Republic of the Maldives

National Strategic Plan for TB Control
2015-2020
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1 BACKGROUND INFORMATION ON THE MALDIVES

1.1 GEOGRAPHY
The republic of Maldives is an archipelago in the Indian Ocean located 600 Km south west of India. Maldives consists of 1 190 coral islands which form a chain 820 km long and 120 km wide, with an area of 90,000 sq km. The total land area is 300 sq km which only 10% are suitable for agriculture. India and Sri Lanka are the countries nearest neighbors, lying some 600 km and 750 km north and north-east respectively.

The islands form 26 natural atolls, which for purposes of administration are grouped into 20 units each of which is referred to as an administrative atoll. Most of the islands are small, few with a land area in excess of one sq km. They are low lying with an average elevation of 1.6 m above main sea level.

1.2 DEMOGRAPHY
The country’s population of 309,575 (2008 projection), lives in over 196 inhabited islands. There are, in addition, 84 tourist resort islands and 14 islands serve an industrial purpose. Ninety percent of inhabited islands have populations less than 1 000 and only a few islands have more than 4 000 people. Around 27% of the population live in Male, the capital island. The population growth rate is 1.9%, with nearly 50% of the population under the age of 15 years. The under-five mortality rate is 4/1000 as is the crude death rate. The average life expectancy is 71 years and the male: female ratio is 1.03:1.00.

1.3 ECONOMY
The per capita GDP is US $ 2195 (Source Statistical year book of Maldives 2005) with an annual growth rate of 2.1%. The small size of economy, which largely depends on tourism and fisheries, makes the Maldives vulnerable to external shocks, such as Global economy and tourism and from natural disasters like the economic recession following the tsunami of December 2004.

The country lacks land-based natural and mineral resources. As a result, virtually all economic productions depend on imports, creating heavy dependence on foreign exchange earning. Intensive agricultural production is limited because of the poor quality of the soil.

Source: Ministry of economic Development, 2010

1.4 COMMUNICATIONS AND TRANSPORT
Developments in the last 5 years and the installation of earth satellite phone links make it possible to have direct dial phone and fax links with most islands and atolls. In Male’ cell phones and pager devices are in use. E-mail services are developing. There are regular domestic flights to the regional centres. However, inter-island and inter-atoll transports are locally built boats or ‘dhonis’ running regularly on daily or weekly schedules.

1.5 EDUCATION
The overall literacy rate is high at 98.9%. Public expenditure on education (as a percentage of GDP) is 5.1%. The combined primary and secondary school enrolment is between 77-79%.
For university education, students must travel abroad either by their own means or on government scholarships. Human skills development is a top priority in the country.

1.6 **GOVERNMENT**

The Government is headed by the President of the Republic, who is elected every 5 years. The Citizens’ Majlis is the Government’s legislative assembly.

2 **ORGANIZATION OF HEALTH SERVICES**

The Ministry of Health is responsible for the provision of health and health related services in the Republic. Currently, health services are organized in a four-tier system comprising the central, regional, atoll and island levels. The ministry formulates overall health policy, health planning, monitoring and evaluation.

2.1 **STRUCTURE OF THE MINISTRY OF HEALTH**

There are six departments under the MOH, namely the Centre for Community Health & Disease Control, Maldives food and drug Authority, National Drug Agency, National Social Protection Agency, Thalassaemia and other Haemoglobinopathy Center and the National Blood Services.

*Figure 1: Organizational Chart of the Ministry of Health*
2.2 Structure and Levels of Health Services Delivery

Health services in Maldives are currently delivered by a four tier referral system comprising of island, atoll, regional and central level services. The Indira Gandhi memorial Hospital in Male’ serves as the tertiary–level hospital at the central level of the referral system. At the regional level the, the health care is delivered by the regional hospitals in six strategic locations across the country. Each of the six regional hospital serves as the referral centers for 2 to 4 atolls, providing services in a number of specialty areas of medical care. Atoll hospitals provide basic medical care. The lowest level of health service delivery in the system is of the island – level primary health care centers, health posts and the family health care units. Currently the country has 3 island hospitals (including one private hospital), 6 regional hospitals, 13 atoll hospitals and 176 health centers (including 2 Male’).

Figure 2: Organizational Chart of health service delivery for TB control

- Over all program coordination including planning, coordination, awareness, Training and IEC
- DOTS implementation, registration, treatment follow up
- Reporting
- Monitoring and evaluation

Sputum collection, DOTS providing and consultation

- Quality control of sputum microscopy, Proficiency testing and diagnosis of sputum microscopy

- Diagnosis by smear microscopy, Treatment under DOTS and follow up, Motivation and counseling

- Diagnosis by smear microscopy, Treatment under DOTS and follow up, Motivation and counseling

- Treatment under DOTS and follow up, Motivation and counseling
2.3 **STRUCTURE OF HEALTH PROTECTION AGENCY**

The Health Protection Agency (HPA) under the MoHG is responsible for delivering public health related programmes across the country through atoll and island level Public Health Units based in Atoll Hospital and Island Health Centers. Health services under MoHG delivers curative health services across the country through regional hospitals, Atoll hospitals and island health centers. The Ministry of health and gender maintains close links with the Atoll and regional Hospitals in providing health services to atoll and island populations. Additional intersect oral collaboration at the island level is maintained through the established Island Health Task Forces, Island Development Committees and Island Women’s Development Committees. Health Protection Agency is operationally strong and strives for an integrated approach whenever possible.

Currently, HPA is responsible for providing Maternal and child health services, Communicable disease control and other emerging infectious disease control and environmental health. In addition there are specialized national programs such as the skin clinic (for the leprosy control program), The TB Control (for the tuberculosis control program) and the malaria (handling malaria and other vector borne disease) and surveillance.

