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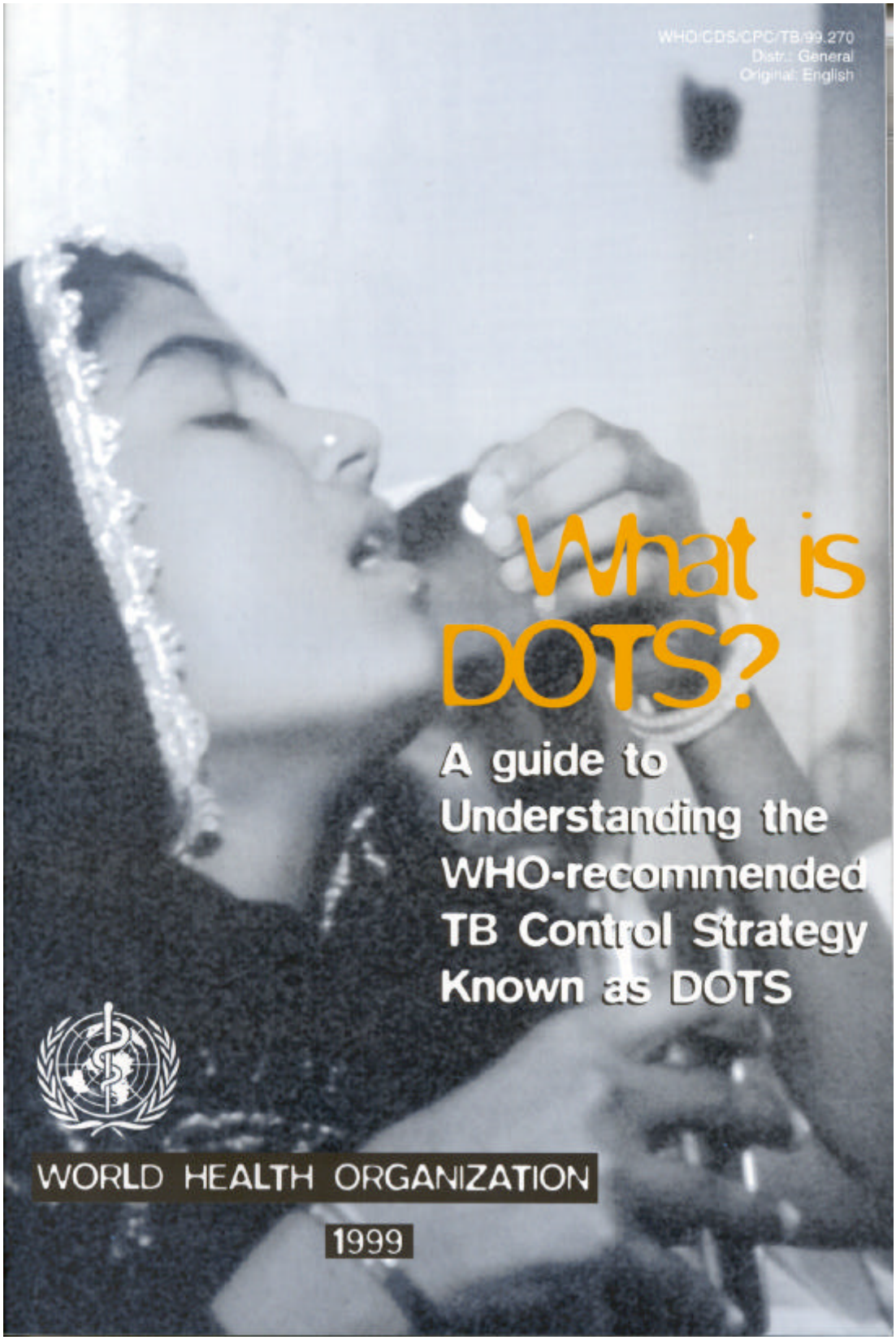

What is DOTS?

A guide to Understanding the WHO-recommended TB Control Strategy Known as DOTS

WORLD HEALTH ORGANIZATION

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Introduction

For more than 100 years we have been able to use microscopes to detect the bacterium that causes tuberculosis. For almost 50 years we have had effective anti-TB drugs. Yet, this year, more people will die of TB than in any other year in history. How can this be?

The problem has not been the lack of ways to detect and cure TB patients. The problem has been the lack of organization of services to ensure widespread detection and cure of TB patients, particularly the infectious ones.

Today, however, there is a proven, cost-effective TB treatment strategy known as DOTS. A combination of technical and managerial components, DOTS quickly makes the infectious cases non-infectious and breaks the cycle of transmission. Using DOTS also prevents the development of drug-resistant strains of TB that are often fatal and almost 100 times more expensive to cure.

The strategy has been successful in large and small countries, both rich and poor. Countries achieving high cure and coverage rates include Benin, Guinea, Peru, Nicaragua, China and Viet Nam. In China, cure rates rose from below 50 percent to more than 95 percent in areas covered by DOTS, and about half the population of China is covered by the strategy today. In Peru, government commitment for the strategy has resulted in almost 100 percent DOTS coverage in the country and cure rates of up to 83 percent.

Several challenges, however, impede the implementation of DOTS. The increasing impact of HIV on the incidence of TB in Sub-Saharan Africa is threatening to overwhelm currently effective TB control programmes. After the collapse of the health care system of the former Soviet republics, TB incidence and mortality are on the rise. Eastern Europe is also seeing a surge in drug-resistant forms of the disease.

Today, the strategy must be adapted to fit specific country situations. For example, in areas of high HIV prevalence, partnerships must be forged between TB and HIV programmes. In Eastern Europe, DOTS must not only be introduced and reinforced, but additional programme elements should be developed to more quickly identify and treat drug-resistant cases.

Since the introduction of the strategy almost five years ago, great strides have been made in spreading the message to governments, health care workers and

the public about the importance of implementing DOTS. As of 1997, 102 countries had accepted the strategy as policy and had implemented it to varying degrees. However, more must be done to ensure the implementation of DOTS more widely.

This document discusses how DOTS was developed, how it is implemented and sustained, how it differs from other control approaches, and its role within a challenging and changing health care system. This document is designed to give decision-makers with health policy and budget authority a good understanding of the strategy so that they can promote effective TB control in their countries.

