engaged in TB care and referral (urgent)
- Introduce standard recording forms for patients enrolled into second-line treatment (urgent)
- Transition from treatment register into register of people with TB. 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)
- Ensure that all prison TB cases are included into 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)
- Improve routine household source contact tracing and contact tracing of adult index cases focusing on potentially exposed children (urgent)
- TB diagnostic algorithm should be 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 solution (e.g. GxAlert) to facilitate smooth data transmission to requesting clinicians for faster patient follow-up and ensure remote monitoring of key performance indicators (mid-term)
- Advocate to improve the quality of vital registration system with systematic registration of cause of death by health care providers (long-term)

Strengthen quality of the TB surveillance system

- Aim for automatic integration or importation of data generated by other electronic systems (such as laboratory systems, digital Xray) into ePIMS without manual data re-entry. This will reduce the staff time and 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[6] (urgent)

- NPTCCD might consider to simplify the ePIMS structure by removing variables that are not used for analysis, decisions-making (e.g. presenting complain and duration, contact history of TB, Mantaux, ESR, civil status, living, occupation, education, complains, investigations) or have hight level of missingness (not feasible to complete). Develop a plan to optimize and upgrade ePIMS with clear action, budget, timeline, indicators and targets in line with WHO requirements[7] for the electronic surveillance systems. Particularly system should be enhanced with dashboard 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 from https://www.who.int/healthinfo/FacilityAnalysisGuide_TB.pdf?ua=1, which could be considered for country adaptation (mid-term)
- Introduce data validation algorithm to be run by designated staff at different level 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 document. 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 (mid-term).
- Parallel runs using paper and electronic systems may be necessary until districts achieve high coverage and consistency of electronic system (mid-term).
- As it is mandatory to transfer the medical officer in every four years, the regular training of the MOs who appoint to the DCC need to strengthen (mid-term).
- Establish the mechanisms to follow-up the implementation of the recommendations made during the central staff supervisory visits, e.g. organization of targeted more frequent visits, follow-up the implementation of the recommendations during the subsequent supervisory visits etc. (mid-term).
- 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).
- 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.

Use of data and informed decision making

- National surveillance and monitoring annual report should include data on laboratory activities which are key in analysis of trends of TB burden, such as number of 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

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

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

area should be analysis to assess unusual, sudden changes for timely investigation and addressing of issues (urgent).

- 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, initial lost to follow-up (long-term).
- Conduct operational research using ePIMS to assess the predictors of unfavorable outcome and specifically for mortality. Operational research results will help NPTCCD to undertake targeted intervention to prevent unfavorable outcomes and on the other hand will identify ePIMS data quality issues and will boost the improvement of ePIMS data quality (long-term)
- Conduct catastrophic cost survey to monitor the progress toward the target to eliminate catastrophic cost and help design interventions toward the social protection of people affected with TB (long-term).

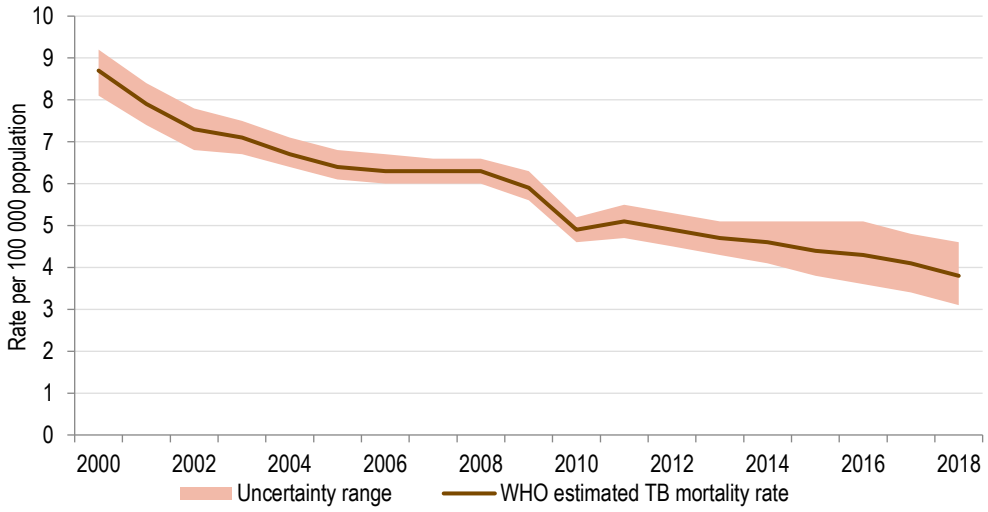
2. TB epidemiology

2.1. TB burden

2.1.1. Trend of TB mortality

Although the coverage of death registration in Sri Lanka is almost universal, however, no country data are available in the global mortality database since 2006 onward[8] which is the key source of WHO to extract and compute disease-specific mortality data. Because of the lack of reliable on number and cause of death from vital registration statistics, for Sri Lanka the TB mortality is measured indirectly by multiplying estimates of TB incidence by estimates of the case fatality rate. According to WHO estimates, in 2000 there were in total 1,600 (range: 1,500-1,700) TB deaths (excluding TB/HIV deaths) equivalent to 7.9 (range: 7.4-8.4) per 100,000 population. Since then TB mortality steadily has been declining with an average annual fall of 4.6%. By the end of 2018, the estimated number of TB deaths in Sri Lanka was reported as 810 (range: 660-860) equivalent to 3.8 (range: 3.1-4.6) per 100,000 population[9]. (*Figure 4*).

Figure 4. Estimated TB mortality rates (excluding TB/HIV) per 100 000 population, 2000–2018
Shaded area around lines indicates uncertainty range



Data source: Global TB database

2.1.2. Trend of estimated TB incidence

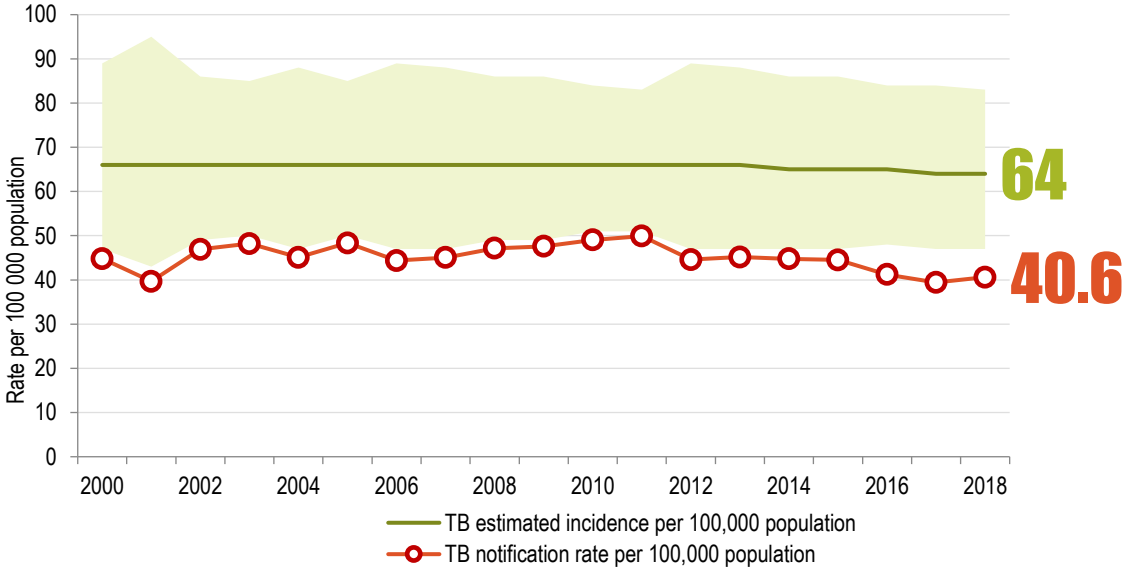
The WHO-estimated incidence for 2018 was 64 (range: 47–83) new and relapse cases per 100,000 population. In absolute numbers this makes 14,000 people (range: 10,000-18,000). The mean annual decline between 2014 and 2018 for estimated TB incidence was -0.4% only. In 2018, the notification rate for new TB cases and relapses in the country was 40.6 cases per 100,000 population using UN

[8] WHO mortality database [online] https://apps.who.int/healthinfo/statistics/mortality/whodpms/ Accessed on 15 August 2020

[9] Global tuberculosis report 2019. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.

population estimates for Sri Lanka. Over the recent four years the gap between estimated and notified cases increased indicating of decline in treatment coverage (Figure 5).

Figure 5. Estimated TB incidence and notification rate of incident TB cases, per 100 000, 2000–2018
Shaded area around line indicates uncertainty range

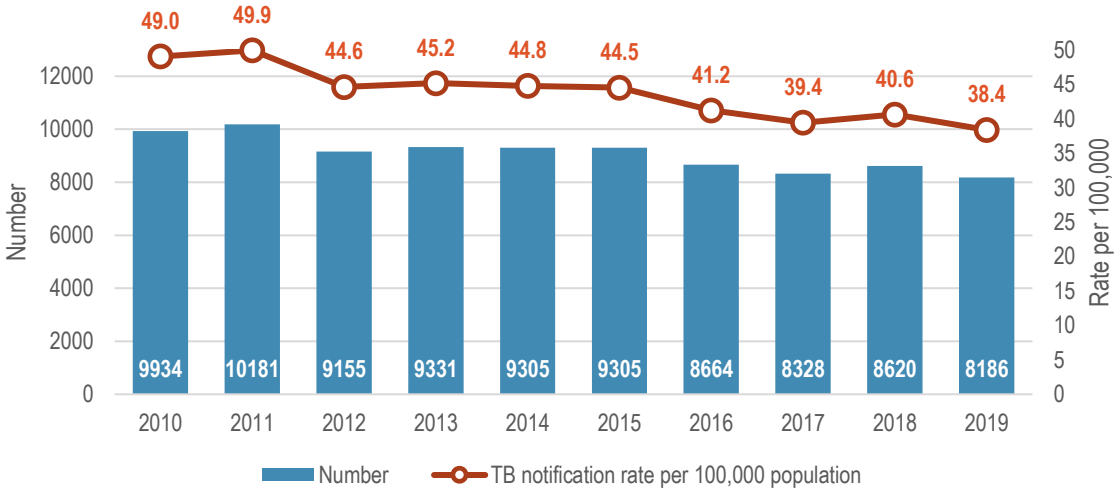


2.2. TB notification

2.2.1. Overall TB case notification and time trend

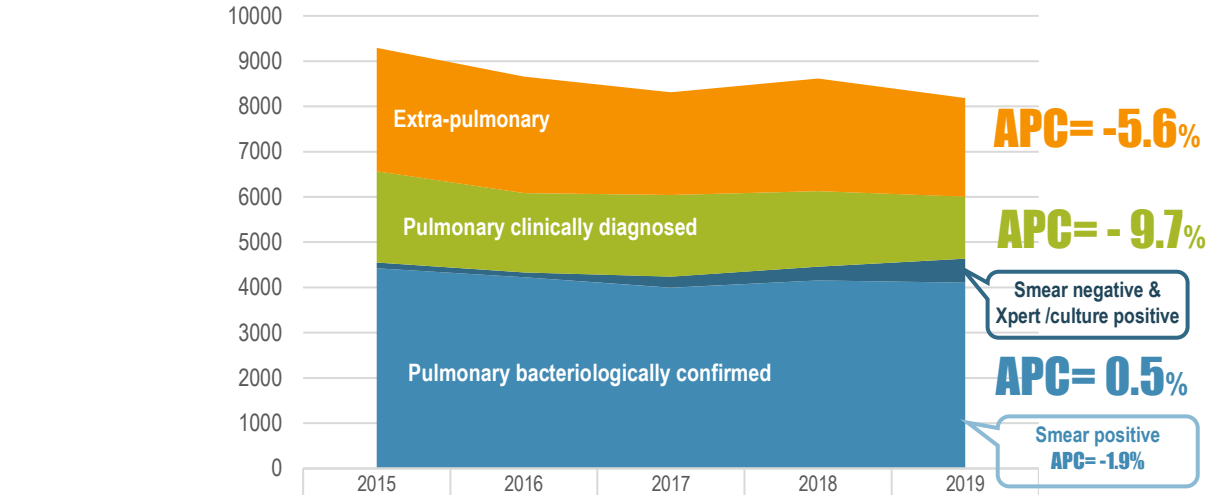
In Sri Lanka, between 2010 and 2019 the number of notified incident TB cases decreased from 9,934 (equivalent to 49.0 per 100,000) to 8,186 (equivalent to 38.4 per 100,000) with an average percent change of 2.7% per year. The rate of decline slightly accelerated over the recent five years reaching 3.7% annually between 2015 and 2019 (Figure 6).

Figure 6. Trend of TB notification number and rate (new and relapse)



When the trend of notification data was analyzed disaggregated by site of disease and bacteriological confirmation, the trajectories slightly differed: the fastest decline was observed in clinically diagnosed pulmonary TB cases, which fell on average by −9.7% per year between 2015 and 2019. In comparison, the average annual decline of extrapulmonary TB cases over the same period was −5.6%, while the number of bacteriologically confirmed cases slightly increased with 0.5% annually (Figure 7)

Figure 7. Notification of new and relapse TB by laboratory confirmation and localization, 2015–2019



	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

Such rapid decline in clinically diagnosed is partially explained by improvement of laboratory diagnostics due to introduction Gen Xpert and scale up testing coverage especially in 2018 and 2019 (Figure 26). However, sputum smear positive TB cases declined just -1.9% annually within the same period, which expressed as a rate per 100,000 population equals -2.3% annually (decline expresses as a rate is faster compared to absolute number due to population growth). The decline in the number and rate of smear positive patients is likely to reflect the trend of true TB burden in the population as unlike clinically diagnosed PTB, EPT forms of TB, the sputum smear positive TB diagnosis in Sri Lanka is not affected by subjective interpretation of clinicians, availability of Xpert, culture, radiologic examination and widely accessible (evidenced by low positivity). Thus, we can conclude that observed overall 3.7% annual decline in TB notification is partially due to change of diagnostic practice, and not only decline of true TB burden in the population.

Figure 8 shows the time trend of TB notification rate of new and relapse TB cases per 100,000 population between 2015 and 2019 by 26 districts in Sri Lanka. It is noteworthy that in majority of districts the trends are internally consistent and stable and free of sharp year to year variation. Special attention should be given to the districts showing unstable notification with year to year sharp change of direction of the trend (e.g. Ampara, Kandy, Killinochchi, Polonnaruwa). Those area might require more in-dept assessment and targeted intervention. Sharp decline over the time may suggest changes in the ability to detect and/or notify TB cases and might require targeted intervention (Figures 8, 9).

Figure 8. New and relapse TB cases per 100,000 population by districts, 2015-2019

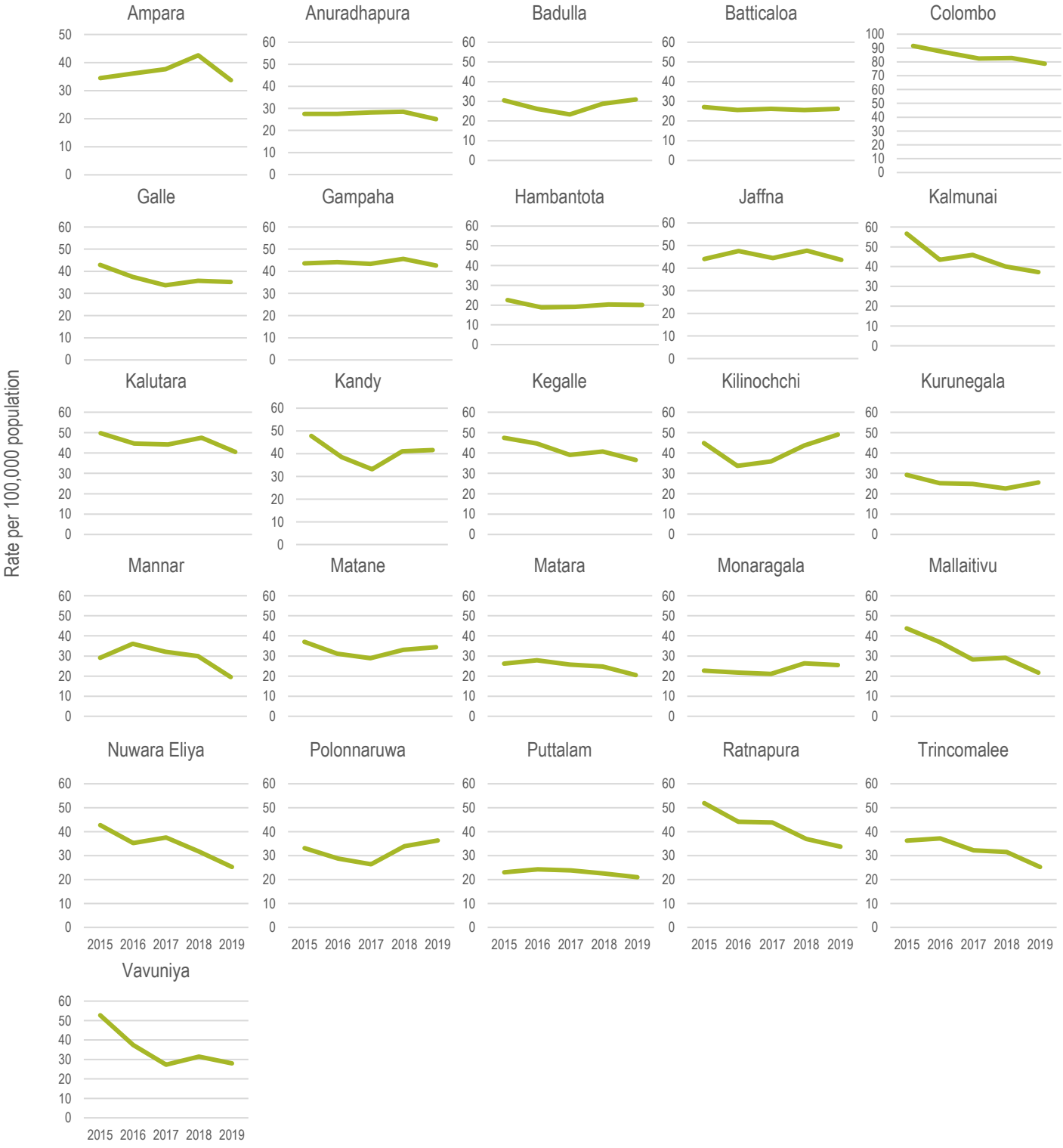
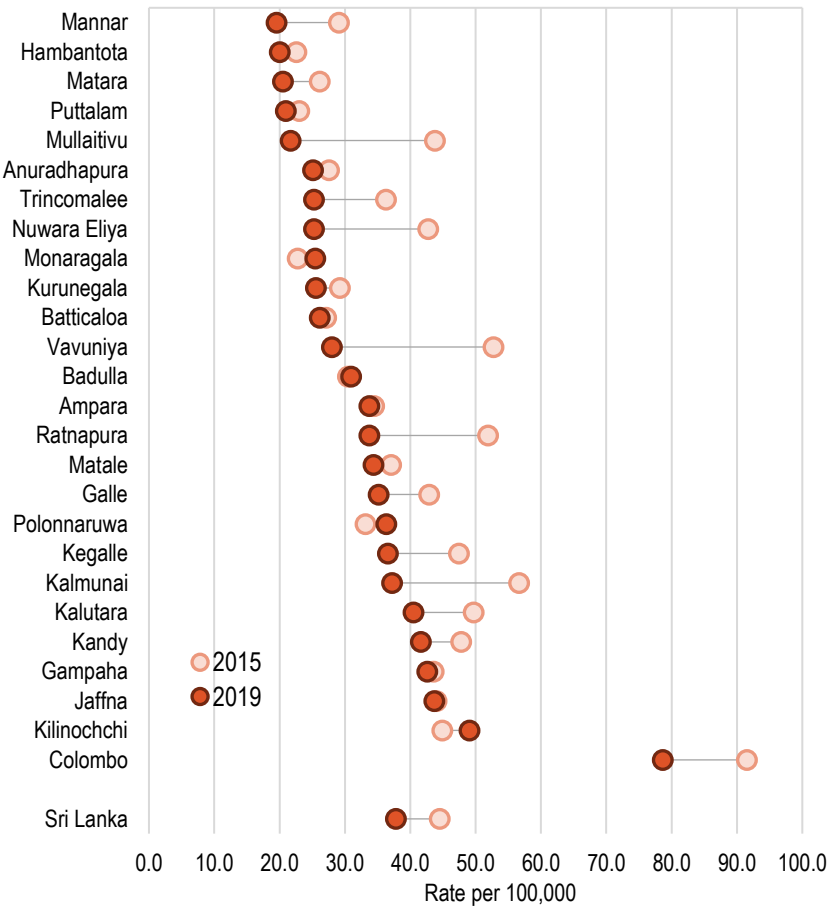
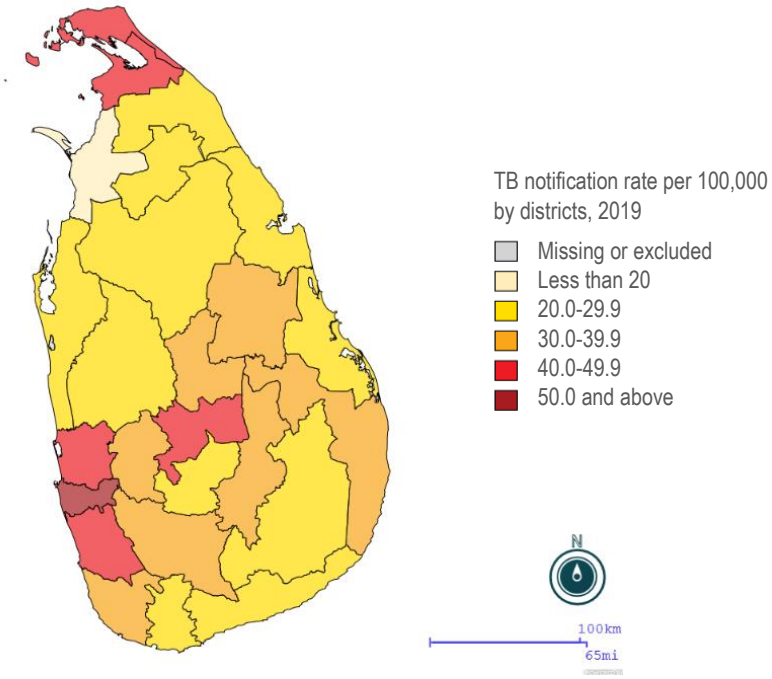


Figure 9. Notification rate by districts in 2015-2019



There was no remarkable difference in magnitude of TB notification rates across the districts. Exception was capital Colombo with 78.6/100,000 notification rate in 2019, representing as an outlier compared to other district, where level notification ranges between 19.5/100,000 in Mannar to 49.0 in Kilinochchi. Between 2015 and 2019 of 26 districts in 24 there has been decline in TB notification rate. The fastest decline was observed in Mullaitivu (APC=-13.1%) followed by Vavuniya (-11.9%) and Nuwara Eliya (APC=-10.0%).

