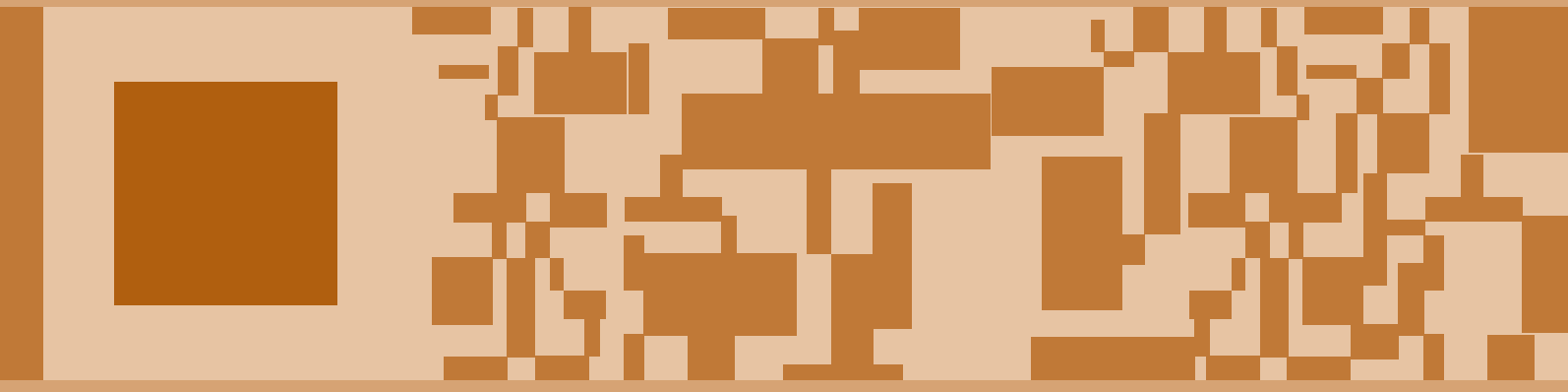
WHO-EM/TUB/257/E

Strategic plan for the prevention and control of multidrug-resistant and extensively drug-resistant tuberculosis in the Eastern Mediterranean Region (2010–2015)



World Health Organization
Regional Office for the Eastern Mediterranean

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Preface

There have been some good achievements over the past decade in tuberculosis control in the countries of the WHO Eastern Mediterranean Region. These countries have addressed the challenge of tuberculosis through implementation of the directly observed treatment, short-course (DOTS) strategy, with the case detection rate reaching 60% for new smear-positive cases, and an 86% treatment success rate.

However, multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) pose a threat to global and regional public health security and to efforts to reduce the global and regional burden of tuberculosis. The Beijing Call for Action on Tuberculosis Control and Patient Care and the World Health Assembly resolution WHA62.15 (2009) on prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis (*1*) recognize the challenges posed by multidrug and extensively drug-resistant tuberculosis (M/XDR-TB) and call for urgent action to address the situation.

The exact burden of multidrug resistance is not known in the Region since drug resistance surveys have been conducted in only eight countries of the Region. According to the fourth WHO global report on drug resistance, *Anti-tuberculosis drug resistance in the world* (*2*), the prevalence of multidrug resistance is 2.0% among new tuberculosis cases, and 35.3% among re-treated tuberculosis cases in the Region. There are an estimated 25 475 incident cases with MDR-TB in the Region annually.

In response to the challenge of M/XDR-TB, the Regional Committee for the Eastern Mediterranean, in its 56th meeting in October 2009, endorsed a special resolution for scaling-up the response to MDR challenge in the countries of the Region (*3*). As a consequence, this five-year regional strategic plan for prevention and control of M/XDR-TB was developed. The goal of the plan is to ensure that all countries achieve universal access to diagnosis and treatment for M/XDR-TB cases by 2015.

1. Introduction

1.1 Regional tuberculosis burden

Worldwide, the Eastern Mediterranean Region contributes 6% of estimated and notified tuberculosis cases (all types), and 6% of estimated, and 5% of notified, smear-positive pulmonary tuberculosis cases.

In 2008, 392 633 tuberculosis cases (new and relapse) were notified from the countries of the Region. Of these, 166 558 cases were new smear-positive. A total of 653 164 tuberculosis cases were estimated in the Region during the same year, with 283 481 new smear-positive cases. The case detection rate for 2008 was 58% for all cases and 57% for new smear-positive cases. Afghanistan, Pakistan and Sudan contribute 58% of the total estimated cases in the Region.

The countries in the Region have been able to make a remarkable improvement in addressing the challenge of tuberculosis control through implementation of DOTS during the past decade in public health facilities, including primary health care centres. The treatment success rate for 2008 was 87%.

National tuberculosis programmes are expanding tuberculosis care to cover new elements in the global Stop TB strategy, such as the private–public mix approach, active case finding among high-risk groups and care for MDR-TB patients.

However, 43% of tuberculosis cases are still not receiving proper care and this is contributing to the development of MDR-TB, and thousands of MDR-TB cases are being left untreated.

1.2 Burden of M/XDR-TB

Globally, more than half a million new MDR-TB cases (defined as resistance to at least isoniazid and rifampicin) are estimated to emerge annually as a result of inadequate treatment and subsequent transmission. XDR-TB is a subset of MDR-TB caused

by strains resistant to second-line medicines (it is defined as resistance to any fluoroquinolone and at least one of three injectable second-line medicines: kanamycin, amikacin and capreomycin), with significantly worse outcomes. It is now reported by more than 50 countries. Yet only some 3% of cases of MDR-TB are being treated according to WHO standards.

In recognition of the threat to global public health security posed by multidrug resistance, ministers of health of countries with a high burden of MDR-TB met in April 2009 and issued the Beijing Call for Action on Tuberculosis Control and Patient Care. This concern was echoed by Member States at the 62nd World Health Assembly in May 2009, who issued resolution WHA62.15 Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis.

Multidrug resistance is a reflection of the mismanagement of tuberculosis cases. This mismanagement includes wrong diagnosis and delay of diagnosis, wrong or interrupted treatment, and the misuse of tuberculosis medicines, both first-line and second-line, such as through poor adherence to standardized treatment by private care providers, unregulated sale of anti-tuberculosis medicines and utilization of tuberculosis medicines of unknown quality.

The exact burden of multidrug resistance in the Region is not known, due to the limited number of national drug resistance surveys and surveillance. In the fourth WHO global report on drug resistance, *Anti-tuberculosis drug resistance in the world* (2), data are reported from eight countries of the Region (Egypt, Islamic Republic of Iran, Jordan, Lebanon, Morocco, Oman, Qatar and Yemen). The population-weighted mean of MDR-TB based on all countries that have reported in the Region is 2.0% among new cases, 35.3% among previously treated cases and 5.4% among combined cases.

Lebanon, Morocco and Oman reported low proportions of multidrug resistance among new cases, from 0.5% in Morocco to 1.3% in Oman. Yemen reported a higher proportion of resistance, 2.9%, and Jordan reported 5.4% multidrug resistance among new cases. However, Jordan reports high success rates and a low number of cases requiring re-treatment, suggesting that further evaluation should be done to confirm the high proportion of MDR-TB found among new cases.

Jordan, Lebanon and Oman reported very high proportions of resistance among re-treated cases, however sample sizes were small and the confidence intervals were wide. Trends for multidrug resistance are available only from Oman and Qatar, but they are difficult to interpret because of the small numbers of cases.

The extent of resistance to second-line tuberculosis medicines is also not known. The only available data has been reported from the Islamic Republic of Iran, Pakistan, Qatar, Oman and United Arab Emirates, mainly among extrapulmonary tuberculosis cases. Yemen tested the MDR-TB isolates collected during the national drug resistance survey, to check for second-line drug resistance, and none was found. Morocco plans to test MDR-TB isolates collected from its nationwide survey for second-line drug resistance.

In summary, the estimated burden of multidrug resistance is moderate in the Region compared to the global burden (25 000 cases out of 500 000) (*4*). However, the real burden of multidrug resistance is unknown. Moreover, the long treatment period and the high cost of treatment, which is far more than the cost of non-resistant tuberculosis treatment, are also a burden to health systems. It is therefore important to address this challenge and to sustain the achievements. Failure to react by scaling-up the regional and country response to multidrug resistance may lead to an epidemic of M/XDR.

The Stop TB Strategy covers multidrug resistance management and the Global Plan to Stop TB 2006–2015 addresses the activities and resources needed for the implementation of proper management of MDR-TB. However, the response to the challenge of multidrug resistance is still weak in the Region.

2. Current response to MDR-TB

2.1 Measuring the burden using drug resistance surveys

As already noted, the burden of multidrug resistance in the Region is not known, due to the limited number of countries that have conducted nationwide anti-tuberculosis drug resistance surveys.

The primary factor limiting the expansion of survey coverage in the Region is the high number of countries currently facing conflict situations. Another limiting factor is the poor laboratory infrastructure in many countries. Currently, there is only one supranational reference laboratory in the Region, which is the national reference laboratory of Egypt. The national laboratory in Oman has been nominated as a supranational reference laboratory and is undergoing evaluation. There is a plan to identify another two laboratories in the Region during the coming year.

Currently, three countries are planning for a second nationwide drug resistance survey in 2010, namely Egypt, Syrian Arab Republic and Yemen. Saudi Arabia and Sudan have started drug resistance surveys. Libyan Arab Jamahiriya, Pakistan and Somalia are planning to conduct their first nationwide drug resistance surveys during 2010. All 14 countries that are eligible for grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria have included one or two drug resistance surveys in their five-year work plans.

2.2 Case detection through the quality-assured tuberculosis laboratory network

In all countries of the Region, sputum smear microscopy is the basis for diagnosis of pulmonary tuberculosis and is provided free of charge in all diagnostic centres. Although all countries have established a nationwide tuberculosis laboratory network,

some issues related to the laboratory network are detailed below.

As of August 2008, 18 countries report laboratory network coverage for direct smear microscopy within the recommended level of one laboratory per 50 000 to 250 000 population. The four countries that have lower coverage (i.e. one laboratory for more than 250 000) are Egypt, Iraq, occupied Palestinian territory (oPt) and Qatar.

A direct smear microscopy network with full (100%) external quality assurance coverage is in place in only six countries (Islamic Republic of Iran, Kuwait, Morocco, Oman, Qatar and Yemen). Coverage of external quality assurance is less than 50% in 10 countries (Bahrain, Jordan, Lebanon, Pakistan, oPt, Saudi Arabia, Somalia, Syrian Arab Republic, Tunisia and United Arab Emirates).

All countries have culture laboratories except Djibouti and Somalia. Six countries (Afghanistan, Iraq, Pakistan, Sudan, Syrian Arab Republic and Yemen) have inadequate coverage of culture services, with only one culture laboratory for a population of more than five million. The remaining countries have the WHO-recommended culture laboratory coverage of one laboratory per population of five million or less.

All countries have drug susceptibility testing laboratories except Afghanistan, Djibouti, occupied Palestinian territory and Somalia. Proficiency testing for drug sensitivity test laboratories is conducted systematically with 100% coverage in six countries: Egypt, Islamic Republic of Iran, Morocco, Oman, Qatar and Yemen. Proficiency testing for drug sensitivity test laboratories is partially implemented in Bahrain, Kuwait, Pakistan and Syrian Arab Republic. The remaining eight countries have no proficiency testing for drug susceptibility testing laboratories.

All countries have national reference laboratories except Saudi Arabia, Somalia and United Arab Emirates. The national reference laboratories in Egypt, Islamic Republic of Iran, Jordan, Lebanon, Morocco, Oman, Qatar, Sudan, Syrian Arab Republic and Tunisia are linked to a supranational reference laboratory. Djibouti, Iraq, Libyan Arab Jamahiriya and Saudi Arabia are in the process of linking their national reference laboratory to a supranational reference laboratory. The remaining countries will be linked to a supranational reference laboratory gradually during 2010–2011. In the majority of countries with culture and drug susceptibility

testing laboratories, culture and drug susceptibility testing for first-line medicines is recommended for the cases that fail the normal treatment regimen, in addition to re-treated and chronic cases.

2.3 Proper case management of MDR-TB cases

Proper case management includes designing the treatment regimen based on evidence, strict observation of treatment through hospitalization and/or ambulatory treatment with treatment supporters, monitoring adverse effects of treatment, follow-up of treatment and having trained human resources. It also includes prevention of transmission of MDR-TB by providing adequate infection control measures.

The Stop TB Strategy, in its second component, calls for the control and prevention of MDR-TB through increased access to quality-assured second-line anti-tuberculosis medicines and prevention of development of resistance to anti-tuberculosis medicines.

The Green Light Committee (GLC) initiative, together with the Working Group on Multidrug-Resistant Tuberculosis under the Stop TB Partnership, promotes implementation of this strategy in accordance with the Global Plan to Stop TB (2006–2015) and the 2007–2008 XDR and MDR Tuberculosis Global Response Plan *(5)*.

Established in 2000, the GLC initiative is the mechanism that enables access to affordable, high-quality, second-line anti-tuberculosis medicines for the treatment of MDR-TB. The GLC is supporting countries in the direct procurement of second-line anti-tuberculosis medicines through qualified suppliers. Support is obtained through application to the GLC describing the national policy to manage multidrug resistance, including treatment regimens and medicines needed.