Summary – What is DOTS?

DOTS (Directly Observed Treatment, Short-course) is the most effective strategy available for controlling the TB epidemic today. DOTS has five key components:

- Government commitment to sustained TB control activities.
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services.
- Standardized treatment regimen of six to eight months for at least all confirmed sputum smear positive cases, with directly observed treatment (DOT) for at least the initial two months.
- A regular, uninterrupted supply of all essential anti-TB drugs.
- A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control programme overall.

This cost-effective strategy was developed from the collective best practices, clinical trials and programmatic operations of TB control over the past two decades.

Government commitment to sustained TB control is essential for the other four components to be implemented and sustained. This commitment must first translate into policy formulation, and then into the financial and human resources and administrative support necessary to ensure that TB control is an essential part of health services.

An important feature of DOTS is the basic management unit—usually covering a population of 100,000 to 150,000—that has the staff and resources to diagnose, initiate treatment, record and report patient treatment progress, and manage supplies. This basic management unit operates successfully within existing general health services, which is critical for the full integration and effectiveness of TB control services in the primary health care network, particularly during this era of health sector reform.

Another important feature is a recording and reporting system used by health care workers to systematically monitor patient progress and TB programme performance. This results-oriented system enables quality assurance of programme implementation and treatment and cure of TB patients. Data collected as part of TB management can be a useful indicator of access to and quality of the general health system.

Chapter 1 – The TB Epidemic

TB is a contagious bacterial disease caused by *Mycobacterium tuberculosis*. Like the common cold, TB is spread through the air. The main source of infection is a person with TB of the lungs (pulmonary TB) who coughs, sneezes or spits, and spreads infectious droplets containing the bacteria in the air.

TB Infection, Disease, and Treatment

Once infected with *M. tuberculosis*, a person stays infected for many years, and often for life. The vast majority (90 percent) of people infected with *M. tuberculosis* do not develop the disease of tuberculosis. Active disease occurs in an average of 10 percent of those who are infected. Various physical or emotional stresses trigger progression from infection to disease. Any weakening of the immune system—for example, by malnutrition or HIV infection—increases the chances for disease to develop.

Left untreated, a person with active TB will infect on average 10 to 15 persons a year. The most effective approach to TB control is the identification and cure of these infectious cases. Proper treatment of infectious cases makes them very quickly non-infectious so that they can no longer spread TB to others. Because effective treatment breaks the cycle of transmission, cure is the best prevention.

This is even more important because of the emergence of drug-resistant TB. Drug-resistant TB is a human-made phenomenon caused by inconsistent or partial treatment, when TB bacilli become resistant to the most common anti-TB drugs. This happens when doctors or health workers prescribe the wrong drugs or the wrong combination of drugs, the drug supply is unreliable, or patients do not take all their medicines regularly for the required period of time. Once the bacilli become resistant to one or more anti-TB drugs, the infected person can go on to infect others with the same drug-resistant strain. Multidrug-resistant TB is more difficult and more expensive to treat, and more likely to be fatal.

The Global Burden of TB

About one-third of the world's population is infected by *M. tuberculosis*. In 1997, there were about 8 million new cases of TB and 2 million deaths worldwide. TB kills more youth and adults than any other single infectious

agent in the world today. The developing world is the worst affected with 95 percent of all TB cases and 98 percent of TB deaths. And 75 percent of TB cases in developing countries are among those in their most economically productive years (15-45).

Today, HIV is the most powerful factor known to increase the risk of progression from TB infection to disease. By 1997, more than 10 million people were dually infected with TB and HIV. These people have a 50 percent chance of developing active TB during their lifetime. Approximately 640,000 TB cases were attributed to HIV during 1997. In Africa, about 30 percent of all TB cases are now due to HIV. In some of the worst affected countries in Sub-Saharan Africa, more than 60 percent of TB patients are HIV-positive.

TB in the Developed World

With the advent of drugs to cure TB, there was an annual decline in the incidence of TB infections of approximately 12 percent because of widespread case-finding and high cure rates (often obtained through use of prolonged hospitalization) in addition to socio-economic development. Political commitment and funding for TB control led to the widespread and effective application of chemotherapy, resulting in further decline in the annual incidence of TB infections.

TB in the Developing World

The high burden of TB in many developing countries makes TB control a priority public health concern that must be address through the primary health care network. Many developing countries, however, lack the systems and funding necessary to ensure the widespread effective application of anti-TB chemotherapy. The low cost and strong managerial approach of the DOTS strategy enable the effective use of available technologies (sputum smear microscopy and anti-TB drugs) for TB control within existing health systems. Implementation of the DOTS strategy can accelerate the decline in the annual rate of TB infections in these countries.

Developing countries such as Algeria, Chile, Cuba, and Uruguay—which since the 1970s have instituted efficient case-finding with high cure rates—have demonstrated the same effect. The consensus is that high cure rates supplemented by efficient case-finding have an impact in decreasing the transmission of TB infection and the incidence of TB disease.

Chapter 2 – The Development of DOTS

Long-course Drug Treatment

In the era before anti-TB drugs, treatment was intended to strengthen a patient's resistance to TB (for example through special diets and bed rest in sanitoria), and to rest the diseased part of the lung (by various techniques of collapse therapy). Treatment in a sanatorium was expensive and only available to a small number of the world's TB patients. Nevertheless, at least half of the patients with TB eventually died from the disease.

In the 1950s, the development of drugs which in combination kill off TB bacilli and cure TB revolutionized treatment and led to a dramatic reduction in TB case fatality—to 5 percent or less—where used correctly.

Clinical trials in India, East Africa, Singapore and Hong Kong demonstrated the effectiveness of long-course drug treatment. One study in Chennai (then Madras), India, showed that with ample financial and human resources, long-course treatment (for one year) was effective without the need for hospitalization. Both developed and developing countries started to abandon hospitalization.

Short-course Drug Treatment

In the 1970s, the introduction of rifampicin as part of a combination of anti-TB drugs reduced treatment to six to eight months—known as short-course drug treatment. With short-course treatment, patients feel better more quickly as the bacterial load decreases dramatically during an intensive initial two-month phase of treatment. Within these few weeks, patients are rendered non-infectious and are no longer able to spread the disease to family, friends and co-workers.