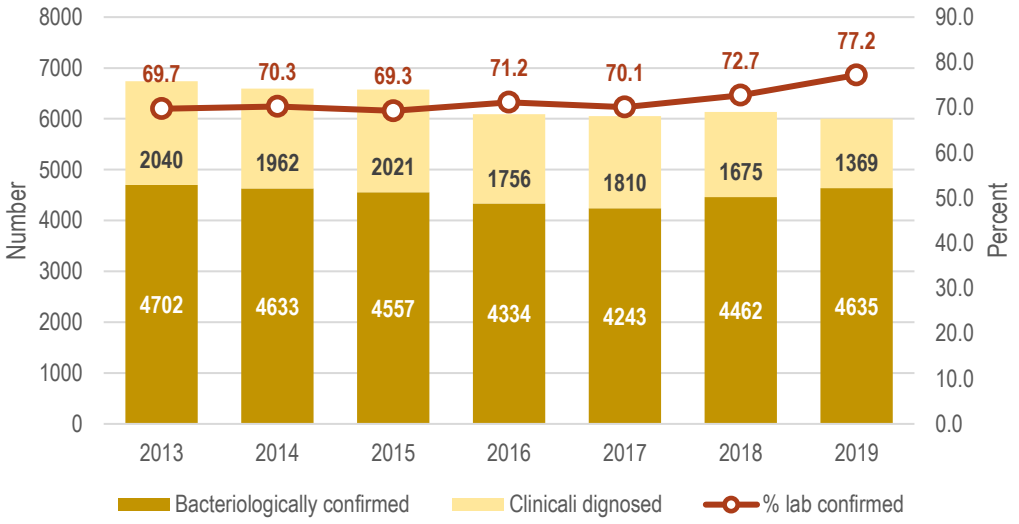
Map 1. TB notification rate (new and relapse) by districts per 100,000 population, 2019



2.2.2. Trend by bacteriological confirmation

Between 2013 and 2019 the proportion of bacteriologically confirmed case among new and relapse pulmonary TB cases increased from 69.7% to 77.2%. Increase in proportion was driven by steady decline in absolute number of clinically diagnosed TB cases.

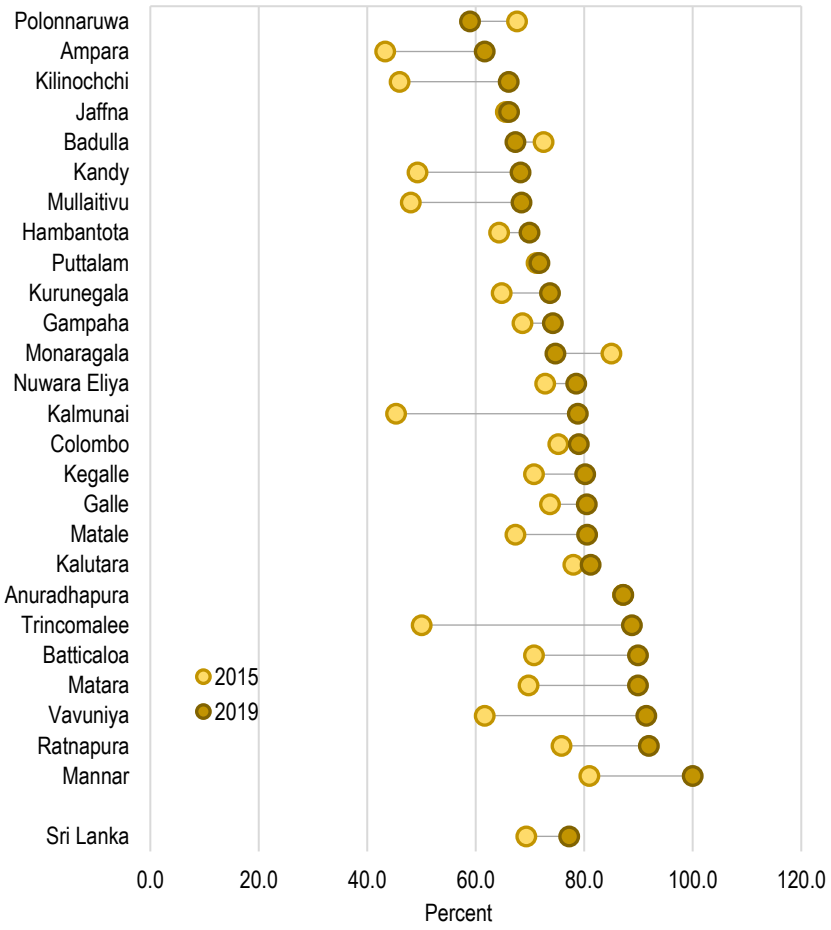
Figure 10. Notification of new and relapse PTB cases by bacteriological confirmation



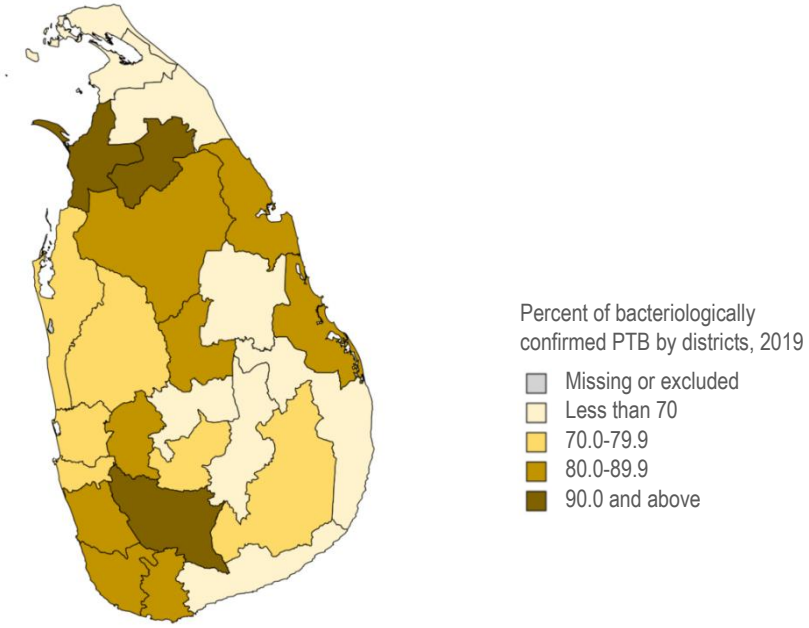
While the number of bacteriologically confirmed dipped up to 2017 and then increased up to 2019. At district level the proportion of bacteriologically confirmed cases in 2019 ranged from 58.9% in Polonnaruwa up to 100% in Mannar, indicating differences in practice of TB diagnosis and/or access to laboratory or clinical diagnostics.

Of 26 districts in 18 there was increase in proportion of bacteriologically confirmed cases (over 2%) in five there was no change and only in three districts (Polonnaruwa, Monaragala and Badulla) the proportion of bacteriologically confirmed cases decreased in 2019 compared to 2014 (Figure 11). Special attention needs to be given to the districts showing unreasonably high percentage of bacteriologically confirmed cases (Mannar, Ratnapura, Vavuniya), which means that clinically diagnosed forms of TB are missed by health systems.

Figure 11. Percent of bacteriologically confirmed new and relapse PTB cases by districts in 2015 and 2019



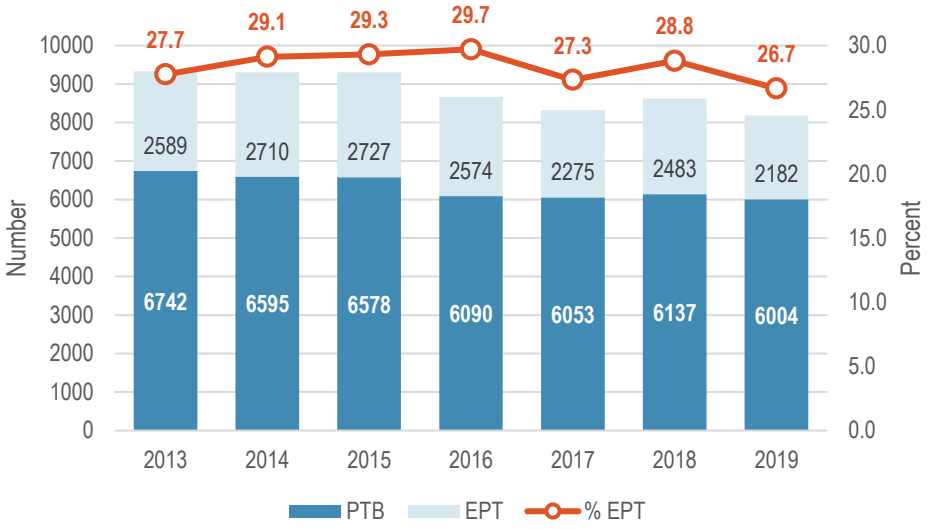
Map 2. Percent of bacteriologically confirmed new and relapse PTB cases by districts in 2019



2.2.3. Trend by site of disease

The proportion of extrapulmonary TB cases among new and relapse case in 2019 is relatively high, with around 27%, but this is still within the normal parameters of South Asia. Between 2015 and 2019, both pulmonary and extrapulmonary TB cases has been declined in Sri Lanka, but because the decline was proportional, the percent of extrapulmonary TB cases at national level has remained stable over the time ranging between 26.7 and 29.7% without clear trend over the time (Figure 12).

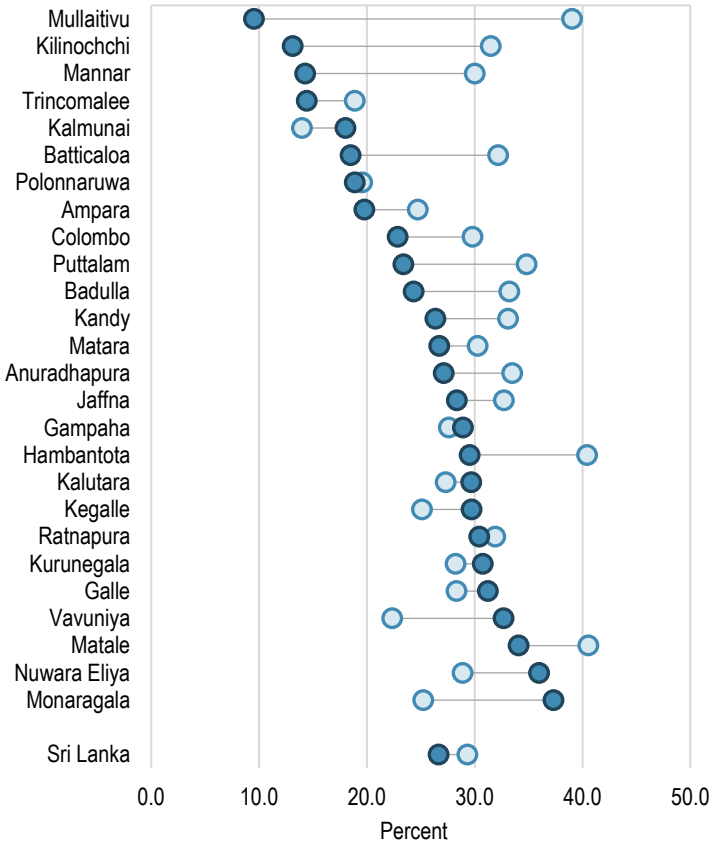
Figure 12. Trend in notification of new and relapse by site of disease



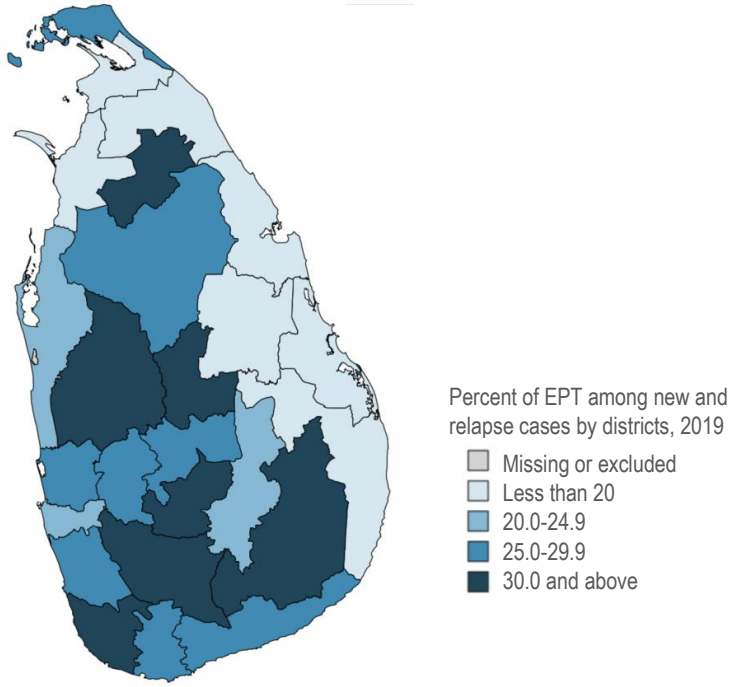
In 2019 the proportion of extrapulmonary TB cases varied from 9.5% in Mallaitivu district to 37.3% in Monaragala, suggesting different level of capacities and/or practices of TB diagnosis. It is noteworthy that within the districts there has been large temporal variation in proportion of extrapulmonary TB cases suggesting unstable diagnostic practice. Of 26 districts in 15 percent of EPTB has decreased, while in eight districts there was increase in percentage of ETP case in 2019 compared to 2019.

Mapping shows some geographic pattern of the proportion of extrapulmonary cases across the country: the percentage of ETP is comparatively lower in the in the eastern districts and at the north (Map 3)

Figure 13. Percentage of EPT in 2015 and 2019 by district among new and relapse TB cases



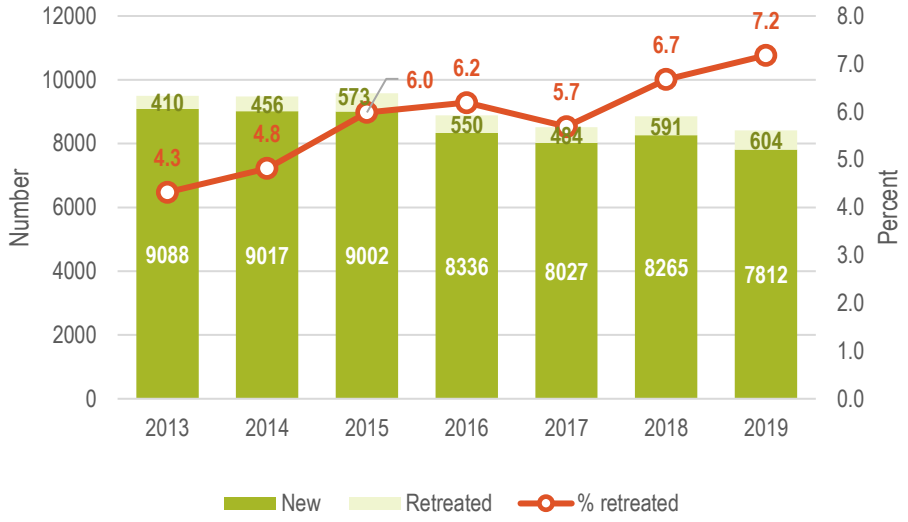
Map 3. Percent of extrapulmonary among new and relapse TB cases by districts in 2019



2.2.4. Trend by history of treatment

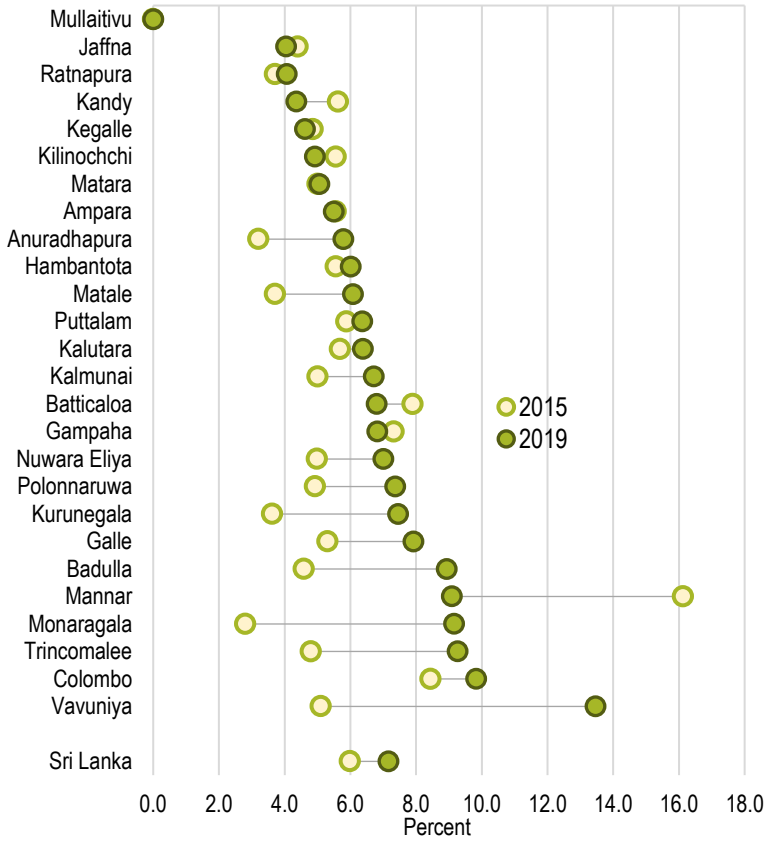
In 2019 only 7.2% of notified TB cases have been previously treated and thus the overwhelming majority of notified cases were new TB patients. The proportion of retreated has markedly increased from 4.3% in 2013 to 7.2% in 2019. This change driven by increase of absolute number of retreated cases and decline of number of new TB cases. Such increase after 2015 was explained by change in TB case definition: before 2015 only bacteriologically confirmed retreated TB cases notified, however, following the adoption of 2013 WHO definition framework clinically diagnosed retreated cases also were included into the notification resulting relative increase of retreated cases.

Figure 14. Trend of notification of TB cases by treatment history

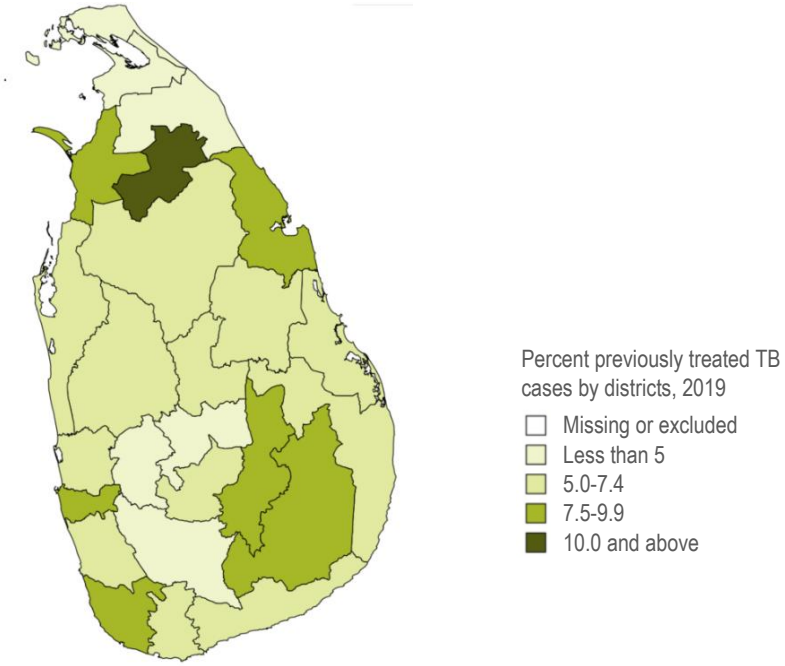


The proportion of retreated cases by districts in 2019 has varied from 0% in Mullaitivu to 13.5% in Vavuniya, however, remarkable variation of proportion of retreated within several districts (e.g. Vavuniya, Mannar, Monaragala), or no reporting retreated cases (Mullaitivu) suggests also some instability or change in practice of diagnosing or notified retreated cases.