Egypt, Jordan, Lebanon, Morocco, Pakistan, Syrian Arab Republic and Tunisia have GLC-approved projects (for country data and activities see Annex 3). Djibouti, Sudan, Iraq and Somalia received technical support to develop GLC proposals. They have submitted their proposals and are currently waiting to receive a response from the GLC.

Human resource capacity for MDR-TB care in the Region was strengthened through sending experts to attend an international training course in Latvia and regional courses in various countries. During 2007–2008, two regional training courses on MDR-TB care were supported by the GLC. Study tours were also carried out in some regional centres, such as those in Egypt and Jordan.

All countries in the Region with GLC-approved projects have complied with the five components of the MDR-TB strategy as shown in Box 1.

Box 1. Five components of the DOTS strategy as applied to MDR-TB (*6*)

1. Sustained political commitment
   - Addressing the factors leading to the emergence of MDR-TB
   - Long-term investment of staff and resources
   - Coordination of efforts between communities, local governments and international agencies
   - A well-functioning DOTS programme
2. Appropriate case-finding strategy including quality-assured culture and drug susceptibility testing
   - Rational triage of patients into drug susceptibility testing and the drug-resistant tuberculosis control programme
   - Relationship with supranational tuberculosis reference laboratory
3. Appropriate treatment strategies that use second-line medicines under proper case management conditions
   - Rational treatment design (evidence-based)
   - Direct observation of treatment
   - Monitoring and management of adverse effects
   - Properly trained human resources
4. Uninterrupted supply of quality-assured second-line anti-tuberculosis medicines
5. Recording and reporting system designed for drug-resistant tuberculosis control programmes that enables performance monitoring and evaluation of treatment outcomes.

National programmes have the following different options for treatment strategies.

Standardized treatment: Countries with GLC-approved projects, namely Egypt, Jordan, Lebanon, Morocco, Pakistan, Syrian Arab Republic and Tunisia, have adopted standardized treatment regimens designed on the basis of representative drug resistance survey data of specific treatment categories. Importantly, the previous history of using second-line medicines should be taken into consideration when deciding which medicines should be a part of a standardized regimen. However, suspected MDR-TB cases should always be confirmed through drug sensitivity testing whenever possible. All patients in a defined group or category receive the same treatment regimen. The treatment period is at least two years, with a six-month initial phase where patients are hospitalized, and the remaining period (or continuation phase) of treatment is provided at home under strict direct supervision.

Individualized treatment: Each regimen is designed on the basis of previous history of anti-tuberculosis treatment and individual drug susceptibility test results. Examples of individualized treatment strategies can be seen in Egypt and Pakistan GLC-approved projects and in other countries, but on a very limited scale.

Direct observation of treatment is one of the key factors in preventing multidrug resistance through ensuring full adherence to treatment. It also provides an opportunity for better tuberculosis care if it is designed properly. Within the context of multidrug resistance management, it is of extreme importance to ensure that the national tuberculosis control programme (NTP) is able to provide sustainable direct observation of treatment through both hospitalization and ambulatory phases. This is to ensure patient adherence, which is the key condition for cure.

All countries have reported that direct observation of treatment is in place at least during the intensive phase for tuberculosis-positive cases in all centres except for Jordan, Saudi Arabia, Sudan and Yemen, where direct observation of treatment is not uniformly conducted for all patients. Health workers are the treatment supporters mainly within primary health care in Djibouti, Egypt and Morocco. Health workers and family members are the treatment supporters in eight countries: Iraq, Lebanon, occupied Palestinian territory, Saudi Arabia, Somalia,

Sudan, Tunisia and United Arab Emirates. Bahrain has reported that family members are the treatment supporters there. In the remaining countries, health workers are the main treatment supporters, in addition to community members and family members. Financial and nutritional support is given to patients in some countries such as Egypt, Iraq, Syrian Arab Republic, Pakistan, Yemen and member countries of the Gulf Cooperation Council (GCC).

The total estimated smear-positive MDR cases per year in the Region is 23 049. As of May 2010, the GLC had approved 2887 patients, and 476 patients had been treated up to 2009 (for more information see Annex 3).

2.4 Monitoring and evaluation system for MDR-TB

The recording and reporting system for MDR-TB includes specifically designed forms. Some programmes, such as those in Egypt and Jordan, use electronic forms in addition to the hard copies. Supervision of the management of MDR-TB is routinely carried out through the GLC and WHO review missions.

Despite the improvement in data management, the recording and reporting system for multidrug resistance is not fully in line with WHO guidelines and there is a need to support countries in standardizing their recording and reporting systems for multidrug resistance.

3. Strategic issues and challenges in the Eastern Mediterranean Region

3.1 Limited care capacity

- The infrastructure of the laboratory network is weak, and this includes: weak surveillance systems to monitor laboratory performance and external quality assurance, lack of proper equipment, lack of standard operating procedures, weak infrastructure in some culture laboratories and weak biosafety.

- Infection control hazards are common in some countries, indicating the need to give more emphasis to infection control measures in laboratory networks and treatment facilities.

3.2 Uncontrolled treatment

- Treatment of tuberculosis cases (both for drug-sensitive and drug-resistant tuberculosis) is still uncontrolled in the private sector, although with the expansion of the public–private mix approach, more non-public facilities have become engaged in the diagnosis and monitoring of the treatment for tuberculosis cases. The quality of laboratory services in other sectors is not always optimum.

- Anti-tuberculosis medicines (both first-line and second-line) are often available over the counter without prescription.

- Direct observation of treatment is still not regularly done, particularly when treatment is provided only at chest facilities without involving primary health care units. As catchment areas for each chest facility are huge, it is impossible for all patients to come to chest facilities on a

daily basis. Non-adherence to direct observation treatment is also found in other sectors.

3.3 Limited use of new technology

- Only a limited number of tuberculosis laboratories are using new technology.

- A limited amount of operational research is conducted in the field of multidrug resistance management, mainly on new technology for diagnosis.

3.4 Stigma and lack of community support

- Many countries report high levels of stigma among patients, their families and communities, and even among health workers.

- Community participation in providing social support to multidrug resistance cases is still very limited.

3.5 Health system weaknesses

- Health system barriers such as lack of networks of well-established laboratories for diagnosis, lack of hospital inpatient facilities for treatment and lack of effective drug management systems, often impede the implementation and expansion of MDR-TB care.

- MDR-TB is a notifiable disease under the International Health Regulations (IHR 2005).

3.6 Lack of sufficient resources

- Although some countries, particularly those eligible for Global Fund grants, have obtained support for MDR-TB care, many did not anticipate the full costs of MDR-TB care, such as biosafety level 3 laboratories, infection control and drug management. Many countries are in need of revising, if not developing, their MDR-TB care plan to address the entire range of needs.

- The number of experts in MDR-TB care, including clinical and laboratory experts, is still limited in the Region, although training is being conducted internationally and regionally.

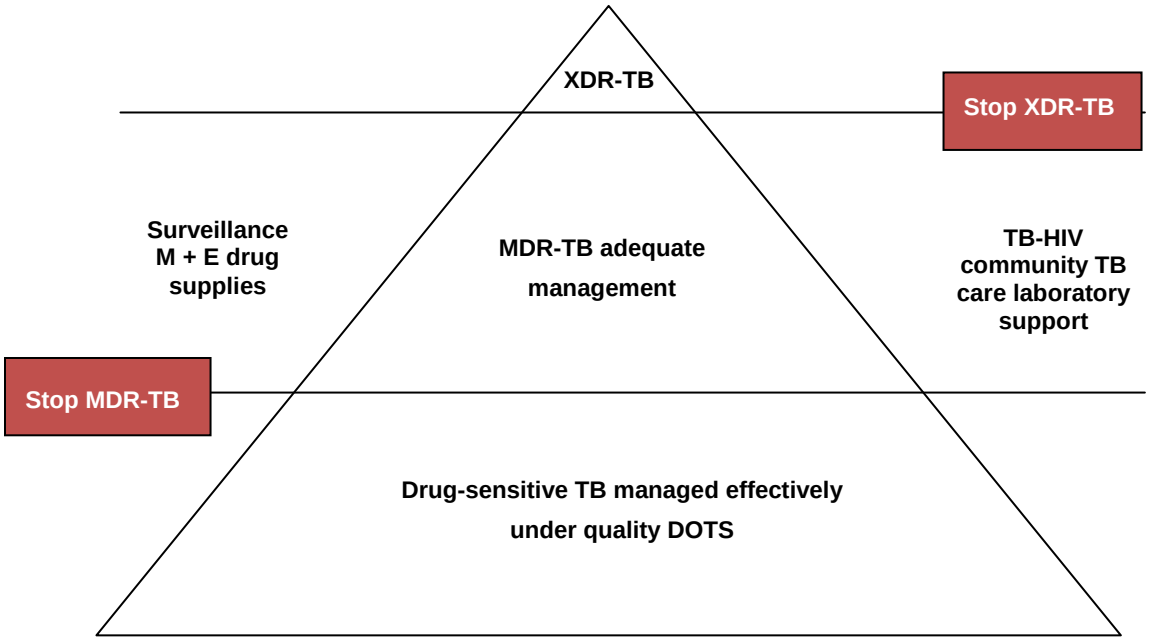

Figure 1. Minimizing the threats of M/XDR-TB

4. Addressing the challenges

Although the Eastern Mediterranean Region is considered as making a low contribution to the global M/XDR-TB burden, it is essential that the countries of the Region further reduce this burden. To achieve this, measures to prevent M/XDR-TB shall be implemented and monitored by all countries. Preventing MDR-TB is the first priority and this can be achieved through quality DOTS implementation. By minimizing the threat of MDR-TB, the expected numbers of XDR-TB are also minimized, and this is accomplished through adequate management of MDR-TB. See Figure 1.

It is therefore vital that the countries of the Region continue improving the quality of DOTS performance, as well as the proper management of MDR-TB by implementing this *Strategic plan for the prevention and control of multidrug-resistant and extensively multidrug-resistant tuberculosis in the Eastern Mediterranean Region (2010–2015)*.

5. Strategic plan for the prevention and control of M/XDR-TB in the Eastern Mediterranean Region (2010–2015)

5.1 Introduction

The global and the regional threat of tuberculosis can only be managed by urgent action and response through a system-based approach, involving partners across the health system and beyond. Failure to do so may result in a large-scale M/XDR-TB epidemic requiring significantly more investment and effort.

In the Eastern Mediterranean Region, until 2008, less than 2% of estimated annual MDR-TB cases have been treated under WHO-recommended treatment (see Annex 3). The response needs a drastic scale-up. This means that policy-makers should provide proper political commitment reflected in securing resources, both financial and human, and in making available a supportive environment for quality management, including legislation to rationalize the usage of tuberculosis medicines and to ensure notification of all cases to the NTP for enrolment in treatment. The role of health-care providers and the community is critical to ensuring wide access to proper care. By addressing all challenges and activities defined in the strategic plan, the countries of the Region will be able to meet global and regional targets and provide universal access to proper care of MDR-TB.

5.2 Goal

The goal of the strategic plan is to ensure that all countries achieve universal access to diagnosis and treatment of M/XDR-TB by 2015.

5.3 Objective

The specific objective of the strategic plan is that all countries will receive the support needed to scale-up their response to the

challenges of M/XDR-TB in order to establish universal access to quality MDR-TB management by 2015.

5.4 Products

The expected products of the strategic plan are:

1. Norms and standards for MDR-TB care including strategic plans, guidelines and training modules, legislation, training of trainers and other outputs.
2. Scaled-up NTP capacity in the areas of diagnostic laboratories, infection control, treatment and treatment follow up, clinical management, monitoring and evaluation (including recording and reporting), drug management, involvement of all health-providers, advocacy, communication, social mobilization and operational research.
3. Developed human resources in all countries, including the establishment of a regional network for MDR-TB management (consisting of consultants and model centres), and providing the needed technical support.

6. Activities

6.1 Development of norms and standards for MDR-TB care

Development of national strategic plans

All countries should prepare a national strategic plan to address M/XDR-TB based on the present *Strategic plan for the prevention and control of M/XDR-TB in the Eastern Mediterranean Region (2010–2015).*

The regional Stop TB programme will provide technical support to countries to develop their national strategic plans for MDR-TB.

Development of national guidelines

The 2008 emergency update (or the latest update when it becomes available) of the WHO guidelines on the management of drug-resistant tuberculosis will be translated into the local languages of all countries of the Region (*6*), and in particular into Arabic, for the development of national guidelines. This should be accomplished by the regional Stop TB programme by the end of 2010.

Additionally, the regional Stop TB programme will provide technical support for countries to adapt the global guidelines/develop national MDR-TB guidelines by mid-2011 (10 countries per year).

Translation and development of training materials

The 2009 WHO global training modules on the programmatic management of drug-resistant tuberculosis will be translated into Arabic and other local languages, and will be adapted by each country according to their needs. The Regional Office will provide the necessary technical support.