2.4 **STAFFING OF HEALTH CARE SERVICES**

At island level, there are Foolhumaas (traditional birth attendants) and Family Health Workers (FHWs) each covering a population of between 500 and 1000. At atoll health centers there is one doctor and two Community Health Workers (CHWs), in addition to the family health workers. Tasks and responsibilities are clearly described for each level and job descriptions are in use at all levels in the health service. The Faculty of Health Sciences at the Maldives National University in Male’ is responsible for training these FHWs and CHWs and for all in-service training. Due to a lack of trained manpower throughout the health services, a number of sanctioned posts are vacant and a large number of expatriate doctors, nurses and medical technologists are recruited on a contractual basis at all levels. Government health services are highly subsidized. The private health sector is gradually expanding through a network of hospitals at Male’ and on the larger islands; several small private clinics operate throughout the country.

2.5 **DECENTRALIZATION OF HEALTH SECTOR**

The government of Maldives had embarked on a program of decentralization with local governance in 2010. However many other changes were also taking place during this period like new democratic changes and party politics. Also state owned health facilities were moved to 8 Health Services Corporations. As it all was brought in a very short time there were problems of implementation and movement of staff to local governing Authorities as well as staff employment changing from Civil Service to Health Services Corporations. This affected public health services delivery across the country including TB program implementation. Reform was brought about again in 2012 to address these issues so clinical services and public health service delivery were reinstalled under the Ministry of Health.
3 BACKGROUND INFORMATION ON TB IN THE MALDIVES

3.1 THE NATIONAL TUBERCULOSIS CONTROL PROGRAM (NTP)

With a population of about 340,000, Maldives has an estimated prevalence and incidence rate of all forms of TB respectively of 65 and 41 per 100,000 population respectively, in 2012. DOTS, the internationally recommended strategy for TB control were introduced in 1994 and nationwide coverage was achieved in 1996. The notification rate of all forms TB and new smear – positive cases were respectively 33 and 15, showing an increase compared to the steady decrease over the previous 5 years (Mainly smear negative and extra pulmonary cases). Treatment success rate among new smear – positive cases is 81% for the cohort of patients registered in 2011.

NTP maintains a national register of TB patients. The register is updated quarterly by input of reports form RMC, Regional and Atoll Health Facilities. Passive case finding is followed with a clear policy that all TB suspects reporting to the various health facilities will have three sputum samples examined and cases confirmed where smears are negative, by radiology and/or other tests as indicated clinically. A facility for sputum Smear examination is available at the Central and Regional level and at some of the Atoll Hospital and Health centers. In addition, Family Health Workers (FHWs) at island level visit houses in their areas every 2 weeks to enquire about chest symptoms and identify TB suspects. Intensification of case finding through regular targeted screening of populations potentially at higher risk of developing TB such as those in accommodation setups for laborers, factories and reprimand facilities is being considered.

The stated policy of contact tracing is actively pursued; lists of contacts at home and at work are entered on the treatment cards and advice given to undergo sputum examinations and/or x-ray, Mantoux examinations. This is largely accepted by the contacts. Children under 5 years are provided treatment for latent infection with TB after screening for active disease, provided if this is acceptable to the family.

Both new sputum smear positive and smear negative patients as well as the new extra-pulmonary TB patients are treated with 2 months of Rifampicin, Isoniazid, Ethambutol, Pyrazinamide and 4 months of Rifampicin and Isoniazid (2RHEZ/4RH) which is also classified as Cat I & III and patients who had received one month or more of prior anti-tuberculosis treatment are treated with 2 months of Sreptomycin, Isoniazid, Ethabutol, Pyrazinamide/ 1 month Rifampicin, Isoniazid, Ethambutol, Pyrazinamde (2SRHEZ/1RHEZ/5HRE) which is also classified as Cat II. Number of patients started on Cat II regimen is very low (3-5 per year). Entire treatment is given under direct observation. Patient kits using fixed drug formulations are being used, currently through a direct purchase mechanism from the Global Drug Facility. Treatment initiation is done centrally at the Indira Gandhi Memorial Hospital and then patients are transferred to the respective health centre for continuing treatment.
However once a patient is told that he has TB some of them go to India or Sri Lanka and show to private doctors and are often started on ATT and given only 3 months treatment and often do not follow WHO recommended protocols.

In 2001, the Government prohibited the sale of anti-TB drugs throughout the country, thereby ensuring that TB drugs are available through NTP for all TB patients. All patients have to pay a sum of MVR 100/- to 200/- for OPD registration. Sputum examination is free of charge provided they are referred through the respiratory clinic at IGMH. Tuberculosis treatment is free of charge for all residents. Fixed-dose combinations (FDCs) were introduced in 2005 through a grant from the Global Drug Facility (GDF). Support from GDF continues through direct procurement of first line drugs. The NTP activities have being well integrated in the general health care system. Diagnosis of sputum-positive cases is possible through a network of microscopy centers in the country, while treatment is available through all health facilities. The National TB control program (NTP) at Health Protection Agency (HPA) continues to act as a central body for registration, planning, monitoring and evaluation of the TB control activities. Continuous support has been received from WHO and from curative services both in public sector and private sector in the country, in TB case finding, treatment, record keeping, follow-up TB patients and contact tracing activities.

The main thrust of the NTP is infrastructure and human resource development for intensified case finding, early case detection, strengthening the microscopy network so as to improve access to diagnostic services and social mobilization for increased community involvement and utilization of available services.

At present priority has been given to improve and strengthen the TB control preventive, promotive activities, and to cure as many patients as possible and to give better services to the community. In this regard efforts have been made to improve the quality of services in terms of case holding and case management. Work has been initiated to establish diagnostic facilities at Regional and Atoll levels. As a result of the intensified activities, the program has maintained the prevalence of TB in the same trend for past 7 years. Also the program has made efforts to develop close coordination and collaboration with other health establishments especially that of private health care institutions, in identifying and accurately reporting of identified cases.

3.2 TB BURDEN AND PERFORMANCE OF THE NTP

Maldives is one of only 5 countries in the world to have achieved the global targets of 70% case detection and 85% cure. This information is referred from WHO referral letter no. T/26 dated on 27th April 1998. WHO estimates the incidence, prevalence and mortality rate of TB in 2010 to be 36 (best estimate, with a range of 31–42), 13 (2.4–34) and 3.4 (2.1–5.4) cases per 100,000 population.1 The WHO case notification rate for new and relapse in 2010 was 95 which correspond to 30 per 100,000 population. Between 2007 and 2011, the number of notified TB cases (new cases and relapses) is steadily decreasing from reported 121 to 86. Since 2006, worsening in treatment outcomes is observed: treatment success rate
which was above 85% until 2006, is 80-81 percent for the last 5 years. Death rate, 9 percent was highest ever reported in 2010 and default 13 percent in 2009.

