

An Expanded DOTS

Framework for Effective Tuberculosis Control



**Stop TB
Communicable Diseases**



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An Expanded DOTS Framework for Effective Tuberculosis Control

1. Background

1.1 Tuberculosis (TB) persists as a global public health problem of a serious magnitude requiring urgent attention. Current global efforts to control TB have three distinct but overlapping dimensions: humanitarian, public health and economic. Alleviating the illness, suffering and death of individuals caused by TB is the major humanitarian concern and calls for a patient-centred approach to TB control. The public health dimension concerns proper diagnosis and treatment of TB patients to decrease disease transmission within communities. This necessitates development of well-organized TB control programmes responsive and adaptable to the reforming health sector. TB is responsible for considerable direct and indirect costs to individuals and society. The economic dimension of TB control relates to reduction of these costs, alleviation of poverty and promotion of development.

1.2 The forty-fourth World Health Assembly (1991) recognized the growing importance of TB as a public health problem and the potential for cost-effective control using currently available tools [1]. This led to a reassessment of ongoing TB control efforts. The persistence of TB has been due chiefly to the neglect of TB control by governments, poorly managed TB control programmes, poverty, population growth and migration, and a significant rise of TB cases in HIV endemic areas. To help address the situation, a new framework for effective TB control was then developed [2] and a global strategy called DOTS was introduced. The five elements of the DOTS strategy, considered essential for global TB control are: political commitment, case detection using sputum microscopy among persons seeking care for prolonged cough, standardized short course chemotherapy under proper case-management conditions including directly observed treatment, regular drug supply, and a standardized recording and reporting system that allows assessment of individual patients as well as overall programme performance [3].

1.3 Since the introduction of the DOTS strategy in the early '90s, considerable progress has been made in global tuberculosis control. By 2000, 148 countries had adopted the WHO DOTS strategy for TB control and 27% of the global TB cases were treated under DOTS. Although considerable, this progress has not been enough. An estimated one third of the world's population is already infected with TB. Each year an estimated 8.4 million new cases are produced from this reservoir of infection, and 1.9 million people die of the disease [4]. The poor and marginalized in the developing world are the worst affected: 95% of all cases and 98% of deaths from TB occur in resource-poor countries. Even within countries adopting the DOTS strategy, much needs to be done to expand the services to the whole population.

1.4 The report of the Ad-hoc Committee on Tuberculosis Epidemic convened by WHO in London in 1998 commended the achievements of a few countries but expressed concerns about the slow progress of DOTS implementation in most countries with a high burden of TB [5]. Identifying the major constraints to DOTS implementation, the committee recommended a comprehensive and multi-sectoral approach to TB control. Subsequently, in late 1998, a global partnership was launched linking health, social and economic sectors in the fight against TB. The partnership, called "Stop TB Initiative", is hosted by WHO. In the year 2000, a high level Ministerial Conference of Ministers of

Health and Finance of the top 20 high burden countries endorsed the "Stop TB Partnership" in what is called the "Amsterdam Declaration" [6]. Global targets for TB control were also set in 1991 and reaffirmed subsequently (see below and Annex I: Definitions of Terms).

2. Why expand the DOTS Framework?

2.1 Several challenges impede sustainable implementation and expansion of TB control activities. Many of these stem from a weak political will failing to elicit the required health system and societal response to control TB. General public health services need to enhance their capacity to sustain and expand DOTS implementation without compromising the quality of case detection and treatment. Community involvement in TB care and a patient-centred approach need emphasis and promotion to improve both access to and utilization of health services. Collaboration and synergy among the public, private, and voluntary sectors are essential to ensure accessible and quality-assured TB diagnosis and treatment. The increasing impact of HIV on the incidence of TB especially in Sub-Saharan Africa calls for new partnerships and approaches. A surge in drug-resistant forms of TB in the former Soviet Union and several other parts of the world requires effective implementation of the DOTS strategy to prevent occurrence of new multidrug-resistant (MDR-TB) cases as well as measures to cure existing MDR-TB cases. Sustaining DOTS programmes will also entail their integration into primary health care and adaptation to ongoing reforms within health sectors worldwide.

2.2 In view of the above challenges and experiences of about a decade of DOTS implementation – achievements and constraints – there is a need to update and expand the current framework of the DOTS strategy. It is now necessary to widen the scope of the DOTS control strategy and make it a comprehensive support strategy – support to all providers, patients, and people to tackle the problem of TB. The expanded strategy lays equal emphasis on technical, managerial, social and political dimensions of DOTS. It acknowledges access to TB care as a human right and recognizes TB control as a social good with large benefits to society. It underscores the contribution TB control makes to poverty alleviation by reducing the great socio-economic burden that the disease inflicts on the poor.