6.2 Scaling-up NTP capacity

Diagnostic capacity

It is essential that tuberculosis bacteriology diagnosis is enhanced in order to establish effective MDR-TB case-finding and management (follow-up tuberculosis culture). In addition, new rapid diagnostic techniques, like the line probe assay (LPA), can significantly improve the bacteriology diagnostic delay of MDR-TB. In this context, the regional Stop TB programme will provide technical support to all countries in the Region in order to improve and upgrade their M/XDR-TB diagnostic capacity, while countries should provide the necessary human resources and mobilize the necessary financial resources for upgrading and strengthening the tuberculosis laboratories.

Establishment of laboratories performing tuberculosis culture

By 2015, all countries in the Region should have at least one quality assured tuberculosis culture laboratory per 5 000 000 population or less, according to their situation (See Annex 5, Table 1). This will ensure quality tuberculosis diagnosis and adequate follow-up and cure of laboratory-confirmed MDR-TB cases.

Establishment of laboratories performing tuberculosis culture and first-line drug susceptibility testing (DST)

By 2012, all countries in the Region should have adequate access to a proficient tuberculosis culture and first-line DST laboratory, qualified by a supranational reference laboratory (SNRL), per 20 000 000 population or less, according to their situation (See Annex 5, Table 2). This will ensure quality diagnosis of all MDR-TB cases in the Region. The regional Stop TB programme will provide technical and coordination support.

Laboratories performing tuberculosis culture and second-line DST

By 2013, all countries in the Region should have, or have adequate access to, a proficient tuberculosis culture and second-line DST laboratory, qualified by a SNRL, per 20 000 000 population or less, according to their situation (See Annex 5, Table 2). This will ensure quality diagnosis of all XDR-TB cases in the Region. The regional Stop TB programme will provide technical and coordination support.

Development of standard operating procedures (SOP) and quality assurance for direct smear microscopy (DSM), tuberculosis culture and DST

By 2012, all countries should have SOP and quality assurance for DSM, tuberculosis culture and DST in place, to ensure quality tuberculosis diagnostic and supportive laboratory services (See Annex 5, Table 3). To this end, the regional Stop TB programme will provide the necessary technical support. In this context, each country should have a national reference laboratory (NRL) (See Annex 5, Table 4) and the Regional Office will provide technical and coordination support to establish another three SNRLs in the Region.

Development of capacity to perform LPA testing

By 2012, all countries should have the capacity to perform/have access to LPA testing for the rapid identification of MDR-TB cases. A minimum of one LPA testing laboratory must be available at the NRL or an average of one LPA laboratory per 20 000 000 population (See Annex 5, Table 5). The regional Stop TB programme will provide technical and coordination support.

Specimen transportation

By 2011, each country should have in place an efficient specimen transportation system for LPA testing, tuberculosis culture and DST. In this regard, the regional Stop TB programme will facilitate coordination and collaboration among countries.

Development of NRL and SNRL networks

By 2013, all countries in the Region should have an NRL for initiating and supervising quality assurance for DSM, tuberculosis culture and DST (See Annex 5, Table 4). The regional Stop TB programme will ensure that by 2012, an adequate number of SNRL (with a minimum increase to a total of four regional SNRL) are in full operation, and will support the NRLs with DST proficiency testing and training. The regional Stop TB programme will publish regional SNRL guidelines after receiving global input (in May 2010). Assessment missions are needed for the three candidate laboratories (Aga Khan University Hospital, Islamic Republic of Iran and Tunisia) in addition to a joint meeting for all designated SNRLs, probably in 2011. A detailed budgeted work plan will be the output of the proposed meeting.

Development of clinical management capacity

Training on clinical experience in managing MDR-TB cases

Training and technical support in the clinical management of MDR-TB will be provided by the regional Stop TB programme and at least one centre of MDR-TB management should be established in all countries by the year 2015.

Technical support for the adoption of standardized, individual or mixed approaches in countries

The regional Stop TB programme will provide technical support to countries to enable them to develop, according to their situation, standardized, individualized or mixed Category IV treatment regimens. It is very important to know the burden of MDR-TB, the rate of MDR-TB among all the re-treatment categories (failures, defaulters, relapses) after receiving Category I regimen, the availability of diagnostic tuberculosis laboratories and the type of care provided. This information is vital in selecting the best approach to treat patients. Knowing the previous history of using second-line medicines is the most important factor in determining the best treatment regimen to be considered. A standardized regimen is the best approach for patients who have never used second-line medicines before. On the other hand, an individualized regimen is the best option for patients who have a history of second-line drug use. Where appropriate, operational research should be conducted.

Management of cases (hospitalization versus ambulatory) and the GLC in the Region

Each country should choose the type of case management suitable at the local level. Ambulatory case management will be encouraged for countries with a strong DOTS policy in place. Additionally, a proper infection control policy and a functioning mechanism for early recognition/management of treatment adverse reactions should be in place. All countries in the Region will be encouraged to apply for and implement GLC-approved projects, while the regional Stop TB programme will provide technical support for this (preparation of applications, monitoring and evaluation).

Treatment follow-up

Follow-up tests

All countries should clearly specify a list of treatment follow-up tests which should be a part of the national MDR guidelines (See Annex 5, Table 9). Follow-up sputum specimens for microscopy and culture shall be channelled through an efficient sputum transportation system in all countries. The regional Stop TB programme will provide technical support.

Strengthening DOTS

DOTS and patient support should be strengthened by all countries in order to achieve high cure rates and prevent XDR-TB (See Annex 5, Table 10). The regional Stop TB programme will provide technical support to achieve DOTS for every MDR-TB patient enrolled for treatment.

Management of side-effects and adverse drug reactions

Health-care workers should be familiar with the management of common adverse drug effects of MDR-TB therapy. Ancillary medicines for the management of adverse drug effects should be available to patients through their treatment centres (See Annex 5, Table 8). During ambulatory treatment, the NTP should utilize the public-private mix network to provide support to patients, nearest to their residence, in case of adverse medicines reaction.

All countries should have suitably trained health-care workers to monitor adverse drug effects through DOTS and relevant laboratory testing, and to manage adverse drug effects and provide ancillary medicines free of charge for the management of adverse drug effects in patients on MDR-TB and XDR-TB therapy.

Infection control

All countries should aim to reduce the risk of transmission of *Mycobacterium tuberculosis*, especially resistant tuberculosis, through a combination of measures aimed at minimizing the risk of transmission.

Development of national guidelines

All countries should develop, distribute and implement national guidelines on MDR-TB and infection control. The regional Stop TB programme will provide guidance and technical support in the development of national guidelines on MDR-TB and infection control based on WHO guidelines.

Clinical management and infection control

All countries should ensure that proper infection control measures, including administrative and engineering controls and personal protection are made available in the clinical management of MDR-TB. The regional Stop TB programme will provide guidance and technical support.

Tuberculosis laboratory safety and security – biosafety levels

Mycobacterial culture and DST generate high-concentration aerosols requiring biosafety level 3 containment precautions. Laboratory standards require the following essential measures to be in place and enforced:

- appropriate and specific administrative controls (good laboratory practice, SOP and accident management plans)
- appropriate engineering controls functioning adequately as designed
- personal protective equipment appropriate for the tasks being performed
- proper waste management procedures
- proper procedures for general laboratory safety (physical, electrical and chemical safety).

Tuberculosis laboratories in all countries should comply with the above requirements.

Infection control at community level

Those countries that choose to treat MDR-TB cases at community level must make provisions for infection control measures at family and community level.

The regional Stop TB programme will provide the necessary technical support, including for the preparation of national guidelines and training.

Logistics

Medicines

All countries should have in place an efficient drug management system (for both first- and second-line tuberculosis medicines) that addresses the following.

- Legislation: Countries should decide whether tuberculosis medicines should be limited to the NTP only and therefore not available in the private sector or over the counter. Quality second-line medicines can be secured through GLC procurement. Quality control of tuberculosis medicines shall be regulated by the national drug regulatory authorities at country level.

- Forecasting: Countries should forecast their needs for second-line anti-tuberculosis medicines based on the expected MDR-TB cases to be treated in a given period of time (e.g. a year), the pattern of drug resistance (as found in nationwide drug-resistance surveys or previously treated cohorts) and the shelf-life of each medicine.

- Procurement: Countries should preferably procure medicines through the GLC to secure second-line medicines. The regional Stop TB programme will provide technical support in coordination with the GLC (See Annex 4, Table 7).

- Distribution: All countries, as part of their drug management system, should develop an efficient storage and distribution system that guarantees uninterrupted quality drug supply for MDR-TB management.

- Effectiveness: All countries should monitor the effectiveness of their drug management system by using the following indicators:
  - Stock-outs in a year
  - Number of laboratory-confirmed MDR-TB patients enrolled for treatment (shall be > 80%)
  - Treatment outcomes of MDR-TB patients (treatment success rate shall be > 75%)

- Facilities monitoring storage temperature for second-line tuberculosis medicines (shall be 100%)
- Wastage of second-line tuberculosis medicines (shall be < 15%)

The regional Stop TB programme will provide the guidance and technical support needed for implementation of the above-mentioned activities.

Ancillary medicines for side-effect management

All countries should make provision for medicines that will be used for adverse drug effects during MDR-TB treatment (See Annex 4, Table 8). These ancillary medicines shall be made available free of charge. The regional Stop TB programme will provide the guidance and technical support needed.

Infection control supplies and equipment

All countries should ensure that all necessary infection control supplies and equipment are available and functioning. The regional Stop TB programme will provide the guidance and technical support needed.

Laboratory supplies and equipment

All countries should ensure that all necessary quality tuberculosis laboratory supplies and equipment are available and functioning. In particular, supplies and equipment shall be secured for direct smear microscopy, tuberculosis culture, first and second-line DST, and LPA. In addition, countries shall ensure appropriate purchase contracts from the suppliers of liquid tuberculosis culture (including maintenance of equipment) and LPA. The regional Stop TB programme will provide the guidance and technical support needed.

Monitoring and evaluation (6)

In order for the Region to be able to adequately respond to the challenge of M/XDR-TB, all countries should be able to provide adequate information on M/XDR-TB epidemiology, in particular on the case-finding of smear-positive MDR-TB patients and the treatment success of laboratory-confirmed MDR-TB cases. The regional Stop TB programme will provide the guidance and

technical support needed.

All countries should develop monitoring and evaluation procedures, including a computerized nominal recording and reporting system to monitor the results of MDR-TB activities (case-finding and treatment outcomes) by 2012. The aim of this system is to allow NTP managers to monitor overall programme performance, follow trends in the number of MDR-TB cases notified and plan drug supply, while providing the basis for programme and policy developments, and aiding clinical providers in the management of individual patients.

In this context the countries shall report the following indicators:

- Number of patients in whom MDR-TB is detected in the laboratory
- Number of MDR-TB patients started on treatment
- Smear and culture conversions
- Final outcomes of MDR-TB treatment
- Relapse rates.

The regional Stop TB programme will provide the relevant training, technical support and support in the establishment of monitoring and evaluation procedures, including the establishment of computerized nominal recording-reporting systems for the management of MDR-TB.

Psychosocial and economic support

Community support

Countries, which treat MDR-TB cases on an ambulatory basis, should create the necessary community support to patients through appropriately trained community health volunteers.

Entertainment

Countries, which hospitalize MDR-TB patients for treatment for long periods, should provide means of entertainment (e.g. television, music, books) and if possible occupational rehabilitation.

Food support

All countries should assess the nutritional needs of each and every MDR-TB patient, and provide food allowances/supplements for those who cannot afford it.

Transport allowance

Countries, which have community-based treatment for MDR-TB patients, should provide the necessary transport cost for patients that have to travel for clinical assessment, laboratory testing or treatment of adverse drug effects.

Financial support

Countries, which have community-based treatment for MDR-TB patients, should plan and coordinate with nongovernmental organizations and other charity organizations in the country to provide the necessary financial support for patients that have to travel for clinical assessment, laboratory testing or treatment of adverse drug effects.

Public-private mix approaches

The regional Stop TB programme will encourage a public-private mix for tuberculosis care and control in the case-finding and management of MDR-TB patients and will provide technical support, including regional training on public-private mix and public-private mix tools, such as the national situation assessment. It will also provide technical support in the development of national operational guidelines on public-private mix for tuberculosis care and control.

At a country level there may be many opportunities for engaging academic institutions, public hospitals, private medical institutions, nongovernmental organizations, etc. in case-finding, diagnosis and management of MDR-TB cases. These institutions may have the capacity and human resources for a rapid start, and the listing and mapping of these resources should be done by countries. Countries pursuing public-private mix should develop national operational guidelines.

All countries should advocate for public-private mix by utilizing the International Standards for Tuberculosis Care (ISTC). The

regional Stop TB programme will provide guidance and technical support.

Operational research

Countries are encouraged to conduct operational research in the areas of the programmatic management of MDR-TB, prevention of M/XDR-TB, infection control and rapid diagnosis of MDR-TB, and on the impact on tuberculosis control of implemented M/XDR-TB prevention and management activities (including TB/HIV and public-private mix activities). The regional Stop TB programme will provide guidance and technical support.

