SEA/TB/211

Combating Tuberculosis

Principles for Accelerating DOTS Coverage

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Foreword

TUBERCULOSIS remains a public health problem of enormous magnitude in the South-East Asia Region. It is imperative that national and local authorities take urgent and appropriate action to prevent the further spread of tuberculosis in the Region. This can be achieved by strengthening national TB control programmes and by expanding the WHO-recommended DOTS (Directly Observed Treatment, Short-course) strategy in each country.

This document, developed by WHO, sets out the basic principles for expansion of the DOTS strategy at national and local levels, without compromising on the quality of implementation. I urge health care workers, NGOs and those in the private sector to promote the expansion of DOTS and participate in the national effort to combat TB. Comments and suggestions for improving this document are most welcome.

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1
Introduction

1.1 Regional Situation Regarding Tuberculosis

Mycobacterium tuberculosis kills more adults than any other single infectious agent. Each year, about eight million people worldwide are estimated to develop TB. Of the 3.8 million cases reported to WHO in 1996, 39 per cent were reported from the South-East Asia Region, with the high burden countries namely Bangladesh, India, Indonesia, Myanmar and Thailand accounting for 90 per cent of the total cases. Tuberculosis is the most common cause of death among adults in the Region; about one million people die of TB each year.

Currently, only 30 to 50 per cent of those diagnosed with TB are cured; the remainder continue to transmit the infection. Each uncured patient infects approximately 10 persons each year, increasing the pool of sources of infection. Patients who do not complete their treatment schedules are likely to develop resistance to anti-TB drugs. When such patients infect other people, these people too become infected with resistant bacilli. Moreover, only 50 per cent of patients on a 12-month long course regimen convert from positive to negative, during the first two

months of treatment, even when administration of chemotherapy is closely supervised. Many patients who do not continue to have closely supervised treatment, often stop taking anti-TB drugs after two months because they begin to feel "better". These patients are likely to become smear-positive failures.

In the past, TB control programmes in the Region have generally not been effective. Their poor quality has been the result of over-reliance on special TB care facilities, inadequate treatment, failure to use standardized treatment regimens uniformly, and lack of an information management system for evaluating treatment outcomes. Without ensuring "directly observed treatment" and making services accessible for all patients, there is every reason to believe that the situation with regard to tuberculosis will in fact worsen with the emergence of multidrug resistant TB and HIV/TB co-infection. Presently, TB accounts for one-third of all deaths from AIDS worldwide and 40 per cent of AIDS deaths in Asia.

1.2 Principles of TB Control

Noting the worsening situation, WHO in 1993, declared TB as a global emergency and advocated that all countries adopt and implement the WHO-recommended Directly Observed Treatment, Short–course (DOTS), considered by the World Bank as one of the most cost-effective strategies available today for TB control.

DOTS is a strategy for ensuring high cure rates in patients with tuberculosis. Once infectious cases have been detected, community health workers or trained volunteers help patients (and their families) to complete a full course

of anti-TB treatment by observing patients swallow the correct dosage of anti-TB drugs, maintaining records and documenting that the patient has been cured.

The DOTS strategy comprises five components:

(1) Political commitment for support to a strong national programme;

(2) Case-detection through sputum smear microscopy of all suspects coming to the general health services;

(3) Directly observed treatment, with short-course therapy of all sputum smear-positive patients;

(4) Regular and uninterrupted supply of anti-TB drugs, and

(5) A monitoring system for evaluation of treatment outcome.

Every country in the South-East Asia Region of WHO has adopted DOTS as a policy and has begun implementing it. In fact, pilot studies have demonstrated that DOTS works well in the Region, with cure rates of 85 per cent or more recorded in all areas where it has been used. However, the overall coverage in the large high-burden countries, except Bangladesh, is still low, covering in total a mere 12 per cent of the population in the Region.

The challenge now lies in rapidly expanding the coverage of DOTS without compromising on its quality. WHO has set the target to cure 85 per cent of detected new smear-positive patients and detect 70 per cent of existing cases by the year 2000. In order to achieve these targets, it is essential to have a decentralized diagnostic and treatment network utilizing the existing health

facilities and integrating TB services into primary health care. The programme requires good management capacity based on accountability and supervision of health care workers and treatment observers, and an in-built evaluation system including analysis and reporting on case-finding and treatment outcomes of smear-positive patients by cohorts.

