

ASIAM PROPOSAL FOR ROUND 10 OF THE GLOBAL FUND

Summary of Round 10 Proposal

Provide a summary of the tuberculosis proposal.

Problem description

The TB burden in Asiam is one of the highest in the world. WHO estimates that in 2008 approximately 99,000 people in Asiam were suffering from TB, including 11,000 HIV-positive persons. The Government of Asiam has implemented the DOTS Strategy since 1994 and in 2010 the people of Asiam had access to 210 laboratories providing diagnostic examinations for TB and more than 1,000 health facilities providing treatment for TB. Though in 2008 Asiam achieved to reduce the prevalence rate of TB, relative to 1990, by 50% well ahead of the 2015 target, it is estimated that the incidence is declining with about 1% per year only. At this stage of the epidemic the main challenge of the program is to accelerate the decline of the incidence by identifying TB cases as early as possible, thus minimizing the period that they are transmitting TB in the community.

Goal of the proposal

The goal of the proposal is to improve the health of the people of Asiam, by reducing the morbidity and the mortality rates due to tuberculosis in order to contribute to socio-economic development and poverty reduction in Asiam

Strategies

The objectives, service delivery areas and activities of the proposal are supporting two complementary strategies to enhance early detection of TB cases, i.e. reducing patient delay by increasing awareness of TB, reducing barriers to diagnosis by increasing access and active case-finding among high risk groups at one side and retooling the laboratory network with technologies, which have a higher sensitivity to detect tuberculosis at the other side.

Objectives of the proposal

1. Pursuing high quality DOTS expansion and enhancement
2. Addressing MDR-TB, TB/HIV, childhood TB, other high risk groups and challenges
3. Empowering people with TB and engaging all health care providers and communities
4. Enabling and promoting research

SDA's, key activities, target groups and expected outcomes

SDA 1.1 Improving diagnosis:

- a. The program aims to examine approximately 900,000 suspects in 5 years. There will be 228 microscopy centers, which will examine approximately 3 million direct smears in 5 years. By the end of the project, 40 additional laboratories will be equipped with LED fluorescence microscopes, taking the total to 65 laboratories. The target group will be all suspects for TB, i.e. about 2% of the population.
- b. The program will expand culture to 5 laboratories. The target

populations for culturing are approximately 6,000 suspects of MDR-TB and 30,000 sputum negative cases (most of them being people living with HIV) in 5 years. 2 samples per suspect will be cultured. The total number of cultures in 5 years will be over 75,000.

- c. The central laboratory will provide DST. The target population for DST is over 6,000 MDR-TB suspects with positive cultures in 5 year. The central laboratory of NTP will be equipped to perform molecular testing to detect HR resistant strains.
- d. Finally, the program will pilot the use of digital X-ray machines to enhance the quality of X-ray reading for the diagnosis of tuberculosis in smear-negative patients, children and PLH. For this purpose 5 units will be procured and installed. The program will further procure 200,000 X-ray films (and related consumables) per year for use by conventional machines.

SDA 1.2: Procuring and supplying first-line drugs: The program will procure anti-tuberculosis drugs for an estimated number of 200,000 new and previously treated tuberculosis patients, including 15,000 children. The treatment regimen for new cases, all forms, is 2ERHZ/4RH and for previously treated cases 2SHRZE/1HRZE/5RHE. The expected outcome is a treatment success rate of at least 85%.

SDA 1.3 Monitoring, evaluation and impact measurement: The implementation and performance of the program will be monitored and evaluated using the WHO recommended recording and reporting system, by regular supervisory visits of TB staff at the different level and by monthly and quarterly review meetings at health district, provincial and national level. Each year the program organizes the annual TB conference to review program implementation countrywide with its partners and staff. The program will introduce an internet based surveillance system for TB linking the provinces in real time to NTP. The program plans to conduct the third drug resistance and prevalence surveys in respectively 2014 and 2015.