6.3 Human resources development

Introduction

Human resources development for the diagnosis and management of MDR-TB requires adequate numbers of appropriately trained health-care workers for both tuberculosis laboratory services and clinical management of MDR-TB cases. These staff may have to spend most of their time on the management of MDR-TB cases. This differs significantly from the implementation of the DOTS strategy, which can be fairly easily implemented through existing well-functioning primary health care systems. The same applies for tuberculosis laboratory services, which have to move beyond sputum smear microscopy, towards the introduction of higher and novel technology.

Trainings of trainers (TOT)

The regional Stop TB programme will provide technical support for the training of trainers for countries in the Eastern Mediterranean Region according to their needs in the following areas of MDR-TB management:

- Clinical experience
- Laboratory experience
- Managerial experience (including infection control and logistics)
- Social support experience.

Technical support

The regional Stop TB programme will provide technical support

for countries in preparing their human resource development plans. Countries should ensure that they develop a human resource development plan for the adequate implementation of MDR-TB diagnosis and management, and should implement this plan and sustain the human resources required through the provision of incentives.

Regional Stop TB programme capacity and consultancy team

By 2010, the regional Stop TB programme will be strengthened with an additional Medical Officer acting as regional focal point for M/XDR-TB. He/she will be responsible for the implementation of the regional strategic plan, for the scaling-up of the response to M/XDRTB in the Region and for effective coordination and technical support to the countries of the Region. He/she will be supported by a recognized team of MDR-TB/tuberculosis laboratory experts (short-term consultants), who will be drawn from the TBTEAM roster and who will cover specific areas of M/XDR-TB management, i.e. tuberculosis laboratory services, clinical management, infection control, recording and reporting, logistics and drug management, psychosocial and economic support, public-private mix approaches, drug resistance surveillance and impact measurement.

MDR-TB model centres

By 2012, the regional Stop TB programme should, with the agreement of the countries of the Region, identify, select and secure specific funding to establish two regional model tuberculosis centres for MDR-TB management (Annex 5, Table 6). These model centres must achieve excellence in the diagnosis and management of MDR-TB. Their role will be to assist countries in the Region in human resource development, through regional training and the development and distribution of appropriate training materials. In addition, due to their specific expertise in the diagnosis and management of MDR-TB, they will also be able to provide technical support to the countries of the Region.

6.4 Budget

A comprehensive five-year proposed budget has been developed to reflect the cost of activities at the level of the Regional Office (see Annex 4). The total estimate of this budget is US$ 2 209 000 divided among the development of national strategic plans

(US$ 212 000), development of guidelines (US$ 84 000), training and materials (US$ 10 000), diagnostic capacity (US$ 163 000) and technical support to countries for human resource development (US$ 1 740 000).

Additionally, in order to provide a guidance tool to countries for development of their MDR-TB strategic plans during the next five years, a separate costing budget has been developed. The country budget file (see Annex 5) includes the cost of the main MDR-TB management activities at country level and is presented as a unit cost of services.

7. Guidance to the countries to prepare their MDR-TB national strategic plans

7.1 National situation assessment

National situation assessments should include all components of the WHO Global Stop TB Strategy (2006–2015) and should address programmatic, managerial, technical and financial aspects. However, for the purpose of the development of the MDR-TB national strategic plan, the situation analysis should focus on MDR-TB burden, drug management, infection control, MDR-TB case-finding, including laboratory services, MDR-TB case management, monitoring and evaluation (including recording and reporting) and the financial gap.

7.2 MDR-TB burden

Drug resistance surveys

In principle, all countries should conduct nationwide drug resistance surveys to accurately identify and monitor the extent and patterns of MDR-TB. Some countries can assess their tuberculosis drug-resistance problem through sentinel drug resistance surveillance (the countries of the GCC, for example), or through continuous analysis of the drug resistance patterns of MDR-TB cohorts treated under the programmatic management of MDR-TB.

The regional Stop TB programme will provide technical support to countries to plan and conduct drug-resistance surveys and to identify gaps.

Drug resistance surveillance systems

Countries that have the capacity, i.e. a laboratory network and proficient DST, can establish a drug resistance surveillance system. The regional Stop TB programme will provide technical

support to countries.

National situation analysis table

In order to provide a guidance tool to countries for development of their MDR-TB strategic plans during the next five years, a national assessment table is presented in Annex 2 with a scoring system to enable NTP managers and MDR-TB focal points to identify gaps and plan their related activities.

Budget tables

Additionally, a separate costing budget has been developed. The country budget file (Annex 5) includes the cost of the main MDR-TB management activities at country level presented as unit costs of services.

References

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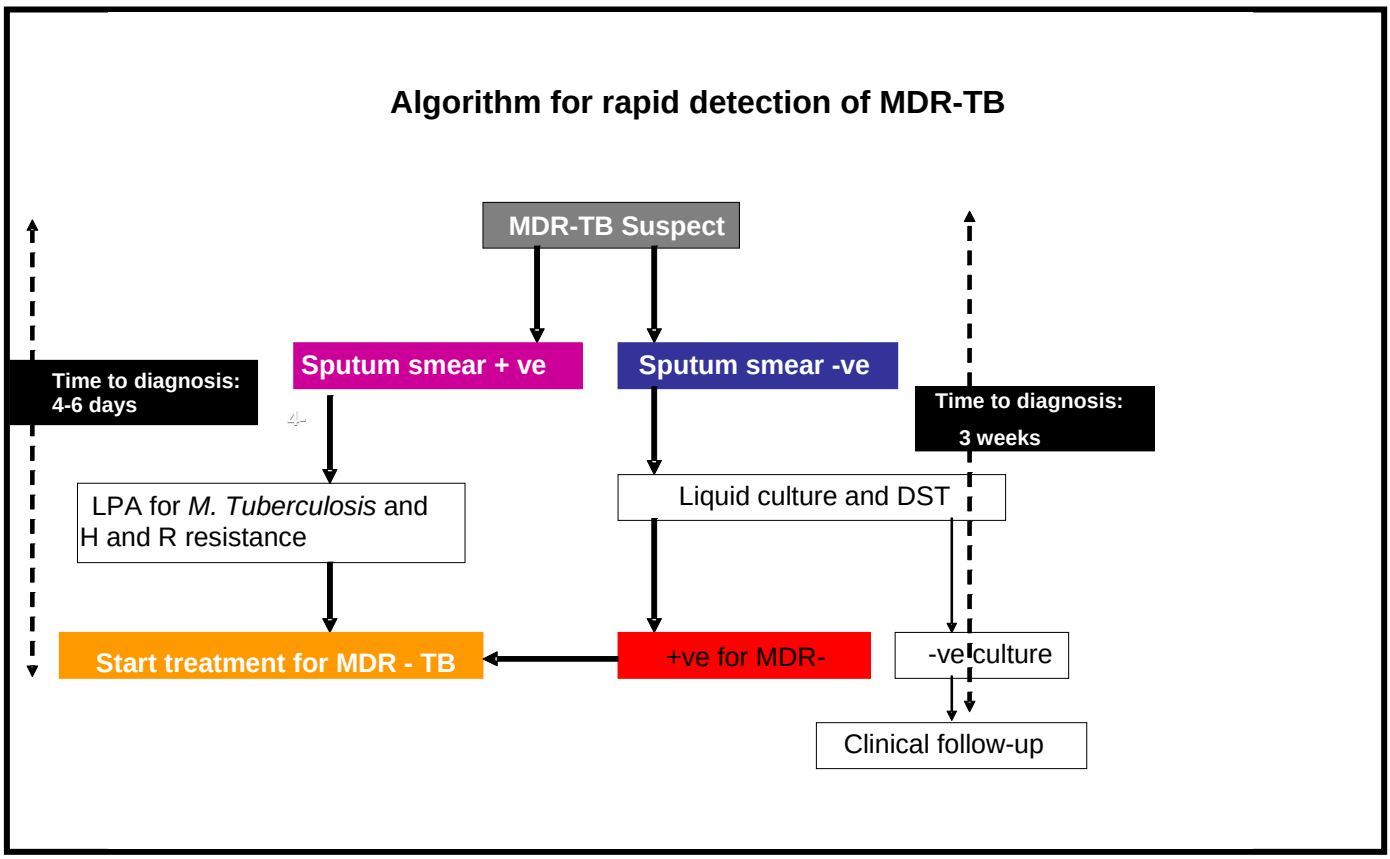
4. *Global tuberculosis control 2009: epidemiology, strategy, financing*. Geneva, World Health Organization, 2009 (WHO/HTM/TB/2009.411).

5. *The global MDR-TB and XDR-TB response plan 2007–2008*. Geneva, World Health Organization, 2007 (WHO/HTM/TB/2007.387).

6. *Guidelines for the programmatic management of drug-resistant tuberculosis: emergency update 2008. WHO report 2009*. Geneva, World Health Organization, 2008 (WHO/HTM/TB/2008.402).

Annexes

Annex 1. Diagnostic algorithm for rapid MDR-TB assessment using LPA



Annex 2. Situation analysis at country level (preparations for national planning for MDR-TB management)

The following template can be used by countries in assessing their situation in order to help prepare the national MDR-TB strategic plan and to monitor annual progress on M/XDR-TB management.

Instructions: The questions aim to gain a broad understanding of the extent to which the country or subnational units have the capacity to address MDR-TB. Users shall expand on specific challenges related to MDR-TB, such as high prevalence of both MDR-TB and HIV among marginalized groups (for example, injecting drug users) and programme design issues that prevent adequate responses to both.

Question	**Answer**	**Identified Gap**	**Action/ Recommendation**	**Data source/ Comments**
1. Are there national treatment guidelines or protocols for M/XDR-TB in use? Are these guidelines consistent with current WHO recommendations?	**1a. Yes**			
	1b. Yes, with deviations (not implemented or not consistent with international recommendations)			
	1c. No			
2. Is there a policy to refer M/XDR-TB cases to clinical facilities identified by the Ministry of Health based on set criteria (e.g. expertise, location and infrastructure) as having the capacity to manage these cases?	**2a. Yes** (Final policy is in place and implemented)			
	2b. Yes, but policy is not yet implemented			
	2c. No (No policy exists)			
3. Are clinical decisions on M/XDR-TB cases taken by individual clinicians only or in consultation with a group of experts?	**3a. Group consultation** (decision is taken by expert panel)			
	3b. Individual decision			
4. Is there a capacity within facilities to provide isolation for M/XDR-TB	**4a. Yes**, **adequate isolation for all cases**			

Question	Answer	Identified Gap	Action/ Recommendation	Data source/ Comments
patients during inpatient treatment?	**4b. Yes, minor problems** (not all cases can be isolated)			
	4c. No, major problems exist			
5. Is adequate infection control protection (administrative, environmental, personal) available for health-care workers in facilities that treat M/XDR-TB?	**5a. Yes**			
	5b. Yes, partial (some infection control measures are implemented or in process, but gaps remain)			
	5c. No (some or all measures are not available. There is a real risk of nosocomial transmission of tuberculosis)			
6. Does the country have access to quality assured and WHO prequalified second-line medicines?	**6.a Yes** (quality assured and pre-qualified)			
	6.b Yes, partial (quality assured but not pre-qualified)			
	6.c No			
7. Are medicines for management of adverse effects of second-line medicines available and are providers trained on how to use them?	**7a. Yes**			
	7b. Yes, partial (medicines are available, but providers are not yet trained, or vice versa)			
	7c. No			
8. Are M/XDR-TB patients managed outside the NTP?	**8a. No** (this means that all M/XDR-TB cases are managed by all sectors according to the NTP guidelines)			
	8b. Yes (this means that M/XDR-TB cases are managed outside and not in line with the NTP guidelines)			
9. Is there an NRL in the country that provides tuberculosis culture and DST to first-line medicines?	**9. a Yes**			
	9.b Yes but not functioning well			

Question	Answer	Identified Gap	Action/ Recommendation	Data source/ Comments
	9.c No			
10. Are there adequate laboratories in the country to provide culture and DST to MDR-TB patients?	**10. a Yes**			
	10.b No			
11. Do M/XDR-TB patients receive social support (transportation/food basket)?	**11. a Yes**			
	11.b Yes but not adequate			
	11.c No			
12. Do M/XDR-TB patients take their daily medicine under DOTS?	**12.a Yes** (means daily DOTS for 24 months)			
	12.b Yes but irregular			
	12.c No			
13. Did the country perform drug resistance surveys to first-line medicines?	**13. a Yes**			
	13.b Yes but not nationwide			
	13.c No			

Annex 3. Data and activities of GLC-approved countries: summary points for the Eastern Mediterranean Region

- Total estimated MDR-TB cases/year: 23 049 (14 120 smear positive)
- Total patients approved: 2887 (cumulative up to May 2010)
- Total patients treated (cumulative): 476 (up to 2009)
- Treatment success rate: 53.4%

Table 1. Enrolled versus planned activities

Project	Planned					Enrolled				
	2005	2006	2007	2008	2009	2005	2006	2007	2008	2009
Egypt	–	30	45	86	–	–	28	42	68	71
Jordan	15	15	15	20	20	14	19	9	9	7
Lebanon	10	10	–	–	–	8	3	3	3	6
Pakistan (Karachi)	–	–	–	–	200	–	–	–	–	–
Syrian Arab Republic	77	42	42	–	–	–	–	31	41	15
Tunisia	45	10	10	–	–		45	36	8	10