Figure 15. Proportion of previously treated TB cases by district in 2015 and 2019



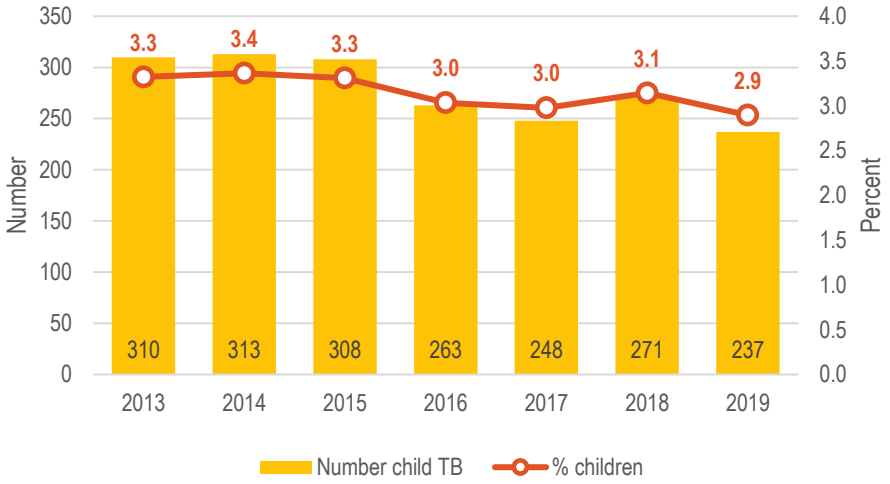
Map 4. Percent of previously treated TB cases by districts in 2019



2.2.5. Trend by childhood TB notification

Between 2013 and 2019 both adult and child TB has declined. However, the decline in child TB cases has been slightly faster, which resulted to decline of proportion of child TB cases from 3.3% in 2013 to 2.9% in 2019. (Figure 16)

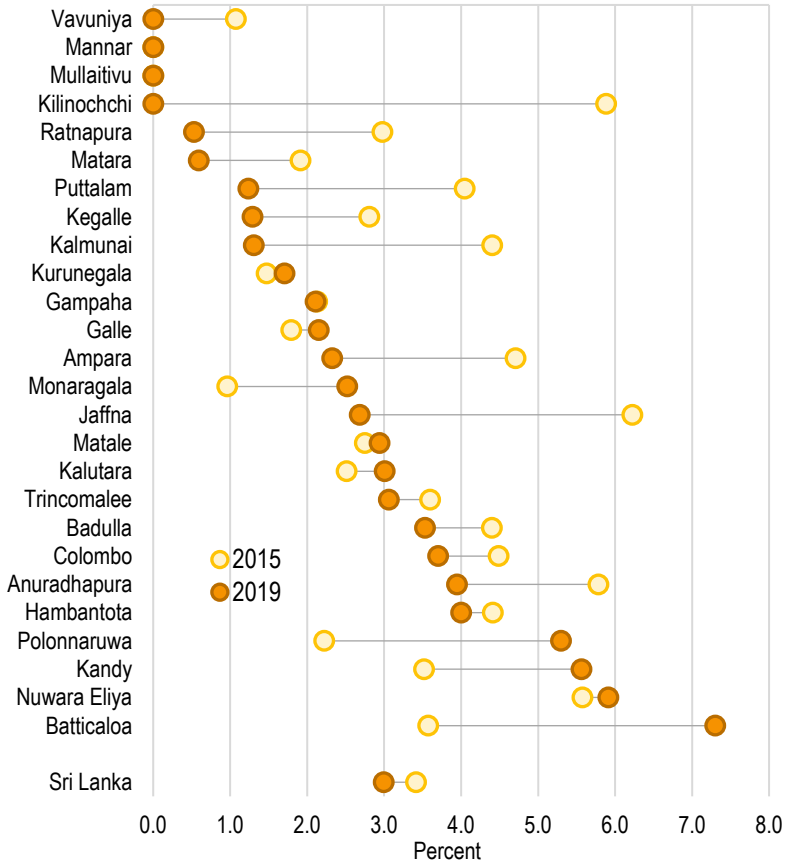
Figure 16. Trend notification of new and relapse cases by child TB cases



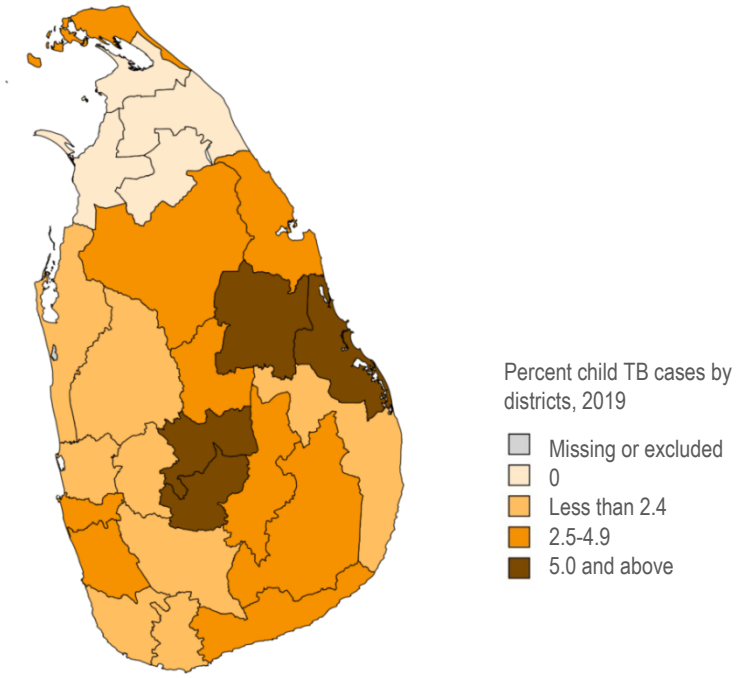
TB is often not considered as a possible diagnosis in case of child diseases and therefore often goes undetected. It is difficult to establish a definitive diagnosis of TB in children because it is rarely bacteriologically confirmed. Evidence suggests that in low- and middle-income countries, like Sri Lanka, the expected proportion of children should be around 5 to 15%. Proportion below 5% suggest under-diagnosis or under-reporting of child-TB cases. Because the proportion of child TB case at national level consistently was below the expected level of at least 5%, it could be assumed that there is a room to improve the child TB diagnostics in Sri Lanka. Observation of proportion of child tuberculosis cases disaggregated by district shows quite sharp year to year variation in percentages of child tuberculosis case, indicating inconsistencies in child TB diagnosis. Moreover, several districts with constant 0 notification rate of child TB suggest that most likely child in those districts has been overlooked (Vavuniya, Mannar, Mullaitivu, Kilinochchi).

At district level the proportion of child TB cases in 2019 ranged from 0% (Vavuniya, Mannar, Mullaitivu, Kilinochchi) to 7.3% (Batticaloa). Only in four districts meet the benchmark of proportion of child TB cases between 5-15% (Polonnaruwa, Kendy, Nuwara Eliya, Batticaloa) (Figure 15). In 14 districts the proportion of child TB cases has declined, in five has increased and in the rest of seven district remained unchanged in 2019 compared to 2015 level.

Figure 17. Proportion of child TB cases by district in 2015 and 2019



Map 5. Percent of child TB cases by districts in 2019



2.2.6. TB notification trend by sex

From 2013 to 2019 in the Sri Lanka, decline in TB notification among males and females was largely proportional and as a result the proportion of all new and relapse TB cases who were men remained stable at around 65% (Figure 18)

Figure 18. Trend of notification of new and relapse TB by sex

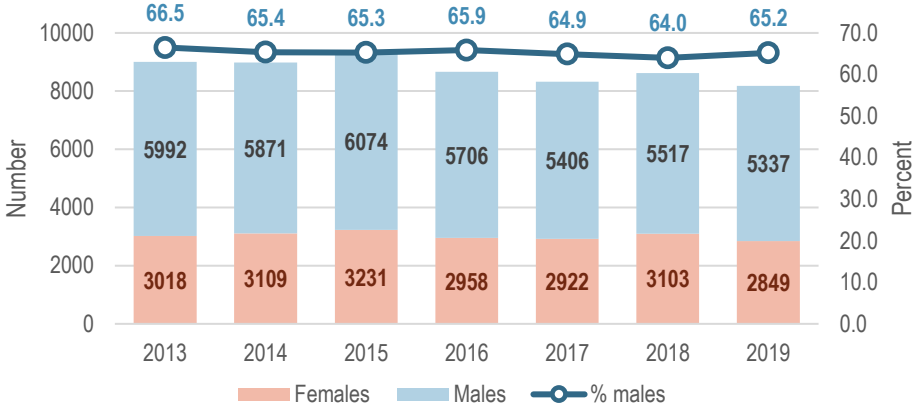
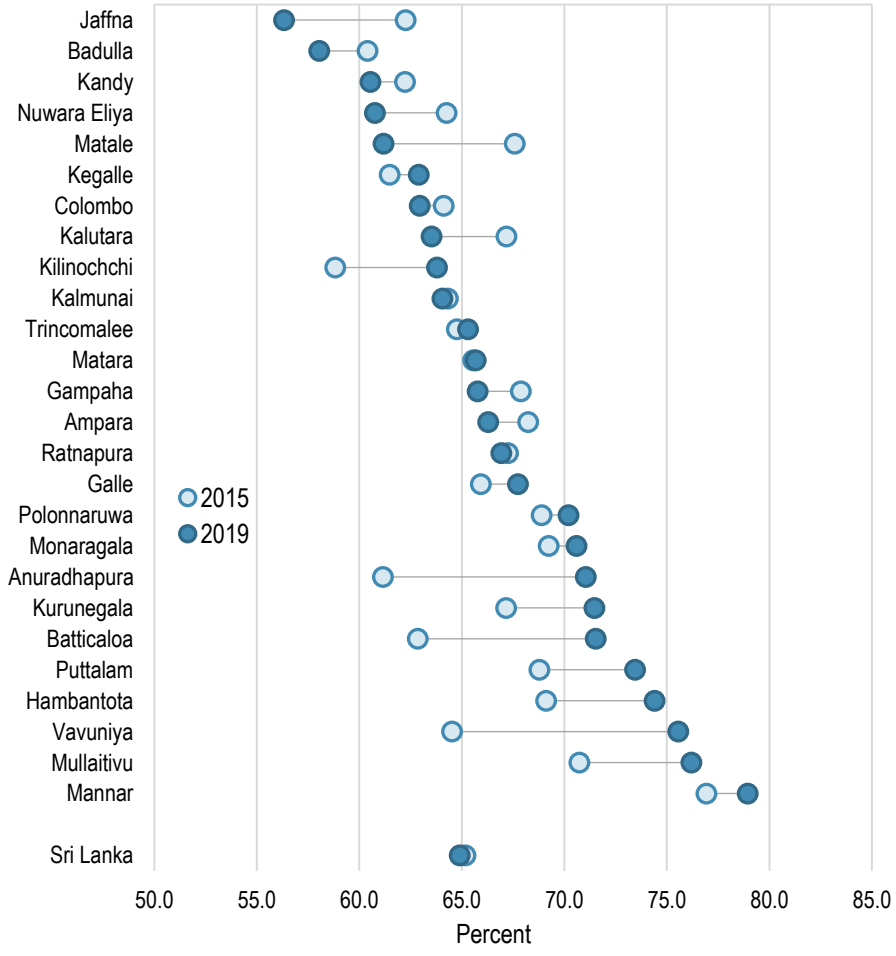


Figure 19. Proportion of TB cases that are males by districts from 2015 and 2019



At district level the proportion of males among notified new and relapse TB cases ranged from 56% in Jaffna to 79% in Mannar. Trend of notification by districts has been largely stable with few exceptions (Anuradhapura, Batticaloa, Vavuniya).

2.2.7. Trend of TB notification by age

In Sri Lanka both absolute and relative number TB notification increases with increase of age in linear patter. Among child TB and those aged "15-24 years" TB notification rates are comparable among males and females. Starting from "25-24 years" age group male to female disparity of TB burden gradually increases (M:F ratio=1.7) up to elderly age group (M:F ratio=2.1).

Figure 20. Notification of number and rates of new and relapse TB patients by age and sex, 2019

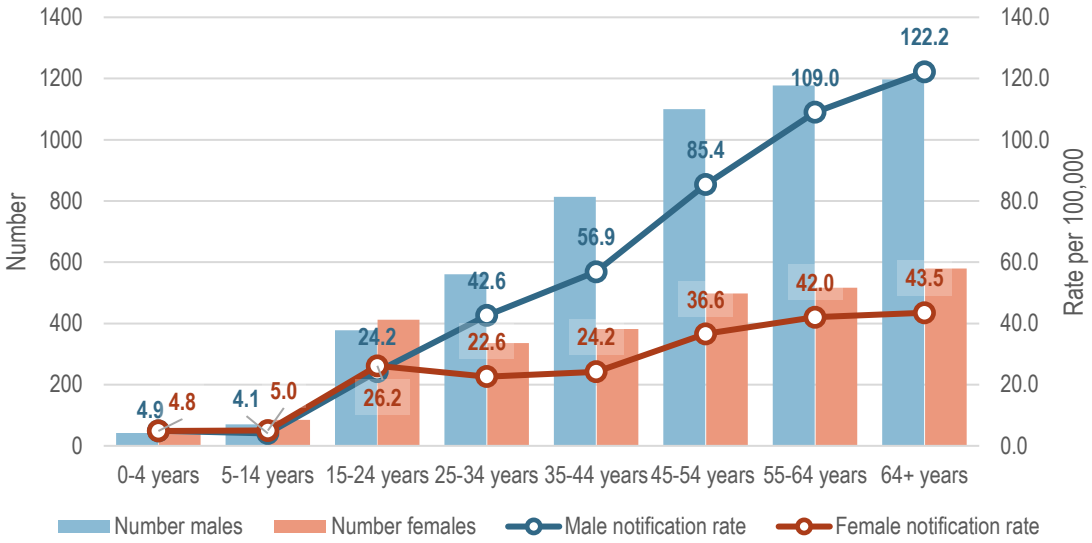


Figure 21 shows the trends in notification rates for new and relapse TB cases disaggregated by age group. Between 2013 and 2019, the TB notification rate declined for all age groups and magnitude of decline dropped with increase of age: thus, in adults population the fastest decline was observed in the "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 the older age was relatively slow declining from -2.6% in "45-54 years" to -0.5% in elderly. This pattern of temporal change is consistent with general understanding of TB epidemiology -"ageing of epidemic", which is a sign of decline of TB burden in the true population. Because TB in the elderly mostly results from the reactivation of latent infection, therefore, the decline in transmission rate has little effect on TB incidence in this age group. In contrast, TB in younger age groups is the result of recent infection, and decreased TB notification in this age groups suggests a decline in annual risk of infection in other words decline of TB burden.

Figure 21. Trend in age-specific notification rate of new and relapse TB cases per 100,000

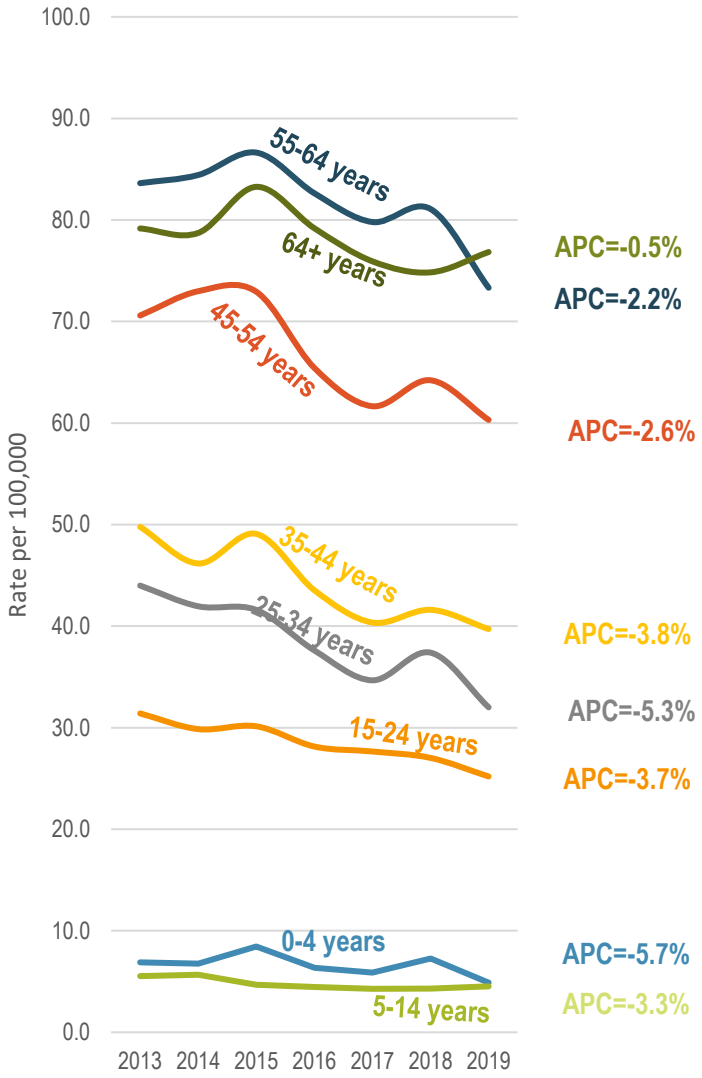
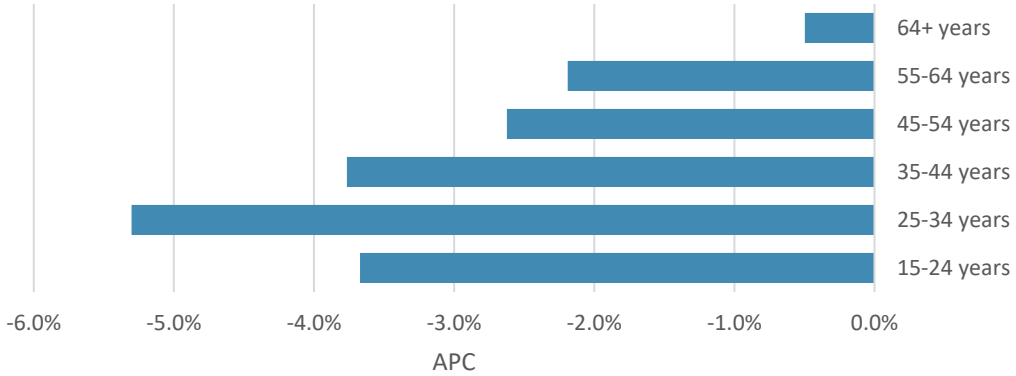


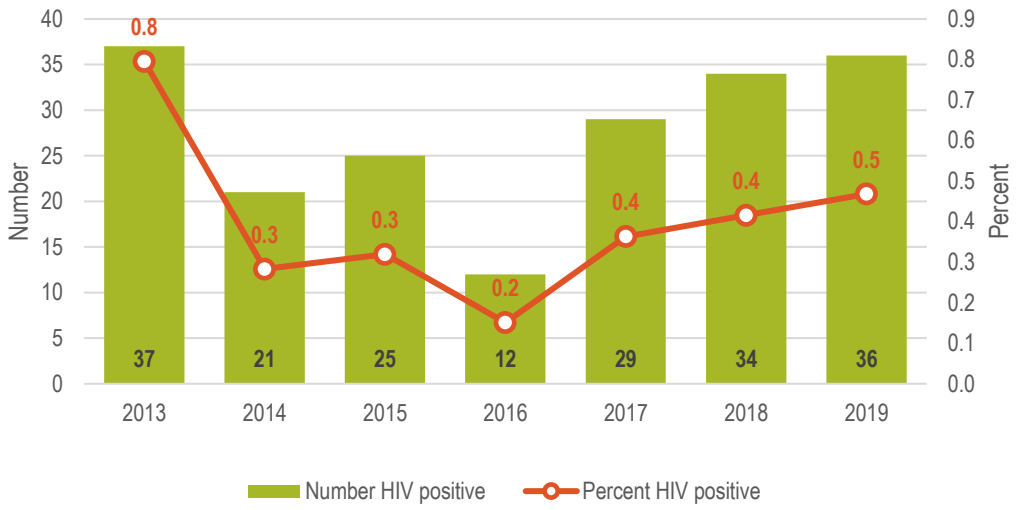
Figure 22. Average annual percent of change in TB notification by age group (2013-2019)



2.2.8. TB/HIV co-infection trend

Despite increased HIV testing coverage, the absolute number of HIV/TB co-infected patients identified did not increase. This is explained by the fact that at early stages the HIV testing was implemented among the hight-risk group population, and as the testing has expanded, patients with lower risk are tested.

Figure 23. Trend in notification of TB/HIV patients among tested



According to NSACP in 2018 in total 45 newly diagnosed TB patients were identified among people living with HIV infection[10] (according UNAIDS report 53 newly TB/HIV cases were detected in 2018)[11]. Thus, at least one in four TB/HIV cases are not known or recorded by Tuberculosis control program.

In 2018 according to UNAID reporting system of 348 people newly enrolled in HIV care 53 (15.2%) had active TB disease.

[10] National Sexually Acquired Disease Control Programme. Annual Report 2018. Ministry of Health Sri Lanka. [online] https://www.aidsdatahub.org/sites/default/files/resource/nsacp-sri-lanka-annual-report-2018.pdf

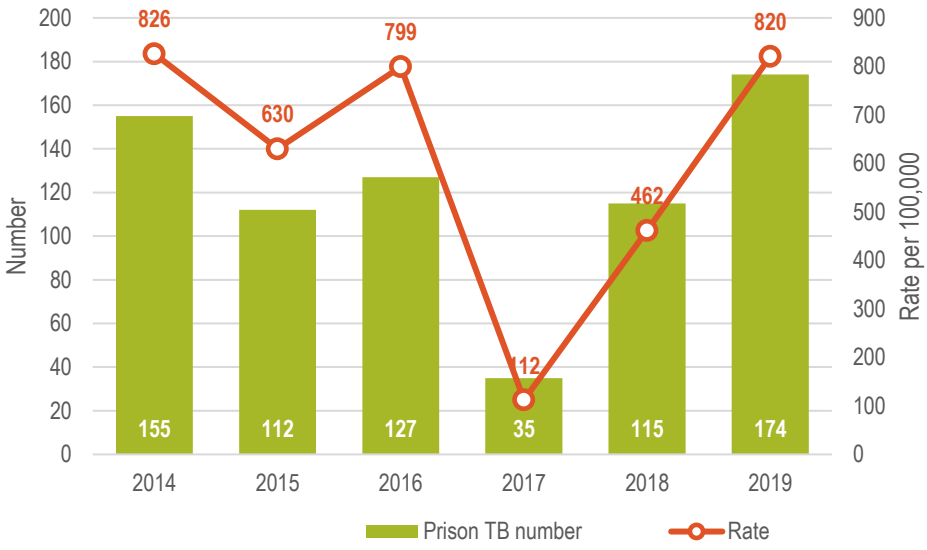
[11] UNAIDS reporting system

2.2.9. TB trend among prisoners

Previous studies demonstrated 1.7% prevalence of sputum smear positive cases among prisoners in Sri Lanka[12]. However, routine surveillance data consistently report much lower burden. Figure 24 shows the number of notified TB cases in prison population and the rate per 100,000 prisoners from 2014 to 2019. Such rapid year to year variations is unusual and indicates change in either screening, diagnostic or reporting practice.

According to NPTCCD the reporting of TB starting form 2017 was changed and only sputum smear positive cases were notified leading to under-reporting of TB.

Figure 24. Trend in number and rate of prison TB cases identified by active case finding



[12] National Programme for Tuberculosis Control and Chest Diseases. Prevalence of Sputum positive Tuberculosis among convicted prisoners in Sri Lankan prisons and its contributory factors. Presented at the National Health Research Symposium. 2017.

3. Determinants of TB

3.1. TB programmatic factors

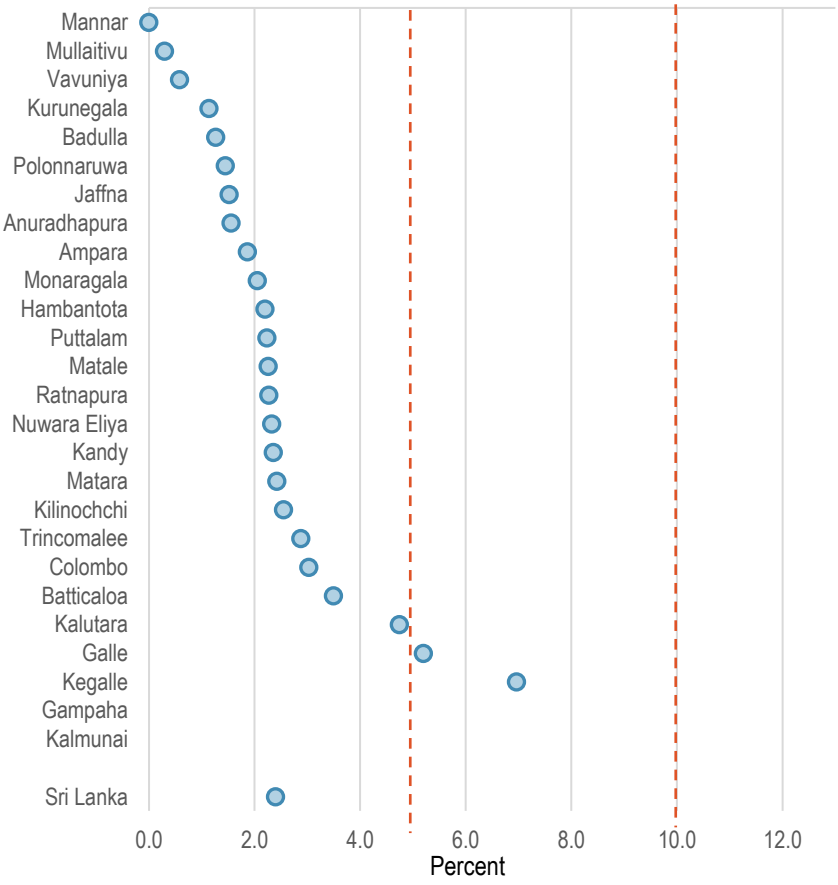
3.1.1. Access to TB diagnostics

Shortening the duration of disease through detection and treatment of cases will reduce the prevalence of TB in the population, and therefore, transmission. In Sri Lanka the first level laboratory network consists of 180 smear microscopy centres, located across the country serving about 120,000 population per microscopy laboratory on average. Despite this is slightly below compared to WHO recommended at least 1 smear laboratory per 100,000 population, however considering that sputum smear positivity is low both at national and district level in 2018 compared to recommended, the number of microscopy laboratories for Sri Lanka could be considered as adequate.