SDA 1.4 Building Human Resource Capacity: The HRD plan includes training of various categories of government staff, non-government staff and community representatives, inter-provincial study tours, participation of program staff in international conferences, meetings and study tours. In all 77 health districts, NGOs will implement and organize workshops for health district and HC staff and for DOT supervisors. TB staff at health facilities will receive incentives in accordance with the policy of the Government. The proposal includes funding to provide external technical assistance to the program by the WHO and other agencies.

SDA 1.5 Managing and administering the grant (as Principal Recipients): The proposal includes funding for staffing and operating the offices of the two PRs, NTP and KNCV. The PRs will meet quarterly with the sub-recipients to review program implementation and financial reporting. The PRs will conduct supervisory visits to monitor the performance of the SRs in the field.

SDA 2.1 Addressing the challenges of multi-drug resistant TB: The NTP

plans to diagnose and treat 700 MDR-TB cases during the plan period, scaling up from 120 cases in Y1, 130 cases in Y2, 140 cases in Y3, 150 cases in Y4 and 160 cases in Y5. The strategy is to provide culture to all previously treated smear-positive TB cases, all new smear-positive cases, which are still smear-positive after 3 months of treatment with the first line regimen and smear-positive contacts of MDR-TB index cases. Proved MDR cases will be treated with 6 Z E Km (or Cm) Lfx (or Mfx) Eto Cs (or PAS)/18 Z E Lfx (or Mfx) Eto Cs (or PAS). The program has currently 9 MDR-TB treatment sites with 45 isolation rooms. The program will expand PMDT to 25 treatment sites.

SDA 2.2 Addressing the challenges of TB/HIV:

- a. The targeted population is all notified TB cases (200,000 in 5 years). The TB/HIV strategy of the NTP is based on the country's revised framework for TB/HIV. The core activity of the TB program is ensuring HIV testing of the majority of notified TB cases and providing them with care. The approach is provider-initiated counseling and testing (PICT) at health center level and withdrawing and sending of blood samples to VCCT centers for HIV testing. The program will further provide X-ray films for screening of PHL and culturing of sputum of smear-negative PHL, who are still suspect of TB. The expected outcome is to increase the proportion of TB cases with HIV test results from 75% to 90%.
- b. The AIDS program and NTP will collaborate in a complementary manner to implement the SOP's of the 3 'I's Strategy. The target population is all registered PHL (approximately 70,000 per year) in 55 OI/ART sites. PHL will be selected for TB screening based on symptom screening. 95% of PHL enrolled in HIV care will be screened for TB. It has been experienced that 10-15% of those screened will have active TB. All HIV-positive TB patients will be enrolled on ART. In addition, all HIV-positive patients who are unlikely to have TB will be put on Isoniazid Preventive Therapy, procured using this grant.

SDA 2.3 Ensuring TB Infection control (TB IC): The program will implement TB IC in 25 sites for MDR-TB treatment, all health district TB wards and OI/ART clinics of the AIDS program. Additionally, all TB supervisors and TB care workers will be trained on TB infection control. 240 TB staff and caretakers will receive N95 masks once weekly. TB suspects and patients will receive surgical masks when attending health facilities.

SDA 2.4 Addressing the needs of vulnerable and high risk groups

- a. Active case finding campaigns using X-ray screening will be conducted annually in high prevalence areas in 12 provinces. Each year, 40 sites will be included. The average number of people screened per site will be 13,500. The experience is that on average the yield per site is 20 to 25 cases. The aim is to detect cases in an early stage of TB in vulnerable populations.
- b. TB control activities for prison settings will be implemented by three NGO's, covering 25 prisons with approximately 14,000 inmates.
- c. To increase case finding of TB in children the program will organize training courses for clinicians to strengthen the capacity to diagnose

childhood TB. The program will implement routine screening of family members of smear-positive index cases. The program aims to detect about 3,000 children with TB each year.

