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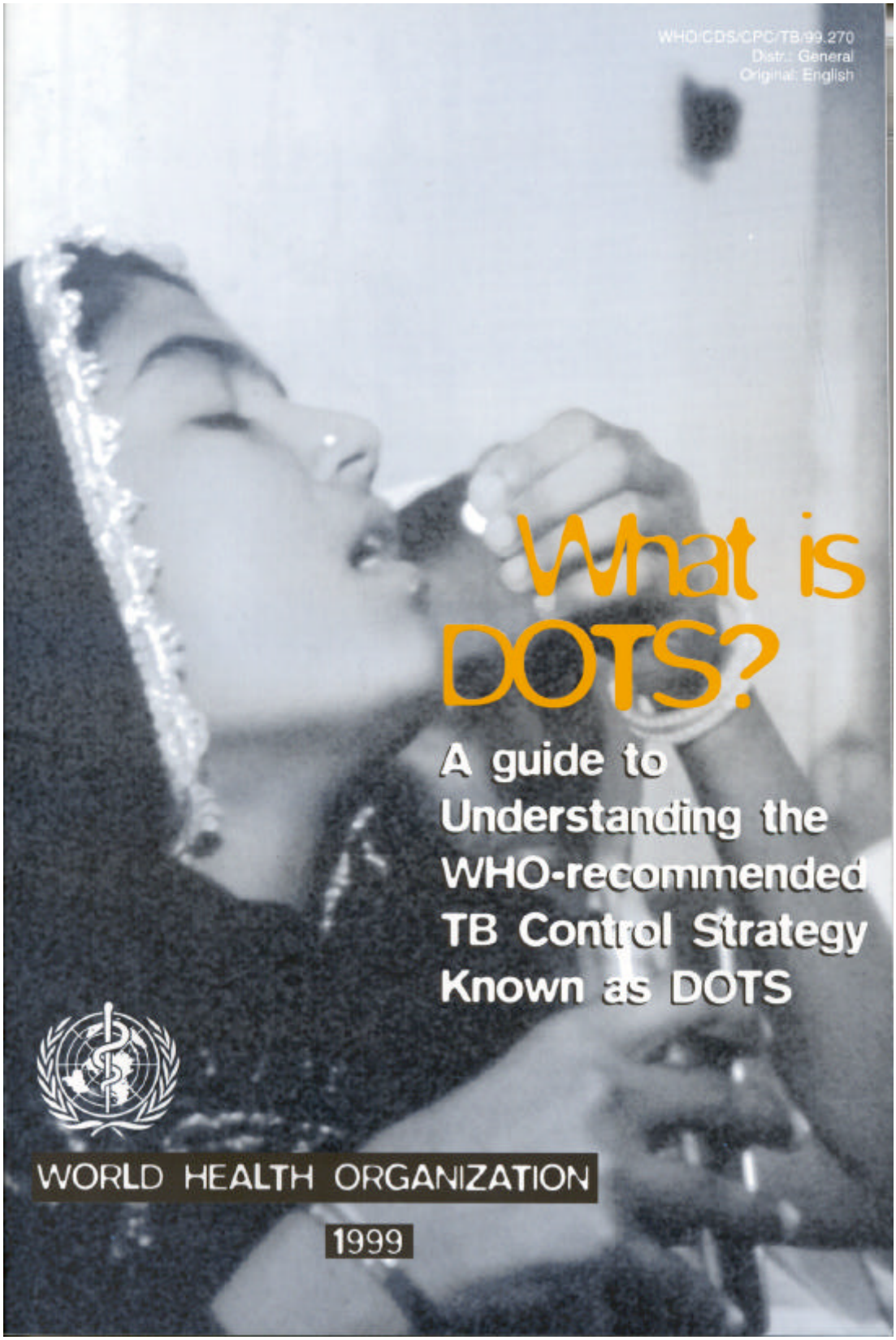

What is DOTS?

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

WORLD HEALTH ORGANIZATION

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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.