NATIONAL STRATEGIC PLAN
FOR TUBERCULOSIS CONTROL (2016-2020)

DISEASE CONTROL DIVISION

MINISTRY OF HEALTH MALAYSIA

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STATEMENT OF INTENT

This National Strategic Plan are meant to be guides for clinical and public health practice, based on the best available evidence at the time of development. Adherence to this plan may not necessarily guarantee the best outcome in every strategies. Every healthcare provider may use his/her own judgment of unique epidemiology and healthcare setting based on the clinical picture presented by the patient and the management options available locally.

REVIEW AND UPDATE

These NSP were issued in 2016 and will be reviewed in 2020 or sooner if new evidence becomes available. Every care is taken to ensure that this publication is correct in every detail at the time of publication. However, in the event of errors or omissions, corrections will be published in the web version of this document, which is the definitive version at all times. This version can be found on the websites mentioned above.

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ABBREVIATIONS

ADRs	Adverse Drug Reactions
AEHO	Assistant Environment Health Officer
AFB	Acid Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ASEAN	The Association of Southeast Asian Nations
BCG	Bacillus Calmette-Guerin
CCRC	Cure & Care Rehabilitation Centre
CDC	Communicable Disease control
COMBAT	Community Bebas Aedes dan Tibi
CPT	Co-Trimazole Prophylaxis Therapy
DNA	Deoxyribonucleic acid
DOT	Directly Observe Treatment
DR-TB	Drug Resistant TB
DST	Drugs Sensitivity Test
EGT	Elaun Gantian Tambang
EQAP	External Quality Assessment Program
EQA-PT	External Quality Assessment-Proficiency Testing
FMS	Family Medicine Specialist
HCW	Health Care worker
HiAP	Health in All Policies
HIV	Human Immunodeficiency Virus
IHSR	Institute for Health System Research
ISTC	International Standard for Tuberculosis care
IPT	Isoniazide Prophylaxis therapy
LED	Light Emitted Diode
LOINC	Logical Observation Identifiers, Names and Codes
LPA	Line Probe Assay
LTBI	Latent TB Infection
MAPTB	Malaysia Association for The Prevention of Tuberculosis
MDG	Millennium Development Goal
MDR TB	Multi Drug Resistant TB
MO	Medical Officer
MOH	Ministry of Health
MR	Mortality Rate
MTB-RIF	Mycobacterium Tuberculosis – Resistant to Rifampicin
NCD	Non-Communicable Disease
NGO	Non-Government Organization
NPHL	National Public Health Laboratory
NR	Notification Rate
NSP	National Strategic Plan
NTBCP	National Tuberculosis Control Program
NTPs	National Tuberculosis Programs
PH	Public health
PLHIV	People Living with HIV
PMDT	Programmatic Management of Drug Resilent Tuberculosis
SOP	Standard Operating Procedure
TAS	Treatment Allowance Scheme
TB	Tuberculosis

TNF	Tumour Necrosis Factor Training of
TOT	Trainers
TST	Tuberculin Skin Test
UHP	Universal Health Precaution
UN	United Nation
WHO	World Health Organization
WRD	WHO- Recommended Rapid Diagnostic
XDR-TB	Extensive Drug Resistant TB

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NATIONAL STRATEGIC PLAN (NSP) DEVELOPMENT

NSP DEVELOPMENT

The members of the Development Group (DG) for this NSP were from the various Division of Ministry of Health (MOH), State TB Officers, National Public Health Laboratory Officers and representative from Prison Department.

Members of DG were divided into six (6) groups and each group were assigned specific topic in this NSP. The NSP was adapted from World Health Organization (WHO) Guidelines, namely:

Regional framework for action on implementation of the End TB Strategy in the Western Pacific, 2016-2020
Implementing the End TB Strategy: The Essentials
Global Tuberculosis Report 2016
Toolkit to develop a national strategic plan for TB prevention, care and control

All strategies and recommendations were adapted, modified and formulated with local practices taken into considerations. The NSP was presented and agreed by the members of National Tuberculosis Technical Working Group Meeting in December 2016.

OBJECTIVES

To provide national referral guideline for action on implementation of effective strategies for prevention and control of TB and Drug Resistant TB in the countries.

TARGET GROUP/USER

This document is intended to guide healthcare providers and relevant stakeholders, local agencies and non-government organizations (NGOs) in the management, control and prevention of TB and Drug Resistant TB including:

State TB Officers
Doctors
Pharmacists
Allied health professionals Patients and their advocates

ACKNOWLEDGEMENT

The editorial team would like to express our gratitude to various departments, civil societies and all individuals who have contributed directly or indirectly to the development of this plan. Support and guidance from all are very helpful in the development of this NSP.

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FOREWARD

Tuberculosis (TB) is a public health issue and occurs in every part of the world. WHO estimated in 2015, 10.4 million new TB cases and 1.4 million TB deaths occurred globally. The End TB Strategy aims to end the TB epidemic by 2035 and Malaysia vows to adapt the policy and guidelines by WHO in order to achieve these targets.

The National Strategic Plan for TB Control (2016-2020) is an ambitious proposal to work through the goal of ending TB by 2035. Ending TB will require major transformation in the national TB control activities. Patient centered TB care and universal access to high quality method in diagnosing and treating TB are the focuses of this national plan. Malaysia has implemented DOTS strategy in combating TB since 2002 and high quality TB management has been established and used ever since.

An effective TB control involved a strong collaborative effort by multiagency. Public-public or public-private mixed approach should be in the strategies at all time. In fact, every individual and local leader should play their role in making sure their health is safe guarded from TB infection. Government alone will not be able to sustain effective interventions and promotion activities to address the problem. Achieving the strategies in the NSP will require concerted efforts, continuous funding and commitments at all levels of healthcare providers in public as well as private healthcare facilities.

My sincere thanks to the committee members and TB/Leprosy Sector of Ministry of Health for their efforts in developing the NSP. I hope all the strategic intervention activities will be the top agenda in prevention and control of TB in Malaysia.

Together, let us 'Unite to End TB'.

DATUK DR. NOOR HISHAM BIN ABDULLAH
DIRECTOR GENERAL OF HEALTH MALAYSIA

EXECUTIVE SUMMARY

Tuberculosis (TB) is an infectious disease that is endemic in the country and remains a major global health problem. In 2015, WHO estimated around 10.4 million new TB cases worldwide with 1.4 million of TB deaths. Malaysia is classified as a country with intermediate burden of tuberculosis with notification rate of TB less than 100 cases for every 100,000 populations. Tuberculosis Control Programme has been in place since 1961 as a vertical programme where *Pusat Tibi Negara* is the main referral centre for Tuberculosis. In 1995, it was integrated into the Malaysian Public Health System where the main control activities are being expanded into the peripheral health clinics as well as the hospitals.

In 1990, the notification rate of TB in Malaysia was 61 cases per 100,000 populations and 79 cases per 100,000 populations in 2015. The mortality rate in 1990 was 4.2 cases per 100,000 populations and 5.5 cases per 100,000 populations in 2015. A new era for TB monitoring as documented in The End TB Strategy (refer Appendix 1) with three high-level indicators are: the TB incidence rate, the absolute number of TB deaths and the percentage of TB patients and their households that experience catastrophic cost as a result of TB disease. Targets for these indicators have been set for 2030 and 2035, with accompanying milestones for 2020 and 2025.

Summary of the National Strategic Plan (NSP) For Tuberculosis Control 2016-2020 (Malaysia) vision, goal, target, strategies and the key indicators are as follows:

VISION

Malaysia free of TB by year 2035

GOAL

The Goal of TB control in Malaysia is to decrease the burden of tuberculosis by ensuring universal access to timely and quality diagnosis and treatment of all forms of TB and prevent development of drug resistance TB in the country.

TARGET

The targets of TB control by year 2020:

1. TB mortality is reduced by 25%
2. TB notification rate (all case) is increase to 100 per 100,000 population
3. Universal access to diagnosis and treatment of all forms of TB, including MDR-TB andXDR-TB;
   - At least 90% of MDR-TB cases are successfully treated

Strategy 1. Enhance case detection of TB.

Key Indicator :

1.1 Increase case finding activities and diagnostic capacity to increase case notification of all forms of TB from 79 per 100,000 populations in 2015 to 100 per 100,000 populations in 2020.

1.2 Symptomatic screening for TB: 2000 per 100,000 populations by year 2020.

1.3 Contact screening coverage at first visit is > 90% and > 50% during 4th visit.

1.4 Treatment success rate >90%.

Strategy 2. To improve control of TB among children.

Key Indicator :

2.1 Case detection of TB among paediatric cases. Proportion of paediatric TB cases increase from 3.1% (2015) to 5% by 2020.

2.2 To achieve treatment success rate of 95% for paediatric cases.

Strategy 3. To decrease the burden of TB/HIV in people at risk of/or affected by both diseases.

Key Indicator:

3.1 Number of new and relapse TB patients with documented HIV status divide by number of new and relapse TB patient :100%

3.2 Number of people living with HIV who were started on LTBI treatment divided by number eligible for treatment :90%

Strategy 4. Strengthen Programmatic Management of Drug Resistant Tuberculosis (PMDT)

Key Indicators:

4.1 DR-TB cases notified annually increases 10% from previous year.

4.2 Treatment success rate for DR-TB: 90%

Strategy 5. Strengthen laboratory networks to find all TB cases

Key Indicator:

5.1 Drug susceptibility test (DST) coverage for TB patients: 100%

Strategy 6. To strengthen programmatic management of LTBI activities

Key Indicator:
6.1 Number of children aged <5 years who are household contacts of cases started on LTBI Treatment divided by the number eligible for treatment :50%

Strategy 7. To enhance BCG vaccination programme

Key Indicator:
7.1 BCG coverage for all new-borns: > 98%

Strategy 8. To ensure uninterrupted supply of quality-assured TB drugs

Key Indicator:
8.1 To ensure uninterrupted supply of quality-assured TB drugs

Strategy 9. To enable supportive environment and systems for effective TB control

Key Indicator:
9.1 Number of TB patient referred by community volunteers/NGOs for TB diagnosis and treatment.
9.2 Number of TB patients under follow-up or DOT with community volunteers/ NGOs.
9.3 Number of TB patient cured or completed TB treatment under supervision of community volunteers/NGOs.

Strategy 10. To ensure no households that experience catastrophic cost due to TB

Strategy 11. To intensify research and innovation as priority issues in TB control programme

Key Indicator:
Establishment of TB research network

The indicators to measure progress towards achieving the STRATEGIES and corresponding targets have been identified for each of STRATEGIES. These indicators and expected results need to be adapted according to the unique situation of each states. All State Health Department are recommended to develop or update their respective State Operational Plans using the NSP for TB Control 2016-2020 as a guiding framework and to mobilize the resources for sustainable implementation of their TB control programme.

1. INTRODUCTION

Tuberculosis remains an important public health and challenges for control in Malaysia. Despite significant effort make in the implementation of TB control interventions, the country still faces a number of important challenges that require further intensified and concentrated efforts to effectively control the TB epidemic. Malaysia National Tuberculosis Control Programme (NTBCP) launched in 1961 with main aimed was to control and reduce Tuberculosis burden in Malaysia. In 1995, the programme was integrated into the general medical and health system following WHO's recommendation and implementation of primary care concept in Malaysia. Since the implementation of NTBCP in 1961, the number of reported TB cases had successfully reduced from 350 cases per 100,000 populations to less than 100 per 100,000 in the 1980's. However, since 1990 to 2009, reported TB cases have remained unchanged in between 60 to 68 per 100,000 populations (refer Figure 1).

The National Strategic Plan (NSP) for TB Control (2011-2015) was introduced to strengthen efforts in TB control in Malaysia towards achieving the MDG by 2015. The NSP (2011-2015) main strategy was to increase case detection activities by increment of active case finding of TB. From 2010 to 2015, TB cases had shown increment with notification rate of 68.4 cases per 100,000 populations to 79.6 cases per 100,000 populations respectively. Although Malaysia has not achieved the target of halting and reversing the incidence of tuberculosis (TB), Malaysia has strengthened management and prevention of TB control activities. This National Strategic Plan (NSP) for TB Control (2016-2020) is developed in line with the Regional Framework for Action on Implementation of the End TB Strategy in the Western Pacific (2016–2020). This NSP aims to further align the national TB response with the latest international evidence, strategic policies and programmatic guidance. The NSP shall be the national guiding principles in control of TB towards achieving The End TB Strategy goal of ending the global TB epidemic by 2035.

The Division of Diseases Control, Ministry of Health, Malaysia took the lead in the NSP development, with important technical inputs provided by the key national stakeholders and in close cooperation with other ministries and government agencies, as well as with the non- government organizations (NGOs) providing support to TB control in the country. The NSP focuses on implementing The End TB Strategy in the coming five years along with baseline and targets in Malaysia context. The NSP contains three elements that are;

i. Integrated, patient-centered care and prevention
ii. Bold policies and supportive systems
iii. Intensifies research and innovation

This NSP consist of first, an overview of TB epidemiological situation in the country presented with the main indicators and time trends. Second, the key features and main achievements of the National TB Program are described, followed by the identification of the key challenges that are addressed by this Plan. Third, the Plan presents the overall Goal, targets and strategies of TB control in the country for the next five years. Fourth, Strategic Interventions are described in detail by each Strategy. Fifth, the roles and responsibilities of the national stakeholders in the implementation of the Plan are discussed, together with the expected inputs from international partners and identified needs in technical assistance. Sixth, the main indicators for monitoring the implementation are proposed, which will form the monitoring and evaluation framework for the NSP. Finally, the financial aspects are presented, including the estimate of the overall financing needs in TB control for the five years of implementation.

The expected impact from this NSP are as follows;

Indicator	2015	2016	2017	2018	2019	2020
Reduction 25% in number of TB deaths compared with 2015 (reduce 5% per year)	1692	1600	1520	1445	1375	1310
TB notification rate per 100,000 population	79	85	90	95	100	100
Treatment success rate, new & relapse TB case (cohort 1 year before)	79.6%	80%	80%	82%	84%	85%
Treatment success rate, laboratory confirmed MDR-TB cases whom started 2ndline TB treatment (cohort 2 year before)	62%	70%	75%	80%	85%	90%

2. TUBERCULOSIS BURDEN IN MALAYSIA

2.1 BACKGROUND

Malaysia consists of thirteen states and three Federal Territories, with landmass of 330,628 square kilometers and total population over 30.09 million in 2014 (15.46 million males and 14.6 million females). Malaysia's population comprise of various ethnic groups with Malays being the majority consists of 54%, followed by Chinese 25%, Indian 7.5%, Indigenous group in Sabah and Sarawak 11.8% and others 1.7%. Healthcare services in Malaysia are provided by various multi agencies with Ministry of Health (MOH) as the major health provider, Ministry of Education, Ministry of Defense, Ministry of Home Affairs and Ministry of Human Resource. Accessible through 326 hospitals (142 governments and 184 private), 1,061 government health clinics with doctors and 6,978 private clinics, and 1,810 community clinics and 307 1Malaysia clinics run by paramedics, the Malaysian health care has improved over years with doctor to patient ratio of 1:661. Life expectancy was 72.5 years for males 77.2 years for females.

Malaysia is classified as a country with an intermediate TB burden that is, notification rate (NR) for TB less than 100 per 100, 000 populations. National Tuberculosis Programmes (NTPs) have expanded the TB control programme with focus on early case detection among symptomatic and high risk patients, ensuring quality laboratory services, development training module, guidelines and MyTB databases, conducting regular course and training to staffs and strengthening collaboration with other agencies.

The country uses the standardized TB recording and reporting system, which has been upgraded to include the latest WHO recommendations and additional country needs. Since 2003, individualized recording and reporting is in place and is incorporated in the national electronic TB database in 2013.

TB control services in Malaysia have undergone substantial changes over the last decade. TB laboratories have been strengthened and integrated in the network of public health laboratories under the management of the National Public Health Laboratory (NPHL) Sungai Buloh. Currently, there are five (5) regional public health laboratory in the states of Johor, Perak, Kelantan, Sabah and Sarawak where the entire network is supervised by the NPHL, Sungai Buloh. The novel Xpert MTB/RIF diagnostic technology was introduced in 2014 and is being expanded; currently, 14 machines are distributed in the country.

