TUBERCULOSIS PROGRAMS

REVIEW
PLANNING
TECHNICAL SUPPORT

A manual of methods and procedures

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Preface

Tuberculosis is, by any estimation, an important health problem: it is estimated by the World Health Organization to be among the leading causes of death and disability among the economically active segment of the world's population. The disease adversely affects child health as most of the victims of tuberculosis are parents of young children; it kills more women than all the conditions related to pregnancy and delivery. It primarily impacts low income countries where resources for dealing with health are severely restricted. Nevertheless, tuberculosis control merits priority as an intervention in the health sector, as national tuberculosis programs are among the most cost-effective of any health intervention in low income countries.

The International Union Against Tuberculosis and Lung Disease (IUATLD) has played a pivotal role in the development of its model for the national tuberculosis program, a model generally applicable for health services delivery in low income countries which has been demonstrated to be feasible and sustainable. This model described by the World Bank as highly cost-effective, has been adopted by the World Health Organization as the basis of their Global Tuberculosis Programme.

The basic elements of this model have been described in the *Tuberculosis Guide for Low Income Countries* in which the IUATLD has outlined its experience with the procedures for diagnosis and treatment of tuberculosis, the organization and management of tuberculosis services and the structure within which such services can be delivered even under the most stringent socioeconomic conditions.

The IUATLD, through its collaborative work with partners throughout the world, has gained a great deal of experience in the field of tuberculosis control. In the programs where the IUATLD is involved, governments in poor countries, donors and technical consultants have joined forces to fight tuberculosis on a national scale. What has characterized this cooperation is partnership, long term planning, consistency and continuity.

With increasing awareness of tuberculosis globally, there is renewed enthusiasm and general optimism in low income countries, and, increased interest within the international donor community for working towards a definitive solution for this long-standing scourge. It is important that this 'tailwind' be utilized in such a way as to maximize the impact towards controlling, and eventually eliminating, tuberculosis.

This manual describes the experience of the IUATLD, in collaboration with national programs, donors and technical organizations, with respect of review, planning and technical support for tuberculosis control so that the various stake holders understand what is expected of them and what they may expect of their partners in collaboration in the field of tuberculosis control. It outlines the experience of the IUATLD over many years and it is hoped it may be of use for those who are, or intend to be, involved in international collaboration for the control of tuberculosis. Together with the *Tuberculosis Guide*, this manual gives a comprehensive view of international partnership towards the goal of eliminating tuberculosis.

Tuberculosis can only be successfully controlled and eventually eliminated in the context of a national tuberculosis program. Such a program must operate within the general health service of each country. The service must be country-wide, permanent, adapted to the realities of each community within which it operates taking note of access to health facilities and integrated within the general health services.

The manual primarily discusses support to national tuberculosis programs. However, close cooperation of all health care providers is essential for success in the fight against tuberculosis. The contribution of national and international non-governmental organizations is important. The advice of the IUATLD to such organizations is simple: support tuberculosis control in the context of, or in close cooperation with, national tuberculosis programs.

There is a long way to go in the control of tuberculosis globally and there are no quick fixes. Short term commitment and support are simply not useful. Thus, in a world constantly changing and moving faster, mastering the endurance that is crucial when working in tuberculosis control is a challenge.

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Introduction

Working in tuberculosis control is relatively straightforward. As a starting point, you need to know where you are. Second, you must know where you want to go, how you intend to get there, who will do what and who will pay for it. Finally, you need to decide how you are going to monitor your course.

This manual addresses these aspects sequentially, starting with program reviews (also called situation analyses), going on to discuss program planning and finally describing technical support for national tuberculosis programs as recommended by the Tuberculosis Division of the International Union Against Tuberculosis and Lung Disease (IUATLD).

This order of subjects is the logical sequence of events in tuberculosis control. Once the tuberculosis problem has been recognized, what follows is:

- a thorough review of the situation,
- planning of activities (intervention),
- implementation,
- support and monitoring.

This then leads to another cycle: review, further planning, etc., etc.

The complete manual is a frame of reference to use in international collaboration in tuberculosis control. Once the reader is familiar with the overall content and has gained some experience and skills in national program support, each section can be used separately for the different purposes of program reviews, planning and technical support.

The manual is not a prescription but rather an attempt at sharing the experience gained by the IUATLD. It is written primarily for program managers and persons interested in becoming technical consultants, but representatives of donor organizations and others interested in international collaboration for tuberculosis control may find it useful. The manual assumes basic knowledge in tuberculosis control and the inexperienced reader is referred to the IUATLD *Tuberculosis Guide for Low Income Countries*, which describes the implementation of tuberculosis services.

The basic principles of tuberculosis control are summarized below with specific

emphasis on political commitment, the crucial element if tuberculosis control is to be achieved.

Principles of tuberculosis control

There are three basic requirements for tuberculosis control:

- a secure supply line,
- diagnosis by sputum microscopy with a quality assurance program,
- recording and reporting,

and three additional requirements for the use of short course treatment:

- special training of personnel,
- supportive supervision of service delivery,
- directly observed swallowing of anti-tuberculosis medications.

Political commitment is crucial if these requirements are to be met and thus the presence of these activities is proof of government commitment.

Tangible evidence of political commitment includes:

- the appointment of a full-time manager of the tuberculosis program with supportive staff to carry out the functions of planning, budgeting, information management, supply management, training and supervision;
- the publication of a manual outlining the standard procedures of the program.

Apart from recognizing tuberculosis as a serious health problem and guaranteeing policy, personnel and infrastructure for its control, political commitment is reflected in:

- sufficient financial resources for tuberculosis control,
- measures to assure mandatory notification of tuberculosis cases, and,
- measures to address the problem of free sale of anti-tuberculosis medications as free sale of these medications fuels the production of resistant, incurable forms of tuberculosis,
- a policy which prevents discrimination against tuberculosis patients in terms of the utilization of health services (admission to hospital and treatment in routine services).

I. Tuberculosis Program Reviews

1. Tuberculosis program reviews

1.1 Who owns the process?

Reviews of tuberculosis programs are always cooperative activities involving a number of stake holders. How do these various stake holders relate to the review, to each other and to the materials produced by the process?

Such reviews usually involve at least three partners: those who operate the program, those who fund the program and the technical experts making the review. Each of the partners have policies for their work and each may have particular reasons for being involved in the process: those in charge of the program usually want to have an independent assessment of their activities to guide them in future work; those who fund the program usually want to be assured that the investment in the program is well spent; the technical experts often undertake the review as part of a scientific activity which enables them to learn. Each partner has objectives for the review in respect to themselves, and each has an interest in what is produced by the review. Finally, each of the partners is keen to ensure that the review itself is well carried out and that the results are credible.

To ensure that each of the partners achieves the intended objectives, it is necessary to structure the review as a partnership with each of the partners having input throughout the process. The most appropriate structure for accomplishing this is the creation of a steering committee. Such a committee should have representation from each of the partners and is responsible for setting out the procedures for undertaking the review, for outlining the objectives of the review, for ensuring that the process is properly undertaken and that the results and recommendations are adopted and acted upon.

This steering committee should take the responsibility for planning the review, following the advice of the technical consultants. The content of the review should follow a standard recommended procedure but the details of the implementation of the review should be decided by the steering committee.

When the review is completed, a formal report is presented to the authorities responsible for the program and submitted to all partners of the review. The report is the property of each of the partners, together. The partners then, each, have the possibility to refer the report to a review by external experts chosen by them; those who drafted the report are then obliged to respond to any criticisms which may be raised by the independent peer review. When this review is completed, all partners must agree to recognize the report formally and to accept its recommendations, at which point it becomes an official document. At the point that it becomes official, the report enters the public domain, unless the partners indicate that the report, or components of it, are to remain confidential. The report then becomes scientific material which can be quoted in the scientific literature, provided due credit is given to the partners involved in the review.

1.2 What is the purpose of a review?

The general objective of a tuberculosis program review is to assess the epidemiological situation and the impact of control activities in order to give recommendations for improving tuberculosis control, i.e., for planning purposes. In addition, the review seeks to assist the personnel responsible for the program to enhance the priority of the program and to be given authorization and resources to make necessary changes.

A program review may be an important occasion for promotion of the program within the health services. Therefore, involvement of key persons from within the health services is important.

A simple management model for tuberculosis control is presented in figure 1.

The review focuses on:

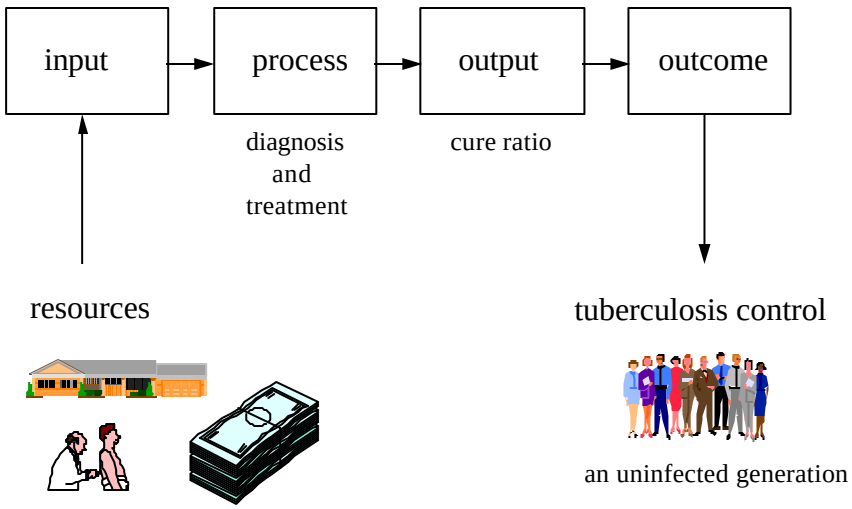
- the input into tuberculosis control, i.e., the resources,
- the implementation of the treatment delivery process,
- evaluation of the output of the tuberculosis services,

and, attempts to predict the impact of tuberculosis control activities on the epidemiological situation, i.e., the outcome.

In order to enhance priority and obtain support to make changes, the highest political authorities must be appraised of the situation and a formal report with limited but clear recommendations is prepared. The report is intended to assist the process of planning future activities and financial needs of the program.

A review should only be undertaken when there is an intention to use the result for supporting tuberculosis control. Thus, the partners undertaking the review, by their participation, make a commitment to follow through with the recommendations in the review report.

Figure 1



2. What are the steps in preparing and executing a program review?

2.1 What are the procedures to follow when undertaking a program review?

A review is initiated by a formal request submitted by local health authorities. The formulation of such a request is the first step in the review process.

The review is often undertaken as a joint venture, i.e. the local health authorities, current or potential donor(s) and a technical organization. A steering committee is created with representatives from each of the partners undertaking the review. The steering committee appoints a leader responsible for coordinating the work. The committee is responsible for making sure the review is properly carried out

and yields useful results.

There are three components in a review: preparation, review visit and follow up. The steering committee is responsible for all preparatory work, including budgeting, pre-visit data collection, setting the dates of the review visit and drafting the agenda of the visit, selection of and correspondence with review team members, travel arrangements, assignment of tasks to the review team members, organizing administrative and secretarial support, selection of persons to be interviewed, selection of sites to be visited and organization of transport.

2.2 What is the cost of a review and who pays?

The cost of the review is the cost of the review visit itself, and coordination and communication before and after the visit. The writing of a budget is the responsibility of the steering committee which needs to correspond with team members for information on expected expenses. The budget proposal should include travel costs, allowances and other expenses of all review team members, communication, material, facilities, and reporting. The financing of the review is negotiated among the parties involved.

Ultimately, it is the responsibility of the program requesting the review to identify the finances required to carry out the review. In most instances, this is part of the regular budget of the program and may be derived from the local authorities or may form part of agreements with donor agencies.

2.3 What is the appropriate time frame of a program review?

Usually six to twelve months are needed for coordination, planning of the review and preparatory work.

