National Programme for Tuberculosis Control and Chest Diseases
Ministry of Health, Sri Lanka

TB Epidemiological Review
Sri Lanka

Final Report

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The Global Fund

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Acknowledgement

On August 14, 2023, the fourth epidemiological review and impact analysis of the Sri Lanka Tuberculosis (TB) surveillance system, commenced through support of the Global Fund to Fight AIDs, Tuberculosis and Malaria, and the Ministry of Health, Sri Lanka. Prior to in-country field visits, interviews, and data analysis; a standard epidemiological review of the TB surveillance system is preceded by data gathering, extraction and preliminary desk/document review usually carried out by the consultant(s) engaged to provide technical assistance for the successful conduct of the entire exercise.The desk review process offered an opportunity to acquire understanding of the country and epidemiological setting, available data, familiarize with the existing structures, and identify themes and focus areas for the epidemiological review. This was followed up with in-country work entailing consultative interviews, field visits, data analysis, in-brief and de-brief presentations, feedback, and result sharing.

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List of abbreviations

ACF	Active Case Finding
AFB	Acid Fast Bacilli
AI	Artificial Intelligence
ART	Anti-Retroviral Treatment
CNR	Case Notification Rate
COD	Cause of death
CPT	Cotrimoxazole Preventive treatment
DS	Drug-susceptible
EPTB	Extra Pulmonary TB
GFATM	Global Fund for fight against HIV/AIDS, TB & Malaria
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HMIS	Health Management Information System
I/LTFU	Initial /Loss to follow up
MDR	Multi-Drug Resistant TB
MTR	Mid-Term Review
M&E	Monitoring and Evaluation
MoH	Ministry of Health
NPTCCD	National Programme for Tuberculosis Control and Chest Diseases
NRL	National ReferenceLaboratory
NSP	National Strategic plan
OPD	Out-Patient Department
OSDV	On-site-Data Validation
PHI	Public Health Inspector
PTB	Pulmonary TB
PTLFU	Pre-treatment Loss to Follow up
RR	Rifampicin Resistant
SDGs	Sustainable Development Goals
SOPs	Standard Operating Procedures
TB	Tuberculosis
TPT	TB Preventive Therapy
VR	Vital Registration
WHO	World Health Organization

Executive Summary

Sri Lanka, a country with a 2022 projected mid-year population of 22,154,406million people[1], commenced its fourth tuberculosis (TB) epidemiological review and Standards and Benchmarks assessment on August 14, 2023, with the support from the Global Fund to Fight AIDs, Tuberculosis and Malaria, World Health Organization, and the Ministry of Health Sri Lanka. The review aimed to strengthen the national TB surveillance system and data produced, for direct measurement of TB cases including drug-resistant and HIV-associated TB. Furthermore, this review precedes the comprehensive Mid-term evaluation of the National Programme for TB Control and Chest Diseases (NPTCCD)National Strategic Plan (NSP), which will inform the development of an addendum to the Sri Lanka TBNSP 2021-2025, as well as the development of the Global Fund New Funding Model 4(NFM4) in 2024 for TB control in Sri Lanka.Key objectives of this epidemiological review included; an assessment of the quality and coverage of the current national TB surveillance, data management, reporting and Vital Registration systems, with particular attention to the capacity and reliability of the surveillance system to measure the level of and trend of TB burden using available data; an in-depth impact analysis of TB data at national, sub-national levels including key populations and underserved communities; follow up on previous recommendations drawn from the 2020 epidemiological review, enhance capacity of the national TB program to lead Epi reviews; and the development of an investment framework in line with the identified gaps in the surveillance and M& E systems.

The first Epi review in Sri Lanka was conducted in 2014, while the second and third Epi Reviews were carried out in 2017 and 2020 respectively through the support of World Health Organization (WHO) and Global Fund consultants. Based on the 2020 Epi Review, TB incidence in Sri Lanka is estimated to continue to fall in the period of 2010-2019 by an average annual rate of decline of 3.7%, yearly[2] in Sri Lanka.

Sri Lankais considered a low-middle income country[3],with an estimatedTB incidence rate at 63 per 100,000 population equivalent to 14,000 incident TB cases annually, and an estimated

[1]2012 Census of Population and Housing, Department of Census and Statistics, Sri Lanka http://www.statistics.gov.lk/Resource/en/Population/CPH_2011/CPH_2012_5Per_Rpt.pdf

[2]TB Epidemiologic review in Sri Lanka, August 2020 Report

[3]https://data.worldbank.org/?locations=LK-XN

mortality of 3.5/100,000 (760 deaths) per year in 2022[4]. However, TB treatment coverage rate in 2022 viz-a-viz estimates was 57.9%, indicating about 42% of the estimated TB cases are missed, and it becomes imperative through a TB Epi review to assess the capacity of the TB surveillance system to directly measure the level and trends of TB disease burden in Sri Lanka nation-wide. The patient pathway analysis (PPA) conducted in 2021, suggests approximately 39% seek care primarily at part-time owned private sectors which has significantly limited access to TB diagnosis. Among the 61% that seek care within government health institutions, only 9% initially utilize District Chest Clinics (DCCs) which is the primary TB basic management unit. A third of those that seek other government facilities (i.e., excluding DCCS) end up being admitted for diagnostic and treatment purposes, and another third are treated without TB diagnosis[5]. These findings are further compounded by TB diagnostic delays ranging from a mean of 4 days within DCCs to 26 days in other Government facilities such as base hospitals, and in private practice settings.

In this epidemiologic review of the surveillance system and impact analysis, the methodology deployedentailed a desk review of TB program documents; consultative interviews with NPTCCDstaff, office of Vital Statistics unit of the Department of Census and Statistics, and health facility staff at DCCs, Base hospitals, Teaching Hospitals, National TB Reference Laboratory, Prisons, and private sectors, facility field visit to view data collection, quality, flow, and systems; the implementation of a standardized WHO checklist of TB surveillance standards and benchmarks, data extraction and analysis.

Out of the **13 standards and benchmarks** assessed using the standardized WHO checklist, six (6) were met in areas of; case definition in accordance with global standards, capturing of minimum set of variables for reported cases, 100% submission of reports from all twenty-six districts,internal consistency of paper-based sub-totals with quarterly reports at national level for a 100% of sampled sites, DRTB surveillance in terms of documentation of rifampicin susceptibility status for >75% of TB cases and the direct measurement of HIV infection prevalence among TB cases. Five (5) benchmark areas were partially met, including; internal consistency of electronic based systems based offthe presence of some validation checks at national level and a significant proportion of case records assessed at sampled sites, the progression in some benchmark ratios e.g. Pulmonary vs. ExtraPulmonary in some districts, measurable access to health coverage based on health and social insurance available mostly to

[4] WHO Global TB Report 2022, https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&entity_type=%22country%22&lan=%22EN%22&iso2=%22LK%22

[5]Care pathways, and care delays among sputum positive pulmonary tuberculosis patients attending District Chest Clinics in Sri Lanka Report

government workers though associated with high percentage of out of pocket health expenditure of 46.58%, the inability to assess timely reporting, and the partially-functioning vital registration system that captures 100% of causes of death (COD) however approximately 40-50% of the COD are still ill-defined and VR system is currently not fully capable to assess a trajectory of year to year change in TB mortality.The external consistency for childhood TB notification for children aged 0-14 years old at 2.6%is not within accepted range of 5-15% for low-income countries, and the overall regression from 0.9 to 0.4 in child TBratio between 0-4 and 5-14 years (expected range of 1.5 - 3.0) were considered as two (2) critical areas unmet.

In year 2022, a total of **8,342 TB cases** were notified through the 26 DCCs, with 37,287 incident TB cases resulting in an overallall forms of TB case notification rate (CNR) of 37.7 per 100,000 population and**treatment coverage rate of 57.9% for incident TB cases**. In comparison to preceding years, the year to year change (YR2YR) in TB notification ratefor all forms of TB between 2022 and the preceding year showed a **23%increase** contrary to historical annual decline. This surge in TB notification is very commendable and suggestsgood recovery from the COVID-19 pandemic impact on TB case notification, effectiveness of ongoing interventions such as active case finding and mobile screening activities using digital X-rays and GeneXpert, and the adoption of GeneXpert as entry point of TB, though slow. Additionally, it may suggest that a significant number of TB cases were missed in previous years, and during peak of the COVID-19 pandemic, and that there are potentially more cases than detected in the communities.

Among the twenty-six districts ofSri Lanka engaged in providing TB services, the highest CNR was observed in Colombo (88/100,000 population), which consistently over the last decade, exceeds country estimates and actual level CNR of 63/100,000 population and 37.7/100,000 population respectively in 2022. Relative to the country's actual CNR of 37.7/100,000 population in 2022, only Colombo, Galle, Gampaha and Kalutara recorded higher CNR of 88/100,000, 39/100,000, 45/100,000 and 43.3/100,000 population respectively. TB isgenerally preponderant amongmales compared to females at a male: female ratio of 1.8. However, TB is approximately 1.5 times commoner in females relative to male children, adolescents, and youths aged 0-24 years. This reverses to approximately 2 times more TB among males compared to females in ages 25 years and above (M:F ratio range of 1.2 to 2.3). TB is also noted to be common in the elderly constituting 21.7% of all forms of TB in 2022.TB casefinding and notification among children is still very low at 2.2% relative to expected range of 5-15% for low middle income countries (LMIC). Furthermore, as a measure of data consistency, the ratio of TB among children 0-4years compared to children aged 5-14yrs has significantly continued on a

decline from 0.9 in 2015 to 0.4 in 2022, relative to expected range of 1.5 to 3.0 annually. Overall, TB is most preponderant in ages 45-64 years (41% of all forms of TB notified in 2022). Conversely, when compared to the Sri Lanka's population age distribution, 45% of the population constitute children aged 0-14 years and 61% of the population are aged 34 years and less. Put together, these data findings suggest a significant low TB case detection among child population, and plausible high latent TB in the general population which become active among the elderly population given the potential for immunosuppression that is associated with aging. Hence, low child TB casefinding may be related to low capacity to diagnose TB among children in Sri Lanka, and the high proportion of TB among the elderly infers the urgent need to scale up diagnosis and treatment for latent TB in Sri Lanka.

Over the last 10 years (2012-2021 cohorts), cure rates and treatment success rates (TSR) among TB cohort cases have remained stable at an average of 40-44% cure rate and 82-84%in treatment success rate. However, the TSR for TB case cohorts registered in 2021 and evaluated at the end of 2022 was 79% representing a decline from 82% in the preceding year. This decline may be attributed to the COVID-19 pandemic related restrictions and limited access to health facilities.Death rate has unfavorably continued to increase from 5% in 2012 to 9% among 2021 TB cohort cases, with highest rates of about 14% in Mannar and Kilinochchi districts. Other key unfavorable outcomes of TB cases lost to follow up (LTFU) was 4% nationally but twice as much in Gampaha (8% LTFU) and Colombo district at 9%.

HIV and TB/HIV burden remains low in Sri Lanka with HIV prevalence of less than 1% among the general populace and among the TB population in Sri Lanka.The NPTCCD has maintainedhigh HIV test rates among TB patients of over 90% but declined to 80% in 2022. ART and Co-trimoxazole preventive therapy (CPT) uptake among the few (40) TBHIV positive cases diagnosed at the end of 2022 is suboptimal at 53% and 52% respectively. Given the undulating rates in CPT uptake since 2017 from 36% to 0%, 3%, 6% and ending at 52% in 2022 depict challenges with access to CPT, documentation, and reporting.

DR-TB surveillance has improved over the last two years following expansion of GeneXpert services, and the centralized linkage to DRTB treatment. The year to year percentage change in DR-TB cases notified in 2022 compared to the preceding year was 60% (from 10 to 16 DRTB cases). However, Rifampicin susceptibility status was documented for less than 20% of new TB cases across sampled facilities, and there still exist a gap in linkages between identifying presumptives, access to diagnosisper national guideline and initiating TB treatment. Additionally, approximately 65-90% of DRTB cases enrolled on treatment comprise are males, and the reproductive workforce of 25-64 years, as well as the elderly population.

Alongside the paper-based data collection and reporting systems, Sri Lanka has a well-designed and robust electronic data system -Electronic Program Information Management System- ePIMS,whichwas established prior the last Epi review in 2020. ePIMS comprises multiple modules including; patient registration, treatment, Follow up, Lab investigation, Drug stock, and MDR-TBmodules). Along with these, there are also ePIMS dashboard and geographic information system (GIS) for data visualization and mapping. However, these modules are nearly fully functional only in one district and varied functionality at the other twenty-five districts. The ePIMS system also requires further review to include automated data validation checks for duplicate entries, as well as capacity for automated linkages to presumptive data and laboratory information systems. Furthermore, Sri Lanka has a strong human resource system with medical officers and consultants available as primary point of contact for TB services at all levels including the basic management unit (DCC) managed by TB control officers. DCC TB control officers are also supported by public health inspectors to provide assistance with patient tracking and household TB symptomatic screening. There is good internal consistency is maintained between quarterly TB data compiled at district level and the nationally aggregated data.

Furthermore, significant progress has been made in terms of access to health in Sri Lanka measured based on the under 5 mortality rate (U5MR) declining from 93.9per 1000 live births in 1960 to 10 in 2011 and to 6.7 per 1,000 livebirths over the last decade (2011 to 2021)[6], way less than the target of 10. However, out of pocket (OOP) health expenditure in Sri Lanka is relatively high at 46.6 in 2020[7], paling in comparison to global targets of <25%.

Overall, the extent to which case notifications and reported deaths reflect Sri Lanka'sestimated TB incidence and mortalityis considered a **challenge**. This is due in part toa combination of findings including; the potential under diagnosis of TB especially among children aged 0-4 years and consistently low child TB proportions due to low adoption of pediatricTB interventions, low investigation rate among children less than 5 years old, low suspicion of TB and TB screening by medical officers and low capacity to diagnose pediatric TB especially at OPD clinics;the low sensitivity in screening and diagnostic methods resulting from low yield of presumptive TB cases, the vast unavailability and underutilization of presumptive register at facilities visited impeding the ability to comprehensively assess outpatients screening, access to TB diagnosisposing risk to pre-diagnosis initial loss to follow up;sub-optimal referral mechanism; the non-standardized TB diagnosis practice among medical officers with the use of TST (Mantoux) test for TB diagnosis contrary to diagnostic algorithm.

[6] https://data.unicef.org/country/lka/

[7] https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=LK

Less sensitive AFB microscopy is still in use for TB diagnosis in most of the centers visited. Both practices pose risk of missing TB cases. , the gross under supply leading to use of non-standardized recording and reporting (R&R) tools at some DCCS visited; the significant underutilization of GeneXpert machines to as low as a single (1) test or 1 run per day in more than 40-54% of GeneXpert facilities relative to minimum expected of at least six (6) to twelve (12) tests daily; lack of external quality assurance (EQA) for GeneXpert; the delayed turn-around time (TAT) for TB diagnosis results using sputum test especially at base and district general hospitals offering TB services, and medical officers are not equipped/authorized to request chest X-rays- a useful tool for TB diagnosis especially among children. Other challenges include; the centralized treatment initiation procedure limited to DCCs only in practice which poses risk for patient pre-treatment initial loss to follow up; the sub-optimal TB supervision and capacity for on-site data verification and cross-validation between presumptive, laboratory and TB treatment register especially at facility levels; sub-optimal engagement of private health care providers and resultant missed TB notification; sub-optimally functioning vital registration system which captures approximately 100% of causes of death but has a high rate of ill-defined causes that ranges from 40-50%; sub-optimal GeneXpert access and utilization for TB diagnosis amidst other facility-based findings.Though TB notification is legally required in Sri Lanka, there are numerous privately owned facilities that are not supervised by the NPTCCD or DCC control officers

Hence, these assessmentfindings suggest potential under-notification of presumptive TB cases, under-detection, and under-reporting of TB cases especially at OPD clinics at facility levels including base hospitals, teaching hospitals and primary health care units.

While the NPTCCDpreparesfor its Program review and plans to develop a concept note for new funding from the Global Fund (TGF), **future investments** need to address theseidentified challenges. Key recommendations to improve the under-notification, under-detection and under-reporting include; phased- decentralization of TB treatment initiation from DCC to base hospitals, Teaching hospitals and nearby government hospitals e.g., PMCU to improve access to treatment, and bridge gaps of pre-treatment initial LTFU. NPTCCD can also leverage World Bank supported ‘Shared care model’ to decentralize TB treatment at PMCU levels. This patient-centered approach to decentralizing TB treatment will be accompanied with regular and rigorous supportive supervision to engaged facilities for the first six months. Secondly, the NPTCCD in collaboration with the MoHshould urgently print, distribute and sensitize use of standard R&R formats particularly the presumptive register so as to enable NPTCCD sufficiently capture and track presumptives identified, tested for TB and linked to care. Thirdly, it is imperative the

NPTCCD reassess the utilization and uptake rates of GeneXpert and consider strategic redistribution of machines to facilities with high OPD attendance. Additionally, trainings of medical officers particularly in the OPD clinics, on TB standard diagnostic algorithms and treatment guidelines, high suspicion of TB, TB screening especially among elderly, diagnosing TB in children, and to generally '**THINK TB'**are all crucial in building capacity health staff and medical officers involved in providing health services. Furthermore, intensifying TB finding among children less than 5 years old requires the NPTCCD actively engage pediatricians, nutrition, and pediatric clinics both in public and private settings in TB screening, child TB case detection and pediatric TB trainings focused on standard child TB diagnostics, diagnostic algorithms and treatment monitoring.To improve the existing ePIMS and use of other modules of the electronic data system, the NPTCCD through support of the Global Fund and World Health Organization (WHO), should identify relevant staff that will be designated as ITofficer to support the M&E teamto regularlyupdate indicators, variables, and their cross-linkages,deploy automated data quality checks on ePIMS and accelerate use of all modules to improve data transmission, management, and quality. Facility-based supervision for TB needs to be regular, supportive, and documented for follow up actions. Furthermore, the NPTCCDshould intensify its current use of mobile digital X-rays (mobile TB screening truck) for community awareness screening activities especially in high density areas and among elderly populations given the high TB proportions among the latter population. In the long run, to better understand the magnitude of under-notification and TB under-reporting, an inventory study is recommended to identify missing cases, sources of under-reporting and determine the extent to which providers of care are unaware, unwilling, or unable to notify TB treated in facilities. Lastly, but not least of needed investments, to ensure timely TB diagnosis, notification and treatment initiation,the NPTCCD using a hub and spoke model, should establish efficient sputum transport systems to facilitate GeneXpert tests from facilities in proximity to GeneXpert sites and facilitate GeneXpert test to be adopted as the primary diagnostic entry point in line with Sri Lanka's national TB guideline.

Overall, using the 2020 epidemiologic review findings as a baseline for comparison, the benchmarks and milestones achieved in 2023 indicates a moderate improvement in surveillance systems to adequately capture TB diseases burden; improved data collection and tracking systems, stability in the country's interventions and strategies for surveillance; but also, a need to intensify current efforts in transcending towards achievingbetter treatment coverage rates and an enhanced quality TB surveillance system.

1 Introduction

Sri Lanka, a country that lies in the Indian ocean, is home to a 2022 projected mid-year population of 22,154,406million people[8], comprises of twenty-five districts in nine provinces, 26 District Chest Clinics (DCCs) with two of these DCCs (Colombo and Gampaha) under the administrative control of the NPTCCD, and one (1) central MDR treatment center. There are160 AFB microscopy labs, thirty-one (31) GeneXpert machines, and one (1)national reference laboratory (NTRL) that provides a combination of AFB microscopy, GeneXpert, solid and liquid culture, DST, and Line Probe Assay test services. Government hospitals such as Base and General Hospitals provide TB treatment and follow up services. These services within these districts are supported by the office of the Medical Officers of Health(MOH) under the leadership of an average of 13 - 14 Medical Officers of Health per district, Public Health Inspectors (PHIs) that assist with patient tracking and contact tracing, Public Health Midwives, nurses, radiographers, medical lab technicians, public health lab technicians that all collectively provide treatment and test services to TB patients and presumptive TB clients. The basic management level for TB services is the District Chest Clinics under the leadership of a physician- the District TB Control Officer (DTCO).

Though Sri Lanka is not a high TB burden country, according to the World Health organization (WHO), the estimated number of incident TB cases in Sri Lanka is 63 per 100,000 population equivalent to 14,000 incident TB cases in 2022[9], and an estimated mortality of 3.5/100,000 (760 deaths) per year in 2022[10]. In 2022, a total of 8,432TB cases were notified, resulting in an average treatment coverage rate of 59.6%for all forms of TB, about 58% treatment coverage among incident TB cases (8109), and case notification rate (CNR) of 37.7 per 100,000 population for all forms of TB. TB treatment coverage rate in

[8]2012 Census of Population and Housing, Department of Census and Statistics, Sri Lanka http://www.statistics.gov.lk/Resource/en/Population/CPH_2011/CPH_2012_5Per_Rpt.pdf

[9] WHO Global TB Report 2022

[10]WHO Global TB Report 2022, https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&entity_type=%22country%22&lan=%22EN%22&iso2=%22LK%22

2022 is the number of new and relapse cases detected and treated in a given year divided by the estimated number of incident TB cases in the same year expressed as a percentage. Hence, a coverage rate of 57.9%(8109/14,000), indicates about 42% of the estimated TB cases are missed annually.

Based off the 2020 Epi Review, TB incidence in Sri Lanka is estimated to have maintained a continuous decline in the period of 2010-2019 by an average annual rate of decline of -3.7%[11].The 2023 epidemiological review (Epi review) assessed the current national TB surveillance and VR systems, with particular attention to their capacity to measure the level of and trends in TB disease burden. The routine TB surveillance and vital registration (VR) systems was assessed, as well as the progress made relative tokey recommendations made to NPTCCD and MoH during the Epi review conducted in 2020. To date, the extent to which actual case notifications and reported deaths reflect Sri Lanka'sestimated incidence and mortalityas estimated by WHO still remains a challenge based on the gap in treatment coverage of 42%.

To review progress made following the last conducted epi review, effectively plan, monitor, and assess recent trends in TB diseases burden, review the impact of interventions and progress towards meeting national and international targets, and identify investment needs, as well as generate better quality data that directly measures trend in TB disease burden; the NPTCCD required accurate epidemiological information about the level of and trends of TB disease burden in Sri Lanka nation-wide.As a result, a revisit and follow up Epi review of the systems in place to collect accurate and complete data on TB cases and deaths was initiated. The lastseries of Epi review were conducted in 2014, 2017 and 2020 through the support of World Health Organization (WHO) and the Global Fund consultants.To conduct this assessment, the Sri Lanka Ministry of Health in collaboration with WHO andwith funding support of The Global Fund engaged an International Epi Review consultant to conduct a fourth Epi Review in collaboration with a national consultant, to examine the national and sub-national TB surveillance data and to establish the status of implementation of recommendations of the 2020 Epi Review. Furthermore, this epidemiological review is part of the overarching TB mid-term program review. This review precedes the forthcoming comprehensive Mid-term review (MTR) of the Sri Lanka TB National Strategic Plan (NSP) 2021-2025and will inform the development of an addendum to Plan, as well as the development of the Global Fund New Funding Model 4(NFM4) in 2024 for TB control in Sri Lanka.

[11] Epidemiologic review of Tuberculosis Surveillance in Sri Lanka, 2020 Report

The assessment of the TB surveillance and VR systems was conducted using a standardized WHO checklist of TB surveillance standards and benchmarks. The expectation was that the results could be used to develop a monitoring and evaluation (M&E) investment plan designed to strengthen TB surveillance and VR systems. Findings and recommendations from this epi review will besynergized with the MTR findings and recommendations, to inform the concept note development for the NFM4. Sri LankaProgramme for TB control and Chest Diseases with support from GFATM and WHO can also use the findings and recommendations of the TB surveillance system assessment to inform targeted M&E investments to strengthen and streamline underlying systems for data collection and systematically assess trends in disease burden and program impact.

2 Purpose of review

The first point of reference is to understand TB disease burden in the countryusing its case notification systempost the 2020Epi review. The trends of time series of TB case notifications and mortality, especially in countries where the surveillance system is expanding electronic based systems coverage and intensifying case finding activities, do not necessarily reflect trends in true disease burden, but provide an extremely useful insight on gaps within its surveillance systems,particularly,areas to target for high impact. Further investigation of notification data at national and sub-national levels, including a detailed analysis of the recording and reporting system, the analysis of mortality data, as well as a study of changes in determinants of TB over time, provides a more comprehensive understanding of TB epidemiology and the shortcomings of routine TB surveillance in a country.

The epidemiologic review is systematically part of the national health reviews and was planned as part of the overarching Sri Lanka TB Program Review implemented in 2023. The following are the specific objectives for TB epidemiological review;

2.1 Objectives

1. Describe and assess the current national TB surveillance, data management and reporting, and vital registration (VR) systems, with particular attention to their capacity and reliability to measure the level of and trends in TB disease burden (incidence and mortality), outcomes (treatment success), coverage and gaps in interventions, as well as the geographical disaggregation of these sub-national levels and by demographic and socio-economic variables.

2. Assess the level of, and trends in, TB burden using available surveillance, survey, programmatic and other data.
3. Define any actions and investments needed to generate more and better-quality data to directly measure trends in disease burden and program data in the future.
4. Build the capacity of the national TB program to analyze and participate in and lead epidemiological and impact analyses.
5. Identify a short list of evidence-based gaps and priorities to improve impact to contribute this focus to the overarching TB program review, to inform on recommendations and prioritization for future program investments.

In addition, the scope of this analysis entails the review of the progress of implementing recommendations from the 2020 epi review.

2.2 Proposed outcomes

- A formal performance assessment of TB surveillance based on WHO standards and benchmarks, with strengths and weaknesses (including data gaps and data quality problems) identified, and any unmet monitoring and evaluation needs described.
- A formal assessment of the level of, and trends in, TB disease burden and their sources of uncertainty.
- Determine if TB control interventions have contributed to changing the course of the TB epidemic while accounting for other external factors and identify key populations that should be targeted with TB control interventions.
- A formal assessment of specific geographical areas or subpopulations or sectors or parts of the health system in which the burden of disease is especially high or the current TB efforts are low and that warrant increased attention including greater investment of financial resources and/or reallocation of resources to focus on more effective, higher impact interventions.
- A status implementation of previous Epi review recommendations
- An M&E investment plan with specific recommendations and related technical assistance needed for the improvement of measurement of TB trends in Sri Lanka.

3 Methods

Assessment methods comprised of continual desk/document review of TB program data, documents and forms, an in-brief meeting with stakeholders, consultation interviews with key stakeholders including staff of the Ministry of Health, NPTCCD, and office of vital registrations; facility visits to view data collection, quality, flow and systems in the field as well as consult with TB health care providers in public and private sectors; the use and implementation of a standardized WHO checklist of TB surveillance standards and benchmarks, data extraction from both paper and electronic databases; as well as the development of an investment plan based on findings. All analysis was conducted using Microsoft excel version 16.72, Stata 17.0 SE (StataCorp LLC, College Station, TX) and mapping for spatial patterns using Tableau creator (2023.1 Tableau Software LLC, Seattle WA) and Google Earth maps. A final de-brief meeting at country level and WHOcountry office level wereheld at the end of the assessment. Slide deck presenting summary analysis and findings pending final analytical report were also disseminated to all stakeholders through the NPTCCD.

3.1 Agenda:

Discussions were held with NPTCCD staff,and other relevant stakeholders in order to finalize the agenda for the exerciseand to complete the checklist with regards to Sri Lanka's national TB surveillance system. A full itinerary for the in-country work is as shown in **Appendix 2**)

3.2 Data collection tool and Interview checklist:

In this review and analysis, the WHO Standard Benchmark and Checklist tool was utilized as a guide to gather information during consultative interviews. The checklist comprises of two

basic sections (Part A and Part B). Part A focuses on assessing the characteristics of the TB surveillance system, while Part B comprises of thirteen standards and associated benchmarks that assesses whether a country's TB surveillance and vital registration system satisfies the associated benchmarks using recommended methods as described in the user guide[12]

The checklist of TB surveillance standards and benchmarks, the associated user guide and the methods to be used are openly accessible online and were shared with the Country team prior to the checklist implementation and in-country field visit.