3. Goals, Targets and Guiding Principles

3.1 The goals of TB control are to reduce mortality, morbidity and transmission of the disease, while preventing drug resistance, until it no longer poses a threat to public health. It also aims to reduce human suffering and the social and economic burden families and communities have to bear as a consequence. To achieve this, it is necessary to ensure access to diagnosis, treatment and cure for each TB patient, and to protect vulnerable populations from TB and its drug-resistant forms.

3.2 The forty-fourth World Health Assembly (1991) set the targets for global TB control to be achieved by the year 2000. These are to cure 85% of the infectious TB cases and to detect 70% of such cases. In view of the slow progress in many high burden countries, the target date was revised to 2005. Two of the WHO's six regions have adopted additional impact targets of reducing the prevalence of pulmonary smear positive

disease as well as TB death rate (all forms) per capita by 50 per cent by 2010. The targets are consistent with those proposed by G8 at Okinawa.

3.3 Enabling achievement of high cure rates for all, and especially infectious TB cases, remains the highest priority. Besides helping to rapidly reduce transmission, TB programmes achieving high cure rates are likely to attract the great majority of existing cases. Giving priority to case finding before ensuring access to high quality care for diagnosed cases could compound the TB problem by producing chronic cases and MDR-TB. Improved and expanded case detection activities should follow sustained achievement of low default and high cure rates. By means of integration of TB activities into general health services, introduction of guidelines for health care providers on proper management of respiratory diseases, incorporation of community health workers and volunteers for service delivery, involvement of private and other non-governmental health providers and adaptation of DOTS implementation to suit local settings and situations, countries are expected to achieve the global targets. This should result in reduction in TB morbidity, mortality and disease transmission leading to a gradual decline in the epidemiological burden of the disease. Annex II presents relevant process and outcome indicators for TB control. (Annex II: Indicators for TB control).

4. The Expanded Strategic Framework

4.1 The expanded framework reinforces the five essential elements of the DOTS strategy. It applies to HIV-related and drug-resistant forms of TB as well. The five elements of the expanded framework are:

- a. Sustained political commitment** to increase human and financial resources and make TB control a nation-wide activity integral to national health system;
- b. Access to quality-assured TB sputum microscopy** for case detection among persons presenting with, or found through screening to have, symptoms of TB (most importantly prolonged cough). Special attention is necessary for case detection among HIV-infected people and other high-risk groups, e.g. people in institutions.
- c. Standardized short-course chemotherapy to all cases of TB under proper case-management conditions including direct observation of treatment** – proper case management conditions imply technically sound and socially supportive treatment services;
- d. Uninterrupted supply of quality-assured drugs** with reliable drug procurement and distribution systems and,
- e. Recording and reporting system enabling outcome assessment** of each and every patient and assessment of the overall programme performance.

4.2 **Sustained political commitment to increase human and financial resources and make TB control a nation-wide activity and an integral part of the national health system.**

4.2.1 The expanded DOTS strategy calls for sustained political commitment by national governments and mobilization of additional resources – human and financial – from within and outside endemic countries to help implement a comprehensive and expanded DOTS programme. The DOTS programme should be made an integral health system activity with nation-wide coverage that anchors TB activities throughout the health system at all levels, including peripheral health facilities and the community. Being a public good with large benefits to

society, adequate resources should be made available to achieve the goal of TB control worldwide.

4.2.2 The effective expansion of DOTS demands a multi-sectoral and sustained response to address the social and environmental factors that increase the risk of developing TB. This requires TB control to be viewed broadly, as a component of international, national and local strategies to alleviate poverty, with due consideration given to the right of every TB patient to access treatment.

4.2.3 Particular efforts are needed to foster local, national and international partnerships for TB control. Such partnerships should be linked to a long-term strategic action-plan that needs to be prepared by national TB programmes taking into account technical and financial requirements at all levels.

4.2.4 Social mobilization is needed to tackle TB within high-prevalence countries. This is essential to further and sustain the political will necessary for effective implementation of a comprehensive DOTS strategy. Governments could facilitate social mobilization by fostering communication among all health care providers, patients and public at large.

4.3 **Access to quality-assured TB sputum microscopy for case detection among persons presenting with symptoms of TB, screening of individuals with prolonged cough by sputum microscopy and special attention to case detection among HIV-infected people and other high-risk groups, e.g. people in institutions.**

4.3.1 The recommended method of case detection remains sputum smear microscopy among symptomatic persons seeking care at health care facilities. This requires health care services to be widely available and accessible to the whole population including the poorest sections of the community. Adequate investments in the health system are essential to provide access to a sputum microscopy network with built-in quality control.

4.3.2 Access to health care may not automatically improve case detection. Every effort must be made to detect infectious cases among those who present themselves to health care facilities including hospitals, medical institutions and non-governmental organizations and to private practitioners. For this, health care providers should be well informed about TB and about use of quality-assured sputum microscopy for case detection.