The Styblo/IUATLD Model of TB Control

In Tanzania in the 1970s, Dr Karel Styblo of the International Union Against Tuberculosis and Lung Disease (IUATLD) pioneered the development of a model of TB control based on a managerial approach to case-finding and treatment.

The use of long-course drug treatment in the first few years in Tanzania did not achieve high cure rates, and so was abandoned in favor of short-course

drug treatment. The Tanzania National TB Control Programme was the first of the IUATLD model programmes with successful nation-wide coverage. Between 1978 and 1991, IUATLD supported national TB programmes in nine high prevalence, resource-poor countries.

Dr Styblo was the first to propose the idea of using an existing basic management unit (usually the district) that would have the staff and resources necessary to diagnose, initiate treatment, record and report patient treatment progress, and manage supplies in a population area of 100,000 to 150,000. This basic management unit allowed the technical aspects of TB control to be integrated within the existing general health services.

WHO and the DOTS Strategy

In 1993, WHO's Global Tuberculosis Programme (GTB) took an unprecedented step and declared TB a global emergency. After defining the nature and size of the global TB problem through expanded monitoring and surveillance, GTB began promoting Styblo's strategy in a technical and management package known by the brand-name DOTS.

The Programme developed necessary tools, such as technical guidelines and training materials, for the marketing and implementation of DOTS. At the same time, GTB embarked on intensified technical assistance to over 60 countries, focusing on big countries with the largest TB burdens.

The number of countries using DOTS expanded from only 10 in 1990 to 102 in 1997. The percent of patients treated under DOTS increased from less than 1 percent in 1990 to 16 percent in 1997.

Chapter 3 – The DOTS Strategy Today

The DOTS strategy takes sound technology—the successful components of TB control—and packages it with good management practices for widespread use through the existing primary health care network.

It has proven to be a successful, innovative approach to TB control in countries such as China, Bangladesh, Viet Nam, Peru, and countries of West Africa. However, new challenges to the implementation of DOTS include health sector reforms, the worsening HIV epidemic, and the emergence of drug-resistant strains of TB.

The technical, logistical, operational and political aspects of DOTS work together to ensure its success and applicability in a wide variety of contexts.

Technical Aspects

Case Detection and Diagnosis

Case detection is the use of sputum smear microscopy to identify people with pulmonary TB among those attending general health services. Sputum smear microscopy is the most cost-effective method of screening pulmonary TB suspects. The types of TB vary according to local situations. Out of all TB cases, approximately 50-60 percent are sputum smear-positive pulmonary cases; 35-40 percent are sputum smear-negative pulmonary cases; and 10-15 percent extra-pulmonary cases.

TB is diagnosed using patient history, clinical examination and diagnostic tests. A sputum sample is submitted to the laboratory and the results of the microscopic exam are entered into the laboratory register. The goal is for all suspects to have a sputum smear microscopy exam and for all patients diagnosed with TB to be registered and treated.

Table 1. Technical, Logistical, Operational and Political Aspects of DOTS

TECHNICAL
- Case detection and diagnosis
- Standardized short-course treatment
- Direct observation at least during the initial phase
- Recording and reporting of progress and cure

LOGISTICAL
- Dependable drug supply to the patient level
- Laboratories for microscopy
- Supervision and training of health care workers

OPERATIONAL
- Flexibility in implementation of technical aspects

In areas of high HIV prevalence, it is often difficult to distinguish pulmonary TB from other HIV-related pulmonary diseases. There has also been an increase in reported cases of smear-negative pulmonary TB. The extent of over-diagnosis of smear-negative pulmonary TB in those settings is not known; therefore, it is important to follow recommended guidelines in order to diagnose smear-negative pulmonary TB as accurately as possible.

Standardized Short-course Treatment, with Direct Observation in the Initial Phase

Short-course treatment refers to a treatment regimen that lasts six to eight months and uses a combination of powerful anti-TB drugs. (This compares with a long-course regimen, which lasts 12-18 months.) Standardized regimens are based on whether the patient is classified as a new case or a previously treated case. The most common anti-TB drugs used are isoniazid, rifampicin, pyrazinamide, streptomycin, ethambutol and thioacetazone.

Generally, treatment is the same for HIV-infected as for non-HIV-infected patients, with the exception of thioacetazone. This drug is associated with a high risk of severe, and sometimes fatal, skin reactions in HIV-infected individuals. Ethambutol should be substituted for thioacetazone in patients with known or suspected HIV infection. Some countries, however, do not have the resources to substitute ethambutol for thioacetazone. Where it is not possible to avoid the use of this drug, it is imperative to counsel patients on its potential risks and to advise them to stop thioacetazone at once and report to a health unit if itching or a skin reaction occurs.

Directly observed treatment (DOT)—watching patients taking their medications—is essential at least during the intensive phase of treatment (the first two months) to ensure that the drugs are taken in the right combinations and for the appropriate duration.

With direct observation of treatment, the patient doesn't bear the sole responsibility of adhering to treatment. Health care workers, public health officials, governments, and communities must all share the responsibility and provide a range of support services patients need to continue and finish treatment. One of the aims of effective TB control is to organize TB services so that the patient has flexibility in where he or she receives treatment, for example in the home or at the workplace. Treatment observers can be anyone who is willing, trained, responsible, acceptable to the patient and accountable to the TB control services.

Recording and Reporting

The recording and reporting system is used to systematically evaluate patient progress and treatment outcome, as well as overall programme performance. The system consists of: a laboratory register that contains a log of all patients who have had a smear test done; patient treatment cards that detail the regular intake of medication and follow-up sputum examinations; and the TB register, which lists patients starting treatment and monitors their individual and collective progress towards cure.

The laboratory technician records patient details in the **laboratory register** with a serial identification number. The results of the sputum exam are then recorded in the general health facility where the patient is registered for treatment. At the end of two months (the intensive phase of treatment), between 75–85 percent of all new smear-positive cases normally become sputum smear-negative, and no longer infectious. Monitoring smear-conversion from positive to negative smear after the initial two to three months of treatment is the most effective way to assess that the patient has taken the prescribed medications.