Table 3. Number sites providing smear, Xpert, LPA, culture and DST services

Type of service	2013	2014	2015	2016	2017	2018	2019
Microscopy centers	214	206	186	178	192	180	180
GeneXpert MTB/RIF	1	1	1	1	9	30	29
Line Prob Assay	0	1	1	1	0	1	1
Culture	3	3	3	3	4	5	1
DST	1	1	1	1	1	1	1

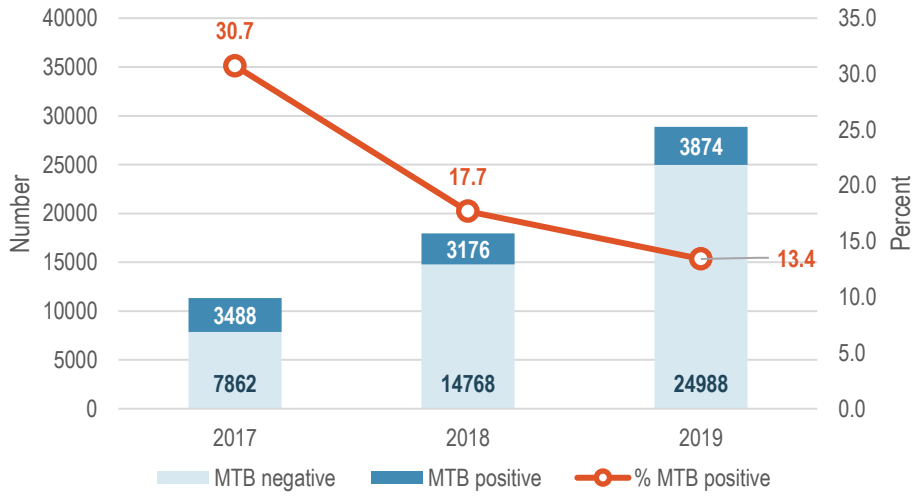
Figure 25. Percent of smear positive cases among presumptive TB by district, 2018



There are no data on the number of trends of microscopy examination at the country. Figure 28 shows the smear positivity rate in 24 districts among those examined for TB (data are missed from two districts). At national level smear positivity is 2.4% only, which is below of recommended against the recommended 5-10% benchmarks. Only two districts (Galle and Kegalle) are within 5-10%. Such low positivity indicates that access to microscopy testing is high and further increase of number of microscopy examination is unlikely to increase case-finding. On the other hand observed modest decline of sputum smear positive cases in the country indicates that still notable part of TB patients are missed by the health system leading to transmission of TB disease in the population, indicating the need for more sensitive tools for TB case-finding, such as chest X-ray, Gene Xpert, culture.

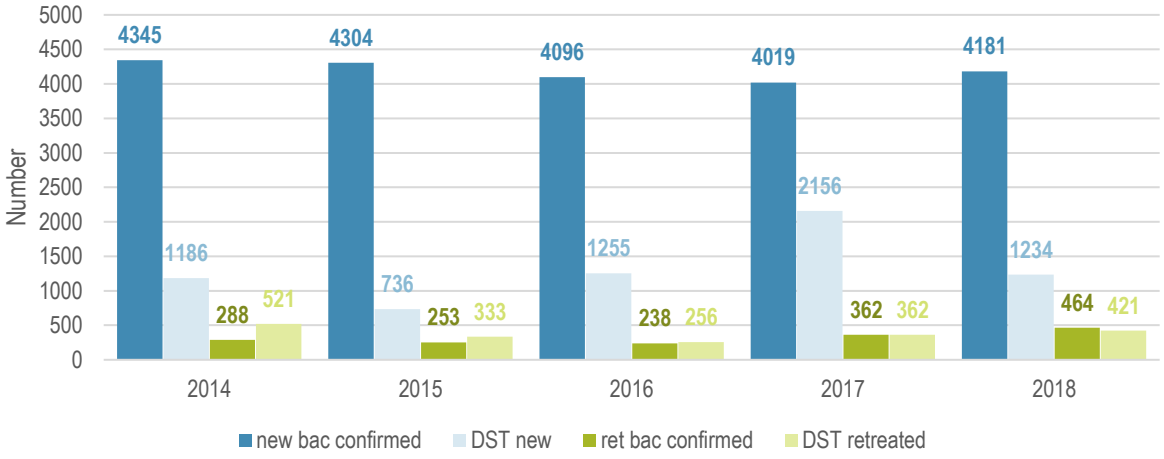
Xpert in Sri Lanka was introduced in2013. But the network of Xpert machines was expanded from 2017 only. The number of Xpert testing increased from 11,350 in 2017 to 28,862 in 2019. At the same period the proportion of MTB positive cases declined from 30.7% to 13.4%. Because of lack of data on presumptive TB cases and diagnosed TB patients with Xpert test results it is not possible to assess the coverage of Xpert testing among those population. However, high MTB positivity in 2019 indicates that increase of Xpert testing coverage would result to improved case finding and current testing coverage is sub-optimal.

Figure 26. Time trend of total number of GeneXpert testing by number and percent of positive results



Routine drug resistance surveillance in Sri Lanka is challenging as data on number of patients with DST to Rifampicin and results are extracted from laboratory registers rather than from TB register. And because one patient might be tested several times, therefore laboratory provided data gives number of tests and not number of patients. Therefore, it is not possible to estimate the trend of DST coverage accurately.

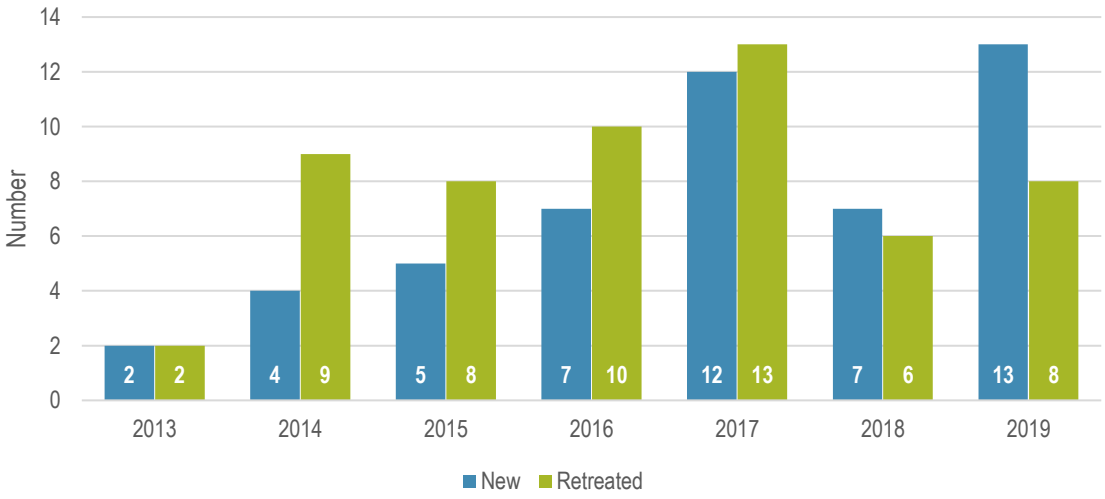
Figure 27. Trend bacteriologically confirmed TB patients and DST among new and retreated



Drug resistance survey conducted in Sri Lanka in 2017 showed that the prevalence of RR-TB among 1356 new PTB patients with DST for R was 0.44% (95% CI: 0.16-0.96) and among 95 retreated PTB patients 4.2% (95%CI: 1.2-10.4%).

Number of annually detected RR/MDR-TB in Sri Lanka over the last five years ranged between 13 and 25 without any clear trend over the time. It was noted some discrepancies between reported number of RR-TB cases in various sources indicating the need to improve routine drug resistance surveillance.

Figure 28. Trend in number of RR-TB cases among new and retreated cases



3.1.2. Active case findings

Increased screening in the population should increase case detection, thus reducing TB transmission in population. The WHO recommends active cases finding among selected at-risk groups such as household contacts, people living with the human immunodeficiency virus (PLHIV), people in prisons and other penitentiary institutions, and geographically defined sub-populations with high levels of undetected TB, such as people living in urban slums[13]. Active case finding in Sri Lanka routinely is implemented in household contacts of TB cases (irrespective sputum smear result) among the prisoners. and HIV positive patients.

Mean number of contacts screened per new and relapse TB cases notified between 2017 and 2019 ranged between 1.4 and 1.6. This is low considering that average household size in Sri Lanka is 3.9, and national guideline recommend screening the contacts of all TB cases.

The yield of TB among the contacts screened was 3.0% in 2018 and 1.1% in 2019. Large variation of yield of TB indicates that about low compliance to TB diagnostic algorithm (table 4).

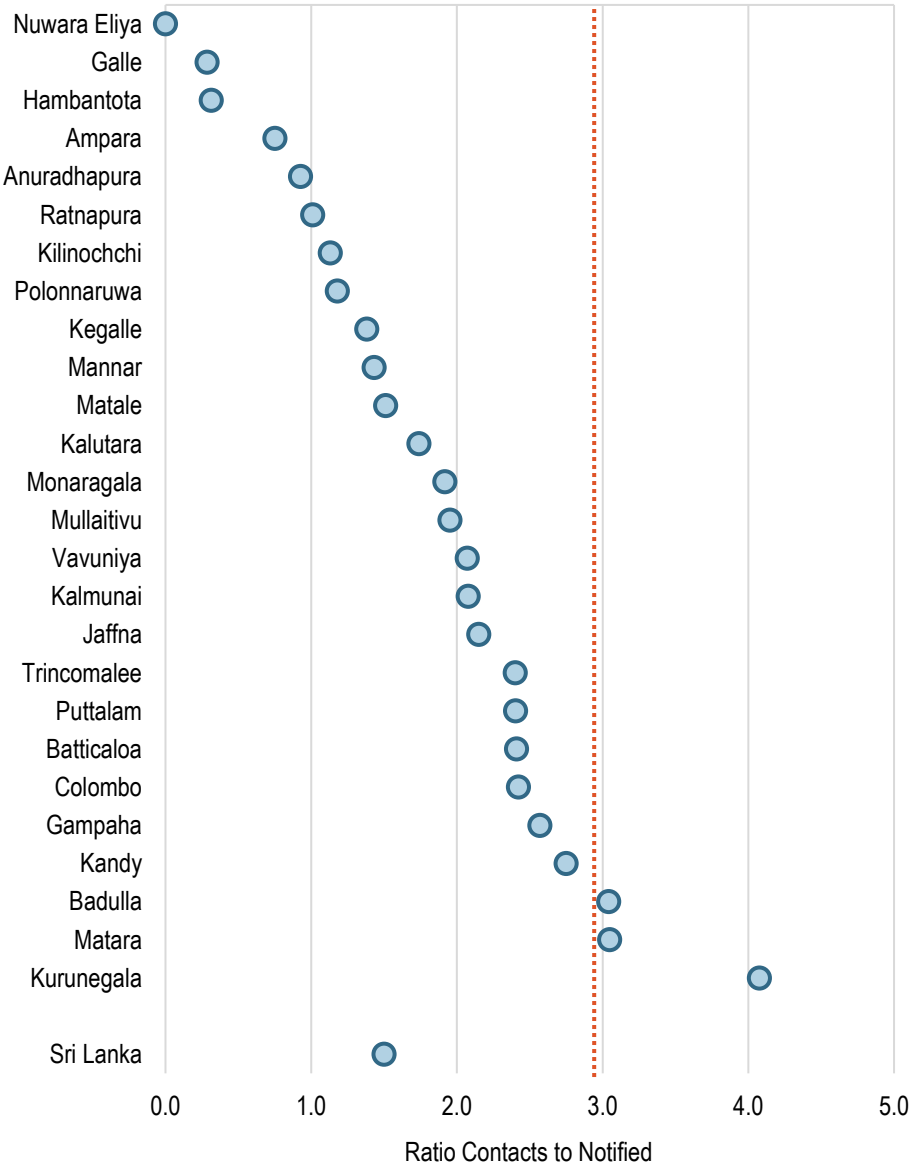
Table 4. Number of TB contacts screened and yield of TB cases among contacts

Year	Number bacteriologically confirmed PTB cases	Number contacts identified	Number of contacts screened	Mean number contacts screened per index	Yield of TB cases among contacts
2017	8,328	18,720	11,367	1.4	
2018	8,620	22,328	14,167	1.6	430 (3.0%)
2019	8,186	17,976	12,660	1.5	137 (1.1%)

At district level mean number of contacts per notified new and relapse cases in 2019 ranged from 0.0 in Nuwara Eliya to 4.1 in Kurunegala, with median of 1.9 contact per index cases. Only in three districts the mean number of contacts met at least 3.0 cases (Badulla, Matara, Kurunegala) which is the expected number of eligible contacts based on average household size of 4 in Sri Lanka. Sub-optimal contact tracing could be one of the factors of observed modest decline of TB burden in Sri Lanka.

[13] World Health Organization. Improving early case detection of active TB through systematic screening. WHO/HTM/TB/2013.04. Geneva, Switzerland: WHO, 2013.

Figure 29. Ratio of household contacts to notified, 2019



As it is shown in table 5, the yield of presumptive TB cases among prisoners' ranges from 3.4% (Jaffna) to 98.2 % (Hambantota), indicating that the tool used to screen for TB is not standard across the country. The yield of TB among the screened is the highest in Kalutara (reaching 14.8%), but null in prisons of four districts (Matara, Jaffna, Batticaloa and Monaragala). Overall, the yield of TB among the screened cases was 1.9%. While TB prevalence among screened overall prison population was 820.4 per 100,000 population.

Table 5 TB control interventions and data in prisons, 2019

No	District	No. of Programs	No. of inmates	Presumptive TB cases		All forms of TB in prisoners		% of TB all forms among presumptive TB cases
				Number	%	Number	Rate per 100,000	
1	Colombo	71	3074	1443	46.9	115	3,741.1	7969.5
2	Gampaha	34	1305	553	42.4	9	689.7	1627.5
3	Kalutara	11	643	27	4.2	4	622.1	14814.8
4	Kandy	3	419	133	31.7	7	1,670.6	5263.2
5	Galle	7	1435	1219	84.9	8	557.5	656.3
6	Matara	3	583	162	27.8	0	-	0.0
7	Hambantota	36	560	550	98.2	8	1,428.6	1454.5
8	Jaffna	6	714	24	3.4	0	-	0.0
9	Vavuniya	10	920	282	30.7	1	108.7	354.6
10	Batticaloa	11	644	508	78.9	0	-	0.0
11	Trincomalee	16	450	135	30.0	1	222.2	740.7
12	Kurunegala	7	1335	355	26.6	1	74.9	281.7
13	Anuradhapura	9	3794	1090	28.7	4	105.4	367.0
14	Polonnaruwa	13	497	127	25.6	1	201.2	787.4
15	Badulla	24	1501	1055	70.3	8	533.0	758.3
16	Monaragala	9	773	723	93.5	0	-	0.0
17	Ratnapura	11	1372	770	56.1	5	364.4	649.4
18	Kegalle	7	1190	238	20.0	2	168.1	840.3
	Total	**288**	**21209**	**9394**	**44.3**	**174**	**820.4**	**1852.2**

3.1.3. LTBI treatment coverage

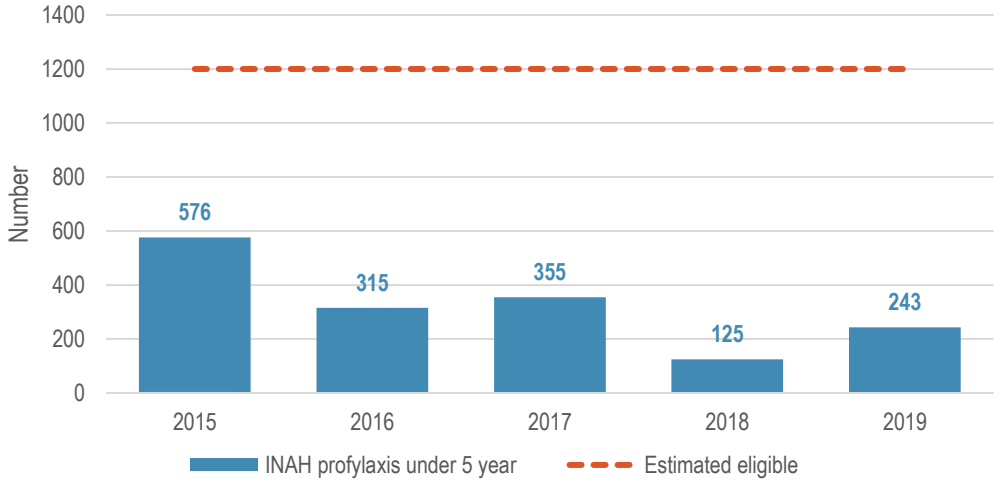
There will be an impact on TB burden if preventive treatment of people with latent TB infection is effectively implemented on a large scale. TB preventive treatment is a key component of the End TB strategy, and LTBI treatment coverage among those eligible is one of the top 10 indicators to monitor the progress of TB control. WHO recommends offering preventive TB treatment to household contacts of adults with pulmonary TB, with priority given to children under 5 years of age[14].

According to WHO estimates, in 2018 there would have been 1,200 (range: 1,100-1,300) children under five years eligible for preventive TB treatment in Sri Lanka[15]. The total number of children enrolled in IPT was 243 in 2019 according to data provided by NPTCCD. This is only about 20% of all children eligible for preventive TB treatment, indicating suboptimal programmatic performance (Figure 30)

[14] Latent tuberculosis infection: updated and consolidated guidelines for programmatic management. Geneva: World Health Organization. https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en/

[15] Global TB database.

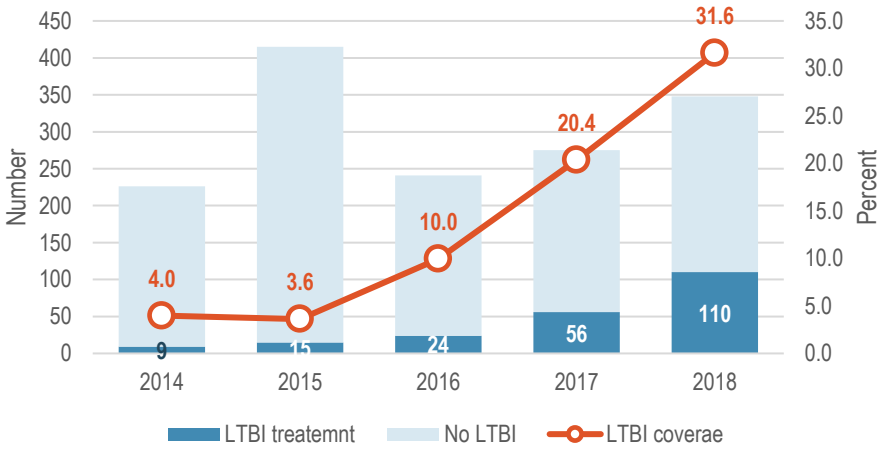
Figure 30. Number of children under 5 years enrolled into LTBI treatment



Data source: NPTCCD
Horizontal red line delineates estimated number of children under 5 eligible for LTBI

Between 2015 and 2019 the number of children under 5 receiving LTBI treatment declined. However, it should be noted that data on preventive TB treatment submitted to global TB database differ, raising concern of data validity. Unlike the children LTBI treatment coverage among PLHIV newly enrolled in HIV care increased from 4.0% in 2014 to 31.6% in 2018

Figure 31. Number and percent of PLHIV newly enrolled in HIV care that started LTBI

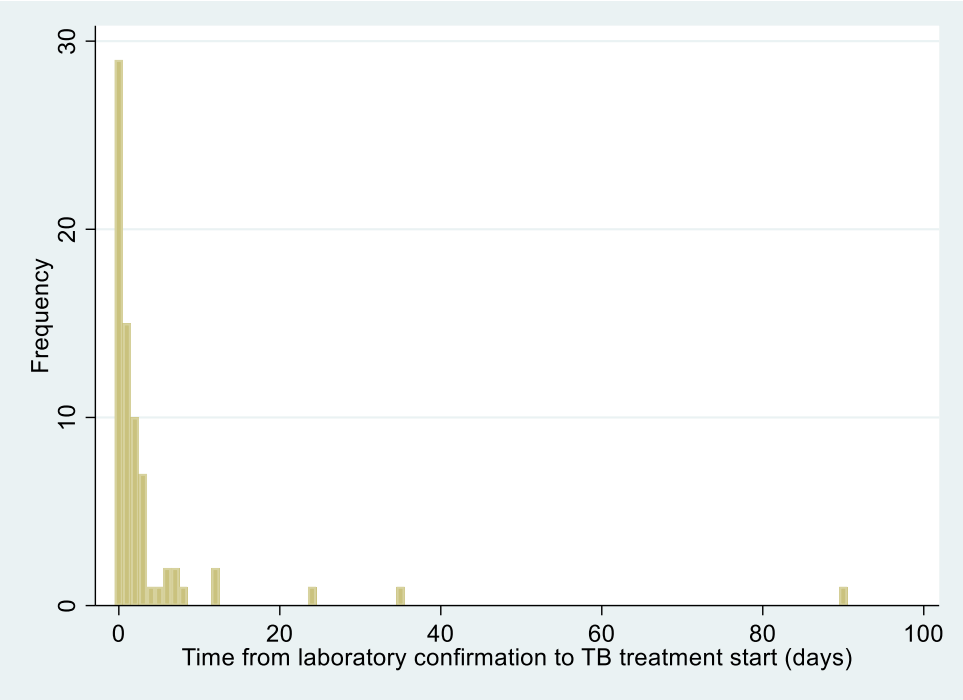


Data source: UNAIDS reporting system

3.1.4. Quantitative data on delay

There was no study done to evaluate delay in diagnosis and treatment of TB patients in Sri Lanka. Patient care pathway survey is in progress now which will fill this gap. For the rough estimation of treatment delay in three facilities visited we calculated the time between the date of laboratory confirmation and the date of the start of the treatment.

