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WHO TUBERCULOSIS PROGRAMME

FRAMEWORK FOR EFFECTIVE TUBERCULOSIS CONTROL



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FRAMEWORK FOR EFFECTIVE TUBERCULOSIS CONTROL

I. Background

Recognizing that TB is one of the most neglected health crises and that the TB epidemic is out of control in many parts of the world, TB was declared by WHO to be a global emergency in April 1993. Worldwide, TB is the leading cause of death due to a single infectious agent. No country can afford to ignore the threat of the current TB epidemic to the health of its population and to its economy and development efforts. Nearly 90 million new cases of TB will emerge during the next decade, the majority amongst the age group 20-49, which represents men and women in their most productive years. Out of them, over 30 million people will die in the next decade unless the response to the global TB problem is improved radically. The high mortality and morbidity due to TB is often the result of inadequate control measures and neglect of the disease.

The main reasons for the resurgence of TB are:

- the neglect of the disease by governments has allowed TB control systems to deteriorate or even disappear in many parts of the world;
- poorly managed and incorrectly conceptualized TB control programmes have contributed to an increase in the burden of the disease as well as to the emergence of multidrug resistant TB. Even in industrialized countries, treatment of multidrug resistant TB cases is difficult and expensive and often fails;
- population growth has contributed to an increase in the number of TB cases. Children born in the last few decades in regions with high population growth rates are now reaching the ages where morbidity and mortality from TB is high;
- the link between TB and HIV co-infection has led to an explosion of TB cases in HIV endemic areas; HIV activates TB in individuals who are TB infected, accelerating the breakdown from infection to disease.

The resurgence of TB led the WHO TB Programme to reassess the TB control strategy in the early 1990s and to develop a new framework for TB control. This document is a concise presentation of the new TB control strategy and policies. It explains the new concept of effective TB control, including key operations for effective programmes and indicators to measure the effectiveness of interventions.

The document is intended to:

- be used vigorously by the whole system of WHO including Regional Offices and WHO Representatives to create awareness and commitment to modern TB control among Government officials responsible for planning and finance including Ministries of Health;
- serve as the basic document for TB programme managers and individuals working in TB control to introduce the new WHO strategy and policies for TB control, to direct National TB Programmes and to avoid misconceptions and mis-allocation of resources;
- serve as a tool to explain to donors the importance and relevance of adequate TB control interventions in the wake of the global TB epidemic.

II. The overall objective of TB control

The overall objective of TB control is to reduce mortality, morbidity and transmission of the disease until it no longer poses a threat to public health.

III. The strategy for TB control

The revised strategy adopted by WHO is simple: All countries with a TB problem must provide standardized short-course chemotherapy (SCC) to, at least, all sputum smear positive TB patients. Effective treatment of cases with SCC cures the disease and prevents future transmission of TB bacilli or stated another way - cure is the best prevention. The implementation of this strategy requires the full commitment of governments and health staff at all levels.

Since BCG vaccination plays an important role in preventing serious, but rarely contagious, forms of TB in children, WHO still recommends BCG vaccination in early childhood for TB high prevalence countries, usually within the Expanded Programmes on Immunization. However, the preventive effect of BCG vaccination on the infectious type of adult TB, and thus on transmission of TB, is limited.

The Forty-fourth World Health Assembly (1991) recognized the growing importance of TB and the potential for cost-effective control using currently available tools. The Assembly endorsed a global TB strategy which is to provide adequate and efficient treatment, - i.e. short-course chemotherapy (SCC) - to, at least, all smear positive TB cases identified.

If resources are scarce, priority must be given to sputum smear positive cases and seriously ill smear negative cases (e.g. cases of TB meningitis or miliary TB), because this will have the greatest impact on reducing mortality, morbidity and transmission of TB. However, ideally, all TB cases should receive SCC.

IV. The targets for global TB control

The World Health Assembly has endorsed the targets for global TB control, which are:

**to cure 85% of the detected new smear positive TB cases and
to detect 70% of existing cases by the year 2000.**

Achieving a high cure rate is the highest priority because TB programmes which achieve a high cure rate should be able to attract - due to the high quality of treatment services they provide - a majority of the existing cases in their catchment area. By fully utilizing existing health services systems for high quality TB control the majority of countries is expected to detect 70% of the existing cases. Even some sub-Saharan countries with poorly developed health services are achieving these targets.