3.3 In-brief:

An inception meeting entailing a briefing presentation followed by discussions was held at the beginning of the visit with staff of the NPTCCD under the leadership and direction of NPTCCD director. Courtesy calls and discussions were also heldwith the WHO Country Representativeto establish and reiterate the purpose of the mission, the application of the checklist and the preliminary findings from the epidemiologic review. An inception report was also shared with the Sri Lanka Country team.

3.4 Data and data sources

In practice, Sri Lanka uses both paper-based, and electronic data collection and reporting systems (Electronic Program Information Management System- ePIMS)for aggregating specified TB data. ePIMS includes modules comprising of -the patient registration,notification and contact screening, treatment, follow up,lab investigation, drug stock, MDR-TB, a dashboard, and geographic information system (GIS) modules. These databases were assessed to conduct the epi review and impact analysis, alongside excel database already provided.Various methods were used to collate and analyze the data, including a desk review of documents, collection of data during consultation interviews using the checklist, and a review of all datasets either held at or made available to the national programme. Additionally, other relevant data sources were assessed for TB risk factors, Sri Lanka's patient pathway analysis report, TB quality assurance results, GeneXpert utilization data, OPD attendance and presumptive TB data from sites other than DCC, HIV/AIDs info and status, health observatory and expenditure data amidst others.A complete list of the documentation,documents sourced, reviewed and utilized for data gathering, cross

[12] Standards and Benchmarks for Tuberculosis Surveillance and Vital Registration Systems, Checklist and User Guide, WHO 2014 https://apps.who.int/iris/bitstream/handle/10665/112673/9789241506724_eng.pdf;jsessionid=511ACB4FF044EC938177A1AA06FB5526?sequence=1

verification, for report writing and data used for the entire assessment are provided in **Appendix 4**. The completed checklist is available in **Appendix 1**.

3.5 Core indicators for analysis

This is a comprehensive review and as such will comprised of trends and time series plots of core indicators including but not limited to; TB estimated incidence and prevalence; TB case notification; TB case notification rates; TB mortality; Year to Year Percentage change in TB notification rates per 100,000 population; Male Female ratio; Ratio of 0-4 to 5-14 years; Childhood TB notification; TB notification in prisons and private health facilities; GeneXpert coverage and testing; GeneXpert versus presumptive data percentages; Proportions of Rifampicin resistant among DS TB cases; DRTB treatment coverage; DS and DRTB treatment outcomes, TB preventive treatment coverage among risk groups including children and persons living with HIV (PLHIV); HIV testing, HIV positivity rates, ART uptake and CPT coverage rates versus targets. These indicators were further assessed at subnational levels (district), and disaggregated by disease types (bacteriologically confirmed, clinically diagnosed and extrapulmonary), by age groups and treatment category (new and retreatment). Other external indicators assessed include percentage contribution of presumptive TB screening from OPD clinics, under 5 mortality rates (U5MR), trend in prison inmate TB data, GDP for Sri Lanka, trend in out-of-pocket expenditure among general population seeking health care services, demographic changes based on age and sex, and overall TB financing and percentages of expenditure. Put together, these indicators were collectively reviewed to provide plausible arguments to the current TB burden in Sri Lanka and identify areas of priority attention.

3.6 Plausible Hypothesis

Considering the WHO estimates of incident TB cases viz-a-viz the current annual decline in TB notifications, there is a plausible gap in case detection, which may suggest the continued decline observed in the previous epi analysis may not be a true decline based on program efforts, but more of that context-specific strategic approaches are required to facilitate an increase in TB detection to meet program targets. While reviewing program efforts or any other external non-programmatic factors that may explain observed changes (declining disease trend), plausible argument to be investigated is whether current program efforts especially expansion of GeneXpert services and changing population dynamic with increased elderly population, impact on TB incidence in Sri Lanka and have helped sustained current

decline in TB notifications. Hence, for this review, the working hypothesis is; *Program efforts have helped sustain current annual decline of incident TB notifications, however Tuberculosis in Sri Lanka is in decline due to low screening, diagnostic delays and under-reporting of TB cases detected among public and private sector providers*. The design to test this hypothesis will be based on historical control. Trends in time and space for TB treatment coverage and other data from and non-TB program factors including determinants of TB will be analyzed.

Given the observed government commitment both in human and financial resources, as well as donor funding support continually received specifically from The Global Fund, it is safe to assume that impact focused investment needs that will be identified during this review will receive the needed support to fully implement the suggested interventions.

3.7 Field visits

Field visits was carried out to sixteen (16) sites located in three provinces (Western, Eastern, and Sabaragamuwa)and three districts (Central Colombo, Batticaloa, and Rathnapura). The type of facilities visited include Government owned, private and prison facilities. Sites include the National TB Reference Laboratory, a central prison, one (1) heavily patronized privately owned hospital, one (1) pediatric clinic, one (1) general practitioner (GP) facility, two (2) teaching hospitals, three (3) base hospitals, one (1) primary medical care unit (PMCU), four (4) DCCs, and the vital registration office of the ministry of health. See table below for list of facilities and their locations. Consultation interviews using the guided benchmark checklist was deployed at these sites (see **Appendix 3**for list of all people met).

S/no	Name of Facility	City/District	Province	Type of facility
1	Colombo DCC	Central Colombo	Western	Government DOTs
2	Welikada Prison			Prison
3	Asiri Medical Hospital			Private
4	Lady Ridgeway Children's clinic (hospital)			Pediatric clinic
5	Gampaha DCC			Government DOTs
6	Dr. Hazari GP	Colombo Municipal council/ Colombo		General Practitioner
7	Vital Registration office	Battaramula/Colombo		Vital statistics
8	Ratnapura DCC	Ratnapura	Sabaragamuwa	Government DOTs
9	Base Hospital Eheliyagoda			Government DOTs
10	TeachingHospital Ratnapura			Teaching Hospital
11	Batticaloa DCC	Batticaloa	Eastern	PHC

12	Teaching Hospital Batticaloa			Teaching Hospital
13	Base hospital Valachchenai			Government DOTs
14	Base hospital Kaaththaankudy			Government DOTs
15	Thiraimadu PMCU			Primary Health care unit

TABLE 1: FACILITIES VISITED FOR EPI REVIEW 2023

3.8 Stakeholders consultation interviews

Various stakeholders were consulted including MoHstaff of Planning and Statistics and NPTCCD core staff, Program and M&E staff of the Global Fund Principal recipient (SCI), other TB implementing Partners, the GF Country Coordinating Mechanism Secretariat, of the Ministry of Health and Population. TB staff and health service providers at facilities visited in both public and private health sectors. TB records were reviewed at this level to assess data collection methods, data quality, consistency, data flow and feedback mechanisms in place.

3.9 Epidemiological review of TB disease:

The collation and analysis of additional TB surveillance at national and sub-national levels, and more general health system data were also undertaken. Data available for this review consisted of; the national level aggregate TB notification and treatment outcome datasets drawn from nationally aggregatedexcel based formats and ePIMS data, and the WHO global database was used to examine incidence and mortality trends in TB and TB/HIV over time,the Sri Lanka patient pathway analysis to access diagnostic delays, facility-based data examined during field visits,and World Bank data for TB- related determinant data and under-5 mortality data.The entire review, categorization of findings, key recommendations,and development of the M&E investment plan, wasdeployed using the section guide of process thinking approach which comprises of four key areas- (i) Surveillance and data management, (ii) Data quality, (iii) Finding missing cases, and (iv) Key populations. This offers a systematic approach in the identification and implementation of strategic interventions that will be valuable to improving Sri Lanka's TB surveillance system. See figure below for details.

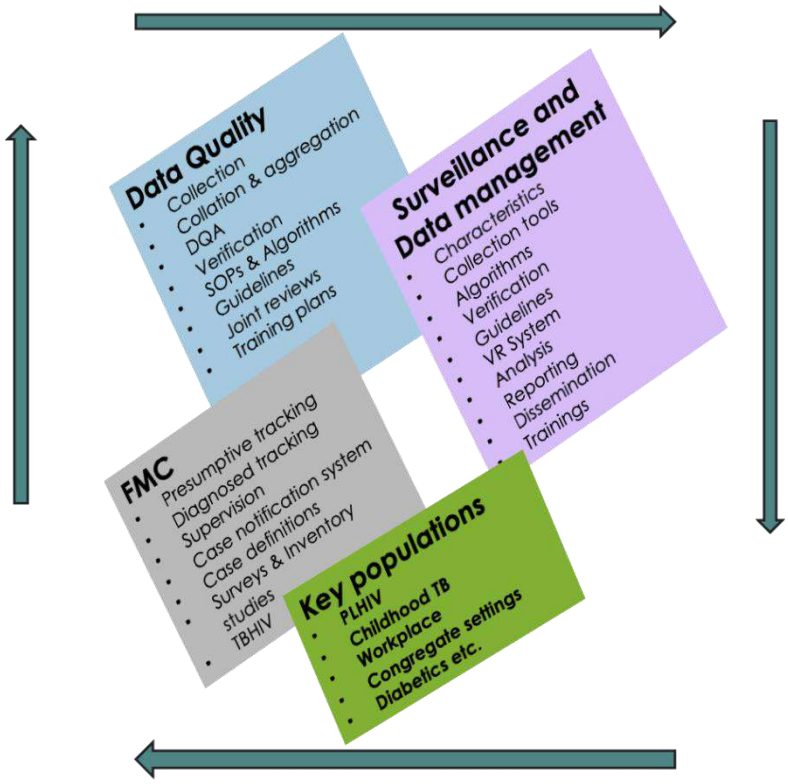


FIGURE 1:SECTION-GUIDED PROCESS-THINKING APPROACH

The key **limitations** of the available data were as follows:

- Limited use of presumptive TB register in >90% facilities visited. Possible reasons includelimitations in supply and distribution, no stipulated adherence to use, substitution of presumptive register with OPD register which does not sufficiently capture relevant TB data elements, or a lack of assessment of its availability and use during routinely conducted supervision.
- The non-aggregation of presumptive TB data from presumptive registers at facility level pre-empts the determination of the total number of presumptives having access to bacteriological examination or total TB cases diagnosed among those tested, hence investigation rates could not be determined
- At present the lack of acomplete unique identifier for both drug susceptible and drug resistant patients pre-empt the full determination of gaps in DS and DR-TB enrolment.
- Vital registration system though it fully captures causes of death (COD) in line with ICD 10, however, 40-50% of COD are still ill-defined, and TB mortality has been aggregated for a single year (2019). Given the modality in place for TB cohort analysis within the NPTCCD which assesses patients registered in the preceding year, in contrast to TB death captured within a given year by the vital registration office, a moving average of at least two years mortality data is required to for an epi review of

TB mortality. Therefore, since the vital registration has only been able to compile TB deaths for a single year, a comprehensivemortality analysis could not be carried out.

3.10 De-brief:

A de-briefing presentation was held on August 23 with the WHO and on August 25 with the NPTCCD, MoH and representation from the Professional Colleges including College of Pulmonologistswhere preliminary analyses were shared. During the debrief with NPTCCD, a practical stakeholder's approach to generating recommendations was applied to ensure stakeholders concurrence with final recommendations (see **appendix 5** for snapshot of stakeholders' recommendations). De-brief presentation is also available and embedded in **appendix 6.**

4 Assessment of surveillance of TB cases and deaths in Sri Lanka

4.1 Checklist of TB surveillance standards and benchmarks – Rationale

Surveillance of TB disease and deaths is essential for effective TB prevention and control. Timely, accurate, and complete recording and reporting of TB cases along with analyzing trends in the number and distribution of TB cases is a necessity to monitor and evaluate TB prevention and control programs. It follows that a reliable TB surveillance system is therefore needed to guide policy decisions and develop national strategies and plans to track and report on progress in control efforts, including progress towards national or global targets.

In addition, a robust VR system, which includes causes of death, is needed to understand, and monitor trends in mortality due to TB, identify health inequalities and priorities, and evaluate the impact and effectiveness of health programs, including TB control and prevention programs.Vital statistics are also needed in TB control to understand emerging health challenges and their inter-relationship with tuberculosis (e.g., HIV/AIDS, COVID-19), to accurately measure progress towards global targets (e.g. the Sustainable Development

Goals).The best methods for measuring TB incidence and mortality are through routine surveillance and VR systems that capture reliable and comprehensive data about new cases of TB and TB deaths. Having robust systems in place means TB notifications can be considered a direct measure, or at the very least, a proxy of TB incidence and mortality.

To assess a national TB program's ability to measure TB incidence and mortality, TB experts from the WHO Global Task Force on TB Impact Measurement publishedthe "Standards and Benchmarks for TB Surveillance and Vital Registration Systems" checklist in 2012, following a two-year development and field-testing phase). This checklist is designed to be uniformly implemented in all countries to assess strengths and weaknesses of national TB surveillance systems and provide guidance to improve these systems so that TB notifications can more closely measure actual TB incidence and mortality. The checklist consists of 13 standards and their associated benchmarks, with nine standards related to measurement of TB cases and one related to measurement of TB deaths. The final three standards are supplementary standards that can be used to assess whether a country's TB surveillance system provides a direct measure of the number of MDR-TB cases, the number of HIV-positive TB cases, and the burden of pediatric TB.

Note that the Checklist only assesses the surveillance system's ability to provide a direct measure of TB incidence and mortality. It does not assess the system's ability to fulfil programmatic requirements. The benchmarks are therefore different from those used in defining programmatic targets. Based on the assessment, gaps and unmet M&E needs in national surveillance systems can be identified, and then strategies and interventions that impact the most can then be developed to address the identified gaps and needs.

4.2 Characteristics of the TB surveillance and vital registration systems

Data collection systems and Reporting

For routine TB surveillance, Sri Lanka continues to use a combination of paper-based data collection and reporting systems, as well as a well-designed and robust electronic data system -Electronic Program Information Management System- ePIMS. ePIMS is functional at district level and comprises of multiple modules including; patient registration,notification and contact screening, treatment, follow up, lab investigation, drug stock, MDR-TB modules. An ePIMS dashboard and a geographic information system (GIS) for data visualization and mapping. Presently, these modules are nearly fully functional only in one district (Colombo DCC) with varied and limited levels of functionality in the other twenty-five district chest clinics. Currently, there is no designated health information and IT manager at NPTCCD that

manages and updates the ePIMS IT structure or ensures support for all modules to be adopted and used by all DCCs. In both paper and electronic formats, standardized data collection forms are in use, however, presumptive registers are unavailable and under-utilized at majority of facilities visited.

When TB data in ePIMS was compared with the district registers for three districts visited, it is worth to note that data was consistent between nationally aggregated data and quarterly reports, suggesting, complete entry of historical data on ePIMS. However, data on presumptive TB cases could not be fully assessed on ePIMS since presumptive registers are underutilized at facility levels. As the NPTCCD continues to scale up in both module content and scope of module utilization across DCCs, it is imperative the NPTCCD endeavors to maximize the use of the ePIMs modules and ePIMs at all DCCs for ***program-level*** data management, analysis, programmatic planning, monitoring, and decision making. It is also critical the NPTCCD deploys an HMIS/IT support specialist to facilitate the refinement and harmonization of indicators on ePIMS, interoperability across modules, full adoption of ePIMS module content use by DCCS and provide continued IT support to the M&E team of the NPTCCD.

At facility level, a centralized TB patient treatment initiation is in practice with only the 26 DCCs initiate TB treatment and utilizing a district TB register. Hence, TB treatment registers are not in use at base hospitals, general hospitals or teaching hospitals. TB cases diagnosed at base hospitals, teaching hospitals and private hospitals are referred to DCCs for TB treatment initiation posing risk for patient initial treatment loss to follow up due to proximity to DCC facility. Aggregated and annual TB notification data from DCCs and TB monitoring data from facilities providing TB continuation of treatment are pooled and reported at district level by DCCs.

A topographical analysis of patients nearness and access to TB diagnosis and treatment initiation was conducted during this review using a 10 kilometer buffer zone distance to functioning AFB microscopy centers, and a 10-20km buffer zone distance between DCCs where TB treatment is centrally initiated to the population density.

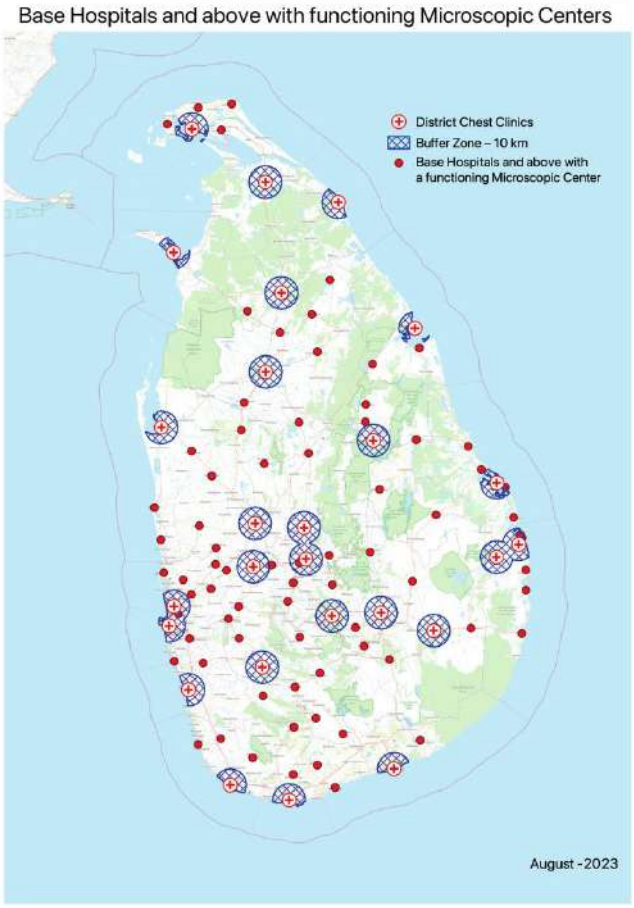


FIGURE 2:MAP OF DCCS WITH 10 KILOMETER BUFFER ZONE DISTANCE TO AFB MICROSCOPY CENTERS LOCATED IN BASE HOSPITALS

While findings as shown in figures 2 above may suggest a good distribution of AFB microscopy in high population density areas, figure 3 below suggest patients experience a significantly limited access to DCC centers for TB treatment initiation with travel at an imprecise average of 20 to 50km, which poses a risk for pre-treatment initial loss to follow up, under-notification and treatment interruptions.

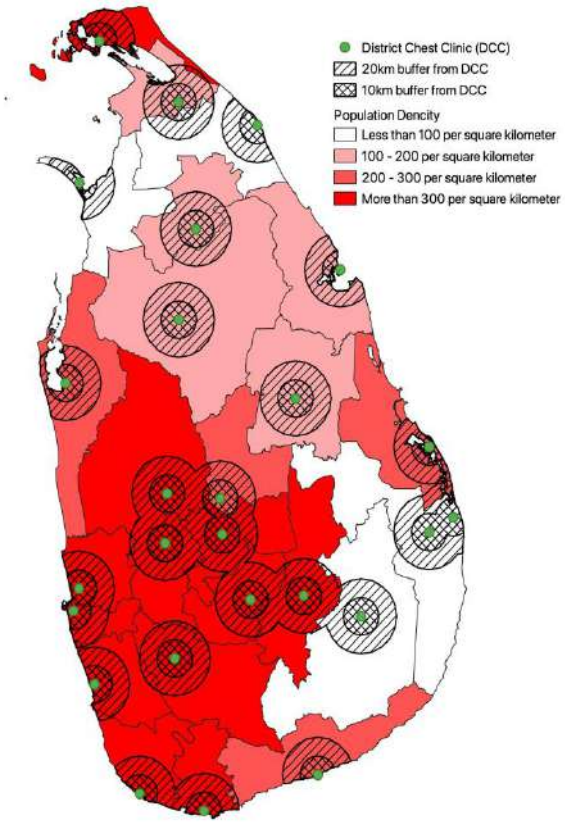


FIGURE 3:: MAP OF DCCS 10-20KMBUFFER ZONE DISTANCE RELATIVE TO POPULATION DENSITY

Therefore, a patient-centered decentralized system is strongly encouraged where patients can be initiated on TB treatment at the first point of entry to accessing care such as Base Hospitals, General Hospitals and Teaching Hospitals. Since ePIMS is yet to be fully optimized and optimally utilized by DCCs, the reporting rates in terms of completeness and timeliness could not be ascertained during this review.

Case-based patient level data is collected using the ePIMsand paper based data forms at district level and aggregated in summaries at both district and national (NPTCCD) levels. Among the 26 DCCs, only DCC Colombo utilizes a significant proportion of the ePIMS modules including patient registration and the program level data components excluding the laboratory components. The other 25 DCCS are still only able to utilize the patient registration module. In comparison to the 2020 Epi review findings, this suggest a very slow adoption or expansion of the ePIMS case-based TB surveillance system, probably due to health facility staff resistance to adopt ePIMs, limited training on ePIMS, non-specified/designated staff to manage ePIMS, track utilization and provide IT support structure for ePIMS use, or a complete preference for paper-based formats. Patient level data available on the ePIMS is yet to meet the standard requirements of patient confidentiality and it still

entails patient identifiers such as full names. However, there is password restricted access at national and district levels. For purposes of confidentiality, names of patients should be restricted to facility levels within treatment registers and treatment cards, and no further beyond this level.

Contributing Health Sectors

Since TB treatment is initiated at only DCCS and TB data is collated at district level, aggregated, and submitted to the NPTCCD using paper formats and ePIMS, data disaggregated by facility type e.g., private and public types of facilities could not be ascertained. Additionally, the underutilization of presumptive data preempted the epi review team from assessing investigation rates among patients attending OPD clinics. To estimate presumptive TB cases among OPD attendees, the 2022 annual OPD attendance records at 206 hospitals (District Hospitals, District General Hospitals, Base Hospitals, and Teaching Hospitals)excluding DCCs in the country was assessed to estimate the number needed to screen, access to diagnosis 3and access to treatment for TB. The 2022 records show that 51,167 patients were referred for AFB microscopy test, but unable to decipher how many patients were symptomatically screened for TBamong 12 million OPD attendees. Additionally, out of an unknown number that were tested and have documented AFB lab results, 1,212 TB cases were diagnosed. Using the 51,167 presumptive TB cases referred for AFB test as a reference and proxy denominator, the presumptive: TB case ratio is 100:2.4 or 2.4%which is very low relative to the expected of 10:1.See figure 4 below for systematic analysis of the 2022 OPD records. Furthermore, when compared with the 12,355,029 OPD attendees and under the assumption that all OPD attendees were screened for TB, the number needed to screen (NNS) to identify a single case of TB is 10,193. Though Sri Lanka is perceived as a low burden country, this number needed to screen deduced from 2022 OPD screening activity, further stimulates the need to conduct more detailed research to determine if the NNS is truly high. This finding is equivalent to a case notification rate of 10 per 100,000 population. Together, this may suggest low TB suspicion, low TB screening activity, patient loss to follow up after referral for AFB test among identified presumptive TB cases, limited access to TB diagnosis using GeneXpert which has a higher sensitivity compared to AFB microscopy, or probably sub-optimal knowledge of identifying presumptive TB cases. This further confirms the findings from the TB patient pathway analysis conducted in Sri Lanka which suggests diagnostic delays and protracted turnaround time for TB diagnosis ranging from a mean of 4 days within DCCs to 26 days in other Government facilities such as

Base Hospitals, and in private practice, with some patients visiting the OPD two to five times before being diagnosed.

Though imprecise, to find the missing 5,700 TB cases in Sri Lanka, and going by the current data of 51,167 presumptives among OPD attendees referred for TB test yielding 1212 TB cases, approximately 2% of OPD attendees screened should yield 247,000 presumptives, which would yield approximately 5,900 TB cases. Therefore, the NPTCCD needs to ramp up the use of presumptive registers and sensitize OPD doctors on the need to routinely screen patients for TB, ensure complete referral and feedback for all GeneXpert/AFB tests/Chest X-rays tests requested, and their documentation in the presumptive register.

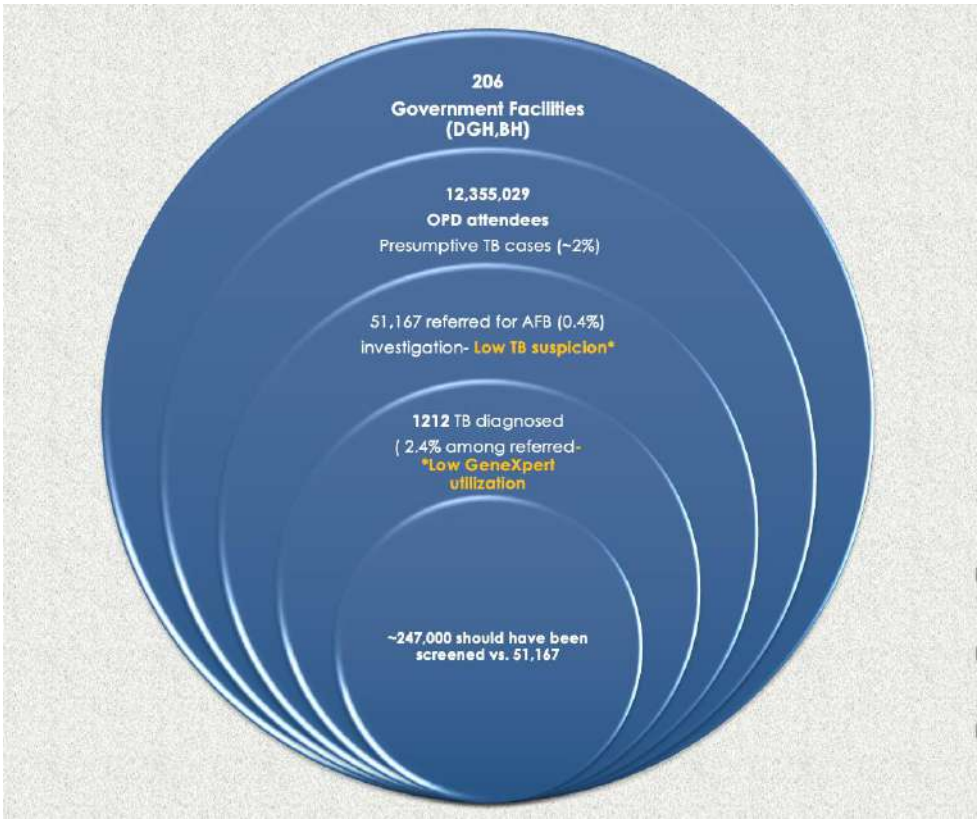


FIGURE 4:ANNUAL OPD ATTENDEES REVIEW FOR TB IN GOVERNMENT FACILITIES EXCLUDING DCCS IN SRI LANKA 2022

Data tools

In all facilities visited majority had the national TB guideline in place for guidance in case definitions, documentation, or instructions.Standardized TB data collection tools and forms are in use at service delivery points at most facilities visited; however, presumptive TB registerswas not sited or in use at more than 90% of the fourteen (14) hospitals visited. Additionally, outdated and ad-hoc laboratory data collection tools were in use in some facilities due to limited supply and availability of standard NPTCCD recording and reporting

tools. Therefore, the number of presumptives having access to GeneXpert tests or diagnosed with TB could not be fully validated to identify the potential gaps that may exist between presumptive TB cases identified, the numbers who had access to TB diagnosis and number of TB cases registered.Assumptions for the unavailable presumptive registers at facilities visited include supply issues, the role of completing the presumptive register not adequately designated at facility level, non-adherence to its use and lack of understanding of its usefulness. In addition, in all facilities visited, OPD registers were used in place of presumptive register, however, it does not capture standard presumptive cases information required for program planning.Hence, potential under-diagnosis, initial loss to diagnosis and initial pre-treatment loss to follow up cases exists. There are considerations by the NPTCCD to include an electronic Presumptive register in the ePIMS. But then, access to ePIMS would have to be made available to all hospitals including Government and private hospitals to capture presumptive TB data at point of contact in the facilities.

Funding and Governance

TB control is a priority of the Government of Sri Lanka including the MoH, with support for TB surveillance through provision of salaries to NPTCCD staff. TB surveillance activities aresignificantly donor driven, with most support from the Global Fund and WHO.To implement the recommendations and investment plan captured in this report to find the missing cases and enhance the capacity of the surveillance system to adequately capture TB burden in Sri Lanka, the NPTCCD will require adequate financial support to complement the efforts of the Global Fund and WHO.