Figure 32. Histogram of delay in start of treatment (n=73)

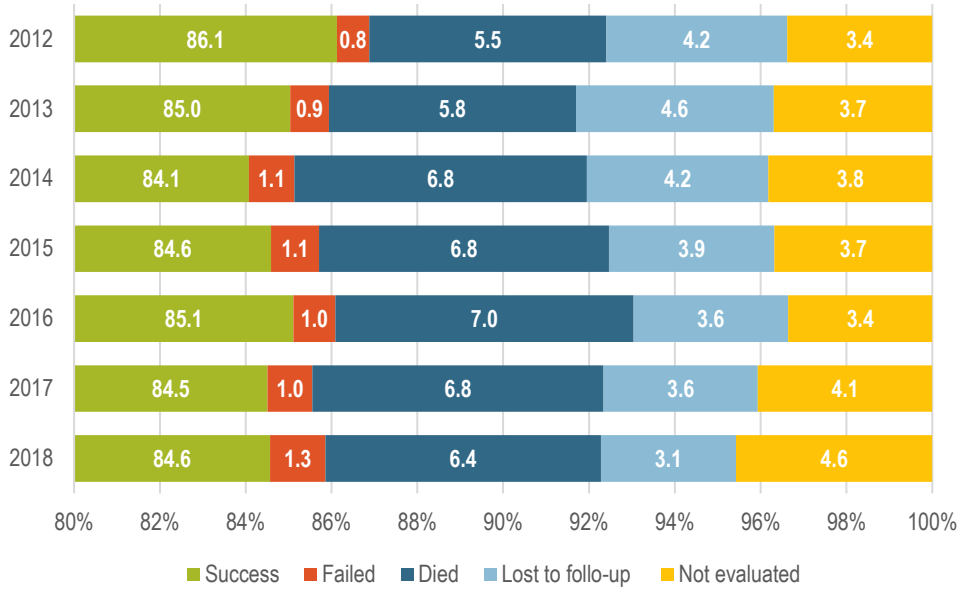


Among the 73 bacteriologically confirmed cases registered during the auditing period the median delay between the laboratory diagnosis and treatment initiation was 1 day (IQR: 0-3 days) ranging from 0 up to 90 days (excluded the patients who did not start the treatment) (Figure 32). Overall, this indicates adequate availability of treatment services, however, in 8% of cases there was unacceptable long delay (> 7 days), which is concerning.

3.1.5. TB treatment outcome

TB treatment is one of the most effective interventions in TB control to reduce the prevalent cases in the population and reduce the transmission of infection. Figure 32 shows the cohort analysis of treatment outcome of new and relapse TB patients at national level between 2012 to 2018. Overall, the proportion of patient successfully treated between 2014 and 2018 was largely stable, however below of global target of 90% treatment success rate. Main reason of unfavorable treatment outcome is the death, which ranged between 6.4 and 7.0% over the recent six years. Despite of introduction of electronic surveillance system, the proportion of patients with “not evaluated” treatment outcome increased over the recent years and is unacceptably high as of 2018.

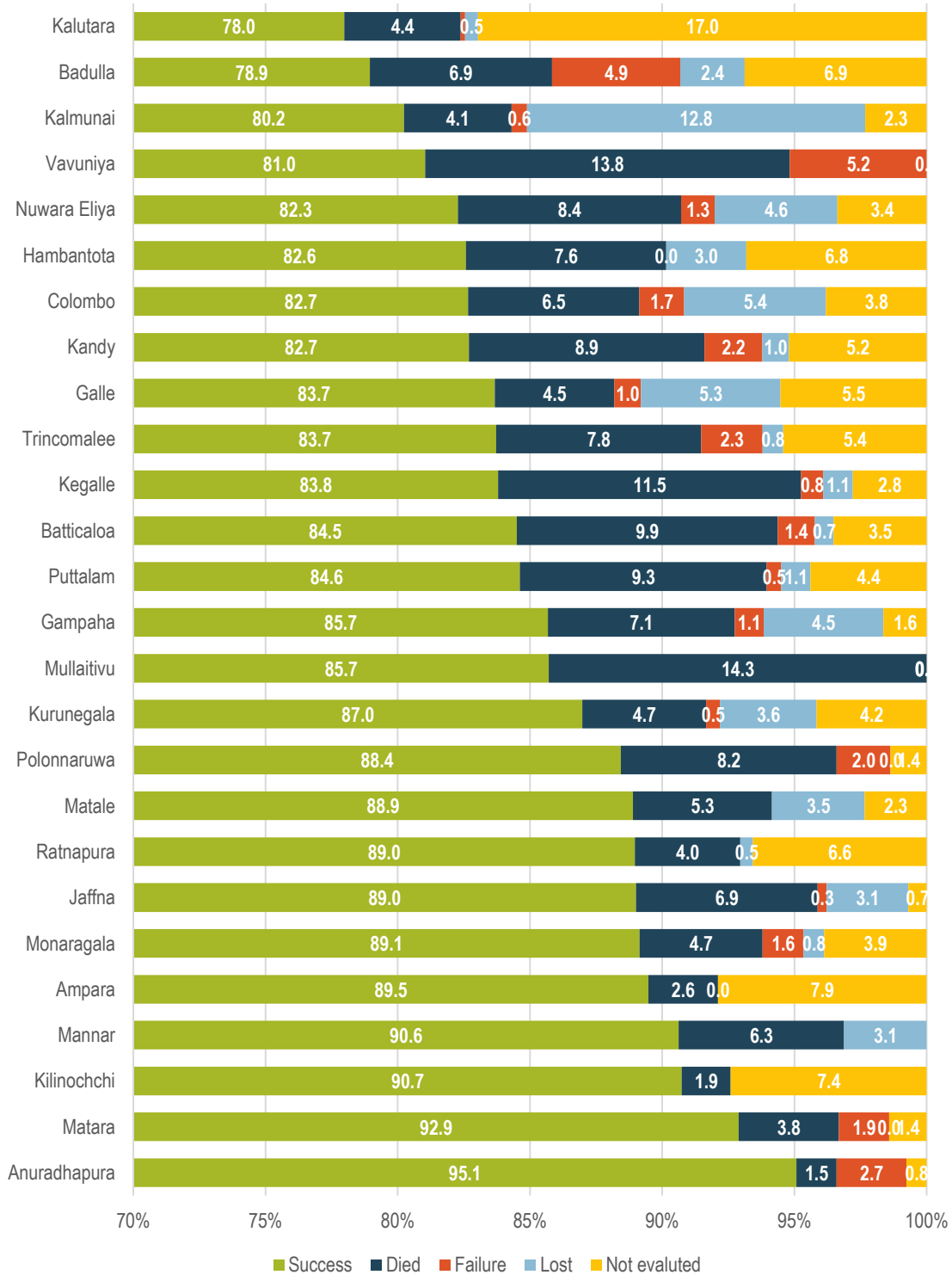
Figure 33. Treatment outcomes of new and relapsed TB patients 2012-2018



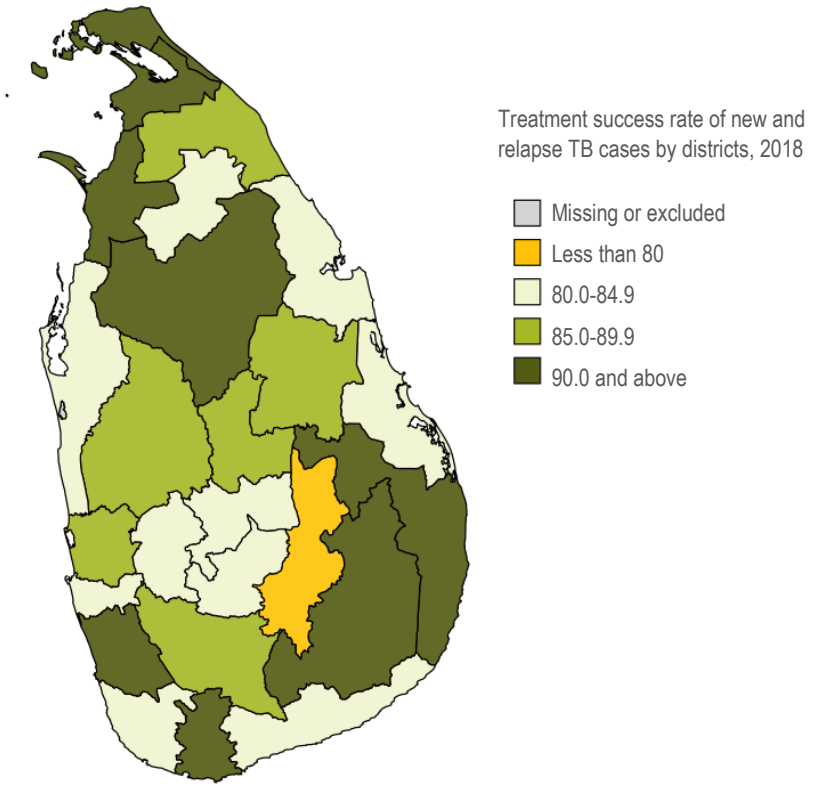
At district level, in 2018 treatment success of new and relapse TB cases ranged from 78% in Kalutara to 95.1% in Anuradhapura. Only four districts achieved the target of at least 90% treatment success rate (Mannar, Kilinochchi, Matara and Anuradhapura).

Death rate by districts among new and relapse cases ranged from 1.5% in Anuradhapura to 14.3% in Mullaitivu. Large variation of death rate is partially explained by low absolute number of notified TB cases resulting large stochastic variation of indicators at district level. Using the opportunity of case-based data on TB patients collected on PMIS, NPTCCD might conduct in-dept analysis to identify predictors of unfavourable treatment outcome, particularly risk factors of death using multivariable analysis.

Figure 34. Treatment outcomes of new and relapse TB patients by districts, 2018

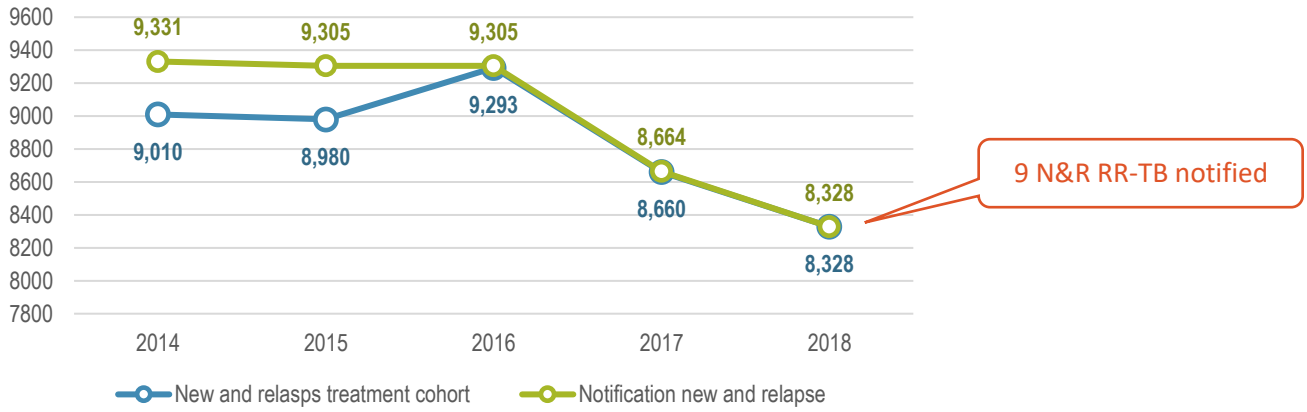


Map 6. Percent of successfully treated new and relapse TB cases by districts in 2018



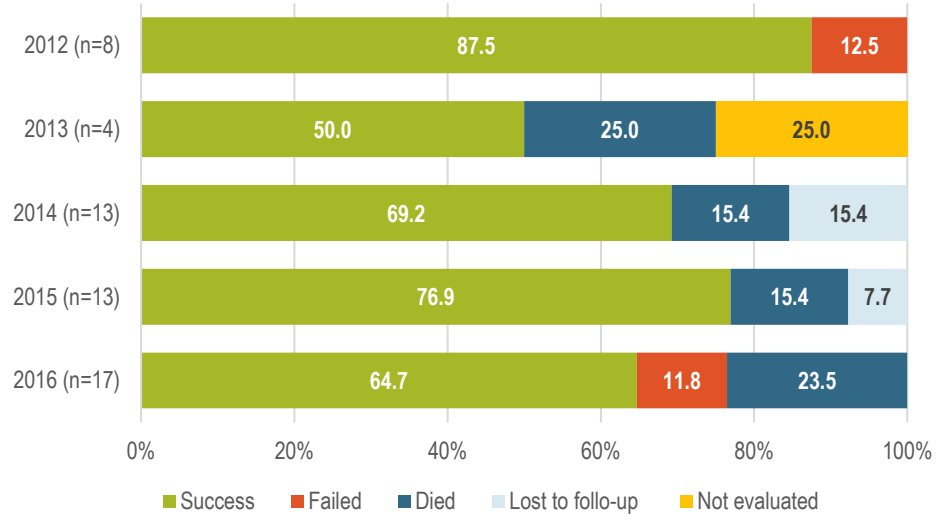
There were about 3.5% difference in number of TB notified and reported in 2014 and 2015, however, starting from 2016 notified and reported number of cases matches. It should be noted that expected difference between notified and TO reported is not present in 2018 (due to nine RR-TB that moved to second-line treatment cohort. According to NPTCCD RR-TB cases are assigned treatment failure outcome in TB 08, which is old approach. According to 2013 revised definition framework RR-TB cases should be moved out from basic TB treatment cohort as "moved to second-line treatment" and should not be included into the denominator in cohort analysis.

Figure 35. Number of new and relapse TB cases notified and treatment outcome reported



Treatment success rate of RR/MDR-TB patients enrolled into treatment between 2012 and 2016 ranged between 50.0 to 87.5% without clear trend over the time. Main reason of unfavorable treatment outcome is death.

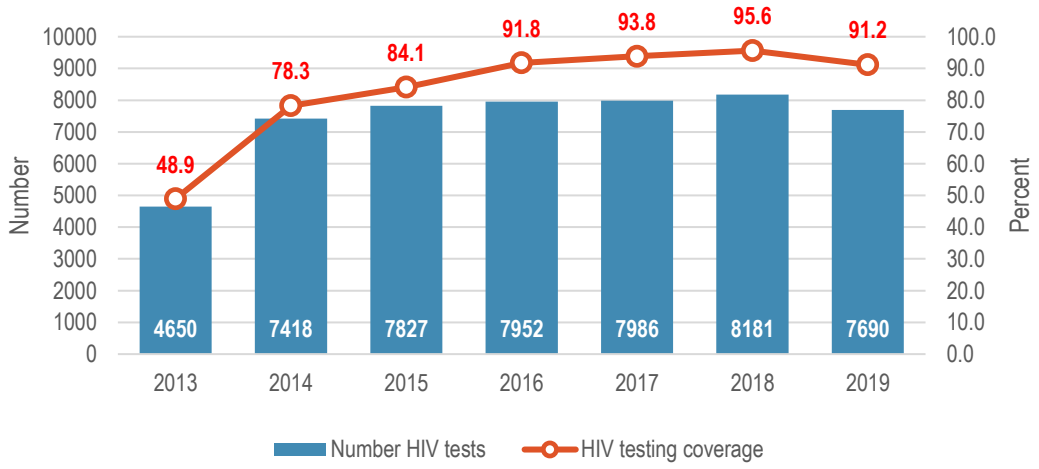
Figure 36. Treatment outcomes of RR-TB patients, 2012-2017



3.1.6. HIV testing and ART coverage among TB/HIV patients

To ensure effective integrated TB and HIV service delivery, WHO recommends provision of HIV testing to all TB patients, providing ART and CPT to TB patients living with HIV, TB screening on regular basis among people living with HIV, and offering IPT to people living with HIV who do not have active TB. Over the recent years there was notable improvement in HIV testing coverage among TB patients in Sri Lanka, which increased from 48.9% in 2013 to 91.2% in 2019.

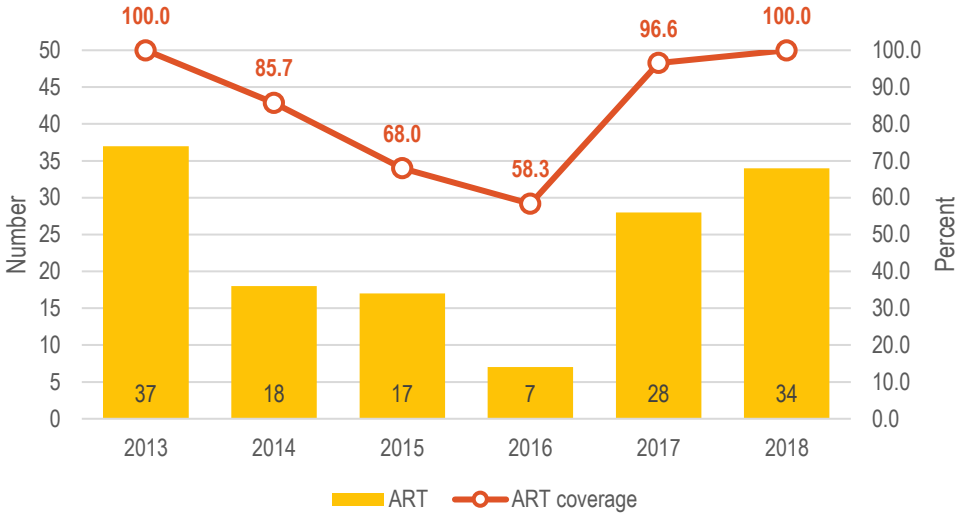
Figure 37. Number and proportion of TB cases with known HIV status, 2013-2019



**Data from 2015-2016 are new and relapse cases*

Reported ART coverage among identified TB/HIV patients was largely high, ranging between 58.3 and 100%

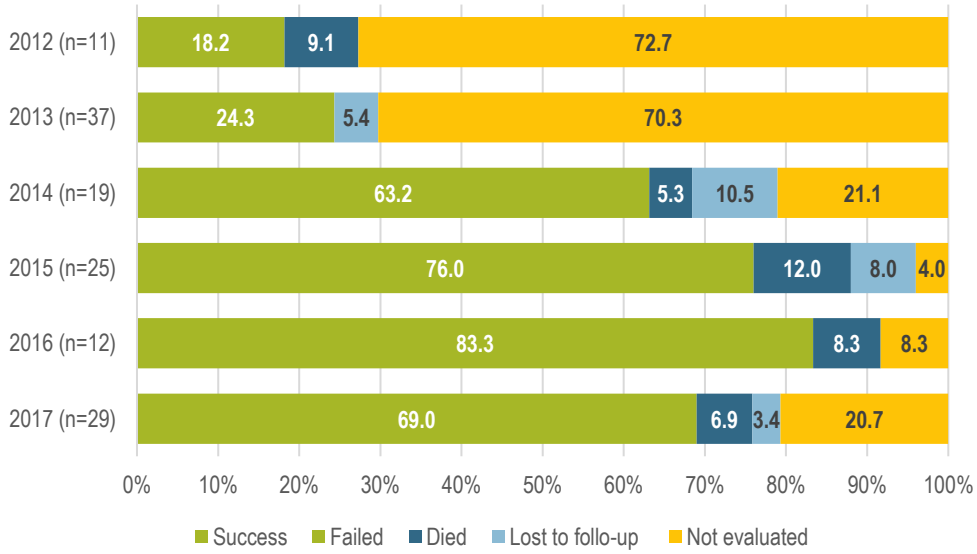
Figure 38. Number and percent of TB/HIV patients enrolled in ART, 2013-2018



**Data from 2015-2018 are new and relapse cases*

Reported treatment success of TB/HIV co-infected patients is low, within the range of 63 to 83% during the recent four years. Main reason of unfavorable treatment outcome was "not evaluated". HIV status is not recorded in DTB registers, as it is handled by several people and current RR system doesn't include treatment outcome report of TB/HIV cases. This explains the large proportion of TB/HIV patients with "not evaluated" treatment outcomes.

Figure 39. Treatment outcomes of HIV/TB cases 2012-2017

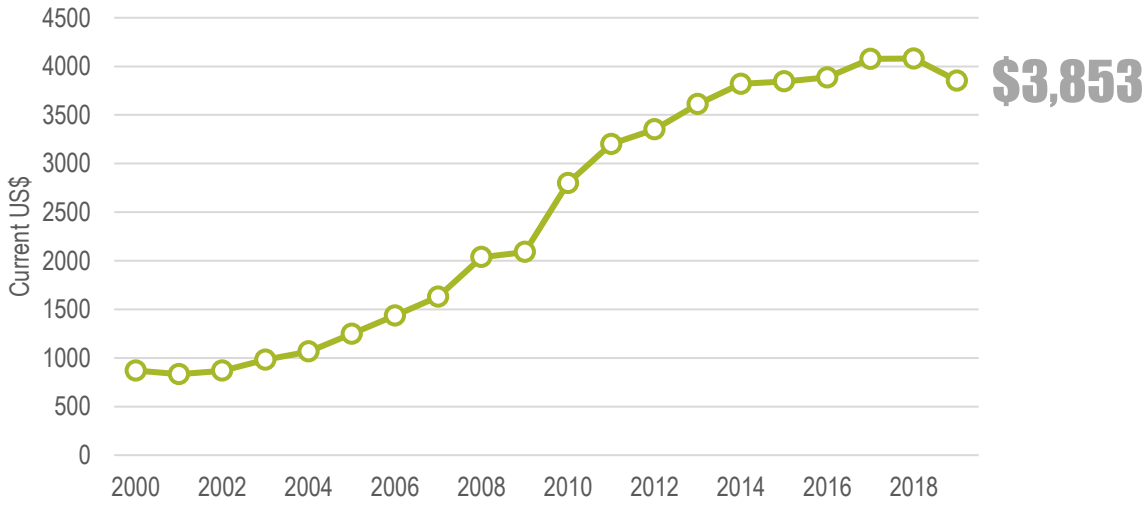


3.2. External factors

3.2.1. Per capita gross national product

Economic growth is expected to drive TB epidemic to downward. It may affect numerous TB determinants such as household overcrowding, education, nutrition and health care-seeking behavior, and thus contribute to reduced transmission of infection and a reduced risk of progression from infection to disease and Gross National Product (GDP) per capita is the most commonly used measures of county economic growth. Between 2000 and 2019 the GDP per capita in Sri Lanka increase about 4-fold[16]. Economic improvement could drive TB epidemic downward (Figure 40)

Figure 40. GDP per capita (current US$), 2000–2019



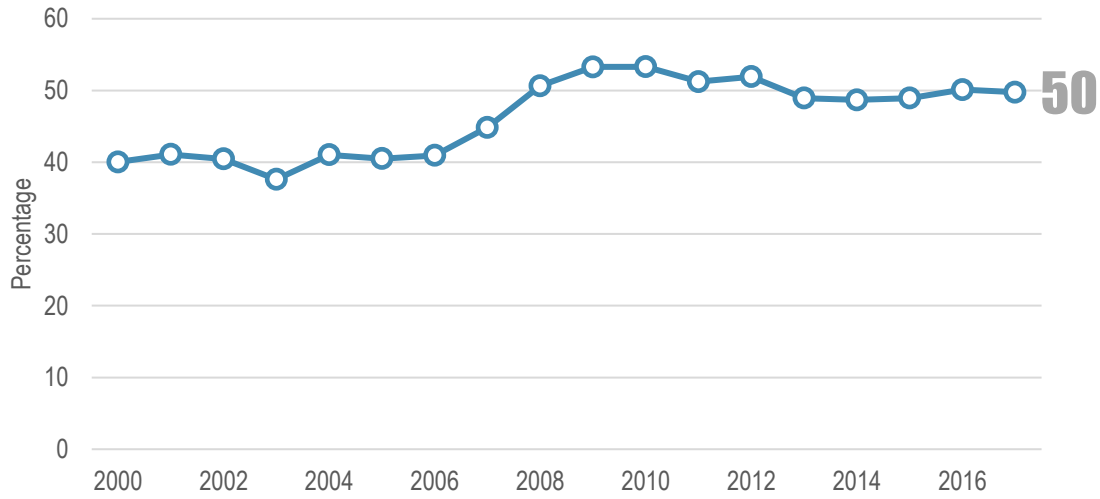
Data source: https://data.worldbank.org/indicator/ny.gdp.pcap.cd

3.2.2. Coverage of financial protection for health care costs

The proportion of out of pocket payment (OOP) out of total health expenditure in Sri Lanka increased between 2006 and 2009 and since then remained almost stable. In 2017 OOP accounted for 50% of total health expenditure (*Figure 40*). This is much higher versus 25% OOP benchmark set by WHO. Such level usually is an indication that access to quality care is not affordable for the vulnerable population in the country and limited access to care is likely to drive TB epidemic to upward. Although OOP expenditure is high, the anti TB drugs, ancillary drugs and diagnostic facilities are provided free of charge to all patients.