Each person diagnosed with TB (smear-positive, smear-negative, or extrapulmonary) has a **patient treatment card**. This card also records basic epidemiological and clinical information, and the administration of drugs. The health worker uses the patient treatment card for recording treatment and for follow-up. During the continuation phase and at the end of treatment, patients are required to submit sputum samples for microscopy to ensure that they become and remain negative – and therefore cured of TB.

A health care worker is responsible for supervising each administrative area or institution in the district, and uses the **district TB register** to monitor progress and treatment outcome for all patients in that district. This provides the district or local health chief with rapid feedback on programme performance in the district and allows for monitoring of the epidemic overall.

Cohort analysis is the key management tool used to evaluate the effectiveness of TB control activities in any given area. A cohort of TB patients consists of patients registered during a certain time period. Cohort analysis refers to the systematic follow-up and reporting on certain indicators such as treatment progress and treatment success.

The quarterly smear conversion report and quarterly and annual treatment success rates (percentage of patients who are cured plus those who finish treatment) give any middle- or higher-level manager timely, concrete indicators of achievement or of problems requiring action (e.g. low cure rate,

high default rate, higher than expected proportion of sputum smear-negative PTB or extra-pulmonary TB, and lower than expected case detection rate).

The DOTS recording and reporting system allows for targeted, individualized follow-up to help patients who may not be making satisfactory progress, and a rapid managerial assessment of the overall performance of each institution, district, region or country. There is a strong system of accountability and a system of cross-checks that make false reporting of data difficult.

Logistical Aspects

Secure Drug Supply

Planning and maintaining drug stocks at all levels can be a challenge for general health services. Where DOTS is implemented, however, an accurate recording and reporting system provides the information needed to plan and maintain adequate drug stocks, such as the number of cases in the different treatment categories notified the previous year, the standardized treatment regimen used, and the existing stocks.

Network of Smear Microscopy Laboratories with Regular Quality Control

Laboratories with competent, trained, motivated and supervised general health service lab technicians are essential. General laboratory services facilitate the diagnosis of pulmonary tuberculosis (including the correct classification of cases in determining the appropriate treatment regimen) and monitoring of treatment of sputum smear-positive cases.

Supervision and Training

Supervision and on-going training are necessary to ensure the quality of TB control services throughout the health care system. Each district should have an individual responsible for implementing TB control activities (case-finding and treatment). This person may be a district TB coordinator or a health care worker who is also responsible for other tasks. In order to maintain quality of service, these coordinators should be trained and supervised by someone at the provincial/regional level. In turn, the central level of the Ministry of Health is responsible for training and supervising the provincial/regional coordinators.

Primary health care workers should also receive basic training in TB control such as how to recognize the symptoms of TB and refer suspected patients for accurate diagnosis and treatment. In many countries, community leaders and volunteers can also be successfully involved in TB control. Communities

can raise awareness about TB and encourage TB patients to complete treatment.

Operational Aspects

The five components of DOTS represent the basic minimum that is necessary for TB control. The implementation of the strategy requires flexibility, with adaptation to a broad range of contexts. The stage of the TB epidemic, availability of human and other resources, existing health infrastructure, the prevalence of HIV and MDR-TB, and the degree of mobilization of health personnel and the community have an impact on how DOTS is implemented. Two specific examples follow:

- ***Health sector reform*** is one area that poses both threats and opportunities for TB control. Because DOTS functions as an integral part of primary health care, it is fully compatible with the aims of health sector reform, including strengthening district-level decision making and action, and improving efficiency and cost-effectiveness of service delivery. In fact, DOTS can serve as a model for maintaining effective prevention and control activities within the context of primary health care delivery. However, health sector reform driven by economic targets rather than health priorities may result in piecemeal introduction of user charges where TB services are now free, reorganization of service delivery, and other changes that may sometimes adversely affect health systems and TB control programmes by weakening the management system and outcome reporting.
- ***The increasing impact of HIV/AIDS*** on the incidence of TB threatens to overwhelm currently effective TB control programmes. In areas of high HIV prevalence, the DOTS strategy needs help from other partners. The dual TB/HIV epidemic requires epidemiological, clinical and programmatic coordination between TB and HIV prevention and treatment programmes at all levels. This cohesiveness is essential for a strong health system. Examples of how to improve the coordination of services include linking TB control activities to existing HIV prevention programmes and improving referral systems between different agencies in the district health system.

Table 2 illustrates the operational flexibility of the DOTS strategy using the example of how to ensure directly observed treatment.

Table 2. The DOTS Strategy and Directly Observed Treatment

SETTING	LOCATION	ADAPTATION OF DIRECTLY OBSERVED TREATMENT
Rural nomads living in an area with a poor health	North-East Province, Kenya	Prolonged intensive phase of treatment in "manyattas"

infrastructure		(village health shelters)
Urban, close-knit families	Guinea, West Africa	Extended family member
Rural villages	Hlabisa, KwaZulu/Natal, South Africa	Community supervisors, e.g. store-keepers
Inner-city deprivation with marginalized groups, e.g. alcoholics, drug users, homeless	New York City, U.S.A.	Outreach health workers
Good rural district hospitals	Malawi, Africa	Hospitalization in intensive phase
Good, rural general health services infrastructure	China	Village doctors and nurses, incentive scheme
Urban, accessible health facilities	Tanzania	Ambulatory attendance at health facilities

Political Aspects

Government commitment to sustained TB control is essential for the other four components to be implemented and sustained. It is necessary for the mobilization of resources and the sustainability of TB programmes. Political commitment is built on an awareness of the TB problem and the availability of a cost-effective proven solution, and an understanding of the benefits of implementing effective TB control which extend beyond the individual patient and the community, since cure of a TB patient prevents transmission of infection to others.

Political commitment begins with the government deciding to make TB control a high priority and a core activity of the primary health care network. To have an impact, political commitment must translate into policy formulation, resource mobilization and programme implementation. Policy makers must draft and disseminate a national policy document that outlines the control strategy, followed by operational guidelines that describe the practical steps to implementation, including national and local plans. These guidelines explain how to integrate DOTS within a country's existing general health services. Once this groundwork has been laid, financial resources and trained staff are needed to put the programme into action.