Human Resource

The NPTCCD surveillance team is equipped with two technical staff who are both physicians- (i) one Planning/Surveillance/M&E lead who is a consultant community medicine physician and epidemiologist engaged on full time and end-post(ii) aM&Emedicalofficer that both carry out significant monitoring and evaluation functions for the NPTCCD. There is one Statistician, twoData managers and three development officers.There is no designated health management information IT expert to provide rigorous and in-depth analysis of the ePIMS architectural structure and support to sub-national teams utilizing the ePIMS platform. At facility level, there are PHIs to support patient follow up and tracking to initiate on TB treatment, however, since presumptive registers are not in use at most facilities, tracking of presumptive TB cases, ensuring complete referral and lab result documentation for TB diagnosis and linkage to treatment, becomes difficult. The NPTCCD needs to urgently ensure presumptive registers use are fully adopted, its completion duly

assigned and presumptive TB patients are fully tracked within facilities and in communities with support of the PHIs.

Data Quality

Standard operating procedures for data management including collection, storage and identification of data sources are available at national level within its training manuals for recording and reporting. Quality assurance procedures such as on-site-data validation (OSDV) exercises are expected to be conducted within the first month after the end of each quarter, however, it is not routinely conducted as there is limited human and financial resources to implement the exercise, and there are no clear SOPs for data quality assurance. On occasions where data verification was conducted at national level, immediate feedback was provided to facility staff, however, there is no systematic data verification and feedback mechanism in place especially at district levels. Data managers at national level routinely review surveillance data quality and provide regular feedback and follow up on action items to improve the overall quality of the data. Some validation checks and rules are in place for electronic data systems (ePIMS) including an auto aggregation of follow up test results, for which if follow up results are not entered, the system preempts order of continuation drugs. It also contains contact screening reminders to assist DTCOs to conduct contact screening for newly enrolled patients. However, the surveillance team do not have standard data validation SOPs and tools and do not conduct periodic data audits or on-site data validation (OSDV) visits.

To align with the number of district chest clinics, twenty-six (26) supervisory visits are expected to be conducted annually by the NPTCCD M&E team comprising of 3-4 persons visiting three facilities per district, conducted by the NPTCCD but not fully implemented due to conflicting TB program activity implementation. Thissub-optimal conductof supervision in frequencyfrom national, provincialor district levels, as well as the use of supervisory checklist that is not extensive enough to capture key areas for supervision e.g., availability and use of presumptive registers, are likely to result in under-utilization of presumptive registers, tracking of presumptive TB cases for TB diagnosis and missed notification of TB cases.TB district review meetings that address data quality reporting, comprehensive discrepancy check, and feedbackwere previously conducted annually at district levels under the leadership of the DTCO in collaboration with clinicians, PHIs and public health laboratory technicians, and discontinued due to limited funding and reprogramming of funds for high priority TB control activities. At the end of this Epi review, funding for district

review was re-instated through support of Global Fund. Despite these challenges in surveillance data quality assurance, data is usually ready for analysis by the end of the first quarter of the following year, with excellent descriptive epidemiological report produced in form of an annual report and consistent data between nationally aggregated and quarterly data generated at district levels.

Surveillance planning

The NPTCCD has developed a national strategic plan 2021-2025 which entails a section for M&E planwith written goals and core objectives for improving monitoring and evaluation of TB activities. However,activities specific to surveillance, monitoring and evaluation are not specified or budgeted in the NSP or as a stand-alone M&E plan to clearly monitorthe implementation of National TB programme activities aimed atstrengthening the existing surveillance, monitoring, and evaluation system.Aside the Global Fund specific activities for surveillance, monitoring and evaluation, there is also no long term national financial plan and budget to support TB surveillance activities. Regardless of this planning challenge, through support of Global Fund and WHO, the NPTCCD organizes trainings on all modules of the ePIMS system annually, including trainings on R&R, supervision, treatment counselling, treatment interruption management and contact tracing. The NPTCCD will benefit more strongly from revisiting and reviewing its current supervision checklist, developing SOPs to improve data quality, designating an IT specialist to provide technical support and management of the ePIMS system, review its ePIMS system to enhance current module content, validation checks and automate aggregated data analysis, and create an interoperable interface between the various modules contained in the ePIMS, amidst other investment plan activities contained in this report.The NPTCCDis commended for its continued commitment, efficient planning interest in improving its TB surveillance system, having successfully conducted three previous epidemiological reviews including this review over the last five to nine years.

Laboratory surveillance

Sri Lanka has a national reference laboratory, four intermediate culture labs, and thirty-one (31) GeneXpert machines. The National TB reference Laboratory (NTRL) is fully functional with level 3 Biosafety unit. It provides a combination of AFB microscopy, GeneXpert, solid and liquid culture, DST, and Line Probe Assay (LPA) test services, as well quality assurance support to 160 AFB microscopy laboratories engaged in TB diagnostic services. There are seven biosafety units at the NTRL, but with outdated service maintenance agreements. Five out of the seven units are fully functional. Out of the 32 GeneXpert machines in the country,

three (3) are domiciled at the NTRL. The NTRL is supported by four medical doctors, a microbiologist, eleven (11) medical Laboratory technicians (MLTs) and four (4) healthcare assistants that assist with collection of sputum samples, washing and autoclaving of supply culture bottles. Among this team of staff, there is staff trained to support LPA and IGRA testing for latent TB. There is also no designated maintenance specialist for the GeneXpert machines in the country. There is no EQA for GeneXpert. EQA for AFB microscopy is expected to be conducted monthly to all AFB microscopy centers through support of the district PHLTs, however, there are varied levels of EQA support-slide rechecking, at facilities visited ranging from regular monthly EQA support at major base and teaching hospitals, to a lack of EQA activities in the recent 4months in Teaching Hospital Ratnapura and no EQA up to 12 months ago in Base Hospital Kaaththaankudy.Thirteen (13) EQA visits to AFB sites at district level is expected to be carried out by the NTRL staff annually, however, during the course of this review in August, only four visits had been successfully conducted in 2023. The NPTCCD through the NTRL staff will benefit from prioritizing AFB EQA sites visits to AFB microscopy centers with peculiar quality challenge such as low positivity rates and sub-optimal frequency of EQA support from district levels.

According to the national diagnostic algorithm and TB guidelines, AFB microscopy test is the entry point of diagnosis and GeneXpert is indicated as an initial point of test in specific vulnerable groups such as children, persons living with HIV/AIDS, presumptive MDR TB cases, and immunocompromised groups such as pregnant women and critically ill persons. Three samples are collected for AFB, one sputum sample is collected for rapid diagnostic tests using GeneXpert when indicated and two additional samples are further dispatched to NRL for SL-LPA, Culture and DST. Based on laboratory results, treatment regimen are adjusted based on the drug resistance for LPA, culture, and DST. Rifampicin resistant (RR) cases are admitted and enrolled for DRTB treatment at NHRD Welisera. Hence, a centralized DRTB management is in practice.

Following a 2023quarterly review of GeneXpert uptake and utilization rates conducted in this review for all its 31 GeneXpert machines locatedat 29 facilities including 5 DCCs, 13 General Hospitals, 4 Teaching hospitals, the NTRL, NHSL, NIHS, Prison and the Faculty of Medicine, Colombo, approximately 39% (11/31) have all four modules fully functioning, while about 45% have at an average of 2- 3 functioning modules in a four module machine. Only two facilities (NTRL and DCC Colombo) have two machines; a 4 and 16 module machine in the former, and two 4 module machine in DCC Colombo. See figure 5 below.

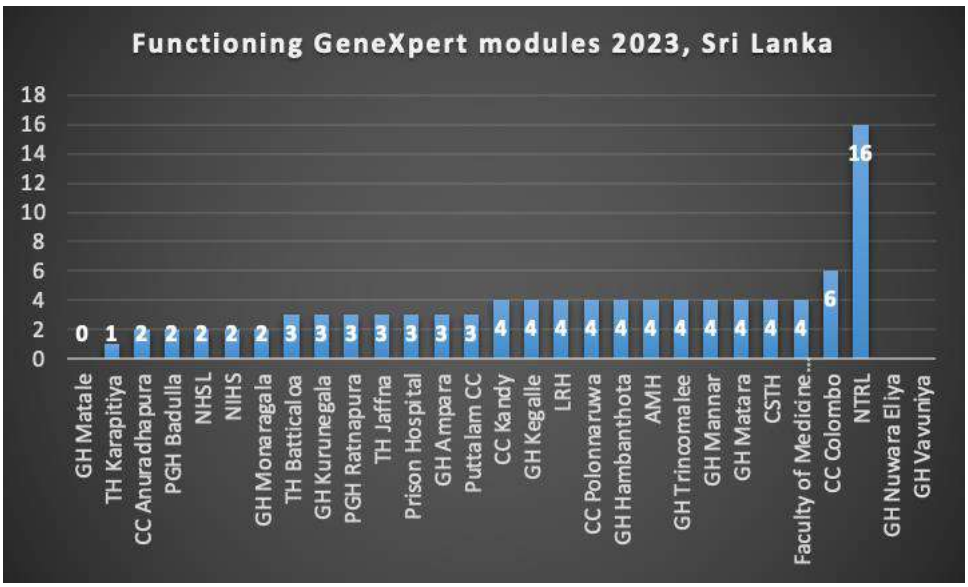


FIGURE 5: STATUS OF GENEXPERT FUNCTIONING MODULES IN 2023, SRI LANKA

The uptake rate was assessed based on number of functioning modules per site, 22 working day period per month and an average uptake rate of 3 runs per day assuming 3 rounds of test over an 8 hour working day period. On average, about 29% of all GeneXpert facilities did not process any sample for two consecutive quarters in (6 months) 2023.

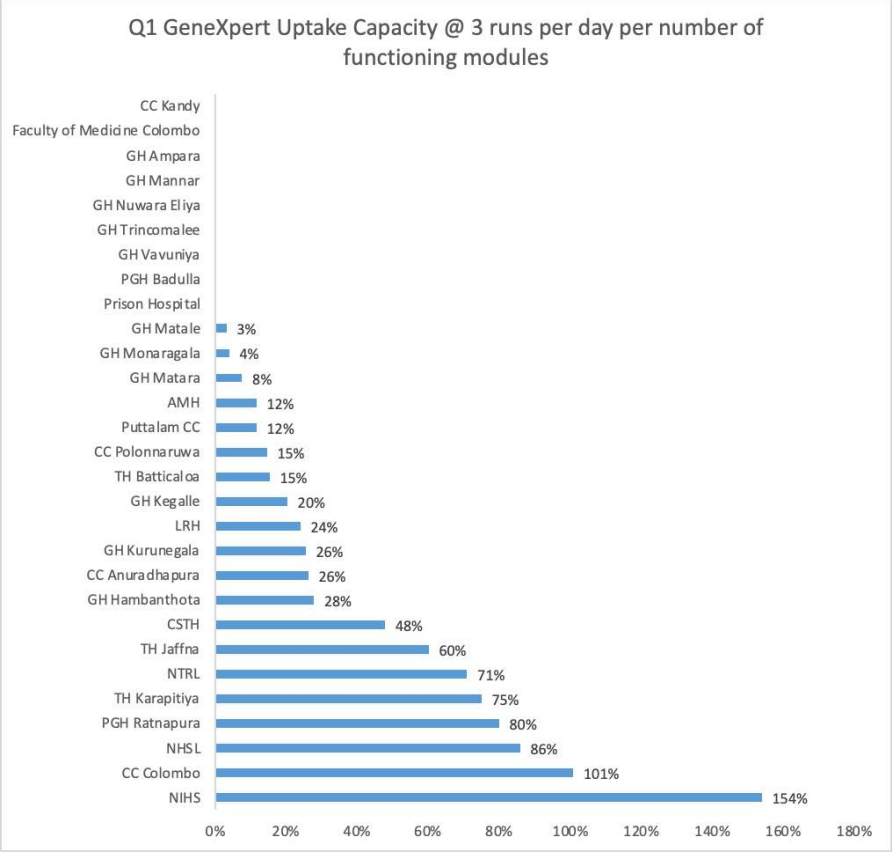


FIGURE 6: GENEXPERT UPTAKE CAPACITY, Q1 OF 2023, SRI LANKA

Based on the foregoing, only three facilities operated at optimum above 100%; NIHS in both quarter 1 and 2 of 2023, CC Colombo in quarter 1 only, and Faculty of Medicine Colombo in quarter 2 of 2023. Approximately 68% (n=21/31) of GeneXpert sites operate at <33% capacity equivalent to 1 run per day or an average of 3 samples processed per day in contrast to expected 3 runs per day or 3 times the number of functioning modules. These findings as shown in figures 6 and 7 indicate a gross underutilization of GeneXpert test as an entry point of diagnosis, and an urgent need for NPTCCD to increase efforts in sensitizing physicians to request GeneXpert tests for TB diagnosis, and a possible redistribution of GeneXpert machines to sites with strong structural support system, and high OPD attendance. Overall MTB positivity rate in quarter 1 of 2023 was 13% and 15% in quarter 2 of 2023. MTB positivity rate ranged from 1% to 46% suggesting a left tailed low positivity as a result of low symptomatic TB screening sensitivity, and a right-tailed high MTB positivity due to GeneXpert testing of TB cases already diagnosed using AFB microscopy. Thus, the use of GeneXpert as first point of diagnostic tool should be actively promoted by the NPTCCD particularly to medical officers in hospitals and OPD clinics.

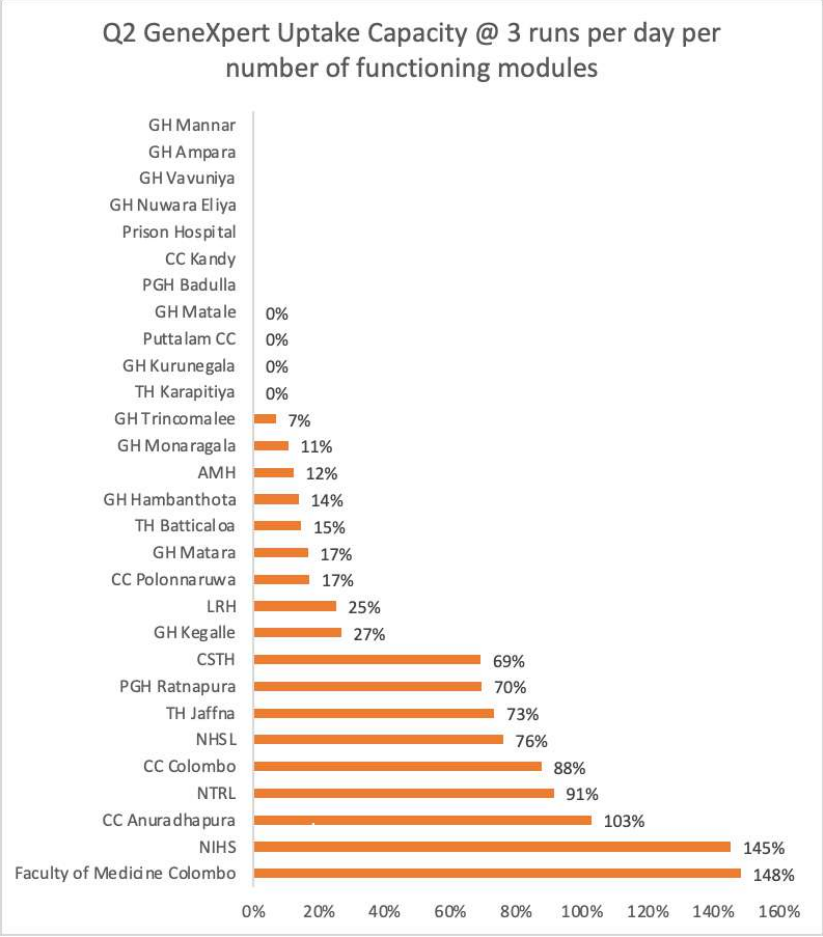


FIGURE 7: GENEXPERT UPTAKE CAPACITY, Q2 OF 2023, SRI LANKA

RR cases detected through GeneXpert tests are commenced on DR-TB treatment at DCC Gampaha, whilst awaiting further sputum evaluation and ancillary laboratoryresults. Most of the results are received within a period of one to two months. A DR-TB register is in use at DCC Gampahafor DR-TB treatment monitoring.

TBHIV surveillance

In terms of TB/HIV collaborative activities and surveillance, there is a strong integration of TB and HIV services where TB/HIV patients receive TB and HIV health care at all facilities visited.However, HIV status were documented for approximately 80% of TB patients registered in 2022which is a decline by 17 points compared to 97% in 2021.

TB Mortality burden

Sri Lanka's vital registration system is fully established, and it captures 100% of causes of death, however, at least 40% of causes of death are ill-defined. This challenge make accurately measuring TB deaths difficult. A preliminary review of 2019 VR data suggests plausible lower TB-related death rate recorded in NPTCCD surveillance compared to VR (567 vs. 675)TB-related deaths in VR 2019 data records. TB deaths as a cohort report from the NPTCCD is derived from TB patients registered in the preceding year only that could have died within the year of registration or at least in the first six to nine months of the following year, while TB related deaths in the VR system is a flip such that it captures patients that died within a given year onlyand could have been registered in the preceding year or registered in the same year under review; hence categorized as a different cohort by the NPTCCD. Therefore, it is insufficient to conclude given the overlap of TB treatment registration cohort across two calendar years in the VR system. As such, a moving average of TB-related deaths across multiple years should be analyzed by the NPTCCD to estimate the gaps that exist, if any, between annual TB deaths per NPTCCD report and annual TB-related deaths per VR report.

Table 2 below highlights a summary of the TB surveillance system in Sri Lanka, specifically thecharacteristics of the surveillance systemusing part A of the checklist. Sections requiring improvement are highlighted in shades of red, orange and beige in descending order of concern.

SRI LANKA TB EPI REVIEW PART A CHECKLIST SUMMARY

Description of the TB Surveillance System		Comment
A1	System for recording	NPTCCD has advanced in progress in its electronic data systems since last Epi review. with full function of national ePIMs at Central Colombo and gradual expansion to full use to other DCCS. However, a significant section of the ePIMS modules are not utilized e.g drug stock, , Lab investigations
A2	Standardized Data collection forms and tools	Standardized forms and tools in use. **Presumptive register in very limited use** (> 90% of facilities sampled for visit not utilizing presumptive register either for notification and program planning). Assumptions include supply issues, unclear designation of staff to complete presumptive register. In some facilities visited, OPD registers were used in place of presumptives, however, it does not capture standard presumtive cases information required fro program planning.Hence, potential under-diagnosis, pre-diagnosis loss to follow up and pretreatment loss to follow up exists. Efforts are in place to finalize the inclusion of an electronic Presumptive register in the ePIMs
A3	Cases/care providers excluded	TB cases/care providers not excluded. Non-NTP providers are included in National HMIS. NTP engaged facilities and other facilities not engaged with NTP that directly provide TB referral services assessed, but proportion of referrals could not be determined due to low to non-utilization of presumptive register. TB notification is a legal requirement.
A4	Data type available nationally	Case based data for majority of NTP sites through the e-PIMS and paper based reports are available and aggregated in summaries at the NPTCCD
A5	Frequency of Data Transmission	Daily data entry, monthly transfer from branch clinics and base hospitals to DCCS, and quarterly data transmission from district to national; using paper and electronic formats
A6	Levels of Data Verification	Moderate verification systems in place at district, and national level. Occasional verification at district level by Public Health Information officers when conducting contact tracing, while DTCOs crosscheck occasionally when collecting quarterly data to be summarized . No procedures or SOPs for Data verification in sighted
A7	Quality Assurance Procedures	Validation checks occasionally done at national level by data clerks.
A8	Systematic feedback on Data quality	Weak systematic Feedback mechanism in practice and follow-up not consistent
A9	National data readiness for analysis and reporting	Three months after a preceding calendar year (April)
A10	National guidelines for recording and reporting	Available only in training materials, and contained in TB manuals domiciled at facilities
A11	Training plan for Data collection and reporting	Training plan for surveillance exist
A12	Frequency of training	Scheduled trainngs in place
A13	# staff in National TB surveillance	Eight NTP staff supports the TB Surveillance M&E : Consultant physician as Planning, M&E Lead and epidemiologist, 1 Technical officer/M&E and 3 Development officers , 2 Data managers and 1 statistician
A14	Annual report produced and disseminated	Yes, in form of annual reports
A15	Written goals of the surveillance system available	Written goals incorporated in M&E plan section of NSP
A16	Confidentialty policies and procedures	No; names are available across all levels including national level but with password encrypted restricted access control
A17	Financial plan	Partially; as contained in GF plan, but not available as a NPTCCD surveillance M&E plan or long term financial plan and budget
A18	TB surveillance system evaluated	Within the past 5 years (specifically 3 years ago in 2019)

Color code	Very good
	Good achievement and requiring minimal adjustments
	Moderate achievementrequiring significant action
	Requiring urgent attention

TABLE 2: CHARACTERISTICS OF TB SURVEILLANCE SYSTEM, SRI LANKA, CHECKLIST PART A

4.3 Checklist of TB surveillance standards and benchmarks – Summary results

Out of the 13 standards and benchmarksassessed using the standardized WHO checklist, six (6) were met in areas of; case definition in accordance with global standards, capturing of minimum set of variables for reported cases, 100% submission of reports from all twenty-six districts,internal consistency of paper-based sub-totals with quarterly reports at national level for a 100% of sampled sites, DRTB surveillance in terms of documentation of rifampicin susceptibility status for >75% of TB cases and the direct measurement of HIV infection prevalence among TB cases. Five (5) benchmark areas were partially met, including; internal consistency of electronic based systems based off the presence of some validation checks at national level and a significant proportion of case records assessed at sampled sites, the

progression in some benchmark ratios e.g. Pulmonary vs. Extra Pulmonary in some districts, measurable access to health coverage based on health and social insurance available mostly to government workers though associated with high percentage of out of pocket health expenditure of 46.58%, the inability to assess timely reporting, and the partially-functioning vital registration system that captures 100% of causes of death (COD) however approximately 40-50% of the COD are still ill-definedby the VR unit. The VR system is also currently incapable to assess a trajectory of year to year change in TB mortality. The external consistency for childhood TB notification for children aged 0-14 years old at 2.2% is not within accepted range of 5-15% for low-income countries, and the overall regression from 0.9 to 0.4 in child TBratio between 0-4 and 5-14 years (expected range of 1.5 - 3.0) were considered as two (2) critical areas unmet.See tables 3 and 4 for status of benchmark checklist achieved by the NPTCCD Sri Lanka in previous epi review conducted in 2020, and the current status of achievement in this 2023 epi review respectively. The TB surveillance system has some strengths but also important gaps that need urgent action. For a summarized detailed description of each section of the benchmark checklist with the achievements, see table 5.

2020 CHECKLIST SUMMARY					
STANDARD		MET	PARTIALLY MET	NOT MET	NOT APPLICABLE
B1.1	Case Definition	☒	☐	☐	
B1.2	Min. set captured	☒	☐	☐	
B1.3	100% submission	☒	☐	☐	☐
B1.4	Int. Consistency Qtrly (paper)	☐	☒	☐	☐
B1.5	Int. Consistency Natnl. (electr.)	☐	☒	☐	☐
B1.6	Ext. consistency (new child)	☐	☐	☒	
B1.7	Int. Consistency (ratios)	☐	☒	☐	
B1.8	Reporting rates	☐	☒	☐	
B1.9	Access to Health care	☐	☒	☐	
B1.10	VR Coverage	☐	☒	☐	
B2.1	DRTB Direct measure	☒	☐	☐	
B2.2	TBHIV Direct measure	☒	☐	☐	
B2.3	Childhood TB	☐	☐	☒	

TABLE 3: 2020EPI REVIEW SUMMARY CHECKLIST RESULTS, SRI LANKA

2023 CHECKLIST SUMMARY					
STANDARD		MET	PARTIALLY MET	NOT MET	NOT APPLICABLE
B1.1	Case Definition	☒	☐	☐	
B1.2	Min. set captured	☒	☐	☐	
B1.3	100% submission	☒	☐	☐	☐
B1.4	Int. Consistency Qtrly (paper)	☒	☐	☐	☐
B1.5	Int. Consistency Natnl. (electr.)	☐	☒	☐	☐
B1.6	Ext. consistency (new child)	☐	☐	☒	
B1.7	Int. Consistency (ratios)	☐	☒	☐	
B1.8	Reporting rates	☐	☒	☐	
B1.9	Access to Health care	☐	☒	☐	
B1.10	VR Coverage	☐	☒	☐	
B2.1	DRTB Direct measure	☒	☐	☐	
B2.2	TBHIV Direct measure	☒	☐	☐	
B2.3	Childhood TB	☐	☐	☒	

TABLE 4: 2023 EPI REVIEW SUMMARY CHECKLIST RESULTS

Met (5)	Partially Met (6)	Not Met (2)
B1.1 Case definitions are consistent with WHO guidelines	B1.5 Data in national database are accurate, complete, internally consistent, and free of duplicates	B1.6 TB surveillance data are externally consistent (Percentage of children between 5-15%)
B1.2 TB surveillance system is designed to capture a minimum set of variables for reported TB cases	B1.7 Number of reported TB cases is internally consistent	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
B1.3 All scheduled periodic data submissions have been received and processed at the national level	B1.8 All diagnosed cases of TB are reported	
B1.4 Data in quarterly reports (or equivalent) are accurate, complete, and internally consistent	B1.9 Population has good access to health care	
B2.1 Surveillance data provide a direct measure of drug-resistant TB in new cases	B1.10 Vital registration system has high national coverage and quality	
B2.2 Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases		

TABLE 5:DETAILS OF CHECKLIST PART B DESCRIPTION AND ACHIEVEMENTS

4.4 Key strengths

Based on the assessment, the greatest strengths of TB surveillance include:

- YR2YR change in notification rate per 100,000 population for all forms of TB increased by **+22.8%**between 2021and 2022), suggesting a recovery surge from COVID-19 pandemic related lockdowns and restrictions
- Some advancement achieved compared to 2020 Epireview- **Good internal consistency** between quarterly data at district level and nationally aggregated data. Compared to 2020 Epireview, approximately 46% fully achieved, 38.5% partially met and 15.4% unmet but are ongoing
- Strong human resource structure at all levels, commendable and very committed Surveillance/M&E team available at national level, with sufficient clinical and programme to provide country level oversight of surveillance tracking and system management.
- Surveillance, R&R in compliance of WHO definitions and reporting framework
- The existence of a national electronic web-based TB surveillance system in place (ePIMS) which is in use for at least patient registration across all 26 DCCs
- Case based/Patient level TB data deployed through ePIMS (electronic) and utilized at DCC level. Comprises of multiple modules including TB registration, Notification, Contact screening, Laboratory investigations, MDR-TB management, Drug stock, etc. (~80% fully utilized in Central Colombo but underutilized at other DCCs.)
- Correct and complete entry of DS, DR and TBHIV patient records in registers at most facilities visited
- NPTCCD develops and disseminate quarterly progress updates and annual epidemiological reports
- Vital Registration system well equipped with adequate staff, 100% capture of causes of deaths or deaths due to TB (TB fatality accessed in place of mortality) using standard coding for cause of death (ICD 11, 2022).
- Per national guideline and diagnostic algorithm, the NPTCCD has adopted the WHO recommended rapid diagnostic testing for detection of TB and rifampicin resistance, as entry point of diagnosis for specific groups of all presumptive TB cases including children, PLHIVs, critically ill, TB meningitis, and pregnant women (refer to diagnostic algorithm for detailed list if groups)
- Good data recording (correctness and completeness) at sampled facilities.
- Good data analysis capacity at national level and some facilities visited

- † Reporting of childhood TB data in practice
- † Good contact tracing efforts by PHIs in practice
- † Good HIV testing among TB patients
- † Low HIV and TBHIV prevalence (less than 1%), and surveillance data provides a direct measure of the prevalence of HIV infection among TB patients
- † Free Health care services,social protection systems and - nutrition supplementation for the patients arein practice
- † One mobile screening truck in use and equipped with a digital chest X-ray,with subsequent collection of sputum for AFB and /or GeneXpert. - Used for **community** campaigns, awareness, and screening services for prisons and other high risk settings
- † Latent TB treatment has been provided for PLHIV and children <5years (contacts of bacteriologically confirmed TB patients) and recently expanded covering children >5years who are contacts of index TB cases(Jan 2022), and other clinical risk groups.
- † National level advisory bodies such as National multi stakeholder committee on TB, National TB advisory committee, technical support group(TSG), Peadiatric steering committee and private public steering committee are in place.