Table 2. MDR-TB treatment outcome up to 2008 in GLC-approved countries in the Eastern Mediterranean Region: Egypt, Jordan, Lebanon, Pakistan (Karachi), Syrian Arab Republic and Tunisia

Data	Cured	Treatment completed	Died	Failed	Defaulted	Transferred out	Still on treatment	Grand total	%
New	14	–	4	–	–	–	57	75	15.8
Relapse	11	3	6	3	5	1	18	47	9.9
After default	8	3	11	3	9	1	28	63	13.2
Failure Cat 1	12	–	5	–	1	1	39	58	12.2
Failure Cat 2	56	15	26	4	18	7	98	224	47.1

Data	Cured	Treatment completed	Died	Failed	Defaulted	Transferred out	Still on treatment	Grand total	%
New extra-pulmonary	2	–	–	–	1	0		3	0.6
Other	–	–	1	–	1	–	4	6	1.3
Total	103	21	53	10	35	10	244	476	–
	21.6%	4.4%	11.1%	2.1%	7.4%	2.1%	51.3%	–	–
Treatment success excluding still on treatment	44.4%	9.1%	22.8%	4.3%	15.1%	4.3%	–	–	–

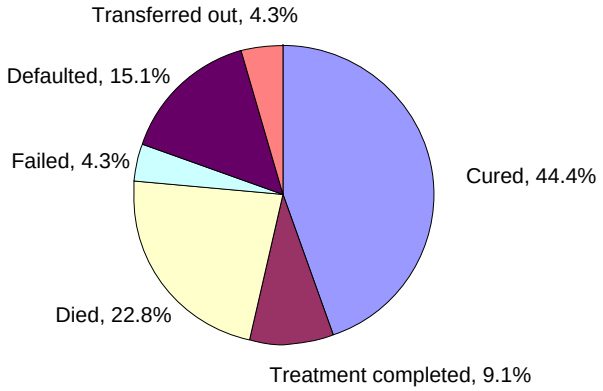


Figure 1. Eastern Mediterranean Region outcome data

Annex 4. Regional budget

Table 1. Regional budget

Development of norms and standards to manage MDR-TB cases	Entity in charge	2010	2011	2012	2013	2014	Total		
1. Developing a national strategic plan									
1.1 For the provision of technical assistance to countries, two regional meetings for 5 working days each attended by the DR-TB focal points and NTP managers of 10 countries (one per year)	STB programme in the Regional Office		45 000		60 000		105 000		
1.2 Technical assistance missions to support countries developing national MDR strategic plan, 10 countries/year	Regional Office and DR-TB consultants	50 000		50 000			100 000		
1.3 Developing legislation	STB programme in the Regional Office	7000					7000	212 000	
2. Developing guidelines									
2.1 Translation and editing of the WHO programmatic management of DR-TB guidelines with the emergency update 2008	STB programme in the Regional Office	6000					6000		
2.2 Cost of editing and printing of national guidelines for IC	STB programme in the Regional Office	8000					8000		
2.3 Technical assistance for developing national guidelines of infection control	STB programme in the Regional Office	35 000		35 000			70 000	84 000	
3. Training materials									
3.1 Translating WHO training modules for country adaptation	STB programme in the Regional Office	10 000					10 000	10 000	

Diagnostic capacity									
1. EQA for DSM, culture and DST									
1.1 Annual support to 4 SNRLs including panel testing	STB programme in the Regional Office	8000	30 000	30 000	30 000	30 000	128 000		
1.2 Provision of technical assistance and coordination support to establishment of SNRL network	STB programme in the Regional Office	5000	5000	5000	5000	5000	25 000		
1.3 Technical assistance for establishing the LPA lab	STB programme in the Regional Office		5000	5000			10 000	163 000	
Human resources development									
1. Technical assistance to countries									
1.1 Appointing a focal medical officer for scaling up MDR/XDR-TB response	STB programme in the Regional Office	300 000	300 000	300 000	300 000	300 000	1 500 000		
1.2 Preparation of consultant team (one from each country)	STB programme in the Regional Office	20 000	20 000				40 000		
1.3 TOT on programmatic management of DR-TB, TB lab, drug management and infection control	STB programme in the Regional Office		35 000		35 000		70 000		
1.4 Training of country teams on management of MDR-TB cases and medicines side-effects	STB programme in the Regional Office		35 000		35 000		70 000		
1.5 Development of 2 MDR model centres	STB programme in the Regional Office			20 000	20 000	20 000	60 000	1 740 000	2 209 000
		449 000	475 000	445 000	485 000	355 000	2 209 000		

Annex 5. Country budgets

Table 1A. Laboratories performing TB culture: current situation and gaps

	Country	Population	Laboratory performing TB culture in 2008	Minimum target	Gap
1	Afghanistan	27 145 276	1	5	4
2	Bahrain	752 647	2	2	0
3	Djibouti	833 025	0	1	1
4	Egypt	75 497 912	18	15	0
5	Iran (Islamic Republic)	71 208 384	27	27	0
6	Iraq	28505 843	1	6	5
7	Jordan	5 924 247	50	50	0
8	Morocco	31 224 136	14	14	0
9	Kuwait	2 851 144	1	1	0
10	Lebanon	4 099 114	4	4	0
11	Libyan Arab Jamahiriya	61 60 481	3	3	0
12	Oman	2 595 132	10	10	0
13	Pakistan	163 902 400	3	33	30
14	Opt	4 017 496	1	1	0
15	Qatar	821 313	1	1	0
16	Saudi Arabia	24 734 532	11	11	0
17	Somalia	8 698 534	0	2	2
18	Sudan	38 560 492	1	8	7
19	Syrian Arab Republic	19 928 518	1	4	3
20	Tunisia	10 327 285	7	7	0
21	United Arab Emirates	4 380 439	3	3	0
22	Yemen	22 389 172	3	4	1
Laboratory performing culture needed to reach at least one per 5 million population					53

B. General costing

Budget needed in US$	
Cost of establishment of one new culture laboratory (infrastructure)	30 000
The cost of standard equipment (assuming that the quantity required for each item is 1)*	178 000
Consumables	159 000
Total	367 000

Note: These figures are estimated.

* Refer to culture laboratory unit cost equipment sheet.

C. Cost of equipment for culture laboratory (solid media)

Items (solid media)	Number	Unit cost (US$)	Possible alternatives	Number	Unit cost (US$)
Base support for Laminar Air Flow Cabinet	2	1025			
BSC, class I or II	2	17 762			
UPS for BSC	2	1640			
Minishaker or Vortex	3	478			
Optional : overhead stirrer, for at least 10 tubes (50 ml)	2	1640			
Test tube rack 18/8 stainless steel, diameter 16 mm	5	38			
Test tube rack 18/8 stainless steel, diameter 35 mm	5	31			
Safety gas burner with glass chimney, footswitch for temporary ignition	2	574	Electric micro incinerator for loops	1	246
Safety gas tubing with safety clamps on both ends, inner diameter 9 mm	2	41			
Inoculation loops, Platinum/Iridium wire, closed, 10 µl	6	123	Disposable loops,100 x 10 pieces per pack	15	82
Loop holder	12	10			
Racks for loop holder	4	16			
Stainless steel bucket with lid, capacity 10 L	5	150			
Discard bottle, stainless steel or thick walled glass with screw cap	5	4			
Funnel, stainless steel 18/8, top diameter 120 mm	3	18			
Safety box, PP, approx 3 L, for all sharps	25	4			
Laboratory chair, disinfectable, 5 wheels, no arm rests	2	246			
Incubator	2	9291			
Centrifuge	1	8881			
Centrifuge rotor	1	1230			
Centrifuge rotor buckets	4	410			
Aerosol tight lids for rotor buckets	4	137			
Reducing adapter for 50 ml centrifuge tubes	4	109			
Reducing adapter for 15 ml/12 ml centrifuge tubes	4	109			
Autoclave	2	15 029			
Autoclave control unit for fully automated process control	2	3006			
Exhaust air filtration system for autoclave	1	3552			

Items (solid media)	Number	Unit cost (US$)	Possible alternatives	Number	Unit cost (US$)
Autoclave control unit for sterilization of liquids, including temperature probe	1	3361			
Autoclave re-cooling system to shorten the time of liquid sterilization	1	3416			
Wire baskets or stainless steel buckets for autoclave	2	246			
Wire baskets with drip tray for autoclave	2	478			
Hot-air oven	1	3826			
Optional ion exchanger cartridge, flow rate approx. 950 L/h	2	1093			
Conductivity measuring device for laboratory grade water, digital	2	437			
Ion exchanger resin for laboratory grade water, pack of 5x10 L resin	5	82			
Water distiller	1	1776			
Balloon high-density poyethylene (HDPE) with discharge cock, 30 L	1	82			
Balloon high-density poyethylene (HDPE) with discharge cock, 10 L	4	55			
Stop cock, winding for HDPE balloon	10	4			
Racks for test tubes, PP, autoclavable, 60 positions	12	11	Racks for 28 ml universal vials, PP, autoclavable, 48 positions	150	11
Alarm clock / digital timer, 4 digits	1	27			
Safety-pipetting ball, standard	10	3			
Automated pipetting aid, battery capacity for 8 h work, 200 g weight	2	478	Set of mechanical pipetting aids: up to 0.2 ml; up to 2 ml and up to 10 ml	2	68
Pipette washer	1	171			
Transport boxes for specimens meeting WHO requirements of P650 package	10	20			
Electronic maxima-minima-thermometers, two channels, thin cable with sensor, battery, measuring range -50 °C/+60 °C	10	27			
Electronic maxima-minima-thermometers, two channels, battery, measuring range -10 °C/+50 °C	10	27			
Dispenser for 1000 ml bottle for liquid soap, for wall mounting, 1 per sink	2	68			
Dispenser for hand towels, for wall mounting, 1 per sink	2	48			
Goggles, according to EN 166 and EN 170, frame adjustable, integrated side and top protection, total weight <40 g	5	8			
Emergency spill-kit	1	34			
First aid kit	1	328			
Anemometer	1	2049			
Analytical balance	1	4782			
pH meter	1	820			

Items (solid media)	Number	Unit cost (US$)	Possible alternatives	Number	Unit cost (US$)
Bunsen burner with fine tuning	1	143			
Tripod stand	1	16			
Water bath, capacity approximately 20 L	1	1503			
Magnetic stirrer	1	581			
Magnetic stirring bars, round-shaped, polytetrafluorethylen (PTFE) coated. Set of 10: 1 x 15 mm, 2 x 20 mm, 2 x 25 mm, 1 x 30 mm, 2 x 40 mm, 2 x 50 mm length	1	68			
Sterile filling station of culture media, consisting of 1000 ml Squibb sedimentation funnels or cylindric dropping funnels, with tube for pressure exchange, stopcocks made of glass and Teflon stopper, outlet diameter 4 mm	3	68			
Stative for Squibb sedimentation funnels consisting of plate, rod and clamp	3	137			
Inspissator for coagulation of egg-based culture media	1	8198			
Refrigerator with freezing department	1	820			
Refrigerator	2	410			
Stainless steel funnel, short wide stem with air drain, diameter 150 mm on top	5	14			
Swan neck bottles (PE flask, narrow neck with screw cap and water dispenser) set of one each 250, 500, 1000 ml	5	16			
Bowl, plastic, 500 x 350 mm	5	3			
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 2000 ml	2	34			
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 1000 ml	10	164			
Erlenmeyer flasks, borosilicate 3.3, wide neck, autoclavable, 500 ml	10	82			
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 250 ml	10	61			
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, 100 ml, pack. unit 10	20	55			
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 50 ml	20	55			
Measuring cylinder, class A; TPX, autoclavable, 1000 ml, graduated 10.0 ml	5	22			
Measuring cylinder, class A; TPX, autoclavable, 500 ml, graduated 5.0 ml	5	14			
Measuring cylinder, class A; TPX, autoclavable, 250 ml, graduated 2.0 ml	5	9			
Measuring cylinder, class A; TPX, autoclavable, 100 ml, graduated 1.0 ml	5	6			
Measuring cylinder, class A; TPX, autoclavable, 50 ml, graduated 1.0 ml	5	5			
Thick-walled glass flask for preparation of culture medium; with flanged rim; 2500 ml	6	59			
Thick walled bottles, borosilicate 3.3, graduated, transparent, PP ring and cap, 2000 ml	3	25			
Thick walled bottles, borosilicate 3.3, graduated, transparent, PP ring and cap, 1000 ml	10	14			
Thick walled bottles, borosilicate 3.3, graduated, transparent, PP ring and cap, 500 ml	5	9			
Thick walled bottles, borosilicate 3.3, graduated, amber, PP ring and cap, 11 000 ml	3	16			
Thick walled bottles, borosilicate 3.3, graduated, amber, PP ring and cap, 12 000 ml	2	27			
Screw caps with weld in PFTE membrane, 0.2 µm pore size, autoclavable to 140 °C	10	3			
Laboratory beaker, EFTE, low form with graduation and spout, 2000 ml	3	137			
Laboratory beaker, EFTE, low form with graduation and spout, 1000 ml	3	68			

Items (solid media)	Number	Unit cost (US$)	Possible alternatives	Number	Unit cost (US$)
Laboratory beaker, EFTE, low form with graduation and spout, 600 ml	10	55			
Laboratory beaker, EFTE, low form with graduation and spout, 250 ml	10	25			
Laboratory beaker, EFTE, low form with graduation and spout, 100 ml	10	15			
Laboratory glassware drying rack, wall mounted; polystyrene; minimum 24 pegs	1	184			
Funnel, soda lime glass, plain, short stem, d = 75 mm	5	7			
Funnel, soda lime glass, plain, short stem, d = 125 mm	5	11			
Powder funnel, diameter 100 mm	5	11			
Glass beads, massive glass, 5 mm diameter	2	34			
Glass beads, massive glass, 3 mm diameter	1	34			
Thick walled Pyrex tubes with ISO winding and autoclavable screw cap with tight gasket, 16x100 mm; package of 100	10	109			
Strainer, stainless steel, 1 grip, 2 eyes, diameter 20 cm	1	22			
Forceps; pointed; straight; 18/8 stainless steel, polished	5	9			
Optional: Laboratory washer-disinfector for laboratory glass, 2 baskets	1	5055			
Separate water supply for de-ionised water with conductivity measure R 3/4" with digital display and hose-set for in- and outflow	1	929			
Aqua purificator cabinet for two de-mineralising cartridges	1	410			
Cost of equipment for culture laboratories (solid media)					177 698

Indicated quantities are based on experience and estimated for a laboratory performing approximately 12 000 cultures. Quantities should be adjusted according to the actual workload and methods used.