The increasing number of TB poses a great challenge to control and reduce TB transmission in Malaysia. TB is usually associated with the low financial income

family. Although diagnosis and treatment are provided free to all Malaysians; however, some of TB patients are still suffering from a heavy financial burden. Patient have to bear the cost of transportation to the clinic for DOT and fear of losing job is still happen in the country. This will affect the compliance and treatment outcome of TB patient. Ensuring direct observation of treatment (DOT) is the goal for all TB patients; incentives are provided to the patients by the Malaysian Association for the Prevention of Tuberculosis (MAPTB) and government contribution to increase adherence to treatment.

2.2 SITUATIONAL ANALYSIS

2.2.1 Cases, notification and socio-demography

Since implementation of NSP (2011-2015), notified TB cases had increased from 20,666 cases in year 2011 (NR 72.4 per 100,000 populations) to 24,220 cases in year 2015 (NR 79.4 per 100,000 populations) that was 17.2% increment (refer figure 1). Of the 24,220 TB cases notified in 2015, about 22,427 (92.6%) were classified as new cases and 1,793 (7.4%) were retreatment case. Of the retreatment case, 1,141 (4.71%) were relapse cases, 88 (0.36%) were treatment after failure cases, 564 (2.33%) were treatment after default cases.

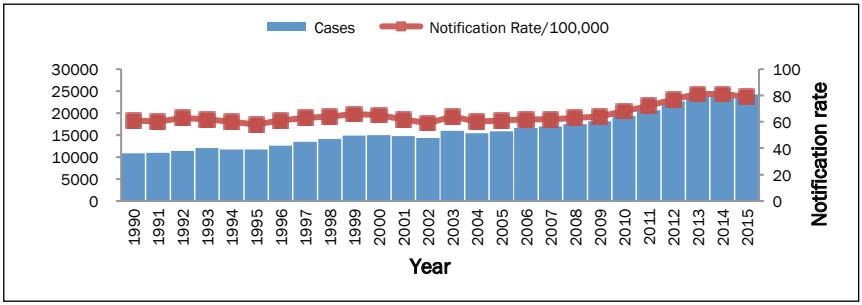


Figure 1. Notification rate (NR) of TB for Malaysia (2000-2015)

During the last four years, a trend of increase in the retreatment case was documented; between 2012 to 2015, the retreatment case increased from 6.4% to 6.7%, 7.3% and 7.4% respectively (refer figure 2).

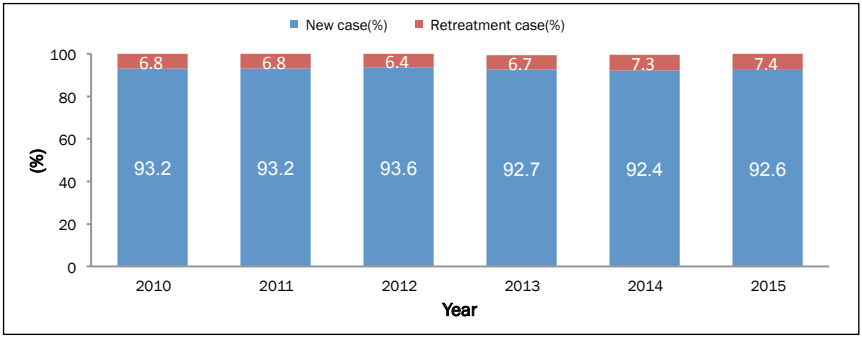


Figure 2. Proportion of New Cases and Retreatment Cases, 2010-2015

In the year 2015 Sabah contributed the highest number of TB cases i.e. 4,464 cases (18.4%) followed by Selangor 4,429 cases (18.3%), Sarawak 2,575 cases (10.6%), Johor 2,409 cases (9.9%), Federal Territory of Kuala Lumpur 1,819 cases (7.5%), Perak 1,657 cases (6.8%), Penang 1,283 cases (5.3%), Kedah 1,279 cases (5.3%), Kelantan 1,233 cases (5.1%), Pahang 936 cases (3.9%), Terengganu 710 cases (2.9%), Negeri Sembilan 667 cases (2.8%), Malacca 513 cases (2.1%), Perlis 130 cases (0.5%) and Federal Territory of Labuan 116 cases (0.5%).

Table 1: Total TB case, Notification Rate, TB Death and TB Mortality Rate according to states (2015)

States	Total Case	TB Notification Rate (per 100,000 population)	TB Death	TB Mortality Rate (per 100,000 population)
Johor	2409	67.8	135	3.8
Kedah	1279	61.7	142	6.8
Kelantan	1233	71.8	93	5.4
Melaka	513	58.8	39	4.5
NS	667	60.7	60	5.5
Pahang	936	57.7	80	4.9
Perak	1657	66.9	162	6.5
Perlis	130	52.8	14	5.7
PP	1283	77.1	132	7.9
Sabah	4464	126.0	264	7.4
Sarawak	2575	97.7	195	7.4
Selangor	4429	75.4	255	4.3
Terengganu	710	61.6	58	5.0
WPKL	1819	98.0	58	3.1
Labuan	116	119.8	9	9.3
MALAYSIA	**24220**	**79.4**	**1696**	**5.5**

For the past six years, majority of TB cases reported were from reproductive age group; for 2015 percentage TB cases for age group of 25-54 years old was 53%, 28.3% from senior citizen group age 55 and above. Cases among children less than 15-year-old was 3.0%. Although proportion by percentages had not shown much different among age group 15-year- old and above, age group specific rate (per 100,000 age group specific populations) shown increased number of TB cases as age increased (refer figure 3).

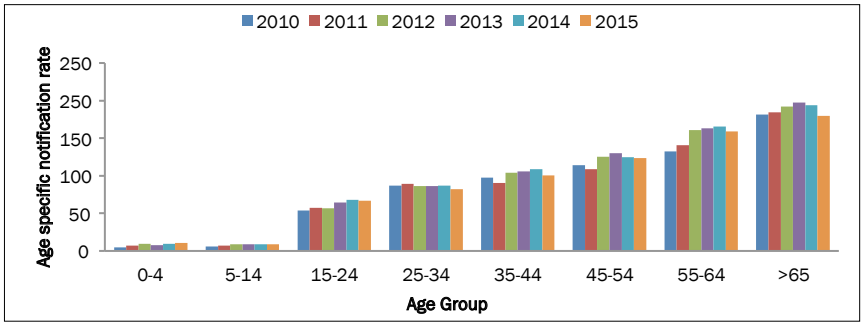
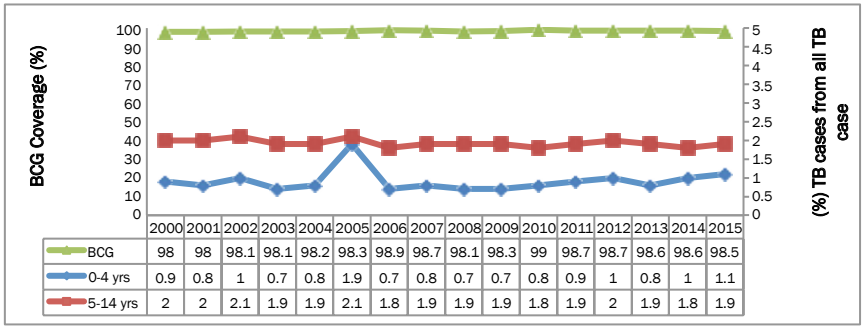


Figure 3. Age Group Specific Notification Rate per 100,000 Age Group Specific Populations, (2010- 2015)

2.2.2 TB in children

Since 2013 there was increase in percentage of TB cases in less than 5-year-old age group; 0.8% in 2013 to 1% and 1.1% respective years. Age specific notification rate for children less than 5-year-old has double from 4.8 to 10.7 per 100,000 in a period of six years.



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
BCG	98	98	98.1	98.1	98.2	98.3	98.9	98.7	98.1	98.3	99	98.7	98.7	98.6	98.6	98.5
0-4 yrs	0.9	0.8	1	0.7	0.8	1.9	0.7	0.8	0.7	0.7	0.8	0.9	1	0.8	1	1.1
5-14 yrs	2	2	2.1	1.9	1.9	2.1	1.8	1.9	1.9	1.9	1.8	1.9	2	1.9	1.8	1.9

Figure 4. BCG Coverage and TB Cases in 0-4 years old, (2000-2015)

2.2.3 TB among Non-Malaysian

For the past five years, TB cases among non-Malaysian contributed to 12% to 14% of TB cases in Malaysia (refer figure 5). In 2015, there were 2969 cases of TB among non-Malaysian which account for 12.3 % from total cases. TB cases among Non-Malaysian had increased from 2,870 cases in 2011 to 2969 cases in 2015. Indonesian (33%) and Philippines (31%) are major contributing countries for TB cases among Non-Malaysian.

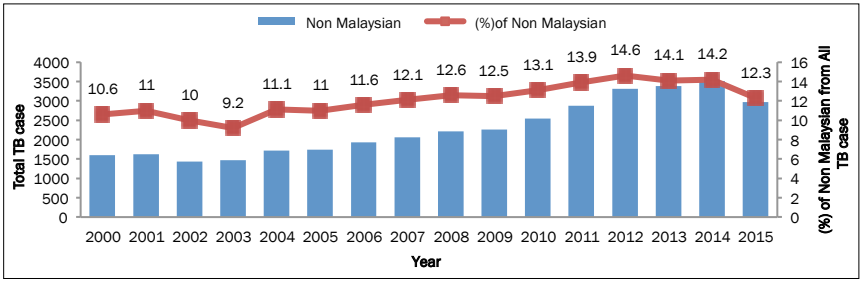


Figure 5. TB among non- Malaysian (2000-2015)

2.2.4 TB among healthcare workers

In the year 2015 there were 284 TB cases among Ministry of Health worker and compared to 273 cases notified in 2014. NR of TB among HCW had increased from 98.4 per 100,000 HCWs in 2011 to 121.5 per 100,000 HCWs in 2015.

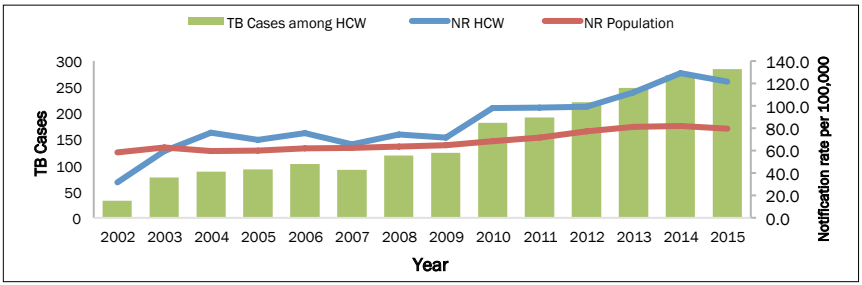


Figure 6: Notification Rate per 100,000 (NR) and Cases of TB among Ministry of Health Workers, HCW, (2002 -2015)

2.2.5 Drug Resistant TB

Drug resistant TB continues to threaten global TB control and remains a major public health concern in many countries including Malaysia.

WHO estimated that stimated that 3.3% of new TB cases and 20% of previously treated cases have MDR-TB. The coverage for culture and drug sensitivity testing (DST) for bacteriological confirmed cases was 92.2%.

There were 101 cases of MDR-TB notified in the year 2015. In 2015 proportion of MDR-TB cases from new cases was 0.16% (35 cases) and 3.7% from previously treated cases (66 cases). In 2013, among 124 cases MDRTB, with 68 cases were enrolled in TB treatment. (55%). The 2013 cohort cases resulted in 62% treatment success.

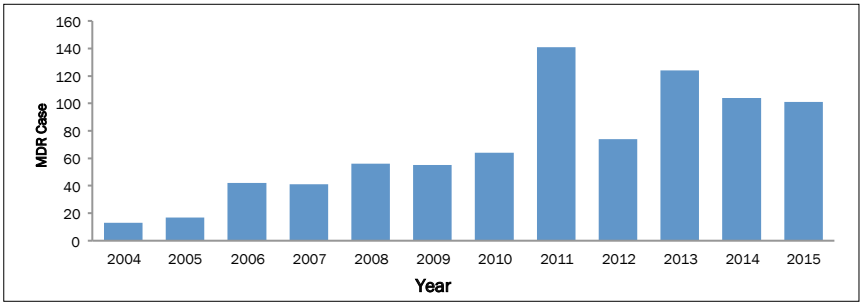


Figure 7. Cases of MDR-TB, Malaysia (2004-2015)

2.2.6 HIV associated TB

Total of 21,296 (87.9%) notified TB cases underwent HIV screening. Of these 21,296 cases, 1346 cases (6.3%), were found to have HIV positive (1,234 pre-diagnoses and 112 post- diagnoses). TB/HIV collaborative activities between the National TB Control Programme and the National HIV/AIDS Control Programme were initiated and are continued through joint programme meeting and technical consultations.

Collaborative activities include adjusting of guidelines and case management protocols, and collaboration and coordination of activities related to the provision of HIV counselling and testing for TB patients, screening for active TB among PLHIV, administration of antiretroviral therapy (ART) in patients with TB/HIV co-infection, data exchange and integration of monitoring / reporting systems, as well as through alignment and coordination of interventions among high- risk groups.

2.2.7 TB Screening Programme
Management of contact of Index case of TB

Contact tracing is one of the core activities and have been implemented in Malaysia to control TB transmission. Follow up of contact of index TB cases will be first visit at 0 months; second visit at three month after first visit, third visit by 6 month after second visit and fourth visit by one year after third visit (0,3,6,12-month interval). In 2015, about 189,337 (78.2%) contacts were screened for TB for first visit out of 242,200 contacts estimated.

Data also showed that only about 8.7% of contact came for fourth visit screening (contact of cohort 2014), refer table 3. Thus, screening and follow-up of TB contact especially contact screening at fourth visit need to be strengthens.

Table 2. Achievement of contact TB screening, Malaysia (2010-2015)

Year	TB cases	Contact examine	Index case: Contact
2010	19,337	74,426	1:4
2011	20,666	87,265	1:4
2012	22,710	90,275	1:4
2013	24,071	12,2091	1:5
2014	24,711	179,136	1:7
2015	24,220	189,337	1:8

Table 3. TB screening at first and fourth visit according to state

States	Total Case 2015	Contact Examine At 1st Visit (cohort 2015)	Percentage (%)	Contact came at first visit (cohort 2014)	Contact came for fourth visit (cohort 2014)	Percentage contact screened at fourth visit (%)
Johor	20154	2409	83.7	12216	716	5.9
Kedah	8101	1279	63.3	5573	31	1.6
Kelantan	13103	1233	106.3	11637	598	5.1
Melaka	3649	513	71.1	3469	64	1.8
NS	3266	667	49.0	2079	44	2.1
Pahang	5803	936	62.0	3870	150	3.9
Perak	15585	1657	94.1	14311	302	2.1
Perlis	1528	130	117.5	1241	783	63.1
PP	9817	1283	76.5	6961	95	1.4
Sabah	31120	4464	69.7	42405	5328	12.6
Sarawak	19261	2575	74.8	23647	4424	18.7
Selangor	42593	4429	96.2	830	3	0.4
Terengganu	6397	710	90.1	5057	330	6.5
WPKL	8689	1819	47.8	13464	0	0
Labuan	271	116	23.4	934	0	0
MALAYSIA	**189,337**	**24,220**	**78.2**	**147,694**	**12,868**	**8.7**

Screening of high risk group

Malaysia has implemented national guideline for systematic screening of high-risk group of TB since 2015. Screening of contact is under TBIS programme since year 2003. The high-risk groups include contact of Index TB case, TB/ HIV co-morbidities, inmate for prisons and CCRCs, diabetes patients, smokers, chronic renal failure on dialysis, patient on tumour necrosis factor (TNF), chronic obstructive pulmonary diseases, elderly and patient in methadone replacement therapy and substance abuse clinic.

Systematic screening of this high-risk group should be strengthened in order to increase case detection rate and reduce TB transmission. In 2015, total of 849,449 high-risk group were screened via symptomatic and chest x-ray screening (refer table 4) and about 3039 TB cases were detected. Data recording and reporting of high-risk group screening at health clinics and hospitals need to be strengthens.