4.5 Major challenges

The primary challenges of the system have been categorized into four groups includingsurveillance system, data quality, finding missing cases and key populations;

4.5.1 Surveillance system

- o The full complement of modules in the ePIMS case-based electronic system excluding the Laboratory module is fully utilized in Central Colombo and in gradual expansion to full scale in other 25 DCCs.
- o **Presumptive register** is significantly underutilized at a significant number of sampled facilities visited, which impacts on capacity of NPTCCD to routinely assess patient access to diagnosis and suspicion rate of TB especially in OPDs. Plausible reasons for underutilization include unclear designation to complete register; limitations in supply, distribution, no stipulated adherence to use, substitute OPD register in use in a few facilities which does not sufficiently capture relevant TB data elements, assessment of its availability and use not routinely addressed in supervision.Hence, the number of presumptives having access to GeneXpert tests or

diagnosed with TB using AFB could not be fully determined but estimated from laboratory register which is insufficient to identify the potential gaps between presumptive TB cases referred and tested for TB, presumptive TB cases diagnosed to have TB, and the numbers registered (often referred to as 'pre-treatment initial loss to follow up cases'). Lab register in use in place of presumptive register

- Trial TB treatment procedures in practice by physicians. (Risk of anti-TB medicines mis-management, under-notification,and/or delayed case reporting).
- CentralizedTB patient treatment initialization(not patient-centered)- risk of under-utilization of large to moderate size facilities in public and private sectors
- Non-standardized TB diagnostic in practice- TST (**Mantoux)** test in practice as a diagnostic tool in some facilities visited (risk of DR), FBC & ESR, dominance of AFB microscopy, and medical officers at OPD are not equipped or sufficiently empowered to request Chest x-ray tests
- Non-standardized R&R formats in use in some facilities visited, with gross undersupply & sub-optimal documentation on treatment outcomes (TOs) in some DCCs visited
- Unable to assess reporting rates as all aspects/modules of ePIMS is not fully utilized at all DCCs and program still heavily dependent on paper reporting formats
- Sub-optimal TB linkages between patients, AFB and GeneXpert sites, and national reference labs, given the median TAT of 4 to 26 days
- TB and Lab training deficient among most field staff
- Weak anti-TB drugs monitoring vis-à-vis patient drug administration (one patient-per-pack not in practice)
- In-built treatment monitoring data quality feedback system in ePIMS, however, systematic, and routine feedback system is sub-optimally in practice for data quality (given no quality check/feedback report sighted during this review)
- Long term interventions, financial and budget plans for the TB surveillance system are not defined in M&E section plan of the 2021-2025 national TB strategic plan.
- VR system has a high ill-defined cause of deathat a range of ~40-50%
- Patient records confidentiality(partial-adherence)-restricted access at national and district level but with identifiable PI.

4.5.2 Data quality

- Sub-optimal supervision systems at facility levels (Supervision reports or documentation not sighted in some sampled facilities
- OSDV not routinely done at national level, and sub-optimal capacity for systematic data quality validation procedures especially at subnational levels with sub-optimal feedback mechanism
- No standard operating procedures, tools or template for monitoring data quality orepidemiological indicators sighted
- EQA not in place for GeneXpert and varied strengths for IQC and EQA at AFB microscopy laboratories visited.

4.5.3 Finding Missing Cases

- Relatively very high OPD attendance at all sites visited- but low screening for TB by medical officers especially at OPD clinics at base and general hospitals due to lowsuspicion for TB, lack of TB knowledge, non-adherence to standard diagnostic algorithm in practice, limited access to TB diagnostics
- Underutilization of GeneXpert machines with an average of 1 round of test per day at most sites. On average, about 27% of all GeneXpert facilities did not process any sample for two consecutive quarters in (6 months) 2023. Approximately 68% (n=21/31) of GeneXpert sites operate at <33% capacity equivalent to 1 run per day or 3 samples processed per day in contrast to expected 3 runs per day or 3 times the number of functioning modules
- Potential Under-diagnosis and under-notification especially at Base and District General Hospitals offering TB services, due to delayed TAT for laboratory results, low uptake for GeneXpert test, low TB suspicion, low TB screening, centralized treatment initiation procedure in practice posing risk for patient initial loss to follow up
- Declining rates in TB notification observed in recent years before 2022 compared to 2013baseline which can easily be misconstrued for attaining the END TB targets of reductions in TB incidence
- Delayed turn-around time for TB diagnosis particularly among part-time private practitioners and base hospitals with a mean range of 4 days among government hospitals to 26 days among private practitioners. On average, 26-33% of TB patients are diagnosed with TB on first contact with part-time private practitioners and Base

hospitals, and 95% of TB cases diagnosed on the 5th contact with the patients after multiple contact[13].

4.5.4 Key populations

- Low capacity to diagnose paediatric TB especially at OPD clinics. Ratio of children less than 5 years relatively low when compared with 5-14yrs (0.4) relative to expected for LMIC of 1.5-3, very low child TB proportion of 2.6% relative to expected for LMIC of a range of 5-15%. Put together, these suggest under-detection and under-notification of child TB cases as a result oflow child TB adoption of paediatric TB interventions, low investigation rate among children less than 5 years old, and low capacity to diagnose paediatric TB especially at OPD clinics
- Weak integration of TB services into other parallel programs e.g., Maternal and Child Health for paediatric TB, and routine symptomatic TB screening across other service delivery points (SDPs) within facilities such as the MOPD, SOPD, treatment wards etc.
- High TB proportions especially among elderly malepopulation which suggests limited access to TB diagnosis, health seeking behavior of delayed presentation for care, low awareness about TB, increased risk of transmission given the high mobility among men, and increased risk for DRTB, and high latent TB infections
- **Congregate** populations; dedicated prison health staff and support system in place, with relatively high TB notification, yet prisons are heavily dependent on mobile and mass screening exercises

Other major challenges include the relatively high out of pocket health expenditure in Sri Lankaat 46.6% in 2020 [14]when compared to other low middle income countries in the Asia and pales in comparison to global targets of <25%.

4.6 Recommendations

A rapid review of progress made relative to the 2020 Epi review recommendations was conducted with the NPTCCD. Table 6 below summarizes the achievement levelwith remarks (*)[15] for key recommendations, and the significant milestones achieved. On average, more than half of the recommended actions had been achieved by the NPTCCD.

[13]Care pathways, and care delays among sputum positive pulmonary tuberculosis patients attending District Chest Clinics in Sri Lanka Report

[14]https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=LK

[15]* A- Achieved, PA- Partially Achieved, NA- Not Achieved

s/no	2020 Key highlights (Recommendation)	Remark *(A/PA/NA)
1	• Develop a plan and appropriate more resources to improve TB surveillance systems and optimize ePIMS (revise variables, generate reports and analysis)	PA- M&E section Plan developed as part of NSP, but no detailed line of interventions and costed activities .
2	• Address under-reporting	In-conclusive
3	• Optimize use of presumptive register	NA
4	• Introduce automated connectivity solutions of data generated by GeneXpert machines	NA
5	• Revise and deploy TB diagnostic algorithm to improve sensitivity methods	A
6	• Conduct national data quality audits	A
7	• Designate staff to oversee ePIMS data and ensure quality checks	A
8	• Revise and simplify casefinding and treatment outcomes reporting forms	A
9	• Improve collaboration with STD/AIDS program for accurate surveillance	A
10	• Include prison data in routine report	A
11	• Conduct an inventory study	PA
12	• Conduct catastrophic cost survey	PA

TABLE 6:SUMMARY OF PROGRESS OF 2020 EPI REVIEW SRI LANKA

The existing gaps and challenges identified in this review and outstanding recommendations from the previous epi review, need to be addressed by the NPTCCD through support of Global Fund, the WHO, other donors and the MoH.

Short and long-term recommendations that would yield high impact are listed below. Recommendations contributed by stakeholders from the brainstorming session that held during debrief as captured on stick notes (see appendix 5), have all been incorporated. It is highly recommended that the NPTCCD through support of the Global Fund and WHO country office, develop a comprehensive plan detailing the necessary step-by-step tasks (**operational plan**)needed towardsimplementingthe Epireview recommendations proffered during this exercise and itemized in the investment plan detailed in chapter 7.Furthermore, as it develops a new concept note for the upcoming NFM cycle and beyond, the NPTCCD/MoH in collaboration with Global Fund and WHO, should allocate specific budget to support TB surveillance activities and the implementation of the M&E investment plan.

These recommendations are all critical for TB program improvement, however, given the available funding, they have been arranged in order of priority (return on investment and feasibility) for each of the four sections- surveillance system, data quality, finding missing cases and key populations.

4.6.1 Short term Recommendations

Surveillance system

- ⇒ Print and disseminate adequate quantities of standard **R&R** tools including **presumptive registers** tohospitals and DCCs, and ensure their use, while also identifying and designating feasible key facility **staff** that will routinely **complete** the presumptive **register**.
- ⇒ The NPTCCD should promote a **patient-centered approach** to TB care such that a **phased- decentralization of** TB treatment initiation from DCC to base hospitals, General Hospitals, Teaching Hospitals, and other Government Hospitals e.g PMCU is implemented to improve TB diagnosis TAT, ensure early access to TB treatment and care is available to patients proximal to their residence.The NPTCCD can leverage the World Bank supported 'Shared care model' to decentralize TB treatment at PMCU, accompanied with frequent supervision in the early six months to sites with decentralized TB treatment services
- ⇒ All patients initiated on TB treatment should be registered and notified promptly including patients placed on TB trial treatments to prevent under-notification, ensure adequate patient treatment monitoring and accountability of drug stock management
- ⇒ NPTCCD should organize sensitization meetings for physicians to desist from using Mantoux as a TB diagnostic test
- ⇒ NPTCCD to advocate to medical officer of health and administrative leadership for authorization of TB trained medical officers at OPD clinics to utilize the full complement of TB diagnostic tools including the use of chest-X-ray for TB diagnosis among children and immunosuppressed patients
- ⇒ The NPTCCDsurveillance team should identify and engage a **health information management IT specialist** that will be designated as the IT architectural and maintenance support staff to assist in reviewing and harmonize variables and indicators on ePIMS to include relevant cascade-driven data elements,incorporate an electronic format of the presumptive register and reporting rate by completeness and timeliness, and deploy automated data quality checks on ePIMS, while also accelerating use of all modules by all DCCs to improve data transmission, management, and quality
- ⇒ Reassess **utilization rates** of **GeneXpert** and consider strategic **redistribution** of machines to facilities with high OPD attendance, functioning biosafety cabinet, high TB screening capacity and respiratory tract infections complaints

⇒ Develop **M&E plan** to include clear goals, objectives and clearly define budgeted line of activities that incorporates investment needs derived from this epi review and secure MoH endorsement for approval. The comprehensive M&E plan will serve as a national TB surveillance shopping tool to secure additional funding, as a tracking tool to monitor improvement, and a live document subject to updates

⇒ Comprehensively assess **drug stock management** at patient level such that each patient is assigned a pack for easy tracking and accountability. NPTCCD may require identifying and designating a procurement and supply chain management focal person at national level to facilitate this process and routinely monitor drug stock management especially if/when it adopts a decentralized patient treatment initiation approach

⇒ Maintain and accelerate use of **mobiledigital AI x-rays (mobile TB screening truck)** for community awareness screening activities in key population targeted areas

Data quality

⇒ Revise NPTCCD supervision checklist to more strategically target specific gaps and areas of need identified in the review, including the availability of presumptive registers, minimum patient loss rateetc.

⇒ Train TB management team including DTCO and staff at provincial level and national level on efficient supervision/ including revised checklist

⇒ Develop annual and quarterly priority-driven supervision plans, harmonize supervisory **checklist** to meet TB surveillance needs (DSTB, DR-TB, Laboratory, and ACF), conduct routine joint facility-based supervision from national and provincial levels, and ensure documentation for follow up actions.

⇒ Using standardized tools and formats, conduct **periodic** data quality **audits on annual basis,** optimizeon-site data verification checksduring routine supervision, and provide regular feedback, to ensure regular internal and external consistency checks, and improve quality data reporting

⇒ **Cascade analysis**; Systematic collection and on-site validation of presumptive TB data in the following cascade is recommended; registered presumptives, presumptives with sputum samples collected, presumptives with documented TB results. The routinely aggregated data from the presumptive register on ePIMS should capture at minimum; Total Presumptive TB registered, Total tested, total bacteriologically confirmed/MTB detected, and total on treatment. At the level of the OPD, a systematic data aggregation that captures at minimum; number of OPD attendees,

number screened for TB, number of presumptive TB cases, number referred for TB test, number tested, number of TB cases diagnosed, and number on TB treatment. This is not a prescription but serves as a guide to aid the NPTCCD in determining gaps if any, in enrolment, in tracking 'pre-diagnosis loss to follow up cases/Pre-treatment loss to follow up (Pre-LTFU), strategic implementation of active case finding approach, and better plan for forecasting and quantification of laboratory supplies for TB testing.

⇒ Develop EQA for GeneXpert and ensure regular IQC and EQA at AFB laboratories particularly in laboratories with substitute lab staff (without PHLT or MLTs)

⇒ Conduct periodic refresher on-site laboratory trainings at minimum of every 2-3 years on AFB microscopy to improve and assure quality

Finding Missing cases

⇒ Organize facilitators training (training of trainers) for Medical officers to cascade in clusters to other medical officers on knowledge of TB, standard diagnostic algorithms, treatment guidelines, and establishing high suspicion of TB and screening especially among **elderly** and **children**

⇒ **OPD screening** should be systematic with adequate documentation using presumptive registers, and linked to existing paper and electronic based data collection system

⇒ To complement NPTCCD ongoing effortsin mobile screening using**digital X-rays** (mobile TB screening truck) for community awareness screening activities, the NPTCCD should develop a quarterly community awareness campaign **plan** to allow adequate planning and community sensitization well ahead of upcoming mass screening programs. The quarterly plan will also assist to accelerate active case finding targeted at high density areas and key populations,and monitor its timely implementation

⇒ NPTCCD should strategically scale up engagements with private practitionersin high density private practice dense areas such as Gampaha district anddevelop concrete modalities for engagement with signed MOUsto provide referral and/or diagnosis services and/or treatment in the long run.

⇒ Review contact investigation and referral mechanismsamong privately ownedhospitals, and improve presumptive patient referral linkages

⇒ Intensifying TB finding among children less than 5 years old requires the NPTCCD actively **engage medical officers, pediatricians and pediatric clinics** both in public and private settings to provide TB screening services, child TB sputum induction support, andfacilitate pediatric TB trainings focused on standard child TB diagnostics, diagnostic algorithms, and treatment monitoring.

⇒ Strengthen diagnostic linkages to GeneXpert sites as primary diagnostic entry point and establish efficient sample transport systems to facilitate prompt transportation and feedback from facilities in close proximity to GeneXpert sites and improve timely TB notification and treatment initiation

Key populations

⇒ NPTCCD should engage TA for pediatric TB to provide technical assistance to develop and implement Childhood TB strategies and interventions

⇒ Constitute a time-limited childhood TB task force to review existing pediatric TB directed strategies, contact investigation, tracing processes, including tools and diagnostic capacity of the NPTCCD for childhood TB

⇒ Develop training curriculum for childhood TB diagnosis in line with WHO recommended strategies and KNCV's benchmarking policies, practices and planning that targets child TB screening, TB diagnosis in children and diagnostic algorithm, out-patient sputum collection options and procedures such as nebulized induction, contact investigation, TB treatment and TB preventive treatment

⇒ Organize **consensus building meetings on childhood TB** withumbrella bodies of **pediatric association**, association of **private practitioners**, national **immunization** programmes, maternal and child health services (**MCH**), and actively participate in health summits organized by these bodies to provide orientation on national TB diagnostic algorithms and treatment guidelines for pediatric and adult TB

⇒ Identify **medical officers and nurses** from strategically selected referral facilities, build their diagnostic capacity for **childhood TB**, and thereafter, using the hub and spoke model; utilize these trained service centers and personnelto serve as receptacles for referralsfrom peripheral health facilitiesand as **care mentors**for TB diagnosis in children under 5 years

⇒ Organize TB awareness campaigns that targets the elderly population, using the mobile screening truck, and mass screenings for latent TB diagnosis and treatment

4.6.2 Long term Recommendations

Surveillance system

⇒ Establish use of **unique identifiers**for TB case managementto strengthen linkages between GeneXpert sites, peripheral decentralized service hospitals, DCCS and NTRL, reduce duplicate entries, ensure patient confidentiality, and improve TB notification

⇒ Develop a comprehensive training plan and curriculum to include M&E and refresher training on TB data quality, refresher trainings on AFB microscopy, data analysis and surveillance including data collection tools, diagnostic algorithms, and patient monitoring

⇒ Registrar General Department through support of MoH to ensure annual coding of causes of death are compiled for subsequent years after 2019, to sufficiently aid the NPTCCD to assess the moving average in TB related deaths to compare with routine deaths reported in the national TB programmes and determine gaps in mortality and areas requiring urgent attention

⇒ Conduct **TB inventory studies** to monitor the level and sources of '*under-reporting'* and *directly 'assess missing cases'* in public and private sectors (this will help identify where efforts should be focused for higher impact). See WHO website on how to conduct one and the resources required[16]

⇒ Conduct a follow up TB surveillance assessment in 3-5 years to assess progress and changes in the TB surveillance system over time

Data quality

⇒ Institute Refresher trainings on QA and laboratory updates among Lab staff at least every 3 years

⇒ Conduct regular desk review of human resource capacity engaged by the NPTCCD to provide TB diagnostic servicesin laboratories to assess quality of services and address HR challenges

⇒ Provide incentives such as recognition awards and participation at meetings or joint supervision, for high-performing facility staff, public or private facilities particularly when phased decentralization of TB treatment initiation services are initiated.

[16] https://www.who.int/tb/publications/inventory_studies/en/

⇒ M&E team will benefit from international cross-country ‘shadowing and under-study’ of surveillance systems and Supply Chain Management of TB drugs and logistics supplies for best practices

Key populations

⇒ Using a mentorship approach, integrate child TB services into maternal and child health clinics at Base, General, and Teaching Hospitals

⇒ MoH should facilitate collaboration with the Ministry of Justice and Law Reforms to integrate universal routine TB screening in prisons during inmate enrolment (on enrolment card), periodically on biannual basis,and prison-cell contact investigation among inmates of index cases. It would require stakeholder consensus building, revising, and updating the health information tool used by the Prison health units to include screening criteria such as cough and its duration

Finding Missing cases

⇒ Given the high TB proportions among the elderly, it is imperative NPTCCDaccelerate and expand**latent TB infection detection** and short treatment regimens especially among key populations such as children, elderly and diabetic patients

⇒ Develop a well-designed modality of engagement of private care providers in the long run, that assures adequate knowledge about TB diagnosis and treatment, efficient linkage to NPTCCD surveillance systems for tuberculosis and aim to reduce diagnostic delays for tuberculosis in Sri Lanka

⇒ Identify clear incentives for engagement of private practitionersin TB services including but not limited to participating in advocacy to engage other private facilities, attendance of high performing private practitioners at national level meetings, sponsorship ads and panel sessions on regulatory body annual health summits, conference attendance and recognition awards

⇒ Periodically conduct cascade analysis of active case finding activities and community awareness campaigns to ascertain, monitor and immediately address challenges such as, undocumented sputum collection or GeneXpert results, rate of inability to produce sputum, delayed laboratory results, weak referral linkages to treatment, delayed treatment enrolment, and sub-optimal documentation.

⇒ Adopt use of social media and other social mobilization tools for TB awareness creation

5 TB epidemiology

The following analysis was carried out using the aggregate data obtained from the excel databases archived at national level and the electronic ePIMS.

5.1 TB case notifications

5.1.1 Levels and time trends of TB burden, national level

In 2022, a total of 8,432 of all forms of TB cases and 8,109 incident TB cases were notified, resulting in a case notification rate (CNR) of 37.7 per 100,000 population for all forms of TB and 36.6/100,000 population for incident TB cases. CNR for all forms of TB cases has continued to decline from 46.5 per 100,000 population in 2013 to 30.7/100,000 in 2021, followed by an uptick in 2022 to 37.7/100, 000 relatively significant when compared to the preceding year. Same trend is observed among incident TB cases; see figures 8 and 9. TB treatment coverage rate in 2022 is the number of new and relapse cases detected and treated in a given year divided by the estimated number of incident TB cases in the same year expressed as a percentage. Hence, a treatment coverage rate of 57.9% (8109/14,000), indicates about 42% of the estimated TB cases are missed annually.

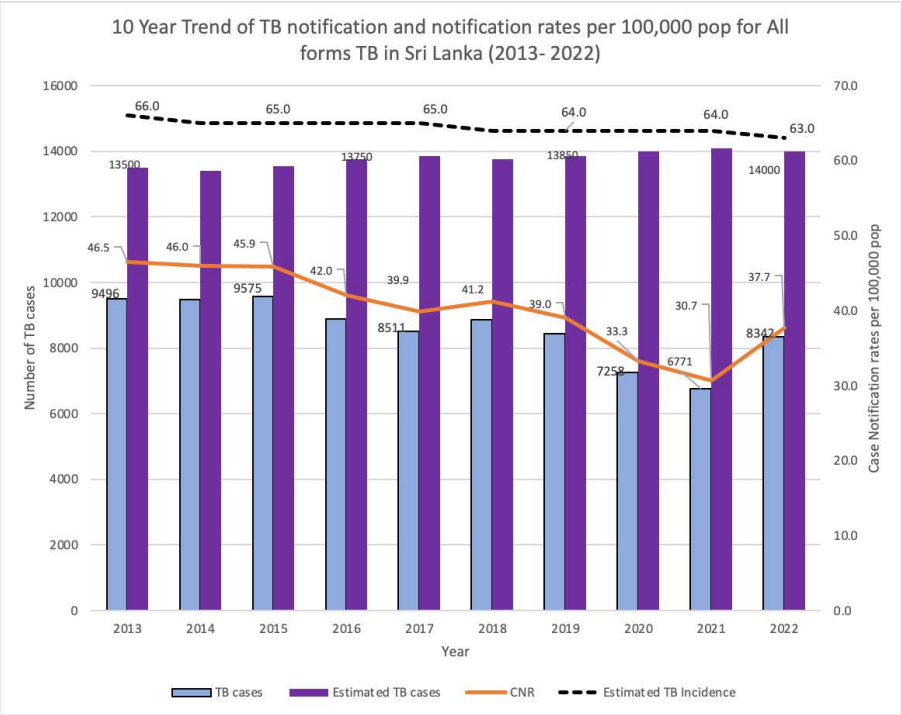


FIGURE 8: TREND OF TB CNR AND NOTIFIED CASES (ALL FORMS) 2013 – 2022, SRI LANKA

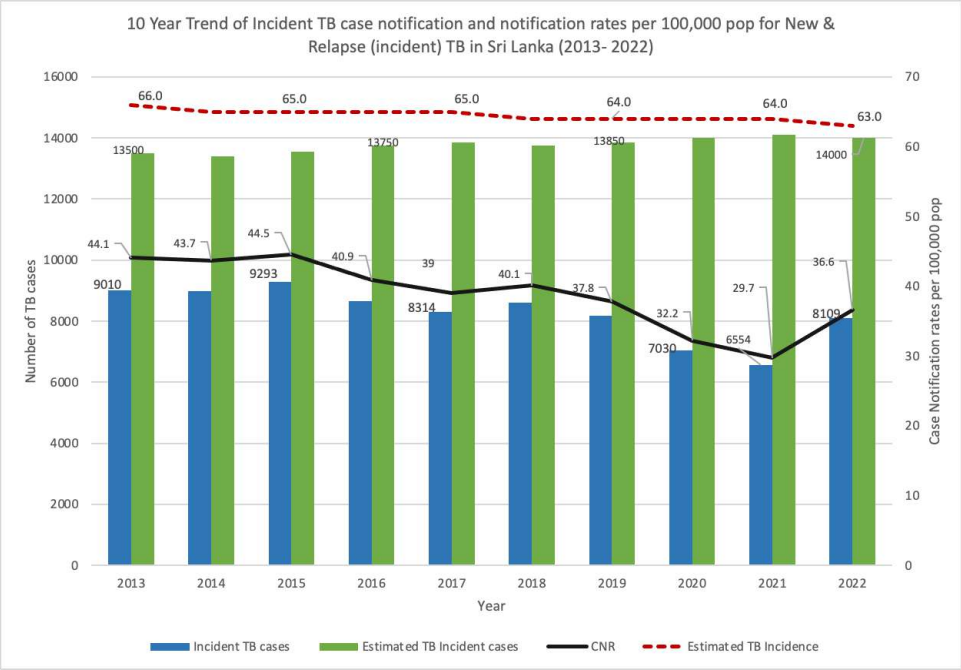


FIGURE 9: TREND OF CNR AND NOTIFIED CASES (INCIDENT CASES) 2013 – 2022, SRI LANKA

Out of the 8,342 cases enrolled for TB treatment, 75% were pulmonary TB, and 25% EPTB, while 97% were new and relapse TB cases. (see table 7 below). About 20% are clinically diagnosed.

2022

Case type	Percentage of TB case type
New	93.0%
Relapse	4.2%
Others	0.3%
Treatment Aft. Failure (TAF)	1.3%
Treatment After Loss to Follow up (TALF)	1.1%
Treatment History Unknown	0.1%

TABLE 7: PERCENTAGE CONTRIBUTION OF TB CASES BY TYPE NOTIFIED IN 2022, SRI LANKA

Figure 10 below further displays in a pie chart of the percentage contribution of TB cases notified in 2022 by case types.

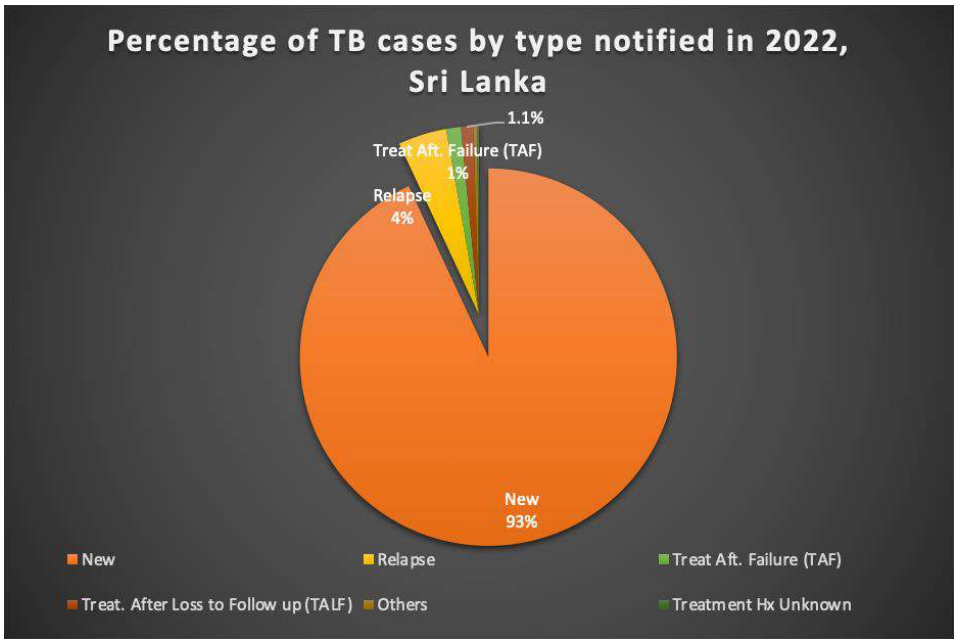


FIGURE 10:PERCENTAGE OF TB CASES BY CASE TYPE NOTIFIED IN 2022, SRI LANKA

Based on historical within the last decade up until the emergence of COVID 19 from 2013to2021, the absolute number of incident TB cases (new and relapse)declinedat an average of -4.6% from9,010 incident TB cases in 2013 to 6,544 cases in 2021, and then surged from -7.8% YR2YR change to 23.2%and from 6,544 to 8,109for all new and relapse TB cases between 2021 to 2022. During this period, there have been recovery interventions following the generalized lockdowns and restrictions impacted by COVID-19, and accelerated implementation of community awareness campaigns on.