D. Culture laboratory consumables

Items (solid media)	Number	Unit cost (US$)	Possible alternatives	Number	Unit cost (US$)
Culture tubes, diameter 16 mm, pack of 100	260	41	Universal glass bottle 28 ml, pack of 100	260	102
PP-tubes for centrifuge, 50 ml; 500 pieces/pack	60	164			
PP-tubes for centrifuge, 15 ml; 500 pieces/pack	4	164			
Loop, disposable 10 μ, 10 pieces/pack	1500	82			
Plastic Pasteur pipettes, 1.5 ml, 500 pieces/pack	30	55			
Cryo-vial, sterile with cap, 2 ml	1	199			
Deep freeze storage box with lid for 2 ml cryovials , autoclavable PP	10	11			
Gloves, vinyl or nitrile, powder free, disposable, size S, 100/pack	60	16			
Gloves, vinyl or nitrile, powder free, disposable, size M, 100/pack	90	16			
Gloves, vinyl or nitrile, powder free, disposable, size L, 100/pack	30	16			
Plastic bags for waste bins, 1000 pieces per pack	1	30			
Stands for small plastic bags (2 L)	5	11			
Autoclavable bags at 134 °C, 410 x 620 mm, 100 pieces per pack	10	55			
Filter paper round, diameter 185, packs of 100	3	11			
Filter paper round, diameter 150, packs of 100	6	10			
Marker pen, water resistant	3	7			
Adhesive labels, pack of 4800 labels	2	63			
Cryo-tags sized to fit for use on cryo-tubes, rolls of 1000	5	57			
Sterilindicator tape (rolls), 55 m long, for hot air sterilizer (green/brown)	5	30			
Sterilindicator tape (rolls), 55 m long, or autoclave (beige/dark brown)	5	18			
Aluminium foil, 100 m long	3	157			

Items (solid media)	Number	Unit cost (US$)	Possible alternatives	Number	Unit cost (US$)
Parafilm, 100 mm width with dispenser	3	31			
Plastic-foil rolls, 30 cm	5	11			
Tube brush 280 mm long	20	3			
Brush for glassware 120 mm long	10	7			
Laboratory coat, size L	10	48			
Laboratory coat, size M	20	48			
Laboratory coat, size S	10	48			
FFP2 or FFP3 respirators, individually packed, packs of 10	1	102			
Disinfectant for floors, container 10 litres	6	72			
Disinfectant, ethanol-based, container 5 litres	8	64			
Spray hand for bottle with disinfectant of 1 litre	6	7			
Liquid soap, pH neutral, bottle of 1 litre	12	10			
Disinfectant for hands, alcohol-based, 1 litre bottle	15	11			
Paper towels, single-use, box. 150 towels/pack, 30 packs/carton	5	59			
Cotton wool, 1 kg	10	3			
Tissue pulp, absorbent sheets, approx. 550 x 350 mm	30	7			
Detergent/washing powder for laboratory dish washer, 10 kg/pack	36	82			
Salt for dish washer, 10 kg/pack	10	20			
Rinse aid for dish washer, 1 litre	10	16			

Cost of consumables for culture laboratory (estimate of 12 000 cultures) (solid media).

Table 2. Laboratories performing TB culture and DST (solid/liquid media) for first- and second-line medicines

A. Current situation, gaps and target with estimated budget for upgrading culture laboratory to do DST for first- and second-line medicines on solid media/country (estimated budget to upgrade one laboratory = US$ 68 000)

	Country	Population	Culture	DST (on solid media)	Target (at least one/20 million population)	Gap	2010	2011	2012	2013	2014	Total cost per country of upgrading culture laboratory to perform DST for first-line medicines (solid media)
1	Afghanistan	27 145 276	1	0	1	1	1					68 000
2	Bahrain	752 647	2	2	2	0	0					0
3	Djibouti	833 025	0	0	1	1	1					68 000
4	Egypt	75 497 912	18	1	4	3	1	2				204 000
5	Iran (Islamic Republic)	71 208 384	27	2	4	2	1	1				136 000
6	Iraq	28 505 843	1	1	1	0	0					0
7	Jordan	5 924 247	50	1	1	0						0
8	Morocco	31 224 136	14	2	2	0						0
9	Kuwait	2 851 144	1	1	1	0						0
10	Lebanon	4 099 114	4	1	1	0						0
11	Libyan Arab Jamahiriya	6 160 48	3	3	1	2	1	1				136 000
12	Oman	2 595 132	10	1	1	0						0
13	Pakistan	163 902 400	3	1	8	7	1	3	3			476 000
14	Opt	4 017 496	1	0	1	1	1					68 000
15	Qatar	821 313	1	1	1	0						0
16	Saudi Arabia	24 734 532	11	11	1	0						0
17	Somalia	8 698 534	0	0	1	1	1					68 000
18	Sudan	38 560 492	1	1	2	1	1					68 000
19	Syrian Arab Republic	19 928 518	1	1	1	0						0
20	Tunisia	10 327 285	7	5	1	0						0
21	United Arab Emirates	4 380 439	3	0	1	1	1					68 000
22	Yemen	22 389 172	3	1	2	1	1					68 000
	Total			36			11	7	3			1 428 000
	Total per region						748 000	476 000	204 000			

B. Current situation, gaps, target and estimated budget for upgrading one DST (on solid media) laboratory on to do DST for first- and second-line medicines on liquid media/country (estimated additional budget to upgrade one laboratory = US$ 239 000)

	Country	Population	Culture	DST on liquid	Target (at least one/20 million population)	Gap	2010	2011	2012	2013	2014	Total cost per country for upgrading DST labs for first- and second-line medicines (liquid media)
1	Afghanistan	27 145 276	1	0	1	1		1				160 000
2	Bahrain	752 647	2	0	1	2			1	1		320 000
3	Djibouti	833 025	0	0	1	1			1			160 000
4	Egypt	75 497 912	18	2	4	2			1	1		320 000
5	Iran (Islamic Republic)	71 208 384	27	Data not available	3	3			2	1		480 000
6	Iraq	28 505 843	1	0	1	1			1			160 000
7	Jordan	5 924 247	50	0	1	1			1			160 000
8	Morocco	31 224 136	14	0	2	2			1	1		320 000
9	Kuwait	2 851 144	1	Data not available	1	1			1			160 000
10	Lebanon	4 099 114	4	0	1	1			1			160 000
11	Libyan Arab Jamahiriya	6 160 48	3	0	1	1			1			160 000
12	Oman	2 595 132	10	Data not available	1	1			1			160 000
13	Pakistan	163 902 400	3	0	8	8		2	3	3		1 280 00
14	Opt	4 017 496	1	0	1	1			1			160 000
15	Qatar	821 313	1	0	1	1			1			160 000
16	Saudi Arabia	24 734 532	11	0	1	1			1			160 000
17	Somalia	8 698 534	0	0	1	1			1			160 000
18	Sudan	38 560 492	1	0	1	1			1			160 000
19	Syrian Arab Republic	19 928 518	1	0	1	1			1			160 000
20	Tunisia	10 327 285	7	0	1	1			1			160 000
21	United Arab Emirates	4 380 439	3	0	1	1			1			160 000
22	Yemen	22 389 172	3	0	1	1			1			160 000
	Total							3	24	7		5 440 000
	Total per region							480 000	3 840 000	1 120 000		

C. Costing sheet: standard equipment for one DST laboratory on solid media

Items (solid media)	Number	Unit cost (US$)
Desiccator, borosilicate glass, inner diameter 150-200 mm, lid with thread GL 32	2	273.26
Membrane vacuum pump for desiccator, pressure endpoint < 20 mbar	1	1093.04
Woulff flask consisting of borosilicate glass, 1000 ml with thread GL 45 screw cap	1	47.8205
Vacuum tube, 3m	1	27.326
Precision balance	1	1366.3
Sterile filling station of culture media, consisting of 250 ml Squibb sedimentation funnels or cylindric dropping funnels, with tube for pressure exchange, stopcocks made of glass and Teflon stopper, outlet diameter 4 mm	7	40.989
Refrigerator with freezing department	1	819.78
Refrigerator	1	409.89
Optional: chest freezer, 70 L, temperature range: -18 °C to - 28 °C, complete with cassettes and racks	1	1366.3
Pipettes 1 ml, glass, graduated 0,01 ml, conformity certified, pack of 10 pieces	3	27
Pipettes 2 ml, glass, graduated 0,02 ml, conformity certified, pack of 10 pieces	3	29
Pipettes 10 ml, glass, graduated 0,05 ml, conformity certified, pack of 10 pieces	3	30
Pipettes 5 ml, glass, graduated 0,1 ml, conformity certified, pack of 10 pieces	3	31
Pipette box aluminium with lid, autoclavable, suitable for 35 cm long pipettes	10	136.63
Total		7683

Note: All prices indicated are “free on board” (FOB) i.e. do not include shipping, insurance, import duties, local distributor margin for service and support, installation and maintenance.

Indicated quantities are based on experience and estimated for a laboratory performing 1000 first-line DST (and possibly 100 second-line DST) in addition to cultures. Quantities should be adjusted according to the actual workload and strategy used.

D. Costing sheet: standard equipment for one DST laboratory on liquid media

Additional equipment for liquid culture and/or DST		
Items	**Number**	**Unit cost (US$)**
Automated analyser for liquid culture media with growth detection based on a fluorescent signal, 960 vials	2	79 655
Cost of additional equipment for culture and DST laboratories (liquid media)		159 311

Note: Cost of standard equipment needed for upgrading one culture laboratory to do DST for first line medicines on liquid media US$ 160 000.