[16] GDP per capita (current US$)) [online]. Washington, DC: World Bank (*https://data.worldbank.org/indicator/EG.CFT.ACCS.ZS,* accessed on 31 July 2020)

Figure 41. OOP expenditure as a percent of current health expenditure, 2000–2017

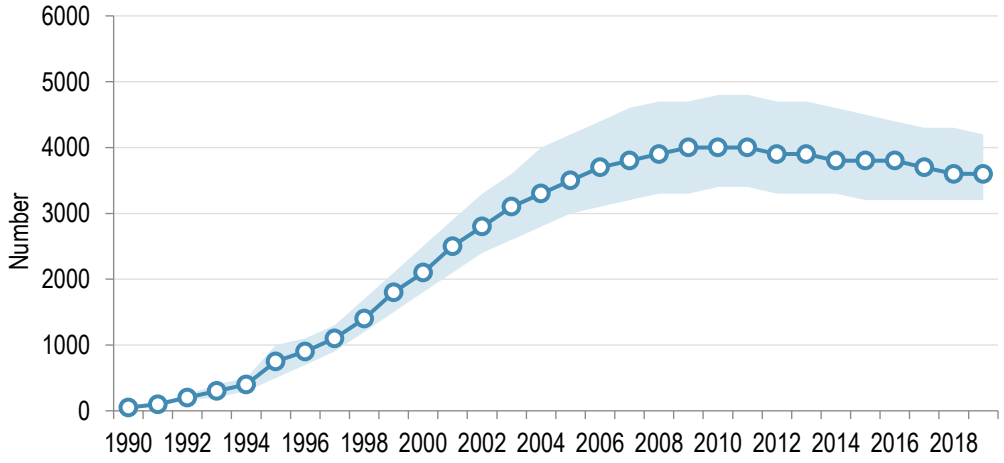


Data source: https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS

3.2.3. Prevalence of HIV in the general population and ART coverage

HIV is the most potent risk factor for TB within the individual and the increase in its burden would drive TB epidemic upward. In 2018 the estimated number of people living with HIV in Sri Lanka was 3,600 (range: 3,200-4,200). HIV prevalence remains low, with an estimated prevalence of below 0.1% among the population (all ages). Figure 41 shows time changes in estimated number of PLHIV in Sri Lanka in recent decades.

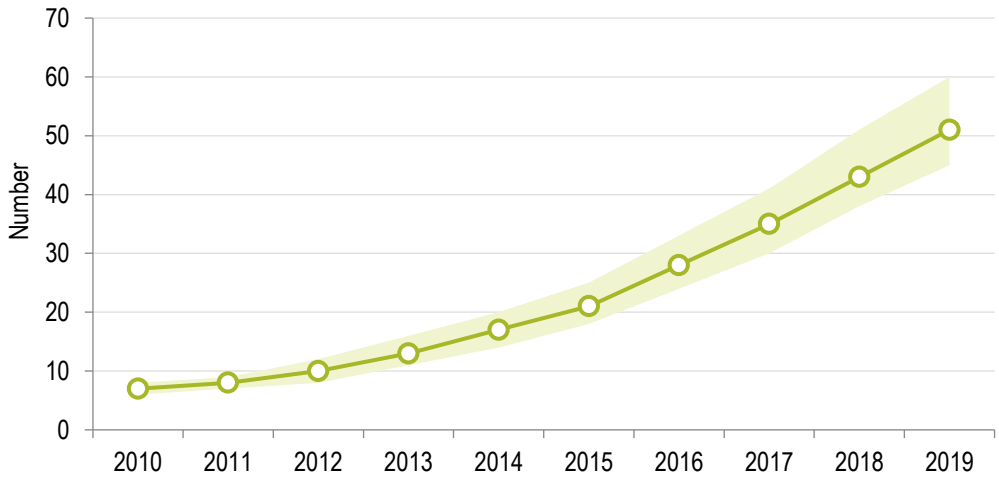
Figure 42 Trend in number of people living with HIV (all ages)



Data source: https://aidsinfo.unaids.org/

There is strong evidence that timely initiated anti-retroviral treatment (ART) and preventive Isoniazid therapy may reduce the risk of progression from infection to disease. Access to antiretroviral therapy in Sri Lanka gradually increased from 7% in 2010 to 51% in 2018. (Figure 42Figure 43).

Figure 43. Coverage of people receiving ART (all ages), 2010–2019

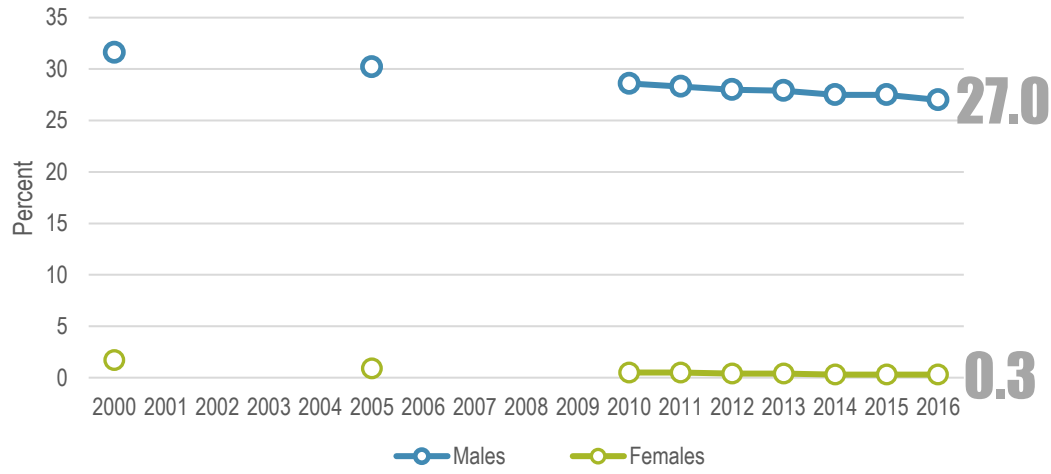


Data source: https://aidsinfo.unaids.org/

3.2.4. Smoking

Tobacco consumption doubles the risk of developing TB and remains a public health issue in Sri Lanka. Smoking prevalence since 2000 declined slowly in both males and females. In 2016, the prevalence of male and female smokers in the country was 27.0% and 0.3%, respectively[17] (Figure 43). According to WHO estimates 1,100 (8-4,800) TB cases notified in 2018 were attributable for tobacco smoking.

Figure 44. Trend in prevalence of smoking in adult males and females, Sri Lanka



[17] Smoking prevalence, males (% of adults) [online]. Washington, DC: World Bank (https://data.worldbank.org/indicator/sh.prv.smok.ma accessed 30 July 2020) and Smoking prevalence, females (% of adults) [online]. Washington, DC: World Bank (https://data.worldbank.org/indicator/sh.prv.smok.fe accessed 30 July 2020)

3.2.5. Problem Alcohol Use

The prevalence of alcohol use disorders in Sri Lanka is low: 5.9% among men and 0.7% among women aged >=15 years[18].

Table 6. Prevalence of alcohol use disorders and alcohol dependence ratio

Prevalence of alcohol use disorders and alcohol dependence (%), 2016*

	Alcohol use disorders**	Alcohol dependence
Males	5.9	4.9
Females	0.7	0.6
Both sexes	3.1	2.6
WHO South-East Asia Region	3.9	2.9

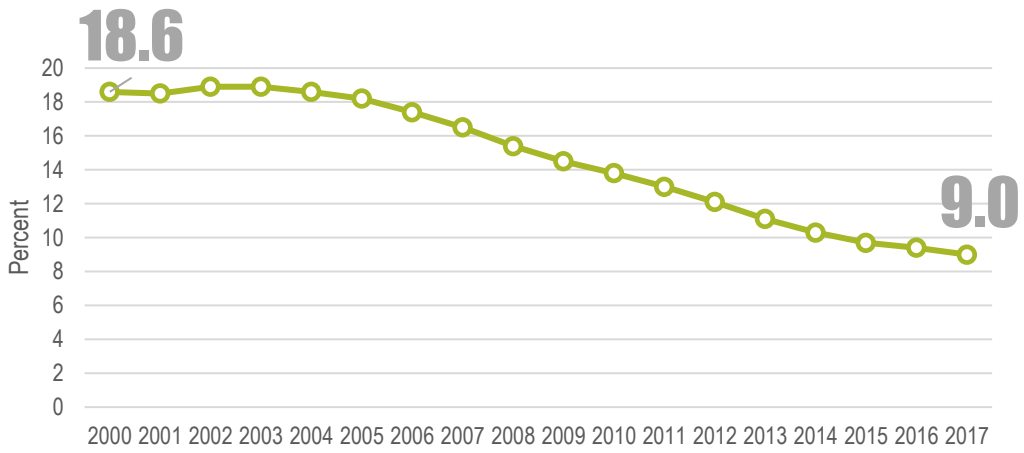
* 12-month prevalence estimates (15+); **including alcohol dependence and harmful use of alcohol.

According to WHO estimates 1,100 (36-3,900) are attributable for alcohol use

3.2.6. Malnutrition

Malnutrition almost triples the risk of TB. It is a proximate risk factor for TB with its effect of impairing the host defense against infection. In addition, it is a direct marker of poverty. In 2017, 9.0% of the population was undernourished (i.e. they received below the minimum level of dietary energy consumption, also referred to as 'prevalence of undernourishment')[19]. According to World Bank database, the prevalence of malnutrition in Sri Lanka since 2003 steadily declined. Such improvement would drive TB epidemic downward. According to WHO estimates about 2,600 (range: 1,900-3.400) cases of TB in Sri Lanka are attributed to malnutrition.

Figure 45. Trend in prevalence of undernourishment, 2000-2017



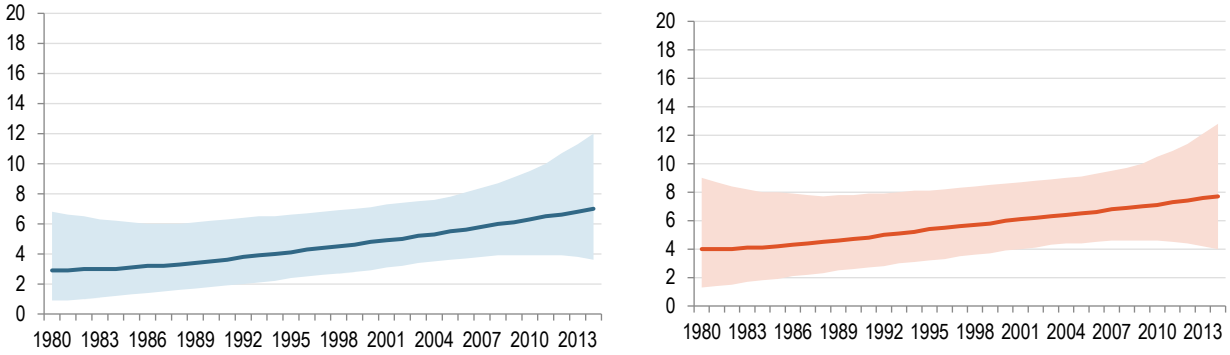
[18] Global status report on alcohol and health 2018. Geneva: World Health Organization; 2018. License: CC BY-NC-SA 3.0 IGO. https://www.who.int/substance_abuse/publications/global_alcohol_report/en/

[19] Prevalence of undernourishment (% of population) [online]. Washington, DC: World Bank (https://data.worldbank.org/indicator/SN.ITK.DEFC.ZS, accessed on 31 July 2020)

3.2.7. Diabetes Mellitus

Diabetes triples a person's risk of developing TB. According to WHO Global Health Observatory[20] database age-adjusted estimates of diabetes among male population aged over 18 years has been increased from 4.8% in 2000 to 7.0% 2014. Among females in the same period the estimated age-adjusted diabetes prevalence increased from 6.0% to 7.7% (Figure 46).

Figure 46. Trend in age-adjusted prevalence of diabetes in adult males (left graph) and females (right graph), 1980–2014



According to International Diabetes Federation report Sri Lanka has the second highest (10.7%) age-adjusted comparative diabetes prevalence in adults aged 20-70 years in the South East Asia Region after Mauritius[21]. Estimated number of people with diabetes in 2018 was 1.2 million (95% CI 0.8-1.9 million). Increase of diabetes prevalence could be one of the factors moderating the decline of TB burden in the population. According to WHO estimates around 470 (67-1,100) cases of TB occurring in Sri Lanka in 2018 were attributed to diabetes[22].

To assess the burden of TB among patients with diabetes mellitus a cross-sectional study was conducted among 4548 systematically recruited patients over 45 years who were attending the diabetic clinic at the National Hospital of Sri Lanka, Colombo. Of those six patients (0.1%, 95% CI=0.0%-0.3%) were detected with bacteriologically confirmed PTB through Xpert MTB/RIF and /or TB culture. Together with the 13 patients (0.3%) who were found to be already on treatment for PTB at the time of recruitment to the study, the total PTB prevalence in the study sample was 400 (19/4,548) per 100,000 population (95%CI=200/100,000-600/100,000)[23].

[20] WHO Global Health Observatory database [online]. https://apps.who.int/gho/data/node.main.NCDRGLUCA?lang=en accessed on 03 August 2020

[21] IDF Diabetes Atlas 2019 [online]. https://diabetesatlas.org/en/resources/ accessed on 03 August 2020

[22] Global TB database. [online]. https://www.who.int/tb/country/data/download/en/ accessed on 03 August 2020

[23] World Health Organization. Proportion of pulmonary tuberculosis among patients attending diabetes clinic of the National Hospital of Sri Lanka: a guide to inform the national policy on active screening for pulmonary tuberculosis. May 2020. Colombo, Sri Lanka.

3.2.8. Incarceration rate

The level of TB in prisons has been reported to be up to 100 times higher than that of the civilian population[24]. Therefore, the changes in incarceration rates might notably affect county TB epidemic. Between 2000 and 2010 the incarceration rate in Sri Lanka has been increased about by 42% and then trend was reversed up to 2016. In 2018 the incarceration rate in Sri Lanka was only 105 per 100,000, which is much lower compared to global median incarceration rate of 140 per 100,000 population[25]. Decline of prison population could be one of the predictors of driving of TB epidemic in the country to downward (Figure 47).

Figure 47. Trend in number and rate of prisoners per 100,000 population, 2000-2018

Data source: https://www.prisonstudies.org/country/sri-lanka

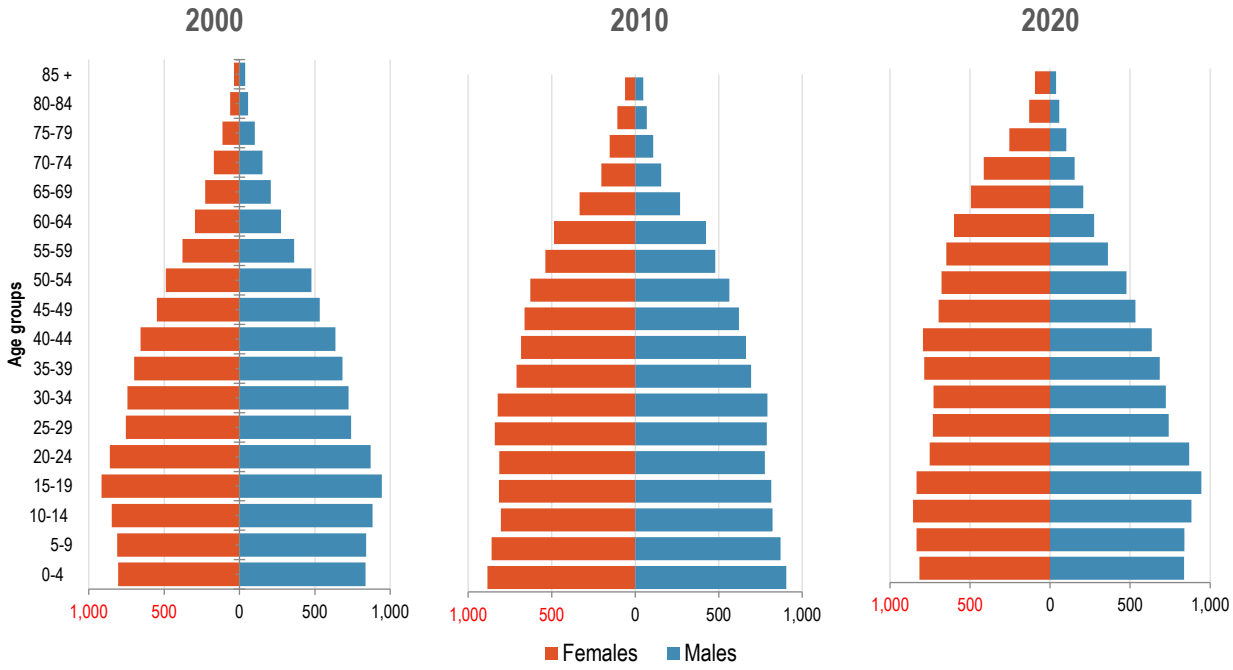
[24] Tuberculosis in prisons. Fact Sheet. https://www.who.int/tb/areas-of-work/population-groups/prisons-facts/en/

[25] World Prison Brief Data, Sri Lanka [online]. https://www.prisonstudies.org/country/sri-lanka accessed on 31 July 2020

3.2.9. Demographic changes

TB is strongly associated with age and sex, being more common in elderly the population and in males. Therefore, demographic changes caused by natural movements or migration can drive the TB epidemic in a country upwards or downwards, depending on changes in the proportions of different age groups. Figure 48 shows the age pyramids for Sri Lanka in 2000, 2010 and 2020.

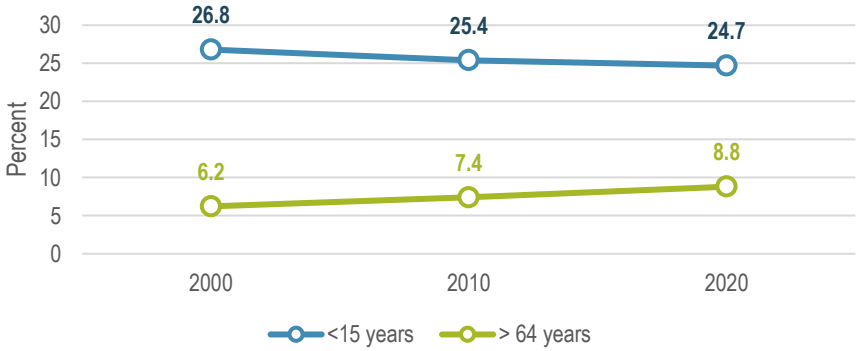
Figure 48. Population pyramid (number in thousands) in Sri Lanka in 2000, 2010 and 2020



Data source: World Population prospects https://population.un.org

Each pyramid shows the distribution of the population by age and sex. There is slight change of shape of population pyramid toward population "aging": the pyramid for 2020 is larger at the top due to increase of life expectancy, especially among the women compared with the pyramids for 2000 and 2010. Thus, the ratio of elderly over the children under 15 was 1: 4.3 in 2000, while in 2010 and 2020 this ratio was 1: 3.4 and 1: 2.8 respectively. Such changes in the proportion could drive the TB epidemic upward and could be one of predictors to moderate decline of TB burden. (Figure 49)

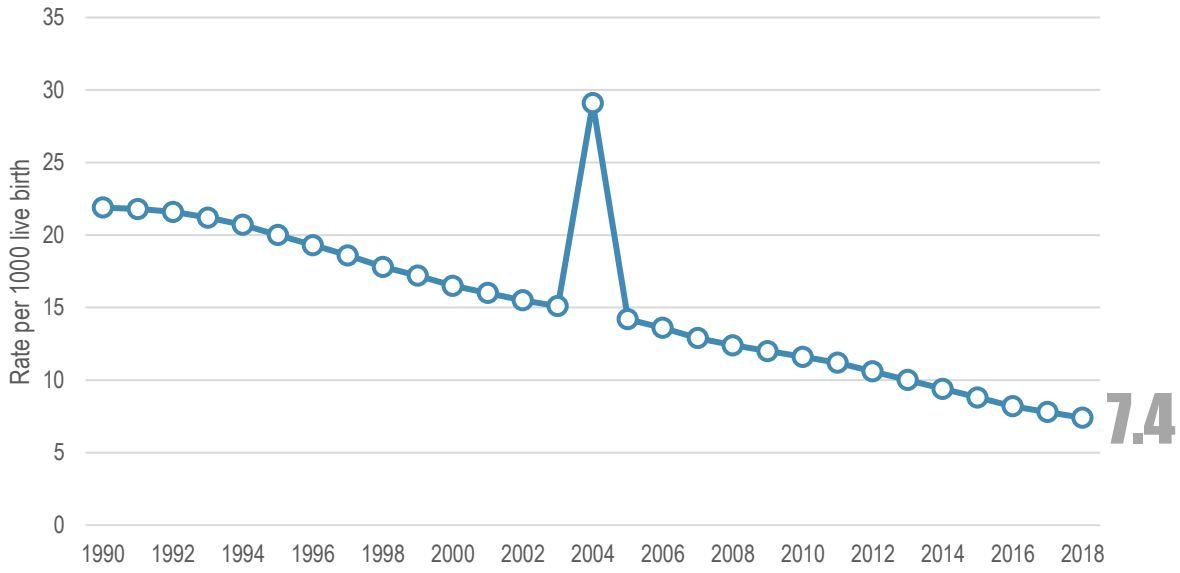
Figure 49. Percent of children and elderly (64+) in Sri Lanka in 2000, 2010 and 2020



3.2.10. Under-5 mortality

It is assumed that an improvement in the general population's health is associated with a decreased TB burden. Under-five mortality is commonly used as a proxy indicator of overall population health and therefore for access to health services. The figure below shows the estimated trend in under-five mortality in Sri Lanka since 1990. The estimated under-five mortality steadily declining. The observed spike in 2004 was due to Indian Ocean tsunami on December 26, 2004, which killed 35,322 people in the country of which about one third were children[26]. Between 2008 and 2018 annual average decline of child mortality was -5.2%, (Figure 50) indicating remarkable and fast improvement of population health and access to health care. Such development might be one of the key contributing factors of driving TB burden in the population to downward.