The year to year change (YR2YR) in all forms of TB notification per 100,000 population over the last decade between 2013 to 2022 was -1.2%. Further decline occurred during the

COVID-19 pandemic from -5.3 in 2019 relative to 2018, -14.6% in 2020, then -7.8% in 2021. These continued decline and deep in 2020 could be attributed to the COVID-19 pandemic which impacted access to health facilities and treatment services due to social distance, restrictions, and lockdowns. A rebound surge in the YR2YR change was observed from a previous annual decline of -7.8% between 2020 and 2021 to an increase of +22.8% between 2021 and 2022. Combined, the average YR2YR annual change from 2020 through 2022 increased by 7.5% in all forms of TB case notification. See figure 11 below.

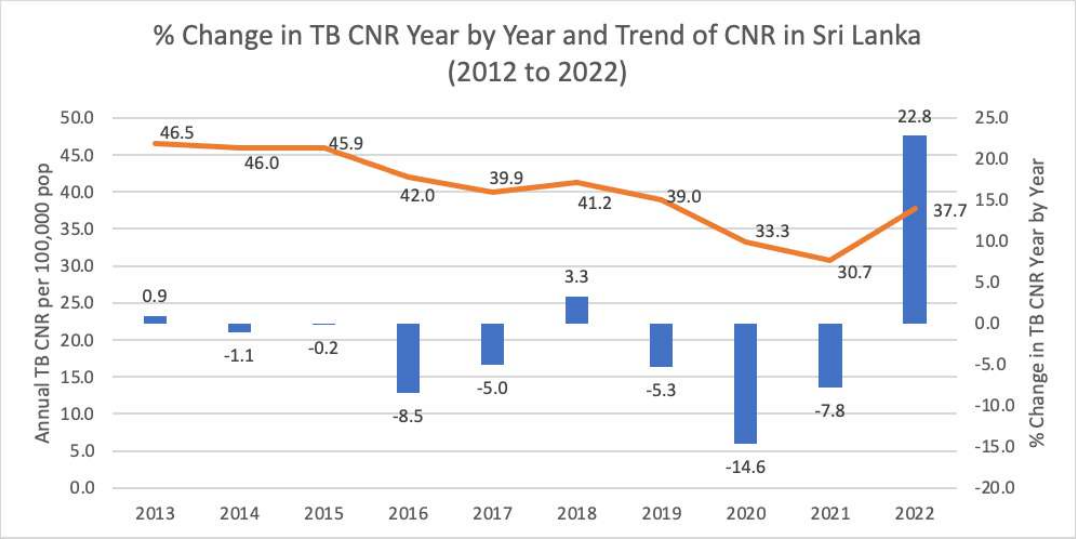


FIGURE 11:YR-TO-YR % CHANGE IN TB CNR PER 100,000 POP., SRI LANKA (2017/2018 -2021/2022)

The number of bacteriologically confirmed TB cases between 2021 and 2022 increased by 31%, the number of clinically diagnosis TB cases increased by 21%, while the extrapulmonary TB cases increased by 9%. Overall, in 2022, extra pulmonary cases were approximately 25% of all forms of TB, 20% were clinically diagnosed and about 55% of notified TB cases bacteriologically confirmed; (see figure 12).

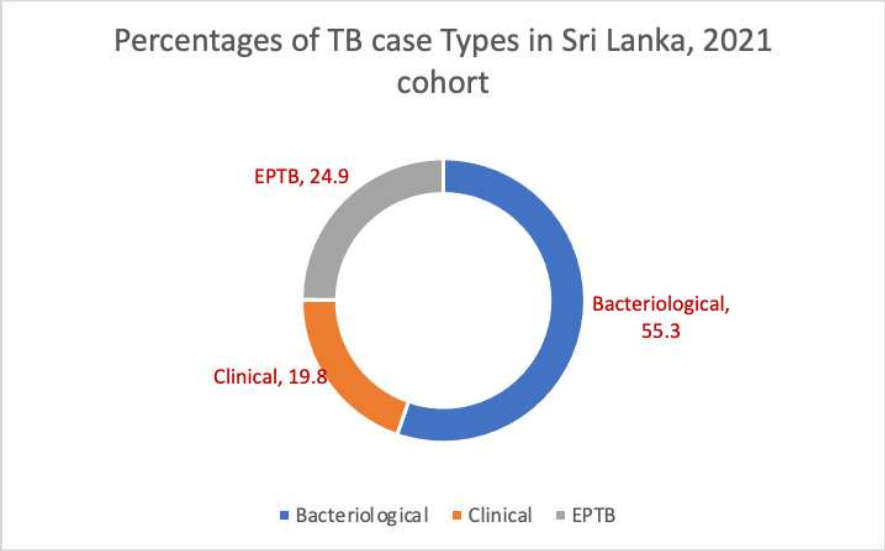


FIGURE 12:: PERCENTAGE OF TB CASE TYPES IN SRI LANKA, 2022

The patient pathway analysis (PPA) conducted in 2021, suggest approximately 39% seek care primarily at part-time owned private practitioners which has significantly limited access to TB diagnosis. Among the 69% that seek care within government health institutions, only 9% initially utilize district chest clinics (DCCs) which is the primary TB basic management unit. A third of those that seek other government facilities (i.e., excluding DCCS) end up being admitted for diagnostic and treatment purposes, and another third are treated without TB diagnosis.

On average, the part-time private practitioners and base hospitals are the most patronized when compared to teaching hospitals, general hospitals, district hospitals and primary medical care units. However, only 26% and 33% of TB patients are diagnosed on first contact with part-time practitioners and doctors at base hospitals respectively. In teaching hospitals (TH), general hospitals (GH), district hospitals (DH) and primary medical care units (PMCU), approximately 22%, 40%, 46% and 39% of TB patients respectively are diagnosed during first time contact. Majority of the TB patients that go undiagnosed are given symptomatic treatment without testing. Others are either sent to another hospital for investigations, referred to a DCC, admitted or referred to a consultant. These findings suggest a low knowledge about TB, low suspicion for TB and low capacity to diagnose TB. These findings are further compounded by TB diagnostic delays particularly in private hospitals, ranging from a mean of 4 days within DCCs to 26 days in other Government facilities such as base hospitals, and in private practice settings. Put together, this calls for the development of a well-designed modality of engagement of private care providers in the long run, that assures adequate knowledge about TB diagnosis and treatment, efficient linkage to NPTCCD

surveillance systems for tuberculosis and aim to reduce diagnostic delays for tuberculosis in Sri Lanka.

5.1.2 Age and sex, national level

Age groups for TB notification are disaggregated into eight (8) groups of 0-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64 and 65+, by male and female gender. As seen globally, the incident TB cases at the end of 2022 were higher in men compared to women for all age groups excluding children (0-14yrs) and youths ages 15-24 years where the male: female ratio is 1: 1.4 among children and 1: 1.5 among female youths compared to male youths. This finding is similar to published literatures that suggest a children and adolescent females are more susceptible to TB and even more for extra pulmonary TB[17]. With reference to figure 13 and 14 below; the highest number of TB notifications were in ages **55-64 years**, **65+ and 45-54 years** in decreasing order of magnitudefor both gender (21.8%, 21.7% and 20%).On average it is of equal proportions in the three age bands (45-54, 55-64 and 65+ years old) contrary to findings in other Asian countries where it is highest among the reproductive/workforce ages 15-44 and the elderly 65+ years.

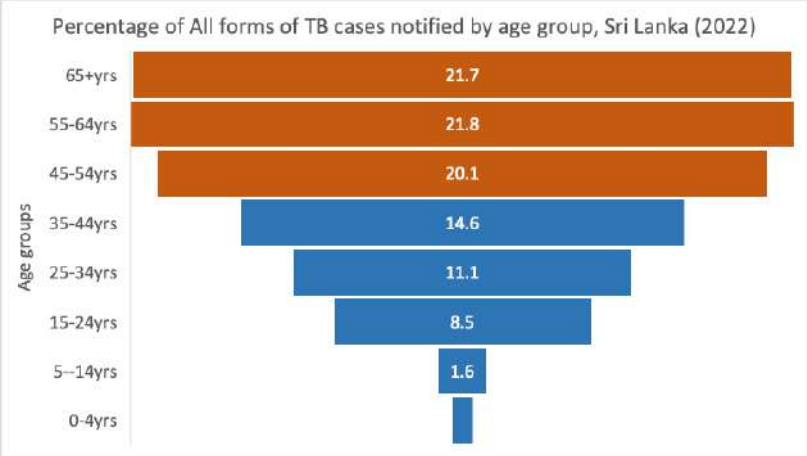


FIGURE 13: PERCENTAGE DISTRIBUTION OF TB CASES BY AGE GROUP, SRI LANKA 2022

Among the elderly65+ years and ages 35 to 64 years old age bands,TB is twice higher in males compared to females.

[17] Thakur S, Chauhan V, Kumar R, Beri G. Adolescent Females are More Susceptible than Males for Tuberculosis. J Glob Infect Dis. 2021 Jan 29;13(1):3-6. doi: 10.4103/jgid.jgid_229_20. PMID: 33911445; PMCID: PMC8054790

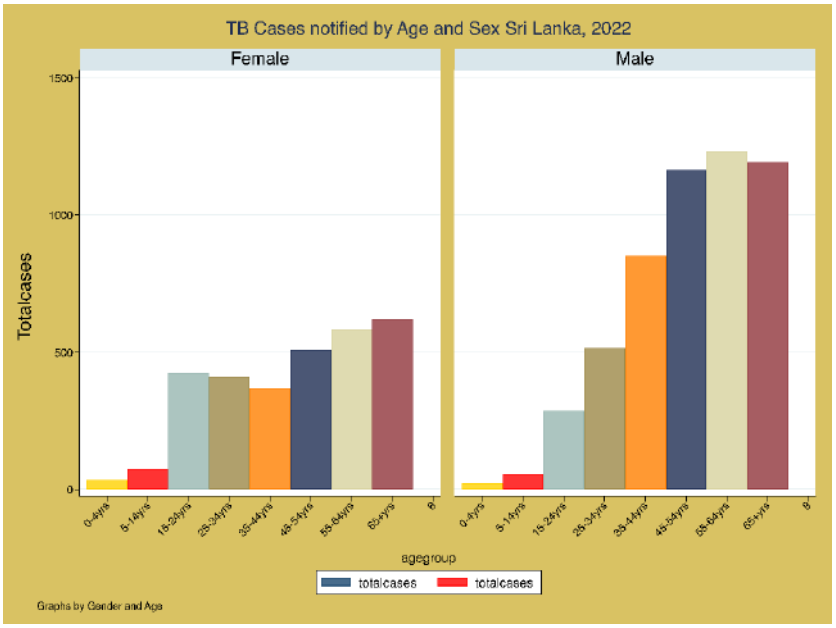


FIGURE 14:TB CASES NOTIFIED BY AGE AND SEX IN SRI LANKA, 2022

When this observation is compared with the population distribution in Sri Lanka, there is no imminent aging population as Sri Lanka portrays a youth-dominated populace aged 0-24 years old constituting approximately 45% of the projected population (0-14 years are 26%, while 15-24 years old are 19% of population). On the contrary, given the high proportion of children in Sri Lanka, the low proportion of TB cases detected among children becomes more evident at 2.6% at the end of 2022, compared to the expected range of 5-15% among low middle income country as Sri Lanka.Therefore, the proportion of TB in the elderly is high given the population dynamics in Sri Lanka and may indicate a combination of many factors including; limited access to TB diagnosis, delayed TB diagnosis, delayed treatment initiation, and plausible high latent TB infections in the communities. See current population dynamic in Sri Lanka for 2022 in figure 17 below.

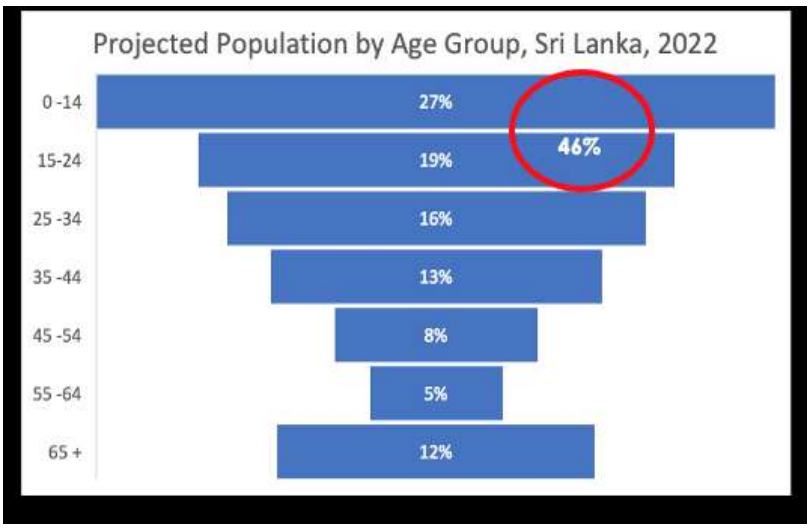


FIGURE 15:PROJECTED POPULATION BY AGE GROUP IN SRI LANKA, 2022

Additionally, being old and frail comes with immunosuppression, and as such, in the long run, latent TB infections if present in the elderly, are likely to become active TB cases which probably explains the high proportions among the elderly. Therefore, patient-centered strategies and interventions that target elderly male population should be adopted to increase access to early diagnosis and treatment. It is imperative that the NPTTCD promptly accelerate its efforts in latent TB detection strategies and short treatment regimen, to treat the 'dormant' TB affecting Sri Lanka's populace at risk for active TB.

5.1.3 Internal consistency of data

Data consistency and quality check conducted at the health facility level visited showed consistency between data cases recorded at DCCs, in the laboratory registers, data reported on the quarterly reports and data aggregated at national level. Age disaggregation within the NPTCCD TB excel database was consistent with total cases.

Thetrend of notified PTB and EPTB cases both show a gradual decline over the preceding four years and an upsurge in 2022 as shown in the graph below (figure 16) while the ratioofproportions of PTB to EPTB have continued to remain steadily at an average range of 2.6and ending at 3.0 with an average contribution of 72% for PTB and 28% for EPTB from 2013 to 2022, as seen in the trend graphbelow.

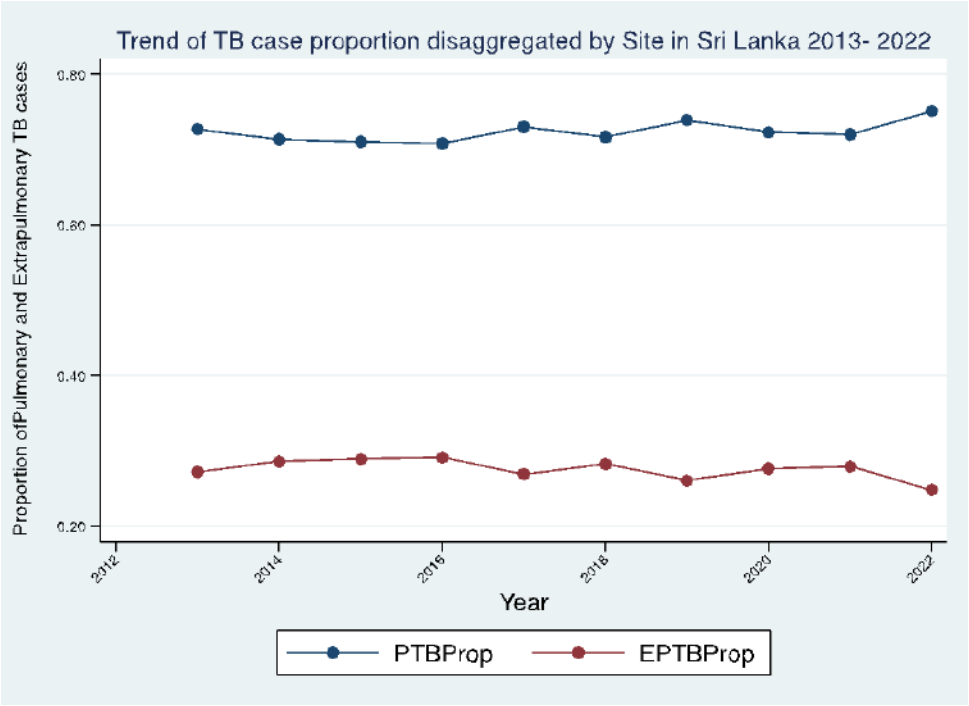


FIGURE 16:TREND OF PTB CASES VS. EPTB CASES NOTIFIED IN SRI LANKA (2013-2022)

The proportion of EPTB at the end of 2022 was 25% versus 75% PTB (PTB3.0: EPTB 1) which is in concurrence withmost of the facilities visited and consistent with Sri Lanka's low HIV prevalence.

The trend in proportions between Pulmonary and extra pulmonary TB at district level from 2018 to 2022 is marginally different across all twenty-sixdistricts with equal steady ratesas seen at national aggregates such that as the pulmonary TB proportions increase, extrapulmonary proportions declined. However, in three districts- Kilinochchi. Mulliativu and Vavuniya, there are nearly inverse proportions whereby the proportion of pulmonary TB to EPTB was 1.0 (average of 50% equally) or even more of EPTB as shown in figure17. The latter finding particularly in Vavuniya where the EPTB proportion is increasing and the pulmonary TB proportion is decreasing, is commonly observed when there is high EPTB diagnosis due to limited access to bacteriological diagnosis, or over-diagnosis of clinically diagnosed TB with EPTB among physicians.

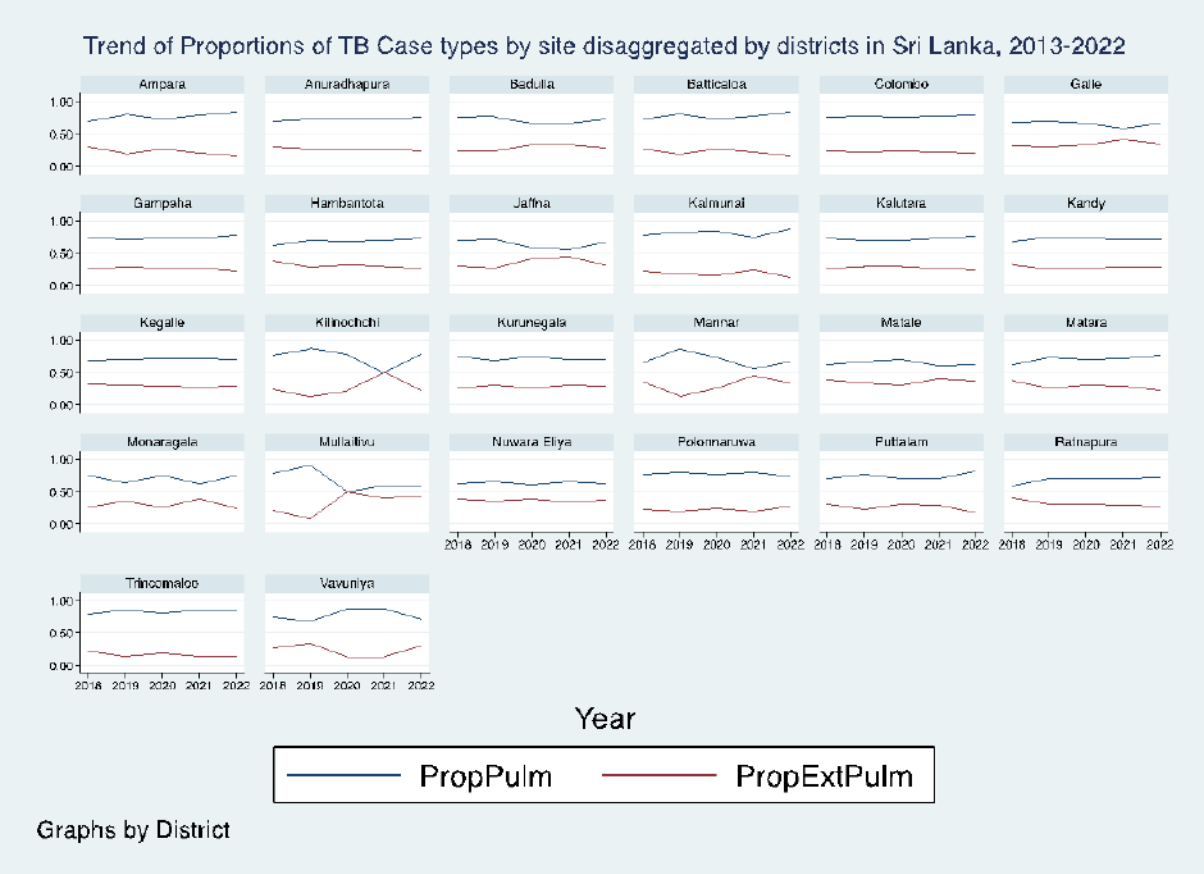


FIGURE 17:TREND IN PROPORTION OF PTB VS. EPTB CASES NOTIFIED IN SRI LANKA BY DISTRICT(2018- 2022)

From 2018 to 2022the M:F ratio has considerablyremained high at an average of 1.75:1over the last five years for the period under review as shown in figure 18. This suggest a far higher risk of TB transmission within male settings. Hence, the NPTCCD and funding partners should adopt more innovative strategies that target men in congregate settings such as social groups, smoking hubs, and among the migrant working population.

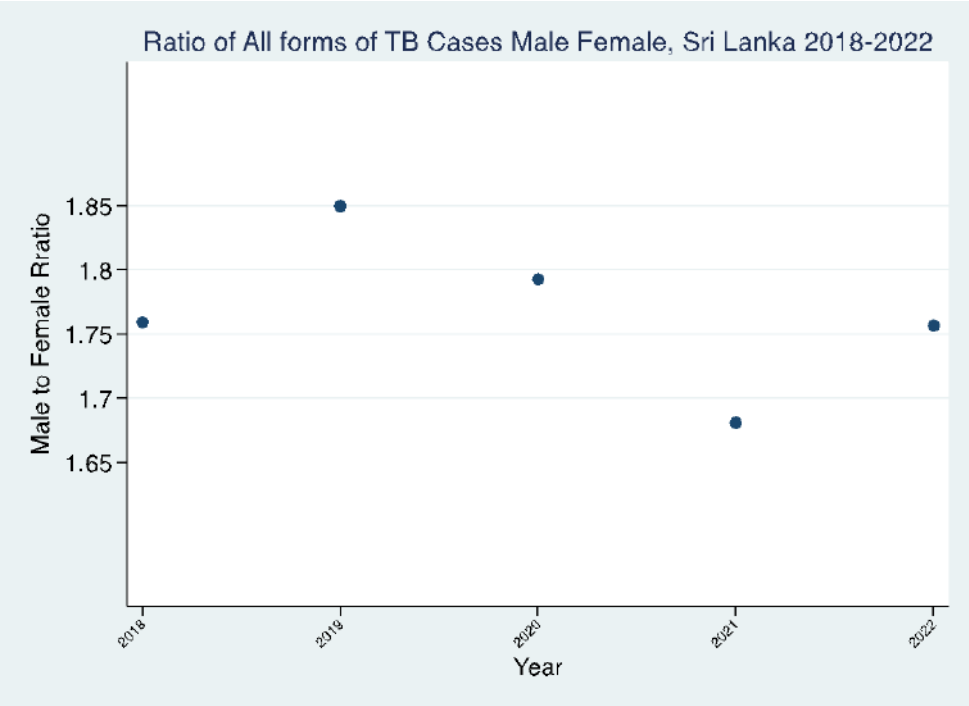


FIGURE 18:: GRAPH OF MALE : FEMALE RATIO OF ALL FORMS OF TB, SRI LANKA (2018-2022)

The ratio between 0-4 years and 5-14 year has remain inconsistent and further declining from 0.9:1 in 2015 to 0.4:1 in 2022, and therefore, does not meet expected consistency ratio of 1.5-3.0, as shown in table 8 and figure 19 below. This finding suggest an under-detection and notification of TB in younger children less than 5 years as a result of low suspicion of TB among medical officers and private care providers due to lack of TB knowledge and management in children, non-standardized diagnostic algorithm for child TB, limited capacity to obtain sputum production through gastric washings and nebulized induction etc. To intensify efforts in finding TB among children less than 5 years old, the NPTCCD should actively engage pediatricians, pediatric clinics, maternal and child health clinics both in public and private settings in TB screening, to facilitatechild TB case detection and pediatric TB trainings focused on standard child TB diagnostics, diagnostic algorithms, and treatment monitoring. The hub and spoke model of identifying pediatricians, designating their location as a pediatric referral hub and care mentor location may prove useful in scaling up capacity among medical officers to diagnose and treat TB among children.

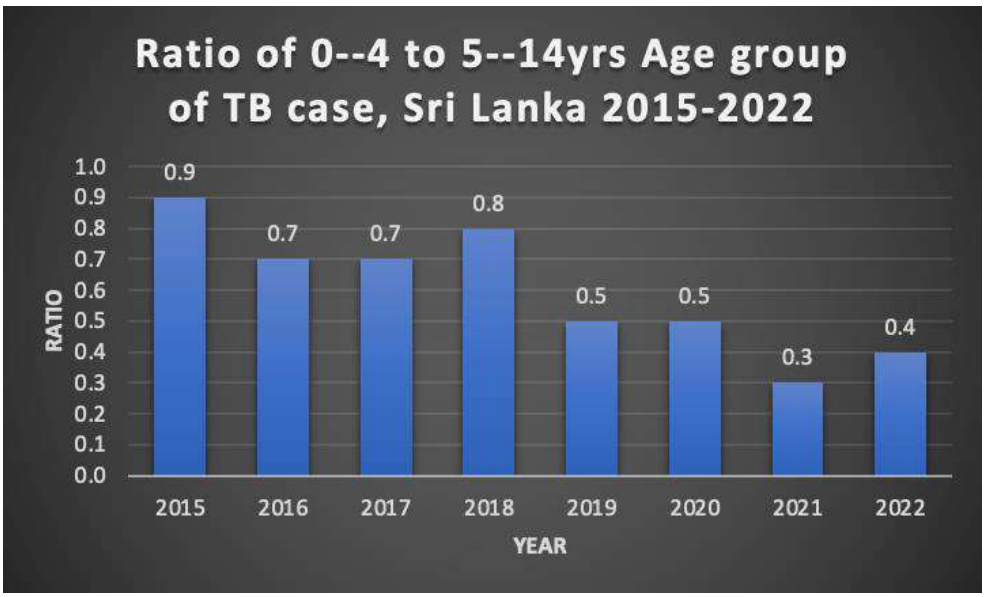


FIGURE 19:RATIO OF 0--4 TO 5--14YRS AGE GROUP OF TB CASES IN SRI LANKA 2015 -2022

Period	Ratio of TB cases male: female (new and relapse, all forms)	Ratio of TB cases aged 0-4:5-14 (new and relapse, all forms)
2018	1.76	0.8
2019	1.85	0.5
2020	1.79	0.5
2021	1.68	0.3
2022	1.76	0.4

TABLE 8: RATIO OF M: F AND AGES 0-4:5-14 YEARS SRI LANKA (2018-2022)

The ratio of presumptive TB cases compared with TB cases notified for consistency, could not be validated on field, as presumptive register was observed to not be in use for more than 90% of sampled facilities visited. However, presumptive TB cases are routinely aggregated at national levels from multiple sources including the laboratory register and from reviews conducted at district level with medical officers of health. The 2022 records show that 51,167 patients were referred for AFB microscopy test, but unable to decipher how many patients were symptomatically screened for TBamong 12,355,029 OPD attendees at 206 facilities. Additionally, out of an unknown number that were tested and have documented AFB lab results, 1,212 TB cases were diagnosed. This is equivalent to a presumptive: TB case ratio of 100: 2.4 or 2.4% which is very low relative to the expected of 10:1. Furthermore, under the assumption that all OPD attendees were screened for TB, the number needed to screen to identify a single case of TB is 10,193. This misrepresents the common findings in scientific literature which suggest screening about 1,000 OPD attendees to find

one TB case[18]. This finding is equivalent to a case notification rate of 10 per 100,000 population. Together, this suggests low TB suspicion, low TB screening activity, patient loss to follow up after referral for AFB test among identified presumptive TB cases, limited access to TB diagnosis using GeneXpert which has a higher sensitivity compared to AFB microscopy, and sub-optimal knowledge of identifying presumptive TB cases. Though imprecise, to find the missing 5,700 TB cases in Sri Lanka, and going by the current data of 51,167 presumptives among OPD attendees referred for TB test yielding 1212 TB cases, approximately 2% of OPD attendees screened should yield 247,000 presumptives, which would yield approximately 5,900 TB cases.