The amount of time required for carrying out the review is usually two weeks. This allows time for *initial meetings* with responsible officials (two days), *site-visits* to health facilities (two sets of three days), *discussions* among the team members, *report writing* (another three days) and *presentation of findings* (two days).

A summary of the report and main recommendations should be written and presented to local health authorities during the review visit and the full report finalized within one month of departure of the review team. If this is to be achieved, the team members should come well prepared with an outline of the final report, completed sections on those items for which information has been obtained prior to the visit and must work each day on the report while on site. By

the end of the visit in country, the first draft of the report should be ready for review by team members.

2.4 How is the review team selected?

The optimal size of a review team depends on the partners involved in the process and on the logistics of the visit but it must also take into account the work to be reviewed in the specific circumstances. The latter consideration determines which disciplines should be represented in the review team. The disciplines which must be represented in a review include clinical medicine, public health/program management, and laboratory science; additional disciplines may be included such as epidemiology, social science, education, economics, and AIDS, leprosy or other specialties if tuberculosis is part of a combined disease control program.

There should be a balance in the number of national and international team members. It should be a rule that all review team members must be present throughout the review visit; should individuals not be able to dedicate the required amount of time, they should not be included in the team.

2.5 What are the activities during the review visit?

The review visit starts with a briefing session where the review team meets to finalize the agenda, organize tasks, discuss and organize the background material and the information collected during the preparation of the review.

The program manager is requested to present a formal summary of the work of the program. Subsequently, the team meets with the responsible health authorities before proceeding with site-visits.

Enough time is set aside after the site-visits for discussion among the team members and for report writing.

Finally, the team meets with the authorities where the conclusions and recommendations are presented and discussed. A press conference may be organized on the last day of the visit

The meetings with responsible health authorities are extremely important components of the review process. In order for the review to have legitimacy and to proceed to action, the highest possible level of authorities should be represented at these meetings. A crucial requirement for success in tuberculosis programs is political commitment which is reflected in the degree of priority given to the problem by the relevant authorities. The level of authorities represented at

the official meetings usually reflects the degree of priority given. The initial meeting with the authorities should clearly spell out the objective and procedures of the review and indicate the expected outcome. The final meeting should review precisely the summary and recommendations which have been made.

Site-visits should involve all levels: the central team, intermediate level(s), the level of implementation where the services are delivered and the recipient, i.e., the patient and the community. In addition to site-visits it may be important to interview other representatives from within the governmental health services [1], representatives of other sectors[2] and of bilateral and multi-lateral[3] agencies to discuss their involvement and role in tuberculosis control and relation to the tuberculosis program.

The purpose of the site-visits is to provide an opportunity for the review team to *verify* the information provided, i.e., to assess whether policy is reflected in practice, whether available quantitative information is credible, whether resources are sufficient, and, to observe how tuberculosis control services are implemented in practice and how they relate to the general health services and the community.

Apart from the site-visits the review team spends time *analyzing* and *interpreting* the information provided for the review, and evaluating the adequacy of the services to control tuberculosis, i.e. relating resources, policy, structure and results to the objectives, targets and outcomes in tuberculosis control.

2.6 How should the review report be written?

The review report should be written in such a way that it will capture the attention of decision makers (politicians, administrators and health personnel) and lead to action.

All details of the review findings, conclusions and recommendations should be included in the main report. The agenda of the visit, a list of persons met and a map of the country should be presented in annexes and the relevant quantitative information in tables and annexes.

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[1] E.g., the Director of Health, the department of planning, the department of financing, the department of medical supplies, the national health information system, the Expanded Program on Immunization, the AIDS control program the leprosy program.

[2] Such as medical and nursing schools, the social security system, the military, the penitentiary systems, non-governmental agencies and private practitioners if there is an organized private sector.

[3] Such as the European Commission, the World Bank, the World Health Organization and other UN agencies (United Nations).

No more than one page should be reserved for the general information on the country and on health, respectively, and a page or two on the health system and services. The bulk of the report is reserved for the information on tuberculosis. However, it is recommended that this section not exceed ten pages (excluding tables and annexes).

Apart from the detailed report, a summary report, no more than one page, is useful. The purpose of the summary report, or an executive action document, is to communicate the general impression and recommendations of the review team. The summary report should describe the magnitude of the tuberculosis problem in general terms. There should be a list of the key strengths and the key weaknesses of the program and the main recommendations of the review team. These should be worded in general terms, rather than repeating more specific conclusions and recommendations from the main report.

2.7 What constitutes follow up after the review visit?

After the review visit the report is finalized. Within a month from the departure of the review team the report is submitted to the partners of the review for approval. All partners must formally approve the report at which point it becomes official. This process is the responsibility of the steering committee.

What then follows is medium and long term planning of tuberculosis control based on the recommendations in the review. The planning is carried out by the tuberculosis program with assistance from the donor(s) and/or the technical consultant(s) if such assistance is needed. The planning includes a budget proposal for a defined period, usually three to five years. The proposal is submitted to the government for approval and funding. The government, after deciding the need for external assistance, submits the proposal to the donor(s) who participated in the review if this was the case. It is the responsibility of all the partners of the review to follow through with this process. When the process is well under way the steering committee may be dissolved.

If action does not follow a program review, the review must be considered a failure.

3. What are the methods used in site-visits?

Primary prevention of tuberculosis is achieved by proper clinical case management of infectious patients. For this reason, the review specifically focuses on the quality of clinical practice by health personnel responsible for the care of

such patients. It is a review of the management of consecutive tuberculosis cases which is systematically carried out during the site-visits.

On a given review, particularly if the country is large, the review team may be split up for the purpose of site-visits. Thus there will be more than one 'field team'. If this is the case a standardized method of data collection should be agreed upon by the field teams beforehand.

A group of two to five people on site-visits is a convenient size of a field team. When deciding on the size of the field teams it is important to think in terms of transport to the sites to be visited. It should also be kept in mind that the team will be joined by health personnel from the site visited so that the total number of individuals working together at any point in time may be twice the number selected for the field team.

In order for the review to be carried out thoroughly and efficiently, at any given site the field team should remain together and one of its members should be selected to direct the review at a given site. This will help to avoid confusion and will permit the team to arrive at a consensus regarding the findings. In addition to the individual directing the review at the site, an individual should be identified to record the observations made during the visit who will prepare the first draft of the report of the visit to that particular site. In this way, all relevant information is systematically and correctly recorded.

When the field team visits health facilities, the designated member of the team should chart the progress of a consecutive series of individual patients through the system in order to understand fully the process and procedures routinely followed. The key question is whether the patient achieves cure without relapse. The only certain way to arrive at the answer is by reviewing records of consecutive patients, following a 'cohort' (a consecutive series) of patients, in the order that they are registered, who have gone through the full process to completion and can be evaluated. Thus, the period selected for review should commence at a date sufficiently prior to the time of the review that the full duration of treatment should have been completed (for example, if the usual treatment is an eight-month course, the patients selected should be those who were registered prior to twelve months previously). The patients must be carefully listed one by one as they are identified in the system, and then each patient must be traced as far as possible through the system. This exercise requires considerable time in order to do the analysis correctly; this is the most vital aspect of the entire review. It is therefore recommended to strictly limit the number of health facilities visited and to focus on those actually carrying out the management of cases to ensure

that sufficient information is obtained on the basis of which to make a reasonable evaluation. In practice, it is usually necessary to spend several hours in a single facility simply identifying and following the course of the patients. This requirement should be explicitly stated to the personnel responsible for the institution prior to the visit to ensure that the time is efficiently utilized.

A site-visit should commence where tuberculosis suspects present for care in order to study the procedures of identification and management of tuberculosis suspects. The laboratory is then visited, in order to review routine procedures and to verify whether patients' names can be found in the laboratory register. Subsequently, the team should visit the treatment services, to look at the records of individual patients, to review the tuberculosis register, to compare the tuberculosis register with the laboratory register and to talk to the health personnel and to a selection of patients.

A site-visit is team work. A different member should be selected for leading the discussion in the various facilities visited, rather than the same person throughout.

At the completion of the visit to specific facilities, the leader of the field team should summarize the findings and conclusions of the team to the local authorities. The national authorities should be requested to provide a copy of the review report to the local authorities of each of the facilities visited.

4. What information should be collected and when?

In the process of the review the following *objective* information is collected:

- general information on the country,
- general information on the health status of the population,
- information on the health system and the health services, and,
- specific information on tuberculosis.

Additionally, *subjective* information on awareness of tuberculosis as a health problem may be collected from representatives of decision makers, health personnel, the general public and tuberculosis patients.

Most, if not all, of the information can be collected by colleagues within the country and provided to the steering committee before the review visit. This certainly applies to the objective information, as well as much of the specific information on tuberculosis, and could apply to the subjective information as well, in which case the interviews are carried out and the information analyzed in

advance.

Summary of the sources of specific information on tuberculosis.

- *Policy*. This is reflected in the program manual and in policy documents.

- *Official statistics*. These are reflected in (annual) reports. The information should be verified during site visits.

- *Practice*. Observations are made during site-visits.

- *Perceptions*. This information is collected by use of questionnaires or structured interviews.

The process of data collection needs to be initiated three to six months before the planned review visit. This is done by correspondence among members of the steering committee and with designated colleagues in the program to be reviewed. The material prepared in the process should be sent out to all review team members to reach them two to four weeks before the review visit. Alternatively (but much less efficiently), time may be set aside at the outset of the review for studying the material.

Indispensable background material for a review includes program policy documents, annual reports, manuals, guidelines and forms, health policy documents and country profiles. This material should be selected carefully however, and only distributed to the review team if the members of the steering committee consider it relevant and useful.

It should be stressed, that if the required information is not available beforehand, it usually cannot be produced during the visit of the review team. In this case, it should be assumed and recorded that information is not available. The activities of the review team are: organization, verification and interpretation of available information. The bulk of the time of the review team is spent on site-visits, interviews with health services personnel and patients, discussions with the authorities and local health personnel, discussions among the team members, and, on reporting. Without information available ahead of time, the ability of the review

team to draw valid conclusions is seriously hampered.

5. What objective information is needed?

All the information in this category should be collected in advance and should be available to the review team members prior to the first day of the review.

It may happen that some of the requested information is not available. In this case, information gaps can be filled during the preparatory process. However, some of the information may not be available at all. Essential information which has not been provided should be assumed to be, and recorded as, not existing.

This section lists the objective (quantitative, qualitative and descriptive) information which is important in a program review.

5.1 General information on the country

5.1.1 Population

Demographic information is important to estimate the size and distribution of the tuberculosis problem, i.e., to calculate absolute and specific rates of tuberculosis.

Information is collected on:

- population size,
- composition by age and sex,
- ethnic groups,
- urban / rural, and,
- the geographical distribution of the population.

5.1.2 Economic situation

Economics deals with resources, which are always limited, and their utilization, i.e., ability and willingness to pay. Most important is the commitment from the decision makers, in the case of tuberculosis control, the government. If the government does not give priority to the health of its citizens, the wealth of a country is irrelevant for the tuberculosis program (but still important for the incidence of tuberculosis).

The wealth of a country is best expressed by the gross national product (GNP), which is the sum of all economic activities in a country. Adjusted for the size of the population the indicator is GNP per capita.

The potential for official activities is measured by total government expenditure. If available, information on the sources of government revenues should be documented.

Information on average household income and expenditure is not useful. In the first place, the simple fact that it is an average makes it not useful as tuberculosis affects the poor disproportionately. Second, tuberculosis control is a public health problem and its cure should not depend on the patients' ability or willingness to pay. The fight against tuberculosis has pay-offs for the entire community and should therefore be financed by public funds.

5.1.3 Political commitment to health

The commitment of the government is measured by means of the total health expenditure of the central government, expressed in absolute figures or as proportion of total government expenditure or proportion of the GNP.

5.1.4 Administrative structure

The general administrative structure should be described briefly (regions / provinces / districts, etc.). This should indicate the process by which political decisions are taken and who is responsible for them. An organigram may be provided to illustrate the administrative structure.