- d. The NCHP will conduct education campaigns in two provinces to create awareness about the relation between TB and smoking and promote cessation of smoking.

SDA 3.1 Implementing Advocacy, Communication and Social Mobilization

- a. The program aims at creating awareness about TB and influencing health-seeking behavior regarding TB of the general public by messages on TB through the different media. The proposal includes hiring mass media agencies to develop the messages, materials, spots and campaigns in close collaboration with NTP.
- b. Influential people at provincial level, teachers, religious leaders and journalists will be reached by organizing workshops and meetings. NTP will organize annual World TB Days in all 77 health districts.
- c. The Ministry of Education, Youth and Sport will contribute to TB control by creating awareness about TB in the educational system of Asiam. The Ministry will organize training of trainers at regional and district levels, consisting of 3,600 teachers of different schools, literacy classes and community learning centers. These trained teachers will then sensitize about 180,000 students, and conduct TB awareness competitions in six provinces.

SDA 3.2 Implementing Community DOTS (C-DOTS): The overall goal of C-DOTS implementation is to assure early case finding through referral of TB suspects by communities and to ensure DOT in patients who are unable to take drugs every day at HC level. 13 NGO's will implement C-DOTS activities covering all health centers from 2012. 67 health districts will be covered by Global Fund grants (Round 7 and 10), while the remaining 10 health districts will continue to be covered by one NGO using other sources of funding. The core activities of C-DOTS concern: conducting sensitizing workshops for all stakeholders, training of HC staff and DOT watchers, providing enablers to TB suspects and patients and monitoring and evaluating C-DOTS.

SDA 3.3 Implementing PPM-DOTS

7 NGOs will implement PPM-DOTS in 65 health districts. The core activities regard identification and referral of suspects by private providers. The proposal aims to increase the number of referrals till 20,000 per year, improve the proportion of successful referrals till 80% and contribute around 5% of the national number of all cases notified.

Objective 4: Enabling and promoting research

SDA 4.1: Conducting operational research

The program will conduct operational research regarding the following programmatic areas: smoking cessation in smoker-contacts of TB patients, diagnosing smear negative cases (using diagnostic committees), health seeking behavior and KAP survey (especially, including diagnostic and

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treatment delays), diagnosis and treatment of Mycobacterium Avium Complex in TB-HIV cases, intensified case finding among people living with HIV and their household contacts, and TB infection control in continuum of care, MDR-TB and prison settings.

4.1 National program

Describe:

- (a) current tuberculosis national prevention, treatment, and care and support strategies;
- (b) how these strategies respond comprehensively to current epidemiological situation in the country; and
- (c) the improved tuberculosis outcomes expected from implementation of these strategies.

(a) Current strategies

The current tuberculosis national prevention, treatment and care and support strategies are described in the *National Health Policies and Strategies for Tuberculosis Control in the Kingdom of Asiam 2011-2015*, published in 2010 and *National Strategic Plan for Tuberculosis Control in Asiam 2011-2015*. Both plans are in line with the Global Plan to Stop TB and the Regional Strategic Plan to Stop TB in the Western Pacific 2011-2015.

The main goal of the NTP is to contribute to improving the health of the people of Asiam in order to contribute to socio-economic development and poverty reduction in Asiam by reducing the morbidity and the mortality due to tuberculosis.

The major objectives of the NTP are:

- a. To consolidate and maintain high quality services nationwide in order to achieve universal access to quality diagnosis and treatment;
- b. To improve and ensure equitable access to TB services focusing on the poor and community participation;
- c. To effectively respond to TB/HIV co-infection, drug-resistant TB, childhood TB and other high risk groups and challenges;
- d. To ensure adequate resources and strengthening coordination for TB control and contribute to health systems strengthening;
- e. To strengthen Monitoring and Evaluation System and to promote research activities for TB control.