Figure 3: Case detection and treatment success rates 1990-2011

Case Detection and Success rates for All types of TB - 1990 - 2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Case Detection rate</th>
<th>Treatment Success</th>
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<tbody>
<tr>
<td>1990</td>
<td>66-98</td>
<td>80</td>
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<td>2011</td>
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Table: Estimates and Notification rates for 2012, Maldives – Source: Tuberculosis Control in the South –East Asia Region - 2014

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<tr>
<th>Indicator</th>
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<tr>
<td>Population</td>
<td>338,442</td>
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<tr>
<td>Incidence of all forms of TB</td>
<td>140 (110-170)</td>
</tr>
<tr>
<td>Incident rate of all forms of TB (100,000 population per year)</td>
<td>41 (33-49)</td>
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<tr>
<td>Prevalence of all forms of TB</td>
<td>220 (100-380)</td>
</tr>
<tr>
<td>Prevalence rate of all forms of TB (100,000 population per year)</td>
<td>65 (30-113)</td>
</tr>
<tr>
<td>TB death rate (per 100,000 per year, excluding deaths among TB/HIV co-infected)</td>
<td>2 (1.8-2.2)</td>
</tr>
<tr>
<td>Notification rate of all forms of TB (per 100,000 population for the year 2010)</td>
<td>33</td>
</tr>
<tr>
<td>Notification rate of new smear-positive cases (per 100,000 population for the year 2010)</td>
<td>15</td>
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<tr>
<td>Case – Detection rate (all forms of TB)</td>
<td>80 (66-98)</td>
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<td>Treatment success rate (%) of new smear-positive cases for 2010 cohort</td>
<td>81</td>
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The TB prevalence rate in Maldives has showed a steep decline from 1990 to 1995, with reduction of prevalence to more than 50% of the 1990 level. From 1995 to 2010 further decline to a low prevalence level is observed. Maldives is likely to maintain prevalence rate at the low level and achieved prevalence target by 2015.
3.3 Indicators of current performance problems of the NTP

Since 2006, a worsening of treatment outcomes has been observed: the treatment success rate, which was above 85% until 2006, has been 80-81 percent for the last 5 years. The death rate of 9 percent in 2010 was the highest ever reported, and default rate was 13 percent in 2009.

It must also be noted that the reported treatment outcome figures are actually only based on an evaluation of about 50% of all enrolled cases, since problems with the recording and reporting system prevent the evaluation of treatment outcomes for all cases. Thus, overall treatment outcomes may even be worse than the currently reported figures.

The percentage of new sputum smear positive cases among new pulmonary cases reported varies has been consistently exceeding 70% during recent years, indicating problems with the detection of smear-negative cases, and potential under-detection of cases of this type.

Figure 7: Percentage of new sputum smear positive cases among new pulmonary cases 2007 – 2011

Paediatric TB notification is around 6% of all cases notified as against the expected 11% by WHO estimates. It can be assumed that many paediatric TB cases are under diagnosed or/and not reported to NTP.

3.4 High-risk Groups

Nearly one third of the Maldivian population are migrants from the neighboring countries and there is almost no mechanism of screening this population. For legal migrants there is a general health screening at the airport. However, this screening is often not strictly enforced and does not specifically target symptoms of TB. In addition, a large proportion of migrant workers are illegal immigrants, and there are currently no efforts undertaken to screen for TB in this population group.

The Department of Penitentiary and Rehabilitation Services (DPRS) functions under Ministry of Home Affairs (MoHA) and has formal responsibility of running Prisons. A system for TB screening is not established at penitentiary institutions in the Maldives, although prisoners undergo general health screening upon entry to a prison.
3.5 MDR TB
Very few MDR-TB cases have been identified. So far 7 cases of MDR-TB have been registered since 1995 to 2012. However there is a risk that this trend may change as the country employs a large expatriate workforce from neighboring countries with higher MDR prevalence.

3.6 TB/HIV Co Infection
Maldives remain among low prevalent country for HIV in the region. However, risk factors that might contribute to spread HIV is high and are increasing at an alarming rate. So far only 15 HIV positives has detected among locals out of whom 11 died, 4 are alive and are on ART treatment. HIV positives among TB patient also remain low. Prevalence of HIV among TB patients was 0.01% at the end of 2011. Screening of all HIV positives for TB infection and TB patient for HIV infection started as a collaborative effort of both the program since 2003. Two TB / HIV cases have been recorded so far.

3.7 TB Drug Management
Anti TB drugs are available only through NTP and public health services and cannot be purchased from private pharmacies or by any other means. Most of the private pharmacies are aware about the free availability of anti TB drugs from NTP and advise people to contact NTP if approached. Similarly all private health care providers refer TB suspects to the NTP for further management. Private Hospitals are also implementing DOTS program under NTP directions and refers TB cases to the NTP for treatment.

NTP introduced fixed dose combination of anti TB drugs in the program starting from 2005, with support from Global Drug Facility (GDF).

Once patient is registered at the central level a full course of treatment is supplied to the respective health facility. Two patient treatments worth supplies are kept at the Atoll or Regional level as buffer stock. All Regions report stock levels on monthly basis using a standardized form which contains information such as stock levels at the beginning / end of month, amount used during the reporting period, date supplies received and expiry dates of the existing stock. However this system has inherent risk for stock outs as the estimation is made for short term.

3.8 ACSM Activities
Traditional Information Education and Communication (IEC) activities to address the long-standing stigma attached to TB and awareness programs are on-going to encourage early self-referrals and to reduce the proportion of nationals seeking care abroad. Sessions on TB have been introduced into school health programs. However, there is no well formulated plan for a comprehensive nation-wide communications campaign and IEC activities are dependent on the availability of resources and staff time.
3.9 **COLLABORATION WITH OTHER PROGRAMS**

The Ministry of Health coordinates with the ministries of Home Affairs and Education in implementing various components of NTP. Collaboration with the HIV/AIDS program has been initiated. Health providers in the private sector and NGOs involved in conducting health programs and refer all suspected or diagnosed cases to the NTP.