5.2 General information on the health status of the population

5.2.1 General health statistics

Information on the ten most frequent diseases during the last ten years, with morbidity and mortality by age and sex describes the health status of a population.

5.2.2 HIV/AIDS

Information on the prevalence of HIV/AIDS among the general population, including trend, and information on risk groups is important in a tuberculosis program review.

5.2.3 Addictive substance use

If information on the use of alcohol, tobacco and addictive drugs is available, this may be included.

5.3 Information on the health system and the health services

5.3.1 Governmental health services

A description of the health sector development plan and recent or ongoing health reforms is important.

- *Structure, organization and delivery of health services*

This should address primary health care and specialized services. It is important to have a description of how patients are being taken care of at primary level, a description which relates to how tuberculosis patients can be diagnosed and treated within the present structure.

Description of the general health information system and supply system is essential.

- *Personnel*

Information on staffing and staff qualifications.

- *Financing*

Information on sources of health care financing, such as, taxation, fee for services (cost recovery), health insurance, and external donor input is important.

- *Priority setting*

A description of which method(s) are used if any.

5.3.2 Private sector

If there is an important private sector, a description of this sector should be provided (structure, personnel, and, finances) with an estimation of the importance of the private sector in terms of the 'share' in overall health services.

5.3.3 Other sectors

If there are other important health care providers / health sectors, such as a prison sector, a military sector, voluntary organizations, a description of these should be provided (structure, personnel, and, finances) with an estimation of the importance of these sectors in terms of the 'share' in overall health services.

5.4 Specific information on tuberculosis

This part of the review findings will serve as a base line for planning activities and for evaluating the results of the program further on (see *Part III, Technical Support*). Part of the information collected, namely *5.4.4 The National Tuberculosis Program*, is strictly technical and uses a standardized format for reporting progress in tuberculosis programs (see annex).

5.4.1 Political commitment to tuberculosis control

The degree of political commitment should be judged by the presence or absence of measures with respect to the issues listed in the summary of the principles of tuberculosis control provided in the Introduction (page 2).

5.4.2 National policy and legislation concerning tuberculosis

A description of the policy of the tuberculosis program as relates to:

- overall objectives and targets in tuberculosis control,
- diagnosis of tuberculosis,
- notification,
- treatment (past and present policy)
- drug policy (as relates to anti-tuberculosis medications),
- contact investigation,
- preventive therapy, and,
- BCG vaccination,

should be provided. It should be mentioned whether the policy and procedures are documented in a manual for the use of personnel involved in the care of tuberculosis patients.

5.4.3 Disease burden

- The situation regarding tuberculosis *disease* (morbidity) should be summarized by age and sex. Information on trends is particularly important.

The information on tuberculosis meningitis in the age group 0-4 years evaluates the Expanded Programme on Immunization (EPI) and recent transmission of tuberculosis.

An attempt should be made to collect information on risk groups (HIV infected persons, immigrants, migrants, foreign born, drug addicts, etc.). This information indicates the size of the tuberculosis problem and the prospects for its control. Information on unemployment should also be documented if available.

An inquiry should be made into how tuberculosis compares with other diseases in priority setting (how tuberculosis is 'ranked' among health problems).

- Information on tuberculosis *infection* from tuberculin skin test surveys should be reported. Comment should be made on the methods utilized for the surveys; was the sample of tested individuals representative? was the tuberculin used standardized? were the test procedures properly carried out?

Results of tuberculin skin test surveys should be displayed, as much as possible, by age, sex and distribution by individual millimeter of induration measured.

- Finally, there is information on *deaths* (mortality). Where tuberculosis treatment is offered this is no longer a useful indicator for the size of the tuberculosis problem as any intervention in the form of treatment reduces case fatality and mortality even if it increases the number of chronic excretors of *M. tuberculosis complex*. By and large, this measure is so inaccurate as to be of little value; if it is available, it should be reported (by age and sex) but its interpretation must be made with extreme caution. An increase in mortality may indicate a deteriorating situation due to an increasing prevalence of infection with HIV among tuberculosis patients or due to the emergence of multi-drug resistant strains of *M. tuberculosis*.

5.4.4 The National Tuberculosis Program

A standardized report format is used for the information collected on the national tuberculosis program (see annex). The following aspects of the Program are described:

- General aspects of the program

◊ The management structure.

◊ The supporting activities: Information management (the forms used and the flow of information), training, supervision of services, supply and procurement of materials and medications, transport.

◊ Financing and planning, including information on past and current expenditure of the government for tuberculosis control from the budget and financial reports of the Ministry of Health (in absolute figures or as proportion of total health expenditure), fee for services, health insurance, and external donor support.

◊ Coordination, intra-sectoral (i.e., within the ministry of health, AIDS, leprosy, EPI, primary health care, supply and information systems), inter-sectoral (i.e., with other government sectors, such as the penitentiary system), the private sector and with donor agencies and multilateral agencies (such as the WHO and the UNDP).

- The diagnostic services

◊ The microscopy services.

◊ Services for bacteriologic cultures for purposes of case management.

◊ Susceptibility testing carried out for purposes of case management.

◊ The radiography services.

- Tuberculosis control

Case notification number, rates and trends, and results of treatment (output) are the most important predictors of outcome of tuberculosis control activities.

◊ Case finding.

A description of the services and of the results of case finding, including the trend in smear positive cases by age and sex. This section should also include a statement about the comprehensiveness of case notification (are there cases in other sectors which are not included in the official statistics?)

◊ Treatment results.

A description of the treatment, of case holding and of the output, including the trend in treatment results.

- Evaluation

The policies and procedures used for evaluation and the results in each of the

following.

◊ Studies of resistance to anti-tuberculosis medications.

◊ Quality assurance of microscopy.

◊ Studies of the prevalence / risk of tuberculosis infection.

◊ Studies of the prevalence of the human immunodeficiency virus (HIV) infection among tuberculosis patients.

5.4.5 Other tuberculosis services

Information on other tuberculosis services, such as:

- other government sectors (e.g. military and prison sectors),
- the private sector (private practitioners),
- tuberculosis associations:
  - ◊ professionals (doctors / nurses / allied professionals),
  - ◊ patient organizations, and,
- other organizations (e.g., non-governmental organizations).

5.4.6. Advocacy and health education

This should address,

- community based health promotion,
- availability of material (printed material, audio-visual material),
- standardization of messages, use of local languages and dialects,
- use of multi-media (radio and television) for promotion of tuberculosis,
- special events (TB week, TB day, etc.), and,
- involvement of traditional healers, employers, family members, etc.

5.4.7 Research

A description of the subject, structure and funding of research in the field of tuberculosis (internal / external funding).

6. What subjective information is needed and from whom?

The information under this heading may be collected by structured interviews. The interviews should aim at evaluating perceptions, attitudes, knowledge and practice

of decision makers, health workers, patients and other members of the community. It is important to interview members of both genders (women and men).

6.1 Are the decision makers concerned about tuberculosis?

Administrators and politicians are interviewed focusing on awareness and understanding of tuberculosis as a problem and what can be done about it.

6.2 Do the medical professionals and other health personnel know what they are doing?

The focus here is on the attitude of health professionals and on professional performance.

6.3 What does the general population think about tuberculosis?

The focus here is on community awareness of tuberculosis as a health problem, what can be done about it, and, on stigmatization.

6.4 What can we learn from tuberculosis patients?

The focus is on care seeking, stigmatization, knowledge (to assess health education) and adherence to treatment.

Even if strict quantitative scientific procedures are not applied, the information collected may be hypothesis generating and be of use in the review and in subsequent planning of interventions. The information collected under this heading can also be valuable for the design of health education and advocacy material and, finally, for formulating research questions and designing operational research.

Note page

Note page

II. Tuberculosis Program Planning

1. Why is program planning important?

As stated in the introduction, tuberculosis control is relatively straightforward. That is, if there is a plan. Planning is important in order to decide:

- *what* needs to be done (targets are set and a policy defined),
- *how* it should be done (describing specific activities),
- *when* it should be done (establishing a time frame for the activities),
- *who* should do what (defining responsibilities), and
- *how much* it will cost.

Furthermore it is important to decide how progress will be monitored and evaluated.

Long term planning in tuberculosis control is important in order to *secure sufficient funding* for the implementation of an effective intervention. It is essential to estimate the need for resources well in advance to guarantee that the needs can be met in time. A long term plan should give a realistic idea of the need for resources. If a reasonable reserve is included in the plans, unexpected events can be dealt with while additional resources are obtained.

It is usually neither possible nor desirable to implement tuberculosis control country wide all at once. Thus, a long term plan is needed for *phased implementation*.

A method of monitoring and *evaluation* is put forward in a long term plan and the actual progress is compared to the plan.

Long term planning must precede regular short term planning. A short term plan is much more precise and takes note of progress and the actual situation at any time.

2. Who plans tuberculosis control?

Political commitment is one of the basic requirements for tuberculosis control. The

government, local and central, is responsible for planning tuberculosis control activities in a country. As a rule, the execution of this responsibility at national level is carried out by the Ministry of Health. Within the Ministry of Health, a director or manager writes an overall development plan for tuberculosis control. The director may need to call upon experts to assist in writing the plan. These may be local experts within or outside of the government sector or external experts. In case of a major external donor, the execution of the long term plan may be a joint venture. In this case, input from the donor is important in the planning process.

3. When should planning take place?

3.1 Micro-planning at local level

The operational planning takes place at the local level. It can be said that this is the most important planning of all since without it any other planning is futile. For this reason, micro-planning is mentioned first.

Activities at the service delivery level should not be planned centrally. Personnel at the peripheral level, where the services are implemented, need to understand in detail how efficient tuberculosis control is organized and implemented in order to be able to perform the necessary planning for their catchment area. This should be part of the training of personnel at this level (as it should be part of training of all personnel).

Micro-planning should be realistic and thus needs to take into account past performance, present activities and estimated progress.

Micro-planning at local level can be long-term and short-term. At this level it is convenient to think of long-term planning for one year at a time and short-term planning for a quarter (three months) to coincide with reporting and ordering of supplies.

3.2 Planning at intermediate level(s)

The same general principles apply for planning at the intermediate level(s) as at the national level. The main purpose of the plan at the intermediate level(s) is organization of the work, timing of activities and expansion of program activities in order to guarantee smooth implementation and high quality services. The plan is also important as a basis for evaluation at this level. Planning at the intermediate level may however also be important for financing purposes, i.e., for locally

funded activities such as transport and supervision or in case the intermediate level is autonomous financially.

In the expansion phase of tuberculosis programs the short term planning at intermediate level should be quite specific as to where and how the program will be expanded and in quantifying all the resources needed.

3.3 Long term planning at national level

Long term planning at national level usually takes place every three to five years, depending on the planning cycle in the country. The main use of a long term plan is for financing and evaluation purposes.

Long term commitment and support is crucial in tuberculosis control as progress may be expected to take place slowly over the long term and only if continuity is guaranteed and support maintained. A five-year planning cycle is thus quite appropriate. It can be said that resources should be guaranteed for five years to justify any major effort in tuberculosis control.

3.4 Short term planning at national level

The main use of a short term plan at national level is to set a realistic agenda in order to move ahead. Based on a long term plan and actual progress, a detailed plan of action is prepared annually, where activities such as supervision, training, work-shops, meetings, implementation, expansion, printing, etc., are planned in detail. Furthermore, detailed orders for supply and equipment are part of a short term plan.

Apart from the action plan for the tuberculosis program, every person at national level should have a personal plan of activities. The same is in fact true for the personnel at all levels. These personal plans are elaborated annually, need to be up-dated periodically taking into account accomplishments, progress of the work and unforeseen activities and should be formally evaluated by those responsible in the structure of the program. The plans should be evaluated at the end of the year before the next yearly plan is written.

4. What should be planned?

Even if the focus in this section is on national planning, much of what is said applies for the panning at other levels.

First of all, the overall *policy* for tuberculosis control needs to be defined. This is

the task of the central unit of the tuberculosis program ideally in coordination with an advisory body. Planning at all levels is then based on the policy and a realistic pace of progress.