Giving priority to case finding before achieving high cure rates in treatment programmes will contribute to the TB problem by producing chronic cases and multidrug resistant TB.

V. WHO TB CONTROL POLICY PACKAGE:

The success of the WHO TB control strategy depends on the implementation of a TB control policy package¹ which includes the following five elements:

1. **Government commitment** to a TB programme aiming at nation-wide coverage, as a permanent health system activity, integrated into the existing health structure with technical leadership from a central unit. Effective leadership requires a permanent team qualified in the management of TB control. The team's task is to initiate, coordinate, supervise and evaluate the key activities of the National TB Programme (NTP) at all levels through the primary health care system wherever it exists. In addition, the team should link up with TB experts to regularly update the knowledge on all relevant aspects of TB.
2. **Case detection through predominantly passive case finding²**, i.e. detection of TB cases among persons presenting themselves to a health worker with symptoms indicative of TB. Such patients should then be referred to health services for confirmation of diagnosis, primarily by microscopy examination³.
3. **Administration of standardized short-course chemotherapy to - at least -all confirmed sputum smear positive cases of TB under proper case management conditions.** Proper case management ensures patient compliance by supervised administration of the recommended short-course chemotherapy with at least three drugs in the initial phase (two to three months), in order to avoid the emergence of resistant strains and, further, to make sure that the patient undergoes a full course of treatment (6-8 months) to avoid relapse. (The recommended treatment regimens are presented in *Treatment of Tuberculosis*, WHO 1993.)
4. **Establishment of a system of regular drug supply** of all essential anti-TB drugs (isoniazid, rifampicin, pyrazinamide, streptomycin, ethambutol and, in some areas, thiacetazone). Advance planning for drug procurement and timely delivery should be based on the number of cases registered during the last complete six-month period and stock levels.
5. **Establishment and maintenance of a monitoring system** to be used both for programme supervision and evaluation. This system is based on recording individual patient information in registers at district/county level and on regularly reporting, preferably on a quarterly basis, from the same level. Definition of case categories, classification of disease and treatment outcome are presented in the annexes.

¹ This policy package remains unaltered even in the presence of HIV infection

² Given the limitation of existing diagnostic tools and incomplete knowledge on high TB risk groups, in most countries active case finding is not cost effective.

³ Cultures can be used as an additional diagnostic tool.

VI. KEY OPERATIONS OF A NATIONAL TB PROGRAMME

After adoption of the WHO policy package for TB control, nine 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. The key operations are:

1. Establish a **National Tuberculosis Programme (NTP) with a central unit** to guarantee the political and operational support for the various programme levels. This support must include the assurance of sustained local and/or external funding for all the essential aspects of the programme.
2. Prepare a **programme manual** which should contain the structure of the programme, job descriptions, case definitions, clear instructions for case finding and diagnosis including laboratory techniques, treatment guidelines specified for the various forms of TB and patient categories, instructions for monitoring including the relevant reporting forms, plans for drug distribution, stock keeping and supervision.
3. 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.
4. 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.
5. Establish **microscopy services** with binocular microscopes and adequate ancillary equipment and with laboratory technicians trained in sputum smear microscopy. 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.
6. Establish **treatment services** within the primary health infrastructure where directly supervised short-course chemotherapy is given priority and patient education is provided.
7. 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.
8. Design a **plan of supervision** of the key operations at the intermediate and district level to be implemented from the start of the programme.
9. Prepare a **project development plan** for the NTP with details on budget, sources of funding and responsibilities.

VII. INDICATORS TO MEASURE PROGRESS TOWARDS TB CONTROL

Three essential aspects of the NTP that need to be monitored:

1. commitment to the revised WHO TB control strategy and policy package;
2. efficient implementation of the new strategy;
3. successful treatment of detected cases.

Details on indicators and definitions of terms are annexed.

1. Indicator of government acceptance and commitment

- A national TB control manual: a clear indication of the Government's acceptance and commitment to TB control based on the revised WHO TB control strategy and policy is the availability or development of a national TB control manual which includes all five elements of the policy package.

Other possible signs of commitment are government efforts to develop or strengthen the key operations of the TB programme, i.e. a project development plan, availability of microscopy and treatment services, organization of drug supply, organization of training courses. These activities are, however, more difficult to measure.