Table 3. Standard operating procedures, current situation, gaps and target

	Country	SOP availability	Gap	2010
1	Afghanistan	N	1	1
2	Bahrain	Y		0
3	Djibouti	N	1	1
4	Egypt	Y		0
5	Iran (Islamic Republic)	Y		0
6	Iraq	Y		0
7	Jordan	N	1	1
8	Morocco	Y		0
9	Kuwait	Y		0
10	Lebanon	Y		0
11	Libyan Arab Jamahiriya	Y		0
12	Oman	Y		0
13	Pakistan	Y		0
14	OPt	N	1	1
15	Qatar	Y		0
16	Saudi Arabia	Y		0
17	Somalia	N	1	1
18	Sudan	Y		0
19	Syrian Arab Republic	Y		0
20	Tunisia	Y		0
21	United Arab Emirates	Y		0
22	Yemen	Y		0

Table 4. National reference laboratory

A. Current situation and gaps

	Country	Current situation	Gap
1	Afghanistan	0	1
2	Bahrain	0	1
3	Djibouti	1	0
4	Egypt	1	0
5	Iran (Islamic Republic)	1	0
6	Iraq	0	1
7	Jordan	1	0
8	Morocco	1	0
9	Kuwait	1	0
10	Lebanon	1	0
11	Libyan Arab Jamahiriya	1	0
12	Oman	1	0
13	Pakistan	1	0
14	Opt	0	1
15	Qatar	1	0
16	Saudi Arabia	1	0
17	Somalia	0	1
18	Sudan	1	0
19	Syrian Arab Republic	1	0
20	Tunisia	1	0
21	United Arab Emirates	0	1
22	Yemen	1	0

B. Costing sheet: equipment for the establishment of a national reference laboratory

Item	Number	Unit cost (US$)
Base Support for Laminar Air Flow Cabinet	2	1025
BSC, class II	2	24 000
UPS for BSC	2	1640
Minishaker or Vortex	3	478
Optional: overhead stirrer, for at least 10 tubes (50 ml)	2	1640
Test tube rack 18/8 stainless steel, diameter 16 mm	5	38
Test tube rack 18/8 stainless steel, diameter 35 mm	5	31
Safety gas burner with glass chimney, footswitch for temporary ignition	2	574
Safety gas tubing with safety clamps on both ends, inner diameter 9mm	2	41
Inoculation loops, Platinum/Iridium wire, closed, 10 µl	6	123
Loop holder	12	10
Racks for loop holder	4	16
Stainless steel bucket with lid, capacity 10L	5	150
Discard bottle, stainless steel or thick walled glass with screw cap	5	4
Funnel, stainless steel 18/8, top diameter 120 mm	3	18
Safety box, PP, approx 3 L, for all sharps	25	4
Laboratory chair, disinfectable, 5 wheels, no arm rests	2	246
Incubator	2	9291
Centrifuge	1	8881
Centrifuge rotor	1	1230
Centrifuge rotor buckets	4	410
Aerosol tight lids for rotor buckets	4	137
Reducing adapter for 50 ml centrifuge tubes	4	109
Reducing adapter for 15 ml/12 ml centrifuge tubes	4	109
Autoclave	2	15 029

Item	Number	Unit cost
First aid kit	1	328
Anemometer	1	2049
Analytical balance	1	4782
pH meter	1	820
Bunsen burner with fine tuning	1	143
Tripod stand	1	16
Water bath, capacity approximately 20 L	1	1503
Magnetic stirrer	1	581
Magnetic stirring bars, round-shaped, polytetrafluorethylen (PTFE) coated. Set of 10: 1x 15 mm, 2X 20 mm, 2x 25 mm, 1x 30 mm, 2x 40 mm, 2x 50 mm length.	1	68
Sterile filling station of culture media, consisting of 1000 ml Squibb sedimentation funnels or cylindric dropping funnels, with tube for pressure exchange, stopcocks made of glass and Teflon stopper, outlet diameter 4 mm	3	68
Stative for Squibb sedimentation funnels consisting of plate, rod and clamp	3	137
Inspissator for coagulation of egg-based culture media	1	8198
Freezing department (-70°C)	1	820
Refrigerator	2	410
Stainless steel funnel, short wide stem with air drain, diameter 150 mm on top	5	14
Swan neck bottles (PE flask, narrow neck with screw cap and water dispenser) set of one each 250, 500, 1000ml	5	16
Bowl, plastic, 500 x 350 mm	5	3
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 2000 ml	2	34
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 1000 ml	10	164
Erlenmeyer flasks, borosilicate 3.3, wide neck, autoclavable, 500 ml	10	82
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 250 ml	10	61
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, 100 ml, pack. unit 10	20	55
Erlenmeyer flasks, borosilicate 3.3, wide neck, graduated, autoclavable, 50 ml	20	55
Measuring cylinder, class A; TPX, autoclavable, 1000 ml, graduated 10.0 ml	5	22
Measuring cylinder, class A; TPX, autoclavable, 500 ml, graduated 5.0 ml	5	14
Measuring cylinder, class A; TPX, autoclavable, 250 ml, graduated 2.0 ml	5	9

Item	Number	Unit cost (US$)
Measuring cylinder, class A; TPX, autoclavable, 100 ml, graduated 1.0 ml	5	6
Measuring cylinder, class A; TPX, autoclavable, 50 ml, graduated 1.0 ml	5	5
Thick-walled glass flask for preparation of culture medium; with flanged rim; 2500 ml	6	59
Thick walled bottles, borosilicate 3.3, graduated, transparent, PP ring and cap, 2000 ml	3	25
Thick walled bottles, borosilicate 3.3, graduated, transparent, PP ring and cap, 1000 ml	10	14
Thick walled bottles, borosilicate 3.3, graduated, transparent, PP ring and cap, 500 ml	5	9
Thick walled bottles, borosilicate 3.3, graduated, amber, PP ring and cap, 11000 ml	3	16
Thick walled bottles, borosilicate 3.3, graduated, amber, PP ring and cap, 1, 2000 ml	2	27
Screw caps with weld in PFTE membrane, 0.2 µm pore size, autoclavable to 140 °C	10	3
Laboratory beaker, EFTE, low form with graduation and spout, 2000 ml	3	137
Laboratory beaker, EFTE, low form with graduation and spout, 1000 ml	3	68
Laboratory beaker, EFTE, low form with graduation and spout, 600 ml	10	55
Laboratory beaker, EFTE, low form with graduation and spout, 250 ml	10	25
Laboratory beaker, EFTE, low form with graduation and spout, 100 ml	10	15
Laboratory glassware drying rack, wall mounted; polystyrene; minimum 24 pegs	1	184
Funnel, soda lime glass, plain, short stem, d = 75 mm	5	7
Funnel, soda lime glass, plain, short stem, d = 125 mm	5	11
Powder funnel , diameter 100mm	5	11
Glass beads, massive glass, 5 mm diameter	2	34
Glass beads, massive glass, 3 mm diameter	1	34
Thick walled Pyrex tubes with ISO winding and autoclavable screw cap with tight gasket, 16x100 mm; package of 100	10	109
Strainer, stainless steel, 1 grip, 2 eyes, diameter 20 cm	1	22
Forceps; pointed; straight; 18/8 stainless steel, polished	5	9
Optional: Laboratory washer-disinfector for laboratory glass, 2 baskets	1	5055
Separate water supply for deionised water with conductivity measure R 3/4" with digital display and hose-set for in-and outflow	1	929
Aqua purificator cabinet for two de-mineralising cartridges	1	410
microscope	2	2000
MGIT BACTEC machine	1	80 000
UVL	1	2000

C. Additional equipment for DST on solid media

Items (solid media)	Number
Desiccator, borosilicate glass, inner diameter 150-200 mm, lid with thread GL 32	2
Membrane vacuum pump for desiccator, pressure endpoint < 20 mbar	1
Woulff flask consisting of borosilicate glass, 1000 ml with thread GL 45 screw cap	1
Vacuum tube, 3m	1
Precision balance	1
Sterile filling station of culture media, consisting of 250 ml Squibb sedimentation funnels or cylindric dropping funnels, with tube for pressure exchange, stopcocks made of glass and Teflon stopper, outlet diameter 4 mm	7
Refrigerator with freezing department	1
Refrigerator	1
Optional: Chest freezer, 70 L, temperature range: -18 °C to - 28 °C, complete with cassettes and racks	1
Pipettes 1 ml, glass, graduated 0,01 ml, conformity certified, pack of 10 pieces	3
Pipettes 2 ml, glass, graduated 0,02 ml, conformity certified, pack of 10 pieces	3
Pipettes 10 ml, glass, graduated 0,05 ml, conformity certified, pack of 10 pieces	3
Pipettes 5 ml, glass, graduated 0,1 ml, conformity certified, pack of 10 pieces	3
Pipette box aluminium with lid, autoclavable, suitable for 35 cm long pipettes	10
Development of a manual	**Cost in US$**
Developing a manual for laboratory TB diagnosis, laboratory infection control and EQA	10 000
Equipment	277 000
Additional equipment for DST on solid media	
Additional equipment for DST on solid media	8000
Total for one NRL	295 000
Cost of additional items to establish links with supranational reference laboratory	
Panels of isolates (US$ 5000 per panel x 22 countries per year)	110 000
Training room	5000

Table 5. Line probe assay

A. Current situation and gaps

	Country	Population	LPA availability	Target (1 lab/20 000 000)	Gap	Cost of expertise/technical assistance from Regional Office (US$)
1	Afghanistan	27 145 276	0	1	1	5000
2	Bahrain	752 647	0	1	1	5000
3	Djibouti	833 025	0	1	1	5000
4	Egypt	75 497 912	0	4	4	5000
5	Iran (Islamic Republic)	71 208 384	0	4	4	5000
6	Iraq	28 505 843	0	1	1	5000
7	Jordan	5 924 247	0	1	1	5000
8	Morocco	31 224 136	0	2	2	5000
9	Kuwait	2 851 144	0	1	1	5000
10	Lebanon	4 099 114	0	1	1	5000
11	Libyan Arab Jamahiriya	6 160 48	0	1	1	5000
12	Oman	2 595 132	0	1	1	5000
13	Pakistan	163 902 400	0	8	8	5000
14	Opt	4 017 496	0	1	1	5000
15	Qatar	821 313	0	1	1	5000
16	Saudi Arabia	24 734 532	0	1	1	5000
17	Somalia	8 698 534	0	1	1	5000
18	Sudan	38 560 492	0	2	2	5000
19	Syrian Arab Republic	19 928 518	0	1	1	5000
20	Tunisia	10 327 285	0	1	1	5000
21	United Arab Emirates	4 380 439	0	1	1	5000
22	Yemen	22 389 172	0	1	1	5000
Total						110 000

B. Costing sheet: standard equipment needed to establish one laboratory doing LPA

Items	Number	Unit cost (US$)
PCR-Workstation UV	1	3142.49
Thermocycler	1	4782.05
Ultrasonic bath	1	1639.56
Thermoshaker for hybridization	1	3005.86
Optional 8-channel pipette, 5 - 50 µl	1	587.509
Optional 8-channel pipette, 50 - 300 µl	1	587.509
Optional Electrophoresis, horizontal mini gel system	1	409.89
Optional Power supply for electrophoresis	1	478.205
Optional UV-light illuminator at least 200 x 200 mm window	1	1639.56
Optional Microwave oven, approx. 900 W, inner volume minimum 20 litres	1	819.78
Racks, for tubes 1.5 - 2 ml, 10 mm diameter, at least 20 positions	10	6.8315
Centrifuge for standard reaction tubes	1	2459.34
Floating rack for 20 seats, diameter 10 mm, 2ml, for ultrasonic bath	2	9.5641
Deep freeze storage box with lid for 2 ml cryovials , autoclavable PP	10	10.9304
Deep freeze storage box with lid for 0.2ml PCR tubes, autoclavable PP	10	11.06703
1-channel pipette, variable from 0.5 - 10 µl,	3	273.26
1-channel pipette, variable from 10 - 100 µl	4	273.26
1-channel pipette, variable from 100 - 1000 µl,	4	273.26
Racks suitable for pipettes offered, at least four positions	4	109.304
Refrigerator with freezing department	1	409.89
Freezer	1	546.52
Stand for multichannel pipettes	1	122.967
Hand-dispenser pipette, 5 dosage steps, suited for combitips	2	218.608
Tripod stand for waste bags of 2 L	5	10.24725
Cost of equipment for molecular tests		24 870.07575

Note: Indicated quantities are based on experience and estimated for a laboratory performing approximately 1000 line-probe assays. Quantities should be adjusted according to the actual workload and strategy used.

Table 6. MDR-TB centres

A. Establishment of two MDR-TB centres per country

Activities	Entity in charge	Cost per country (US$)	Cost per region (US$)
2.1. Establishment/upgrade/renovation of two DR-TB centres	Countries	200 000 per country	4 200 000
2.2. One medical store appended to every center for second-line medicines	Countries	10 000	210 000
2.3. Infection control supplies (permanent) for the two centres	Countries	53 000	1 166 000
2.4. Consumable infection control tools	Countries	9230 per centre per year	203 060 per centre per year per region
2.5. One room for minor procedures with negative pressure in each centre	Countries	120 000 for two centres in every country	2 640 000
2.6. Negative pressure room per centre to isolate XDR-TB cases	Countries	120 000 for two centres in every country	2 640 000
2.7. Incentivs of the working staff (2 doctors, 8 nurses, 1 pharmacist, 1 admin, 2 workers per centre: about US$ 1500 per centre per month)	Countries	18 000 per centre per year	792 000 per year per region

B. Detailed cost of establishment one MDR-TB centre

Air conditioning					2000
Refrigerators					2000
Shelves/thermometers/registers/cards					1000
Cost of upgrade/renovate one ward (including administrative measures of infection control)					30 000
Maintenance per year					3 000
Total cost of upgrade/renovations					38 000

Note: Infrastructure for one centre/cost of upgrade/renovate one medical store for second-line medicines.
The proposed design of the ward comprises 6 rooms (3 for males and other 3 for females, one room every different patient category) each of 6 x 6 x 3 metres in dimensions and accommodates about four beds.

C. Infection control measures for MDR centre

	Unit cost (US$)	No. needed*	Total (US$)
Cost of one exhaust fans according to room volume to ensure at least 12 air changes per hour ACH and control air direction	100	12	1200
Smoke tube kit	110	1	110
Cost of one vaneometer	29	1	29
Cost of one UV radiometer	650	1	650
Cost of one fit testing kit	500	1	500
One UVL (open) covers about four square metres (the fixture with 2 UV lambs) about 6000 hour usage	2000	12	24 000
Total for permanent infection control supplies per one ward once			26 489
Sputum collection booth (optional)	24 000		
Negative pressure for one isolation room (for XDR-TB cases) optional	60 000		
Maintenance of one UVL/year	50	24 UVL	1200
Annual calibration of UV of one radiometer	80	1	80
Surgical masks for the patients (100 units)	15	100	1500
Cost of one box of N95 respirator (20 units)	60	50	3000
Cost of one gown	5	300	1500
Cost of one package of slipper/shoe cover (for 100 units)	3	100	300
Cost of one goggle	15	50	750
Cost of one hair cover	4	100	400
Gloves (for 50 pairs)	5	100	500
Total cost of consumable infection control tools for one ward per year			9230

* Based on the proposed design mentioned in the note under Table 16.