4.3.3 Standardized practice guidelines for those providing care of respiratory diseases may improve case detection among patients with respiratory symptoms, increase quality of TB diagnosis and strengthen the ownership of TB control activities by general health care providers.

4.3.4 HIV infection remains the single most important factor that increases the risk of developing TB. For this purpose, TB control programmes should be linked closely with HIV/AIDS prevention and control programmes. Strategies for patient care in particular should be developed in a coordinated manner (Annex III: TB/HIV).

4.3.5 Special efforts are also required to systematically detect cases at an early stage among institutionalized captive and vulnerable populations such as prisoners.

4.3.6 As resources increase, additional diagnostic tools such as chest X-ray, mycobacterial culture and drug susceptibility testing may be added to supplement sputum smear microscopy in a systematic manner.

4.4 Standardized chemotherapy to all confirmed cases of TB under proper case-management conditions including direct observation of treatment; proper case management conditions imply technically sound and socially supportive treatment services.

4.4.1 The mainstay of TB control is administration of standardized chemotherapy to all confirmed cases. This ought to be done under technically sound and socially supportive case-management conditions. To ensure the accountability of TB services, help TB patients to adhere to treatment and avoid emergence of drug-resistant forms, direct observation of treatment is recommended whenever rifampicin is being administered. WHO recommended and published guidelines on patient categorization and management should be followed [7, 8].

4.4.2 Harnessing community contribution to TB care could increase access to effective TB care. To enable them to adhere to treatment, TB patients need support and care that is sensitive to their needs. In practice it means providing a treatment partner or supporter acceptable to patients to reinforce their motivation to continue treatment and counter the tendency of some to interrupt treatment. TB control programmes should explore the use of locally appropriate and acceptable ways of community-based or work place-based direct observation of treatment [9].

4.4.3 In settings where private and voluntary providers play a role in providing TB case detection and treatment, public health services should collaborate in mutually acceptable ways. This collaboration is necessary to ensure that standardized TB treatment is available for every patient through all qualified health providers. Context-sensitive use of enablers and incentives that can be sustained may help improve provider compliance with treatment guidelines as well as adherence to treatment by patients.

4.4.4 Quality-assured sputum microscopy should be accessible to monitor the treatment progress, assess treatment outcomes and certify cure among patients of pulmonary tuberculosis.

4.4.5 High prevalence of MDR-TB is a problem some countries are facing and more are likely to encounter. The first action of paramount importance in this regard is to demonstrate and ensure high detection and cure rates of all new cases in a sustained manner through the existing health system. There is no alternative to first accomplishing this basic requirement. Secondly, management of MDR-TB cases must follow clear guidelines. DOTS programmes achieving high detection and cure rates, possessing the capacity to manage MDR-TB cases, and having access to sustained flow of adequate resources may consider incorporation of second-line drugs for treatment of drug-resistant cases. This must be undertaken

in a systematic and standardized manner (see Annex IV: DOTS Plus for MDR-TB). WHO guidelines on treatment of MDR-TB within programme conditions should be followed [10].

4.5 **Uninterrupted supply of quality-assured drugs with reliable drug procurement and distribution systems.**

4.5.1 The cornerstone of any TB programme hoping to achieve effective control is an uninterrupted and sustained supply of quality-assured anti-TB drugs.

4.5.2 It is essential to establish a reliable system or strengthen the existing system of periodic procurement and regular distribution of all essential anti-TB drugs to all levels of health services.

4.5.3 The TB recording and reporting system is designed to provide the information needed to plan, procure, distribute and maintain adequate stocks of drugs.

4.5.4 Anti-TB drugs should be available free of charge to all TB patients since curing TB patients is beneficial to society at large. Their proper utilization in practice should be strictly monitored.

4.5.5 The use of fixed-dose combinations (FDCs) of proven bioavailability, rather than single drugs, could help improve drug supply logistics as well as drug administration, reduce non-adherence to treatment and prevent development of drug resistance.

4.6 **Recording and reporting system enabling outcome assessment of each patient and assessment of the overall programme performance.**

4.6.1 A strength of the DOTS strategy is the establishment and maintenance of a surveillance and monitoring system with regular two-way communication between the central and peripheral levels. This system is based on standardized recording of individual patient information including information on treatment outcomes in registers maintained at an appropriate peripheral level and on analysis and reporting in a prescribed format on a quarterly basis.

4.6.2 Such a system is useful not only to monitor progress and treatment outcomes of individual patients but also to evaluate overall programme performance. Definitions of case categories, classification of disease and treatment outcomes are presented in Annex I.

4.6.3 In applying the expanded DOTS framework, the recording and reporting system may be expanded to incorporate additional information such as results of culture and drug susceptibility testing. In settings where MDR-TB treatment is undertaken as a programme activity, the information system will require adaptations and these should be undertaken in such a way to ensure strict monitoring. A key requirement would be to keep the system simple enough for analysis and use at the basic management level.