More pro-active approaches need to be planned to reach and screen the vulnerable group such as the homeless, immigrants and prisoners in Malaysia. About 5% of TB cases were detected and managed by private healthcare facilities. Collaboration with private healthcare facilities needs to be strengthened for

screening of symptomatic TB and optimal care of the TB patient.

Table 4. Achievement of high risk group TB screening, Malaysia (2015)

		Contact	DM	HIV	Elderly	Smoking	COPD	Renal Failure	HCW	Prison	CCRC	Total
X-ray	Normal	70500	107389	4839	38818	16606	4824	4366	8924	7105	2654	266026
	Abnormal	3089	1689	701	1111	771	230	85	379	1484	408	9946
	Total	73589	109078	5540	39929	17377	5054	4451	9303	8589	3062	275972
Symptomatic	Yes	12572	17515	573	5571	2352	915	1109	1534	4448	364	46953
	No	136205	217366	3883	57348	20883	4493	1877	7552	73260	3657	526524
	Total	148777	234881	4456	62919	23235	5408	2986	9086	77708	4021	573477
Total screening		**222366**	**343959**	**9996**	**102848**	**40612**	**10462**	**7437**	**18389**	**86297**	**7083**	**849449**
Positive TB		**679**	**742**	**295**	**391**	**354**	**52**	**23**	**37**	**412**	**55**	**3039**

Screening of TB in Prison

TB remains an important health problem in prisons. The number of TB cases, all forms, in the prison was 271 in 2011 to 344 in 2015. The Ministry of Home Affairs, through its Prison Department, is responsible for TB control activities in the penitentiary system. Case detection in the penitentiaries combines passive case finding and active case finding (at entry and regular screening). Medical assistants and Medical Officers provide TB treatment in prisons.

Table 5. TB cases and incidence in prisons, Malaysia (2011-2015)

Year	TB cases in prison	TB Incidence in prison (per 100,000 population	TB cases in population	Incidence in population (per 100,000 population)
2011	272	774.8	20666	71.3
2012	231	608.0	22710	77.4
2013	219	518.2	24071	81.0
2014	340	683.6	24711	82.1
2015	344	653.8	24220	79.4

2.2.8 Directly Observed Treatment (DOT)

National TB treatment strongly recommend using a patient-centered case management approach including directly observed therapy (DOT) when treating

persons with TB diseases. DOT means that a trained health care worker or other designated individual (including a family member) provides the prescribed TB drugs and watches the patient swallow the medication.
DOT should be initiated when TB treatment starts. The prescribing doctors should show support for DOT by explaining to the patient that DOT is widely used and very effective. The DOT provider should reinforce the message. DOT works best when used with a patient-centered case management approach, helping patients finish TB treatment without gaps, prevent TB spreading to others and decreases chances of treatment failure and relapse.

Data showed that in 2015, about 21,702 cases (89.6%) patients practiced DOT for TB case management and treatment. Among patient whom practiced DOT, 12,824 (59.1%) cases were supervised by healthcare workers, 8637 (39.8%) supervised by family members 252 (1.2%) by NGO and community volunteers. Data showed that off 8350 new and relapse patients whom DOT's supervisor were family members, treatment success rate was 87.1% while off 12,243 cases DOT's supervisor were healthcare workers, treatment success rate was 85.8%. Treatment success rate of patients whom DOT's supervisor was NGO (n=236) and volunteers was 77.1%. More lost to follow-up cases seen when patient supervised by NGO & volunteers versus family members and healthcare workers (6.4%, 4.7% and 3.5%) respectively. More cases with treatment outcome of not evaluated seen as supervised by NGO & volunteers versus family members and healthcare workers (14%, 5%, and 3.4%) respectively, refer figure 8.

Monitoring and supervision by District Health Office should be done regularly for cases that DOT given by family members and NGO& volunteers.

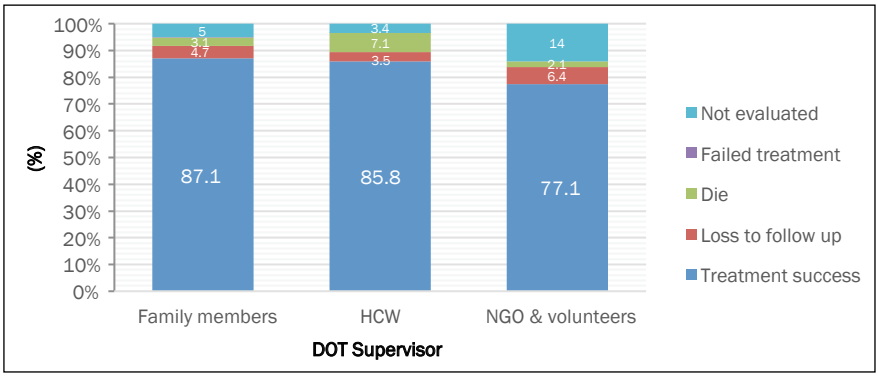


Figure 8. Treatment outcome (%) of new and relapse cases cohort 2015 according to DOT's supervisor

2.2.9 Treatment outcomes of Pulmonary TB smear positive

Over the last decade, significant progress has been achieved in treatment outcomes of TB cases. Cure rate of pulmonary smear positive TB cases increased from 67% in 2009 (cohort 2008) to 77.0% in 2015 (cohort 2014). The full cohort analysis of the 2014 cohort of new AFB- positive cases are the following: treatment success: 78.1%, loss to follow-up: 4.9%, failure: 0.2%, death: 9%, not evaluated : 7.5%.

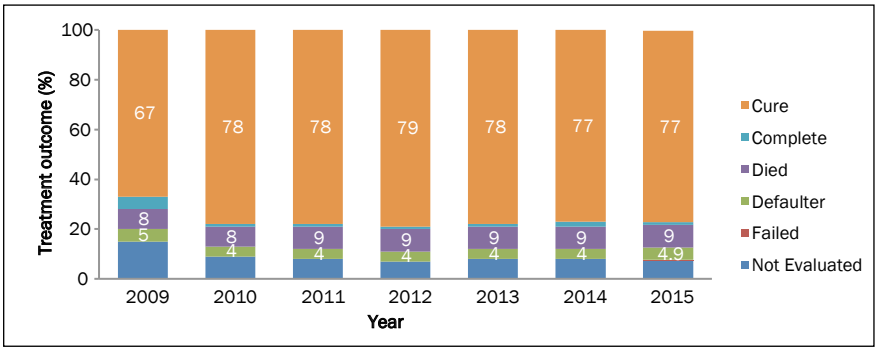


Figure 9. Treatment outcome of Pulmonary TB smear positive TB, Malaysia (2009-2015)

2.2.10 Treatment outcomes of MDR /XDR-TB

Treatment outcomes of MDR /XDR-TB patients are the major concern for the national program. Regarding the management of drug-resistant TB, all smear positive cases should send specimen for drug susceptibility test (DST).

Malaysia ensure universal access to diagnosis and treatment of all forms of TB including treatment of extensively resistant forms of the disease (XDR-TB). Newly developed anti-TB drugs such as Bedaquiline have been used as treatment for XDR-TB patients.

Treatment outcome for MDR-TB treatment cohorts 2013 were 61.7% successfully treated, 17.6% died, 1.5% failed treatment, 14.7% loss follow up and 4% of cases were not evaluated at the end of treatment. The very high rates of treatment interruption are attributed by the difficulties by patients to complete the lengthy (up to 2 years) course of therapy due to social and economic circumstances and also to insufficient adherence support and medical complications of treatment related to adverse drug reactions caused by second-line TB drugs, and failures of health care providers to manage these complications effectively.

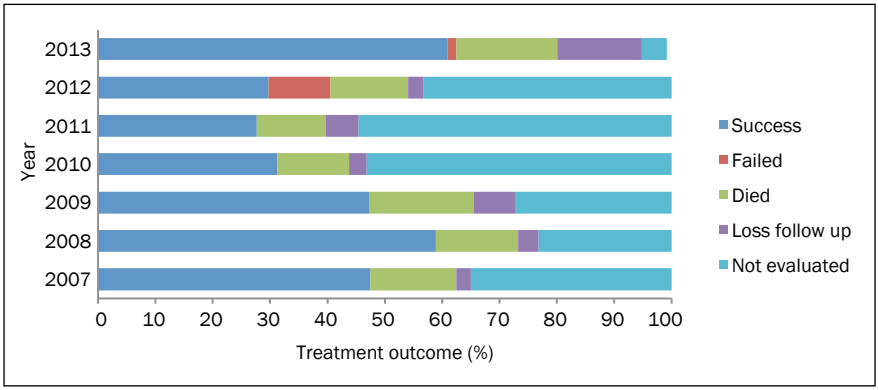


Figure 10. Treatment outcome of MDR-TB cases, Malaysia (2007-2013)

2.2.11 TB Mortality

TB mortality was stagnant between 4.5 to 5.5 per 100,000 populations since year 2000 to 2015. Number of TB deaths had increased from 1,644 deaths (Mortality Rate (MR) 5.8 per 100,000 populations) in 2011 to 1,696 deaths (MR 5.5 per 100,000 populations) in 2015.

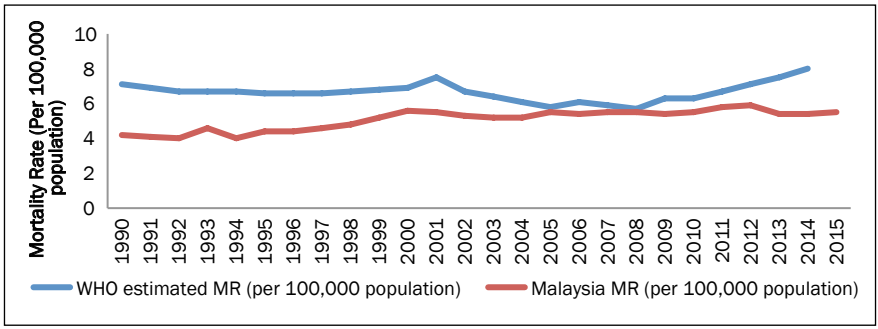


Figure 11. TB Mortality Rate (MR), Malaysia (1990-2015)

The following are considered as the main achievements of the National TB Program;

a) The National TB program has achieved remarkable successes in the uptake and implementation of contemporary international strategies and guidance in TB control. All of the main components of the Stop TB strategy are in place and the country is continuously developing and upgrading and developing its practices in order to align to the emerging challenges of TB epidemic and approaches to ensure an effective national TB response.

b) Visible improvements have been documented during the recent years in relation to TB burden, proven by the increasing number of TB cases and TB rates. The prevalence of drug-resistant forms of TB has been consistently contained at levels that are substantially lower compared to other countries in the region.

c) Universal access is ensured to diagnosis and treatment of all forms of TB including M/XDR-TB. The use of novel rapid diagnostic methods for TB and DR-TB, as well as that of newly developed drugs is being scaled up.

d) As a key indicator of the positive developments in the national TB control program, treatment outcome of TB cases is improving although proportion of patient lost to follow-up remains unchanged.

e) TB control in the rehabilitation centre is integrated in the overall national TB program. The effectiveness of TB control measures in prisons is consistent with the overall trend in the country.

f) Malaysia has aligned its TB care delivery system to the epidemiologic challenges and international best practices. In particular, this refers to the implementation of a predominantly outpatient TB case management, with reduced frequency and duration of hospitalization as a result of optimized and downsized TB hospitals' capacity.

2.3 TB GAP, CHALLENGES AND OPPORTUNITIES

TB remains an important public health issue in the country, and the overall TB epidemiological situation continues to be worrisome. Despite the important positive developments achieved in TB control, Malaysia continues to face a number of serious challenges, which need to be addressed and reflected in this Plan.

i. Low case detection of TB and MDR-TB cases
The detection of TB cases in Malaysia is still below estimated by World Health Organization (WHO). Estimated incidence rate for Malaysia (2014) was 103 per 100,000 populations, whilst actual achievement was 81 per 100,000 populations, hence about 6000 cases were still undetected in the country.

With the current trend of notification rate of TB, it is projected that incidence of TB will remain increase by 2030 (Ismail N, 2012) (refer figure 12). Using

predicted data between 1990-2010 and notification data between 1990-2014, the annual mean difference or underrepresentation is 13.49% (95% CI: 10.39; 15.84). Therefore, more pro-active intensified case finding activities need to be planned.. Attention should be given to ensure an effective systematic screening of high-risk group of getting TB and early diagnosis are implemented.

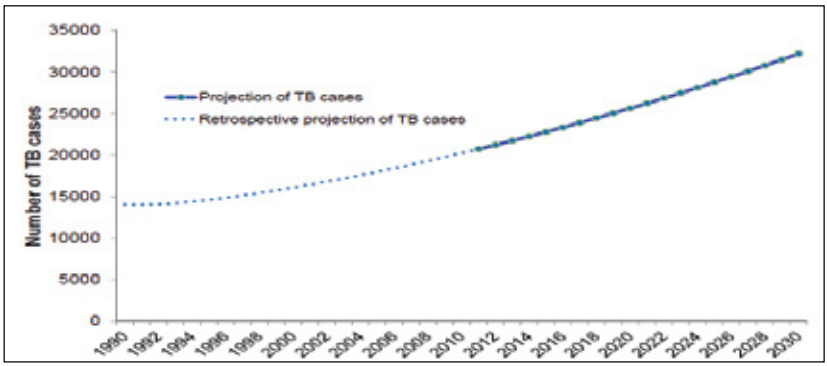


Figure 12. TB Projection in Malaysia (1990-2030)

Contact screening especially contact examination at 4th visit are still weak. PPM activities are Insufficient and need to be enhance.

ii. Resources available not parallel with the disease burden capacity
Besides strengthening the governance and management of the national TB program and adjusting financing and allocation arrangements, proper attention should be given to the development of required human and infrastructural resources for providing essential TB services to the entire population.

Lack of sensitivity of sputum smears microscopy resulting in missing TB cases or can only be detected at the advance stage. Rapid adoption of new diagnostic tools such as fluorescence stain for AFB smear examination and XpertMTB/RIF Assay, integrate into laboratory testing algorithm in laboratory networking will enhance the early detection capacity. At the moment the coverage for LED fluorescent microscope is 58%.

In addition, new molecular tools, which are more sensitive and specific, should be used for specific criteria of patients/specimens for example Line Probe Assay. The rational used of all existing diagnostic tools facilitates the early diagnose and treatment, decrease transmission, reduce fatality and prevent adverse sequelae of the disease. Introduction of new test needs appropriate policy and facility to accommodate the safety

requirement, competence personnel, assured quality and budget and fit for propose.

Strengthening of TB units at district and clinic level is justifiable for effective TB control programme. With online data of registration for TB cases, contact, treatment outcome and mortality TB audit information giving new challenges to the staffs to continuously update the data through MyTB online system. With the current available human resources, additional manpower is needed especially in the states with high TB cases.

iii. Low case detection of TB among children

No proper guideline for screening of TB among children available in the country. Low proportion of pediatric TB cases (<5%) among total cases diagnosed.

iv. Insufficient TB-HIV collaborative activities and co-morbidities

TB control interventions need to be effectively integrated in all divisions and units affecting the overall health system's organization and management as a priority public health function of the government. This situation can be improved through integrated service delivery initiative, which increases the coverage of antiretroviral treatment (ART), shortens the time to treatment initiation, and eventually reduces mortality, by almost 40%. Strong commitment between NTPs and national AIDS programmes in delivering collaborative TB/HIV activities are very important.