1.3 Why Must DOTS be Expanded?

Pilot studies carried out in all countries in the Region show that DOTS is very effective – cure rates in excess of 85 per cent have been achieved wherever DOTS has been properly implemented. Given the burden of the disease and the need to enhance the accessibility to good quality treatment services, DOTS must be expanded urgently. This is an essential initial step towards achieving global, regional and national targets.

With the achievement of 85 per cent cure rate in patients with sputum smear-positive pulmonary TB, it is expected that both TB prevalence and the rate of TB transmission will decrease immediately, as would the acquired drug resistance. National programmes which fail to achieve high cure rates on the other hand will not only have more cases of sputum smear-positive treatment failures but acquired drug resistance will also increase. National tuberculosis programmes are presently concentrating on achieving high cure rates or treatment success. Increasing the case-finding rate will become a priority only when high cure rates have been achieved.

Since governments have the responsibility to ensure effective TB control, progress will ultimately depend on each government's commitment in terms of policy, allocation of adequate resources, and expansion of DOTS in as many districts as possible in the country. Failure to implement DOTS will mean that: (1) the TB case-load and deaths will continue to increase; (2) multidrug resistant TB will increase considerably, and (3) a currently treatable disease will become untreatable.

In order, therefore, to address these issues adequately, political commitment is absolutely essential for financially supporting and expanding the DOTS strategy now, before the situation gets completely out of control.

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Steps in Accelerating DOTS Implementation

THE implementation of the DOTS strategy is generally carried out in three phases: (i) the pilot project phase; (ii) the expansion phase, and finally (iii) the maintenance phase. The pilot phase in the South-East Asia Region has not only shown that DOTS is highly effective but it has also provided important practical insights and experiences on the basis of which the DOTS strategy can be expanded rapidly. All countries in the Region, including those with a high burden of TB are now in the expansion phase.

Since the expansion phase must be implemented efficiently and expeditiously, the procedures and systems established during the pilot phase must now be used as guidelines for accelerating the DOTS implementation, without compromising on the quality of work. The following step-by-step approach is recommended:

Step 1: Identifying and Assessing Districts for DOTS Implementation

Before preparing a plan for expansion, it is important to make a needs assessment in each district where DOTS is to be implemented. You will need to assess:

- Number and location of all hospitals (NGO hospitals as well as public hospitals), peripheral health units, and microscopy laboratories;
- Number and types of key health workers at hospitals and primary health units who identify suspects, diagnose TB cases, and/or administer treatment;
- Anti-tuberculosis drugs and supplies available with adequate storage facilities and a system for distribution (e.g. sputum containers at health units), and
- Number of laboratory personnel as well as supplies and equipment available for sputum smear microscopy.

The resources found in each district should be compared with what is needed to implement the DOTS strategy. Determine if there are other programmes with which to coordinate with and share costs for training or supplies, such as ARI, EPI, Leprosy, Malaria, STD/AIDS, Integrated Management of Childhood Illnesses and Health Education. It may also be useful to prepare a map of the district, and mark the location of health facilities and population concentrations in order to determine access.

The following should be the criteria for selection of a district for DOTS expansion:

- A suitable candidate for appointment as a District Tuberculosis Coordinator (DTC).
- A well-equipped laboratory with sensitized personnel.

- A health unit capable to identify suspects and monitor the diagnosis of patients after training.
- A developed mechanism for ensuring the implementation of directly observed treatment and identification of Treatment Observers such as health workers or trained volunteers.
- Availability of sufficient drugs and other supplies that are planned for.
- Presence of health-related NGOs interested to incorporate DOTS into primary health care.

Step 2: Mobilizing the Community and Obtaining Commitment

The implementation of the DOTS strategy in a district requires commitment from the community and the stakeholders. It is essential to inform and convince the community leaders, the health personnel, both in public and private sectors and NGOs, about the effectiveness and importance of DOTS in the management of TB patients. This is important for motivating communities to utilize the services that are made accessible to them. Political commitment is essential for prioritizing TB at local levels and having funds allocated at the district level towards implementing the TB control programme in the district and making it sustainable. For achieving this, the following approaches could be adopted:

A consensus meeting be held of all stakeholders to develop a sense of ownership for DOTS, to build alliances and coalitions with other relevant organizations and individuals involved in TB control activities and to disseminate the message that DOTS can cure TB patients and thereby control TB in the district.