Figure 50. Trend in Under-five mortality rate per 1000 live births, 1990–2018

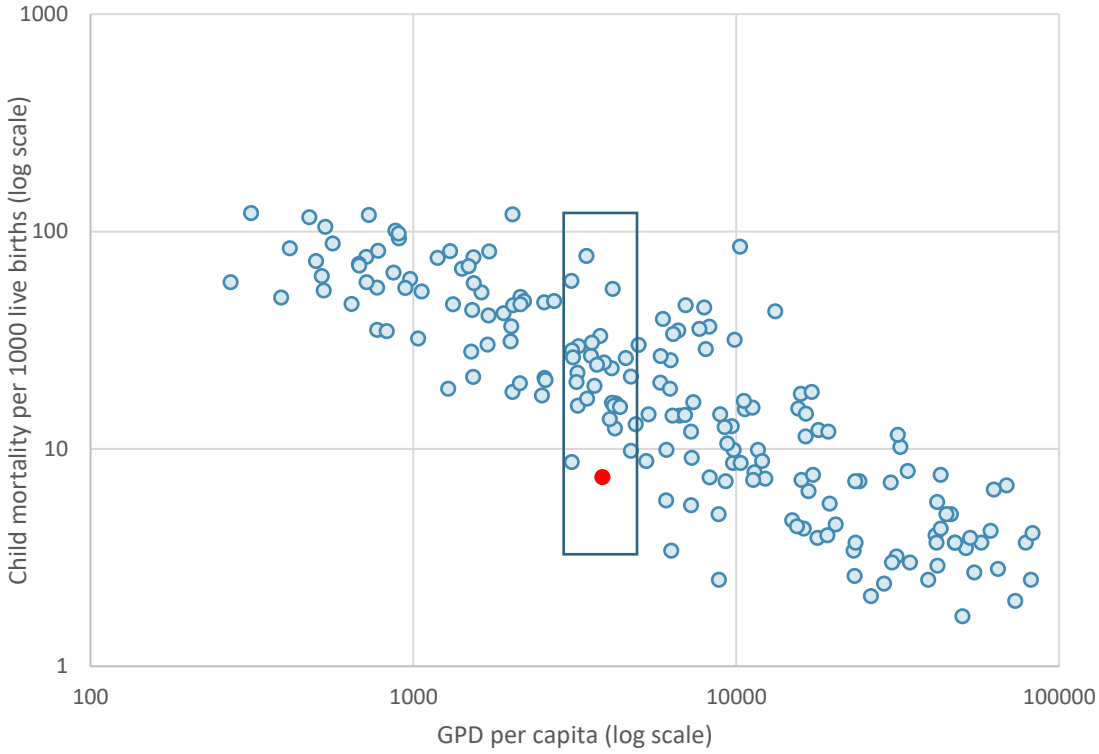


Data source https://data.worldbank.org/indicator/SH.DYN.MORT

Compared to other countries with the similar income U5MR in Sri Lanka was remarkably lower in 2018 than it would be expected from the size of the economy expressed in GDP per capita (Figure 51)

[26] UNICEF. Children and the 2004 Indian Ocean Tsunami: Evaluation of UNICEF's Response in Indonesia, Sri Lanka and Maldives. Overall Synthesis Report. (UNICEF), New York, 2009. https://www.unicef.org/evaldatabase/files/Children_and_the_2004_Indian_Ocean_tsunami_Indonesia-Sri_Lanka-Maldives.pdf accessed on 03 August 2020

Figure 51. Scatterplot of under-5 mortality rate against GDP per capita (2019).
Each blue dot represents a country pair of data points. Sri Lanka s is shown in red

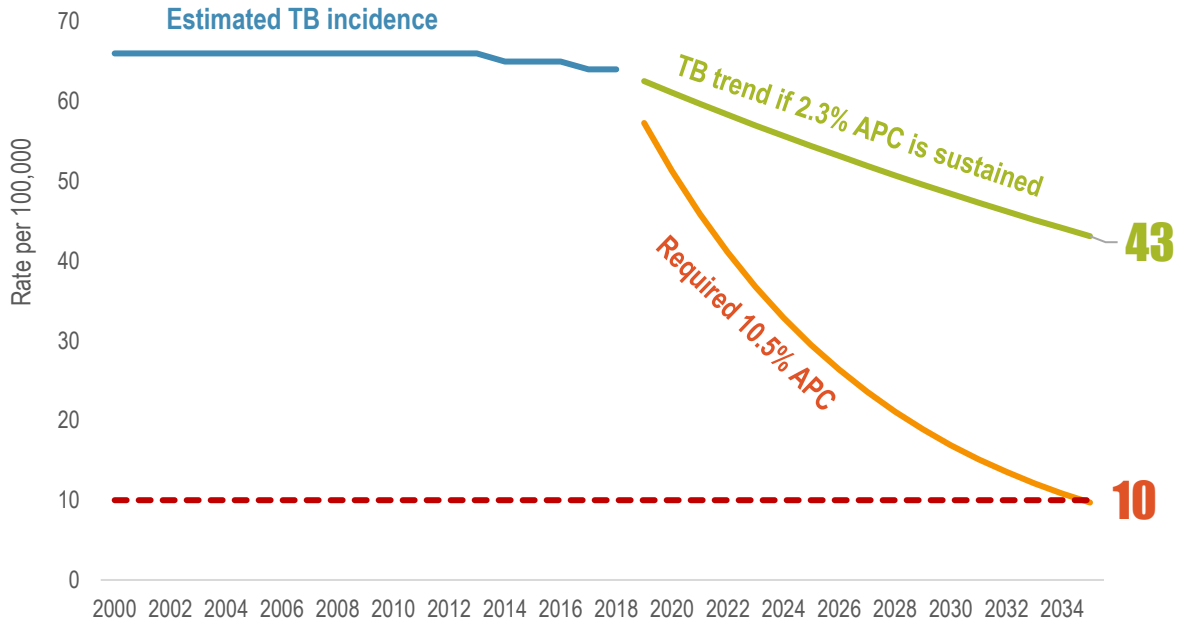


4. Discussion

4.1. Synthesis

According to WHO estimates TB incidence rate between 2000 and 2013 in Sri Lanka has remained unchanged. Only started from 2014 onward there was some slight decline. The mean annual decline in TB incidence between 2014 and 2018 was 0.4% only by WHO estimates. However, between 2015 and 2019 the notification of incident TB cases according to routine surveillance system declined 3.7% annually. Because there were various drivers of TB notification over the recent years affecting increase of bacteriological confirmation and decline of clinically diagnosed TB cases, we believe that the best proxy of trajectory of true TB burden in the population is the trend of sputum smear positive TB rate, which has shown 2.3% annual decline between 2015 and 2019. This is slightly favorable compared to 2% mean annual decline observed globally, however if current pace of decline is sustained Sri Lanka will fail to achieve End TB strategy target of 90% reduction of TB incidence in 2035 compared to 2015. To reach at least 10 per 100, 000 TB incidence rate by 2030, Sri Lanka should attain at least 10.5% mean annual decline in TB incidence (=notification) rate (Figure 52).

Figure 52. Projections of trends of TB estimate in Sri Lanka



Current methods of TB screening and case finding such as symptoms-check and sputum smear microscopy most likely will not allow to increase case-finding even if they are expended. The positivity of sputum smear microscopy in Sri Lanka in 2018 was 2.8% only, suggesting that microscopy testing coverage in the country is more than adequate while long-lasting stagnation and very slow decline of TB burden in the country suggests that large proportion of infectious TB cases in Sri Lanka are not detected by health system and continue to spread the disease in the communities. Due to low HIV prevalence in the population, negligible level of drug-resistance, outstanding efficiency of the health systems (as

shown by low child mortality rate) and equity (as shown by no difference of child mortality between lowest and higher wealth quantiles[27]) and favorable external factors (decline of malnutrition, increase of economic growth) Sri Lanka has great potential for much faster fall of TB burden.

The observed decline in notification could be attributed mainly to a true decrease in TB incidence in the population, and partly to the change of practice of clinically diagnosed TB patients (showing fastest decline). The hypothesis of a true decline in TB transmission in the population is supported by a number of factors: the faster decline in the age-specific notification rate among younger age groups; the change in the age structure of TB patients towards older groups; consistent trend of decline across all geographical areas, and when disaggregated by type, sex, and site of disease. However, various pace in decline of TB by bacteriological confirmation, sputum smear and site of disease indicate that the decline in TB notification could in part be due to a change/inconsistency in diagnosis of clinically diagnosed PTB cases.

There is a heterogeneity in distribution of TB notification across the country which most likely reflect the difference in true burden of the disease. The key trends of TB disease observed in Sri Lanka are as follows:

- In the period 2015–2019 TB notification decreased across most of districts (24 of 26). TB notification rate in 2019 ranged from 19.5 per 100,000 (Mannar) to 78.6 per 100,000 (Colombo);
- The proportion of bacteriologically confirmed PTB cases among new and relapse TB cases increased from 69.3% in 2015 to 77.2% in 2019.
- Proportion of bacteriologically confirmed TB cases across the geographic area is high, ranging from 58.9% in Polonnaruwa to 100% in Mannar.
- The proportion of extrapulmonary cases among new and relapse TB cases is stable over time but with notable geographical variation, ranging between 9.5% in Mullaitivu to 37.3% in Monaragala.
- TB notification decreased in both males and females proportionally, with males accounting about 65% of notified TB cases.
- In the period 2013–2019 the proportion of previously treated cases among all notified cases increased from 4.3% to 7.1%.
- Age-specific notification rates of new TB cases in the period 2015–2019 decreased across all age groups. The fastest decline was observed among those aged 25-34. The magnitude of annual change declined with the increase of age. The highest age-specific notification rate in 2019 was observed in elderly age group (over 64 years).
- The proportion of child TB cases among new cases in the period 2013 and 2019 slightly declined from 3.3 to 2.9%.
- The percentage of TB cases with TB/HIV co-infection stable around 0.5%.
- RR-TB prevalence among new TB patients is below 0.5% according to drug resistance survey.

The main TB program specific factors that drive the TB epidemic downwards include: some increase in access to Xpert MTB/RIF testing.

[27] Department of Census and Statistics (DCS) and Ministry of Health, Nutrition and Indigenous Medicine 2017. Sri Lanka Demographic and Health Survey 2016 Sri Lanka

The external factors that are expected to drive the TB epidemic downwards, by reducing TB transmission and population vulnerability and by increasing protection and prevention at health system level, include health system strengthening (decrease in under-5 mortality); improved nutrition of population, economic growth (expressed as increase of GDP), low HIV prevalence and access of population to health care.

Factors that are likely to prevent a faster decline in the TB epidemic include: limited coverage of with sensitive diagnostic techniques (e.g. Gene Xpert, chest Xray, culture), modest coverage of contact tracing, preventive TB treatment, suboptimal treatment success rates, as well as increase of diabetes prevalence and aging of the population.

4.2. Strengths

- Compliance of WHO definitions and reporting framework;
- Established web-based real-time electronic database at national and district levels;
- Availability of data quality assurance mechanisms;
- Internal consistency of routine notification data at national and district levels for most of parameters of surveillance system;
- High access to HIV testing;
- Presence of highly skilled and dedicated staff at national level
- Operational research undertaken by the local staff.
- Annual surveillance reports produced and disseminated

4.3. Gaps, Challenges, and Weaknesses

- Under-reporting of initial lost to follow-up, deaths before the start of the treatment
- Sub-optimal quality of vital registration system
- Inadequate GeneXpert testing coverage
- Delay and inconsistent reporting of laboratory data; unreliable method of transmission of data.
- Lack of validation checks and routine standardized procedures for data quality control.
- Limited functionality of ePIMS to produce standard reports of programmatic indicators, rates, charts, maps, time series analysis.
- Unnecessary disaggregation of TB reported data
- Uncertainty about the number of under-reporting (no inventory study conducted)
- Inadequate and insensitive contact tracing
- Legal restrictions to conduct on-site monitoring in prison system
- Under-notification of TB cases in penitentiary system

5. References

1. Baussano, I., Williams, B. G., Nunn, P., Beggiato, M., Fedeli, U., & Scano, F. (2010). Tuberculosis incidence in prisons: a systematic review. PLoS medicine, 7(12), e1000381. doi:10.1371/journal.pmed.1000381
2. Department of Census and Statistics (DCS) and Ministry of Health, Nutrition and Indigenous Medicine 2017. Sri Lanka Demographic and Health Survey 2016 Sri Lanka
3. IDF Diabetes Atlas 2019 [online]. https://diabetesatlas.org/en/resources/ accessed on 03 August 2020
4. Fonseka W. A Study in the Quality and Coverage of Death Registration in a District of Sri Lanka. MD dissertation in Community Medicine, University of Colombo, Sri Lanka; 1996.
5. Global Laboratory Initiative. (2016) GLI quick guide to TB diagnostic connectivity. http://www.stoptb.org/wg/gli/assets/documents/gli_connectivity_guide.pdf
6. Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka. Monitoring and evaluation system for the National tuberculosis control program in Sri Lanka, 2015-2020 (Amended according to End TB targets)
7. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka. Annual report 2018
8. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka. Annual report 2017
9. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka. Annual report 2016
10. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka (2016). National manual for Tuberculosis Control
11. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka (2018). National Guidelines for management of tuberculosis in children.
12. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka. National strategic plan for tuberculosis control, 2015-2020
13. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka. Prevalence of Sputum positive Tuberculosis among convicted prisoners in Sri Lankan prisons and its contributory factors. Presented at the National Health Research Symposium. 2017.
14. National Programme for Tuberculosis Control and Chest Diseases, Sri Lanka. Survey of Annual risk of infection of tuberculosis among children 10 years of age.
15. National Sexually Acquired Disease Control Programme. Annual Report 2018. Ministry of Health Sri Lanka. [online] https://www.aidsdatahub.org/sites/default/files/resource/nsacp-sri-lanka-annual-report-2018.pdf
16. Onozaki I, Law I, Sismanidis C, Zignol M, Glaziou P, Floyd K. National tuberculosis prevalence surveys in Asia, 1990-2012: An overview of results and lessons learned. *Trop Med Int Heal*. 2015;20(9):1128-1145. doi:10.1111/tmi.12534
17. Ministry of National Policies and Economic Affairs. Household Income and Expenditure Survey – 2016. Poverty indicators. Department of Census and Statistics.
18. Paul Nunn. Mission report to national TB program, Sri Lanka, 18-30 November 2017
19. Paul Nunn, Deepthi Perera, Sunil Senanayake. Midterm review of the national TB program of Sri Lanka, 17-28 July 2019
20. Registrar General's Department [online] http://www.rgd.gov.lk/web/index.php/en/services/civil-registration/death-registration.html#, accessed 29 August, 2020

21. Sri Lanka Implementation Working Group. Sri Lanka: *Strengthening the quality and availability of mortality statistics. CRVS country reports.* Melbourne, Australia: Bloomberg Philanthropies Data for Health Initiative, Civil Registration and Vital Statistics Improvement, University of Melbourne; 2019.
22. Vanessa Veronese, Shamini Prathapan. TB epidemiological review and impact analysis of Tuberculosis in Sri Lanka, Final report, July 2017
23. World Bank data repository [online] Washington, DC: World Bank (https://data.worldbank.org/indicator)
24. World Health Organization. Proportion of pulmonary tuberculosis among patients attending diabetes clinic of the National Hospital of Sri Lanka: a guide to inform the national policy on active screening for pulmonary tuberculosis. May 2020. Colombo, Sri Lanka.
25. WHO Global Task Force on TB Impact Measurement. Standards and benchmarks for tuberculosis surveillance and vital registration systems: checklist and user guide. WHO/HTM/TB/2014.02. Geneva: World Health Organization; 2014 http://www.who.int/tb/publications/standardsandbenchmarks/en
26. WHO Global Task Force on TB Impact Measurement. "Understanding and using Tuberculosis data" WHO/HTM/TB/2014.09, Geneva: World Health Organization 2014 https://www.who.int/tb/publications/understanding_and_using_tb_data/en/
27. World Health Organization. (2012). Electronic recording and reporting for tuberculosis care and control. World Health Organization. http://www.who.int/tb/publications/electronic_recording_reporting/en/
28. World Health Organization. Global tuberculosis report 2019. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.
29. World Health Organization. Improving early case detection of active TB through systematic screening. WHO/HTM/TB/2013.04. Geneva, Switzerland: WHO, 2013.
30. World Health Organization Global status report on alcohol and health 2018. Geneva: World Health Organization; 2018. License: CC BY-NC-SA 3.0 IGO. https://www.who.int/substance_abuse/publications/global_alcohol_report/en/
31. WHO mortality database [online] https://apps.who.int/healthinfo/statistics/mortality/whodpms/ Accessed on 15 August 2020
32. WHO consolidated guidelines on tuberculosis. Module 1: prevention – tuberculosis preventive treatment. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO
33. WHO operational handbook on tuberculosis. Module 3: diagnosis - rapid diagnostics for tuberculosis detection. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO
34. World Prison Brief Data, Sri Lanka [online]. https://www.prisonstudies.org/country/sri-lanka accessed on 31 July 2020

Annex 1 - Checklist for TB surveillance and vital registration system

PART A: CHARACTERISTICS OF THE TB SURVEILLANCE SYSTEM

QUESTIONS	OUTCOMES (Best practices are in bold)	Description details	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
A1. How are data recorded for individual TB cases at the service delivery level (e.g. in TB diagnostic units, health centres, clinics)? *(Tick all that apply)*	☒ Data are recorded electronically on a national internet-based system ☐ Data are recorded electronically on a state/provincial/regional internet-based system ☐ Data are recorded electronically on a local system ☒ Data are recorded on paper ☐ Data are not recorded	Data at service delivery points are recorded on paper (tools: presumptive TB registers, laboratory request forms, notification form, treatment cards, TB treatment registers, contact tracing register, investigation register). In Colombo data are recorded only on electronically. In addition, data are recorded electronically on internet-based system -Patient Management Information System (PMIS)	Close monitoring of these activity by the central level is essential
A2. Do all service delivery points systematically use standardised TB data collection forms and tools?	☒ Yes, completely ☐ Mostly ☐ Partially ☐ No, not at all	In three facilities visited we have seen that most standard recording and reporting forms were used to collected data. There were no standard forms for RR/MDR-TB recording (individual treatment card and register). Currently used excel sheet to record the patients enrolled into second-line treatment was not in-line with WHO recommended standard RR/MDR-TB register. Presumptive TB register is not maintained/ consistently completed by the facilities engaged in TB detection and referral.	Ensure that presumptive TB register is consistently used in all facilities engaged in TB referral. Introduce standard recording forms (MDR-TB treatment card and MDR-TB register and for patients enrolled into second-line treatment.
A3. Which TB cases are included in the national TB	☒ All TB cases from all parts of the country ☒ Some TB cases are excluded ☐Some part(s) of the country are excluded	As a rule, in TB register and PMIS patient registration module are entered only those cases, who start first line TB treatment. While the patients who die before the start	All diagnosed TB patient regardless of the status of the treatment and drug-resistance profile should be notified, included into TB register, PMIS and into case finding quarterly

QUESTIONS	OUTCOMES (Best practices are in bold)	Description details	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
surveillance data? (*Tick all that apply*)	☐Some case types are excluded ☒Some care providers, e.g. non-NTP providers, prisons, private practitioners, are excluded. ☐ Others: _____	of treatment, or do not return to health clinic after laboratory confirmation are not recorded in TB register, consequently, those cases are not included into surveillance. In addition, it was revealed that smear negative prison TB cases from several districts were not notified, due to an issue of data entry operators, which means that they are not included in TB notification as well.	reports. Initial lost to follow-up cases and those who died before the start of the treatment should be included into cohort analysis as well. TB register (both paper and electronic) should be considered a notification register, rather than treatment register. Laboratory register and TB register and PMIS should be cross-checked regularly, to ensure that all patients diagnosed with TB are followed and included into notification system. Resolve the issue with human to monitor and ensure smooth recording and reporting of TB cases from prisons. Regularly monitor the trend notification data in prison. Investigate any sharp and unexpected changes of notified data from prison for timely identification of issues.
A4. What types of TB data are available at the national level? *(Tick all that apply)*	☒ Patient level data that allow multiple episodes of TB in the same person to be identified are available ☐ Case level data are available for all of the country ☐ Case level data are available for parts of the country ☒ Aggregated data are available, i.e. summaries for groups of cases	Aggregated data are available at the national level based on paper records. And case-based data (at least registration module) are available from PMIS starting from 2020. Because national identification code (NIC) is entered into the database, and NIC coverage is almost universal among those over 16 years, it is possible to allow multiple episodes of TB in the same person to be identified.	Current paper-based reporting tools and standards automated reports in PMIS needs to be simplified in line with WHO recommended standard reporting tools by avoiding of un-necessary dis-aggregations. NPTCCD needs a dedicated person(s) to ensure regular data cleaning, deduplication, cross-check, provision of feedback data users.