4.6.4 Local analysis and use of routinely collected data should be encouraged. This helps to identify constraints in achieving desirable results. The progress by NTPs towards developing a capacity of detecting and curing every infectious case

of TB may be assessed at different levels by several process and outcome indicators. These are also presented in Annex III.

5. Key operations

After adoption of DOTS -- the WHO policy package for TB control, some key operations need to be established and sustained until TB is no longer a public health threat. A stepwise implementation of the key operations is recommended, with pre-testing in a demonstration zone before full implementation. In reality, implementation requires adaptation to local circumstances and there may be an overlap of steps mentioned below in revising the programmes. All DOTS programmes should aim at achieving total geographical and total patient coverage in due course.

The expanded DOTS framework touches upon several aspects of TB control operations ranging from basic sputum microscopy to management of MDR-TB. The nature and magnitude of problems faced in DOTS implementation, the phase of implementation and the extent of resources available will require national TB programmes to carefully decide on priorities and the logical sequence that needs to be followed in applying the expanded framework. This would be context-specific in large part. As a part of expansion, the basic operations need to be supplemented by additional key operations. All these are listed below.

5.1 Basic operations for DOTS implementation in a country

5.1.1. Establish a **National Tuberculosis Programme (NTP) with a central unit** to guarantee the political and operational support for the provincial, district and sub-district levels. This support must include the assurance of sustained local and/or external funding for all the essential aspects of the programme.

5.1.2. Prepare a **programme development plan** for the NTP based on findings of a systematic review of the prevailing situation, with details on budget, sources of funding and responsibilities [11, 12]. Consider opportunities and challenges posed by health sector reforms under way (see Annex V). Describe strategy for involving other health programmes, other public sector institutions, non-governmental organizations and private sector. Coordination of activities with HIV/AIDS programmes and joint HIV/AIDS and TB programme support to different service providers is required in high HIV prevalence populations.

5.1.3 Prepare a **programme manual** which should contain the following: structure of the programme, job descriptions, case definitions, clear instructions for case finding and diagnosis including laboratory techniques, treatment guidelines eventually integrated with treatment guidelines for other priority diseases, instructions for monitoring including the relevant reporting forms, plans for drug distribution, stock keeping and supervision.

5.1.4. Establish the **recording and reporting system** using standardized material, which provides, through sputum smear examination, clear information on type of disease and case category and, through cohort analysis, information on treatment results. This system is a tool to evaluate the essential aspects of the control programme and should be used in preparing an annual evaluation report on the programme.

5.1.5 Plan and initiate a **training programme** covering all aspects of the policy package and prepare a plan for training regional and district primary health care staff and laboratory technicians involved in the TB programme. The strength and sustainability of DOTS programmes would depend on timely, adequate and ongoing training of personnel, which ensures that the quality of services is assured and maintained. Implementation of the expanded DOTS strategy cannot be successful without additional and improved human resources. Earmark adequate funding to make human resource development an integral part of DOTS implementation.

5.1.6 Establish a **microscopy services network** with binocular microscopes and adequate ancillary equipment and with laboratory technicians trained in sputum smear microscopy. The microscopy network should also include laboratories at provincial levels with responsibility for quality control. Within the first year establish a reference laboratory. This laboratory should develop a system of quality control for sputum smear microscopy, conduct training courses and supervisory visits. If additional resources are made available, establish culture and drug susceptibility testing in order to monitor drug resistance.

5.1.7. Establish **treatment services** with the primary health infrastructure where directly **observed** short-course chemotherapy is given priority and patient education is provided.

5.1.8 Secure a **regular supply of drugs and diagnostic material** based on previous case notification data. Organize the logistics support through a distribution system, which meets the country specific needs to guarantee the patients' uninterrupted intake of drugs throughout the course of treatment

5.1.9 Design a **plan of supervision** of the key operations at the intermediate and district level to be implemented from the start of the programme.

5.2 **Additional key operations**

5.2.1 **Information, Education, Communication and Social Mobilization**

Information, Education, Communication(IEC), advocacy and social mobilization constitute essential elements for furthering DOTS implementation and expansion. Appropriate communication of information to the community and patient education can improve health seeking behaviour, treatment adherence and treatment outcomes. IEC campaigns should be used where well functioning DOTS programmes are in place and avoided in areas where they are not well established. In countries not achieving high cure rates, advocacy strategies and not IEC should be the first priority to encourage governments to first support establishment and expansion of DOTS. Social mobilization is necessary to sustain support for TB control. This is best accomplished when many partners are mobilized to demand effective TB control for their communities [13].