The National Health Strategic Plan for TB control has 7 building blocks:

1) Management structures. NTP assumes overall responsibility for the NTP to be implemented countrywide through the general health care delivery system. The major roles and functions of the NTP are:

- Formulation, monitoring and evaluation of the national policies, strategies, guidelines, protocols and plans for TB control with the purpose of providing quality TB services to all TB patients
- Promotion of Human Resource Development for TB Control at all levels

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- Provision and/or reinforcement of supervision, monitoring and evaluation of TB control activities at all levels.
- Organization of surveillance and research on topics relevant to the NTP.
- Promotion of advocacy communication and social mobilization for TB control.
- Strengthening of the National TB Reference Laboratory and the TB laboratory network.
- Coordination of TB control activities including those conducted by other government agencies, International Organizations, NGOs, private providers and communities.
- Coordination of partners and resource mobilization for TB control.
- Contribution to the strengthening of the health care system in both public and private sectors.

2) Plans and Guidelines. The National TB Control Program ensures the existence of clear and practical Policies, Strategies, Plans and guidelines for TB control.

3) Service Delivery. The National TB Control Program ensures, according to the national protocol and guidelines and in line with the International Standard of Tuberculosis Care, good quality, diagnostic, curative, preventive and promotive TB services, which are accessible to the community and free of charge. These TB services deliver and promote:

- Free TB diagnosis and treatment in public health services.
- Quality services by trained staff and persons using hospitalization, ambulatory, and DOT at home approaches, giving emphasis on the implementation of DOTS at health center and in the community.
- TB screening and diagnosis, which include support for accessing service facilities, antibiotic therapy and X-ray examination as well as capacity building in related fields.
- Specific services to deal with TB/HIV, MDR-TB, smear-negative PTB, EPTB and TB in children.
- Laboratory examinations for TB including culturing, using solid and liquid media, DST, LED fluorescence microscopy, and molecular tests.
- Community involvement in TB control, including community members and former TB patients.
- Partnerships with the private sector, NGOs, and IOs and other government institutions for TB control, including TB in the workplace.
- BCG vaccination to be delivered to all children according to the national immunization program strategies.
- Preventive activities including infection control in health facilities.
- Chemoprophylaxis, including IPT, to target groups such as PLH and TB contacts under five years of age.
- Physiotherapy to TB patient as a supplement to curative care at hospital level.
- Active case finding among selected groups such as TB contacts, in particular children, PLH, and targeted people in high prevalence areas/settings.
- ACSM activities.

4) Anti-TB drugs and TB laboratory supplies. The Ministry of Health will seek to ensure that financial inputs are fully mobilized from all sources for TB control activities and used effectively and efficiently in TB control, and that there is uninterrupted supply of good quality first and second line anti-TB drugs, and diagnostic and laboratory equipment and supplies.

5) Investment. The Ministry of Health will seek to ensure that priority is given to investment in human and material resources for TB control activities. The strategies are among others to:

- Strengthen the management structure at all levels.
- Developing human resources for TB control at all levels.
- Investing in physical infrastructure and in logistic support for the delivery of appropriate TB services, which include TB wards, laboratory and x-ray facilities.

6) Health Information and Research. NTP will strengthen the information system and promote research activities in order to better manage the program. Research topics include the epidemiological patterns of the disease, health-seeking behavior and other issues related to TB in Asiam. Strategies include:

- Enhancing information technology including the use of telecommunication, appropriate database, electronic system, and software for effective planning, monitoring and evaluation
- Conducting surveys that are critical for the NTP, such as TB Prevalence and Drug Resistance Surveys, etc.
- Organizing other studies including clinical/operational research necessary for the NTP such as the health-seeking behaviors of TB patients, client satisfaction, impact of TB on socio-economic development etc.

7) Partnerships. Both internal and external partnerships are seen as core elements in achieving NTP objectives.