Once service delivery such as drugs and treatment observation is ensured, efforts would be needed to mobilize the community by disseminating messages through identified stakeholders, private sectors, NGOs, professionals, political, social and religious leaders and teachers. One simple way to involve the community would be to arrange the inauguration of a DOTS implementation programme in a particular district or treatment centre where people actually see the way services are being made available. This message would then get disseminated more easily through the wide spectrum of public service providers, especially through 'word of mouth" so that the community would gradually begin to know where to go and how to receive TB treatment services. Subsequently, through seminars, workshops, exhibitions and other health education activities, a demand for DOTS can be created and the sustainability of the programme ensured.

Step 3: Identifying the Most Appropriate Persons to Provide Directly Observed Treatment

People who have access to TB patients on a daily basis and who are accountable to the health services are the most appropriate persons to provide directly observed treatment.

Health workers in the field are usually accountable to health services and are accessible to patients. In the absence of health workers, NGO workers, trained community volunteers and the social elite are a good alternative. Family members are usually found to be the least accountable to health services and unless trained, may be unable to perform the task adequately.

District TB coordinators (DTCs) should ensure that each patient gets directly observed treatment with proper health education.

Step 4: Training

Training is critical for the success of implementing the DOTS strategy. The first priority must be given to train district personnel before they start registering and treating cases. It is also important to train other personnel in the district who have TB-related responsibilities.

While planning a training programme, first find out which personnel will need training. These generally should include the District Medical Officer, the DTC, the Laboratory Technician, doctors and nurses in hospitals and health centres, general health workers as well as NGO representatives who provide treatment services to TB patients. It is important that personnel must be trained close to the time they will begin to use the new knowledge imparted during training. The district level staff must be trained before the peripheral health workers.

Training does not always ensure that the personnel will correctly apply the DOTS strategy. District-level staff must follow up with trainees to ensure this, as well as help workers solve problems. It may be necessary to provide on-the-job training and refresher training as and when needed. For this, regular supervisory visits to the district and peripheral health units will be needed to evaluate the training programme, to ensure that the health workers are performing their jobs adequately, and to identify staff who need to build additional skills through re-training.

Step 5: Ensuring the Availability of Drugs and Other Supplies

An important element of a successful TB control strategy is the assurance of an uninterrupted administration of a full course of chemotherapy to all TB patients reporting to health services. In addition, laboratory essentials, and recording and reporting materials, should also be in place.

Drugs and other related supplies, including laboratory supplies, must be estimated one year in advance of implementing the DOTS strategy and must be ordered four times in a year. Also, make sure that a one-year reserve stock is always available. Forms and registers can however be ordered once a year.

Step 6: Establishing a System of Recording and Reporting

Health care workers should be trained on how to maintain accurate records using formats established by the National TB Control Programme (NTP). These include maintaining a patient treatment card that details the regular intake of medicines and contact with a health worker, a district TB register which provides all information on a patient and is used to monitor the progress and outcome of treatment, and a TB laboratory register which enters results of sputum examination.

A system also has to be set up at the district level for reporting data to the central unit on a quarterly basis. This quarterly report is an important report. It gives information on how many new pulmonary smear-positive cases, relapses, new pulmonary smear-negative cases and extra pulmonary cases were diagnosed and registered during a

three-month period. The quarterly report is then forwarded to the regional or central unit for analysis, to be used by the Regional TB Coordinator as information to assess and evaluate the implementation of the DOTS strategy more efficiently.

The system of recording and reporting in the district should begin at the same time DOTS is introduced. In addition, DTCs and health workers should be trained on the use of forms. Extra on-the-job training will be needed to help solve difficulties and to assess the quality of reports for completeness, consistency and credibility.

3
Time-frame for DOTS Expansion

DOTS expansion must be done gradually and with appropriate and adequate preparation. The speed with which districts can start to implement DOTS depends on: (1) how quickly can the key staff from a district be trained. Theoretical training can be given at one time to staff from a few districts. However, practical on-the-job training should be given for staff from one or possibly two districts only, from the same region, at a time; (2) how quickly district-level staff will be able to train health workers who perform activities related to case-finding and treatment of tuberculosis patients, and (3) the ability of NTP to ensure timely provision of drugs and other supplies to selected districts.