5.2.2 **Involving private and voluntary health care providers**

Effective involvement of private health care providers is imperative in order to achieve total geographical and patient coverage for DOTS implementation. The private health sector comprising private practitioners, voluntary and for-profit organizations, professional societies, private hospitals and corporate health

providers offers major opportunities to further DOTS implementation. By involving them, DOTS programmes can enhance patient access and acceptance, increase case detection and improve treatment outcomes. Involvement of the private sector in DOTS implementation may be achieved through a variety of approaches [14]. For this however, TB programme managers should initiate and maintain dialogue with private providers at all levels, solicit their representation on advisory and monitoring bodies of NTP, encourage development of locally relevant models of private sector involvement at district level and below and include guidelines on private providers involvement in the national TB control frameworks.

5.2.3 Economic analysis and financial planning

Many NTPs continue to be implemented under severe financial constraints. They have to compete with other health programmes for budget allocations from government and donors. In recent years, there have been efforts to rationalize the allocation process through application of economic analysis. For instance, cost-effectiveness analyses seek to relate the economic costs of health interventions to their outcomes which may be TB specific indicators such as cure rates or generic health outcomes such as years of life or DALYs saved. TB programme managers should familiarize themselves with the main types of economic analysis and understand how they are undertaken and how they can be used. This could equip them to convince policy makers about relative benefits of investing in DOTS implementation.

The development of a sound financial plan for DOTS implementation and expansion is a key task for TB programme managers. Effective budgeting has to ensure that sufficient funds will be available for all activities required to implement the five DOTS components. This needs to include both sufficient funds for TB -specific activities and any investment required in general health services for DOTS implementation. In addition to a comprehensive analysis of resource requirements, the budget should comprise a description of available funding from government and donor sources. The identification of any funding gap should be actively brought to the attention of the government and the donors in an effort to secure adequate funding. DOTS implementation under conditions of funding shortage is likely to result in inferior outcomes.

5.2.4 Operational research

Programme-based operational research should be an integral component of DOTS implementation. Designing and conducting locally relevant operational research can help identify problems and reasons for weak performance and determine workable solutions. For this purpose, informed collaboration between programme managers and researchers is essential. Acquiring basic skills in identifying and addressing issues related to programme operations and performance could help programme managers initiate operational research in collaboration with researchers and academia. This would facilitate sustaining and strengthening DOTS implementation, expanding it effectively and establishing productive collaborations and sustainable partnerships.

ANNEXES

Annex I

Definitions of Terms

DOTS

The recommended strategy for TB control. It comprises:

- Government commitment to ensuring sustained, comprehensive TB control activities
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services.
- Standardised short-course chemotherapy using regimens of six to eight months, for at least all confirmed smear positive cases. Good case management includes directly observed therapy (DOT) during the intensive phase for all new sputum positive cases, the continuation phase of rifampicin-containing regimens and the whole re-treatment regimen.
- A regular, uninterrupted supply of all essential anti-TB drugs
- A standardized recording and reporting system that allows assessment of case-finding and treatment results for each patient and of the TB control programme performance overall.

Targets for TB control established by the forty-fourth World Health Assembly (1991)

- To cure 85% of the sputum smear-positive TB cases detected.
- To detect 70% of the estimated new sputum smear-positive TB cases.

Tuberculosis suspect

Any person who presents with symptoms or signs suggestive of TB, in particular cough of long duration.

Case detection

Activity of identifying infectious cases, mainly among adults attending an outpatient health facility for any reason with cough for 2 or 3 weeks or more, through sputum smear examination.

Case definitions:

Case of tuberculosis. A patient in whom tuberculosis has been bacteriologically confirmed, or has been diagnosed by a clinician.

Note: Any person given treatment for tuberculosis should be recorded.

Definite TB case: Patient with positive culture for the *Mycobacterium tuberculosis* complex. (In countries where culture is not routinely available a patient with two sputum smears positive for AFB is also considered a “definite” case.)

By localisation and bacteriology:

Pulmonary tuberculosis, sputum smear positive (PTB+)

Two or more initial sputum smear examinations positive for Acid-Fast Bacilli (AFB), **or**
One sputum smear examination positive for AFB plus radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician, **or**
One sputum smear positive for AFB plus sputum culture positive for *M. tuberculosis*.

Pulmonary tuberculosis, sputum smear negative (PTB-)

Case of pulmonary tuberculosis which does not meet the above definition for smear positive TB.

Note: In keeping with good clinical and public health practices, diagnostic criteria should include: at least three sputum specimens negative for AFB, **and**
radiographic abnormalities consistent with active pulmonary tuberculosis, **and**
no response to a course of broad spectrum antibiotics, **and**
decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy.