(b) How these strategies respond to the current epidemiological situation

By the end of 2009 the NTP provided the following services:

- 210 sputum microscopy centers provide sputum smear-examination by direct microscopy. The diagnostic network further includes culturing in three laboratories and DST in one laboratory. All referral hospitals are providing Chest Radiography for screening of suspects with negative sputum smear results.
- Standardized short-course chemotherapy services are available in the following numbers of health facilities of the country: five national hospitals, 80 referral hospitals, 960 health centers and 25 health posts. Patients receive the WHO recommended regimens: 2HRZE/4RH for new cases and 2HRZES/1HRZE/4RHE for previously treated cases.
- Treatment is provided to TB patients under DOT by a health worker either in a hospital or on ambulatory basis in TB units or health centers.
- 744 (76%) of the health centers provide TB treatment at village level, as a considerable proportion of the patients are not able to attend daily at the health centers due to distance, condition and poverty. This approach called C-DOTS is implemented in partnership with several NGO's in 68 health districts. Different types of village health workers, referred to as DOTS watchers, have been trained in identifying and referring suspects of TB and supervise treatment of TB cases.
- Up till 2009 staffs of 74 health districts were trained in TB-HIV collaborative activities. In 2009 more than 25,000 TB patients were tested for HIV. HIV-positive TB patients are started on CPT and referred to the OI clinics. ART is provided by the AIDS program to all HIV-positive TB patients. In 2009 4,667 PHL were screened for

TB. 33% were diagnosed with active TB and 43 patients received IPT.

- By the end of 2009 there were 9 PMDT sites with 45 isolation rooms. 329 MDR suspects were screened with DST and 39 were confirmed MDR-TB. The cumulative number of MDR-cases started on SLD from 2006 till end 2009 is 86. There was one XDR patient.
- By the end of 2009 the NTP had engaged in PPM-DOTS in 38 health districts in 11 provinces. In 2009 the private providers referred 9,781 suspects of which 5,540 reported to a public health facility. 564 (10%) proved smear-positive. In total 769 TB cases were treated by the private sector in 2009.

(c) Improved outcomes expected

In addition to the strategies and policies in the plan period 2006-2010, the Strategic Plan for TB control in Asiam 2011-2015 aims at improving TB outcomes in three main areas: a) Early case detection of new cases, b) Case detection and treatment of MDR cases, and c) Reducing mortality in HIV-positive TB patients by early initiation of ART. The related strategies are:

- Introducing new diagnostic tools in accordance with the Global Laboratory Initiative of WHO
- Expanding of C-DOTS and PPM-DOTS.
- Scaling up of PMDT
- Testing of all new TB cases for HIV and, in collaboration with the AIDS program, providing of ART to all HIV-positive TB patients.

Improved outcomes expected are:

- Increased case-detection of low smear-positive and smear-negative and culture positive PTB cases.
- Increased number of suspects examined and reduced patient delay.
- Reduced transmission of MDR and reduced morbidity and mortality of MDR
- Reduced morbidity and mortality in HIV-positive TB patients

4.2 Epidemiological profile of target populations

(a) Describe the current epidemiological profile of the target populations, and how this profile is changing with respect to tuberculosis.

The burden of TB

- It is estimated by WHO, that in 2008 in Asiam there were 99,000 cases of TB. The prevalence rate of 680 TB cases per 100,000 people is **one of the highest in the world.**
- WHO further estimates that annually 71,000 people develop TB, of which 35,000 have highly infectious smear-positive TB.
- It is further estimated that each year about 11,000 of HIV-negative TB patients die of TB.
- The HIV prevalence in TB patients increased from 2.5% in 1995 till 11,8% in 2003 as a result from the spread of the HIV epidemic in the country. However, national HIV prevalence surveys conducted in 2003, 2005, 2007 and 2009 show a declining trend.

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In the respective years the HIV prevalence was 11.8%, 10%, 7.8% and 6.4%.