Chapter 4 –
How DOTS Differs from Other TB Control Approaches

Many aspects of DOTS set it apart from other TB control approaches. It is the combination of all these aspects that has led to the success of the strategy. The following table describes how a non-DOTS approach differs from the DOTS strategy according to a number of components of TB control.

Table 3. How a Non-DOTS Approach to TB Control Differs from DOTS

	Non-DOTS	**DOTS**
Case finding and diagnosis	Depends on unreliable, often expensive methods: • excessive use of x-ray • often ill-defined symptomatic-based diagnosis Systematic case detection among TB suspects, in order to identify the infectious cases, usually absent	Depends on a simple, cost-effective and reliable method: • three sputum examinations for all infectious cases • limited use of x-ray for specific cases • tightly defined symptomatic diagnosis as a supplemental diagnosis of some cases
Patient categorization for treatment	Often **weak**. As a result, the following are not well determined: • that a patient does have TB • type/degree of TB • infectiousness • treatment category	**Strong**, ensuring the following are determined: • type (pulmonary/extra-pulmonary) • SS+ or SS- • treatment category: new or re-treatment (relapse, failure, re-treatment, treatment interruption, chronic)

Treatment	• Individualized, often inappropriate or inadequate regimens for each patient • No directly observed treatment and little patient counseling • Often centralized, specialized TB services to which patients have limited access • No structure – no flexibility or adherence to specific patient needs	• Standardized proven regimens for each case type • Directly observed treatment by a suitable trained person; patient education/counseling • Drugs may be taken daily or 3x/week • Health worker can administer treatment 1x/week, trained volunteer on other days • Treatment can be administered at health facility, patient's home, or community center
Progress toward cure	• Information by individual sometimes available, but often not used or analysed • Information by cohort is almost never available	• Information recorded by individual • Aggregate data by cohort always available; enables progress to be reliably documented
Treatment follow-up	• Either not done at all or is unsystematic • Findings not acted upon • Often x-ray based, which adds to expense • Main indicator is patient adherence (collection of drugs) • Often no record of patients' whereabouts; follow-up contact impossible	• Systematic in content at fixed times • Based on inexpensive sputum smear microscopy • Findings acted upon to achieve or improve cure prospects • Main indicator is patient outcome (cure/completion of treatment • Location of patient is kept in the register which allows health worker to follow up if patient misses treatment
Results	• Low treatment success in most cases • Unreliable outcome information • Poor value for money • Increasing number of chronic, uncured cases • Increased infection • Growing drug resistance and creation of drug-	• High sputum smear conversion rate at end of initial phase • High cure rates • Decreased prevalence of chronic cases • Decreased transmission of infection • Prevention of drug resistance

	resistant cases	
LOGISTICAL ASPECTS		
Drug supply	• Often irregular with no system to ensure right amount, or for exact numbers of patients • Quality of drugs questionable in many circumstances	• Regular, reliable supply for all registered cases • Simple process to forecast supply for following year • Adequate stocks at higher levels • Better quality assurance of drugs
Lab	• May or may not produce accurate results or follow safety guidelines • Lab registers often not standardized and quality of work highly variable	Guidelines ensure: • systematic, standardized practices and registries provide accurate results in a timely manner from a higher level • quality control • safety • training
TB register	**May** exist. If so, this is often held at national or provincial level, is remote from patients, and does not permit cohort analysis. The register may consist of: • variable patient information • unsystematic recording of information on type of case, progress and results	**Always** exists, which permits systematic analysis. Includes the following: • people starting treatment • individual progress towards cure • consistent data • methodical monitoring at fixed times
POLITICAL ASPECTS		
Political commitment	• Often not addressed, since seen as outside the parameters of health agencies • Communication activities focused mainly on patients, ignoring the policy-makers	• Policy of financial support seen as central to sustainable TB control services • Advocacy and social mobilization seen as core activities

Chapter 5 – Implementing DOTS

There are three phases to DOTS implementation: a pilot project phase, an expansion phase and a maintenance phase. The different phases of implementation of DOTS in a particular setting require a different emphasis on the technical, logistical, and operational aspects of the strategy. The pilot stage emphasizes technical and operational aspects. The expansion stage emphasizes logistical aspects. Maintenance—or sustained effective TB control—emphasizes all three, but also includes on-going political commitment from governments.

Pilot Projects

Careful planning is necessary when implementing the DOTS strategy. Use of the existing health infrastructure facilitates initial implementation. The first step is to implement the strategy in a few demonstration and training districts. When these demonstration and training districts are fully implementing the strategy and are demonstrating high cure rates, they can serve as the training sites for staff from other districts in the same region. The demonstration and training districts test the feasibility of implementing all aspects of DOTS, integrated within the general health services.

Expansion

Expansion throughout the whole country takes place in stages and requires emphasis on training, monitoring and supervision. Demonstration and training districts serve as training sites for staff in districts which then become the demonstration and training sites in other regions. The regional demonstration and training districts then serve as training sites for staff throughout the same region. In this way, over a period of about 5 years, the strategy expands step by step throughout the whole country. After some time, when there is maximum use of the existing health infrastructure, the emphasis shifts to mobilization of the community to contribute to country-wide implementation.

Maintenance

The challenge after country-wide expansion is to maintain effective performance over time. In the maintenance phase training is important—training for new staff because of turnover, refresher training, and training for innovations. Politicians and decision-makers must be convinced of the economic returns that justify long-term investment—both commitment and funding—in TB control.

Chapter 6 – DOTS in Low-incidence Countries

Most industrialized countries can allocate more human, technical and financial resources to health care than developing countries, and are provided with a better health infrastructure. In these countries, TB incidence is generally much lower than in developing countries, and the annual risk of infection in the general population is low. A major issue in these settings is maintaining adequate expertise in TB control at all levels.

In these low-incidence countries the majority of TB cases typically occur in the elderly or in defined risk groups among the indigenous population and in young adults among foreign-born persons from high-prevalence countries. In some countries, the percentage of cases among foreign-born is as high as 50-70 percent.