Extra-pulmonary tuberculosis

Tuberculosis of organs other than the lungs: e.g. pleura, lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, meninges etc. Diagnosis should be based on one culture positive specimen, or histological or strong clinical evidence consistent with active extra-pulmonary tuberculosis, followed by a decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy. (A patient diagnosed with both pulmonary and extra-pulmonary tuberculosis should be classified as a case of pulmonary tuberculosis.)

Categories of patients for registration on diagnosis

New: patient who has never had treatment for TB or took anti-tuberculosis drugs for less than one month.

Relapse: patient previously treated for TB who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (smear or culture) tuberculosis.

Failure: patient who, while on treatment, is sputum smear positive at 5 months or later during the course of treatment.

Return after default: patient who returns to treatment with positive bacteriology, following interruption of treatment for two months or more.

Transfer in: patient who has been transferred from another tuberculosis register to continue treatment.

Other: all cases which do not fit the above definitions. This group includes **chronic cases:** patient who is sputum positive at the end of a re-treatment regimen.

Note: Although smear negative pulmonary and extra-pulmonary cases may also be relapses, failures or chronic cases, this should be a rare event, supported by pathological or bacteriological evidence.

Treatment outcomes for smear positive pulmonary TB patients:

Cure: patient who is sputum smear negative in the last month of treatment and on at least one previous occasion.

Treatment completed: patient who has completed treatment but who does not meet the criteria to be classified as cured or failure.

Treatment failure: patient who is sputum smear positive at five months or later during treatment.

Died: patient who dies for any reason during the course of treatment.

Defaulter: patient whose treatment was interrupted for 2 consecutive months or more.

Transfer out: patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known.

Treatment success: sum of patients cured and those who completed treatment.

Notes:

In countries where culture is current practice patients can be classified as cure or failure on the basis of culture results.

Other definitions:

Cohort: Group of patients diagnosed and registered for treatment during a time period (usually one-quarter of the year). **Note:** New and previously treated patients form separate cohorts.

Directly Observed Treatment (DOT): A trained and supervised person observes the patient swallowing the medication.

Annex II

Indicators for TB control

<p>COVERAGE</p>	<p>At national level: Number and % of districts with DOTS strategy; Population living in areas covered by DOTS strategy.</p> <p>At district level: Number of health facilities with DOTS services / total health facilities.</p>	<p>Surrogate for population coverage by DOTS strategy.</p> <p>Particularly public facilities, but may include NGO and/or private sector if needed.</p>
<p>DETECTION</p>	<p>At health facility and district levels: Number of symptomatic patients detected with cough > 2 – 3 weeks / total outpatients.</p> <p>Number of smear-positive cases detected / number of symptomatic patients detected with cough of over 2 – 3 weeks.</p> <p>At laboratory level: Number of smear examinations done for diagnosis (or of examined patients). Percentage of positive slides for diagnosis (or of smear-positive patients).</p> <p>At region / state / national level: Number of new smear-positive cases detected / number of estimated new smear-positive cases. Number of total new cases detected / number of total estimated new cases.</p>	<p>Needed for resource planning.</p> <p>Needed for resource planning and is surrogate for TB frequency and trend in community.</p> <p>Indicates workload and case detection; for resource planning. Under the same conditions, the trend over time can indicate the trend of TB.</p> <p>To be compared with WHO target of 70% case detection. Analysis of trends.</p>
<p>DIAGNOSIS QUALITY</p>	<p>At health facility and district levels: Number of smear-positive pulmonary cases / Total pulmonary TB cases. Number of smear-positive cases / Total TB cases.</p> <p>Percentages of discordance for positive smears and for negative smears.</p>	<p>Indicate whether clinicians are using microscopy or clinical / X-ray in TB diagnosis and the priority of smear-positive case in diagnosis and detection of TB. Indicates quality of microscopy examination.</p>

TREATMENT OUTCOME	<p>At all levels:</p> <p>Cohort analysis of registered smear-positive new cases: % cure, % treatment completion, % failure, % death, % default, % transfer out; % treatment success = % cure + % treatment completion.</p> <p>Cohort analysis of re-treatment smear-positive cases by category: relapses, failures, treatment interruption and chronic / MDR cases</p> <p>Sputum conversion rate : % of TB patients who are smear-negative at 2nd-3rd month of anti-TB treatment</p>	<p>Should be done for all patients registered in specified period (on quarterly basis)</p> <p>To be compared with WHO target: 85% treatment success rate. Should be done for each category.</p> <p>Early surrogate for treatment success.</p>
EPIDEMIOLOGY	<p>National / regional trends:</p> <p>Incidence of smear-positive cases and total cases.</p> <p>Age and sex distribution.</p> <p>TB meningitis under 5 years of age.</p> <p>TB mortality rate.</p> <p>Annual risk of TB infection.</p> <p>HIV sero-prevalence in TB patients.</p> <p>Drug resistance prevalence.</p>	<p>Incidence: Number of new cases per population per year.</p> <p>Distribution of numbers and rates.</p> <p>Surrogate for transmission in community at constant level of BCG coverage.</p> <p>From vital statistics.</p> <p>Tuberculin prevalence survey in children (usually between 6 and 8 years of age; first school grade).</p> <p>Estimated through survey.</p> <p>Estimated through survey or surveillance system</p>
ECONOMIC ANALYSIS	<p>At region / state / national level:</p> <p>Cost per patient treated</p> <p>Cost per patient cured</p> <p>Cost per life-year saved</p> <p>Total required funding per fiscal year Total available funding Funding gap</p>	<p>To compare the efficiency of budget usage between various implementation sites</p> <p>Cost-effectiveness measure to establish the efficiency of resource use in relation to outcomes (program-specific)</p> <p>Cost-effectiveness measure to establish the efficiency of resource use in relation to outcomes (for sectorwide comparisons)</p> <p>Financial planning indicators; any funding gap will diminish the probability of successful programme implementation</p>