Second, the *structure* for the services needs to be defined.

Thirdly, the *process* needs to be described, i.e., the process for service delivery including identification of tuberculosis suspects and diagnosis, treatment and cure of tuberculosis patients.

Finally, specific *activities* need to be planned. These are,

- the pace of expansion (if the program is in the expansion phase),
- training and coordination (including work-shops and meetings),
- supplies and logistics,
- quality assurance
  - ◊ evaluation of clinical practice (supervision of services),
  - ◊ assessment of diagnostic services (especially sputum microscopy),
- information management,
- routine evaluation of tuberculosis control, and,
- research to assist implementation.

As a general rule, for each of the activities planned it is necessary to provide a description of the activity based on the policy and structure, to assess the need for resources involved and to calculate the cost.

Planned accomplishments should be measurable. If activities have a clear plan and a time table for implementation, the evaluation of progress within the program is easy for everyone, both those directly involved in the program and those who are not. Thus, when elaborating a plan for tuberculosis control it is useful to keep in mind that what is written down may later be read by someone not directly involved in the program to determine whether planned activities have been accomplished.

4.1 National policy, strategies and structure

There should be a clear national policy concerning tuberculosis control. Policy that is not reflected in practice is not useful. Thus, any change in policy must be communicated to all persons involved in the care of tuberculosis patients. A

change in policy is thus a major undertaking and changes in policy should not be made too often and only after careful consideration.

As long as anyone is at risk of being infected, tuberculosis should be considered a public health problem in a community. The general objective of tuberculosis control is to reduce the chance of members of the community becoming infected with *M. tuberculosis*. This is achieved by preventing transmission of tuberculosis infection. The likelihood of transmission is reduced by detection and cure of infectious tuberculosis patients.

The World Health Assembly has endorsed the targets for control. These are:

- to cure 85% of detected smear positive patients (these are the most important sources of transmission), and
- to detect 70% of existing cases in the community.

It is difficult to evaluate progress in terms of the latter target as it is usually not known how many cases there are in a given setting at a given time. Suffice it to say that the first target - a high cure ratio - is the important one, since it guarantees that the intervention will not result in deterioration of the epidemiological situation with propagation of bacterial resistance. If the cure ratio is high and the services are accessible it may be assumed that case detection will increase to reach acceptable levels. To this aim it is useful to have a service related target. Such a target may be set by population based planning with the aim of having one unit for diagnosis and treatment of tuberculosis serving on average 100 000 persons (50 000 to 150 000)[4]. When such a coverage has been achieved and a high cure ratio has been demonstrated, community health education may further increase case detection. However, community health education is not useful, and may be harmful, if the other conditions are not met.

To support the general objectives and to reach the targets, specific objectives or policies are needed concerning the level of implementation, diagnosis, treatment, surveillance, etc.

Strategies need to be defined that support each of the specific objectives (strategy relates to long term planning for success).

Likewise, a structure needs to be provided to implement the strategies. The administrative structure for tuberculosis control needs to be compatible with the

[4] Note that population based planning does not imply imposing a 'vertical' or 'artificial' structure. The tuberculosis program is indeed part of the general integrated health service. Population based planning simply aims to identify the appropriate level of implementation.

organizational structure of the health care administration. The IUATLD advocates certain basic principles in terms of administrative structure (starting at the most important level, the community):

- The structure at community level depends on the local arrangement. It is important to activate the existing community structure for tuberculosis control. Only when the community is aware of the problem and how to deal with it can tuberculosis control be achieved.

- For service delivery, population based planning facilitates appropriate decentralization to achieve a balance of the accessibility and quality of services.

- An intermediate level is important in all but the least populous countries. At the intermediate level, a (public) health worker is given the responsibility to organize and supervise tuberculosis control activities in an area.

- The role of a central unit is in policy formulation, procurement of supplies and overall planning and evaluation of the intervention.

4.2 Organization of services

When organizing the delivery of services it is important to think of:

- accessibility, to provide services close to the patients' home,

- quality of services, this is influenced by the degree of centralization,

- equity, all segments of the community must be assured access (women, minority groups, etc.),

- cost, which is often a limiting factor in low income countries.

It should be kept in mind that wherever tuberculosis control services are implemented, training and supervision of personnel must be guaranteed and the information and supply systems must function at the point of implementation.

Population based planning guides appropriate decentralization. If *the unit of management* is a center of diagnosis and treatment serving *on average* 100 000 persons the services will be reasonably accessible, case load should be sufficient to maintain the quality of care, evaluation will be possible and the cost reasonable. It should be emphasized here, however, that population based planning does not imply inventing an artificial ('vertical') structure for tuberculosis control. Rather, the existing structure within the health care administration is used but the appropriate level for implementation is identified as the level coming close to

serving the desired population size.[5]

At the *tuberculosis management unit* the *tuberculosis manager* is a focal point. This is a person within the existing health service who, among other tasks, undertakes to ensure the proper functioning of the program. Such a person can be said to be 'designated' but not 'dedicated' (in other words, has other tasks to perform than simply those of tuberculosis). The tuberculosis manager is responsible for tuberculosis control in the population served by the unit and will liaise with the laboratory and with other partners in ensuring effective tuberculosis control.

The tuberculosis management unit is the point of micro-planning and this is the responsibility of the tuberculosis manager at this level. The unit needs to have as a minimum general *out-patient services* attending health care seekers, a *multi-purpose laboratory* and a *tuberculosis program* for case management. In most instances, provision should be made at this level for *hospitalization* of patients should this be judged necessary to their care.

When planning *urban* tuberculosis control the basic principles are similar as in *rural* areas. Population based planning still applies because even if distances are shorter, transport is frequently badly organized and poverty may prevent mobility. Furthermore, case rates in cities are often very high because of poverty and crowded living conditions. It is difficult to provide high quality individualized care in overcrowded central hospital facilities, thus adherence to treatment is likely to suffer unless population based planning is used. Moreover, the case load in such circumstances requires health personnel to spend full time in tuberculosis services; even if such personnel should be part of the overall health services. In addition, the diagnostic services become completely overwhelmed and the quality of the examinations cannot be assured unless population based planning is used.

It is no less important to have public health workers for supervision of services in cities than it is in rural areas. The supervisors are responsible for overall coordination of tuberculosis control in the city. This coordination is often a great challenge in large cities as the diversity of services is usually greater than in rural areas (government services, industrial health, private sector, penitentiary system, etc.).

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[5] In many countries, but by no means all, the appropriate level is the 'district'. Because the term 'district' is not used in all countries and where it is used the population size is not uniform (may vary from 30 000 to 50 000 population in some countries to as much as half a million or more in other countries) we prefer to talk about population based planning rather than 'district' based planning.

It may be necessary to have specialized out-reach workers in large cities. This applies particularly in cities where income distribution is uneven like in many middle and high income industrialized countries where marginal populations are created who have a risk of tuberculosis infection which is comparable to that of the general population in low income countries. Tuberculosis control services everywhere must take into account the characteristics of the population suffering from tuberculosis, and these characteristics are not necessarily the same in all countries.

In low income countries with poorly developed rural health services the health facilities in the cities may attract patients from the rural areas. This is a hopeless situation for tuberculosis control. Thus, improving health services in rural areas is a prerequisite for good results in tuberculosis control in urban areas.

In some low income countries it is necessary to think specifically about women's access to services which may be impaired for various reasons.

4.2.1 Identification of suspects

Responsive case finding is recommended. This implies looking for tuberculosis suspects among health care seekers rather than among the general population out in the community. This does not imply that there should be no involvement of the community. Information on tuberculosis is part of general community health education, and such education may increase responsive case finding (see 4.6.2).

Screening for symptoms of tuberculosis should take place at all health facilities and in all places within a facility, i.e. all health workers should be aware of which symptoms to look for and how to proceed if tuberculosis is suspected. The general rule is that a patient with cough of more than three weeks duration is referred for sputum examination.

There is frequently a specific common point of entry for all health care seekers at health facilities, the 'out-patient clinic' or 'screening'. The personnel here, need special orientation or training in order to be able to identify and manage tuberculosis suspects. This needs to be planned.

4.2.2 Diagnosis

When organizing the laboratory network, population based planning is used. With too much decentralization there will not be enough work load to maintain quality and training and quality assessment will be expensive and operationally difficult. Too much centralization will result in overcrowded services, less personal attention and problems in coordination. High work-load in laboratories may also

compromise quality.

The laboratory network should be planned and described, listing the participating units. The network is made up of peripheral laboratories, intermediate laboratories and a central reference laboratory. The role of each level should be defined.

The chest X-ray facilities, which are commonly more centralized than laboratory services in low-income countries, should be planned and described in a planning document.

4.2.3 Treatment

Classification of cases and standardized treatment regimens are set in the national policy. A policy on directly observed treatment needs to be in place. There are different options, the traditional methods of hospitalization or ambulatory treatment with regular attendance as out-patients being the most common. Other options, such as directly observed treatment administered by community health workers are popular in certain circles. Suffice it to say that any method of directly observed treatment must be carefully field tested before being recommended as official policy. Field testing is carried out in demonstration sites.

The tuberculosis program in the management unit is responsible for tuberculosis patients from the moment of diagnosis. If the laboratory network is well planned and appropriately decentralized as described in 4.2.2 the best way to plan tuberculosis control is to have a tuberculosis management unit wherever acid-fast bacilli microscopy is performed.

Satellite units are health posts or units serving a smaller population than the tuberculosis management unit. If satellite units are used there should as a rule not be more than three to five such units per tuberculosis management unit and good coordination must exist between a satellite unit and the management unit.

The tasks of the tuberculosis manager include: coordination with out-patient screening services, the laboratory and satellite units, registration of patients, treatment and follow-up of patients, contact investigation, defaulter prevention, reporting of case finding and reporting of outcome of treatment.

4.3 Implementation / expansion of services

If a program is new as well as when important changes in policy and strategy are made, phased expansion must be planned.

In this case, it is good practice to start implementation in a demonstration site for testing. Even so, a plan for country wide expansion should exist from the start. This plan should roughly lay down expansion within regions / provinces and expansion to new regions / provinces.

Depending on the experience from demonstration sites, adaptations can be made concerning operational details in implementation before expansion starts. Such adaptations are difficult to make on a large scale and thus the importance of the demonstration sites.

There should be certain prerequisites for implementation in a new site. An example:

- operational micro-planning completed
- designation of personnel according to national policy
- training of personnel
- supply system in place
- equipment in place.

Expansion should be based on satisfactory progress. Criteria for expansion need to be defined. An example:

- microscopy functioning well (<5% discordance on proficiency testing)
- recording and reporting acceptable (no important errors)
- supplies correctly managed
- smear conversion at two months of treatment acceptable (80%).

The criteria should be adhered to throughout the expansion phase. The final pace of expansion will thus be decided by the success and may be slower than planned or even faster if financial resources allow. It is wise to be optimistic and plan rather rapid expansion for the following reasons. To take advantage of the enthusiasm which is common in the early phase; to prevent care seeking by patients from neighboring areas, limiting the feasibility of directly-observed treatment; to prevent having to slow down because of financial constraints if

circumstances allow rapid expansion.

4.4 Supply and materials management

Tuberculosis is controlled by treating people who have the disease. The treatment is complicated and of long duration. Personnel and patient adherence to correct treatment is crucial because of the risk of propagating drug resistance. People with tuberculosis are disproportionately poor and may not be able to afford adequate treatment. The benefits of treatment are not only for individuals with tuberculosis but for the community as a whole. To control the epidemic and to prevent the emergence and transmission of resistant bacteria, a continuous supply of high quality medications must be guaranteed. The IUATLD recommends that the procurement of medications for treatment of tuberculosis be undertaken centrally and that the central health authorities guarantee sufficient and uninterrupted supplies of these medications at all levels.

A national materials management system needs to be in place with a set frequency of orders and distribution. The system can be independent ('vertical') or integrated within a national supply system if an efficient system is in place. In the latter case, the tuberculosis program should be involved in designing the forms used and when deciding on the method used to calculate the needs.