The burden and impact of TB co-morbidities in the country is underestimated and needs to be properly addressed. Many of the important co-morbidities are managed in different specialized care settings. Thus, sensitization, collaboration and coordination between TB specialists and other expert groups are critical in effectively addressing TB among patients with co-morbidities.

v. Inadequate policy for treatment of LTBI

No specific guideline including such as high-risk group for LTBI screening, notification, and IPT treatment which is important for effective management of LTBI in the country. Financial resources should be adequately allocated in order to establish a programmatic approach focused on population risk groups. Cost-effectiveness needs to be assessed in each specific context in order to develop tailored strategies based on local epidemiology. Systematic recording and reporting and surveillance should be established and improved within the national health information system to allow effective monitoring of LTBI diagnosis, treatment and outcome. Research gaps include the development of diagnostic tests with improved

performance and predictive value for reactivation TB and drug regimens that can be provided for short duration and with less adverse events. The role of future research in the detection of LTBI in the Malaysian setting might be necessary to gauge the disease reservoir before implementing prophylactic measures for high risk groups involved.

vi. Inadequate knowledge and awareness regarding benefit of BCG vaccination. Missed information regarding vaccine and development of anti-vaccine group.

vii. Poor TB treatment outcomes
Poor outcomes of treatment of TB and MDR-TB cases needs to be addressed through integrating TB cases management and DOT at primary healthcare center. Strengthening the application of patient-centered approaches with appropriate patient support and covers a broader set of adherence determinants.

viii. Lack of adequate engagement of communities in active TB case finding and treatment adherence. Need more communication and training with communities.

ix. Lack of TB support group and policy to address social determinants of TB patients

x. Inadequate research and innovations in TB programme

3. NATIONAL STARTEGIC PLAN FOR TB CONTROL (2016-2020)

3.1 GOAL, TARGET AND PRINCIPAL

VISION

Malaysia free of TB by year 2035

GOAL

The Goal of TB control in Malaysia is to decrease the burden of tuberculosis by ensuring universal access to timely and quality diagnosis and treatment of all forms of TB and prevent development of drug resistance TB in the country.

TARGET

The targets of TB control by year 2020:

1. TB mortality is reduced by 25%
2. TB notification rate (all case) is increase to 100 per 100,000 population
3. Universal access to diagnosis and treatment of all forms of TB, including MDR-TB and XDR-TB;
   - At least 90% of MDR-TB cases are successfully treated

PRINCIPLES

1. Government stewardship and accountability, with monitoring and evaluation
2. Strong coalition with civil society organizations and communities
3. Protection and promotion of human rights, ethics and equity
4. Adaptation of the strategy and targets at states level, with global collaboration

PILLARS AND COMPONENTS

1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

A. Early diagnosis of TB including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups

B. Treatment of all people with TB including drug-resistant TB, and patient support

C. Collaborative TB/HIV activities, and management of co-morbidities

D. Preventive treatment of persons at high risk, and vaccination against TB

2. BOLD POLICIES AND SUPPORTIVE SYSTEMS

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

3. INTENSIFIED RESEARCH AND INNOVATION

A. Discovery, development and rapid uptake of new tools, interventions and strategies
B. Research to optimize implementation and impact, and promote innovations

The End TB Strategy vision is a world free of TB, with zero deaths, disease and suffering due to the disease, with goal to "end the global TB epidemic" by 2035 (refer Appendix 1). Ending the TB epidemic can be translated as 90% reduction in TB incidence and 95% reduction in TB deaths compared with 2015. To strengthen this effort, the National Strategic Plans (NSP) for Tuberculosis Control (2016- 2020), Malaysia was developed in line with the Regional Framework for Action on Implementation of the End TB Strategy in the Western Pacific 2016– 2020. The NSP shall be the national guiding principles in control of TB towards achieving The End TB Strategy goal of ending the global TB epidemic by 2035.

The NSP focuses on implementing The End TB Strategy in the coming five years. Agreed milestones for 2020, along with baseline and targets in Malaysia context, are presented in Table 6.

Table 6. The NSP milestones for 2020 (Malaysia)

Target indicators	2015	2016	2017	2018	2019	2020
Reduction25 % in number of TB deaths compared with 2015(reduce 5% per year)*	1692	1600	1520	1445	1375	1310
Increase Incidence rate of TB to 100 per 100,000 population compared with 79 per 100,000 populations in 2015 (per 100,000 population)*	79	85	90	95	100	100
TB-affected families facing catastrophic costs due to TB	0%	0%	0%	0%	0%	0%

Achieving such a drastic impact will require not only delivering adequate TB services, but also pursuing universal access to health care and social protection while rapidly improving nutrition and economic conditions. To this effect, elimination of catastrophic costs that TB-affected families face has also been included as an important target to be achieved under The End TB Strategy. The NSP introduces new interventions and approaches to guide the development of strategic plans to control TB. The NSP contains five elements that are;

i. a paradigm shifts in the structure and operation of NTPs from a limited view of service provision to an expanded holistic approach;

ii. a focus on equity to ensure all people receive quality care despite disparities resulting from socioeconomic development and changing epidemics;

iii. emphasis on health system strengthening and promotion of multi-sectoral actions; within the context of universal health coverage (UHC) and social protection;

iv. universal application to all states covering the spectrum of TB epidemiology; and

v. people-centred health care as an approach that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems.

Governance and Stewardship

Effective implementation of The End TB Strategy and this NSP require effective government stewardship, high – level political commitment and enhanced resources. The NSP, the Strategies backbone at country level, guides national health authorities in managing and implementing appropriate TB care and prevention activities, and building effective linkages with other programmes and health and non-health sector partners.

Universal Health Coverage Policy, Drug Regulatory and Management Systems

Universal Health Coverage (UHC) can be define as 'the situation where all people are able to use the quality health services that they need and do not suffer financial hardship paying for them'. Malaysia supports and are moving towards UHC policy and implementation in the country. The current national TB control structure and systems will be maintained and strengthens to minimize and reduce patient costs associated with TB care. No affected families should be facing "catastrophic costs' due to TB.

Diseases Notification and Surveillance System

Medical officers regardless in private or public healthcare facilities who has diagnosed or had treated patients with anti-TB medication are mandatory to notify the case to the nearby District Health Office in Malaysia. Once a TB case were notified, assistant environment health officer (AEHO) in district health office will investigate the case. Once confirmed TB case, the patient will be registered to the electronic web base application; MyTB system. MyTB system comprise of variables such as on patient's socio-demographic, laboratory investigation, anti-TB treatment regime, treatment outcome and list of contact of index case of TB patient.

3.2 NATIONAL STRATEGIC PLAN STRATEGIES, STRATEGIC INTERVENTIONS AND KEY ACTIVITIES

3.2.1 PILLAR 1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

Seven strategies under this Pillar 1 and are as follows:

STRATEGY 1	Enhance case detection of TB
STRATEGY 2	Improving control of TB among children
STRATEGY 3	Enhance TB/HIV collaborative activities and management of co- morbidities
STRATEGY 4	Strengthen Programmatic Management of Drug Resistant Tuberculosis (PMDT)
STRATEGY 5	Strengthen laboratory networks to find all TB cases
STRATEGY 6	Strengthen programmatic management of LTBI
STRATEGY 7	Enhance BCG vaccination programme

STRATEGY 1. ENHANCE CASE DETECTION OF TB

Malaysia has implemented national guideline for systematic screening of high-risk group of TB since 2015. Screening of contact is under TBIS programme since year 2003. The high-risk groups include contact of Index TB case, TB/HIV co-morbidities, inmate for prisons and CCRCs, diabetes patients, smokers, chronic renal failure on dialysis, patient on tumour necrosis factor (TNF), chronic obstructive pulmonary diseases, elderly and patient in methadone replacement therapy and substance abuse clinic.

However, other high-risk group for concern include people living in urban slums, homeless internal and cross-border migrants and other endemic geographical pockets. Management for contact tracing and follow-up until fourth visit need to be strengthened.

Strategic interventions and key activities for Strategy 1:

Strategic Interventions	Key activities for strategic interventions
1.1 To improve access to and quality of TB screening and diagnosis for each high-risk population - ensure all high- risk population screen for TB	1.1.1 Develop national guideline and SOPs for systematic screening of TB among high-risk population 1.1.2 Strengthen screening among contacts especially for first and fourth visit, immigrants and urban slums 1.1.3 To establish peer support group for high-risk group screening and conduct a training course
- Strengthen screening at hospital and private facilities	1.1.4 Increase radiologic diagnostic capacity (x-ray facilities) to health clinics and outsourcing chest radiograph to private facilities. 1.1.5 Strengthen PPM with private facilities for screening and management of TB cases.
- Strengthen screening at institutions such as prison,CCRC and elderly homes	1.1.6 Enhance availability of static x-ray in selected prison, mobile x-ray services for elderly homes
1.2 To integrate diagnosis and management of LTBI into systematic screening of active TB; - among prioritized high-risk group	1.2.1 Develop guideline for integration of LTBIscreening in systematic screening of active TB 1.2.2 Develop collaboration with multiple agencies for management of high-risk group screening

Key Indicator for Strategy 1:

- Increase case finding activities and diagnostic capacity to increase case notification of all forms of TB from 79 per 100,000 populations in 2015 to 100 per 100,000 populations in 2020.
- Symptomatic screening for TB: 2000 per 100,000 populations by year 2020.
- Contact screening coverage at first visit is > 90% and > 50% during 4th visit.
- Treatment success rate >90%.

STRATEGY 2. IMPROVE CONTROL OF TB AMONG CHILDREN

TB illness in children is often difficult to diagnose due to non-specific symptoms at presentation. Proportion of TB among pediatric cases of all TB cases was 3.1%. Childhood TB will be effectively addressed by collaboration with other health programmes (particularly maternal and child health, nutrition, and immunization services), tertiary and secondary health facilities, private and public health-care providers, non-governmental organizations, and community organizations.

Strategic interventions and key activities for Strategy 2:

Strategic Interventions	Key activities for strategic interventions
2.1 To ensure effective screening of TB among pediatrics case and contact	2.1.1 Develop guideline and SOPs for screening and management TB cases among pediatrics age group 2.1.2 Strengthen management of contact among pediatric and provision of IPT 2.1.3 Collaboration with maternal and child health programme
2.2 Availability of pediatric formulation	2.2.1 Ensure availability of pediatric formulation
2.3 Strengthen recording, reporting and data analysis	2.3.1 Ensure all diagnosed pediatric cases notified and registered
2.4 Maintain BCG coverage	2.4.1 Improve awareness in the community and build the capacity of health-care workers.
2.5 Research in pediatric case	2.5.1 Incorporate child-related operational research questions in the national TB research agenda and national TB research strategic plan

Key Indicator for Strategy 2:

- Increase case detection of TB among pediatric cases. Proportion of pediatric TB cases increase from 3.1% (2015) to 5% by 2020.
- To achieve treatment success rate of 95% for pediatric cases.

STRATEGY 3. ENHANCE TB/ HIV COLLABORATIVE ACTIVITIES AND MANAGEMENT OF CO- MORBIDITIES

PLHIV are 29 times more likely to develop TB disease as compared with people without HIV. A leading cause of death among people living with HIV is TB which accounting for one in five HIV- related deaths globally. Whereas, in 2013 one in four TB deaths globally were associated with HIV. All TB patients should be routinely assessed for relevant co-morbidities such as non- communicable diseases (NCDs) including diabetes, kidney, liver diseases, alcohol and drug abuse and tobacco use. Efforts should be made to reduce modifiable risk factors.

Strategic interventions and key activities for Strategy 3:

Strategic Interventions	Key activities for strategic interventions
3.1 To strengthen TB-HIV collaborative activities	3.1.1 Conduct systematic screening of people living with HIV to detect TB and LTBI 3.1.2 To enhance screening of HIV among TB patients and vice versa 3.1.3 To strengthen HIV prevention including IPT and CPT 3.1.4 To promptly initiate ART for TB/HIV patients 3.1.5 Strengthen recording and reporting, as well as monitoring and evaluation, at the care level while adhering to confidentiality. 3.1.6 Promote the principles of people -centered care, reduction of stigma and discrimination, community engagement and social protection
3.2 To strengthen health-system capacity for concurrent management of TB and multiple co-morbidities	3.2.1 To collaborate with the clinical sector to periodically assess important co-morbidities among TB patients 3.2.2 To establish combine clinic for TB with co-morbidities at hospital level

Strategic Interventions	Key activities for strategic interventions
	3.2.3 To incorporate guidance on co-morbidity management into the national TB guidelines 3.2.4 To enhance education in specialize care settings, such as nursing homes

Key Indicator for Strategy 3:

- Number of new and relapse TB patients with documented HIV status divide by number of new and relapse TB patient : 100%
- Number of people living with HIV who were started on IPT treatment divided by number eligible for treatment :90%

STRATEGY 4. STRENGTHEN PROGRAMMATIC MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS (PMDT)

Malaysia is strengthening programmatic management of drug resistant Tuberculosis. Full DST is at the moment performed only at the NPHL, which is insufficient given the increasing needs and geographic access issues. The existing national guidance and operational procedures for laboratories require update in order to accommodate for new technologies and diagnostic algorithms.

Strategic interventions and key activities for Strategy 4:

Strategic Interventions	Key activities for strategic interventions
4.1 To detect MDR-TB cases early	4.1.1 DST for all high-risk group of getting MDR-TB with enhance use of rapid diagnostic tool. 4.1.2 Enforce mandatory notification of drug-resistant TB and treatment initiation
4.2 To strengthen management of patient with DR-TB; - all diagnosed patient promptly notified and enrolled in treatment - all enrolled patients complete their treatment - develop a supportive environment	4.2.1 Develop national guideline for surveillance and monitoring of DR-TB 4.2.2 Develop national guidelines for management of DR-TB including diagnosis, laboratory, clinical and public health management 4.2.3 Develop SOPs for implementation of CDC Act 1998 for loss to follow-up patient 4.2.4 To organize training session for management of DR-TB cases to staffs 4.2.5 To print set of guidelines materials 4.2.6 To ensure availability of second line drugs 4.2.7 To develop online database for DR-TB registration, surveillance

Strategic Interventions	Key activities for strategic interventions
	and monitoring of treatment outcomes. 4.2.8 Engagement with NGO, civil society and communities for treatment support (DOT)

Key Indicator for Strategy 4:

- Notification of MDR-TB cases : <3% of all TB cases.
- Treatment success rate for DR-TB: 90%

STRATEGY 5. STRENGTHEN LABORATORY NETWORKS TO FIND ALL TB CASES

A high-performing laboratory service network with optimum coverage and accessibility is essential to achieve ambitious target of the End TB Strategy outlined by World Health Organization (WHO). It is important to improve case finding through early detection of TB cases, including the smear-negative TB (such as extra pulmonary and children specimens) and early detection of Drug Resistant TB (DRTB) cases especially Multiple Drug Resistant TB (MDRTB).

Strategic interventions and key activities for Strategy 5:

Strategic Interventions	Key activities for strategic interventions
5.1 Increase laboratory capacities for bacteriological diagnosis of TB and DR-TB assessment - ensure all TB patients at high risk of DR-TB received DST at least for RR - Expand WHO-recommended diagnostics to all State Hospital laboratories	5.1.1 Increase number of laboratories using LED microscopic 5.1.2 examination Increase availability of rapid MTB and MDR-TB detection in all states 5.1.3 Procurement of supplies (cartridges) for Xpert MTB/Rif tests 5.1.4 Maintenance and servicing of Xpert MTB/Rif instruments 5.1.5 Supervision/ monitoring of Xpert MTB/Rif implementation 5.1.6 Increased number of laboratory with capability to do identification and drug susceptibility test 5.1.7 Increased number of laboratory with capability to do Line Probe Assay (LPA) for identification and drug susceptibility test 5.1.8 Establish algorithm to facilitate appropriate test performed & ensure result timeliness.
5.2 Strengthening laboratory management towards accreditation	5.2.1 To increase number of lab/ centers enrolled External Quality Assurance Program (EQAP) 5.2.2 To establish EQA-PT programme 5.2.3 To increase number of lab/

Strategic Interventions	Key activities for strategic interventions
	centers with MS ISO 15189 accreditation. 5.2.4 Use of universal coding system (e.g. : LOINC) to assist in the electronic exchange and gathering clinical result (such as lab test, clinical observation, outcomes management and research)

Key Indicator for Strategy 5:

- Drug susceptibility testing (DST) coverage for bacteriologically confirmed TB patients: 100%

STRATEGY 6. STRENGTHEN PROGRAMMATIC MANAGEMENT OF LATENT TB INFECTION

Latent tuberculosis infection (LTBI), defined as a state of persistent immune response to prior- acquired Mycobacterium tuberculosis antigens without evidence of clinically manifested active TB. Approximately 10% of people with LTBI will develop active TB disease in their lifetime, with the majority developing it within the first five years after initial infection. Currently available treatments have an efficacy ranging from 60% to 90%. Systematic testing and treatment of LTBI in at-risk populations is a critical component of WHO's eight-point framework adapted from the End TB Strategy to target pre-elimination and, ultimately, elimination in low incidence countries.