Annex III

TB / HIV

Until recently, the WHO/UNAIDS strategy for TB/HIV (tuberculosis in high HIV prevalence populations) consisted of “a dual strategy for a dual epidemic”. This dual strategy comprised a strategy for HIV/AIDS care (that often neglected tuberculosis) and the DOTS strategy (that often neglected HIV/AIDS care). However, there is increasing recognition of the overlaps between tuberculosis and HIV: tuberculosis is a leading cause of HIV-related morbidity and mortality while HIV is the most important factor fuelling the tuberculosis epidemic in high HIV prevalence populations. There is therefore a clear need for a new evidence-based international strategy to reduce the burden of TB/HIV. HIV/AIDS and tuberculosis programmes need to work together to support general health service providers in making available a full range of HIV and tuberculosis prevention and care interventions [WHO 2002, in preparation].

The new strategy considers the roles of HIV/AIDS and tuberculosis programmes in supporting the general health service response to the needs of people in high HIV populations. The goal is to reduce morbidity and mortality due to tuberculosis (while minimizing the risk of anti-tuberculosis drug resistance), as part of overall efforts to reduce HIV-related morbidity and mortality. The strategy is relevant to all regions where high rates of HIV infection may fuel the tuberculosis epidemic, especially to sub-Saharan Africa, since this region bears the overwhelming brunt of TB/HIV.

The main burden of HIV-related disease in developing countries arises from a limited number of common pathogens, including *Mycobacterium tuberculosis*, the pneumococcus and non-typhoid salmonellae. Revised estimates of global TB/HIV epidemiology indicate that 11% (640 000) of all new TB cases in adults (15-49y) were attributable to HIV infection in 2000[E L Corbett, submitted]. The fraction was much greater in Africa (31%) and some industrialized countries, notably the USA (26%). Of 1.9 million deaths from TB, 18% (342 000) were attributable to HIV. TB was the immediate cause of 15% of all adult AIDS deaths, of which only about one third (32%) received TB treatment. The prevalence of TB-HIV co-infection in adults was 0.41% (13 million people). Co-infection rates exceeded 5% in nine African countries; South Africa alone had 1.9 million co-infected adults. The evolving international response to TB/HIV takes into consideration the perspective of the person living with HIV infection (for whom tuberculosis is often one illness among several in the course of progression of HIV infection) and the public health perspective (reducing HIV and tuberculosis transmission and therefore the TB/HIV disease burden).

HIV infection fuels the tuberculosis epidemic through a sequence of events, starting from the point at which a person becomes dually infected with *M. tuberculosis* and ending with the development of active tuberculosis. Effective case finding and cure (through implementation of the DOTS strategy) interrupts disease transmission by infectious cases at the end of this sequence. To counteract the impact of HIV, significant expansion in the scope of the DOTS strategy for tuberculosis control is required beyond effective case finding and cure, through a range of interventions earlier in the sequence. These interventions include measures to decrease HIV transmission (e.g. condoms, treatment of sexually transmitted infections); administering highly active antiretroviral therapy (HAART); tuberculosis preventive treatment (aimed at prevention of a first ever or

recurrent episode of tuberculosis); and antibiotic prophylaxis against bacterial infections. A new range of partners and activities are necessary to deliver these interventions, in addition to tuberculosis programme implementation of the DOTS strategy, in order to decrease the burden of tuberculosis in high HIV prevalence populations.

Delivering basic medical care in high HIV prevalence populations requires large investments for sustained improvement in health service infrastructure. A framework for a coherent health service response incorporates prioritized interventions relevant at different levels of the health care system according to a country's resource level. Field experience and policy analysis should inform collaboration (leading to integration if demonstrably beneficial) between HIV/AIDS and tuberculosis programmes in support of the general health service response to TB/HIV.