3.10 **RELIABILITY OF OFFICIALLY REPORTED FIGURES OF TB BURDEN.**

According to the figures for TB prevalence and incidence officially reported by WHO, TB epidemiology in Maldives seems to be shifting from a high endemic to a low endemic phase. However, it needs to be recognized that all of these figures are based on model calculations. An empirical basis for disease burden figures does not exist, since a TB prevalence survey has never been performed in the Maldives. For calculating prevalence and incidence figures, the model employed by WHO has assumed that the case detection ratio and has remained stable at 80% since 1995. Accordingly, figures for incidence and prevalence were directly related to the number of cases notified by the NTP. As a result, the reported decline of incidence and prevalence could be due to two factors:

- **a “real” decline of disease burden due to excellent performance of the NTP**
- **an “artificial” decline of disease burden, with lower case detection- and associated disease burden figures resulting rather from poor performance of the NTP than actual changes in the underlying epidemiology**

As noted above, several program outcome figures indicate a relatively poor performance of the NTP, which most likely has been going on for several years. In addition, in conversations with NTP staff it is repeatedly pointed out that staff generally perceive that “many of TB cases are missed by the system”, especially among the high-risk groups described above. Based on these observations, it appears imperative that a reassessment of the TB disease burden in the Maldives is urgently carried out through expert evaluation. Also, for planning purposes it appears appropriate to assume that the current case detection level is significantly lower than the officially reported 80%.

3.11 **PROJECTIONS OF CASE NUMBERS USED FOR PLANNING PURPOSES**

To effectively plan for potential increases in case notifications due to improved NTP performance under the NSP, a current case detection level of 50% was assumed. It is recognized that this figure is substantially lower than the officially reported figure of 80%, and therefore needs to be a urgently validated through expert assessment. In addition, the proportions of bacteriologically confirmed-, clinically diagnosed-, extrapulmonary- and retreatment cases were adjusted to account for potential improvements in diagnostic services. Specifically, we assumed a proportion of bacteriologically confirmed cases of 60%, 20% for clinically diagnosed cases, 10% for extrapulmonary cases, and 10% for retreatment cases. The resulting case numbers used for planning purposes are summarized in the figure below.
Figure 8: Projected case numbers for planning purposes
4 GAP ANALYSIS

To identify key interventions that will most likely contribute to an improved performance of the NTP, a gap analysis was performed describing current gaps in current NTP performance for TB programmatic areas. The programmatic areas that were considered for the gap analysis are listed in the table below.

Figure 9: Programmatic areas considered for gap analysis

- Case finding
- Diagnosis
- Treatment
- Recording/reporting
- MDR-TB
- TB-HIV
- Infection control
- ACSM
- Programme management
  - Staffing
  - Guidelines / standards
  - Training
  - Supervision
  - Financing

4.1 GAPS IN CASE FINDING ACTIVITIES

4.1.1 There are no systematic efforts for TB screening in high-risk populations

About one third of the population of the Maldives consists of migrant workers. A large proportion of these are illegal immigrants from countries with high burden of TB and MDR TB, such as India or Bangladesh. Currently, there are no systematic efforts to screen for TB in these populations, although they largely reside in specific living quarters, which are well-known to officials. For legal immigrants, a health screening procedure upon entry exists, but this is not systematically enforced and does not specifically target TB symptoms. Due to the generally crowded living conditions in the Maldives, especially in the capital Male, undetected TB in migrant workers presents at very high risk for the endemic spread of TB and MDR TB throughout the country.

Another high risk group for the spread of TB are prisoner populations. Currently, no systematic efforts for TB screening among prisoners exist.
4.1.2 A strong stigma associated with TB may prevent diagnosis or lead to primary default after diagnosis

The stigma associated with TB in the Maldives remains extremely high. In general, members of the population remain very scared about receiving a diagnosis of TB, and especially about having other members of the community know the diagnosis. As a result, many cases present in advanced stages of the disease, or seek care from providers outside the public health services after a diagnosis of TB is made. Since TB drugs are currently unavailable through private providers in the Maldives, many patients travel to neighboring countries to obtain TB treatment. Such treatments may consist of inadequate drug combinations, given for insufficient time periods, thereby increasing the risk for the development of MDR TB.

4.1.3 A high proportion of smear-positive cases indicates deficiencies in the diagnosis of smear-negative cases

The proportion of smear positive cases among all pulmonary cases has exceeded 70% during recent years. This very high proportion may result from presentation of cases in advanced stages of the disease. However, it may also indicate that the diagnosis of smear negative disease is insufficient. Causes for this may be insufficient training of health care providers on the diagnosis of smear-negative disease, as well as insufficient access to diagnostic facilities such as chest x-rays.

4.1.4 A low proportion of children among detected cases indicates deficiencies in the diagnosis of childhood TB

The proportion of children among all detected cases has remained at around 6% during recent years, significantly below the generally expected proportion of about 11%. The low proportion may result from inadequate training of health care providers in the diagnosis of childhood TB, as well as lack of access to specific diagnostic methodologies, such as tuberculin testing or molecular tests for TB.

4.1.5 Efforts towards community screening by community health workers have remained limited

Due to its geographical situation, the Maldives principally presents an ideal setting for effective population screening. Such screening efforts have been initiated by the NTP on some islands, however, there has been no systematic effort to expand population screening to cover all islands, due to a lack of resources.

4.2 GAPS IN DIAGNOSTIC PROCEDURES

4.2.1 Smear examination is not available at many peripheral facilities

All regional and atoll hospitals are equipped with laboratory facilities for smear diagnosis. However, in practice most smear examinations are performed at IGMH, as peripheral laboratories are nonfunctional. One reason is the lack of laboratory supplies due to inadequate procurement and the lack of an effective distribution system. Another reason is the lack of routine training activities for laboratory technicians.