The establishment of new districts to be included under DOTS needs careful planning in the same way as establishing a Demonstration District in the pilot phase, i.e. identify key individuals in each district, assess resources, specify activities, prepare a budget, and prepare a work plan. Before the DOTS strategy is expanded to other districts, the status of implementation in pilot demonstration districts as regards all of the five elements of DOTS must be evaluated in order to learn lessons from the implementation.

In evaluating the success of DOTS in demonstration districts, the data in the quarterly report on case-finding, sputum-smear conversion and final treatment outcome should be analysed for the following indicators:

(1) Case detection rate;

(2) Proportion of pulmonary smear-positive TB cases out of all pulmonary cases registered in a quarter;

(3) Ratio of new smear-positive cases to new smear-negative and extra pulmonary cases;

(4) Proportion of smear-positive cases among TB suspects;

(5) Reported case notification rate for new smear-positive cases;

(6) Conversion rates for all smear-positive cases; and

(7) Treatment outcomes.

Criteria for Expansion

1. Sputum smear conversion rates are the most important indicators to evaluate for expansion. A minimum of 85 per cent conversion of new smear-positive cases should be achieved before implementing expansion plans.
2. The percentage of pulmonary smear-positive cases (new and relapsed) should be >65 per cent of all pulmonary cases detected.
3. Capacity to train health workers and supervise the implementation of the programme should be available.
4. There should be sufficient drugs, supplies and other equipment to support programme expansion.

Based on the experience of implementing DOTS in selected districts, revise the estimates for how long it will take to expand the strategy to all districts nation-wide. Within 3-4 years of establishing the demonstration districts, all districts in a country should be able to implement the DOTS strategy as integrated into the existing health system. But this would depend also on the size and terrain of the country. The expansion to new districts will depend on NTP's capacity to train district staff, and its capacity to supply the districts with drugs and other supplies.

4

Monitoring and Supervision

ONCE DOTS is implemented in a district, the success of the programme will depend on the regular monitoring and evaluation of the effectiveness of the programme. Supervisory support must be provided to health workers to ensure that:

- Patients are registered in the district TB register and the results of their follow-up smear examinations are entered in the register;
- Laboratory technicians correctly complete the TB laboratory register;
- Patients on Category 1 treatment have a smear examination done at 2 months, 5 months and at the end of the treatment; and
- Quarterly reports are completed for both new cases and relapses, treatment outcomes and programme management at the beginning of each quarter.

Supervision is an important activity in monitoring the progress and involves frequent visits to health units in the district. Supervisory visits should assess the quality of work being carried out, for treatment of sputum smear-positive cases, for laboratory services, for evaluation of treatment outcome, for drug supplies and ordering systems, as well as for completeness of records. Supervision should not merely be seen as an assessment of the work being carried out, but more as a supportive exercise to educate and train staff. Supervisory activity should also include supervision of programme management activities as well as evaluation of the frequency and quality of reporting of cohort analysis. Supervision is considered as one of the most crucial activities on which the success of DOTS in a district is most likely to depend.

5
Conclusions and Recommendations

ACCELERATING the implementation of DOTS nation-wide is based on strong political commitment and adequate funding. Both these are most likely to be forthcoming when it is demonstrated that DOTS works and that in districts where DOTS has been implemented as a pilot project, both TB cure rates and case-finding rates have improved significantly.

Expanding DOTS from the demonstration districts selected during the pilot phase of the project to other regions/provinces in the country, towards a nation-wide coverage by the year 2000 or soon thereafter, involves adhering closely to the national five-year implementation plan and monitoring the progress of the DOTS strategy at every stage in its implementation.

The success in accelerating the DOTS coverage depends greatly upon realistic planning and preparation of districts for DOTS implementation by way of community involvement and mobilizing commitment from all stakeholders; drug procurement and distribution through good logistics management to ensure that drug and other supplies reach intended users, whenever they are needed;

training of various categories of staff involved in DOTS implementation including volunteers who could work as treatment observers; availability of trained laboratory technicians to ensure good quality laboratory diagnosis; a good supervision, and recording and reporting system that provides effective feed-back to programme implementors, and last but not the least, dedication and commitment of individuals, community leaders and health care workers to control tuberculosis on a war footing in order to avert a national public health crisis.

However successful DOTS at present may be in a few selected districts of the countries, its importance and overall impact on the nation will only be felt when the strategy is expanded to cover the entire population.

The spread of TB can be checked by accelerating the implementation of DOTS, a strategy which has been tested and found to be the most effective and feasible approach in the control of tuberculosis.