5.1.4 Active case finding

In its attempt to intensify case finding and meet NPTCCD strategic plan objectives, active case finding (ACF)interventions including the contact tracing and community awareness campaignstrategies are implemented in all twenty-six districts and prison facilities through support of Global Fund. In Sri Lanka, there are twenty-seven prisons with Welikada in Colombo having the highest number of inmates in the country. According to the Ministry of Justice and Law Reforms, the current number of inmates as at September 4, 2023 was 28, 815 equivalent to a prison population rate of 133/100,000 population and inmate capacity of 220% relative to the official capacity of 11,768[19]. Table 9 below shows the number of prisons between 2015 to 2019, the average numbers of prison inmates at each period, the number of TB screenings/examinations done in each given year which may be repeated on same inmates in each given year, and the number of TB cases detected among inmates.Community awareness campaigns and TB screenings conducted in prisons suggest high TB case notification rates of 820 per 100,000 population of inmates (see extrapolation in table below) and potential risk of continued TB transmission.The deep or sharp decline in 2017 can be attributed to the introduction of new data collection formats which was slow adopted for use. The high rate in 2019 can be attributed to better screening strategies and strategically targeting prisons with high inmates rate and conducting more screening programs in prisons such as Welikada which reports approximately 66% of all TB cases across all 27 prisons.

Period	# Prisons	Average Prison population	# Examined	# TB cases	CNR per 100,000 prison population

[18] Provider initiated tuberculosis case finding in outpatient departments of health care facilities in Ghana: yield by screening strategy and target group https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5709967/

[19] https://www.prisonstudies.org/country/sri-lanka

2015	26	17,771	51,652	112	216
2016	26	15,886	69,272	127	183
2017	26	17,478	31,114	35	112
2018	27	20,384	24,904	115	462
2019	27		21,209	174	820

TABLE 9:TABLE OF ACTIVE TB SCREENING AMONG PRISON POPULATION IN SRI LANKA (2015-2019)

In 2019, among the 174 TB cases detected, 125 were bacteriologically confirmed using AFB smear microscopy. Given the number of examinations and the number of smear positive TB cases detected in 2019, the number needed to screen (NNS) among the prison population to detect one (1) single case of bacteriologically confirmed case is 169.Though a clear cascade of contact tracing data could not be assessed during this review, the PHIs support the NPTCCD to trace new patients yet to be enrolled on TB treatment, screen and invite contacts of index cases for TB screening, and track patients that have interrupted treatment.

5.1.5 Latent TB detection and treatment

Sri Lanka has initiated latent TB (LTB) screening and the six month regimen of treatment. Latent TB screening though currently on a small scale targets key populations including PLHIVs, patients on anti TNF alpha and biologics, dialysis, patients awaiting and received organ transplant and stem cell transplant, and prison inmates. In the first quarter of 2023, out of a total of 3,342 patients tested using TST Mantoux, about 14% were reactive. The highest LTB reactive group was PLHIV (22%) and contacts of index cases (15%). The NPTCCD should endeavor to scale up latent TB testing using more predictive performance test such as interferon-gamma release assays (IGRA), and expand the testings to diabetic clinics given the high prevalence of diabetes in Sri Lanka (see section 5.7.3).

Category	LTBscreened	LTBreactive	LTBI Treatment
PLHIV	172	39	49
Contacts of index cases	2780	408	385
Immunocompromised	131	12	13
Prison	83	0	0
Others	176	10	10

TABLE 10: LATENT TB SCREENING, Q1 AND Q2 OF 2023 IN SRI LANKA

5.1.6 Levels and time trends of TB burden, District level

Sri Lanka comprises of 77.4% rural population and a population density of325 persons/km^2 with its capital city Colombo as the most densely with a population density of 3621 persons

per kilometer square, and a national growth rate of 0.5% in 2020[20]. Colombo's population alone contributes approximately 11% of the total population, and as expected, across the twenty-six administrative districts, the highest contribution is consistently Colombo, contributing about 26% to TB case finding at the end of 2022as shown in the graph below. Gampaha district which has a population density of 1802 persons per km square is second highest in total TB case notification annually, contributing 13% to total TB cases notified each year. Put together, approximately 40% of all forms of TB are notified in two districts only.

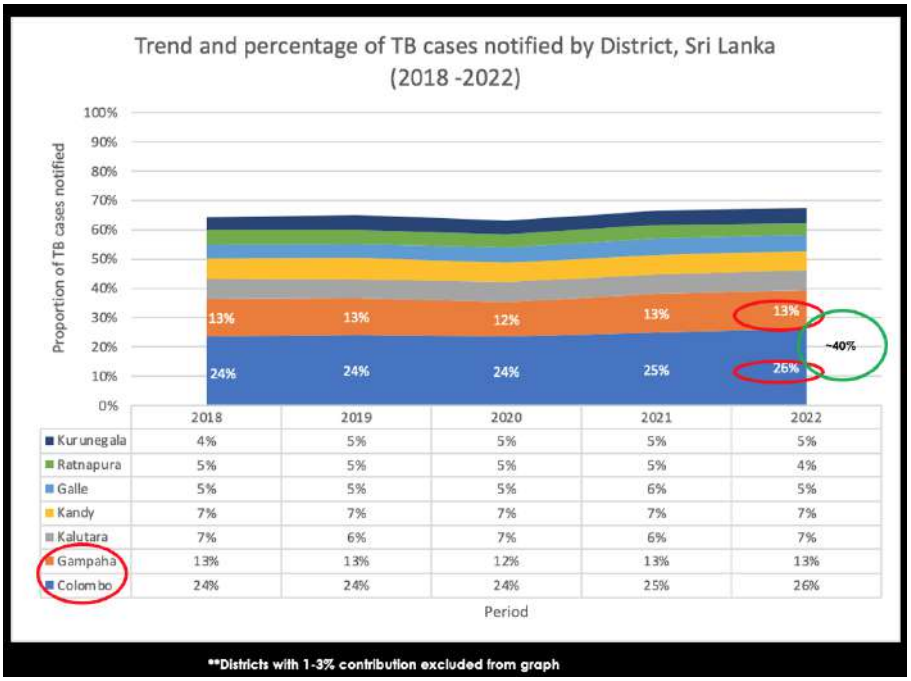


FIGURE 20: TREND AND % OF TB CASES NOTIFIED BY DISTRICT, SRI LANKA (2018-2022)

The crude trend analysis of CNRby districtshowed that only one district has been able to notify more than WHO estimated TB incidence of 63/100,000 in Sri Lanka (figure 21). The highest CNR of incident TB cases in 2022 was consistently observed in Colombo district (84/100,000 population), exceeding national CNR of 36.6/100,000 population. Galle, Trincomalee and Kandy also exceeded national CNR average for incident TB cases. This may be attributed to the distribution and concentration of TB services in thisdistrict, and the relatively high population density which may serve as hubs for continued TB transmission. See time series graph data on CNR per 100,000 population and cases notified by districts in figure 21and 22 below.

[20] https://lankastatistics.com/economic/districtwise-population-and-density.html

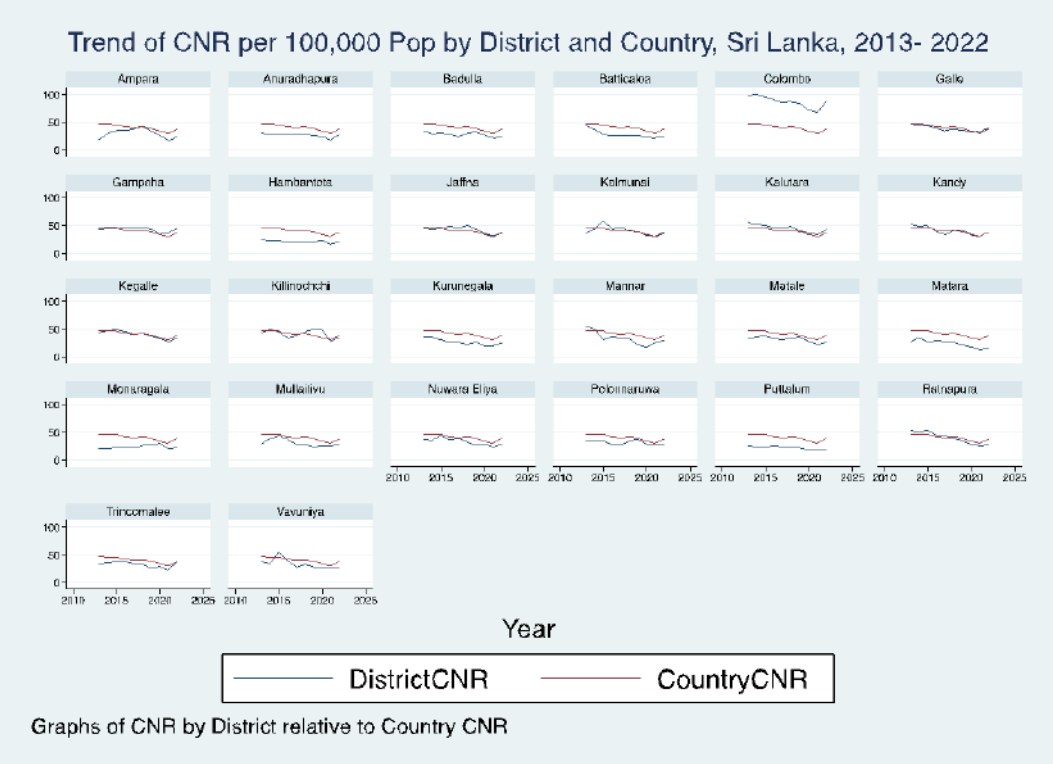


FIGURE 21: TREND ANALYSIS OF TB CNR BY DISTRICT IN SRI LANKA 2013-2022

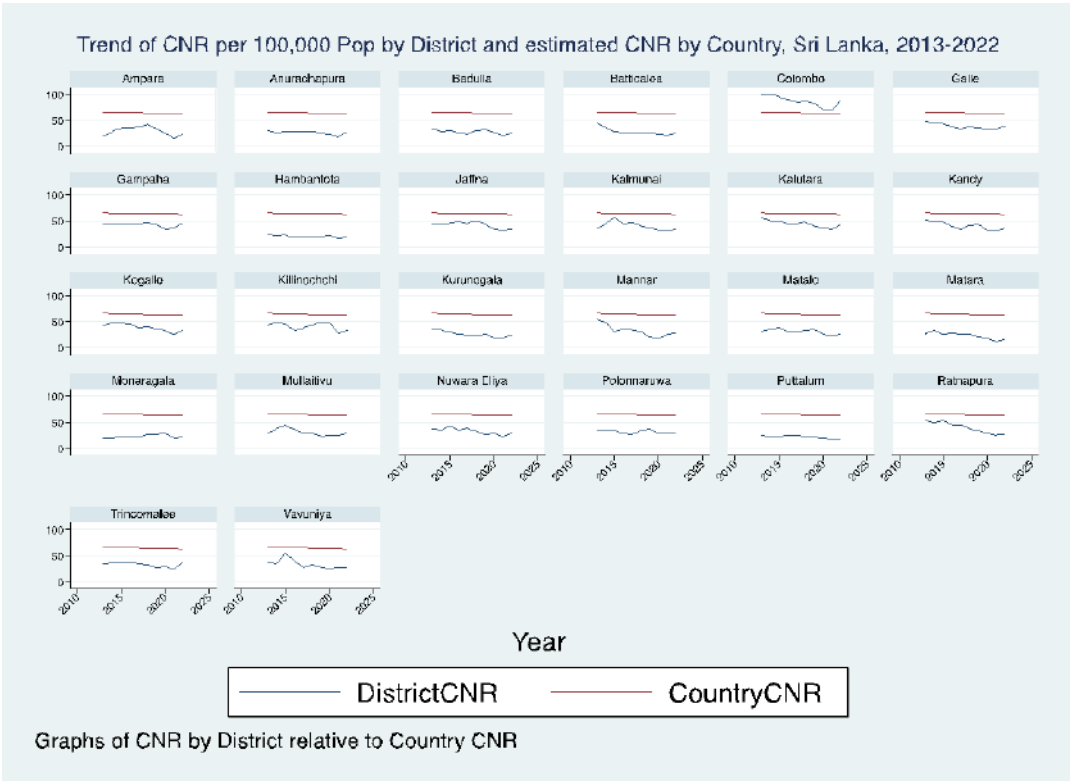


FIGURE 22: TREND OF CNR PER 100,000 BY DISTRICT AND ESTIMATED CNR BY COUNTRY SRI LANKA (2013-2022)

In 2022, four districts including Colombo (134%), Gampaha, Kalutara and Galle (69%, 68% and 60% respectively), exceeded the country level treatment coverage of 57.9%. Colombo

recorded more than a 100% treatment coverage for estimated incident TB cases. See graph of treatment coverage in figure 22. Lowest treatment coverage and CNR is consistently observed in Matara and Puttalum districts.

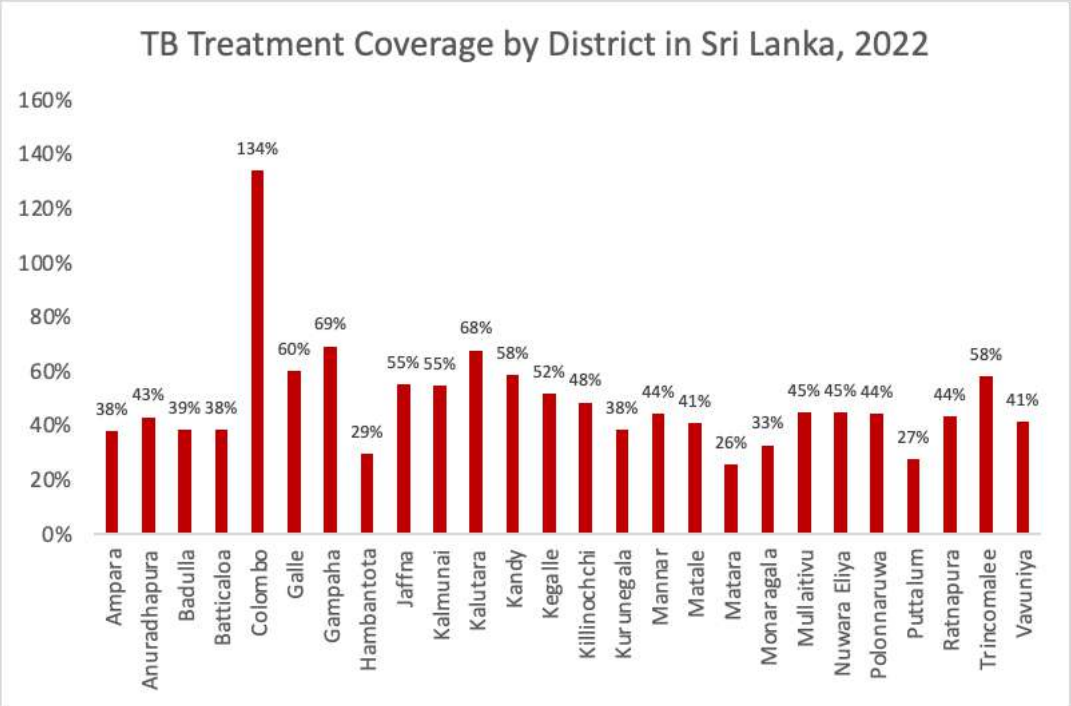


FIGURE 23: TREATMENT COVERAGE RATE BY DISTRICT, SRI LANKA (2022)

5.2 DSTB Treatment outcomes

Sri Lanka has maintained a commendable rate of favorable treatment outcomes with treatment success rate at an average 83% over the last ten year but experienced a decline to a TSR of 79.4% for the last cohort of cases registered in 2021 and reviewed at the end of 2022. This may be attributable to the impact of COVID-19 related lockdowns and restrictions negatively impacting access to TB treatment, patient tracking by PHIs and the collection of sputum for follow up tests in the last month of continuation of care. Figure 24 below shows the national level treatment success rate (TSR) over time among DS-TB cases (cohorts registered in the preceding year and evaluated in 2013 through 2021 with a range of 79.4% - 84.6% TSR. Figure 25 depicts that cure rates have remained stable at an average of 44% and treatment completion rate at a continual decline ending from 43% to 35%.This aligns with the distribution of bacteriologically confirmed cases constituting an average of 55% and clinical cases combined with EPTB constituting the other half. The gradual increase in cure rate vis—vis declining treatment completion rate is good and suggest good case holding. Cure rate among pulmonary bacteriologically confirmed cases enrolled for treatment in 2021 is 77%.The sum total of unfavorable outcomes (LTFU, Died, Failed and Not evaluated)are still high at 20.6%,

particularly the consistently high death rate of 9% suggesting that the TB cases present when they are extremely ill due to delayed access to diagnosis and treatment.

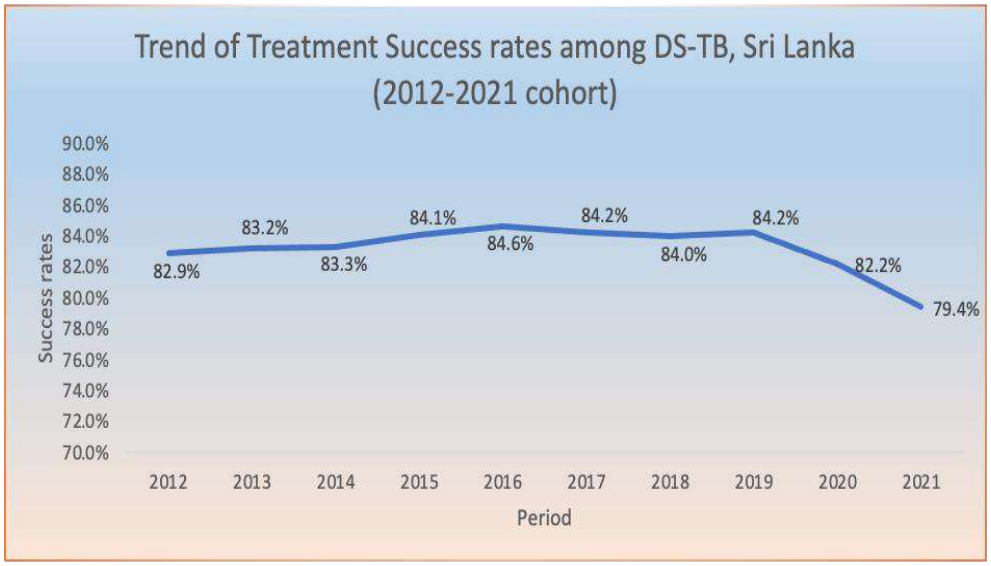


FIGURE 24:TREND OF TREATMENT SUCCESS RATE AMONG DS-TB, SRI LANKA, 2012-2021 COHORT

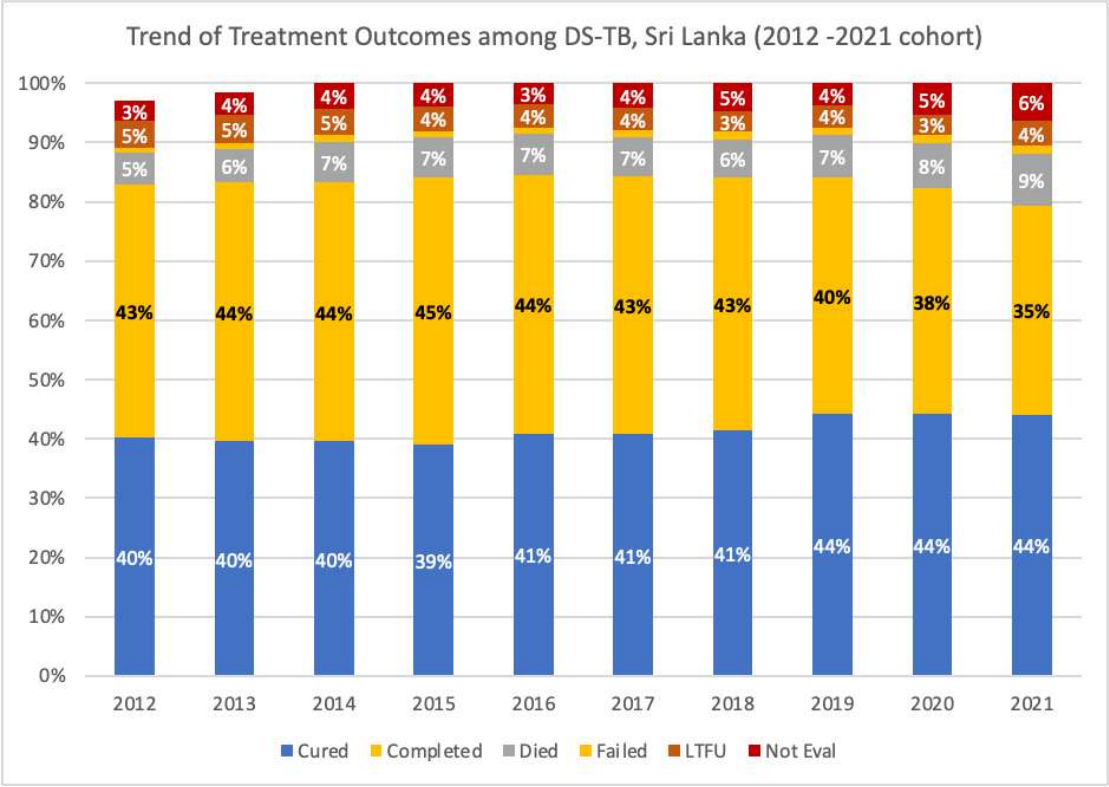


FIGURE 25:TREATMENT OUTCOMES AMONG DS-TB (2012-2021 COHORTS), SRI LANKA

When evaluated at district level, approximately 60% of districts recorded TSR above 80% (see figure 26 below). In terms of unfavorable outcomes, though national death rate is currently at 9%, outcome analysis in absolute numbers, showed most deaths occurred in Colombo and Gampaha (8.5% n=144 and 10.6% n= 95 deaths respectively). However, in

terms of proportion, Mannar and Kilinochchi districts had the highest death rate of 14%. Highest proportion of TB cases unaccounted for (not evaluated) was observed in Kalutara (18.1%) equivalent to 79 patients, nearly as high as Colombo (86 patients). Highest proportion and number of patients loss to follow up was observed in Colombo (9.1% equivalent to 153 cases) and Gampaha district (7.6% n=68).Overall, supervision by the NPTCCD surveillance team should target these key districts to identify and resolve factors contributing to the high unfavorable outcomes.

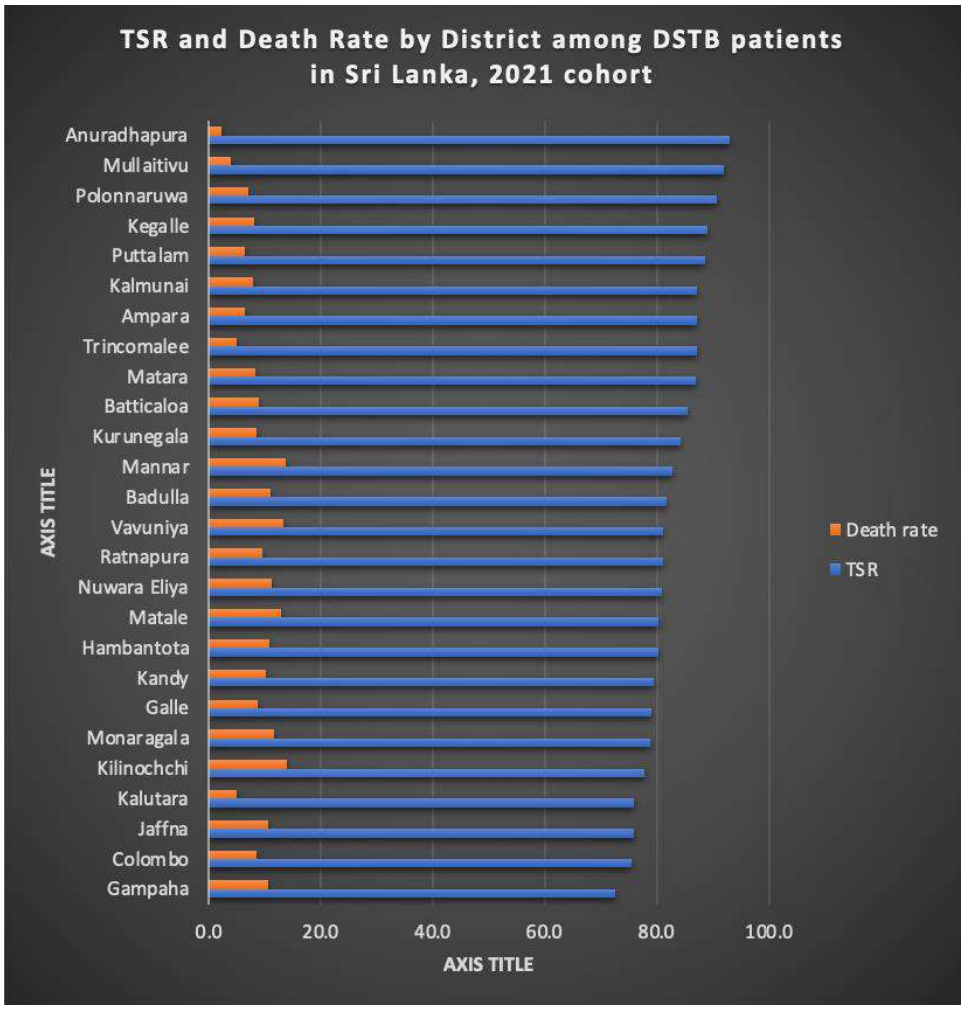


FIGURE 26: TREATMENT SUCCESS AND DEATH RATE BY DISTRICT, 2021 COHORT, EVALUATED IN 2022, SRI LANKA

Sri Lanka has a low HIV prevalence of less than 1%, and as such a combined evaluation of treatment outcomes among HIV negative and HIV positive TB are combined. Therefore, treatment outcomes above includes TBHIV patients.

5.3 Childhood TB

The proportion of all forms of TB notifications who are children under 0-14 years of age at the end of 2022 was 2.2% (187)and remained below expected range as shown in trend analysis in figure 27. When compared with global estimates for low-middle income countries (5-15%), it is considered to be significant under-notification and under-reporting of child TB cases.

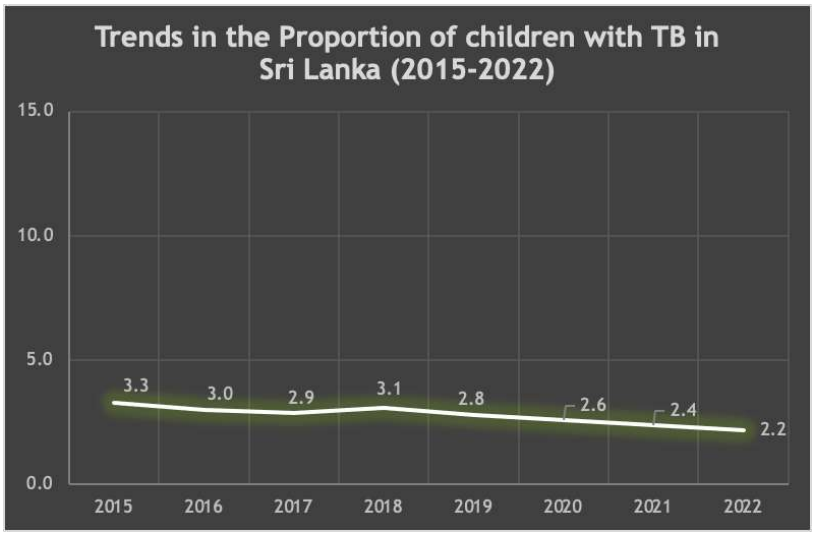


FIGURE 27: TRENDS IN PROPORTION OF CHILDREN (ALL FORMS)2015–2022SRI LANKA

The trend in ratio of 0-4 to 5-14 has also continued to decline in the last decade from 0.9 in 2015 to 0.4 in 2022,as shown in figure 28, which is at a reversal when compared to other South-East Asian countries that show increasing detection of child TB cases over the last decade, and when compared to the expected benchmark of 1.5-3.0.