4.2.2 There is no laboratory quality assurance system

Routine quality assurance is currently not performed, as the NTP has not yet developed a system in line with current international standards.
4.2.3 Currently used procedures for smear examinations are outdated
The NTP still uses three smears for diagnosis, while WHO has recommended two smears for several years. Especially given that access to laboratory services is difficult due to the unavailability of laboratories at peripheral levels, these outdated guidelines may further contribute to insufficient diagnosis.

4.2.4 Procedures for the use of chest x-rays for diagnosis are unclear, and access to chest x-ray remains limited in peripheral settings
While the current NTP manual specifies diagnostic procedures for the diagnosis of smear negative cases including the use of chest x-ray, training of health care staff at peripheral settings in these procedures has remained insufficient. In addition, access to x-ray at the regional and atoll hospitals remains difficult due to unclear organization of services, with most patients presenting for diagnosis at IGMH.

4.2.5 Current guidelines for the diagnosis of children are outdated and training has been insufficient
The methodologies described for the diagnosis of TB in children in the current NTP guidelines is outdated and recent WHO recommendations have not yet been incorporated. In addition, specific training of health workers in methodologies for the diagnosis of childhood TB has remained insufficient.

4.3 GAPS RELATED TO TB TREATMENT ACTIVITIES

4.3.1 The unclear organization of treatment services results in a high default rate
The structure of treatment services and the responsibilities of each level of the health services under the current structure remain unclear. Most patients are initially diagnosed and registered at IGMH, but the referral system to peripheral centers after diagnosis is not clearly defined. Often, patients are supplied with one month drug supplies without organizing adequate follow up. As a result, many patients are lost for follow-up after the initial treatment initiation, and ultimately default.

4.3.2 The DOT system at IGMH is inconvenient for working patients
All patients residing in Male receive DOT at IGMH. While the new facility itself is exemplary due to excellent infection control measures, the restricted working hours at the facility make it inconvenient for working patients to regularly attend. No alternative options for DOT have as yet been developed.

4.3.3 There are no specific treatment facilities for patients with a high default risk
A relatively large proportion of TB patients in the Maldives are patients with a high default risk, such as drugs users. Currently, there are no specific treatment facilities that would allow for the long-term hospitalization and support of such patients until they successfully finish treatment.

4.3.4 There have been drug stock-outs at peripheral facilities due to deficiencies in the procurement and distribution system
During recent years, drug stock outs have been repeatedly observed at peripheral facilities. One reason for this is insufficient procurement of drugs at the central level. Another is an adequate distribution system which does not allow for the regular replenishment of drug stocks at peripheral health facilities.
4.3.5 NTP drugs are perceived as of low quality by many patients, leading them to seek treatment abroad

Due to insufficient public information about NTP activities, there is a frequent impression among patients that the drugs provided free of charge by the NTP are of lower quality. As a result, many patients prefer to buy drugs abroad, e.g. in India.

4.4 GAPS IN THE RECORDING AND REPORTING SYSTEM

4.4.1 The structure of the recording and reporting system is unclear, resulting in a large proportion of cases whose treatment results are not evaluated

Current responsibilities for recording and reporting for the facilities at various levels of the healthcare system are unclear. All patients are initially registered at IGMH, but treatment follow-up is also supposed to be evaluated at peripheral levels. As communication between peripheral facilities and IGMH is not clearly organized, a large proportion of treatment results (more than 50% in recent years) is not evaluated.

4.5 THE NTP USES OUTDATED CASE- AND OUTCOME DEFINITIONS

The currently used definitions for case categorization and treatment outcomes have not been updated following WHO’s 2013 revision.

4.5.1 The electronic registration at IGMH is insufficient and does not allow for an automatic analysis of treatment outcomes

The IGMH has established an electronic register based on an Excel worksheet. However, worksheet functions are rather simple and do for instance not allow for the automatic evaluation of treatment outcomes.

4.5.2 There is no electronic recording and reporting system at peripheral facilities

Recording and reporting at peripheral facilities is currently solely paper-based, although computers and internet connections exist at all facilities.

4.6 GAPS IN THE MANAGEMENT OF MDR TB

4.6.1 A comprehensive policy for the management of MDR TB does not exist

The NTP has developed a PMDT manual in 2010. However, this manual has not yet been officially approved and no training activities based on the manual have been performed. The existing manual does not include recent updates in WHO’s policy related to MDR TB.

4.6.2 There is no regular access to diagnosis of MDR TB

The only option for the diagnosis of MDR TB currently is to send the sample for culture and sensitivity testing abroad. As a result, no routine mechanism for MDR TB detection has been established, and many MDR TB suspects are not evaluated.

4.6.3 The currently used MDR TB treatment regimen is outdated

The regimen currently used by the NTP is not in line with WHO’s most recent recommendations.

4.6.4 There is no specific MDR TB treatment facility

A specific MDR TB treatment facility for the initial hospitalization of cases during the intensive phase with appropriate infection control measures does not yet exist.
4.7 GAPS IN THE MANAGEMENT OF TB HIV

4.7.1 Collaboration between TB and HIV programs has been established, but policies and coverage need to be expanded

The HIV prevalence in the Maldives is currently low, however, there is a potential for rapid increase due to various risks factors, e.g. the potential for the spread of the infection from migrant workers. Collaborative activities between the TB and the HIV programs have been established, however, the policies do not yet cover all WHO recommendations, e.g., there is no standard policy for the provision of IPT. Also, expansion of TB HIV activities has remained limited and does not yet cover the whole country.

4.8 GAPS RELATED TO TB INFECTION CONTROL

4.8.1 No comprehensive infection control policy exists

The NTP has not yet developed a comprehensive infection control policy following WHO’s recommendations. As a result, awareness for infection control at peripheral facilities is currently very low and the potential for the further spread of the disease in healthcare facilities exists. The new DOT facility at IGMH sets a good example of adequate infection control measures, however, these remain to be expanded to the periphery.

4.9 GAPS RELATED TO ACSM ACTIVITIES

4.9.1 A comprehensive ACSM strategy does not exist, and the stigma about TB remains extremely high

The NTP has not yet developed a comprehensive ACSM strategy, and public information about TB and NTP activities is generally insufficient. As a result, the stigma related to TB remains extremely high, leading to lower case detection, and high default rates after a diagnosis of TB has been made. In addition, the public opinion of the NTP appears to be generally low, and NTP services are perceived to be of low quality.