2. Indicators of implementation of the new strategy

- Number of administrative areas in the country implementing the new strategy for TB control
- Absolute number of cases detected

In order to implement the nine key operations efficiently, the programme should be able to monitor regularly the number of newly detected TB cases, based on standardized case definitions (new pulmonary smear positive cases, new pulmonary smear negative cases, extrapulmonary cases and relapses). This information is essential for programme planning and management and for observing trends in case notifications over the years (Annex 2).

The case notification rate of new pulmonary smear positive cases - related to estimates of the TB incidence - provides a measure of the case finding coverage (Annex 2).

The age and sex distribution of notified smear positive TB cases is particularly useful for the long-term monitoring of trends.

3. Successful treatment of detected cases

- Progress towards the target of 85% cure rate can be monitored efficiently through cohort analysis of treatment results of all new smear positive cases detected. Treatment indicators are: cure rate, treatment completion rate, death rate, failure rate, defaulter rate, transferred-out rate, smear conversion rate after two months of treatment (Annex 2). The programme should be able to regularly monitor treatment results of at least all registered smear positive cases by cohort analysis. This is the optimal way of assessing the adequacy of the treatment regimen as well as the quality of case management and thus of the TB programme.

VIII. CONCLUSIONS

To pursue the strategy for TB control - which is to provide adequate and efficient treatment, with short-course chemotherapy, to at least all smear positive TB cases - as endorsed by all WHO Member States, a TB control policy package with five elements must be adopted:

Government commitment, passive case finding based on smear microscopy, provision of standardized short-course chemotherapy to all smear positive cases of TB, regular drug supply, and a system of monitoring and evaluation of programme activities.

The successful implementation of the nine key operations of a NTP should be monitored with the set of essential indicators presented herewith.

Once this framework is in place, systems to monitor HIV seroprevalence and drug resistance in TB patients should be added. Indicators on drug supply, supervision, and management aspects may well be needed for detailed programme monitoring and evaluation at national and district levels.

DEFINITION OF TERMS

I. CASE CATEGORIES:

NEW CASE:

A patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than four weeks.

RELAPSE:

A patient declared cured but reports back to the health service bacteriologically positive.

TRANSFERRED IN:

A patient who has been received into a reporting unit, having commenced treatment and already recorded in another unit.

TREATMENT AFTER DEFAULT:

A patient who returns to treatment after having interrupted treatment for two months or more.

FAILURE CASE:

Smear positive patient who remained - or became again - smear positive, five months or later after commencing treatment.

"OTHER" CASE:

Patients who do not fit into the above-mentioned categories.

II. DISEASE CLASSIFICATION:

Classification of all pulmonary cases should be based on sputum smear examination. Ideally, sputum should also be examined for cases of suspected extrapulmonary tuberculosis.

PULMONARY TUBERCULOSIS, SMEAR POSITIVE (PTB+)

Tuberculosis in a patient with at least two initial sputum smear examinations (direct smear microscopy) positive for Acid Fast Bacilli (AFB+),

- Or: Tuberculosis in a patient with one sputum examination positive for AFB+ and radiographic abnormalities consistent with active pulmonary tuberculosis as determined by the treating medical officer,
- Or: Tuberculosis in a patient with one sputum specimen positive for AFB+ and culture positive for AFB+.

PULMONARY TUBERCULOSIS, SMEAR NEGATIVE (PTB-)

Tuberculosis in a patient with symptoms suggestive of tuberculosis and at least three sputum examinations negative for AFB, and with radiographic abnormalities consistent with active pulmonary tuberculosis determined by a medical officer followed by a decision to treat the patient with a full course of anti-tuberculosis therapy,

- Or: Diagnosis based on positive culture but negative AFB sputum examinations

EXTRA-PULMONARY TUBERCULOSIS

Tuberculosis of organs other than the lungs: TB of the pleura (TB pleurisy), of peripheral lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, tubercular meningitis.

Diagnosis should be based on one culture positive specimen from an extra-pulmonary site, or histological or strong clinical evidence consistent with active extra-pulmonary TB followed by a decision by a medical officer to treat with a full course of anti-tuberculosis therapy.

Pleurisy is classified as extra-pulmonary tuberculosis.

Any patient diagnosed with both pulmonary and extra-pulmonary TB should be classified as a case of pulmonary tuberculosis.