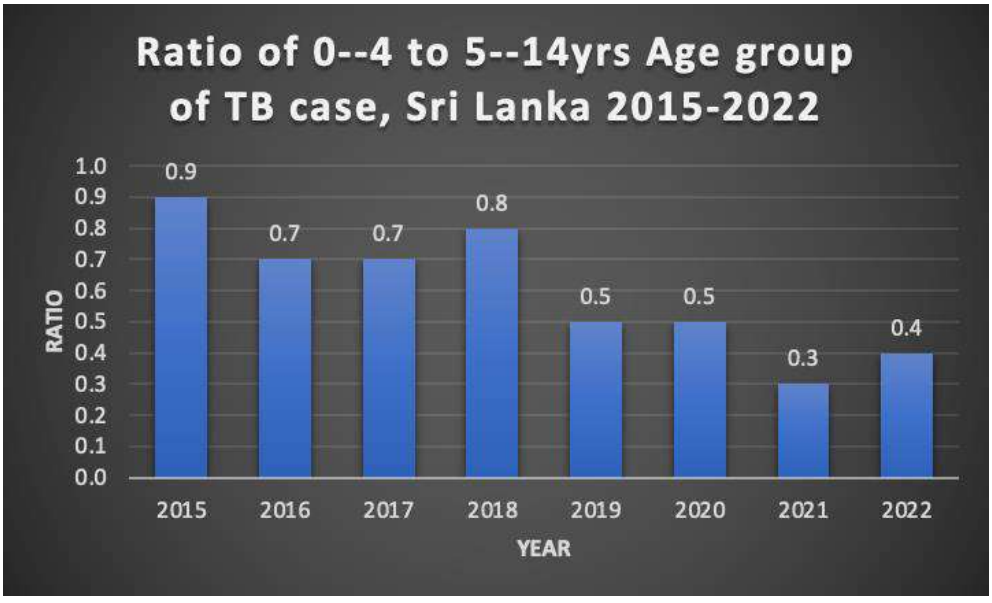


FIGURE 28:RATIO OF 05--5-14 YEARS AGE GROUP OF TB CASES, SRI LANKA 2015-2022

These findings implies a low investigation rate among children less than 5 years old, slow-paced adoption of innovative pediatric TB interventions by the NPTCCD, sub-optimal capacity and understanding the childhood TB diagnostic algorithm and policies, limited capacity among health care providers to induce sputum production in children, possibly low capacity to diagnose pediatric TB among medical officers at OPD clinics, and weak referral linkages to pediatric facilities for further evaluation, are but a few limitations leading to low childhood TB detection. Since a national-level investigation such as an inventory study has not been conducted, it is difficult to conclude 2.2% is a true reflection of the childhood TB proportion or that ≥ 90% of childhood TB cases are reported to the NPTCCD. A combination of the aforementionedindicates potential under-reporting of TB among children aged 0-4 years, which leads us to conclude that the current surveillance data for children with TB do not meet the standards for a reliability.Intensifying TB finding among children less than 5 years old requires the NPTCCD actively engage pediatricians and pediatric clinics both in public and private settings in TB screening, child TB case detection and facilitating pediatric TB trainings focused on standard child TB diagnostics, diagnostic algorithms, and treatment monitoring. The NPTCCD needs to constitute a childhood TB task force to review contact investigation, invitation and tracing processes, including tools and diagnostic capacity for childhood TB, as well as develop training curriculum for childhood TB diagnosis in line with WHO recommended strategies and KNCV's benchmarking policies, practices and planning for childhood TB.Additionally, job aids with shout outs e.g., "**THINK TB",** and laminated **pocket size** copies of TB **diagnostic algorithms** (particularly for child TB diagnosis) should be printed, distributed, and pasted at OPD clinics.

5.4 HIV-associated TB

HIV and TB/HIV burden remains low in Sri Lanka with HIV prevalence less than 1% among the general populace and the TB population. The NPTCCD has maintained high HIV test rates among TB patients at an average of 95% over the last five years up until 2022, when it declined to 80%. Approximately 50% of all TBHIV cases are detected from Central Colombo. ART and CPT uptake are suboptimal ending declining from 72% in 2017 to 53% for ART and from 36% to 18% for CPT in 2022 respectively as shown below.

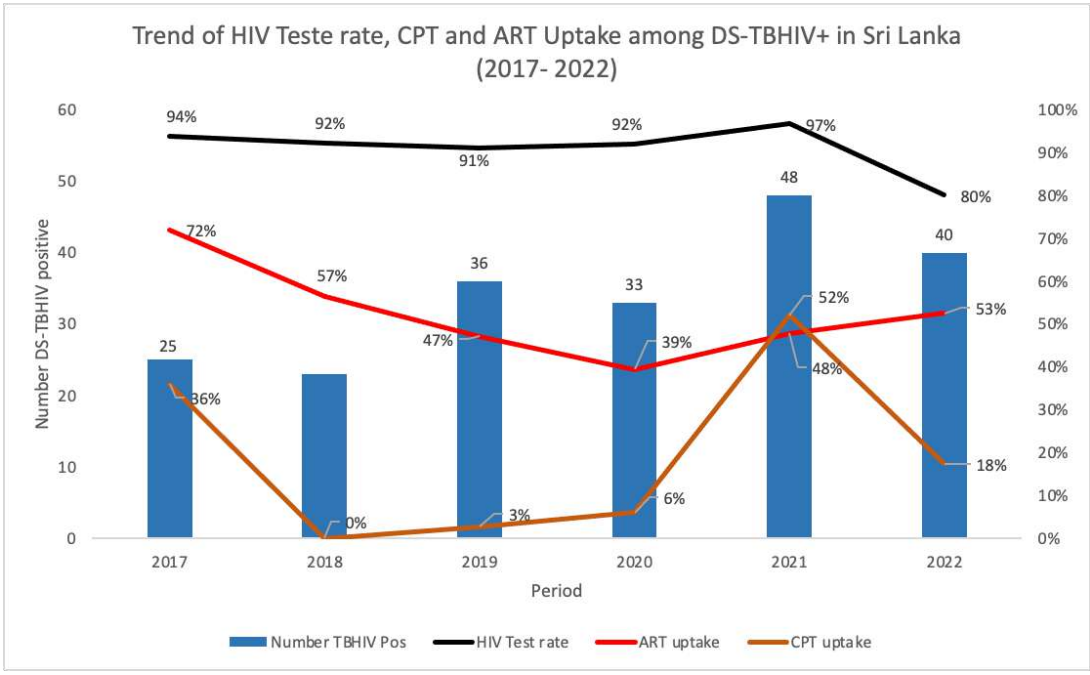


FIGURE 29:TREND OF HIV TEST RATE, DS-TB/HIV POSITIVE, ART, AND CPT UPTAKE, SRI LANKA, 2017-2022

Across the districts, ART and CPT are low as expected relative to national level rates. uptake is very high and greater than 90%, which reflects good uptake of ART and good documentation. It is worthy of note that while all of the six TBHIV patients in Gampaha were placed on ART, none of the TBHIV patients (0/6), were reported to be placed on CPT. CPT uptake has been considerably low in the past years (as low as 0-6% in 2018 to 2020) which may be attributed to, sub-optimal documentation of CPT uptake at facility level, weak linkage between TB and HIV programs to track patients administered CPT at the level of the HIV program, incomplete TBHIV data transmission from paper to electronic TB systems, or non-adherence to stipulated TBHIV guidelines by health staff to administer CPT to TBHIV co-infected patients. See figure 30 for trend of notified TBHIV cases, ART, and CPT uptake. Given the low CPT uptake, the NPTCCD should include CPT uptake audit as a key indicator to track and monitor during on-site data validation and data quality audits to further improve TBHIV surveillance and prevent opportunistic infections among TBHIV co-infected patients.

5.5 Anti-TB drug resistance

Sri Lanka is a low burden DRTB country.The estimated proportion of TB cases with MDR/RR-TB in Sri Lanka is 0.5% (0.11-1.5) equivalent to 15- 210 cases with an average of 70 casesannually[21]or a MDR/RR incidence of 0-200/100,000 population equivalent to 91

[21] https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&entity_type=%22country%22&lan=%22EN%22&iso2=%22LK%22

MDR/RR cases annually. Though Sri Lanka has adopted the policy for WHO- recommended rapid diagnostics (WRD) as the initial test for all presumptive TB cases among specific groups as aforementioned, by using the Xpert MTB/RIF assay to simultaneously detect both mycobacterium TB and resistance to rifampicin, AFB microscopy is still the predominantly utilized diagnostic tool per algorithm. Hence, among all bacteriological cases diagnosed in 2022 (n=3882), only 18% (697)were diagnosed using GeneXpert which suggests limited rifampicin susceptibility status documented for less than 20% of new TB cases diagnosed in 2022. Given the recommended use of GeneXpert particularly for specific groups, GeneXpert testing is grossly under-utilized across majority of sites where they are located. Notably, DRTB cases in Sri Lanka increased from 10 to 16 between 2021 and 2022, and already up to 15 cases by mid-year of 2023.

5.5.1 Age group, sex and Treatment history distribution

When disaggregated by sex, DRTB is consistently higher among men with aratio of nine males to every diagnosed female (9:1 M:F ratio) in 2021 and 3:1 in 2022; see figure 32 below. Out of the 16 cases detected in 202022, only 1 DRTB case was aged 0-14 years.

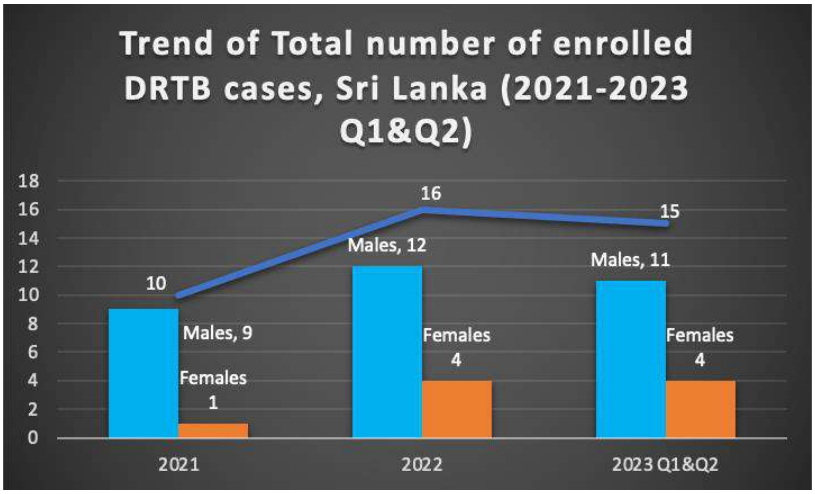


FIGURE 30:TREND OF DRTB ENROLLED IN SRI LANKA(20218 TO Q2 OF 2023 WITH GENDER DISAGGREGATION

Drug-resistance TB patients are managed centrally at National Hospital for Respiratory Diseases, with the standardized shorter regimen and longer regime. Gampaha DCC provides the full range of DRTB care and is hospital-based.

While recognizing the significant strides of the NPTCCD in DR-TB disease surveillance; efforts are needed in ramp up the active use of GeneXpert for TB diagnosis to sufficiently determinerifampicin susceptibility status for at least 75% of new TB cases

registered in Sri Lanka. Since TB is relatively very high among men (M:F ratio of 1.75: 1) and Sri Lanka has high internal and external migrant population, this poses a high risk of treatment interruption and concomitant increase in DRTB cases in the long run.

5.6 Incidence and Mortality

The WHO estimates a TB incidence of 63/100,000 population in Sri Lanka, mortality of TB excluding HIV+TB cases of 3.5/100,000 population (760 deaths) and a HIV positive TB incidence of 0.46/100,000 population equivalent to 100 TBHIV positive cases) annually[22], as shown in figure 31and 32 below.

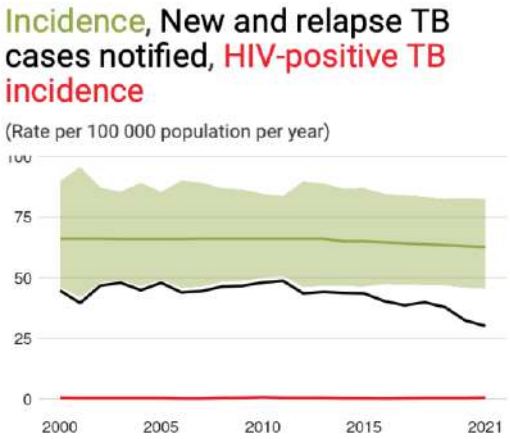


FIGURE 31:TREND OF TB ESTIMATES, SRI LANKA, 2000-2021

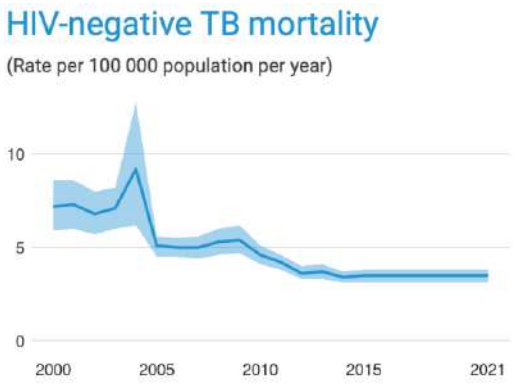


FIGURE 32:TREND OF ESTIMATES OF TB MORTALITY RATE, SRI LANKA, 2000-2021.

Source@WHO

In comparison to the 567 deaths reported in NPTCCD surveillance among 2019 cohorts, the 2019 VR data suggests plausible higher TB-related deaths of 675 TB related deaths. As described in section 4.2, TB deaths as a cohort report from the NPTCCD is derived from TB

[22] https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&entity_type=%22country%22&lan=%22EN%22&iso2=%22LK%22

patients registered in the preceding year only that could have died within the year of registration or at least in the following year, while TB related deaths in the VR system captures patients that died within a given year onlyand as such a moving average across a combination of years is required sufficiently extrapolate gaps if any in TB deaths reported by the NPTCCD. Implementing a fully functioning vital registration system will allow direct measure for TB death and provide more precise estimation.

5.7 Determinants of TB

Access to health care, TB risk factors such as diabetes, smoking, and alcohol, impact on the TB burden for any given society, thus requiring limiting exposure to these risk factors, early diagnosis, and improved co-management of diseases such as diabetesand HIV.

In Sri Lanka, we evaluated access to health care at macro levels and the prevalence of smoking, out of pocket health expenditure, under-nutrition and mortality among children which put together, can worsen the TB disease course as well as predispose to its development.

5.7.1 Access to health care macro level indicators

Indicators such as under 5 mortality (U5)rates (probability of dying by age 5 per 1000 live births) which is expected to be less than 10, and the percentage of total out of pocket health expenditure expected to be < 25%, offer some estimation of access to health care in a given population. The trends in these indicators in Sri Lanka suggest that access to health care has improved to substantial impact and help reduce the burden of TB in Sri Lanka.

Sri Lankans have made significant progress in the percentage of stunting among children, with about 17.3% of children under 5 affected, which is relatively lower than the average for Asia region at 21.8%. However, the percentage of wasting is still high at 15.1% above the average for Asia region which is 8.9%[23]. Sri Lanka has achieved great strides in reducing U5 mortality (U5MR) over half a century from93.9 per 1000 live births in 1960 to 10in 2011 and to 6.7 per 1,000 livebirths in 2021[24]as shown in figure 33, which is far lower than the global target of 10.

[23] https://globalnutritionreport.org/resources/nutrition-profiles/asia/southern-asia/sri-lanka/

[24] https://data.unicef.org/country/npl/

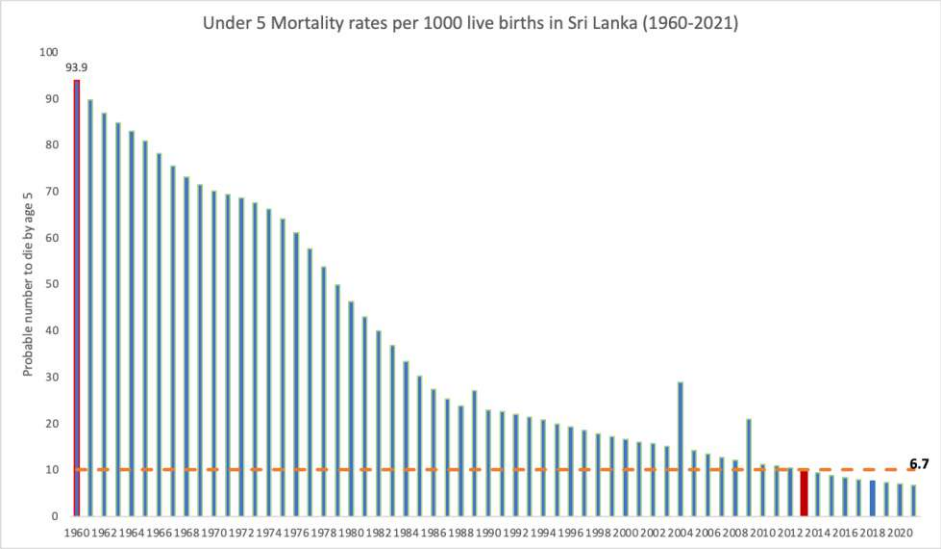


FIGURE 33:UNDER 5 MORTALITY RATE PER 1,000 LIVE BIRTHS IN SRI LANKA (1960-2021)

According to the World bank data, out of pocket (OOP) health expenditure in Sri Lanka is relatively high at 46.6 in 2020[25] paling in comparison to global targets of <25% (see figure 41), and when compared to the Asia region.

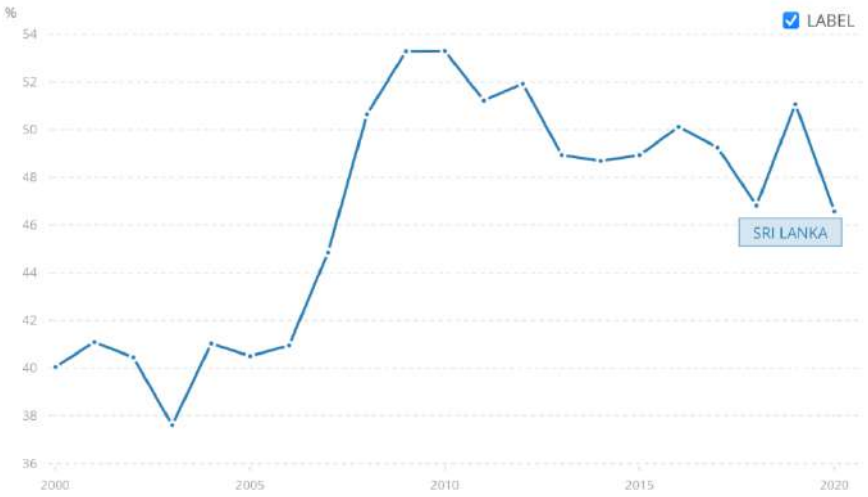


FIGURE 34:TREND OF OUT OF POCKET HEALTH EXPENDITURE IN SRI LANKA (2000-2020)

5.7.2 TB and smoking

According to the 2019WHO age- standardized estimated prevalence (STEPS) survey and 2021 WHO global report on global tobacco epidemic, the prevalence among ages 15 years and older of any current tobacco use is 22.6% among both sexes (42.4% among males: 2.8% female), while prevalence of any tobacco smoking is 12.9% in both sexes (25.6% males:

[25] https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=LK

0.3% females)in Sri Lanka[26]. Sri Lanka's prevalence of tobacco smoking is moderately lower than the world's average of 19.6%[27].Tobacco smoking increases the risk of TB 2-3-folds and is associated with poor TB treatment results. Given that males in Sri Lankaare the majority of smokers (less than 3% prevalence in females), it becomes imperative to target men that use or smoke tobacco in combating TB. Smoking prevalence is often high among people with TB, and prevalence of other smoking-related conditions can be high as well.

5.7.3 TB and diabetes

People with a weak immune system, as a result of chronic diseases such as diabetes, are at a higher risk of progressing from latent to active tuberculosis. Diabetes triples a person's risk of developing TB, with about 15% of TB cases notified globally, estimatedto be linked to diabetes.According to the international diabetes federation the prevalence of diabetes in Sri Lanka among adult population is 9.8%[28].World Bank estimatesthe prevalence of diabetes in Sri Lanka at the end of 2020was11.3% among adult population ages 20-79 years[29]. Studies have shown high rates of pre-diabetes at 30.5%[30] suggesting future risks and higher rates of diabetes in the long run in Sri Lanka. In collaboration with diabetic clinics and organizations with vested interest in curbing diabetes in Sri Lanka, active TB screening using the standard TB screening tool for TB, and the use of latent TB testing using TST or IGRA should be institutedin these clinicsto ensure early diagnosis of TB, and latent TB treatment for LTB reactive cases that active TB has been ruled out.

[26] https://cdn.who.int/media/docs/default-source/country-profiles/tobacco/who_rgte_2021_sri_lanka.pdf?sfvrsn=c96fde73_5&download=true

[27] https://tobaccoatlas.org

[28] https://idf.org/our-network/regions-and-members/south-east-asia/members/sri-lanka/

[29] https://data.worldbank.org/indicator/SH.STA.DIAB.ZS?locations=LK

[30] Rannan-Eliya RP, Wijemunige N, Perera P, Kapuge Y, Gunawardana N, Sigera C, Jayatissa R, Herath HMM, Gamage A, Weerawardena N, Sivagnanam I, Dalpatadu S, Samarage S, Samarakoon U, Samaranayake N, Pullenayegam C, Perera B; SLHAS Collaborators. Prevalence of diabetes and pre-diabetes in Sri Lanka: a new global hotspot-estimates from the Sri Lanka Health and Ageing Survey 2018/2019. BMJ Open Diabetes Res Care. 2023 Feb;11(1):e003160. doi: 10.1136/bmjdrc-2022-003160. PMID: 36796852; PMCID: PMC9936281.

6 Summary of epidemiological analysis

Sri Lanka has about 42% of undiagnosed TB patients every year (WHO estimates of 14,000 compared to 8,342 TB patients notified in 2022). Finding missing TB cases in Sri Lanka is a priority and understanding the true burden and changing trends of TB based on WHO estimates or epidemiological reviewsremains important. Based on the epidemiological reviewfindings with some degree of uncertainty, there is a substantial under-notification and under-reporting. The quality of monitoring, on-site data validation and supportive supervision activities from national and district levelsare sub-optimal and can be improved. Active case finding strategies are currently being carried out in a limited frequencyat districts and congregate settings, and more than 60% of patients visiting private practitioners (part-time) and base hospitals are not diagnosed on first contact. When combined with the low child TB proportions; low TB screening activities in OPDs; low suspicion for TB among doctors; non-standardized diagnostic approaches at facility levels; centralized TB treatment which limits access to diagnosis, treatment initiation and increases risk of pre-treatment initial loss to follow up and treatment interruption; and Sri Lanka's slow adoption of GeneXpert testing as an entry point of TB diagnosis; put together, the likelihood of under-notification and under-reporting of TB cases in Sri Lanka is high. The high TB proportions in the elderly population and low TB notification among children under 5 calls for community-based strategies and strategic engagement of institutions involved in child care and child well-being programs. It is essential that the short and long-term recommendations highlighted in earlier sections be urgently implemented in a sequential manner. Simultaneously, the NPTCCD through support of TGF, WHO and her supporting NGOs should endeavor to incorporate these recommendations as part of its newconcept for funding through the Global Fund and other donor sources.

7 M & E investment plan

For all captured items below refer to section 4.6.1 and 4.6.2 under recommendations for more details.

s/no	Recommendation	Activities	TA	Funding
1	Print and distribute standard R&R tools including Presumptive Register to hospitals and DCCs	-Secure funding for printing -Print, disseminate and orient staff on use during review meetings -Designate staff at facility to complete presumptive registers	NPTCCD/WHO	WHO/GF
2	Recruit a full time Health Management IT specialist or staff at NPTCCD	Define job descriptions, advertise and interview candidates. To provide architectural and maintenance support for ePIMS electronic surveillance system	Local TA- refer to short term recommendations for details)	Budget required - GF
3	Review and harmonize data on ePIMS to include relevant cascade-driven elements and indicators, including systematic collection of presumptive TB data in cascade flow.	Organize a two-day meeting with IT expert to update/revise data cascade for TB/TBHIV/DRTB and other relevant indicators	Local TA-IT expert	Budget required - MoH
4	Fully roll out all modules of ePIMS modules to all DCC sites, and monitor utilization	Software and hardware, materials, Internet, supportive supervision	None	None

5	Implement phased-decentralization of TB treatment initiation services from DCCs to base, general and teaching hospitals	-Organize high level advocacy to medical officers of health -Organize one-day consensus building meeting with leadership of targeted hospitals -Identify facility focal persons e.g., medical officer, nurse, health care worker, as DOTS focal point -Train focal point on TB diagnosis and treatment -Supply R&R tools and access to ePIMS -DTCO to conduct two-weekly supervision t newly decentralized site for the first 2-3 months -Leverage World Bank supported shared care model to decentralize to PMCU	WHO/GF TA	Budget required-MoH/GF
6	Establish use of unique identifiers (UI) for presumptive TB cases and registered TB patients on electronic registers	Secure UI system	WHO/ NPTCCD HMIS IT	None
7	Revise supervision checklist, develop annual supervisory plan, and train staff at national level on use	-Organize one day surveillance team meetingto develop annual supervisory plan with timelines, and revise supervision checklist to target areas of need e.g. availability of R&R tools, patient loss rate, AFB IQC etc. - Organize one day refresher training on supervision and revised checklist	None	Budget required-WHO
8	Develop standard operating procedures for data validation, data quality assurance and feedback mechanism	Organize two day workshop of M&E experts to develop SOPs for DQA, OSDV/bi-annual and annual audit plans/schedule/tools and carry out DQA on yearly basis	GF/WHO	Budget required -GF
9	Conduct periodic (6-monthly) OSDV and annual DQA	Conduct bi-annual joint field trips of M&E, Lab and other program staff	None	Budget required -GF
10	Develop EQA for GeneXpert and ensure regular IQC at AFB laboratories	Organize three day workshop to develop and finalize EQA guides and tools	WHO LAB TA	Budget required -GF

11	Reassess utilization rates of GeneXpert and consider strategic redistribution of machines to private and public facilities	Conduct detailed desk review exercise Develop MOU with recipient site	None required	Budget required -GF
12	Comprehensively assess drug stock management at facility level for tracking and accountability	Engage procurement and supply TA to assess drug stock management systems and recording, particularly important for decentralization of TB treatment initiation	International PSM TA	GF
13				
14	NPTCCD to advocate to medical officer of health and administrative leadership for authorization of TB trained medical officers at OPD to utilize full complement of TB diagnostic tools including the use of chest-X-ray for TB diagnosis among children and immunosuppressed patients	Print, disseminate and orient staff on use during review meetings	None required	Budget required - MoH
15	NPTCCD to urgently advocate and sensitize medical doctors on the use of TST Mantoux test as a proxy diagnosis for TB	Conduct half day sensitization meetings with clusters of hospitals	Local Chest Physician	Budget required -GF
16	Urgent sensitization of consultants on the need to adopt standard TB treatment regimens and desist from the practice of trial treatments	-Sensitize consultants on TB treatment regimen options - Sensitize DTCOs that all patients initiated on TB treatment irrespective of treatment regimen to be promptly registered and notified	None	None- Incorporate in facility sensitization meetings
17	Engage pediatricians and pediatric clinics both in public and private clinics on child TB screening, case detection and pediatric TB trainings	-Engage TA for pediatric TB to provide assistance to strategically develop, implement childhood TB strategies and interventions, and develop strategic plan of work and training curriculum to improve pediatric TB casefinding and management -Engage pediatricians as 'hubs' to support 'spoke' facilities to enhance capacity of pediatric TB -Organize two day mentorship training for childhood TB	Local TA	Budget required -GF

18	Review contact investigation, invitation tracing, tools, and diagnostic capacity for childhood TB	Constitute a childhood TB task force to carry out review and organize a meeting to support development of a training curriculum for childhood TB diagnosis in line with WHO recommendations and KNCVs' benchmarking policies, practices and planning for childhood TB	WHO Country office/ Partners/NPTCCD	Budget required -GF
19	Organize consensus building meetings on childhood TB with umbrella bodies of pediatric association, association of private practitioners, national immunization programmes, maternal and child health services (MCH).	-Organize one day meeting with umbrella bodies -Actively participate in health summits organized by these bodies to provide orientation on national TB diagnostic algorithms and treatment guidelines for pediatric and adult TB	None	Budget- WHO
20	Integrate TB services into maternal and child health clinics in secondary and tertiary health facilities	Identify and train care mentors on child TB diagnosis and treatment	None	Budget required - WHO/MoH
21	Identify medical officers and nurses as care mentors and referral hub to support peripheral health facilities for TB diagnosis in children under 5 years and among elderly population	Conduct desk review and consultation interviews to identify and select pediatric/elderly care mentors	Local TA	Budget required -GF
22	Organize facilitators training (TOT) for **care mentors** among Medical officers and nurses on childhood and elderly TB diagnostic algorithms and treatment among children and the elderly, and support cascade of training	- Organize batches of one-day training of pediatric TB hubs for sputum induction and child TB diagnosis -Conduct four batched childhood TB refresher training annually for medical officer and nurses	Local TA	Budget required -GF
23	Engage private practitioners in high density areas to provide referral and diagnostic services, and treatment in the long run	-Conduct desk assessment to select private practitioners based on OPD attendance, and review referral mechanisms - Advocate and develop MOU for engagement for referral, diagnosis and/or treatment services -Provide R&R tools and identify	None	Budget required -GF