4.10 GAPS RELATED TO PROGRAM MANAGEMENT

4.10.1 The NTP is given a low priority within the MOH system

TB services are currently considered to be of low priority within the MOH system. This low priority is indicated by the dismantling of the previously well-functioning NTP structure in the MOH’s decentralization process. Also, there have been repeated problems with the procurement of essential NTP requirements, such as drugs and laboratory supplies, due to insufficient budgeting for these items with in the MOH. Finally, the central level of the NTP appears to be extremely understaffed to be able to cope with the managerial demands to address the rapidly declining TB situation in the country.

4.10.2 Staff training is insufficient

During recent years, there have been insufficient training activities for staff at all levels. All central level staff have received no specific training for TB. Similarly, staff at peripheral levels have either had no training, or training has been performed a long time ago without any refresher. The NTP does also not have any standardized training material.
4.10.3 There is no functioning supervision system
A functioning supervision system does not exist. There are no NTP supervision guidelines, no standardized supervision material, and staff at all levels of the Healthcare Services do not receive any regular supervision. As a result, serious quality deficiencies in NTP services may remain unnoticed.

4.10.4 Current NTP guidelines are outdated
The currently used NTP guidelines have not been revised since 2007 and do not reflect recent WHO policy changes for TB diagnosis, treatment, new diagnostics, MDR TB, TB HIV, TB in children, and the recording and reporting system.

4.10.5 The NTP is severely underfunded
The sole source for NTP funding is currently the MOH, which currently does not even ensure sufficient funding for essential NTP requirements such as drugs and laboratory supplies. As a result, there is no funding for essential program activities such as training, supervision or ACSM, and the quality of NTP services has severely declined during recent years.
5 NTP GOALS AND OBJECTIVES

5.1 USE OF SMART CRITERIA
In defining goals, objectives, strategic interventions and activities for the NSP, and asked for was made to use smart criteria for each item specifically, these criteria should ensure that each item is:

- specific
- measurable
- attainable
- relevant
- time-bound

5.2 DEFINITION OF NTP GOALS AND OBJECTIVES FOR 2014 - 2019
The goal of the NTP is in line with WHO’s global TB strategy. The objectives for the NSP 2014 - 2019 have been developed to specifically address the deficiencies identified in the gap analysis shown above.

Goal of the NTP

- Decrease the prevalence of TB by 25% by 2019, based on a re-calculation of existing prevalence to be conducted in 2014

  Indicator:

  Due to uncertainties around current estimates of prevalence described above, the NSP proposes to conduct a recalculation of TB burden figures for the Maldives through an expert assessment. Since the conduct of prevalence survey does not appear feasible, the use of an in direct method, such as that described in WHO’s global TB report 2013, is anticipated. The assessment will be initially conducted in 2014, and repeated in 2019 to determine impact.

Objective 1:

- Ensure availability of quality-assured TB services, in line with current international standards and provided by qualified personnel, at 100% of all MOH facilities by 2016

  Indicator:

  To assess whether a health facility provides quality assured to TB services, the NSP proposes the use of a composite indicator, in which the achievement of the following criteria will be assessed for each health care facility:

  - availability of revised manuals and training materials
  - staff positions filled according to requirements specified in NSP
Maldives NSP 2014-2019 Core Plan

- all staff trained
- case finding/outcome reports produced timely and accurate
- scheduled supervisions received (based on availability of supervision reports)
- for laboratories: scheduled QA activities performed (based on availability of reports)

Only facilities meeting all criteria will be counted as “quality assured facilities”, and the proportion of such facilities among all facilities will be determined in 2014 and 2019.

Objective 2:
- Detect 80% of incident cases (based on a recalculation of incident cases to be performed in 2014) by 2016, and 90% by 2018; successfully treat 85% of detected cases by 2016 and 90% by 2018
- Indicators:
  - case detection rate
  - treatment success rate

Objective 3:
- Provide diagnostic services for MDR-TB for 50% of MDR-TB-suspects by 2016, and 100% of suspects by 2018; successfully treat 70% of detected MDR-TB cases by 2018
- Indicators:
  - proportion of MDR-TB suspects (i.e., suspects with previous treatment and HIV-positive suspects) tested for MDR-TB (using Gene Xpert)
  - treatment success rate from MDR-TB register

Objective 4:
- Provide effective ACSM activities to ensure that 50% of the population has adequate knowledge about TB and a positive attitude towards NTP services by 2016, and 100% of the population by 2018
- indicators:
  - Indicators of population knowledge about TB and attitude towards NTP, based on results of KAP surveys to be performed in 2016 and 2018
6 STRATEGIC INTERVENTIONS FOR SPECIFIC OBJECTIVES

Strategic interventions have been developed to address the specific NTP deficiencies outlined in the gap analysis described above. The listing of strategic interventions below provides a brief explanation of the rationale for including each intervention in the NSP.

6.1 STRATEGIC INTERVENTIONS FOR OBJECTIVE 1

Ensure availability of quality-assured TB services, in line with current international standards and provided by qualified personnel, at 100% of all MOH facilities by 2016

6.1.1 Increase MOH commitment to TB control by 2015
The current lack of MOH commitment has led to severe deficiency in the NTP, such as stock outs for essential drugs or laboratory reagents. Obtaining a high priority for TB control in the MOH is the key requirement for improving NTP performance.

6.1.2 Ensure adequate financing of all NSP activities by 2014
The NTP is currently severely underfunded, with the MOH the sole provider of funds. As a result, essential NTP activities such as training and supervision cannot be performed due to lack of resources. Obtaining adequate funding from available external resources such as the GF ATM is a requirement for successful NSP implementation.

6.1.3 Ensure adequate staff capacity at central level by 2014 (M&E officer, Training/supervision officer, ACSM officer)
The current staff capacity at the NTP central level appears insufficient, especially with respect to the comprehensive managerial world requirements to implement all activities foreseen in this NSP.

6.1.4 Produce revised national manual (including MDR-TB, TB/HIV, childhood TB) and training material by 2014
The currently used NTP manual has not been updated since 2007. A new version containing recent WHO policy changes needs to be produced urgently.