WHO Global Surveillance and Monitoring Project estimated the global prevalence of LTBI were 32%, with strong regional variation.

Strategic interventions and key activities for Strategy 6:

Strategic Interventions	Key activities for strategic interventions
6.1 To strengthen programmatic management of LTBI activities	6.1.1 To develop national guideline and SOPs for management of LTBI 6.1.2 To establish recording and reporting systems for LTBI. 6.1.3 To develop database for screening of LTBI 6.1.4 To expand the target population for LTBI diagnosis and treatment including patient on TNF, patient receiving dialysis, patient preparing for organ transplant. 6.1.5 Training for programmatic LTBI 6.1.6 Accessibility to Rifapentine 6.1.7 Research on LTBI

Key Indicator for Strategy 6:

- Number of children aged <5 years who are household contacts of cases started on LTBI Treatment divided by the number eligible for treatment :50%

STRATEGY 7. ENHANCE BCG VACCINATION PROGRAMME

Bacillus Calmette-Guerin or Bacille Calmette-Guerin (BCG) is a live attenuated vaccine against tuberculosis.The BCG vaccine is normally given to children as it has been shown to provide 70- 80% effective against the most severe forms of the disease, such as TB meningitis in children. Protection has been shown to last for 10 to 15 years.

In Malaysia, the National BCG Vaccination Program was initiated in 1961. Routine BCG vaccination is given to newborns at birth (primary BCG vaccination). Thereafter, an additional booster dose is given to children at the age of seven (Sabah) and twelve years (other states). However, this booster dose was discontinued since July 2002. Starting 2016, BCG revaccination is only given to those children without BCG scar or with no BCG vaccination history.

Parents rejecting immunization for their children is increasing in trend in Malaysia with 216 cases in 2013, increased to 309 in 2014. Reason for refusing vaccination include fears of side effects likes autism and false belief that vaccines contain DNA of forbidden likes pigs. The growing of anti-vaccination group is worrying although National Fatwa Council has recommended parents to immunize their children.

Strategic interventions and key activities for Strategy 7:

Strategic Interventions	Key activities for strategic interventions
7.1 To ensure all live newborns received BCG vaccination	7.1.1 To review and update BCG TBIS 7.1.2 To increase awareness of BCG vaccination particularly in anti-vaccine group

Key Indicator for Strategy 7:

- BCG coverage for all newborn: > 98%

3.2.2 PILLAR TWO: BOLD POLICIES AND SUPPORTIVE SYSTEMS

The second pillar include strategic actions within and beyond the health sector to support TB care and prevention programme. The action in this pillar is to enhance government stewardship and accountability, pursuing TB policy across government agencies to improve access to social and economic consequences of TB. Three strategies under this pillar include:

STRATEGY 8.	To ensure uninterrupted supply of quality-assured TB drugs
STRATEGY 9.	To enable supportive environment and systems for effective TB control
STRATEGY 10.	To ensure no households that experience catastrophic cost due to TB

STRATEGY 8. TO ENSURE UNINTERRUPTED SUPPLY OF QUALITY-ASSURED TB DRUGS

The End TB strategy emphasizes strengthening the national regulatory framework to ensure a sustained supply of quality-assured drugs. Adherence to anti tuberculosis (anti-TB) medicines is among the key factors to achieve good treatment outcomes and prevent drug resistance. Medication counselling, especially upon initiation of treatment, could enhance patients' adherence by increasing patients' understanding about the importance of adherence, side effects of treatment and handling of those side effects. Pharmacists are expected to have more active involvement in educating TB patients about their medication, thus promoting rational use of anti-TB medicines. Referral and notification of TB case to other countries should be strengthen to ensure continuity of care and treatment of TB patients.

TB patients frequently suffer from adverse drug reactions (ADRs).1 Good documentation of adverse reactions due to anti-TB medicines is necessary to provide local data on the safety of the medicines being used. This will enable appropriate measures being taken to ensure safe treatment and increase confidence in the treatment. Throughout the year 2014, 273 ADRs with regard to anti-TB medicines were reported to the National Centre for Adverse Drug Reactions Monitoring,3 an increment by 133% from the number reported in the year 2010.4 Despite this trend, it is believed that there are a number of ADR cases which had not been reported.

Medication are provided free to patients treated with first line anti-TB drugs at all MOH hospitals and clinics. Procurement of all anti-TB medicines is done by the Pharmacy Department/ Unit at hospital and district levels using

the existing operational budget. First line anti-TB medicines are available at all TB treatment centres 1 and 2 although there is limited use of fixed-dose combination medicines. Nonetheless, supply of medicines, including second line medicines, remains adequate.2 Lack of pharmacist's integration into the treatment process of TB patients had limit the involvement of pharmacists in providing medication counselling. This is one of the factors that cause them to default TB treatment.

Paediatric and adult patients with special needs such as those who need tube feeding have to consume anti-TB medicines in oral liquid form. Commercial liquid preparations are preferable than extemporaneously prepared formulations in terms of stability. Currently, there is no commercial preparation of anti-TB medicine in oral liquid form available in Malaysian market. Paediatric patients as well as adult patients with special needs being prescribed with oral formulations are given extemporaneous preparations.

Strategic interventions and key activities for Strategy 8:

Strategic Interventions	Key activities for strategic interventions
8.1 To provide counselling on TB medication	8.1.1 Pharmacists integration into the treatment process of TB patients. Counselling on TB medication must be provided by pharmacists for newly diagnosed patients.
8.2 Strengthen International notification and referral of TB case	8.2.1 Development of International Tuberculosis referral form for referral of TB case to other countries.
8.3 Strengthen ADRS reporting	8.3.1 Training doctors and paramedics in ADR reporting in order to strengthen the pharmacovigilance of anti-TB medicines.
8.4 Enhance registration of anti-TB medicines in liquid formulations for Malaysian market	8.4.1 Review submissions for registration of anti-TB medicines in oral liquid forms under fast-track registration by the National Pharmaceutical Control Bureau.

Key Indicator for Strategy 8:

- To ensure uninterrupted supply of quality-assured TB drugs

STRATEGY 9. TO ENABLE SUPPORTIVE ENVIRONMENT AND SYSTEMS FOR EFFECTIVE TB CONTROL

Engagement and Partnerships

Partnership between health and social sector including patients, families, communities and civil society organizations are important to end the epidemic of TB. Community engagement can assist in identify people with suspected TB and refer them for diagnosis and treatment. They can also assist in alleviating stigma and discrimination. Local agencies can help in reaching out to vulnerable and underserved groups and addressing determinants of TB.

In Malaysia, TB diagnosis and treatment is delivered by public and private care providers. TB cases notification are mandatory by all health-care providers. Collaboration, regular meeting and discussion between these providers are encouraged to provide quality diagnosis and TB case management.

Strategic interventions and key activities for Strategy 9:

Strategic Interventions	Key activities for strategic interventions
9.1 To strengthen and coherent health and other agencies among TB Control Programme	9.1.1 Joint committee meeting between health and social sectors regarding the National TB Control Program at National level
9.2 To enhance the community engagement in TB Control Program: - To partner with people who have personally experienced TB to ensure central focus of the program - To well-equip the community members	9.2.1 To establish COMBAT Team in enhancing TB Control activities in the community with higher burden of TB - Community volunteers (ie Panel Penasihat) are the community agents. 9.2.2 Ensuring that affected populations are represented in the venues to discuss national TB response and relevant bodies at national and local levels. 9.2.3 Integrating community-based TB activities to other community-based activities to support primary health care services such as HIV, maternal and child health

Strategic Interventions	Key activities for strategic interventions
9.1 To strengthen and coherent health and other agencies among TB Control Programme 9.2 To enhance the community engagement in TB Control Program: - To partner with people who have personally experienced TB to ensure central focus of the program - To well-equip the community members	and non-communicable diseases and outside of health sector 9.2.4 Engaging them in TB program planning, service delivery and monitoring, information and education activities, support to peer patients and families, research and advocacy 9.2.5 Creating workplace program (health promotion) that comprehensively addresses TB prevention, diagnosis, treatment and care in high burden settings as well as alleviating stigma & discrimination in the congregate institution
9.3 To enhance engagement of civil society organizations in National TB Control Program - To select civil society organization with specific capacities that TB program can benefit	9.3.1 To strengthen the roles of MAPTB in TB Control Program: a. Reaching out to vulnerable and undeserved groups b. Detecting defaulters c. DOTS Supervisor d. Responsible for logistic arrangements in screening of elderly nursing homes e. Mobilizing communities f. Channelling information to the public hence, creating demand for TB care g. Addressing determinants of TB epidemic
9.4 Engaging all public and private care providers -To establish and expand public-private mix approach including private clinics and hospitals, pharmacies,	9.4.1 Joint Meeting between public & private health care provider Scaling up the collaboration with private sectors and strengthening the notification system Enforcing CDC Act that includes mandatory

Strategic Interventions	Key activities for strategic interventions
laboratories, and health facilities in other sectors	notification of TB cases by all healthcare providers

Key Indicator for Strategy 9:

- Percentage of TB patient referred by community volunteers/NGOs for TB diagnosis and treatment :1%
- Percentage of TB patients under follow-up or DOT with community volunteers/NGOs:1%
- Percentage of TB patient cured or completed TB treatment under supervision of community volunteers/NGOs:1%

STRATEGY 10. TO ENSURE NO HOUSEHOLDS THAT EXPERIENCE CATASTROPHIC COST DUE TO TB

Addressing Social Determinants and Social Protection

The End TB Strategy expresses three main areas for expanding social protection;

i. schemes for compensating the financial burden associated with illness such as sickness insurance, disability pension, social welfare payments, other cash transfers, food packages
ii. legislation to protect people with TB from discrimination such as expulsion from workplaces, educational or health institutions, transport systems or housing
iii. instruments to protect and promote human rights, including addressing stigma and discrimination, with special attention to gender, ethnicity and protection of vulnerable groups.

Strategic interventions and key activities for Strategy 10:

Strategic Interventions	Key activities for strategic interventions
10.1 To provide social protection mechanism to support patient and families affected by TB	10.1.1 To create TB support groups 10.1.2 Ensure protection and promotion of human rights, including addressing stigma and discrimination and protection of vulnerable groups
10.2 Addressing poverty and social determinants by promoting HiAP approach (Health in All Policies)	10.2.1 Refer TB patient with low socioeconomic income to receive financial aid from MAPTB / Social Welfare Department / Pusat Zakat by mapping of risk factors & local social determinants 10.2.2 Revised criteria for eligibility of receiving TAS (Treatment Allowance Scheme) & EGT (Elaun Ganti Tambang)

3.2.3 PILLAR THREE: INTENSIFIED RESEARCH AND INNOVATIONS

TB imposes a significant threat towards human health. In 2014, an estimated 9.6 million new cases and 1.5 million deaths has occurred worldwide. The vast majority of cases occur among the poor people from low and middle income countries who are at risk. In 2014, WHO estimated more than 3 million people who developed TB and three quarter of the estimated 480,000 cases of multidrug-resistant TB (MDR-TB) were missed by national health systems.

The progress in controlling TB worldwide is hindered by the lack of widely accessible & effective diagnostic tools, drugs and vaccines in addition to the failure of many health systems that are unable to guarantee the provision of these factors in areas where they are needed the most.

An intensification of TB research is therefore urgent and crucial. An invigorated effort is needed in research, along a continuum that links upstream fundamental research to discovery and new tool development, and ultimately to operational and implementation research allowing innovative strategic approaches to be adapted to our needs. In order to eliminate TB, it is important to address the key areas of research that range from the basics of science to the implementation of novel tools. The following areas particularly demand attention;

i. fundamental research: to shed better light on the basic mechanisms involved in the pathogenesis of TB as a gateway towards the innovation of new control tools: the development of rapid and sensitive point-of-care diagnostic tests, effective short-term treatment regimens for drug-sensitive, resistant and latent forms of TB, as well as vaccines and other preventive interventions.

ii. operational research: aims to pursue knowledge on strategies, interventions or tools to enhance the quality, effectiveness and coverage of the healthcare program. This is to seek for the most efficient means to provide optimal TB care and to guarantee an effective implementation of new and existing tools in diagnosing, treating and preventing TB in health care services.

STRATEGY 11. TO INTENSIFY RESEARCH AND INNOVATION AS PRIORITY ISSUES IN TB CONTROL PROGRAMME

The third pillar in the *End TB Strategy* demands for intensified research and innovation for better detection, treatment and control of TB. This approach calls attention to the development of a rapid point-of-care diagnostic test, new drugs and treatment regime for all forms of TB, improved detection of latent infections, and effective vaccines that includes a post-exposure vaccine to

prevent the development latent TB.

The End TB Strategy suggests a change in approaching TB research. National Tuberculosis Programmes (NTPs) are encouraged towards progressing beyond programmatic operational research and to contribute to the global evidence base for research and development. The suggested actions include the establishment of a national research network, tactical research plan and priorities, capacity building of human resources and increasing research funds through various means.

The Health Ministry will intensify its Research and Development capacity and competency in Tuberculosis in an effort to avert tuberculosis-associated morbidity and mortality and support a shared global vision of a world free of tuberculosis. The National TB Research Network should be regarded as a partnership between the public and non-government sectors. The potential stakeholders include but are not limited to;

i. **Internal Stakeholders**
   - National TB Programme of the Ministry of Health
   - Health services representatives from different levels of TB programmes, MOH
   - National Institutes of Health Malaysia

ii. **External Stakeholders**
   - Community and civil society representatives
   - Non-Governmental Organizations (NGOs) representatives
   - National Universities (University of Science Malaysia, University of Malaya, UKM, IMU)
   - Other government agencies e.g. Ministry of Science & Technology and Ministry of Higher Education
   - Industry representatives e.g. pharmaceutical industry
   - International partners e.g. WHO, UN, ASEAN, International NGOs or universities

The National Action Plan under pillar three is an effort to articulate a comprehensive strategy to
identify knowledge gaps that need to be addressed through Basic and fundamental research, Clinical and translational research, Operational and implementation research, Epidemiologic research, and Policy, health and social system research with the aim to Increase our understanding of TB and its control; improve the evidence base for its control; and develop better tools for its diagnosis, treatment and prevention. Among the major research action plans are;

i. formulate a TB research strategy to fill evidence gaps, especially in the fields of:
   - better drugs, diagnostics and vaccines
   - service delivery
   - risk factors

ii. latent TB infection, its diagnosis and management

iii. undertake a national audit of treatment failures and deaths from TB, learn lessons from it and implement improvements

iv. foster academic interest in TB epidemiology, clinical tuberculosis and international research collaborations

Strategic interventions and key activities for Strategy 11 :

Strategic Interventions	Key activities for strategic interventions
11.1 Intensify research and innovation activities	11.1.1 Establish mechanisms for the collaboration between stakeholders at national and international levels towards the development of a national TB research network. 11.1.2 Construct a set of unique and country specific TB research priorities based on the current TB epidemic, assessment of the national health system and research capacity, and an understanding of the requisites in achieving the WHO End TB Strategy targets by 2030/2035. 11.1.3 Increase capacity and leadership for TB research and plan relevant trainings for sustainable capacity building that includes researchers and research careers development. 11.1.4 Warrant adequate funding for training, infrastructure and research operations. 11.1.5 Initiate and encourage public support and funding of TB

Strategic Interventions	Key activities for strategic interventions
	research throughout all phases of the plan. 11.1.6 Set up methods, milestones and indicators for a continuous monitoring and evaluation of the implementations of the research plan.

Key Indicator for Strategy 11:

- Establishment of TB research network

4. MONITORING AND EVALUATION

Monitoring and evaluation is an essential in strategic plan. Supportive supervision will be maintained at NTP as a key instrument for implementation. Supervision will cover all aspects related to implementation of TB control interventions outlined by this plan.