III. POSSIBLE TREATMENT RESULTS:

CURED:

Initially smear positive patient who completed treatment and had negative sputum smear results, on at least two occasions, one of which at completion of treatment.

TREATMENT COMPLETED:

Sputum smear positive cases who completed treatment, with negative smears at the end of the initial phase, but with no or only one negative sputum examination in the continuation phase and none at the end of treatment.

or: sputum smear negative patient, who received a full course of treatment.

DIED

Patient died during treatment, regardless of cause.

FAILURE:

Smear positive case who remained or became again smear positive five months or later after commencing treatment.

DEFAULTED:

A patient who - at any time after registration - had not collected drugs for two months or more.

TRANSFERRED OUT:

A patient who has been transferred to another reporting unit and his/her treatment results are not known.

IV. OTHER TERMS:

SUSPECT OF TUBERCULOSIS:

Suspect TB in a person presenting to a health facility with:

- persistent cough for three weeks or more.
- production of sputum, sometimes bloodstained

or with less specific signs and symptoms:

- fatigue, loss of appetite and weight, night sweats, fever and shortness of breath, chest pain.

For extra-pulmonary tuberculosis, symptoms depend on the organs involved.

SHORT COURSE CHEMOTHERAPY (SCC):

Chemotherapy, six months or eight months regimen. It is based on the combination of at least three major TB drugs (isoniazid, rifampicin, pyrazinamide). This combination is given for two to three months during the initial phase of treatment and followed by a combination of at least two drugs given for four to six months during the continuation phase of treatment.

SPUTUM SMEAR EXAMINATION:

A laboratory technique, where Acid Fast Bacilli (AFB) are stained with the Ziehl Neelsen method, then identified and counted through microscopy.

RETREATMENT CASES:

"Retreatment cases" are previously treated cases (for at least four weeks) including failures, relapses, defaulters who returned to the health service, with positive sputum smear examination. All should be put on fully supervised retreatment regimen.

INDICATORS FOR EFFECTIVE TUBERCULOSIS CONTROL

Case finding indicators

Absolute numbers of all newly notified cases by **disease classification** and:

- proportion of pulmonary smear positive out of all newly notified cases
- proportion of pulmonary smear negative out of all newly notified cases
- proportion of extra-pulmonary cases out of all newly notified cases

Absolute number of newly notified cases by **case category**:

- new cases
- relapses
- age and sex specific breakdown of all newly notified smear positive cases

Cases put on retreatment, other than relapses, or transferred in from other treatment areas should be included in the district registers. However, to avoid duplicate reports, they should not be included in reports of new cases or relapses. It is important that the indicators on new cases and treatment results are used for programme assessment at all levels: central/regional and district/county level.

Case notification rate of PTB+ cases

- New PTB+ cases notified during a given year per 100 000 population (based on the official population estimate for the year studied)

Treatment indicators

The progress towards the overall objective of 85% cure rate can be measured by cohort analysis of data from the standard district register. All indicators listed below provide relevant information on programme activities.

- **Cure Rate:** Number of new sputum smear positive cases who completed treatment and had at least two negative sputum smear results, one of which at completion of treatment, out of the total of new smear positive cases registered for treatment.
- **Treatment Completion Rate:** Number of new sputum smear positive cases who completed treatment, with negative smears at the end of the initial phase, but with no or only one negative sputum examination in the continuation phase, and none at the end of treatment, out of the total number of new smear positive cases registered for treatment.

- **Death Rate:** Number of new sputum smear positive cases who died during treatment, regardless of cause, out of the total number of new smear positive cases registered for treatment.
- **Failure Rate:** Number of new sputum smear positive cases who remained or became again smear positive at five months or later during treatment, out of the total number of new smear positive cases registered for treatment
- **Defaulter Rate:** Number of new sputum smear positive cases who have interrupted treatment two months or more, out of the total of new smear positive cases registered for treatment
- **Transferred out Rate:** Number of new sputum smear positive cases who were transferred to another region or province during the course of treatment, out of the total of new smear positive cases registered for treatment

The same system should be used to evaluate results of re-treatment regimens.

In addition to these six possible outcomes of treatment, the smear conversion rate at two months provides an early assessment of the effectiveness of treatment/treatment services in the initial phase:

- **Smear conversion rate:** Number of new smear positive cases who were negative at the end of the second month of the initial phase of SCC, out of all new smear positive cases registered in the respective time period