6.1.5 Train 100% of staff at all levels in new NTP strategy by 2016
The complete lack of training activities during recent years has led to a deterioration of the quality of NTP services. Comprehensive training activities to cover all staff by 2016 are required.

6.1.6 Ensure availability of comprehensive TB/HIV care package for all patients by 2016
While TB HIV collaborative activities have been initiated, the current policy is not yet covering all aspects of WHO’s recommended strategy. The development of a comprehensive package is required.

6.1.7 Ensure regular supervision for 100% of staff at all levels by 2016
Regular supervision of staff at all levels is key requirement to ensure quality NTP services.
6.1.8 Implement infection control strategy to cover 100% of all facilities by 2016
The current lack of TB infection control provides the threats of the spread of infection in healthcare facilities. The countrywide implementation of WHO’s comprehensive infection control policy is urgently required.

6.2 STRATEGIC INTERVENTIONS FOR OBJECTIVE 2

Detect 80% of incident cases (based on a recalculation of incident cases to be performed in 2014) by 2016, and 90% by 2018; successfully treat 85% of detected cases by 2016 and 90% by 2018

6.2.1 Revise current estimates of prevalence and incidence based on methodology described in 2013 Global TB Report
Due to uncertainties concerning current WHO estimates of prevalence and incidence, a reassessment of the TB disease burden needs to be performed.

6.2.2 Revise national TB screening requirements for legal immigrants by 2014, ensure 100% screening by 2015
While as screening policy for legal immigrants exists, this policy is currently not adequately enforced, and does not specifically target TB symptoms.

6.2.3 Develop screening and treatment strategy to reach 80% of illegal immigrants by 2016
A large proportion of migrant workers in the Maldives are illegal immigrants. These workers come from countries with a high TB burden and need to be adequately screened to prevent the spread of the disease in the Maldives.

6.2.4 Develop screening strategy for prison inmates to reach 100% of inmates by 2016
An effective screening policy for prison inmates currently does not exist.

6.2.5 Expand CHW population screening activities to reach 100% of the population by 2016
Population screening activities by CHW’s has been initiated in some islands, but a countrywide expansion of this activity is required to improve case detection.

6.2.6 Ensure contact tracing and provision of IPT if necessary for contacts of 50% of cases by 2016, 100% by 2018
The tracing of contacts of bacteriologically confirmed cases is an effective method to improve case detection.

6.2.7 Engage 100% of TB care providers in National StopTB partnership by 2015
A national stop TB partnership does not yet exist in the Maldives. Effective collaboration with other partners is likely to improve the quality of NTP services.

6.2.8 Revise procurement and distribution system to ensure uninterrupted supply of laboratory reagents by 2015
Insufficiencies of the current distribution system has led to frequent stock outs of laboratory reagents in many look oratories
6.2.9 Establish reliable transport system for sputum samples from all peripheral facilities by 2015
Adequate access to diagnostic services at peripheral health centers will require the availability of an efficient sample transport system.

6.2.10 Ensure (re-) training of all laboratory staff by 2015
Laboratory staff need to be adequately trained to ensure quality diagnostic services.

6.2.11 Establish regular lab QA system by 2015
Regular lab QA is a key requirement to ensure quality diagnosis.

6.2.12 Revise procurement and distribution system to ensure uninterrupted drug supply to all facilities by 2015
Insufficiencies of the current distribution system has led to frequent drug stockouts many peripheral facilities.

6.2.13 Ensure availability of convenient DOT options for all patients by 2015
Flexible DOT options are the requirements to ensure adherence to treatment by specific patient groups, e.g. workers.

6.2.14 Ensure immediate follow-up for all defaulters by 2015
The current follow-up system is inefficient and has led to a high level of patient default.

6.2.15 Provide special treatment facility for high-risk patients by 2016
A specific facility is required for the long-term hospitalization and supports of high risk patients such as drug users.

6.2.16 Revise R&R system in line with current WHO standards by 2014
The current system is outdated and needs to be adapted to WHO’s new definitions introduced in 2013.

6.2.17 Design and implement electronic recording/reporting system for all facilities by 2016
The routine use of an electronic system is currently recommended by WHO to improve reporting timeliness and accuracy.

6.3 STRATEGIC INTERVENTIONS FOR OBJECTIVE 3

Provide diagnostic services for MDR-TB for 50% of MDR-TB-suspects by 2016, and 100% of suspects by 2018; successfully treat 70% of detected MDR-TB cases by 2018

6.3.1 Revise national TB manual to include updated PMDT strategy by 2014
Rather than producing as separate p.m. DT manual, the NTP should in food of p.m. DT section in the revised NTP manual.

6.3.2 Establish Gene Xpert facility at IGMH by 2015
It is anticipated that one gene expert facility bill will be sufficient to provide MDR TB diagnostic services for the whole country.
6.3.3 Revive culture facility at IGMH by 2015 (needed for follow-up investigations)
Despite the use of gene expert for diagnosis, routine culture services will still be required for follow-up examinations.

6.3.4 Establish MDR-TB treatment facility at central level by 2015
A separate MDR TB treatment facility will be required to provide support during the intensive phase of treatment

6.3.5 Procure MDR-TB drugs based on revised regimen by 2015
The treatment regimen for MDR TB cases should be revised in accordance with current WHO recommendations.

6.3.6 Establish reliable transport mechanism for Gene Xpert samples from peripheral facilities (50% by 2016, 100% by 2018)
An efficient sample transport mechanism is required to provide access to diagnostic services from peripheral facilities.

6.3.7 Train staff at peripheral facilities in diagnosis and treatment of MDR-TB (50% by 2016, 100% by 2018)
A comprehensive training program is required to ensure adequate diagnosis and treatment of MDR TB cases

6.4 STRATEGIC INTERVENTIONS FOR OBJECTIVE 4

Provide effective ACSM activities to ensure that 50% of the population has adequate knowledge about TB and a positive attitude towards NTP services by 2016, and 100% of the population by 2018

6.4.1 Assess ACSM requirements in KAP survey 2014
A KAP survey will be required to identify specific ACSM needs..

6.4.2 Develop comprehensive ACSM strategy by 2015
The strategy can be developed in collaboration with the Department of Sociology of the local university.