4.1 Monitoring Milestone and Impact Indicators

	Indicator	2015 (baseline)	2016	2017	2018	2019	2020
1	Reduction 25% in number of TB deaths compared with 2015 (reduce 5% per year)	1692	1600	1520	1445	1375	1310
2	Reduction 25% in number of TB deaths compared with 2015 (reduce 5% per year)	79	85	90	95	100	100
3	Treatment success rate, new & relapse TB case (cohort 1 year before)	79.6%	80%	80%	82%	84%	85%
4	Reduction 25% in number of TB deaths compared with 2015 (reduce 5% per year)	62%	70%	75%	80%	85%	90%

4.2 Monitoring Key Indicators

	Indicator	2015 (baseline)	2016	2017	2018	2019	2020
1.1	Symptomatic screening for TB : (per 100,000 populations)	1801	2000	2000	2000	2000	2000
1.2	Contact screening coverage at first visit is > 90% and > 50% during 4th visit.	1st visit :78.2% 4th visit: 5%	1st visit :75% 4th visit: 25%	1st visit :80% 4th visit: 25%	1st visit :85% 4th visit: 50%	1st visit :90% 4th visit: 50%	1st visit :90% 4th visit: 50%
1.3	Treatment success rate > 85%.	79.6%	80%	80%	82%	84%	85%
2.1	Case detection of TB among paediatric cases. Proportion of paediatric TB cases increaseto 5% by 2020.	3.1%	3.5%	4.0%	4.5%	5%	5%
2.2	To achieve treatment success rate of paediatric cases	90.4%	91%	92%	93%	94%	95%

	Indicator	2015 (baseline)	2016	2017	2018	2019	2020
3.1	Number of new and relapse TB patients with documented HIV status divide by number of new and relapse TB patient	88.3%	90%	95%	95%	100%	100%
3.2	Number of people living with HIV who were started on IPT treatment divided by number eligible for treatment :90%	29.3%	90%	90%	90%	90%	90%
4.1	MDR-TB cases notified <3% of all TB cases	101 cases (0.4%)	<3%	<3%	<3%	<3%	<3%
4.2	Treatment success rate for DR-TB: 90% (cohort previous 2 years)	62%	70%	75%	80%	85%	90%
5.1	Drug susceptibility testing (DST) coverage for bacteriological confirmed TB patients: 100%	92.2%	95%	100%	100%	100%	100%
6.1	Number of children aged <5 years who are household contacts of cases started on LTBI Treatment divided by the number eligible for treatment :(WHO 90%	No data	20%	25%	30%	40%	50%
7.1	BCG coverage for all newborn: > 98%	98.5%	>98%	>98%	>98%	>98%	>98%
9.1	Percentage of TB patient referred by community volunteers/NGOs for TB diagnosis and treatment.	No data	0.1%	0.2%	0.4%	0.5%	1%
9.2	Percentage of TB patients under follow-up or DOT with community volunteers/NGOs.	0.1%	0.1%	0.2%	0.4%	0.5%	1%
9.3	Percentage of TB patient cured or completed TB treatment under supervision of community volunteers/NGOs.	0.1%	0.1%	0.2%	0.4%	0.5%	1%

4.3 Monitoring Output and Process Indicators

Item	Strategic Activities	Indicator	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
1	1.1.1 Develop national guideline and SOPs for screening of TB among high-risk population	Process	Guideline document	YBMK's KPI	Document ready by 2017	Annual
	1.1.2 Strengthen screening among contacts, immigrants and homeless	Output	a. Screening of contact at first visit :90% b. Screening of contact at 4th visit:50% c. No. of immigrants been screened for TB d. No. of homeless been screened for TB	a. 80% b. 5% c. nil d. nil	a. 100% b. 100% c. 5% d. 100%	Annual
	1.1.3 To establish peer support group for high-risk group screening and training	Process	No. of peer support group for high–risk group been trained; a. PLHIV b. Diabetes patient c. Chronic renal failure	nil	600 been trained	Annual
	1.1.4 Increase radiologic diagnostic capacity (x-ray facilities) to health clinics	Process	No. of health clinic equip with static x-ray	177	Additional of eight (8) unit of static x-ray	Annual
	1.1.5 Strengthen PPM with private facilities for screening and management of TB cases.	Process				Annual
	1.1.6 Ensure availability of static x-ray in selected prison,	Output	No. of prison equip with static x-ray	Nil	Nine (9) prisons will be equip with static x-ray facilities	Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	1.1.7 Mobile x-ray services for elderly homes	Output	No. of mobile x-ray services	2 unit	Additional 2 unit	Annual
	1.2.1 Develop guideline for integration of LTBI screening in systematic screening of active TB	Process	Guideline document	Nil	Document available by 2018	Annual
	1.2.2 Develop collaboration with multiple agencies for management of high-risk group screening	Process	Qualitative			Annual
Str 2	2.1.1 Develop guideline and SOPs for screening and management of TB cases among pediatric age group	Process	Guideline document	CPG Mx. of TB (1ST Edition 2012)	Document available by 2017	Annual
	2.1.2 Strengthen management of contact among pediatric and IPT	Output	No. of contact among pediatrics age group given IPT	No data	50% of eligible for IPT among contact of children <5 years old	Annual
	2.1.3 Collaboration with maternal and child health programme	Process	No. of meeting	1 per year	2 / per year	Annual
	2.2.1 Ensure availability of pediatric formulation	Process	Pediatric formulation		Available by 2020	Annual
	2.3.1 Ensure all diagnosed pediatric cases notified and registered	Output	No of registered pediatric TB cases/ no of diagnosed and treated pediatric cases		100%	Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	2.4.1 Improve awareness in the community	Process	Qualitative			Annual
Str. 3	3.1.1 Conduct systematic screening of people living with HIV to detect TB and LTBI	Output	No. of PLHIV screen for TB (cohort) per No. of PLHIV X 100	9909/90603=10.9%	100%	Annual
	3.1.2 To enhance screening of HIV among TB patients and vice versa	Output	No of registered TB patients screened for HIV per No. of registered TB patients x 100	98.5%	100%	Annual
	3.1.3 To strengthen HIV prevention including IPT and CPT	Output	No. of PLHIV started on IPT treatment per No of PLHIV eligible for IPT	29.3%	>90%	Annual
	3.1.4 To promptly initiateART for TB/HIV patients	Output	Percentage of HIV-positive incident TB cases that received treatment for TB and HIV	55.1%	90%	Annual
	3.1.5 Strengthen recording and reporting, as well as monitoring and evaluation.	Process	Qualitative			Annual
	3.1.6 Promote the principles of people-centred care, reduction of stigma and discrimination	Process	Qualitative			Annual
	3.2.1 To collaborate with the clinical sector and relevant professional bodies to periodically assess important co-morbidities among TB patients	Process	TB co-morbid management including TB-HIV, TB -DM			Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	3.2.2 To establish combine clinic for TB with co-morbidities at hospital level	Process	No. of combine clinic	Nil	1 combine clinic/tertiary hospital	Annual
	3.2.3 To incorporate guidance on co-morbidity management into the national TB guidelines	Process	Chapters on co-morbidity management incorporated into National TB guidelines			Annual
	3.2.4 To enhance education in specialize care settings, such as nursing homes.	Process	No of visiting, training and supervision of nursing home	No data	100%	Annual
Str. 4	4.1.1 DST for all high-risk group of getting MDR-TB with enhance use of rapid diagnostic tool.	Output	No of high risk group with MDR-TB test result/ No of high risk group eligible for MDR-TB test x 100%	No data	20%	Annual
	4.1.2 Enforce mandatory notification of drug-resistant TB and treatment initiation	Output	100% notification of DR-TB			Annual
	4.2.1 Develop national guideline for surveillance and monitoring (DR-TBIS)	Process	Document guideline available		2017	Annual
	4.2.2 Develop national guidelines for management of DR-TB including diagnosis, laboratory, clinical and public health management	Process	Document guideline available		2017	Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	4.2.3 Develop SOPs for implementation of CDC Act 1998 for loss to follow-up patient	Process	Document guideline available		2017	Annual
	4.2.4 To organize training session for management of DR-TB cases to staff.	Process	TOT training		2017	Annual
	4.2.5 To print set of guidelines materials	Process	No of guideline printed		2017	Annual
	4.2.6 To ensure availability of second-line drugs	Output				Annual
	4.2.7 To develop online database for DR-TB registration, surveillance and monitoring of treatment outcomes.	Output	Data base available online		2020	Annual
	4.2.8 Engagement with NGO, civil society and communities for treatment support (DOT)	Process	a. Percentage of patient supervised/ DOT by NGO b. Percentage of patient cured/completed treatment by NGO	a.0.1% b.0.1%	a.1% b.1%	Annual
Str 5	5.1.1 Increase number of laboratories using LED microscopic examination	Output	Percentage of lab equipped with LED microscope	40%	70%	Annual
	5.1.2 Increase availability of rapid MTB and MDR-TB detection in all states	Output	Number of lab in equipped with Xpert MTB/RIF Assay.	4	20	Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	5.1.3 Procurement of supplies (cartridges) for Xpert MTB/Rif tests	Process				Annual
	5.1.4 Maintenance and servicing of Xpert MTB/Rifinstruments	Process				Annual
	5.1.5 Supervision/ monitoring of Xpert MTB/Rif implementation	Process				Annual
	5.1.6 Increased number of laboratory with capability to do identification and drug susceptibility test	Output	Number of laboratory with capability to do identification and drug susceptibility test according to WHO recommendation	1	6	Annual
	5.1.7 Increased number of laboratory with capability to do Line Probe Assay (LPA)	Output	Number of laboratory with capability to do Line Probe Assay (LPA) for identification and drug susceptibility test	1	6	Annual
	5.1.8 Establish algorithm to facilitate appropriate test performed & ensure result timeliness	Process	% of requests using completely filled standardized TB lab investigation form			Annual
5.2	5.2.1 To increase number of lab/centres enrolled External Quality Assurance Program (EQAP)	Output	Percentage of lab (microscopy, culture, ID & DST centres) having EQA for the test provide.	80%	100%	Annual
	5.2.2 To establish EQA-PT programme	Process	Number of EQA-PT established	1	3	Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Annual
	5.2.3 To increase number of lab/centres with MS ISO 15189 accreditation.	Process	Number of lab/centres with MS ISO 15189 accreditation (Microscopic)	10	35	Annual
	5.2.4 Use of universal coding system (e.g. : LOINC) to assist in the electronic exchange and gathering clinical result	Process	Percentage of lab using the code.	0	25%	Annual
	5.2.5 Develop and expand capacity to conduct molecular technique for cluster detection and outbreak investigation	Process				Annual
Str.6	6.1.1 To develop national guideline and SOPs for management of LTBI	Process	Document guideline available		2017	Annual
	6.1.2 To establish recording and reporting systems for LTBI.	Process	Reporting system		2017	Annual
	6.1.3 To develop database for screening of LTBI	Process	Database available		2018	Annual
	6.1.4 To expand the target population for LTBI diagnosis and treatment including patient on TNF, patient receiving dialysis, patient preparing for organ transplant.	Output	a. Percentage of high risk group with systematic testing of LTBI b. Percentage of positive LTBI screening given IPT treatment	No data	25% 10%	Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	6.1.5 Accessibility to Rifapentine	Process	Rifapentine available for LTBI treatment		2018	Annual
	6.1.6 Training for programmatic LTBI	Output	No of MO/FMS been trained for management of LTBI		100%	Annual
	6.1.7 Research on LTBI	Process	No of research publish			Annual
Str.7	7.1.1 To review and update BCG TBIS	Process	Document update available		2017	Annual
	7.1.2 To increase awareness of BCG vaccination particularly in anti-vaccine group	Process	No of parents/ caretaker refuse BCG vaccination	470 case	<0.1% of total live birth	Annual
Str 8	8.1.1 Counselling on TB medication must be provided by pharmacists for newly diagnosed patients.	Output	Proportion of newly diagnosed TB patients counselled by pharmacists	No data	50% by year 2018 100% by year 2020	Annual
	8.1.2 Development of International Tuberculosis referral form for referral of TB case to other countries.	Process				Annual
	8.2.1 Training doctors and paramedics in ADR reporting	Process	Number of ADR reporting			Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	8.3.1 Review submissions for registration of anti-TB medicines in oral liquid forms under fast-track registration by the National Pharmaceutical Control Bureau.	Process	Number of submission for registration of oral liquid formulations being reviewed under fast-track registration.			Annual
Str.9	9.1.1 Joint committee meeting between health and social sectors at National level	Process	No of meeting per year	Nil	2 times per year	Annual
	9.2.1 To establish Combat Team in enhancing TB Control activities in the community with higher burden of TB.	Process	No of Combat team established	Nil	60 teams	Annual
	9.2.2 Ensuring that affected populations are represented in the venues to discuss national TB response and relevant bodies at national and local levels.	Process				Annual
	9.2.3 Integrating community-based TB activities to other community-based activities to support primary health care services	Process				Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	9.2.4 Engagement in TB program planning, service delivery and monitoring, information and education activities, support to peer patients and families, research and advocacy	Process				Annual
9.3	9.3.1 To strengthen the roles of MAPTB in TB Control Program: a. Reaching out to vulnerable and undeserved groups b. Detecting defaulters c. DOTS Supervisor d. Responsible for logistic arrangements in screening of elderly nursing homes e. Mobilizing communities f. Channelling information to the public hence, creating demand for TB care g. Addressing determinants of TB epidemic	Process	a. No of TB reach-out activities b. No of defaulter tracing by NGO c. Percentage of patient DOT with NGO d. Elderly at nursing homes assisted screening by NGO e. No of activities with community	No data	a. Once per year per state b. Loss to follow-up cases <2% c. 1% d. Once per year e. Once per year	Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
9.4	9.4.1 Joint meeting between public & private health care provider	Process	No of meeting with private healthcare facilities	1 per year	Once per year	Annual
	9.4.2 Scaling up the collaboration with private sectors and strengthening the notification system	Process				Annual
	9.4.3 Enforcing CDC Act that includes mandatory notification of TB cases by all healthcare providers	Process	No of notified TB cases by private sector	1590 cases (6.6%)	100% cases diagnosed at private will be notified	Annual
Str. 10	10.1.1 To create TB support groups	Process	No of TB support groups established	Nil	1 per states	Annual
	10.1.2 Ensure protection and promotion of human rights, including addressing stigma and discrimination and protection of vulnerable groups	Process				Annual
	10.2.1 Refer TB patient with low socioeconomic income to receive financial aid from MAPTB / Social Welfare Department / Pusat Zakat by mapping of risk factors & local social determinants	Output	No of TB patient referred for financial aid when indicated			Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	10.2.2 Revised criteria for eligibility of receiving TAS (Treatment Allowance Scheme) & EGT (Elaun Ganti Tambang	Process	Total amount of TAS given to NGO after criteria been revised	RM440,000.00	Pending	Annual
Str 11	11.1.1 To establish mechanisms for the collaboration between stakeholders at national and international levels towards the development of a national TB research network.	Process				Annual
	11.1.2 To construct a set of unique and country specific TB research priorities based on the current TB epidemic, assessment of the national health system and research capacity	Process				Annual
	11.1.3 To increased capacity and leadership for TB research and plan relevant trainings for sustainable capacity building	Process				Annual

Item	Strategic Indicator	Purpose	Monitoring	Baseline (2015)	Target (2020)	Frequency monitoring
	11.1.4 To warrant adequate funding for training, infrastructure and research operations.	Output	Funding allocated for research		RM150,000.00	Annual
	11.1.5 To initiate and encourage public support and funding of TB research throughout all phases of the plan.	Process				Annual
	11.1.6 To set up methods, milestones and indicators for a continuous monitoring and evaluation of the implementations of the research plan	Process				Annual

5. FINANCING

This section will estimate the total TB program needs for implementation of TB intervention in this document. Financial needs estimates were performed for each of the strategic interventions, presented per Strategy. The total estimated need of budget to be allocated was RM14,583,000.00. Table 10 below summarizes the breakdown of the estimated needs by Strategy and Intervention.