Whatever the system adopted, great care must be taken that the medications are not stolen or misused as the consequences are much greater than simply the loss of resources. The creation of drug resistant organisms is an error which can not be rectified within the context of most national programs and is a threat to the entire community. Should security not be assured in the general system, an independent and accountable system is preferable.

For planning supplies the IUATLD recommends a system where the running requirement for supplies is calculated on the basis of the number of cases detected. Apart from the running requirement a reserve is kept at all levels of the system in case of problems. This reserve requirement should be equivalent to a running requirement for one year and may be distributed as follows: Six month reserve at central level, three months at intermediate level(s) and three months at tuberculosis management units. The materials management system is described in detail in the IUATLD *Tuberculosis Guide For Low Income Countries*. The order form from the Guide may be used when planning supplies for medications and material for diagnosis.

4.5 Information

Tuberculosis programs use a multi-purpose information system for surveillance, management and evaluation.

In a planning document the information system is described, the components and forms and the process (information flow). In short the essential components are:

- a form for requesting sputum examination,
- individual treatment cards for monitoring treatment,
- registers, and
- reports.

For effective management the system is planned as follows:

- the registers are facility based (placed at tuberculosis management units),
- intermediate level managers operate with reports,
- the treatment cards are kept by the person who administers directly observed treatment.

The basis of reporting is the tuberculosis management unit and reporting is quarterly. There is one report for case finding and another report for outcome of treatment. Evaluation is by cohort analysis.

If satellite units are part of the structure for tuberculosis treatment, these units operate with treatment cards only. In this case coordination with the tuberculosis management unit is crucial. Without regular coordination the information system collapses as the treatment card is the key to cohort analysis of treatment results. Coordination must be monthly as a minimum, and can be in the form of satellite unit personnel presenting at the tuberculosis management unit or the tuberculosis manager traveling to all satellite units. The involvement of satellite units thus obviously results in a more costly program, both when considering training of personnel and coordination and quality assurance (supervision of services).

4.6 Training

Under this heading we consider training of key personnel in the tuberculosis program and health education.

4.6.1 Training of personnel in the tuberculosis program

The points to consider here are the program manual, training curriculum, initial

training of personnel and continuous training or refresher training.

There should be a tuberculosis program manual explaining national policy and procedures of tuberculosis control. The manual should be written in a simple format and in such a way that it is easy to use as a hand book for problem solving in the day to day management of patients and of the program. The personnel in the tuberculosis program should be encouraged to consult the manual in their daily work. The manual should also be used as part of the curriculum in initial training of program personnel.

A plan of initial training is part of a long term plan in a new or revised program. Initial training precedes implementation and is followed by supervision. The questions to be addressed when writing the training plan are:

- who should be trained?
- why?
- how many?
- where?
- how?

Also the duration of each training activity planned must be determined; this is important when calculating the cost of the training plan.

The trainers should be persons with sound knowledge and experience in tuberculosis patient and program management. Thus, it is not recommended to have special multi-purpose trainers who have no link to practice within the tuberculosis program. Rather, key personnel in the program should be trained to become trainers.

Ideally, there should not be a long interval from initial training to implementation. Thus the training plan must be consistent with the plan of implementation / expansion (see 4.3). When the program is implemented in a new site it is wise to repeat training in reporting of treatment results (cohort analysis) six to twelve months after implementation. This can be done informally during supervisory visits or formally in work-shops.

The best method of evaluating initial training is to evaluate the services. This can be done during supervisory visits. Supervision can be seen as on-the-job training and is one component of refresher training. Supervision of personnel soon after training is crucial to guarantee maximal impact of training activities and the establishment of good practice right from the start. Thus, the plan of training must

be consistent with the plan of supervision (see 4.7.4).

Refresher training should be planned for all personnel regularly. This may be in the form of periodic work-shops and it is convenient to plan such work-shops to coincide with annual evaluation meetings (see 4.9).

4.6.2 Health education and community participation

The points to consider here are:

- Who should be educated? Health workers, patients and the community.
- Why? Each target group needs to learn different things for a different purpose.
- Where? In medical / nursing schools, in the health services, in the community.
- How? By using posters, pamphlets, manuals, books, videos, plays, etc.
- What other methods should be used? Radio, television, campaigns, etc.

A word of warning must be said here. When working in tuberculosis control, quality is more important than quantity. The community should never be mobilized to participate in tuberculosis control until the services are ready to meet the demand created by such activities. The demonstration of a high cure ratio is the most important sign that the services are ready. To attract patients to badly functioning services is malpractice.

It is well to remember that good tuberculosis services advertise themselves, i.e., the cured patient who has been well treated in every sense of the word is a walking poster. This method is guaranteed not to create demand before the services are ready to meet it.

4.7 Quality assurance

The points to be considered under this heading are, the quality of diagnosis and the quality of case management (patient care).

4.7.1 Quality assurance in the network of sputum microscopy

The presence of tuberculosis micro-organisms in sputum in sufficient amounts to render them visible on direct microscopy is a sensitive indicator of infectious tuberculosis. It is reasonably simple to organize and maintain a network for diagnosis of tuberculosis by sputum microscopy within the general laboratory network in low income countries. For these reasons, microscopy is used in the diagnosis of tuberculosis in control programs. To monitor competence of

laboratory workers, regular quality assessment should be organized.

A system may be set up where a sample of microscopic slides is sent from peripheral laboratories to intermediate and central laboratories for re-examination. Alternatively, the slides may be collected from the peripheral laboratories during supervisory visits. The re-examination must be blinded, i.e., the second reader should not know the result of the previous reading, and therefore in routine laboratory work the results of sputum examination must never be written on the microscopic slide itself but rather in the laboratory register and on the sputum request form. This requires that the slides be numbered in a systematic manner for identification in case a slide will be re-examined. Thus, slides should, as a minimum, have the laboratory serial number written on them.

Regular quality assurance makes necessary that arrangements be made so that slides are kept until a sample has been selected for quality assessment, i.e., there must be a sufficient number of slide holding boxes at the peripheral laboratories. As a simple rule, after examination and reporting of results, all slides should be kept in a slide holding box. This will allow later sampling for proficiency testing. When slides from a defined time period have been sampled, the remaining slides in the box may be discarded.

It is not enough to organize the delivery / collection of slides for quality assessment. A reverse path for feed-back to the peripheral laboratory must be set up as well and a policy should exist for action in case of inadequate performance.

4.7.2 Quality assurance of diagnosis of cases other than those smear positive

When patients are given treatment, although they are not smear positive, the quality of their diagnosis must be assured. At a minimum, the records of smear examinations must be checked to ensure that these examinations have been performed. In addition, it is worthwhile to review the diagnostic features of selected cases: in adults with pulmonary tuberculosis, this should, at a minimum, include examination of the chest radiograph; in children, the features of the case, including symptoms, radiography, tuberculin skin testing and history of contact with another case should be reviewed.

4.7.3 Quality assurance of case management

Because prevention of tuberculosis is accomplished by proper case management, the care given to individual patients (particularly those who are smear positive) is of vital importance.

The quality of care given should be apparent from the records kept for each

patient. A review of the case records of consecutive individual patients provides a clear indication of this care. Specific items may be reviewed, for example: the correspondence between the diagnostic category and the type of treatment given; the recording of the weight of patients and the correspondingly correct doses of medications; the delay between diagnostic examination and the commencement of treatment.

Quality of care can also be determined by interviewing individual patients. Examples of items to consider are: delay between visiting health facilities and having diagnostic examinations; correct assignment of treatment according to history of previous treatment; proper understanding of the disease and its treatment by the patient.

In planning quality assurance of case management, methods (such as standard check lists or guidelines) can be developed, field tested and adopted to assist those responsible for the activities and to ensure standardization of the assessments.

4.7.4 Realizing quality assurance in practice through supervision

It is very important that training be followed by supervision. Supervision has several objectives. It is primarily thought of as support for the personnel delivering the services. Supervision is important to stimulate and motivate personnel, to support them to gain the political commitment from local leaders for the policies and resources needed and to guarantee the quality of services.

In a planning document, the line of supervision, frequency, methodology and responsibilities should be described.

The central level personnel support the intermediate level personnel who in turn support the personnel at the tuberculosis management unit. However, all supervisory visits should reach the level of implementation, i.e., the tuberculosis management unit and beyond.

Immediately following training and implementation supervision should be frequent until performance is acceptable. Then, routine supervision commences. It is recommended that a tuberculosis management unit be routinely visited once in three months. The frequency of supervision by the central level personnel should not be less than once a year to each region / province / state.

Supervision is time consuming and as a rule a visit to a tuberculosis management unit should be of no less than half day duration. Supervision is ideally performed by a person knowledgeable and experienced in tuberculosis patient and program

management. Thus, it is not recommended to have special multi-purpose supervisors (i.e., 'integrated supervision') since they are less likely to be able to give specific advise when it comes to technical issues.

The methodology of supervision needs to be clear and should be part of the curriculum when training staff whose responsibility includes supervision. If check lists are used it is important that the supervisory visit not be reduced to the mere filling out of forms. In no case should information be collected that has already been reported through the information system. The procedures recommended for supervision are similar as described in *section 3 in Part I Tuberculosis Program Reviews* and in *section 4.2. in Part III Technical Support*.

Transport must be planned if supervision is to be possible. The transport may be with public transport or transport provided by the health services for this purpose. In the latter case, usually transport will be shared with other disease control programs. Occasionally, vehicles or motorcycles are purchased specifically for tuberculosis control.

4.8 Coordination

Coordination within the tuberculosis management unit is crucial for success and is the responsibility of the tuberculosis manager as discussed in 4.2.3.

Coordination within the tuberculosis program, between the different levels, is also important. This coordination is established with meetings, evaluation work-shops (see 4.9) and supervisory visits (see 4.7.4).

Coordination within the government sector is important, i.e. coordination within the Ministry of Health[6], the coordination of the tuberculosis program under the Ministry of Health with the Ministry of Planning, Ministry of Finance, Ministry of Defense and/or Ministry of the Interior (for health care in the military and prison systems).

The goal of the tuberculosis program is to coordinate all tuberculosis control in the country. A well organized and well functioning government program is a prerequisite for coordination with other sectors; the establishment of such a program is thus first priority for the government. The tuberculosis program should then take the initiative in coordination with other sectors, such as non-governmental organizations, private practitioners, etc.

[6] I.e., department of planning, finances, information, supply, AIDS control, etc.

4.9 Routine evaluation of tuberculosis control activities

Routine evaluation of activities and the impact of intervention should be planned.

Case by case monitoring of treatment outcome is a key element in tuberculosis control. This evaluation is built into the information system.

Monitoring of drug resistance is another key activity in evaluation of tuberculosis control. Standardized guidelines have been developed by the IUATLD and the World Health Organization (WHO) for planning and execution of this activity. The guidelines are available upon request.

Periodic studies or continuous surveillance of the prevalence of infection with HIV is important in countries where dual infection is likely to affect the tuberculosis situation. Standardized guidelines have been published by the IUATLD and WHO for planning and execution of this activity. The guidelines are available upon request.

Surveillance of infection with *M. tuberculosis* is accomplished by means of tuberculin surveys. The methods for carrying this out have been standardized and published by IUATLD and are available upon request.

Yearly meetings or work-shops should be planned at all levels in the program where the activities and the output of the program are evaluated. This is a form of peer review and is highly effective in developing management capacity and a research strategy to strengthen the program. These events also serve for coordination within the program.

4.10 Research

On-going research within the program is an absolute requirement if the program is to be relevant to the changing conditions encountered. Research should address actual problems within the program. In this way the research findings are likely to contribute to program improvement and development.

According to international recommendations a designated portion of the budget of the program should be set aside for carrying out research. It is recommended that this portion should amount to 5% of any external aid and 2% of the internal contribution to the program.

Research may be planned as part of a long term plan or there may be a separate research plan.