6.4.3 Produce ACSM material according to strategy by 2015
ACS and material will be developed based on the information needs of patients, providers, and the general population.

6.4.4 Assess performance of ACSM strategy in KAP surveys 2016 and 2018
The survey will include standardized questionnaires to enable the assessment of changes in knowledge and attitudes between 2014 and 2019.
A detailed budget for the NSP has been developed using WHO’s standard TB planning and budgeting tool. Summary tables for the cost calculations are provided below. The detailed calculations are available in the corresponding Excel file, which form an integral part of the NSP.
Figure 10: Summary of total costs and funding sources

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<th>3%</th>
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<td>$ 1.162.378</td>
<td>$ 1.164.855</td>
<td>$ 1.281.224</td>
<td>$ 1.315.024</td>
<td>$ 1.360.298</td>
<td>$ 1.019.100</td>
<td>$ 1.026.281</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of funding sources and funding gap, including inflation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government, intermediate / provincial</td>
</tr>
<tr>
<td>Government, local / district</td>
</tr>
<tr>
<td>Loans</td>
</tr>
<tr>
<td>Global Fund</td>
</tr>
<tr>
<td>Other Grants</td>
</tr>
<tr>
<td>Funding Gap</td>
</tr>
</tbody>
</table>

Total: $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281 | $ 1.026.281
### Figure 11: Summary of costs by activity

<table>
<thead>
<tr>
<th>Activity Type</th>
<th>Total Costs</th>
<th>Breakdown</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>TB prevention</td>
<td>$276.002</td>
<td>$276.002</td>
<td>TB prevention</td>
</tr>
<tr>
<td>TB diagnosis</td>
<td>$11.979</td>
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<td>TB diagnosis</td>
</tr>
<tr>
<td>TB treatment</td>
<td>$32.461</td>
<td>$32.461</td>
<td>TB treatment</td>
</tr>
<tr>
<td>TB control</td>
<td>$48.438</td>
<td>$48.438</td>
<td>Tuberculosis control</td>
</tr>
<tr>
<td>Other Items</td>
<td>$18.834</td>
<td>$18.834</td>
<td>Other Items</td>
</tr>
<tr>
<td>Total</td>
<td>$51.603</td>
<td>$51.603</td>
<td>Total</td>
</tr>
</tbody>
</table>

### Breakdown of Costs

- **Maldives NSP 2014**: All costs are in Maldivian rupees (MVR).
- **First-line drugs procurement and management**: Includes procurement and management costs for first-line drugs.
- **Supervision from peripheral level**: Includes costs associated with supervision from the peripheral level.
- **Training on PAL**: Includes costs associated with training on patient alert lists.
- **Involving all care providers**: Includes costs for involving all care providers.
- **Activities and costs at sub-national level**: Includes activities and costs at the sub-national level.
- **Total for TB control**: Includes all costs associated with TB control.
Figure 12: Summary of funding sources
## Figure 13: Summary of costs by objective

### Ensure availability of quality-assured TB services, in line with current international standards and provided by qualified personnel, at 100% of all MOH facilities by 2016

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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1.1 First-line drugs procurement and management</td>
<td>$2,550</td>
<td>$4,697</td>
<td>$5,773</td>
<td>$6,849</td>
<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>1.2 M&amp;E</td>
<td>$2,550</td>
<td>$4,697</td>
<td>$5,773</td>
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<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>1.3 Programme management and supervision</td>
<td>$2,550</td>
<td>$4,697</td>
<td>$5,773</td>
<td>$6,849</td>
<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>1.4 HRD: Staff</td>
<td>$2,550</td>
<td>$4,697</td>
<td>$5,773</td>
<td>$6,849</td>
<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>1.5 HRD: Training</td>
<td>$2,550</td>
<td>$4,697</td>
<td>$5,773</td>
<td>$6,849</td>
<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>1.6 Infection control</td>
<td>$2,550</td>
<td>$4,697</td>
<td>$5,773</td>
<td>$6,849</td>
<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
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</tbody>
</table>

### Detect 80% of incident cases (based on a recalculation of incident cases to be performed in 2014) by 2016, and 90% by 2018; successfully treat 85% of detected cases by 2016 and 80% by 2018

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<tbody>
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<td>2.1 Improving diagnosis</td>
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<td>$8,022</td>
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<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>2.2 Patient support</td>
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<td>$4,697</td>
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<td>$8,022</td>
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<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>2.3 Collaborative TB/HIV activities</td>
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<td>$5,773</td>
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<tr>
<td>2.4 High risk groups</td>
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<tr>
<td>2.5 Childhood TB</td>
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<td>$8,904</td>
<td>$9,371</td>
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### Provide diagnostic services for MDR-TB for 50% of MDR-TB-suspects by 2016, and 100% of suspects by 2018; successfully treat 70% of detected MDR-TB cases by 2018

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</thead>
<tbody>
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<td>$8,904</td>
<td>$9,371</td>
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### Provide effective ACSM activities to ensure that 50% of the population has adequate knowledge about TB and a positive attitude towards NTP services by 2016, and 100% of the population by 2018

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<tbody>
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<td>4.1 Partnering initiatives</td>
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<td>$4,697</td>
<td>$5,773</td>
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<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
</tr>
<tr>
<td>4.2 Community involvement</td>
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<td>$6,849</td>
<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
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Provide effective ACSM activities to ensure that 50% of the population has adequate knowledge about TB and a positive attitude towards NTP services by 2016, and 100% of the population by 2018

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<tr>
<td>4.1 Partnering initiatives</td>
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<td>$8,438</td>
<td>$8,904</td>
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<td>$8,022</td>
<td>$8,438</td>
<td>$8,904</td>
<td>$9,371</td>
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ANNEXES

The following Annexes form an integral part of the NSP:

- Annex 1 shows a detailed description of all planned activities for each strategic intervention
- Annex 2 shows the operational plan with timelines and, funding sources and responsibilities for activities and sub-activities
- Annex 3 contains the M&E plan with indicators for each objective and intervention
- Annex 4 shows the TA plan with requirements for technical assistance for individual activities