Table 10. Estimates of financial needs for Implementation of TB control activities (2016-2020)

No	STRATEGY	Estimated budget
1.	Enhance case detection of TB	RM10, 581,000.00
2.	To improve control of TB among children	RM400,000.00
3.	Enhance TB/ HIV collaborative activities and management of co morbidities	RM217,000.00
4.	Strengthen Programmatic Management of Drug Resistant Tuberculosis (PMDT)	RM490,000.00
5.	Strengthen laboratory networks to find all TB cases	RM1,870,000.00
6.	To strengthen programmatic management of LTBI activities	RM735,000.00
7.	To enhance BCG vaccination programme	-
8.	To ensure uninterrupted supply of quality-assured TB drugs	RM60,000.00
9.	To enable supportive environment and systems for effective TBcontrol	RM500,000.00
10.	To ensure no households that experience catastrophic cost due to TB	RM60,000.00
11.	To intensify research and innovation as priority issues in TB control programme	RM230,000.00
12.	TOTAL	RM14,583,000.00

STRATEGY 1: Enhance case detection of TB
Strategic intervention 1.1: To improve access to and quality of TB screening and diagnosis for each high-risk population

				2016		2017		2018		2019		2020		Total
		Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
1.1.1	Develop national guideline and SOPs for screening of TB among high-risk population													
1.1.2	Strengthen screening among contacts, immigrants and homeless	x-ray Screening	RM25					1000	RM25,000.00	1000	RM25,000.00	1000	RM25,000.00	RM75,000.00
1.1.3	To establish peer support group for high-risk group screening and conduct a training course	Training peer support group	RM 10 per person			150	RM1,500.00	150	RM1,500.00	150	RM1,500.00	150	RM1,500.00	RM6,000.00
1.1.4	Increase radiologic diagnostic capacity (x-ray facilities) to health clinics.	x-ray facilities	RM500,000.00			2	RM 1,000,000.00	2	RM 1,000,000.00	2	RM 1,000,000.00	2	RM 1,000,000.00	RM4,000,000.00
1.1.5	Strengthen PPM with private facilities for screening and management of TB cases.													

				2016		2017		2018		2019		2020		Total
1.1.6	Ensure availability of static x-ray in selected prison	Static x-ray	RM500,000.00	Cost	RM500,000.00	Cost	RM 1,000,000.00	Cost	RM 1,000,000.00	Cost	RM 1,000,000.00	Cost	RM 1,000,000.00	RM 4,500,000.00
				No of unit	1	No of unit	2	No of unit	2	No of unit	2	No of unit	2	
1.1.7	mobile x-ray services	Moble x-ray	RM 1,000,000.00						RM 1,000,000.00		RM 1,000,000.00			RM 2,000,000.00
									1		1			
Strategic intervention 1.2 To integrate diagnosis and management of LTBI into systematic screening of active TB;														
1.2.1	Develop guideline for integration of LTBI screening in systematic screening of active TB												1	RM20,000.00
1.2.2	Develop collaboration with multiple agencies for management of high-risk group screening													
STRATEGY 2: To improve control of TB among children Strategic intervention 2.1:To ensure effective screening of TB among pediatrics case and contact														
2.1.1	Develop guideline, SOPs for screening and training and management of TB cases among pediatric age group	Training	RM20,000.00											

		Unit	Unit cost	2016		2017		2018		2019		2020		Total
				No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
2.1.2	Strengthen management of contact among pediatric and IPT	Rifapentine							RM100,000.00		RM100,000.00		RM100,000.00	RM300,000.00
2.1.3	Collaboration with maternal and child health programme													
Strategic intervention 2.2: Availability of pediatric formulation														
2.1.1	Ensure availability of pediatric formulation	TB Kidz							RM20,000.00		RM20,000.00		RM20,000.00	RM 60,000.00
Strategic intervention 2.3: Strengthen recording, reporting and data analysis														
2.3.1	Ensure all diagnosed pediatric cases notified and registered													
Strategic intervention2.4: Maintain BCG coverage														
2.4.1	Improve awareness in the community and build the capacity of health-care workers.													

				2016		2017		2018		2019		2020		Total
		Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
2.5.1	Incorporate childrelated operational research questions in the national TB research agenda	Research funding	RM20,000.00					1	RM20,000.00					RM20,000.00
STRATEGY 3. To decrease the burden of TB/HIV in people at risk of/or affected by both diseases. Strategic intervention 3.1 To strengthen TB-HIV collaborative activities														
3.1.1	Conduct systematic screening of people living with HIV to detect active TB and latent TB	x-ray screening	RM35.00			50	Rm1,750.00	50	Rm1,750.00	50	Rm1,750.00	50	Rm1,750.00	RM7000.00
3.1.2	To enhance screening of HIV among TB patients and vice versa													
3.1.3	To strengthen HIV prevention including IPT and CPT	IPT/ Rifapentine						1000	RM20,000.00	1000	RM20,000.00	1000	RM20,000.00	RM60,000.00
3.1.4	To promptly initiate ART for TB/HIV patients													

		Unit	Unit cost	2016		2017		2018		2019		2020		Total
				No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
3.1.5	Strengthen recording and reporting, as well as monitoring and evaluation													
3.1.6	Promote the principles of people-centred care, reduction of stigma and discrimination, community engagement and social protection	Community engagement	RM10,000.00					5	RM50,000.00	5	RM50,000.00	5	RM50,000.00	RM150,000.00
Strategic intervention 3.2 To strengthen health-system capacity for concurrent management of TB and multiple co-morbidities														
3.2.1	To collaborate with the clinical sector and relevant professional bodies to periodically assess important co-morbidities among TB patients													
3.2.2	To establish combine clinic for TB with co-morbidities at hospital level													
3.2.3	To incorporate guidance on co-morbidity management into the national TB guidelines													

			2016		2017		2018		2019		2020		Total
	Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
3.2.4 To enhance education in specialize care settings, such as nursing homes													
STRATEGY 4. Strengthen Programmatic Management of Drug Resistant Tuberculosis (PMDT) Strategic Intervention 4.1 To detect MDR-TB early													
4.1.1 DST for all high-risk group of getting MDR-TB with enhance use of rapid diagnostic tool.	Cartridge	RM75.00 per test	500	Rm37,500.00	1000	RM75,000.00	1000	RM75,000.00	1000	RM75,000.00	1000	RM75,000.00	RM3000,000.00
4.1.2 Enforce mandatory notification of drug-resistant TB and treatment initiation													
Strategic Intervention 4.2 To strengthen management of patient with DR-TB													
4.2.1 Develop national guideline for surveillance and monitoring of DR-TB													
4.2.2 Develop national guidelines for management of DR-TB including diagnosis, laboratory, clinical and public health management													

					2016		2017		2018		2019		2020		Total
		Unit	Unit cost		Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	
4.2.3	Develop SOPs for implementation of CDC Act 1998 for loss to follow-up patient														
4.2.4	To organize training session for management of DR-TB cases to staffs	Training	RM210 per person				Rm20,000.00	45	Rm20,000.00	45	Rm20,000.00	45			RM60,000.00
4.2.5	To print set of guidelines materials	Printing	RM20.00 per unit				RM10,000.00	500	RM10,000.00	500	RM10,000.00	500			RM30,000.00
4.2.6	To ensure availability of second line drugs														
4.2.7	To develop online database for DR-TB registration, surveillance and monitoring of treatment outcomes.	Online data base	RM100,000.00						RM100,000.00	I unit					RM100,000.00
4.2.8	Engagement with NGO, civil society and communities for treatment support (DOT)														

				2016		2017		2018		2019		2020		Total
				Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	
STRATEGY 5. Strengthen laboratory networks to find all TB cases Strategic Intervention 5.1 Increase laboratory capacities for bacteriological diagnosis of TB and DR-TB assessment														
5.1.1	Increase number of laboratories using LED microscopic examination	LED Microscope	RM9000.00	RM198,000.00	22	RM198,000.00	22	RM198,000.00	22	RM198,000.00	22	RM198,000.00	22	RM990,000.00
5.1.2	Increase availability of rapid MTB and MDR-TB detection in all states	Gene xpert	RM100,000.00	RM500,000.00	5									RM500,000.00
5.1.3	Procurement of supplies (cartridges) for *Xpert MTB/Rif* tests	cartridge	RM75.00 per test	RM75,000.00	1000	RM75,000.00	1000	RM75,000.00	1000	RM75,000.00	1000	RM75,000.00	1000	RM375,000.00
5.1.4	Maintenance and servicing of *Xpert MTB/Rif* instruments	Maintenance	RM5000.00 per machine			RM70,000.00	14	RM95,000.00	19	RM95,000.00	19	RM95,000.00	19	RM380,000.00
5.1.5	Supervision/ monitoring of *Xpert MTB/Rif* implementation													

			2016		2017		2018		2019		2020		Total
	Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
5.1.6 Increased number of laboratory with capability to do Line Probe Assay (LPA) for identification and drug susceptibility test													
5.1.7 Increased number of laboratory with capability to do Line Probe Assay (LPA) for identification and drug susceptibility test													
5.1.8 Establish algorithm to facilitate appropriate test performed & ensure result timeliness.													
Strategic intervention 5.2 Strengthening laboratory management towards accreditation													
5.2.1 To increase number of lab/centres enrolled External Quality Assurance Program (EQAP)													
5.2.2 To establish EQA-PT programme													
5.2.3 To increase number of lab/centres with MS ISO 15189 accreditation.													

				2016		2017		2018		2019		2020		Total
		Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
	5.2.4													
	6.1.1													
	6.1.2													
	6.1.3	Database	Online system					RM100,000.00						RM100,000.00
	6.1.4	TST test	RM75.00 per unit					1000	RM75,000.00	1000	RM75,000.00	1000	RM75,000.00	RM225,000.00

		Unit	Unit cost	2016		2017		2018		2019		2020		Total
6.1.5	Accessibility to Rifapentine	Rifapentine												RM300,000.00
												Cost	RM100,000.00	
												No of unit		
										Cost	RM100,000.00			
										No of unit				
								Cost	RM100,000.00					
								No of unit						
6.1.6	Training for programmatic LTBI	Training	RM20,000.00											RM60,000.00
												Cost	RM20,000.00	
												No of unit		
										Cost	RM20,000.00			
										No of unit				
								Cost	RM20,000.00					
								No of unit						
6.1.7	Research on LTBI	Funding	RM50,000.00											RM50,000.00
												Cost		
												No of unit		
										Cost	RM50,000.00			
										No of unit				
								Cost						
								No of unit						
STRATEGY 7. To enhance BCG vaccination programme Strategic Intervention 7.1To ensure all live newborns received BCG vaccination														
7.1.1	To review and update BCG TBIS													
7.1.2	To increase awareness of BCG vaccination particularly in anti-vaccine group													
7.1.3	To develop monitoring for BCG potency													
STRATEGY 8. To ensure uninterrupted supply of quality-assured TB drugs Strategic Intervention 8.1 To provide counselling on TB medication														

			2016		2017		2018		2019		2020		Total
	Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
8.1.1 Counselling on TB medication													
Strategic Intervention 8.2 Strengthen ADRS reporting													
8.2.1 Training doctors and paramedics in ADR reporting	Training	RM20,000.00						RM20,000.00		RM20,000.00		RM20,000.00	RM60,000.00
8.2.2 Development of International Tuberculosis referral form													
Strategic Intervention 8.3 Enhance registration of anti-TB medicines in liquid formulations for Malaysian market													
8.3.1 Review submissions for registration of anti-TB medicines in oral liquid forms under fast-track registration													
STRATEGY 9. To enable supportive environment and systems for effective TB control Strategic Intervention 9.1 To strengthen and coherent health and other agencies among different stakeholders in National TB Control Program													
9.1.1 Joint committee meeting between health and social sectors at National level													
Strategic intervention 9.2: To enhance the community engagement in TB Control Program:													

				2016		2017		2018		2019		2020		Total	
		Unit	Unit cost	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit		
9.2.1	To establish community volunteers programme COMBAT Team in enhancing TB Control activities in the community with higher burden of TB.	Establish 60 community team	RM5,000.00			RM 75,000.00	15	RM 75,000.00	15	RM 75,000.00	15	RM 75,000.00	15	RM300,000.00	
9.2.2	Ensuring that affected populations are represented in the venues to discuss national TB response and relevant bodies at national and local levels.														
9.2.3	Integrating community-based TB activities to other community-based activities to support primary health care services														
9.2.4	Engage in TB program planning, service delivery and monitoring, information and education activities, support to peer patients and families, research and advocacy														
9.2.5	Creating workplace program (health promotion)														

			2016		2017		2018		2019		2020		Total
	Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
Strategic Intervention 9.3 To enhance engagement of civil society organizations in National TB Control Program													
9.3.1 To strengthen the roles of MAPTB in TB Control Program:	Health promotion to NGO	RM10,000.00			5	RM50,000.00	5	RM50,000.00	5	RM50,000.00	5	RM50,000.00	RM200,000.00
Strategic Intervention 9.4 Engaging all public and private care providers													
9.4.1 Joint Meeting between public & private health care provider													
9.4.2 Scaling up the collaboration with private sectors and strengthening the notification system													
9.4.3 Enforcing CDC Act that includes mandatory notification of TB cases by all healthcare provider													
STRATEGY 10. To ensure no households that experience catastrophic cost due to TB Strategic Intervention 10.1 To provide social protection mechanism to support patient and families affected by TB													

				2016		2017		2018		2019		2020		Total
		Unit	Unit cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	
10.1.1	To create and training for TB support groups	Training	RM20,000.00						RM20,000.00		RM20,000.00		RM20,000.00	RM60,000.00
10.1.2	To ensure protection and promotion of human rights, including addressing stigma and discrimination and protection of vulnerable groups													
Strategic Intervention 10.2 Addressing poverty and social determinants by promoting HiAP approach (Health In All Policies)														
10.2.1	Refer TB patient with low socioeconomic income to receive financial aid from MAPTB / Social Welfare Department / Pusat Zakat by mapping of risk factors & local social determinants													
10.2.2	Revised criteria for eligibility of receiving TAS (Treatment Allowance Scheme) & EGT (Elaun Ganti Tambang)													
STRATEGY 11. To intensify research and innovation as priority issues in TB control programme Strategic Intervention 11.1 Intensify research and innovation activities														

				2016		2017		2018		2019		2020		Total
		Unit	Unit cost	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	Cost	No of unit	
11.1.1	Establish mechanisms for the collaboration between stakeholders at national and international levels towards the development of a national TB research network.													
11.1.2	Construct a set of unique and country specific TB research priorities based on the current TB epidemic,													
11.1.3	Increase capacity and leadership for TB research and plan relevant trainings for sustainable capacity building	Training	RM20,000.00			RM20,000.00		RM20,000.00		RM20,000.00		RM20,000.00		RM80,000.00
11.1.4	Warrant adequate funding for training, infrastructure and research operations.	Research funding	RM50,000.00					RM50,000.00		RM50,000.00		RM50,000.00		RM150,000.00
11.1.5	Initiate and encourage public support and funding of TB research throughout all phases of the plan.													