Table 7. Second-line medicines

A. Cost of second-line medicines

Country	Estimated MDR no in new TB cases	Average price of treatment course* (US$)	Budget needed (US$)
Qatar	2	6200	12 400
Lebanon	5	6200	31 000
Bahrain	7	6200	43 400
Kuwait	13	6200	80 600
United Arab Emirates	16	6200	99 200
Jordan	17	6200	105 400
Opt	25	6200	155 000
Libyan Arab Jamahiriya	28	6200	173 600
Tunisia	68	6200	421600
Morocco	137	6200	849 400
Syrian Arab Republic	192	6200	1 190 400
Djibouti	220	6200	1 364 000
Saudi Arabia	232	6200	1 438 400
Somalia	328	6200	2 033 600
Egypt	395	6200	2 449 000

Country	Estimated MDR no in new TB cases	Average price of treatment course* (US$)	Budget needed (US$)
Iraq	478	6200	2 963 600
Yemen	500	6200	3 100 000
Iran (Islamic Republic of)	777	6200	4 817 400
Afghanistan	1415	6200	8 773 000
Sudan	1696	6200	10 515 200
Pakistan	9880	6200	61 256 000
Total	16 431		101 872 200

* Based on the mean of treatment course price per patient estimated in the study conducted in four countries (the Phillippines, Estonia, Latvia, Russian Federation-budgeting tool) and Egypt average cost of treatment according to latest IDA prices.

Estimated number of MDR-TB cases in the Region among new and retreatment cases is about 25 475 cases per year costing US$ 157 945 000 to treat.

B. Mode A/Capreomycin use

The following tool can be used to calculate the total budget needed to treat one patient according to the medicines constituting the treatment regimen. The numbers in red can be changed according to the regimen used.

Group	Medicine name (choose the medicines constituting the regimen used)	No of patients	Number of treatment days*	Number of units per day**	Amount needed for the whole treatment course	Units per pack supplied by GDF/IDA	No of packs needed for complete course of treatment	Price of one pack (US$)	Total (US$)
Oral first-line anti-TB medicines	Ethambutol 400 mg	1	730	3	2190	672	3.3	17.0	55.4
	Pyrazinamide 400 mg	1	730	4	2920	672	4.3	10.0	43.5
Injectable	Capreomycin 1 gm vial	1	240	1	240	1	240.0	4.0	960.0
Fluoroquinolones	Levofloxacin 250 mg	1	730	4	2920	100	29.2	6.0	175.2
Oral second-line bacteriostatic medicines	Cycloserine 250 mg tab	1	730	3	2190	100	21.9	67.0	1467.3
	Ethionamide 250 mg tab	1	730	4	2920	100	29.2	11.0	321.2
	PAS sodium (dose in grams)	1	240	12	2880	100	28.8	25.0	720.0
	Para amino saliycilic acid (4 gm sachets)	1	490	3	1470	30	49.0	58.0	2842.0

*Number of treatment days calculated on the assumption that the majority of the patients convert sputum by the sixth month and treatment continues for at least 18 months after conversion.

** The number of units per day calculated according to the maximum daily dose.

The cost of treatment course is calculated based on the assumption of using PAS sodium during the hospitalization period and PASER during ambulatory treatment to facilitate handling of the medicine by health staff.
Ethambutol is added to the regimen based on the assumption that DST reveals susceptibility to Ethambutol otherwise it should be removed from the list.

C. Mode B/Kanamycin use

Group	Medicine name (choose the medicines constituting the regimen used)	No of patients	Number of treatment days*	Number of units per day**	Amount needed for the whole treatment course	Units per pack supplied by GDF/IDA	No of packs needed for complete course of treatment	price of one pack (US$)	Total (US$)
Oral first-line anti-TB medicines	Ethambutol 400 mg	1	730	3	2190	672	3.3	17.0	55.4
	Pyrazinamide 400 mg	1	730	4	2920	672	4.3	10.0	43.5
Injectables	Kanamycin 1 gm vial	1	240	1	240	1	240.0	1.0	240.0
Fluoroquinolones	Levofloxacin 250 mg	1	730	4	2920	100	29.2	6.0	175.2
Oral second-line bacteriostatic medicines	Cycloserine 250 mg tab	1	730	3	2190	100	21.9	67.0	1467.3
	Ethionamide 250 mg tab	1	730	4	2920	100	29.2	11.0	321.2
	PAS sodium (dose in grams)	1	240	12	2880	100	28.8	25.0	720.0
	Para amino saliycilic acid (4 gm sachets)	1	490	3	1470	30	49.0	58.0	2842.0
Total									5766

* Number of treatment days calculated on the assumption that the majority of the patients convert sputum by the sixth month and treatment continues for at least 18 months after conversion.

** The number of units per day calculated according to the maximum daily dose.

The cost of treatment course is calculated based on the assumption of using PAS sodium during the hospitalization period and PASER during ambulatory treatment to facilitate handling of the medicine by health staff.

Ethambutol is added to the regimen based on the assumption that DST reveals susceptibility to Ethambutol otherwise it should be removed from the list.

D. Mode C/Amikacin use

Group	Medicine name (choose the medicines constituting the regimen used)	No of patients	Number of treatment days*	Number of units per day**	Amount needed for the whole treatment course	Units per pack supplied by GDF/IDA	No of packs needed for complete course of treatment	Price of one pack (US$)	Total (US$)
Oral first-line anti-TB medicines	Ethambutol 400 mg	1	730	3	2190	672	3.3	17.0	55.4
	Pyrazinamide 400 mg	1	730	4	2920	672	4.3	10.0	43.5
Injectable	Amikacin 500 mg vial	1	240	2	480	10	48.0	15.0	720.0
Fluoroquinolones	Levofloxacin 250 mg	1	730	4	2920	100	29.2	6.0	175.2
Oral second-line bacteriostatic medicines	Cycloserine 250 mg tab	1	730	3	2190	100	21.9	67.0	1467.3
	Ethionamide 250 mg tab	1	730	4	2920	100	29.2	11.0	321.2
	PAS sodium (dose in grams)	1	240	12	2880	100	28.8	25.0	720.0
	Para amino saliycilic acid (4 gm sachets)	1	490	3	1470	30	49.0	58.0	2842.0
									6246

*Number of treatment days calculated on the assumption that the majority of the patients convert sputum by the sixth month and treatment continues for at least 18 months after conversion.

** The number of units per day calculated according to the maximum daily dose.

The cost of treatment course is calculated based on the assumption of using PAS sodium during the hospitalization period and PASER during ambulatory treatment to facilitate handling of the medicine by health staff.

Ethambutol is added to the regimen based on the assumption that DST reveals susceptibility to Ethambutol otherwise it should be removed from the list.

Table 8. Cost of ancillary medicines

Estimated number of MDR-TB cases per year in the Region	25 475
Cost of ancillary medicines per patient*(US$)	600
Total for the Region	15 285 000

Note: Average US$ 25 per month for the 24-month treatment period per patient.

Table 9. Initial investigation and follow-up

A. Total cost of initial investigations and follow up according to the estimated number of MDR-TB patients in the Region

Country	Estimated MDR no in new TB cases	Estimated MDR no in previously treated TB cases	Total number of expected MDR-TB patients per country per year	Cost of initial investigation and follow up for one patient* (US$)
Lebanon	5	6	11	1400
Bahrain	7	4	11	1400
Kuwait	13	3	16	1400
United Arab Emirates	16	12	28	1400
Jordan	17	3	20	1400
Opt	25	11	36	1400
Libyan Arab Jamahiriya	28	5	33	1400
Tunisia	68	16	84	1400
Morocco	137	134	271	1400
Syrian Arab Republic	192	95	287	1400
Djibouti	220	229	449	1400
Saudi Arabia	232	143	375	1400
Somalia	328	84	412	1400
Egypt	395	567	962	1400
Iraq	478	492	970	1400
Yemen	500	73	573	1400
Iran (Islamic Republic of)	777	402	1179	1400
Afghanistan	1415	724	2139	1400
Sudan	1696	681	2377	1400
Pakistan	9880	5353	15 233	1400

B. Detailed cost of initial investigation and follow up for one MDR-TB patient during treatment period

Initial and follow-up investigations:	Expected no. during treatment*	Unit cost (US$)	Total cost (US$)
Direct smear microscopy	24	3	72
Culture on solid media	15	20	300
Culture on liquid media	15	20	300
DST on solid media	2	35	70
DST on liquid media	2	35	70
HIV	1	5	5
Liver function	8	10	80
serum electrolytes	8	15	120
Fasting and PP blood glucose**	3	5	15
X ray	5	5	25
Audiometery***	4	20	80
Visual acuity	4	5	100
Pregnancy test	1	2	2
TSH	5	5	25
Haemoglobin and CBC	15	5	75
Creatinine and blood urea and urina analysis	7	4	28
Total			1367

Note: The average cost is about US$ 1400.00 per patient.
The unit cost is estimated.
***Please calculate the cost by re-visiting the consumable cost in your country: the above are examples obtained from the WHO price list.
** 10% of the patients are expected to be diabetic and frequency of the test will be on a monthly basis on average with excess budget of US$ 120 per patient.
*** One at baseline then monthly for some patients, at least four times.

Table 10. Strengthening DOTS

A. Treatment supporter incentives

Country	Estimated MDR no in new TB cases	Estimated MDR no in previously treated TB cases	Total number of expected MDR-TB patients per country per year	Number of treatment supporters needed per country for MDR-TB patients*
Qatar	2	0	2	1
Lebanon	5	6	11	6
Bahrain	7	4	11	6
Kuwait	13	3	16	8
United Arab Emirates	16	12	28	14
Jordan	17	3	20	10
Opt	25	11	36	18
Libyan Arab Jamahiriya	28	5	33	17
Tunisia	68	16	84	42
Morocco	137	134	271	136
Syrian Arab Republic	192	95	287	144
Djibouti	220	229	449	225
Saudi Arabia	232	143	375	188
Somalia	328	84	412	206
Egypt	395	567	962	481
Iraq	478	492	970	485
Yemen	500	73	573	287
Iran (Islamic Republic)	777	402	1179	590
Afghanistan	1415	724	2139	1070
Sudan	1696	681	2377	1189
Pakistan	9880	5353	15 233	7617
Total	16 431	9037	25 468	12 734

Note: WHO cost list for treatment supporter incentive is US$ 10 per week or US$ 960 per each treatment course based on the assumption that treatment course duration is 24 months.
* Calculated on the assumption that one treatment supporter manages two patients.
• Please calculate the cost by re-visiting the following consumable cost in the country; the following are examples obtained from the WHO price list.

B. Patient incentives

Country	Total number of expected MDR-TB patients per country per year
Qatar	2
Lebanon	11
Bahrain	11
Kuwait	16
United Arab Emirates	28
Jordan	20
Opt	36
Libyan Arab Jamahiriya	33
Tunisia	84
Morocco	271
Syrian Arab Republic	287
Djibouti	449
Saudi Arabia	375
Somalia	412
Egypt	962
Iraq	970
Yemen	573
Iran (Islamic Republic of)	1179
Afghanistan	2139
Sudan	2377
Pakistan	15 233
Region	25 468

Note: WHO cost list for incentives for patients (US$10 per week = US$960 per treatment course for every patient. Please calculate the cost by re-visiting the consumable cost in your country, the following are examples obtained from the WHO price list.

C. Training costs of treatment supporters per country

Country	Number of treatment supporters needed per country for MDR-TB patients*	Training workshops per country	Cost of training workshops
Qatar	1	1	2800
Lebanon	6		
Bahrain	6		
Kuwait	8		
United Arab Emirates	14	1	2800
Jordan	10	1	2800
Opt	18	1	2800
Libyan Arab Jamahiriya	17	1	2800
Tunisia	42	2	5600
Morocco	136	5	12 647
Syrian Arab Republic	144	5	13 393
Djibouti	225	7	20 953
Saudi Arabia	188	6	17 500
Somalia	206	7	19 227
Egypt	481	16	44 893
Iraq	485	16	45 267
Yemen	287	10	26 740
Iran (Islamic Republic of)	590	20	55 020
Afghanistan	1070	36	99 820
Sudan	1189	40	110 927
Pakistan	7617	254	710 873
Total	12 734	427	1 196 860

Note: 10% of the training budget of treatment supporters will be allocated yearly to increase the number of supporters to cover newly-detected patients and catchment areas.

D. One-day training of treatment supporters

Items	Unit	Total cost (US$)
1. Number of participants requiring per diem (per session)	30	
2. Per diem (average per person and per day) (US$)	30	900
3. Cost of transportation (per participant) (US$)	10	300
4. Number of national facilitators (average per course)	1	
5. Per diem (per national facilitator and per day) (US$)	100	100
6. Cost of transportation (per national facilitator)	10	10
7. Miscellaneous		200
Total		1510