- MDR is present, but still relatively low with 1.4% in new and 10.5% in previously treated cases in 2006.

Trend of the epidemic

- According to WHO data the estimated prevalence declined from 1,400 per 100,000 in 1990 till 680 in 2008. Therefore Asiam may have achieved the target of reducing the prevalence rate of TB by 50%, taking the 1990 level as the baseline. The total number of prevalent cases decreased from 140,000 in 1990 to 99,000 in 2008, i.e. a reduction of 29%.
- The mortality declined from per 150 per 100,000 in 1990 till per 79 per 100,000. With the current trend it is probable that Asiam will achieve the target to reduce mortality by 50% in 2015.
- The estimated incidence declined from 590 per 100,000 in 1990 to 490 per 100,000 in 2008. The decline of the trend is about 1% per year on average. The total number of new TB cases per year increased from 57,000 in 1990 to 71,000 in 2008 as the population increased from 9,690,107 in 1990 to 14,562,008 in 2008 (UN data).

Case notifications

In 2009 the NTP of Asiam notified 40,199 TB cases. There were 38,770 new cases, divided in 17,863 smear-positive cases (46%), 8,378 smear-negative cases (22%) and 12,529 extra-pulmonary cases (32%). There were 492 previously treated cases, divided in 432 relapses, 57 failure cases and 12 patients returning after default. The NTP also registered 928 cases not fitting one of the other categories.

In 2009 the case-notification rate of all new cases and relapses was 293 per 100,000 people and of new smear-positive cases alone 133 per 100,000 people. The male/female ratio in new smear-positive patients was 1.1. One percent of the smear-positive cases were in the age-group 0-14 year.

Trend of case notifications

- During the period 1990-2001 the notification rate of new cases, all forms, and relapses fluctuated between approximately 100 and 150. During the period 2002-2008 the rate gradually increased from 186 in 2002 to 267 in 2008.
- During the period 1994-2001 the notification rate of new smear-positive cases fluctuated between approximately 98 and 126. During the period 2001-2008 the rate gradually increased from 111 in 2001 to 136 in 2008 with a peak of 151 in 2005.
- In the medium to long term (2008-2015), the notification rate is likely to decline along with incidence.

Treatment results

The results of treatment achieved by the NTP are above the WHO target of 85% since the start of DOTS. In 2008 92% of new smear-positive cases were cured, 3% completed treatment without smear results, 2% died during treatment, less than 1% failed treatment, 1% defaulted from treatment and 2% were transferred elsewhere.

How the profile is changing

- Though the NTP will achieve the 2015 targets the TB burden in Asiam is still one of the highest in the world.

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- Though the incidence of TB is declining, the decline is still beyond the level to achieve an annual reduction of the incidence of 5% or more needed to substantially reduce the size of the problem in the next decade.
- The male/female ratio of 1.1 reflects both the still relatively high level of transmission of TB, as well as the gender and age distribution of the population of Asiam.
- The ratio of new smear-positive and new smear-negative PTB cases is 2.1 indicating, that smear-negative cases are still under-diagnosed.
- So far age specific data are collected only for new smear-positive cases. It is therefore not possible to comment on the proportions of childhood TB in smear-negative and EPTB cases.
- The treatment success rate of 95% is one of the highest in the region.
- Detailed studies are recommended regarding the death and failure rates reported. It is in particular worthwhile to analyze the death rate separately in HIV-positive and HIV-negative TB patients.
- Operational research studying the impact of early initiation of ARV on the death rate of HIV-positive TB cases on TB treatment has completed, with the findings that early initiation of ARVs can save 1000s of additional lives.
- Following the decline of the HIV epidemic in Asiam, the HIV prevalence in TB patients is declining.
- Due to the rapid socio-economic development of Asiam new high risk groups for TB are developing. These include factory workers in the garment industry and urban slum dwellers. Other high-risk groups are the elder and institutionalized people, such as prisoners.