Interventions that supplement the essential components of the DOTS strategy may be appropriate in industrialized countries. This modified strategy would apply to countries where the basic policy package is already in place and functioning successfully.

Table 4. DOTS in Low-incidence Countries

The Required Components of the DOTS Policy Package	Additional Elements of TB Control for Low-incidence Countries
Government commitment to sustained TB control	Government commitment to TB control, with the aim of elimination: • Legal framework including laws on mandatory notifications, cohort analysis of treatment results, and drug policy • TB control policy based on consensus by national authorities and leading organizations • Maintenance of an efficient network for TB control by ensuring technical leadership at national level and trained human resources at lower levels
Sputum smear microscopy to detect the infectious cases among those people attending health care facilities with symptoms of pulmonary TB	In the general population, case-finding among symptomatic patients Risk group management (e.g. active case-finding in high-risk groups) Diagnosis confirmed by culture Drug susceptibility testing, especially in groups at high risk of drug resistance Outbreak management (e.g. source and contact tracing)
Standardized short-course chemotherapy for all TB cases, with directly observed treatment (DOT) for at least the initial two	Directly observed treatment for more than the initial two months for high-risk groups and where cure rates are low

months among infectious cases	Specialized treatment for multidrug-resistant TB Preventive therapy for newly infected persons and for some high-risk groups, e.g. HIV-infected
Regular, uninterrupted supply of anti-TB drugs (preferably quality-controlled fixed-dose combination drugs)	Regulations on drug use; second-line drugs for drug-resistant TB available only in highly qualified centers
Evaluation and supervision: use of sputum smear microscopy for evaluation of patient progress towards cure	Surveillance based on a uniform reporting system Culture and sputum smear examination to assess treatment outcome Drug resistance surveillance Quality assurance of TB control data (e.g. auditing system)

Chapter 7 – The Future of TB Control

A commitment to TB control means that we must find ways to make better use of the DOTS strategy, we must accelerate research into new diagnostic tools, treatment options and vaccines, and we must encourage the mobilization of new partners in the fight against the epidemic.

Making Better Use of the Existing Strategy

Of all the WHO member states, 102 had accepted the DOTS strategy as of 1997. However, not all of these countries have implemented the strategy throughout the whole country. Several socio-economic and political constraints must be addressed immediately in order to ensure effective TB control reaches more of the world.

- ***More funds must be allocated to TB control***. Governments in some developing countries spend as little as $7 per capita on health care each year. In such situations, government health workers may be unable to obtain a regular supply of drugs and diagnostics, chronics will be created, cases will increase, people are likely to seek health care elsewhere or not at all, and the number of cases that go undetected is likely to rise.

- ***Health sector reform should enhance, not jeopardize, TB control services.*** Health sector reform may result in piecemeal introduction of user charges, reorganization of service delivery and other changes that may sometimes adversely affect health systems and TB control programmes. Governments must be made aware that investing in and strengthening TB control as part of the general health services will translate into future economic gains by ensuring a healthy population and workforce.

- ***Health workers, especially in low-income countries, must be trained and compensated appropriately to ensure a motivated workforce***. In some cases, health workers can survive only with informal payments from their patients or by conducting additional, private practice. This may create disincentives to best practice.

- ***Governments must take ownership of TB as a national problem rather than relying solely on international agencies to combat the disease.*** If TB programmes are reliant on external funding, for example from donors, rather than government support, they may be difficult to sustain in the long term.

- ***Physicians must support the implementation of DOTS and be a full partner in TB control efforts.*** Some doctors prefer to emphasize individual clinical judgement and drug regimens, while others may feel threatened by the fact that the strategy can be delivered by less highly trained workers. The full participation by doctors in the private sector is required for more widespread use of DOTS.

- ***Countries must not tolerate TB as an inevitability.*** In cultures where TB is socially tolerated, there is unlikely to be adequate commitment to reducing the burden of the disease.

Development of New Tools

Progress in improving the tools for the diagnosis, treatment and prevention of TB has been very slow. Sputum smear microscopy for the diagnosis of infectious TB cases represents technology that is over 100 years old. There has been no new anti-TB drug since the introduction of rifampicin in the 1970s. There has been little progress toward a new anti-TB vaccine since the development of BCG in the 1920s. The development of new diagnostic techniques, anti-TB drugs and vaccines has the potential to make a dramatic impact on TB control.

Diagnosis

Sputum smear microscopy is slow and labor-intensive. There is a need for rapid, robust and simple diagnostic tests for TB that are suitable for use in high prevalence countries. Until recently there have been few efforts to develop such tests. Simplified diagnosis would make a patient's access to the DOTS strategy much easier, more reliable and more widely available.

An accurate, rapid diagnostic test for smear-negative pulmonary TB is also needed because of the increase in reported cases of this form of TB in association with HIV.

Treatment

There is a need for a reliable combination product (a *single* tablet or capsule) that includes all four drugs for the initial phase of treatment. The development and widescale use of this combination product has the potential to reduce the risk of further emergence of anti-TB drug resistance. There is a need for shorter courses of anti-TB treatment, since the current treatment (at least six months) represents one of the most important obstacles to ensuring completion of treatment and cure. The development of new anti-TB drugs has

the potential to simplify and shorten anti-TB treatment, as well as to expand the range of drugs available to counter drug resistance.

Prevention

Vaccines

The currently available BCG vaccine is valuable in substantially decreasing the risk of TB in children. However BCG appears to be of little if any benefit in adults in decreasing the risk of TB infection or the risk of active disease in those already infected with TB. Vaccines are needed that provide protection against both infection *and* disease. The development and widespread use of such vaccines would dramatically reduce the number of TB patients who need the DOTS strategy.

Preventive therapy in HIV-infected individuals

Preventive therapy against tuberculosis involves giving the anti-TB drug isoniazid to individuals with TB infection in order to prevent the progression to active disease. Several large randomized controlled trails have demonstrated that preventive therapy can be effective in preventing TB in individuals dually infected with HIV and *M. tuberculosis*. WHO and UNAIDS have recommended that preventive therapy be a part of the package of care offered to people living with HIV, but that it only be used in settings where it is possible to provide testing and counseling for HIV ***and*** where it is possible to exclude active TB cases and ensure appropriate monitoring and follow-up. The feasibility and cost-effectiveness of large-scale use of preventive therapy in resource-poor countries still needs assessment. The priority for TB control programmes continues to be the detection and cure of infectious TB cases.