		DOTS staff -Provide routine monitoring and supportive supervision -Conduct regular performance assessment and shortlist for TB treatment service provision		
24	Identify clear incentives for engagement of private practitioners in TB services e.g. (attendance at national level meetings, sponsorship of ads and panel sessions on regulatory body annual health summits, conference attendance and recognition awards	Organize consultative meetings with umbrella bodies of private practitioners for consensus building and information gathering	WHO	Budget required -GF
25	Conduct six-month or yearly desk review of HR capacity for TB diagnosis at AFB microscopy centers	Conduct desk assessment and field visits	None	Budget required-MoH
26	Evaluate Pre-treatment LTFU and delay in diagnosis and treatment enrolment analysis	-Develop assessment tool -Conduct detailed desk review and field assessment	Local Research TA	GF budget
27	Institute Refresher trainings on QA and laboratory updates among Lab staff at least every 3 years	Conduct two day refresher trainings on Lab QA	None	Budget required-MoH/WHO
28	Develop M&E plan to include clear goals, objectives and clearly defined financial plan these incorporates investment needs	Organize five day M&E plan development workshop	GF/WHO	Budget required -GF
29	Develop a comprehensive training plan and curriculum to include M&E and refresher training on TB data quality, analysis and surveillance	Organize three-day workshop to identify training needs, develop plan and schedule, and update existing training curriculum	None	Budget required-MoH
30	Develop quarterly, six-monthly and annual plan/schedule for community awareness campaign using mobile truck	Organize half day meeting to conduct desk review and develop targeted community awareness campaign screening plan/schedule	NPTCCD/WHO	None
31	Develop annual and quarterly supervision plans, harmonize supervisory checklist to meet TB surveillance needs	Organize one- day desk review meeting and planning	DSTB/DR-TB/LAB Local TA team/HMIS IT as necessary	Budget required-MoH

32	Enhance M&E team capacity on effective supportive supervision	Organize one day refresher trainings biannually at national and provincial level on supportive supervision, TB data surveillance, data quality and analysis	WHO Country office/ NPTCCD local TA	Budget required -GF, WHO, partners
33	Provide incentives such as recognition awards and participation at meetings or joint supervision, for high-performing facility staff, public or private facilities.	Procure recognition awards and support participation of recognized staff at national meetings	None	MoH/WHO budget
34	Facilitate collaboration with Ministry of Justice and Law Reforms to integrate routine TB screening in prisons during inmate enrolment (on enrolment card) and contact investigation among inmates of index cases.	Organize stakeholders meeting with MoH and MoJ to endorse revision and update of prison health unit information card to include inquiry about TB symptoms	None	Budget required - MoH
35	Scale up latent TB infection detection and short treatment regimens	Organize one day sensitization meetings and screenings at health clinics including Diabetic clinics, Cancer clinics, PLHIV clinics, maternal and child health clinics (MCH)	WHO	Budget required - WHO/GF
36	Adopt use of social media and other social mobilization tools for TB awareness campaigns	Collaborate with advocacy and health promotion programs and Partners to promote TB awareness programmes through social media	None	Budget required - WHO/MoH
37	M&E team to participate in international cross-country 'shadowing and under-study' of surveillance systems and Supply chain management of TB drugs and logistics supplies for best practices	Sponsor participation of two staff on a one week international travel for shadowing and peer-2-peer learning	GF	Budget required -GF
38	Support annual coding of COD VR department and assess moving average of TB-related mortality rates	-Support analysis of TB related deaths moving average analysis	None	None

39	Carry out an inventory study to assess level of under-reporting	Develop study proposal, implement study, Conduct a capture-recapture modeling to estimate completeness of TB registers for its utilization in providing accurate unbiased estimates Write report and disseminate	WHO HQ	GF budget
40a	Share Epi review report and recommendations	Print and disseminate epi review report to staff and Partners	None	NPTCCD/GF
40b	Conduct an epi-review in a minimum of 3 years to 5 years	Field visit, data analysis, NPTCCD capacity building, report writing	GF	Budget required -GF and WHO

Appendix 1: Completed Standards and benchmarks assessment

PART A: CHARACTERISTICS OF THE TB SURVEILLANCE SYSTEM_SRI LANKA

QUESTIONS	OUTCOMES (best practises in bold)	RESULTS (DESCRIPTION)	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 are recorded on paper at the health facility and then aggregated by DCC staff in web-based electronic systems ePIMS	Expand coverage of ePIMS comprehensive module content use to full scale beyond Colombo DCC to other 25 DCCs Validate and crosscheck aggregated dataroutinely
A2. Do all service delivery points systematically use standardised TB data collection forms and tools?	☐ Yes, completely ☒ Mostly ☐**Partially** ☐ No, not at all	Standardized tools in use in some facilities, but presumptive register is not fully in use	Print and disseminate presumptive registers.

QUESTIONS	OUTCOMES (best practises in bold)	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
A3. Which TB cases are included in the national TB surveillance data? *(Tick all that apply)*	☒All TB cases from all parts of the country ☒ Some TB cases are excluded ☐Some part(s) of the country are excluded ☐Some case types are excluded ☐**Some care providers, e.g. non-NTP providers, prisons, private practitioners, are excluded.** ☒ Others: _____	Some patients on trial treatments are excluded from notification until months after consultant makes a decision to place on four fixed dose regimen Presumptive data not aggregated completely, as main source is laboratory register, hence, making it difficult to ascertain cases that may have been missed out in the surveillance data system	Ensure all trail patients initiated on TB treatment are registered and notified. Ensure use of presumptive register during supervision and trainings
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**	Aggregate data for all cases (DS & DR-TB) available. Data on presumptive TB cases retrieved from Laboratory register	Designated IT expert to support routine management of ePIMS. Update data entry platform on ePIMSto include presumptive TB
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		
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	Validation is done occasionally at national level but requires improvement. OSDV exercises are conducted on ad-hoc basis by surveillance team at national level. There are limited validation rules or checks on the ePIMS platform	Monitor accuracy and completeness of quarterly reports received from all DCCS regularly. Update the ePIMS platform witha validation check power of'moderate/high', while also ensuring funds are made available for routine monitoring by DTCO.
A7. What types of quality assurance procedures	☐Quality controls are in place for the electronic surveillance system (automated checks at data entry and batch checking, plus SOPs) ☒ Data are reviewed during	Review meetings were previously done annually at district level, and data review is carried out occasionally at national	Review the supervisory checklist to include quantitative components e.g., availability of presumptive register,

QUESTIONS	OUTCOMES (best practises in bold)	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
are systematically undertaken for TB data? *(Tick all that apply)*	supervisory monitoring visits to service units and sub-national levels (How often?) ☒Data are reviewed during meetings with TB staff (How often? *every 4 months*) ☐**Other** (specify: ____)	level. Quarterly DTCO reviews are done. OSDV exercises are not routinely done. There are also no SOPs for data quality assurance	spot check treatment cards and registers for key variables to assess accuracy and count the number of cases reported in the quarterly report compared with register/treatment cards. Develop SOPs for data quality and verification including data quality indicators that should be monitored over time. Conduct OSDV in a strategic manner with focus on sites with data challenges.
A8. Is feedback on TB data quality systematically provided to all lower reporting levels?	☐Yes, completely ☐Mostly ☒**Partially** ☐ No, not at all	Done partially by DTCO and during supervision by national level team. Feedback is provided immediately during visits, but not followed up. There is low capacity at all levels to assess data quality as a routine in a systematic manner	Designate NPTCCD staff at national level should be assigned data quality assurance role, and mentor NPTCCD staff on systematic data quality assessment during supervision. Ensure documented feedback is provided at facility level for follow up and progress tracking
A9. When are national TB case data for a given calendar year considered ready for national analyses and reporting?	☐ **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	Data is considered ready three months post the end of the preceding calendar year	
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 available online	
A11. Does the national TB programme have a training plan which includes staff	☒**Yes** ☐No	Global Fund Project and WHO supported trainings are conducted in accordance with line budget	

QUESTIONS	OUTCOMES (best practises in bold)	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
involved in data collection and reporting at all levels of the reporting process?			
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**	Annually, on all ePIMS modules, completing R&R tools, Supervision, Counselling, contact tracing and TB treatment monitoring	
A13. How many staff work on TB surveillance at the national level? *(Tick all that apply)* •	☒ Epidemiologist, full-time (_1) ☐ Epidemiologist, part-time (_) ☒ Statistician, full-time (_1____) ☐ Statistician, part-time (_____) ☒ Data manager, full-time (_2__) ☐ Data manager, part-time (____) ☐Data quality officers, full-timeplanned but not currently in post. Data quality officers, part-time (__) ☒**M&E Manager** (_1_) ☒**Other** (specify: 3 Development officers and 1 Technical officer)	Robust surveillance team in place, however, no HMIS IT specialist to support management of electronic system	Recruit a HMIS IT officer at national level into the M&E team to actively support ePIMS monitoring and quality data management.
A14. Is a national TB surveillance report routinely produced and disseminated on an annual basis?	☒ Yes ☐**No**	Annual report is available.	
A15. Are there written goals of the surveillance system?	☒ Yes ☐ No	Yes, goal contained in NSP.	
A16. Policies and procedures are in place to protect the confidentiality of all surveillance data e.g.	☐ Yes, completely ☐Mostly (names only appear on TB registers/treatment cards/lab registers at facility level) ☒ Partially ☐**No, not at all**	Password restricted access to case level data available at national and sub-national level s	Unique identifiers should be applied in the electronic systems

QUESTIONS	OUTCOMES (best practises in bold)	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
records, registers.			
A17. Is there a long term financial plan and budget in place to support TB surveillance activities?	☐**Yes** ☒ No	No. There is no National financial Plan and budget to support TB surveillance activities	The NPTCCDshould develop a plan and allocate budget for required activities and recommendations from this review to support TB surveillance activities
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)	The first, second and third TB epidemiological reviews was conducted in 2014, 2017and 2020respectively	

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)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
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[i] are distinguished from clinically diagnosed cases • New cases are distinguished from previously treated cases • Pulmonary cases are distinguished from extra-pulmonary cases	☒**Met** ☐Partially met ☐Not met	All done and written in the guidelines.	

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
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	• All are done and can be verified at the registers. • Age and sex available for DS and DR-TB	
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 sub-national (e.g. provincial or regional) electronic systems:* • 100% of expected data files have been imported	☒**Met** ☐Partially met ☐Not met ☐Not applicable	Reports from facilities were complete for 100%, but promptness in submission could not be ascertained	
B1.4 Data in quarterly reports (or equivalent) are accurate, complete, and internally consistent *(For paper-based systems*	All benchmarks should be satisfied to meet this standard: • Sub-totals of the number of TB cases by age group, sex, and case type equals the total number of reported TB cases in ≥95% of	☒**Met** ☐Partiallymet ☐Not met ☐Not applicable	Quarterly data are consistent with nationally aggregated data	

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
only)	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 source documents (patient treatment cards and laboratory register) • Data for a minimum set of variables are available for ≥95% of the total number of reported TB cases in quarterly reports.			
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	Data validation checks occasionallyconducted at national level	Update ePIMS with data validation checks, and carry out routine OSDV to facilities

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
B1.6TB surveillance data are externally consistent	• Among new TB cases, the percentage of children is between 5-15% in low- and middle-income and <10% in high-income countries	☐Met ☒**Not met**	Inconsistent. Current proportion is 2.2%	Implement child TB specific strategies recommended in this report
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 extra-pulmonary 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	☐Met ☒**Partially met** ☐Not met	Year to year change in TB notifications shows sudden upsurge by +22.8% Ratio of PTB: EPTB is consistent (75%:25%), while ratio of M:F is consistent with expectations with a range of 1.7-1.8 Ratio of presumptive TB to total notifications of TB cases could not be determined because presumptive data could not be assessed or validated at facility level due to unavailable use of registers in most facilities visited.	Ensure use of presumptive register

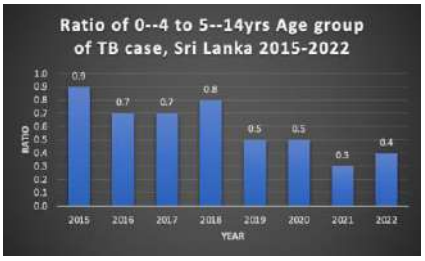
STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
	TB 6. Year-to-year change in the case notification rate for new smear-positive TB and if data are available, 7. Ratio of the number of people with presumptive TB to total notifications of TB cases			
B1.8 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 last 10 years	☐Met ☒**Partially met** ☐Not met	TB reporting is a legal requirement. Findings from Epi review are suggestive of under-notification and under-reporting. No TB inventory study conductedyet in Sri Lanka	Inventory study (capture recapture analysis) can be performed to estimate the level of underreporting of TB cases and provide estimated TB incidence
B1.9 Population has good access to health care	Both benchmarks should be satisfied to meet this standard: • Under-5 mortality rate (probability of dying by age 5 per 1000 live births) is <10 • <25% total health expenditure is out-of-pocket	☐Met ☒**Partiallymet** ☐Not met	Although there is significant decline in U5M from 93.9 per 1000 live births in 1960 to 6.7 in 2021, OOP health expenditure is still very at 46.6%	
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	☐Met ☒**Partially met** ☐Not met	Vital registration is fully established in the country; however, ill-defined causes percentages are still high at 40-50%	

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
	a) national vital registration system OR b) sample vital registration system • <10% of deaths have ICD codes for ill-defined causes (defined as ICD-9 780-799 and ICD-10 R00-R99)			

PART B (Section 2): 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)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
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 susceptibilitystatus (positive/negative) documented for a nationally representative drug resistance survey of new pulmonary TB cases	☒**Met** ☐Partially met ☐Not met	WRD using Xpert MTB RIF Assay is in useand fully incorporated in the national guideline. Uptake generally low.	
B2.2 Surveillance data provide a	One of the two benchmarks should be satisfied to meet	☒**Met** ☐Partially met	Very low level of HIV prevalence. HIV status is available on a representative sample from all TB cases notified at facilities visited.	

STANDARD	BENCHMARK(S)	RESULTS	RESULTS (DESCRIPTION)	KEY ACTION(S) REQUIRED TO ADDRESS THE GAPS
direct prevalence of HIV infection in TB cases	this standard: (positive/negative) documented for≥80% of all notified TB cases • HIV status is available from a representative sample from all TB cases notified in settings with a low-level epidemic state[ii] where it is not feasible to implement routine surveillance.	☐Not met	Routine surveillance of HIV prevalence	
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 last 10 years	☒**Met** ☐Partially met ☐Not met	The ratio of children under 5 years to children aged 5-14 years continues on a decline ending at 0.4 at the end of 2022 (figure 29). Hence, inconsistent. When combined with the potential under-reporting, we may conclude that the current surveillance data for children with TB does not meet the standards for a reliability, accuracy and completeness. 	Conduct an Inventory study

Day	Time	Activities	Meeting venue	Person(s) in charge

Appendix 2: Country visit Agenda for Epi Review for Sri Lanka

TABLE 11: AGENDA FOR EPIDEMIOLOGICAL REVIEW FOR SRI LANKA

July 31st- August 5th	Varied	Desk Review		Epi Consultant
Day 0: Sunday **13 August**	16:20	Arrival	Epi Consultant	
Day 1: Monday 14 April	9:00-12:45	**Courtesy call-** NPTCCD Brief Courtesy call- GF CCM &WHO Orientation Meeting with Epi Review Coordination Team - Inception/In-brief Meeting with Epi Review Coordination Team and Partners • Overview of Epi Review (Presentation) • Introduction to TB/TBHIV/DRTB burden in Sri Lanka (Presentation) Finalize Epi-review plan with consultant	Colombo Colombo NPTCCD	Epi consultant Epi review team Epi Review Consultant NPTCCD designee Epi Review Team
	12:45-14:00	Lunch		
	14:00-15:00	Security briefing as applicable		Logistics POC
	15:00-15:30	Finalize Logistics	Colombo	NPTCCD Team
Day 2: Tuesday 15August	9:00-12:00	Field visit in **<u>Colombo</u>** High burden facility (TB/TBHIV/GeneXpert services) - Colombo Chest Clinic **(I)**	**Central Colombo**	Epi review Team
	13:00-14:00	Lunch		
	14:00-16:30	• Welikada Prison, Colombo **(II)** • PPM Site – Asiri hospital, GP in Colombo Municipal Council area **(III)**	**Central Colombo**	Epi review Team
	5.00pm	**Courtesy call-** MoH: DGHS and DDG (PHS)1		
Day 3: Wednesday 16August	6.00am-12:30	Travel from Colombo to **<u>Batticalao</u>**	**Eastern Province**	Epi review Team
	12:30-14:00	Field Visit to Facility (Low case load)- BH Valachchenai (enroute) – **(IV)**		
	14:00-14:30	Lunch		
	14:30-16:30	Field Visit - Local travel and visits to Facility (moderate to high case load)- BH Kaaththaankudy**- (V)**		
Day 4: Thursday 17August	8:00-11:00	Facility visits (High case load)- TH Batticaloa and DCC Batticaloa (GeneXpert site in TH Batticaloa) **(VI, VII)**	**Eastern Province**	Epi review Team
	11:00-12:30	Facilities visits • **PHC-**Chenkalady DH- **VIII** • **PPM site-** Batticaloa private hospital **- IX**	**Eastern Province**	
	12:30-13:00	Lunch		
	14:30-16:00	Travel back to Colombo		
Day 5: Friday 18August	9:00am-12:30pm	Department of **VR**(Discuss Vital statistics) Visit Department of Birth and Death Registrar		Epi review Team
	12.30-1.30pm	Lunch		
	1.30pm - 4.00pm	**Technical meetingI-** NPTCCD Thematic Leads • Provide overview of their functions with Epi review consultant -TBHIV, HMIS, PPM, CTBC, M&E etc.		
Day 6: Monday 21August	9:00-12:30	Local travel from Colombo to Ratnapura Field Visit to **<u>Ratnapura</u>** - Facility (High case load) - PGH **(X)** -DCC **(XI)**	**Sabaragamuwa Province**	Epi review Team PR Team Epi review

	12.30-1.30	Lunch		Team
	1.30-5.00pm	Continue facility visits and travel back to Colombo		
Day 7: Tuesday 22August	9:00-12:30	Field visit to **Colombo** Visit to NTRL/MDR TB and Discussions on Management of DRTB	**Central Colombo**	Epi review Team
	12.30-1.30	Lunch		
	1:30- 4:00pm	**Technical meeting II**- NPTCCD Thematic Leads • Provide overview of their functions with Epi review consultant- PMDT and Lab	NPTCCD Office/Virtual	
Day 8: Wednesday 23 August	9:30-12:30	Consultant working session: Epidemiological Analysis	NPTCCD Office/Virtual	Epi review Team
	12:00-16:00	Consultant working session: • Epidemiological Analysis	NPTCCD Office/Hotel	Epi Consultant
Day 9: Thursday 24 August	9:00-16:00	Consultant working session: Epidemiological Analysis and Debrief deck development	NPTCCD Office/Hotel	Epi Consultant
Day 10: Friday 25 August	8:30- 10:30	Prepare for Final Debrief	NPTCCD/TBD	Epi Consultant
	10:30- 13:00	Debrief for NPTCCD, WHO WR and Director Public Health MoH and other stakeholders		
Saturday 26 April	Departure from Colombo		Epi Consultant	
Monday August 28- September 11	Report Writing		Epi Consultant	

Appendix 3: List of persons met

Date	Name	Surname	Designation	Organization	Email Address
14-08-2023	Dr. N.C.	Pallewatte	Director NPTCCD	NPTCCD	ddnptccd@gmail.com
14-08-2023	Dr. Mizaya	Cader	Head, Planing M&E/CCP	NPTCCD	milubee@yahoo.com
14-08-2023	Dr. Onali	Rajapakshe	Consultant Community Physician (CCP)	NPTCCD	onalir@yahoo.com
14-08-2023	Dr. Hemali	Jayasekera	Consultant Community Physician (CCP)	NPTCCD	hemalisenatilleke@gmail.com
14-08-2023	Dr. Ahmed	Shiyam	Registrar	NPTCCD	shiyan_ala@yahoo.com
14-08-2023	Dr. Suwani	Dasanayaka	Registrar NPTCCD	NPTCCD	
14-08-2023	Dr. Chamila	Abeywickrama	Medical Officer (MO)	NPTCCD	chamila.ppm@gmail.com
14-08-2023	Dr.Ruwanthika	Kariyakarawana	Medical Officer (MO)	NPTCCD	
14-08-2023	Dr. H.L.D.U	De Silva	Medical Officer (MO)	NPTCCD	
14-08-2023	Dr. Sujeeva	Theannilawu	Medical Officer (MO)	NPTCCD	sujeevanptccd@gmail.com
14-08-2023	Dr. P.A.M	Perera	Medical Officer (MO)	NPTCCD	
14-08-2023	Mr. K. A. L	Kumarasiri	DO	NPTCCD	
14-08-2023	Mr. S. H. P. J. S	Thilakaratna	DO	NPTCCD	
14-08-2023	Mr. K. J. S	Sampath	DO	NPTCCD	
14-08-2023	Ms. Awanthi	Dissanayaka	Accountant	GF	
14-08-2023	Mr. Maduka	Rupasinghe	Procurement Assistant	GF	

TABLE 12:: PLANNING MEETING PARTICIPANTS LIST

Date	Name	Surname	Designation	Organization	Email Address
14-08-2023	Dr. N.C.	Pallewatte	Director NPTCCD	NPTCCD	ddnptccd@gmail.com
14-08-2023	Dr. Sumal	Nandesena	National Consultant Epi review		sumalnandasena@gmail.com
14-08-2023	Dr. Mizaya	Cader	Head, Planing M&E/CCP	NPTCCD	milubee@yahoo.com
14-08-2023	Dr. Onali	Rajapakshe	Consultant Community Physician (CCP)	NPTCCD	onalir@yahoo.com
14-08-2023	Dr. Hemali	Jayasekera	Consultant Community Physician (CCP)	NPTCCD	hemalisenatilleke@gmail.com
14-08-2023	Dr. W. D	Galagedara	NTRL/Acting CM	NTRL	wdg.wathi@gmail.com
14-08-2023	Dr. Amitha	Fernando	Consultant Respiratory physician	Colombo Chest Clinic	
14-08-2023	Dr. Suwani	Dasanayake	Registrar NPTCCD	NPTCCD	
14-08-2023	Dr. Ahmed	Shiyam	Registrar	NPTCCD	shiyan_ala@yahoo.com
14-08-2023	Dr. Chamila	Abeywickrama	Medical Officer (MO)	NPTCCD	chamila.ppm@gmail.com
14-08-2023	Dr.Ruwanthika	Kariyakarawana	Medical Officer (MO)	NPTCCD	
14-08-2023	Dr. H.L.D.U	De Silva	Medical Officer (MO)	NPTCCD	
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25-08-2023	Mr. K. A. L	Kumarasiri	DO	NPTCCD		
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TABLE 18: DEBRIEF SESSION PARTICIPANTS LIST

Appendix 4: List of documents and data used

Data required for Sri Lanka 2023 Epi Review

1. NTP manuals and guidelines
2. National TB policy documents
3. National M&E Plan, TB surveillance plan if available
4. Documentation or mapping of the Surveillance system
5. Surveillance-related training documents
6. Data collection tools/ Copies of National TB reporting forms, registers, treatment cards, National laboratory register
7. National surveillance database listing the dataset of minimum variables
8. SOPs and data dictionary
9. Quarterly reports of TB cases sent to the NPTCCD from basic management units (BMUs) over the period of one year*
10. QA reports
11. NPTCCD annual reports
12. Reports or publications on data quality or surveillance evaluations e.g. SARA or DQA report as applicable
13. Assessment reports of Private sector engagement for TB services
14. Other reports are received outside the quarterly report system e.g. NGOs, non-NTP providers
15. System logs that show which data files were imported for the reporting year /quarter and when they were imported.
16. List of automated checks run at the time of data entry
17. List of data queries used to check data quality at the national level
18. SOPs for detection and removal of duplicate TB cases
19. Total number of files expected, and total number of data files received and included in the datasets provided to the national level for the years being assessed (2021 & 2022)
20. If available, TB mortality rates (HIV negative TB cases) at the national level obtained from vital registration (VR) systems
21. If available, Presumptive TB registry data at the national level.
22. TB Inventory study reports
23. Periodic surveys about vital statistics
24. HIV sentinel survey report

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25. **DHIS2 data base access if used**
26. **NPTCCD TB excel database for five to ten years**
27. **Previous/most recent Epi review report**

Consultant sourced

28. **Country income grouping from the World Bank country-classifications/country-and lending-groups (http://data.worldbank.org/about/ , https://data.worldbank.org/country/sri-lanka**
29. **WHO Global Health Observatory** (https://www.who.int/data/gho/data/countries/country-details/GHO/sri-lanka?countryProfileId=8fe27182-4df7-4acf-8bf2-68147850f894
30. **Proportion of national health expenditures that are out-of-pocket: WHO national health accounts database** https://apps.who.int/nha/database/country_profile/Index/en
31. **WHO Global Health Expenditure Atlas** (https://apps.who.int/nha/database/country_profile/Index/en)
32. **WHO Mortality Database** (**http://apps.who.int/gho/data/node.main.686?lang=en**
33. **World Bank mortality data** (**https://data.worldbank.org/indicator/SP.DYN.CDRT.IN?locations=NP**)
34. **Tobacco and smoking data for Sri Lanka/** WHO global report on trends in prevalence of tobacco use 2000-2025, third edition (2019) (https://www.who.int/teams/noncommunicable-diseases/surveillance/data/sri-lanka)

Appendix 5: Stakeholders recommendation chart

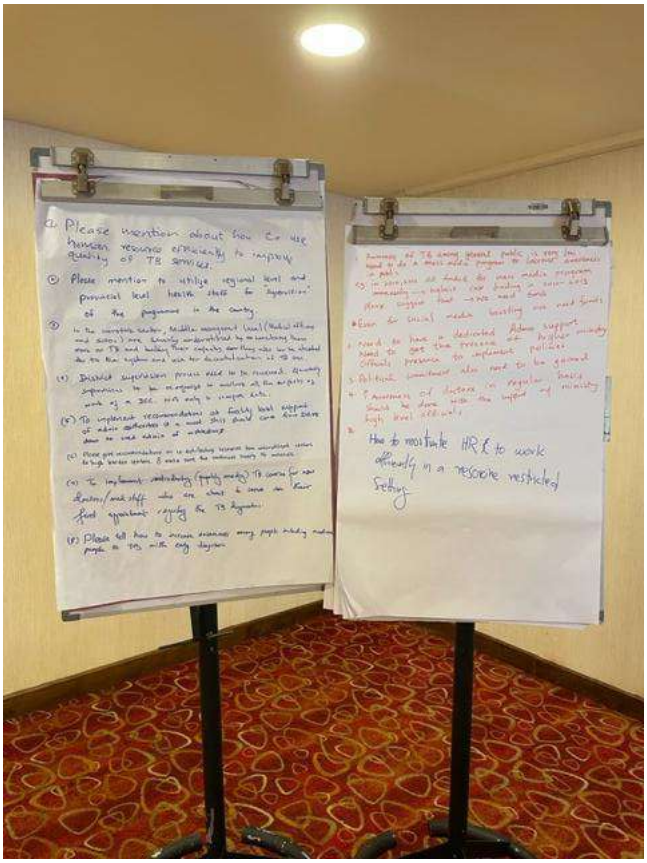

FIGURE 35:STAKEHOLDERS BRAINSTORMING RECOMMENDATIONS

Appendix 6: Debrief presentation

Double click to open

COUNTRY NAME: SRI LANKA ASSESSMENT PERIOD: AUGUST 14th-25th 2023