5. How should a long term plan be written?

A long term plan is based on the findings of a program review (situation analysis) and has an introductory chapter where the situation is summarized and the problems and prospects highlighted.

A long term plan contains a description of available infrastructure and resources and an assessment of the need for the same for implementation of effective tuberculosis control. In case of discrepancy - available versus needed - it may be necessary in short term planning to make modifications in the program according to what is available. In long term planning however, the aim is to improve infrastructure and increase resources as needed.

In long term planning it is important to specify responsibilities carefully so that the parties involved know what is expected of them.

5.1 Objectives of a long term plan

The objectives of a development plan are to provide guidelines for tuberculosis control, to describe an organizational structure to manage a tuberculosis program and a plan of action for the implementation of activities.

5.2 Objectives, strategy and policy of the program

There should be a clear description of the objectives, strategy and policy of the program, including legislation. Section 4.1. provides some advice in this respect. For further reading the reader is referred to material published by the IUATLD and the WHO where the policy recommended by the organizations is described.

5.3 Organizational structure and personnel

A long term plan contains a description of the organizational structure of the program. The personnel involved is listed and individual responsibilities and tasks are described. Detailed job descriptions may be annexed to the plan.

5.4 Activities

After describing the policy and the structure for implementation, activities are listed and described.

The activities include:

- training of personnel

- implementation
  - ◊ expansion of the program to involve new sites
  - ◊ maintenance / development in sites previously involved
- supplies
- quality assurance
  - ◊ quality assurance of diagnosis
  - ◊ quality assurance of patient care
- program evaluation
  - ◊ surveillance of case finding and results of treatment
  - ◊ drug resistance surveillance
  - ◊ surveillance of prevalence of HIV infection among patients
  - ◊ tuberculin / tuberculosis surveys.

Finally, any planned research activities should be listed.

5.5 Plan of action

A plan of action should be provided. A plan of action should be short, to the point and realistic, keeping in mind that achievement will be evaluated. The essential components of a plan of action are:

- a list of activities with justification,
- time frame,
- evaluation method (how will progress be measured), and
- cost.

Furthermore, it should be stated with whom the responsibility for carrying out individual activities lies.

The plan of action should be written in such a way that it is easy to evaluate accomplishments qualitatively and quantitatively. It should describe specific measurable operational steps.

5.6 Cost

Cost may be divided into investments and operating or running cost. Investments

include infrastructure, vehicles and equipment (such as microscopes and X-ray equipment). Training and reserve supplies may also be classified as investments. Running cost includes supplies for diagnosis and treatment, the cost involved in quality assurance (including supervision of services), routine evaluation and coordination. Salaries of personnel are also part of the running cost.

With integration, some of the cost in tuberculosis control is shared with other activities within the health services, such as infrastructure, personnel cost and administration. Equipment for X-ray examination, antibiotics for smear negative tuberculosis suspects and the cost of hospitalization is also considered part of the cost of the general health services and will not be dealt with here. However, if it is desired to have a detailed cost analysis for tuberculosis control all this must be included.

In large countries with poor information it is convenient to plan on the basis of standard operational units, the tuberculosis management units. When a program is functioning well and reliable information is available, financial planning based on past performance is easy.

Taking note of the plan of action the cost of planned activities is calculated after considering the components involved. When calculating the cost involved in the execution of a long term plan the following is needed:

- a description of the network of services and a plan of expansion (4.2-4.3).
- a plan of training (4.6.1)
- a plan of supervision (4.7.4)
- an estimation of case load
- an estimation of suspect to case ratio.

When good information is available, case load can be estimated by using reports of the number of cases detected and projections based on the trend in case finding. The case load will increase if prevalence of infection with HIV increases in a country where the prevalence of tuberculosis infection is high in people of reproductive age. The case load will also increase if coverage of the tuberculosis program increases or even without expansion if a special effort is put into increasing case detection.

If there is little or no good information available in a country or area, other methods have to be used for estimating and projecting case load. Statistics from neighboring countries or areas may be used. Another alternative is to use

estimates of prevalence of tuberculosis infection and / or disease. This method is however often very imprecise. Obviously such estimates are more useful if based on actual recent surveys than when they are based on historical estimates or are just wild guesses. But even information from actual surveys may be difficult to interpret[7]. The practical point here is that an estimate has to be made, otherwise we cannot plan. It is recommended to be on the generous side in *long term planning* (but still realistic) particularly where there is little information available since it is unacceptable to run out of supplies. There is not much danger that medications will expire unless *orders* are way off, since the expiration date for tuberculosis medications should be three to five years from the manufacturing date. In *yearly planning* the estimate in the long term plan is adjusted before orders are placed and the quantities in stock at the time of ordering are taken into account. Thus, if ordering is correctly managed surplus medications should not accumulate. The planning of a one year reserve supply is very important in order to prevent shortage in case of higher than expected case load.

The suspect to case ratio tells how many tuberculosis suspects need to be examined by sputum microscopy to diagnose one smear positive tuberculosis patient. This information is used when calculating the need for laboratory supplies. In programs assisted by the IUATLD this ratio has been found to vary between countries from 5 to 30% at national level[8]. Note that the number of smear negative patients does not enter into this calculation, or rather these are included in the number of suspects. See *section 4.2.3 in Part III Technical Support* for more detail on the suspect to case ratio.

A description of the cost items to be considered when developing a budget for tuberculosis control follows. Prices will vary depending on the source and prices change from one time to another. Information on latest prices of individual items available through the IUATLD can be obtained from the IUATLD upon request.

5.6.1 Diagnosis

It is recommended that each tuberculosis management unit be equipped with a binocular microscope, with an oil immersion lens, an appropriate light source and a screw controllable stage to move the slide. Additionally, microscopes are

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[7] Rieder HL. Methodological issues in the estimation of the tuberculosis problem from tuberculin surveys. Tubercle Lung Dis 1995; 76: 114-121.

[8] Rieder HL, Arnadottir T, Tardencilla Gutierrez AA, Kasalika AC, Salaniponi FLM, Ba F, Diop AH, Anagonou S, Gninafon M, Ringdal T, Trébucq A, Enarson DA. Evaluation of a standardized recording tool for sputum smear microscopy for acid-fast bacilli under routine conditions in low income countries. Int J Tuberc Lung Dis 1997; 1: 339-45.

needed for quality assessment and for training of laboratory technicians.

Each tuberculosis management unit needs a laboratory register and several slide holding boxes for microscopic slides since the slides must be kept for a certain period of time for the purpose of quality assessment. Expected case load will determine the number of registers needed per unit of time (a year for example) and the number of slide holding boxes needed.

Material such as Bunsen burners, applicators, pencils to write on microscopic slides and material for cleaning and waste disposal is frequently available in multi-purpose laboratories and is considered part of the shared costs in integrated health services. Otherwise, this material has to be budgeted specifically for sputum microscopy.

Other than this, the material needed for sputum microscopy is: Sputum request forms, specimen (sputum) containers, microscopic slides and reagents. Given an estimate of the case load and a suspect to case ratio the need for these supplies can be calculated. If the suspect to case ratio is not known the ratio of ten suspects to a smear positive case can be used until further information is available. This ratio is used in the calculations on the standardized form described and demonstrated in the IUATLD *Tuberculosis Guide for Low Income Countries*. The form includes supplies needed for diagnosis and follow up sputum examinations during treatment.

For laboratory supplies, it is often recommended to have a larger reserve supply than for medicines. IUATLD recommends a two-year reserve stock for laboratory supplies in the country, twelve months at the national, and six months each at the intermediate and peripheral level. Thus, remember to take into account a reserve supply when calculating the need for laboratory supplies.

Banking costs, insurance and transport should be added to the FOB (free on board) price (the abbreviation CIF is used for cost-insurance-freight). The difference between the FOB cost and the cost until the product reaches the point of final destination (i.e. the tuberculosis management unit) will vary depending on volume to cost ratio, transport means, etc. In general, it is safe to say that this will not exceed 30% of the FOB cost but might very well be lower.

If procurement is undertaken by an agency or organization, overhead will usually be charged.

Finally, the cost of printing the order forms for laboratory supplies is calculated.

5.6.2 Treatment

Each tuberculosis management unit needs a tuberculosis register to register patients. The case load determines how many registers a unit needs in a given time period.

Each patient diagnosed, whether smear positive or smear negative, needs a treatment card, an identity card and sufficient quantity of medications to complete a given treatment regimen. If the treatment includes streptomycin, needles, syringes and sterile water must be added.

Whenever supplies for diagnosis and treatment are planned or ordered the current supply situation should be taken into account. For example, if calculations show that ten million tablets of ethambutol are needed in the period and there are fifteen million tablets of ethambutol in store obviously no ethambutol should be ordered. If supplies are correctly managed the quantities of items in store will be balanced. However, it is surprisingly common to find in the field that the stock situation is not taken into account when planning and ordering supplies and that large quantities of some items pile up and eventually expire while a stock out may occur for other items. A phenomenon that further contributes to this mis-management are unplanned donations. Such donations can be very problematic when it comes to managing supplies. Furthermore, such donations may have an expiration date that prevents them to be of any use.

It is recommended to take into account a reserve supply when calculating the need for treatment supplies at national level (see 4.4).

When ordering medications, the number of tablets required rather than the number of units (boxes or bottles) should be specified as packaging may vary and thus serious errors in deliveries can occur when the number of units is used.

There is a certain lag period from ordering of materials to delivery. This lag period is variable depending on the source and the recipient country and must be taken into account when planning and ordering supplies. It is not uncommon to find in the field that shortage of medications and materials is blamed on this lag period when in fact it is a consequence of bad planning.

For medications and other material for treatment, banking costs, insurance and transport should be taken into account (CIF). The difference between the FOB cost and the cost until the product reaches the point of final destination (i.e. the tuberculosis management unit) will vary depending on volume to cost ratio, transport means, etc. In general, it is safe to say that this will not exceed 30% of the FOB cost but might very well be lower.

If procurement is undertaken by an agency or organization, overhead will usually be charged. The advantage however is that the WHO, the IUATLD and several other organizations are able to negotiate low prices as they buy large quantities of medications. Thus, considerable resources can be saved this way and this may enhance the sustainability of the program.

The cost of printing the order forms for treatment supplies needs to be calculated. Finally, the expected cost of contact investigation and defaulter prevention per unit is estimated if these are important activities in the given setting.

5.6.3 Training

The cost of printing the program manual should be included here. The program manual should be up-dated and published regularly, at least once every five years.

The cost of implementing the training plan is easily calculated by referring to the plan of training (see 4.6.1). The costs involved are for curriculum development, facilities and equipment, transport and daily allowances for participants and faculty, and refreshments if any.

International training activities, such as courses, work-shops, meetings and conferences should be budgeted.

5.6.4 Health education

The price of developing any planned health education material and of distribution, communication and training activities is estimated.

5.6.5 Supervision of services

From the plan of supervision (see 4.7.4) it is clear what the expected number of visits is to each level, how many persons travel and how long on average a visit will take. The price of transport and daily allowances is needed to calculate the cost.

5.6.6 Coordination

Planned meetings and work-shops need to be budgeted taking into account the number and duration of activities, the expected number of participants, transport, daily allowances and any material and refreshments.

5.6.7 Routine evaluation

The cost of printing the reports in the information system, i.e., quarterly reports on case finding and quarterly reports on treatment outcome is calculated taking into account the number of reporting units and how many copies of each report are

required.

Quality assurance (quality assessment of microscopy and supervision of services) is discussed elsewhere (see sections 4.7.1, 5.6.1 and 5.6.5).

The costing of surveillance of drug resistance, surveillance of HIV infection among tuberculosis patients and tuberculin / tuberculosis surveys will not be dealt with here.

3.6.8 Technical support

If it is decided that technical support is needed, the cost is estimated. The cost depends on the technical agency contracted and will usually include travel expenses and a service fee.

5.6.9 Research

Research may be planned and budgeted separately from other program activities.