				2016		2017		2018		2019		2020		Total					
			Unit	Unit cost		Cost		Cost		Cost		Cost							
						No of unit		No of unit		No of unit		No of unit							
11.1.6	To set up methods, milestones and indicators for a continuous monitoring and evaluation of the implementations of the research plan																		

APPENDIX 1

THE END TB STRATEGY : AT A GLANCE

VISION: A WORLD FREE OF TB

Zero death, diseases and suffering due to Tuberculosis

GOAL: END THE GLOBAL TB EPIDEMIC

INDICATORS	MILESTONE		TARGETS	
	2020	2025	2030*	2035
Reduction in the number of TB deaths compared with 2015	35%	75%	90%	95%
Reduction in TB Incidence rateocompared with 2015	20% <85 per 100,000 population	50% <55 per 100,000 population	80% <20 per 100,000 population	90% <10 per 100,000 population
TB-affected families facing catastrophic costs due to TB	0	0	0	0

PRINCIPLES

1. Government stewardship and accountability, with monitoring and evaluation
2. Strong coalition with civil society organizations and communities
3. Protection and promotion of human rights, ethics and equity
4. Adaptation of the strategy and targets at states level, with global collaboration

PILLARS AND COMPONENTS

1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

E. Early diagnosis of TB including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
F. Treatment of all people with TB including drug-resistant TB, and patient support
G. Collaborative TB/HIV activities, and management of co-morbidities
H. Preventive treatment of persons at high risk, and vaccination against TB

2. BOLD POLICIES AND SUPPORTIVE SYSTEMS

E. Political commitment with adequate resources for TB care and

prevention

F. Engagement of communities, civil society organizations, and public and private care providers

G. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection

H. Social protection, poverty all eviation and actions on other determinants of TB

3. INTENSIFIED RESEARCH AND INNOVATION

C. Discovery, development and rapid uptake of new tools, interventions and strategies

D. Research to optimize implementation and impact, and promote innovations

APPENDIX 2

OPERATIONAL AND TECHNICAL ASISSTANCE PLAN

Strategic no.	Strategic activities		2016	2017	2018	2019	2020	Responsible/ organization
Objective 1 Enhance case detection of TB.								
1.1	1.1.1	Develop national guideline and SOPs for systematic screening of TB among high -risk population						NTBCP
	1.1.2	Strengthen screening among contacts, immigrants and homeless						NTBCP / State
	1.1.3	To establish peer support group for high -risk group screening and conduct a training course						NTBCP & State
	1.1.4	Increase radiologic diagnostic capacity (x -ray facilities) to health clinics.						PH programme
	1.1.5	Strengthen PPM with private facilities for screening and management of TB cases.						NTBCP / State
	1.1.6	Ensure availability of static x -ray in selected prison						NTBCP& Prison Department
	1.1.7	Mobile x-ray services for screening activities at elderly homes, CCRC and other high risk group category.						PH programme
1.2	1.2.1	Develop guideline for integration of LTBI screening in systematic screening of active TB						NTBCP
	1.2.2	Develop collaboration with multiple agencies for management of high -risk group screening						NTBCP / State

Strategic no.	Strategic activities		2016	2017	2018	2019	2020	Responsible/ organization
Objective 2. To improve control of TB among children.								
2.1	2.1.1	Develop guideline and SOPs for screening and management TB cases among pediatric age group						NTBCP
	2.1.2	Strengthen management of contact among pediatric and IPT						NTBCP / State
	2.1.3	Collaboration with maternal and child health programme						NTBCP/ State
2.2	2.2.1	Ensure availability of pediatric formulation						NTBCP & Pharmac Division
	2.3.1	Ensure all diagnosed pediatric cases notified and registered						NTBCP/ State
	2.4.1	Improve awareness in the community and build the capacity of health -care workers.						NTBCP / State
	2.5.1	Incorporate child -related operational research questions in t he national TB research age da and national TB research strategic plan						NTBCP
Objective 3. To decrease the burden of TB/HIV in people at risk of/or affected by both diseases.								
3.1	3.1.1	Conduct systematic screening of people living with HIV to detect TB and LTBI						HIV/ STI Section
	3.1.2	To enhance screening of HIV among TB patients and vice versa						NTBCP/ HIV/STI Section
	3.1.3	To strengthen HIV prevention including IPT and CPT						HIV/ STI Section

Strategic no.	Strategic activities		2016	2017	2018	2019	2020	Responsible/ organization
	3.1.4	To promptly initiate ART for TB/HIV patients						HIV/ STI Section
	3.1.5	Strengthen recording and reporting, as well as monitoring and evaluation, at the care level while adhering to confidentiality.						NTBCP & HIV/ STI Section
	3.1.6	Promote the principles of people-centred care, reduction of stigma and discrimination, community engagement and social protection						NTBCP & HIV/ STI Section / NGOs
3.2	3.2.1	To collaborate with the clinical sector and relevant professional bodies to periodically assess important co-morbidities among TB patients						NTBCP/ States
	3.2.2	To establish combine clinic for TB with co-morbidities at hospital level						NTBCP/ States
	3.2.3	To incorporate guidance on co-morbidity management into the national TB guidelines, including strategies to reduce modifiable risks						NTBCP
	3.2.4	To enhance education in specialize care settings, such as nursing homes						States /NGOs
Objective 4. Strengthen Programmatic Management of Drug Resistant Tuberculosis (PMDT)								
4.1	4.1.1	DST for all high-risk group of getting MDR-TB with enhance use of rapid diagnostic tool.						NTBCP/ NPHL
	4.1.2	Enforce mandatory notification of drug -resistant TB and treatment initiation						NTBCP/ State

Strategic no.		Strategic activities	2016	2017	2018	2019	2020	Responsible/ organization
Objective 5. Strengthen laboratory networks to find all TB cases								
5.1	5.1.1	Increase number of laboratories using LED microscopic examination						NTBCP /NPHL
	5.1.2	Increase availability of rapid MTB and MDR-TB detection in all states						NTBCP
	5.1.3	Procurement of supplies (cartridges) for Xpert MTB/Rif tests						Medical / Public Health Programme
	5.1.4	Maintenance and servicing of *Xpert MTB/Rif* instruments						Medical Programme
	5.1.5	Supervision/ monitoring of *Xpert MTB/Rif* implementation						NPHL
	5.1.6	Increased number of laboratory with capability to do identification and DST						NPHL
	5.1.7	Increased number of laboratory with capability to do Line Probe Assay (LPA)						NPHL
	5.1.8	Establish algorithm to facilitate appropriate test performed & ensure result timeliness.						NPHL
5.2	5.2.1	To increase number of lab/centres enrolled External Quality Assurance Program (EQAP)						NPHL
	5.2.2	To establish EQA-PT programme						NPHL
	5.2.3	To increase number of lab/ centres with MS ISO 15189 accreditation.						NPHL
	5.2.4	Use of universal coding system						NPHL

Strategic no.	Strategic activities		2016	2017	2018	2019	2020	Responsible/ organization
Objective 6. To strengthen programmatic management of LTBI								
	6.1.1	To develop national guideline and SOPs for management of LTBI						NTBCP
	6.1.2	To establish recording systems for LTBI.						NTBCP
	6.1.3	To develop database for screening of LTBI						NTBCP
	6.1.4	To expand the target population for LTBI diagnosis and treatment including patient on TNF, patient receiving dialysis, patient preparing for organ transplant.						NTBCP / State
	6.1.5	Training for programmatic LTBI						NTBCP/State
	6.1.6	Accessibility to Rifapentine						NTBCP/ Pharmac. Division
	6.1.7	Research on LTBI						NTBCP/ IHR
Objective 7. To enhance BCG vaccination programme								
	7.1.1	To review and update BCG TBIS						NTBCP
	7.1.2	To increase awareness of BCG vaccination particularly in anti -vaccine group						NTBCP/ NGOs

Strategic no.	Strategic activities		2016	2017	2018	2019	2020	Responsible/ organization
Objective 8. To ensure uninterrupted supply of quality-assured TB drugs								
	8.1.1	Counselling on TB medication						Pharmaceutical Division
	8.1.2	Strengthen notification and referral of TB case to other countries						IHR Sector & NTBCP
	8.2.1	Training doctors and paramedics in ADR reporting						Pharmaceutical Division
	8.3.1	Review submissions for registration of anti-TB medicines in oral liquid forms under fast-track registration						Pharmaceutical Division
Objective 9. To enable supportive environment and systems for effective TB control								
9.1	9.1.1	Joint committee meeting between health and social sectors at National level						NTBCP
9.2	9.2.1	To establish COMBAT Team in enhancing TB control activities in the community with higher burden of TB						NTBCP/ State/ NGOs
	9.2.2	Ensuring that affected populations are represented at national and local levels.						NTBCP/ State
	9.2.3	Integrate community-based TB activities to other community-based activities to support primary health care services						NTBCP/ State/ NGOs

Strategic no.	Strategic activities		2016	2017	2018	2019	2020	Responsible/ organization
Objective 10. To ensure no households that experience catastrophic cost due to TB								
	10.1.1	To create TB support groups						NTBCP/ State/ NGOs
	10.1.2	Ensure protection and promotion of human rights, including addressing stigma and discrimination and protection of vulnerable groups						NTBCP/ State/ NGOs
	10.2.1	Refer TB patient with low socioeconomic income to receive financial aid from MAPTB / Social Welfare Department / Pusat Zakat by mapping of risk factors & local social determinants						State/ NGOs
	10.2.2	Revised criteria for eligibility of receiving TAS (Treatment Allowance Scheme) & EGT (Elaun Ganti Tambang)						NTBCP
Objective 11. To intensify research and innovation as priority issues in TB control programme								
	11.1.1	Establish mechanisms for the collaboration between stakeholders at national and international levels towards the development of a national TB research network.						NTBCP/ State /IHR
	11.1.2	Construct a set of unique and country specific TB research priorities based on the current TB epidemic, assessment of the national health system and research capacity, and an understanding of the requisites in achieving the WHO End TB Strategy targets by 2030/2035.						NTBCP/ Stat e/IHR

Strategic no.	Strategic activities		2016	2017	2018	2019	2020	Responsible/ organization
	11.1.3	Increase capacity and leadership for TB research and plan relevant trainings for sustainable capacity building that includes researchers and research careers development.						NTBCP/ State
	11.1.4	Warrant adequate funding for training, infrastructure and research operations.						NTBCP/ State /IHR
	11.1.5	Initiate and encourage public support and funding of TB research throughout all phases of the plan.						NTBCP/ State /IHR
	11.1.6	Set up methods, milestones and indicators for a continuous monitoring and evaluation of the implementations of the research plan.						NTBCP/ State

APPENDIX 3

People –centred care

- In the past, TB control programmes emphasized supportive supervision or directly observed therapy (DOT) by health-care workers or treatment partners by engaging volunteers, families and communities.
- While supportive supervision will remain a foundation of effective TB control, it only partially addresses patient needs. We must go further – towards comprehensive people-centred TB care that is sensitive and responsive to the medical, psychosocial and financial needs of all patients and families affected by TB.
- Many of the challenges faced by NTPs require actions that increase people-centredness and the continuum of TB services.
- The journey towards people-centred health care requires change within four domains:
  (1) individuals, families and communities;
  (2) health-care workers;
  (3) health-care organizations (facilities); and
  (4) health systems.
- The following list illustrates potential actions that can lead to the realization of people-centred health services in the context of TB care.

(1) Informed and empowered individuals, families and communities

- Enable patients, families, community representatives and civil society organizations to be actively engaged in TB programme planning, implementation, service delivery and monitoring, as well as research and advocacy.
- Facilitate the exchange of information among patients, families and peer support groups.
- Promote and empower patient organizations and peer support groups at national, subnational and community levels.
- Disseminate experiences of TB patients, families and communities through media and public events.
- Build a strong coalition of stakeholders that advocate equitable access to people-centred quality TB services, as well as to eliminate stigma and discrimination associated with TB at all levels of society.
- Build a national coalition to drive actions towards addressing the social determinants of TB.
- Empower people and communities to demand quality services to meet their needs and expectations.

(2) Competent and responsive health-care workers

- Review methods and materials for the training of health-care and TB care workers taking into account the core competencies3 that are relevant to people-centred care.
- Adequately prepare all TB care workers to provide holistic care including basic communication and counselling skills, and skills to address non-TB morbidities and psychosocial issues through service coordination.
- Establish patient–provider relationships built on respect, compassion and principles of nondiscrimination and equity.
- *Disseminate the International Standards for Tuberculosis Care* (ISTC), *The Patients' Charter for Tuberculosis Care* and other tools to promote quality TB services appropriate to local contexts.
- Ensure regular, supportive and integrated supervision, including feedback mechanisms, to guide and empower health workers and to instil greater confidence in TB care.
- Ensure workforce sufficiency in terms of quantity and quality, taking into account staff turnover.
- Build a supportive environment for health workers to provide services to TB patients by offering appropriate training and provider incentives, setting up infection control measures and taking steps to eliminate stigma and discrimination against TB care workers.

(3) Efficient and humane health-care organizations (facilities)

- Build capacity to offer psychological, welfare and legal support for TB patients through strong service coordination.
- Support easy referral and continuity of care (one-stop approach).
- Improve access to TB diagnosis and treatment with particular attention to the poorest and most vulnerable population groups e.g. expanding treatment outlets in the poorest rural and urban settings, involving providers who practise close to where patients live.
- Identify and address discrimination, gender and equity issues.
- Ensure facility design with emphasis on access, people and family friendliness, while ensuring patient safety and proper infection control.

(4) Supportive health-care systems

- Ensure TB services are free of charge or heavily subsidized and patient financial burden is minimized.
- Ensure quality and safety of TB care through appropriate, effective mechanisms such as facility standards (e.g. infection control, diagnostic capacity and quality) and professional standards (i.e. ISTC) through

certification, accreditation, registration and renewal of licenses.

- Establish and strengthen mechanisms for feedback, such as routine collection of service evaluation, patient satisfaction surveys and community dialogue.

APPENDIX 4

CASE DEFINITION

Bacteriologically Confirmed Tuberculosis

A bacteriologically confirmed TB case is one from whom a biological specimen is positive by smear microscopy, culture or WRD (such as Xpert MTB/RIF). All such cases should be notified, regardless of whether TB treatment has started.

Clinically Diagnosed Tuberculosis

A clinically diagnosed TB case is one who does not fulfil the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other medical practitioner who has decided to give the patient a full course of TB treatment. This definition includes cases diagnosed on the basis of X-ray abnormalities or suggestive histology and extra pulmonary cases without laboratory confirmation. Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.

Bacteriologically confirmed or clinically diagnosed cases of TB are also classified according to:

- anatomical site of disease;
- history of previous treatment;
- drug resistance;
- HIV status.

Case classification

Classification based on anatomical site of disease

Pulmonary tuberculosis (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. Miliary TB is classified as PTB because there are lesions in the lungs. Tuberculous intra-thoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of extra pulmonary TB. A patient with both pulmonary and extra pulmonary TB should be classified as a case of PTB.

Extra pulmonary tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g.

pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.for the programmatic management of drug-resistant tuberculosis, due for publication by WHO in 2013.

Classification based on history of previous TB treatment (patient registration group)

Classifications based on history of previous TB treatment are slightly different from those previously published. They focus only on history of previous treatment and are independent of bacteriological confirmation or site of disease. Also note that the registration groups for DR-TB are slightly different and are described in the *Companion handbook to the 2011 WHO guidelines for the programmatic management of drug-resistant tuberculosis,* due for publication by WHO in 2013.

New patients have never been treated for TB or have taken anti-TB drugs for less than 1 month.

Previously treated patients have received 1 month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment as follows:

Relapse patients have previously been treated for TB, *were declared cured or treatment completed* at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).

Treatment after failure patients are those who have previously been treated for TB and whose *treatment failed* at the end of their most recent course of treatment.

Treatment after loss to follow-up patients have previously been treated for TB and were declared lost to *follow-up* at the end of their most recent course of treatment. (These were previously known as *treatment after default patients*.)

Other previously treated patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

Patients with unknown previous TB treatment history do not fit into any of the categories listed above.

New and relapse cases of TB are incident TB cases.

Classification based on drug resistance

Cases are classified in categories based on drug susceptibility testing (DST) of clinical isolates confirmed to be *M. tuberculosis*:

- Monoresistance: resistance to one first-line anti-TB drug only.
- Polydrug resistance: resistance to more than one first-line anti-TB drug (other than both isoniazid and rifampicin).
- Multidrug resistance: resistance to at least both isoniazid and rifampicin.
- Extensive drug resistance: resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.
- Rifampicin resistance: resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance.

APPENDIX 5

TREATMENT OUTCOME DEFINITIONS

The new treatment outcome definitions make a clear distinction between two types of patients:

- patients treated for drug-susceptible TB;
- patients treated for drug-resistant TB using second-line treatment

The two groups are mutually exclusive. Any patient found to have drug-resistant TB and placed on second-line treatment is removed from the drug-susceptible TB outcome cohort.

Treatment outcomes for TB patients (excluding patients treated for RR-TB or MDR-TB)

All bacteriologically confirmed and clinically diagnosed TB cases should be assigned an outcome from this list **except** those with RR-TB or MDR-TB, who are placed on a second-line drug regimen.

Outcome	Definition
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.
Treatment completed	A TB patient who completed treatment without evidence of failure BUT with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable.
Treatment failed	A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.
Died	A TB patient who dies for any reason before starting or during the course of treatment.
Lost to follow-up	A TB patient who did not start treatment or whose treatment was interrupted for two consecutive months or more.

Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases “transferred out” to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.
Treatment success	The sum of cured and treatment completed.

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