Mobilizing New Partners

The sustainability of TB control programmes may rest on mobilizing new partners to advocate for effective TB control policies and funding. All feasible and practical inter-sectoral allies—from national policy and decision makers to local religious and social groups—can raise awareness and demand for effective TB control, assist in the delivery of resources and services, and strengthen community participation.

For example, nongovernmental organizations can be mobilized to train health workers, provide funding and service delivery, while religious organizations, civic groups and disease support groups (such as HIV/AIDS patient counseling groups) can observe patients taking their medications or provide psychosocial support.

Glossary of Terms and Abbreviations

AIDS — Acquired immunodeficiency syndrome

BCG — Bacille Calmette-Guerin

Chemotherapy — treatment with chemical drugs, e.g. anti-TB chemotherapy means treatment with anti-TB drugs.

Chronic case — a TB case defined by the failure of the WHO re-treatment regimen given under direct observation by a health worker. A chronic case has received at least two courses of chemotherapy.

Counseling — face-to-face communication in which one person (the counselor) helps another (patient/client) to make decisions and act on them.

DOT — directly observed treatment, or watching the patient take his/her medication to ensure medications are taken in the right combination and for the correct duration.

DOTS — the brand name given to the WHO-recommended TB control strategy that combines five components: government commitment, case detection by sputum smear microscopy, standardized treatment regimen with directly observed treatment for at least the first two months, a regular drug supply, and a standarized recording and reporting system that allows assessment of treatment results.

Drug-resistant tuberculosis — a case of TB, usually pulmonary, excreting bacilli that are resistant to one or more anti-TB drugs.

GTB — The former WHO Global Tuberculosis Programme

Health sector reform — changes implemented to health services to strengthen primary health care and improve efficiency and cost-effectiveness of service delivery, usually driven by economic targets for reform rather than by health system priorities and outcomes.

HIV — human immunodeficiency virus

IUATLD — International Union Against Tuberculosis and Lung Disease

MDR-TB — multidrug-resistant tuberculosis, or TB bacilli resistant to at least the drugs isoniazid and rifampicin. MDR is the most severe form of bacterial resistance today.

NTP — National Tuberculosis Programme

PHC — primary health care

Preventive therapy — treatment aimed at preventing disease, e.g. isoniazid for the prevention of TB in some circumstances.

Regimen — a drug, or several drugs, given in certain doses for a stated duration.

Relapse — disease starting again after a patient was declared cured.

Social mobilization — the process of bringing together all feasible and practical inter-sectoral allies to raise awareness and demand for a particular programme, to assist in the delivery of resources and services, and to strengthen community participation for sustainability and self-reliance.

Sputum smear microscopy — examination of a person's sputum with a microscope to determine if TB bacilli are present.

TB — tuberculosis

UNAIDS — The Joint United Nations Programme on HIV/AIDS

WHO — World Health Organization

Annex

Sample Forms and Registers Used for TB Control Activities

- Tuberculosis Laboratory Register
- Tuberculosis Treatment Card
- District Tuberculosis Register
- Quarterly Report on New Cases and Relapses of Tuberculosis
- Quarterly Report on Results of Treatment of Pulmonary Tuberculosis Patients Registered 12-15 Months Earlier

NATIONAL TUBERCULOSIS PROGRAMME

TUBERCULOSIS LABORATORY REGISTER

Year_____

TB 04

Lab Serial No.	Date	Name (in full)	Sex M/F	Age	Name of Treatment Unit	Address (for new patients)	Reason for Examination		Results of Specimen			Signature	Remarks
							Diagnosis*	Follow up of chemo-therapy**	1	2	3		

* These are diagnosed New or Relapse cases.

** These are patients on chemotherapy.

NATIONAL TUBERCULOSIS PROGRAMME

TB 01

TUBERCULOSIS TREATMENT CARD

District TB No.: _____

Health Unit: _____

Name: _____

Address (in full): _____

Name and address of Contact Person: _____

_____

Sex: M ☐ F ☐ Age: _____ BCG: no scar ☐ scar seen ☐ scar dubious ☐

Disease Classification

Pulmonary ☐ Extra-pulmonary ☐

Site _____

Type of Patient

New ☐ Relapse ☐

Transfer In ☐ Other (Specify) ☐

Treatment after default ☐ _____

I. INITIAL INTENSIVE PHASE - Prescribed regimen and dosages:

Tick the appropriate box and indicate daily number of tablets and dosage of S (grams)

CAT 1	CAT 2	CAT 3	12- month
New case (smear-pos, seriously ill smear-neg or EP) ☐	Retreatment ☐	New case (smear-neg, EP) ☐	New case ☐
☐☐☐ HR Z S (E)	☐☐☐☐ HR Z E S	☐☐ HR Z	☐☐ S HT

HR: Isoniazid and rifampicin Z: pyrazinamide S: streptomycin
E: ethambutol HT: Isoniazid and thioacetazone

Month	Results of sputum examination							Weight (kg)
	Local lab			Reference lab				
	Date	Smear	Lab No.	Smear	Cult.	Sensitivity Sens.	Sensitivity Res.	
0								
2								
5								
8								
> 12								

Tick appropriate box after the drugs have been administered

MONTH \ DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Please turn over for continuation phase

II. CONTINUATION PHASE
(see Guidelines)

Prescribed regimen and dosages

Indicate number of tablets per dose

CAT 1
New case
(smear-pos, seriously ill smear-neg and EP)

Plan A ☐☐ 3 times a week (4 months)
HR H

OR

Plan B ☐ daily (6 months) OR ☐☐ daily (6 months)
HT H E

CAT 2
Retreatment

☐☐☐ 3 times a week (5 months)
HR H E

CAT 3
New case
(smear-neg, EP)

Plan A ☐☐ 3 times a week (2 months)
HR H

OR

Plan B ☐ daily (6 months)
HT

12-month
New case

☐ daily (10 months)
HT

MONTH \ DAY*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

*Enter X on day of supervised drug administration or when drugs are collected. Whenever drugs are collected for self-supervised administration draw a horizontal line (————) to indicate number of days supply given.