However, it is a good rule that 5% of any external assistance and at least 2% of the national budget for tuberculosis control should go for research activities within the program. This will encourage the program personnel to perform research as part of program activities.

5.6.10 Unforeseen costs

It is common to allow for 5-10% of the total budget to cover any unforeseen expenses.

5.7 Financing

The budget is written up in such a way that it should be possible to break the cost up according to activities, levels or (geographic or administrative) areas. This makes it possible to divide the program into 'packs' for financing. This is all the more important if the government cannot cover the total amount needed for the planned activities and it is expected that more than one source of funding will be required.

Ideally, financiers are identified before planning is made and commitments are documented in the plan. Negotiations and compromise may be necessary depending on availability of resources.

5.8 Monitoring and evaluation

The mechanism for monitoring and evaluation of progress of the long term plan

should be described in the plan.

Regular yearly monitoring of progress is recommended. This should form part of routine activities within the program and the program should publish an annual report. External assistance for the purpose of monitoring may be considered also, in this case there will be an external progress reports as well.

A thorough evaluation (program review) at the end of the planning period is important and constitutes the start of another planning cycle. The evaluation is important for policy development. A mid term evaluation is sometimes required by donors.

It is important to have clearly defined quantitative and qualitative measurements. However, in tuberculosis control, quality is more important than quantity. Thus, quality is first priority and even if expansion is not as rapid as planned or case finding is less than expected this does not necessarily warrant criticism.

Examples of measurements that reflect quality are:

- the proportion of new smear positive patients who have become smear negative at two months of treatment, i.e., 'smear conversion' (note that it is not recommended that this be routinely reported by all tuberculosis management units, rather this can be looked into during supervisory visits and program reviews)
- cure ratio among patients with smear positive tuberculosis
- quality of reporting
  - ◊ do all tuberculosis management units report (on time)?
  - ◊ are all smear positive patients registered for treatment?
  - ◊ are all smear positive patients evaluated for outcome of treatment?
- degree of concordance in quality assessment of microscopy
- levels of drug resistance
- supply situation.

Examples of measurements that reflect merely the quantity of activities are:

- progress of a training plan
- progress of a plan of expansion
- accomplishments in supervision (compared to plan),

but program performance will reflect the quality of training and supervision (which is more important).

Monitoring of the tuberculosis epidemic itself is achieved only by periodic surveys of tuberculosis infection and / or tuberculosis disease in the community. Such surveys are both time consuming and expensive and results from the former (tuberculin surveys) are frequently difficult to interpret[9]. However, a time may come in the history of a program when a decision is made to embark on such an endeavor as a community based survey. This however is not usually an issue for each and every long term plan.

5.9 Benefits

Finally, the expected benefits of the long term plan may be pointed out and potential constraints discussed.

Expected benefits may be:

- A certain number of patients will be detected and cured, thus
  - ◊ reducing human suffering,
  - ◊ reducing transmission and the reservoir of infection, and
  - ◊ preventing drug resistance.
- A large pool of health workers will be trained,
  - ◊ an investment for the future.
- There may be benefits beyond the tuberculosis program:
  - ◊ with better case management in other lung diseases, and
  - ◊ with a stronger health service in general.

6. What follows program planning?

When a medium or long term development plan has been written, this is submitted to the government for approval. With government approval the plan becomes official. Tuberculosis control must be put into perspective and the plan is usually a part of a general health sector plan in a country.

As discussed previously, financing of the planned activities must be secured. If the

[9] Rieder HL. Methodological issues in the estimation of the tuberculosis problem from tuberculin surveys. Tubercle Lung Dis 1995; 76: 114-121.

government cannot finance the plan and depending on the priorities of the government, the government may opt to seek external sources of funding in the form of a loan or a grant.

When funding has been guaranteed, the implementation of the plan can start. Regular monitoring is performed as described in the plan and at the end of the project period the implementation of the plan is evaluated and another planning cycle begins.

Regular monitoring may be assisted by external consultants. This is what the IUATLD defines as intensive technical support. A consultant is assigned as responsible for the program and visits the country in question on a regular basis and reports findings and recommendations.

Periodically the progress may be evaluated by external consultants, other than the consultant(s) who have been involved in regular technical support. The regular consultant(s) may or may not take part in such external evaluation (program review), depending on what is decided in each case.

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III. Technical Support to Tuberculosis Programs

1. What is technical support?

Technical support is that given by an expert or agency not directly involved in the implementation of a tuberculosis program, which supports implementation by providing technical advice. Strictly speaking the program in question may be a national program or a program in the non-governmental sector, but we will focus here as elsewhere in this manual on national programs.

A tuberculosis program may request the services of a technical expert to provide advice on a specified issue or it may ask to receive technical advice on a continuous basis. Continuous technical support is usually more productive and is recommended when a tuberculosis control program is first introduced into a country. We will consider continuous support only, which the IUATLD defines as *intensive technical support*. Intensive technical support implies that a technical expert makes regular visits to a program. Intensive technical support can lead to a mutually beneficial collaboration. The partnership may be extended to include advanced training in the science of tuberculosis or its management as well as collaborative research in the field of tuberculosis epidemiology and control.

Technical support to a tuberculosis program usually starts with a clear disadvantage on the side of the expert: The expert has little or no knowledge of the program in question. Before providing any advice, the consultant (henceforth used synonymously to designate the technical expert) must obtain as much information as possible about the program and the local situation, including priorities, resources and limitations of the partner country, to be able to judge adequately where problems may lie.

The consultant must, on the other hand, be equipped with a distinct advantage, i.e., she/he must possess considerable knowledge of all aspects of tuberculosis control, and should have experience in collaboration with more than one national tuberculosis program. It usually takes years of practical experience for a consultant to be able to detect and understand problems in a program and to offer valid and realistic advice.

To request technical support for a program the health authorities may approach a technical agency or organization officially, in writing. The organization, if willing and able to provide technical support, may then convene a meeting of a representative from the agency / organization itself, a designated consultant and a representative of the program in order to determine the nature and modalities of the technical expertise that will be provided. As a result of such talks, a contract between the program and the technical agency / organization may emerge. The contract will specify the nature of the technical expertise, the frequency of visits to the program, the responsibilities of each party and the financial aspects concerning the costs for providing the services (the cost usually includes a fee and travel expenses). The contract should be binding for both parties as long as it is in effect and each party should have the right to leave the contract, if the other party fails to adhere to the contractual agreements.

2. Why is technical support useful?

Technical support by an independent organization / agency is useful because it is external to the program. This can ensure that the program is provided with a fresh and independent view of successes and problems. An outsider may ask questions that have not been asked before and may approach a problem from a new angle which may prove beneficial to the program. The outsider, in addition, may be viewed by local officials as being disinterested and may therefore be more convincing in obtaining resources or political commitment for changes which are required.

The technical expert should have significant knowledge and experience to share with local personnel and thus there is an element of training in intensive technical support.

It should be noted here that a tuberculosis program may receive support from more than one organization and as a consequence there may be more than one technical consultant visiting the program. This can create problems and great care must be taken in such situations so as not to 'confuse' the program management with inconsistent recommendations. Ideally, a single technical consultant is assigned for the program and supported by all the organizations involved or there are different consultants that must then collaborate and preferably visit the program together in order not to put too much strain on the program management. After all, the program management must have time to work in between visits by technical consultants (and others) and thus the number of visits

should be kept to a minimum.

3. Who provides technical support? Who benefits?

The WHO, the IUATLD and various other technical or semi-technical agencies / organizations with expertise in international tuberculosis control provide technical support.

The person providing technical support should be an individual qualified in all aspects of tuberculosis control. As a minimum, a consultant must have sound knowledge of diagnosis and treatment of tuberculosis, and methods of evaluation of tuberculosis control activities within the context of a national tuberculosis program. While knowledge of clinical tuberculosis is desirable for discussions that may arise in the field, the main emphasis of expertise lies with public health as the type of advice necessary concerns management of the program. Any report or advice provided by the consultant should first and foremost target the needs of the central program management, rather than the needs of health workers in the periphery. It is then the task of the program manager to implement on a national scale any recommendations that are accepted and deemed realistic. The program manager operates through appropriate channels within the specific context of the structure of the health services in the country.

Ideally, the beneficiaries of continuous technical support are many. The local tuberculosis program, the local community and individual patients benefit. The local professionals benefit by the knowledge gained and so does the consultant by the practical experience and the technical agency / organization. The international community benefits when the experience is shared in meetings, conferences and scientific publications. Thus, eventually international tuberculosis control benefits.

4. What are the activities of a technical consultant?

4.1 How often does a consultant visit a program?

Intensive technical support requires, as a minimum, one two-week visit per year.

Depending on the level of program development, two visits of two weeks duration per year might be indicated. When progress allows, the frequency of visits may be reduced.

For each two-week visit, two additional weeks should be reserved for preparation and for writing of a technical report following the visit. Furthermore, the designated consultant should be available to respond to queries into specific

problems arising between visits.

4.2 What does the consultant do during a visit?

Each visit will include briefing, a field visit, and debriefing.

4.2.1 Briefing and debriefing

Upon arrival in the country, the consultant is briefed by the program manager and her/his staff on the progress made since the previous visit and any problems that have surfaced. As part of the briefing it may be necessary to pay a courtesy visit to higher officials to ensure that they are well informed of the progress of the program as well as to obtain permission to proceed with field visits.

A plan for the two weeks is then finalized. The program manager proposes sites to be visited. The manager may invite the consultant's opinion in this respect. The final selection is made by the central program management. The selection criteria may vary from one visit to another, i.e., units that function well, units that are functioning poorly, units which present a particular problem.

Apart from the field visit, time needs to be set aside for reviewing the central management and the overall situation in the program. It may be necessary to meet with persons other than those working for the program, i.e., other persons within the Ministry of Health or representatives of external agencies such as donor organizations. Finally, it is important that sufficient time be available at the end of the visit to discuss the findings and conclusions, to come up with proposals to improve any deficiencies observed during the visit, and to plan the next steps.

Ideally, the visit should end with a debriefing, where higher officials are informed of the findings, progress and recommendations. This debriefing provides these officials with an opportunity to bring up any issues of interest to them. Furthermore, the debriefing serves to encourage government commitment for tuberculosis control and finally it may be important for supporting the tuberculosis program manager.

4.2.2 Review of the central management

Overall coordination of the program and policy development lies with the tuberculosis program manager and her/his staff. Two essential supportive services need to function well, if the program is to succeed in achieving its objectives:

- materials management, and
- the tuberculosis national reference laboratory.

The organization and management of the materials management system varies from one country to another. The consultant must be familiar with the procedures applied in the country. A visit to those responsible for supplies is essential. Information needs to be obtained on how tendering is organized, what criteria are utilized to select suppliers, how the quality of products is ensured (e.g., bioavailability of essential anti-tuberculosis drugs).

Furthermore, the calculation of orders for materials needs to be reviewed, the supply situation analyzed and the storage and distribution system discussed.

The priorities of a national tuberculosis reference laboratory within the context of a national tuberculosis program are to ensure:

- training and supervision of personnel working in the network of peripheral laboratories,
- quality assurance within the network, and
- surveillance of drug resistance.

The consultant needs to review each of these three activities together with the chief of the national tuberculosis reference laboratory and the tuberculosis program manager.

Finally, time should be spent on reviewing the functioning of the information system for surveillance of case finding and outcome of treatment.

4.2.3 Field visits

The organization of field visits is as described in *section 3 in Part I Program Reviews*. The team must visit as a single group with an individual identified to lead the discussions in each location as well as one to record the information obtained.

Visits to the field by the consultant are to be seen as demonstration or training sessions for the program manager and the central management. The visits provide an opportunity for demonstration of systematic observation, analysis and problem

solving.

The central management should see to it that a follow-up visit to the areas visited by the consultant be undertaken within six months from the visit of the consultant to ascertain whether the corrections or improvements proposed have been implemented.

At the field level, it is good policy to first visit those responsible for health care at the intermediate level, i.e. the state / region / province level, and then at the level of implementation, i.e. the tuberculosis management unit and beyond. The level of implementation corresponds to the district level in many countries.