QUESTIONS	OUTCOMES (Best practices are in bold)	Description details	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
		Most of modules are not used yet in the majority of the districts. Current tools for data reporting contain multiple unnecessary dis-aggregations, which then require summation at the national level for the data analysis.	
A5. What is the expected frequency of data transmission from the first sub-national administrative level to the national level? *(Tick all that apply)*	☒ Real-time ☒ More often than monthly ☐ Monthly ☒ Quarterly ☐ Less often than quarterly	Paper reports are submitted on quarterly bases. Paper "notification forms H816 A" are sent on continuous basis by currier. Data entered in PMIS are viewable immediately by all levels of the system	
A6. At what levels of the system are TB data systematically verified for accuracy, timeliness and completeness? *(Tick all that apply)*	☒ From the service unit upwards ☒ From the 1st administrative level upwards ☐ From the 2nd administrative level upwards ☐ Only at the national level ☐ Not at any level	During supervision visits quarterly returns of each district are cross checked with the district TB registers (age-sex distribution, type of TB etc). Same with microscopy data, contacts data During the DTCO review meetings the received data are checked with the presentation Data are reviewed during provincial review meeting During PHI review meetings – notification data However, given the observed discrepancy of the data from different sources, most likely	See A7

QUESTIONS	OUTCOMES (Best practices are in bold)	Description details	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
		the efforts of the data verification are not sufficient. There are no standard procedures of the verification and validation of data entered into PMIS.	
A7. What types of quality assurance procedures are systematically undertaken for TB data? *(Tick all that apply)*	☒ Quality controls are in place for the electronic surveillance system (automated checks at data entry and batch checking, plus SOPs) ☒ Data are reviewed during supervisory monitoring visits to service units and sub-national levels (How often?) ☒ Data are reviewed during meetings with TB staff (How often? *every 3 months*) ☐ Other (specify:_____)	At service delivery and province level quality assurance is implemented during the supervisory visits using standard checklist, which contains qualitative measurements of data quality of the facility. Pilot districts are visited 3 times /year and other districts once a year by the central unit. There are some basic validation checks that are undertaken during the data entry to prevent the errors or incomplete entries of core variables. However, there are automated features to assess and alert duplicate entries, incomplete entries and inconsistencies.	Define and introduce data validation SOP to be run by designated staff at district and national level at defined frequencies with defined clean-up processes and full documentation of the results. Define SOP/algorithms for: missing items, suspected duplicate records, assessing completeness. Introduce reports on data quality performance indicators, such as data completeness rates, available to all users so that staff within districts can compare their performance with others.
A8. Is feedback on TB data quality systematically provided to all lower reporting levels?	☐ Yes, completely ☐ Mostly ☐ Partially ☐ No, not at all	During field visits all the data are cross checked by the Central Unit Medical Record officer	
A9. When are national TB case data for a given calendar year considered ready for	☒ Before April the following calendar year ☐ Before May the following calendar year ☐ Before June the following calendar year ☐ On or after beginning of June the following calendar year		

QUESTIONS	OUTCOMES (Best practices are in bold)	Description details	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
national analyses and reporting?			
A10. Are there national guidelines for recording and reporting of TB data e.g. documentation or instructions? *(Tick all that apply)*	☒ Yes. They are posted on the internet. ☒ Yes. They are available in a manual or other reference document, e.g. training materials ☐ No	Guidelines of recording and reporting are embedded in "National manual for tuberculosis control" which is available in electronic and hard copies. http://www.nptccd.info/downloads-2/	
A11. Does the national TB programme have a training plan which includes staff involved in data collection and reporting at all levels of the reporting process?	☒ Yes ☐ No		
A12. How often do TB programme staff receive training specifically on TB surveillance (i.e. recoding and reporting of TB data)? *(Tick all that apply)*	☒ Training is routinely received at national and sub-national levels (How often?) ☒ Training is received on an ad hoc basis ☒ Staff receive training when they are hired ☐ No routine training is received	NPTCCD has plan of modular training on R&R to be conducted for DTCOs, MOs, nursing officers/PHIs at Chest clinics, as well as one day training program for 540 Area PHIs and training workshops for 800 medical officers across the country, which are conducted annually.	
A13. How many staff work on TB surveillance at the national level? *(Tick all that apply)*	☐ Epidemiologist, full-time ( ) ☐ Epidemiologist, part-time (_____) ☐ Statistician, full-time / data manager ☐ Statistician, part-time (_____) ☐ Data manager, full-time (_____)	Filled position at M&E unit include M&E medical officer, and Development officer. Position of health assistant is vacant at the time of epi-review.	Ensure position of IT development officer to develop and carry out data validation checks, clean-up and provide feedback to users.

QUESTIONS	OUTCOMES (Best practices are in bold)	Description details	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
•	☐ Data manager, part-time (_____) ☐ Data quality officers, full-time planned but not currently in post. Data quality officers, part-time (_____) ☒ Other (specify:)	Available staff of HIMU are Medical officer (health informatics), 3 full-time development officers, and one health assistant. The position of IT development officer is not filled yet.	National staff should use WHO "Handbook on understanding and using TB surveillance data". In case of opportunity one national representative to participate in WHO workshops for analysis of TB data.
A14. Is a national TB surveillance report routinely produced and disseminated on an annual basis?	☒ Yes ☐ No	National surveillance report is produced on annual basis and posted on NPTCCD web-site http://www.nptccd.info/downloads-2/	National surveillance and monitoring report should include data on laboratory activities which are key in analysis of trends of TB burden, such as number of 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 analysis to assess unusual, sudden changes for timely investigation and addressing of issues.
A15. Are there written goals of the surveillance system?	☒ Yes ☐ No	Outlined in M&E manual	
A16. Policies and procedures are in place to protect the confidentiality of all surveillance data e.g. records, registers.	☐ Yes, completely ☒ Mostly (names only appear on TB registers/treatment cards/lab registers at facility level) ☐ Partially ☐ No, not at all	Procedures to maintain of confidentiality of surveillance data are in place. Particularly, for PMIS users, access rights are granted at different levels in order to protect patient data and to enforce personal confidentiality data. In addition, access to the PMIS is limited and is only provided to registered users based on the established profiles.	
A17. Is there a long term financial plan and budget in place	☒ Yes ☐ No	National Strategic Plan (NSP) for Tuberculosis Prevention, care and control 2015-2020 provides summary of NSP cost	

QUESTIONS	OUTCOMES (Best practices are in bold)	Description details	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
to support TB surveillance activities?		by activity disaggregated by years and activity, including budget allocated for strengthening surveillance and impact measurement. Likewise, budget for surveillance will be allocated in new NSP.	
A18. When was the last time the TB surveillance system was evaluated?	☒ Within the past 5 years ☐ Within the past 5-10 years ☐ Never (in a systematic and standardised way, but as part of programme reviews)	Last time system was evaluated in 2017 (Epidemiological review)	

PART B (Section 1): CHECKLIST FOR TB SURVEILLANCE AND VITAL REGISTRATION SYSTEMS

For each standard, please assess whether the system is able to satisfy the associated benchmark(s), using the methods recommended in the user guide. Indicate 'Met', 'Partially met', "Not met" or 'Not applicable' in the results column. Describe the key results and any action recommended to improve the quality of the system in the last two columns.

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
TB SURVEILLANCE SYSTEM DATA QUALITY				
B1.1 Case definitions are consistent with WHO guidelines	All three benchmarks should be satisfied to meet this standard: • Laboratory-confirmed cases are distinguished from clinically diagnosed cases; • New cases are distinguished from previously treated cases; • Pulmonary cases are distinguished from extrapulmonary cases.	☒**Met** ☐Partially met ☐Not met		
B1.2 TB surveillance system is designed to capture a minimum set of variables for reported TB cases	Data are routinely collected for at least each of the following variables: • Age or age group; • Sex; • Year of registration; • Bacteriological results; • History of previous treatment; • Anatomical site of disease; • For case-based systems, a patient identifier.	☒**Met** ☐Partially met ☐Not met	Year of registration, history of previous treatment and anatomical site of disease, age and sex are collected for all TB patients. However, the reporting forms are very much complicated with large number of un-necessary dis-aggregations. There are no forms for MDR-TB patients	•

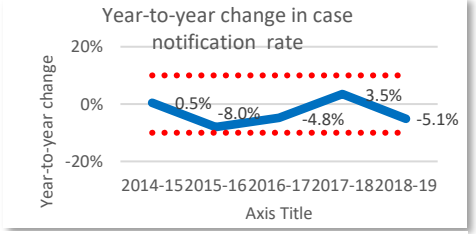
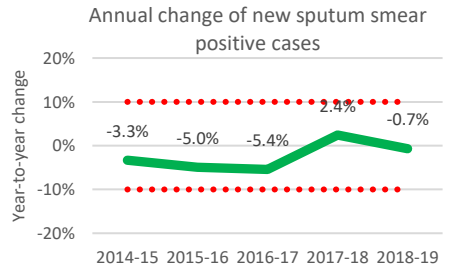
STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
B1.3 All scheduled periodic data submissions have been received and processed at the national level	For paper-based systems: • 100% of expected reports from each TB basic management unit have been received and data aggregated at national level. For national patient-based or case-based electronic systems that import data files from subnational (e.g. provincial or regional) electronic systems: • 100% of expected data files have been imported.	☒**Met** ☐Partially met ☐Not met ☐Not applicable	PMIS registration system in Sri Lanka is real-time and web-based; data for each notified case are entered at DCC. therefore, no import of data file is needed. The completeness of notification data is assessed by comparison of outputs of notification data from the PMIS and quarterly reporting (excel spreadsheets spreadsheets). **Conclusion** Because all expected data submissions from TB reporting unit are received and processed at National level, the standard could be assumed to **be met.**	Although well designed routine procedures are in place for the smooth data transmission, however, there is no clear guidance of periodic data cross-checking between various systems. M&E plan should provide guidance or tool (such as check-list) how, the data should be cross-checked between HIV and TB, Laboratory and TB periodically, to ensure that there is not missed cases in TB register.
B1.4 Data in quarterly reports (or equivalent) are accurate, complete, and internally consistent *(For paper-based systems only)*	All benchmarks should be satisfied to meet this standard: • Subtotals of the number of TB cases by age group, sex, and case type equal the total number of reported TB cases in ≥95% of quarterly reports (or equivalent) from BMUs; • The number of TB cases in ≥95% of quarterly reports (or equivalent) matches the number of cases recorded in BMU TB registers and	☐Met ☒Partially met ☐Not met ☐Not applicable	Subtotals of number of TB cases by age, sex and case type tallied. Number of TB cases in the Quarterly reports were not tallied with the TB register and source documents. In all three facilities they have not considered the primary lost to follow up and the deaths before starting the treatment. Thus, in Colombo of 97 bacteriologically confirmed cases only 89 were matched in TB register, in Trinco 94 of 95 while in Matara only 69 of 83 bacteriologically confirmed cases were matched in TB register. Thus, total under-	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. Reduce under-reporting from prison sector to ensure that all diagnosed TB cases are included into case-finding and treatment outcome report.

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
	source documents (patient treatment cards and laboratory registers); • Data for a minimum set of variables are available for ≥95% of the total number of reported TB cases in quarterly reports.		reporting based on laboratory and TB register cross-check was 8.4% (23/275). Minimum set of variables are available for total number of reported TB cases, but site of the disease not tallied in two visited sites out of three.	
B1.5 Data in national database are accurate, complete, internally consistent, and free of duplicates *(For electronic case-based or patient-based systems only)*	All benchmarks should be met to reach this standard: • Data validation checks are in place at national level to identify and correct invalid, inconsistent, and missing data in the minimum set (B1.2); • For each variable in the minimum set (standard B1.2), > 90% of case records are complete, valid and internally consistent for the year being assessed; • < 1% of case records in the national dataset for the year being assessed are unresolved potential duplicates.	☐Met ☒Partially met ☐Not met ☐Not applicable	ePIMS is designed in a way that during the data entry process data validation checks are undertaken to prevent errors. For most of variables (sex, geographical location, case type, previous history, laboratory results) only pre-defined options are allowed to enter that appear as a drop-down menu during the data entry. Fields are enhanced with the checks so, that only numbers are possible to enter into numeric fields and dates in date fields. Core variables in most of cases are "must enter" fields, therefore, actually there are no missing values for WHO defined core variables. *De-duplication:* system is not enhanced with the automated checks to carry out probabilistic deduplications. There is no periodic procedure for the data validation at the national level. Only procedure include data quality assessment	Evaluate and complete required adaptation of system based on user's feedback Review ePIMS functionality, followed by development of plan of upgrading with clear action, budget, timeline, indicators and targets in line with WHO requirements for the electronic surveillance[28]. Particularly system needs be enhanced with dashboard to allow automated generation of all standard programmatic indicators. WHO has a recommended set of dashboards for programmatic management of TB control program[29].

[28] World Health Organization. Electronic recording and reporting for Tuberculosis care and control, WHO 2012

[29] World Health Organization. Analysis and use of health facility data: Guidance for tuberculosis program managers. https://www.who.int/healthinfo/FacilityAnalysisGuide_TB.pdf?ua=1, WHO 2018

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
			during the monitoring visits. There is no guidance how this should be carried-out. The use of ePIMS to generate national reports and use it for the data analysis and interpretation is still limited. The system has no dashboard, and there are no built-in features to produce time-series analysis tables, figures, maps, no features to calculate rates. There are no automated features to assess duplicate entries, incomplete entries and inconsistencies. Based on all these mentioned it can be concluded that the benchmark is **partially met**.	Review and further develop SOPs for data validation, completeness and cleaning at all levels. IT / M&E consultant to provide technical assistance for the to upgrade systems to adopt WHO dashboard and functionality: USD15,000 Set-up costs for a connectivity diagnostic solution for a network of 30 GeneXperts USD 60,000 Annual running and maintenance cost USD 5,000
B1.6 TB surveillance data are externally consistent	• Among new TB cases, the percentage of children is between 5 and 15% in low- and middle-income countries and < 10% in high-income countries.	☐**Met** ☒Not met	Per World Bank classification Sri Lanka belongs to middle -income countries, suggesting that proportion of child TB cases in Sri Lanka should make up at least 5% of all new TB cases. While, of 7812 new TB cases notified in 2019, only 237 were children aged 14 years and below, representing **3.0%** of the total according to the NPTCCD data reporting. This is below the acceptable range of values for a middle-income country. Thus, this benchmark is not satisfied and the standard is **not met**.	Ensure systematic contact tracing household contacts Coordination with nutrition programme to ensure that screening TB is conducted systematically in malnourished children

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
B1.7 Number of reported TB cases is internally consistent	*If vital registration data are* available, then the following benchmark should be satisfied for this standard to be met: 1. Year-to-year change in the national number of reported TB cases is consistent with year-to-year change in national TB mortality (HIV-negative, from national vital registration) i.e. trajectories with the same direction. *If vital registration data are not* available, then the following benchmarks should be satisfied for this standard to be met: 2. Ratio of notified pulmonary to extrapulmonary TB cases; 3. Ratio of male-to-female TB cases; 4. Proportion of childhood TB out of all TB cases; 5. Year-to-year change in the case notification rate for all forms of TB;	☒**Met** ☐Partially met ☐Not met	In the absence of a vital registration system, alternative benchmarks were used. An analysis of indicators obtained from notification data was performed. Only one benchmark was not met (% of child TB cases), while Ratio PTB:ETB, Ratio Male to Female, Annual change in all TB cases and Annual change in sputum smear positive cases were consistent over the time at national level. **Year** / **Ratio P:EP** / **Ratio M:F** / **% children** **2015** 2.6 1.9 3.3 **2016** 2.4 1.9 3.0 **2017** 2.4 1.9 3.0 **2018** 2.4 1.8 3.1 **2019** 2.7 1.9 2.9   	

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
	6. Year-to-year change in the case notification rate for new smear-positive TB; and if data are available, 7. Ratio of the number of people with presumptive TB to total notifications of TB cases.			
B1.8 All diagnosed cases of TB are reported	Both benchmarks should be satisfied to meet this standard: • TB reporting is a legal requirement; • ≥90% of TB cases are reported to national health authorities, as determined by a national-level investigation (e.g. inventory study) conducted in the last 10 years	☐Met ☒Partially met ☐Not met	TB reporting is legal requirement in Sri Lanka. In Sri Lanka there was no investigation to estimate under-reporting of TB cases. Therefore, only one of benchmark is deemed to be satisfied and therefore standard is ***partially met.***	Conduct inventory study (data audit) to estimate under-reporting of TB case Cost of an inventory study (data audit): USD50,000
B1.9 Population has good access to health care	Both benchmarks should be satisfied to meet this standard: • Under-five mortality rate (probability of dying by age 5 per 1000 live births) is <10;	☐Met ☒Partially met ☐Not met	According to the UNICEF data repository[30], the under-five mortality rate in Sri Lanka in 2018 was 7.3 per 1000 live births, suggesting efficiency of health care system. n 2017 out-of-pocket health expenditure was 50% of current health expenditure according to	

[30] UNICEF Data. Monitoring the situation of children and women: under-five mortality. New York, NY: UNICEF; 2019 https://data.unicef.org/topic/child-survival/under-five-mortality/ [accessed on 21 March, 2020]

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
	• <25% total health expenditure is out-of-pocket		the WHO Global Health Observatory database. This is y above the WHO benchmark of 25% suggesting overall good access to health care services in the country. Thus, only one of the two benchmarks are satisfied and therefore the standard was considered **partially met**.	
B1.10 Vital registration system has high national coverage and quality	Both benchmarks should be satisfied to meet this standard: • Cause of death documented in ≥90% of total deaths recorded in (a) a national VRS OR (b) a sample VRS; • <10% of deaths have ICD codes for ill-defined causes (defined as ICD-9 780-799 and ICD-10 R00-R99)	☐**Met** ☒Partially met ☐Not met	50% of deaths have ill-defined cause of death 80% of deaths are registered by registrars (no medical certificate of death)	Advocate for improved quality of death registration in VRS: e.g. medical certificate of death
SURVEILLANCE OF DRUG RESISTANT TB				
B2.1 Surveillance data provide a direct measure of drug-resistant TB in new cases	One of the two benchmarks should be satisfied to meet this standard: • Rifampicin susceptibility status (positive/negative) documented for ≥75% of new pulmonary TB cases; • Rifampicin susceptibility status (positive/negative)	☒ Met ☐Partially met ☐Not met	Reliable data are available from drug resistance survey (2017) Coverage of RR-testing among new BC PTB 29.5% (1234/4181) There are 3-4 times discrepancy between RR-TB number reported by NPTCCD and NRL (detected by Gene Xpert). This difference is explained that NRL reports the number of tests	Move from periodic survey to routine DR surveillance Revise diagnostic algorithm to include Xpert as routine diagnostic test where it is available Increase Xpert testing coverage (90% per top 10 target)

<table>
<tr><th>STANDARD</th><th>BENCHMARK(S)</th><th>RESULTS</th><th>RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS</th><th>ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)</th></tr>
<tr><td></td><td>documented for a nationally representative drug-resistance survey of new pulmonary TB cases.</td><td></td><td>and not the patients. However, it seems unlikely that one patient to be tested 3-4 times on Gene Xpert.
<table><tr><th></th><th>RR (NRL)</th><th>NTPCCD</th><th>WHO database</th><th>Started treatmen</th></tr><tr><td>2013</td><td></td><td>4</td><td>12</td><td>0</td></tr><tr><td>2014</td><td></td><td>13</td><td>13</td><td>11</td></tr><tr><td>2015</td><td></td><td>13</td><td>15</td><td>13</td></tr><tr><td>2016</td><td></td><td>17</td><td>23</td><td>17</td></tr><tr><td>2017</td><td>67</td><td>25</td><td>30</td><td>22</td></tr><tr><td>2018</td><td>50</td><td>13</td><td>32</td><td>13</td></tr><tr><td>2019</td><td>72</td><td>21</td><td></td><td></td></tr></table></td><td>Introduce automated connectivity solution to 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.

Designate a staff from NPTCCD to cross-check MDR register and with all cases reported with RR-TB to ensure that all RR-TB cases receive appropriate treatment.

Cost of cartridges to provide Gene Xpert for annually 40,000 presumptive TB cases with signs and symptoms suggestive for TB: USD 60,000</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>B2.2 Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases</td><td>One of the two benchmarks should be satisfied to meet this standard:
• HIV status (positive/negative) documented for ≥80% of all notified TB cases;</td><td>☒Met
☐Partially met
☐Not met</td><td>91.2% new and relapse cases were tested for HIV. Standards is fully met.

According to National Sexually Acquired Disease Control Program in 2018 in total 45 newly diagnosed TB patients were identified among people living with HIV infection. Thus,</td><td>Improve collaboration of STD/AIDS control program by regular exchange of case-based data on TB/HIV cases at national level to ensure accurate surveillance and quality care.</td></tr>
</table>

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
	• HIV status is available from a representative sample from all TB cases notified in settings with a low-level epidemic state where it is not feasible to implement routine surveillance.		at least one in four TB/HIV cases are not known or recorded by Tuberculosis control program	
B2.3 Surveillance data for children reported with TB (defined as ages 0–14 years) are reliable and accurate AND all diagnosed childhood TB cases are reported	Both of the benchmarks should be satisfied to meet this standard: • Ratio of age groups 0–4 to 5–14 years is in the range 1.5–3.0; • ≥90% of childhood TB cases are reported to national health authorities, as determined by a national-level investigation (e.g. inventory study) conducted in the last 10 years.	☐Met ☐Partially met ☒**Not met**	The ratio of TB cases in age groups 0–4 and 5–14 in 2019 was 0.5 (82/155), which is not far below of expected range, therefore this benchmark was **not met**. Since a national-level investigation (e.g. inventory study) has not been undertaken in Sri Lanka in the past 10 years, the second benchmark was also not satisfied. As a result, the benchmark was **not met**. .	Possible reasons for under-detection of childhood TB cases in the age group 0–4 years should be investigated by paediatric international and national experts, discussed with paediatricians, intensive care physicians from paediatric hospitals, pulmonologists, family practitioners and all those who make and report diagnoses of childhood TB. (2) After these discussions, it may be necessary to take corrective actions, including training of health care providers, revision of the differential diagnostic algorithm adopted at general hospitals, etc. Update child diagnostic algorithm according to WHO recent recommendations (GeneXpert testing In children with signs and symptoms of

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION) INCLUDING KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS	ESTIMATED BUDGET TO ADDRESS KEY ACTION(S)
				pulmonary TB, Xpert MTB/RIF should be used in sputum, gastric aspirate, nasopharyngeal aspirate, or stool specimens as the initial diagnostic test for TB) Conduct an inventory study to directly assess underreporting of TB cases using recommended WHO guidelines

Annex 2

Epi review participants

Dr. Arax Hovhannesyan, epidemiologist, independent consultant
Dr. A.I.Priyadarshani Samarasinghe, Local consultant providing technical assistance
Dr. H.D.B.Herath, Director/ NPTCCD
Dr. Nirupa Pallewatte, Deputy Director /NPTCCD

Dr. Mizya Cadre, CCP /NPTCCD
Dr. Dushani Jayawardana – consultant microbiologist
Dr. Sumudu Hewage, acting CCP/NPTCCD
Dr. C.M.Wickramaarachchi, SR/ Com Med
Dr. N.R.Liyanage, SR/ Com Med
Dr. Ruwan Perera – SR – Health Informatics
Dr. Lakmal Rathnayake, DTCO Colombo
Dr. K. Rajapaksha – PMDT Co ordinator
Dr. A. Ramachandra – additional DTCO –Colombo
Dr. A.W.A.D.S.N.Abeysekara, MO M&E Unit
Dr. Awanthi Senadheera, MO Planning Unit
Dr. K.Sooriyarachchi, MO Training Unit
Dr. Amali Senanayake, MO Health Education Unit
Dr. S. Kajanan, MO High risk Unit

Dr. N. De Silva, medical officer, Colombo chest clinic
Dr. Aninthitha, Trinco DTCO
Mr. Lasith Jayathunga, chief pharmacist

Mr. Janaka Thilakarathna Acting MRO
Mrs. I.W.S.A.Dissanayaka, GF Accountant
MR. Tharanga Pathirana, project officer

Dr. Marek Lali, Epidemiologist, WHO HQ
Dr. Mari-Christine Bartens, Epidemiologist, WHO HQ