REMARKS: _____

NATIONAL TUBERCULOSIS PROGRAMME

DISTRICT TUBERCULOSIS REGISTER

Date of Registration	District TB No.	Name (in full)	Sex M/F	Age	Address (in full)	Name Treatment Unit	Date start treatment and regimen*	Disease classification P/EP	Type of patient **				
									New (N)	Relapse (R)	Transfer in (T)	Treatmt. after default (D)	Other (O)

* Enter one of the following regimens:

CAT 1: New smear-positive case, or New case (seriously ill smear-negative or seriously ill EP) — HRZS(E)
CAT 2: Retreatment — HRZES
CAT 3: New case (smear-neg, EP) — HRZ
12-mo: New case (12-month) — SHT

** Enter the appropriate code:

N: New case - patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than 1 month
R: Relapse - patient previously treated for tuberculosis and considered cured, but is now smear-positive
T: Transfer in - patient who has transferred into the district from another district
D: Treatment after default - smear-negative patient who is starting treatment again after defaulting
O: Other - situations different from the 4 mentioned above

Year_____ **TB 03**

Sputum examination (M. indicate months of treatment) Upper space: Result Lower space: laboratory number												Date treatment stopped ***						Remarks
Pre-treatment			End of 2nd m. (new) 3rd m. (old)			5th m. Smear	8th month			12th m. Smear	> 12th m. Smear	1. Cured (bact. negative)	2. Treatment completed (no bact.)	3. Died	4. Failure (smear-positive)	5. Defaulted (smear-negative)	6. Transferred Out	
Local Smear	Ref. Lab. Smear	Ref. Lab. Cult.	Local Smear	Ref. Lab. Smear	Ref. Lab. Cult.		Local Smear	Ref. Lab. Smear	Ref. Lab. Cult.									

*** Enter date in the appropriate column:

1. **Cured:** treatment completed and negative smear results on 2 or more consecutive occasions at 5 months and end of treatment
2. **Treatment completed:** treatment completed; no or only 1 negative smear result at month 5 or more
3. **Died:** patient known to have died from any cause whatsoever
4. **Failure:** smear-positive at 5 months or more, or has stopped treatment for more than 2 months before month 5 and was smear-positive at last examination, or smear-negative patient that became smear-positive at 2 month sputum smear examination
5. **Defaulted:** patient who has not collected drugs for more than 2 months, but became (or remained) smear-negative before defaulting
6. **Transferred out:** patient who has been transferred to another district

NATIONAL TUBERCULOSIS PROGRAMME

TB 07

Quarterly report on new cases and relapses of tuberculosis

Patients registered during
☐ quarter of 19

Name of District Tuberculosis Coordinator: _____

Date of completion of this form: _____

Signature: _____

Name of district: _____

District No: _____

Block 1

PULMONARY TUBERCULOSIS							EXTRA-PULMONARY TUBERCULOSIS (4)		TOTAL (5)		
SMEAR-POSITIVE					SMEAR-NEGATIVE (3)						
NEW CASES (1)			RELAPSES (2)								
Males	Females	Total	M	F	M	F	M	F	Males	Females	Total

SMEAR-POSITIVE NEW CASES. from Column (1) above

Block 2

Age-group (years)													TOTAL		
0-14		15-24		25-34		35-44		45-54		55-64		65 or more			
M	F	M	F	M	F	M	F	M	F	M	F	M	F	Males	Females	Total

Explanations on how to fill in the form

District Number = identification number of the district

Quarters: 1st quarter = January, February, March
2nd quarter = April, May, June
3rd quarter = July, August, September
4th quarter = October, November, December

Block 1: NEW CASES AND RELAPSES OF TUBERCULOSIS registered during _____ quarter of (year) _____

Fill in the quarter and the year.

Column (1): SMEAR-POSITIVE NEW CASES = patients with pulmonary tuberculosis, sputum smear-positive, who have never received anti-tuberculosis treatment.

Column (2): SMEAR-POSITIVE RELAPSES = patients with pulmonary tuberculosis, sputum smear-positive, who have been declared cured but have now got the disease again.

Column (3): SMEAR-NEGATIVE CASES = patients with pulmonary tuberculosis, with a negative sputum for AFB, in whom the diagnosis of tuberculosis was made by means other than sputum microscopy.

Column (4): EXTRA-PULMONARY TUBERCULOSIS = patients with tuberculosis of organs other than the lungs.

Column (5): TOTAL
Males - Add all male patients in columns 1+2+3+4
Females - Add all female patients in columns 1+2+3+4
Total - Add all patients (males + females) in columns 1+2+3+4

Block 2: SMEAR-POSITIVE NEW CASES: from Column (1) above

In this block enter the patients [already recorded in Block 1, column (1)] according to their sex and age group. If the exact age of a patient is unknown, at the time of his/her registration it should be estimated to the nearest 5 years (e.g. 15, 20, 25, etc.).

NATIONAL TUBERCULOSIS PROGRAMME

TB 08

QUARTERLY REPORT ON THE RESULTS OF TREATMENT OF PULMONARY TUBERCULOSIS PATIENTS REGISTERED 12-15 MONTHS EARLIER

Name of district: _____ District No.: _____ Name of District Tuberculosis Coordinator: _____	Patients registered during ☐ quarter of 19	Date of completion of this form: _____ 19 ___ Signature:

Total No. of pulmonary patients reported during the above quarter				Regimen	(1) Cured (smear-negative)	(2) Treatment completed (no smear results)	(3) Died	(4) Failure (smear-positive)	(5) Defaulted (smear-negative)	(6) Transferred to another district	Total number evaluated (sum of columns 1 to 6)
New Cases											
M	F	T*		1 New Cases							
				1.1 Smear-positive							
				1.2 Smear-negative							
Relapses											
M	F	T*		2 Retreatment							
				2.1 Relapses							
				2.2 Others							
				2.3 Total (2.1 + 2.2)							

* Of those, _____ (number) were excluded from evaluation of chemotherapy for the following reasons: _____