Well-coordinated activities between tuberculosis and HIV programmes could greatly help reduce morbidity and mortality among people infected with HIV, in implementing the interventions which interrupt the sequence of events by which HIV fuels tuberculosis. Part of this challenge is to minimize the incidence of HIV infection, especially among the one third of the global population harbouring *M tuberculosis* infection. Education of the general public and of target groups can facilitate the uptake of HIV prevention measures (e. g. condoms, treatment of other sexually transmitted infections). TB and HIV programmes can promote voluntary counselling and testing for HIV as an entry point for access to the whole range of measures (psychological, preventive and curative) that are potentially available for people infected with HIV.

Annex IV

DOTS Plus for MDR-TB

High levels of MDR-TB (defined as TB bacilli resistant to at least isoniazid and rifampicin) in some areas are a threat to current TB control efforts. WHO and its partners have established the WHO Working Group on DOTS-Plus for MDR-TB to develop evidence-based policy guidelines for the management of MDR-TB. Pilot projects shall constitute evidence to guide the creation of specific policy to be used by WHO Member States.

DOTS-Plus for MDR-TB is a comprehensive management initiative under development, built upon the five elements of the DOTS strategy. However, DOTS-Plus also takes into account specific issues, such as the use of second-line anti-TB drugs that need to be addressed in areas where there is significant prevalence of MDR-TB. The goal of DOTS-Plus is to prevent further development and spread of MDR-TB. DOTS-Plus is not intended as a universal option, and is not required in all settings. DOTS-Plus should be implemented in select areas with significant levels of MDR-TB in order to combat an emerging epidemic. The underlying principle is that proper implementation of DOTS will prevent the emergence of drug resistance and should be the first step in fighting MDR-TB. It is not possible to conduct DOTS-Plus in an area without having an effective DOTS-based TB control programme in place.

While access to second-line anti-TB drugs must increase, these drugs should only be used in DOTS-Plus pilot projects which meet the standards set forth by the Scientific Panel of the Working Group as indicated in the *Guidelines for the Establishing DOTS-Plus Pilot Projects for the Management of MDR-TB*. Adherence to these Guidelines aims to manage existing cases of MDR-TB while preventing rapid development of resistance to second-line anti-TB drugs. Sample protocols are available to design standardized or individualised treatment regimens with second-line drugs to be used in DOTS-Plus pilot projects [15].

Members of the pharmaceutical industry have agreed to provide concessional prices for DOTS-Plus pilot projects. In order for projects to benefit from any pricing arrangements, the Green Light Committee must approve the projects. The Green Light Committee has been established to review applications of projects and determine whether projects are in compliance with the above-mentioned Guidelines, which is a condition for approval [16].

Annex V

Health sector reforms and TB control

Throughout the world, many health systems are undergoing changes. These so called reforms often have four linked objectives: to improve the effectiveness, equity, efficiency and quality of health financing and health services. These reforms are divergent and comprise various concurrent processes. These may include decentralization; sector-wide programming and financing, a process by which governments and donors agree on priorities and systems for managing and monitoring progress in health sector development; integration of programmes; cost sharing; development of an insurance system; autonomy for hospitals and measures to increase private participation in public health provision. Each of these can have different effects on the organization, management and conduct of TB control interventions.

Experiences on the effects of health sector reforms on DOTS implementation are varied. However, some generalizations can be drawn. Some system reform policies may improve the enabling environment for DOTS. These include increased sustainability of financing, local governmental and community involvement in health service provision, and creation of formal mechanisms to collaborate with the private sector. Measures to improve efficiency and equity can also mean more transparent priority-setting focused on health problems with large benefits to the society, those that especially affect the poor and those for which there are highly cost-effective interventions. Since DOTS meets all these criteria, such policies could prove beneficial to TB control. However, some policies can pose a threat to effective TB control, if not managed properly. Hasty adoption and implementation of decentralization strategies could weaken DOTS implementation. The absence of adequate technical capacity strengthening at local level or failure to transfer adequate resources can result in a breakdown of supervision and may profoundly affect treatment coverage, quality and results.

The lessons in the context of decentralization appear to be that key functions of strategic planning, drug supply supervision, surveillance, monitoring and evaluation must be protected or only gradually adapted. It is also evident that TB programme managers will need to work with their colleagues in other priority public health programmes to collectively advocate for involvement in system reform planning and implementation. If such processes are not adopted the risks to public safety and ongoing patient care may be substantial.

Other major initiatives that are likely have a positive effect on TB control include the development of poverty reduction strategies in highly indebted poor countries. These are linked to debt relief programmes and incorporate the provision of increased resources for public health interventions. Another is global effort, from G8 nations, United Nations agencies, and multilateral agencies to increase the overall pool of resources to address the predominant infectious killers in the developing world, including TB, HIV, malaria and other childhood diseases.

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