The persons to be visited should be informed beforehand about the visit of the technical review team and about the purpose of the visit. Local protocols should be respected. When the necessary courtesy visits have been complied with the team will usually be free to visit any health facilities which deal with tuberculosis patients.

The intermediate level manager

The office of the intermediate level manager is visited and the manager is given an opportunity to present briefly the organization and results of the program in her/his area and discuss any operational problems she/he is dealing with. The principal points of interest in intermediate level management are: training, quality assurance, information and material management. The intermediate level manager is responsible to organize the visit in her/his 'jurisdiction' and invariably accompanies the team throughout the field visit.

The tuberculosis management unit

When health facilities are visited it is recommended to follow the path a patient will take under routine conditions.

- *Identification of tuberculosis suspects*

  The first contact of a patient is usually with a non-specialized outpatient clinic. The team should interview the personnel of the outpatient clinic to find out how they identify and subsequently manage tuberculosis suspects. If line listings are available, the team may take the opportunity to ascertain the proportion of health care seekers who present with respiratory symptoms, and to estimate the proportion of those who present with respiratory symptoms who are then classified as tuberculosis suspects and referred for sputum examination. The coordination between the outpatient clinic and the laboratory services should

be scrutinized.

- *The laboratory*

The team then proceeds to visit the laboratory. The physical facilities are inspected and the laboratory technician in charge of sputum examination is requested to give an overview of the tasks of the laboratory in general and the organization of acid-fast microscopy in particular. Questions of interest include the division of work among the personnel if more than one person works in the laboratory and the proportion of person-time devoted to tuberculosis work in order to get an idea of the work-load in the laboratory. Laboratories with a considerable work-load in acid-fast microscopy have more practice and are thus likely to do well in terms of maintaining quality, but if over-charged will be forced to do their work more superficially. Laboratories with very low work-load in acid-fast microscopy may not be able to maintain expertise.

The procedures in specimen collection and the management of specimens from receipt to examination should be reviewed. The production of a specimen of sputum is an occasion which represents a risk to the health services personnel to become infected with *M. tuberculosis*; accordingly, the specimen must be produced in a well ventilated location, preferably outdoors and in direct sunlight.

Opening hours of the laboratory, for receiving specimens are important. For the convenience of the patients it is recommended that specimens be received at any time during the day. It is good practice to label the specimen on the side of the container rather than on the lid which may become detached from the specimen.

It is essential to have good quality microscopes as examination by oil immersion is needed in acid-fast microscopy. A technician cannot be expected to perform well if the microscope does not have a screw-controllable, functioning stage to move the slides, eye-pieces are not adjustable, objectives are hazy, or the light source is insufficient. It is more difficult to perform acid-fast microscopy with a monocular microscope than with a binocular one. The best way to verify the status of a microscope is to examine a slide on the spot. It is a good rule to travel with a well prepared slide for this purpose in case no slides are available at the laboratory at the time of the visit. If slides are available in the laboratory, two or three slides are examined in order to ascertain the quality of smearing and staining to allow a discussion of any problems with the proper technique that might be encountered.

The laboratory technician is asked whether microscopic slides are kept for the purpose of proficiency testing and if so what principles guide the selection of slides to be kept. It should be observed how slides are labeled and whether the results of sputum examination are written on the slide itself which should never be done as it prevents subsequent un-blinded reading. The technician is asked when the last supportive supervision visit was made and whether the laboratory has ever been included in a quality assessment exercise, and if so how often, what type of quality assessment has been used and whether they were informed of the results.

The supply situation is reviewed and it may be asked if microscopic slides are washed and re-used. Re-using slides is not recommended in acid-fast microscopy as it may result in false positive readings.

Finally, the laboratory register is examined. It is important that the register recommended by IUATLD is used. First, it is verified that the principles of recording are understood. Second, the laboratory register provides exact information concerning the work load in the laboratory. The number of smears recorded in the last completed one-month period is counted for this purpose. A comparison with the same month in the previous year serves as an indicator for the trend in the work load. Third, an important indicator that should always be evaluated is the proportion of positive suspects out of all suspects examined (a positive suspect, a 'case', defined as a person with at least one positive smear, thus different from the case definition used in the program where two smears should be positive before a patient is defined as a sputum smear-positive case). The suspect to 'case' ratio may differ considerably between countries, but is not expected to vary widely between comparable areas within a country. If the proportion is much lower than expected, clinicians might have too lax a definition of a tuberculosis suspect, referring any patients with cough for sputum examination irrespective of the duration of the cough, quality of specimens may be inadequate (a high proportion of saliva) or the laboratory is not capable of correctly identifying smear-positive 'cases'. Conversely, if the proportion of 'cases' among suspects is much higher than expected, clinicians might be referring patients for sputum examination only if they have far advanced tuberculosis, clinicians might be using radiology for selecting patients for sputum examination, the services might not be sufficiently accessible so that patients seek care only late in the course of their disease or the laboratory might falsely classify sputum smear-negative suspects as sputum smear-positive.

After completing the visit in the laboratory, the technician is requested to provide the laboratory register for the rest of the visit as it will be used during the remaining part of the visit. If the technician has time, she/he is invited to join the team for the remaining part of the visit.

- *The tuberculosis program management*

The team now proceeds to interview the tuberculosis manager who is in charge of the tuberculosis register. The tuberculosis manager should accompany the team during the entire visit to be fully aware of the lessons learned.

Questions to be asked from the tuberculosis manager concern the size of the population served, the overall organization of the tuberculosis services in the catchment area and the coordination between the different components of the services (out patient clinic, laboratory, the hospital sector / ward, peripheral / satellite units, etc.). Details of the practical aspects concerning directly observed treatment are important. Who administers directly observed treatment, where and how?

The tuberculosis register is the center piece of information in the tuberculosis program. Again, it is important that the register recommended by IUATLD is used. Information of epidemiological and management relevance is abstracted from this register in quarterly reports. Misconceptions about its use or erroneous entries will distort the picture and may result in shortage of supplies.

Every suspect examined in the laboratory and recorded in the laboratory register as having positive sputum should be registered in the tuberculosis register. Thus the laboratory register is now consulted and it is checked whether this was done by reviewing consecutive entries in a determined period. At the same time it is verified whether there is unjustified delay in starting treatment once a patient has been diagnosed. This is done by comparing the date of registration in the laboratory register and the date treatment was started (from the tuberculosis register).

Persons in the laboratory register with even a single positive smear result should be traced if they do not voluntarily show up for treatment. If there is no such mechanism the problem and potential solutions should be discussed. The proportion of smear positive cases which are recorded in the laboratory register but do not appear in the tuberculosis register should be determined and recorded in the report of the visit. There may be a number of explanations

but the point must be made that each such patient must be accounted for.

Because patients with sputum smear-negative pulmonary and extra-pulmonary tuberculosis receive a different treatment regimen and are reported separately, it is important that such patients are examined properly before commencing treatment. To verify this, consecutive patients recorded as sputum smear-negative in a determined period are identified in the tuberculosis register and traced in the laboratory register to ascertain whether they really had three sputum examinations performed before being classified as sputum negative. This cross-examination is easy to perform if the laboratory serial number is recorded in the tuberculosis register.

Similarly, it should be checked whether information on a few randomly selected treatment cards is properly transcribed in the tuberculosis register. If, while reviewing the case register, defaulters and treatment failures are identified, it should be verified whether these patients have been correctly managed. This is done by examining their treatment cards, asking about defaulter action and verifying whether patients who fail first-line treatment are registered for retreatment.

The tuberculosis register also provides information on sputum conversion after two months of treatment, preliminary treatment results at five months, and the results at the end of treatment. A cohort (consecutive series) of patients enrolled during a selected quarter may be analyzed to obtain the sputum conversion at two months and preliminary treatment results at five months of treatment. The period selected should be a recent one, i.e., a final report of treatment outcome should not have been sent for the cohort at the time this analysis is made. However, all patients in the selected cohort should have had the opportunity to complete the examination in question. Approximately 85% to 90% of new sputum smear positive patients are expected to convert their sputum by the end of a two-month, directly-observed, four-drug combination treatment. If this proportion is found to be considerably higher than expected, then it may be that follow-up smears are not carefully examined. If the proportion is found to be considerably lower than expected, then the execution of directly observed treatment may need to be re-examined.

The most recent report on treatment outcome and the corresponding report on case finding (from the same quarter) should be reviewed by consulting the tuberculosis register. This exercise serves to verify whether reports are correct. The purpose of this exercise is two-fold. First, the number of new smear positive patients reported on the quarterly report on case finding in the

quarter reviewed should correspond exactly to the number of new smear positive patients whose treatment outcome is subsequently reported, i.e. evaluation of treatment should be complete. Second, each patient in the cohort should have a valid treatment outcome recorded in the tuberculosis register.

- *The tuberculosis hospital ward*

If patients with tuberculosis are hospitalized, the ward should be visited.

Consecutive patients may be interviewed as time allows and their treatment cards reviewed. The clinical information on the treatment card allows an assessment of whether the prescribed treatment regimen is the correct one. The initial body weight of the patient should be recorded on the treatment card, and the drug dosages recorded on the card should correspond to this weight. Every day, a tick mark should be written in the appropriate spaces at the time of administration of directly observed treatment.

Interviews with patients should aim to assess whether they have been correctly assessed concerning previous treatment, whether treatment is directly observed and whether they have received effective health education concerning the nature of their illness and its treatment. Often the patient's account of the onset of symptoms and of the diagnosis and treatment reveals the quality of the health care system and the beliefs of the population. If patients repeatedly contact healers outside the health care system this testifies for the traditional beliefs among the population. If patients report having attended a health care facility repeatedly without being referred for sputum examination in spite of prolonged respiratory symptoms, this suggests that there may be weaknesses in the primary health care system and / or lack of coordination with the tuberculosis program.

Some of the information above may also be obtained by observing health workers at work which additionally provides the consultant with an idea of the quality of communication between health workers and patients and the attitude of health workers towards the patients.

During the visit to a ward, clinical problems are frequently presented by nurses as well as by attending clinicians. Thus, it is useful if the consultant is knowledgeable in this respect. Should that not be the case, she/he must admit so freely rather than saving face by offering questionable advice that might be followed because the consultant is perceived as an expert.

- *The tuberculosis out-patient clinic*

It may be possible to interview patients when they attend for ambulatory directly observed treatment. The information collected is the same as described for the visit to the tuberculosis ward.

- *Pharmacy /store*

The quality and the credibility of the services depend to a large extent on the ability to provide uninterrupted supplies of material for diagnosis and treatment. A visit to the pharmacy and / or store is important to ascertain the degree with which the logistics system is serving its role.

The items to consider here are the physical facility, the quantity of items in store (is the stock balanced?), expiration dates (is the FIFO system used, first-in/first-out?). Even if there happen to be sufficient supplies in store at the time of the visit it is well to inquire about any shortages in the recent past.

The opportunity may also be used to verify the security of the pharmacy as pharmaceutical products may represent a considerable value for thieves and embezzlers.

- *Satellite units*

If satellite units participate in tuberculosis control in the area it is well to include a sample of these in the visit. However, this may be logistically difficult due to large distances and difficult access. It must be carefully considered in every case whether it is justified to travel the required distance to review a very small number of patients. Frequently these units participate only by managing the continuation phase of treatment. If satellite units manage directly observed treatment in the intensive phase of treatment it is quite important that time be taken to visit one or two such units. The main purpose of such a visit is to obtain first-hand knowledge of the quality of services, case management and coordination with the tuberculosis management unit.

A wrap up meeting

At the end of the visit to a health unit it is recommended to gather together all those involved during the visit for discussion of the findings, conclusions and recommendations. In such a meeting, as in fact throughout the visit to the country, it is important to be polite, to mention positive points first before turning to the problems that have been detected. It is also important to be constructive when discussing problems and possible solutions. In this context it is well to mention two golden rules concerning supervision:

- Supervision is for support, not punishment.
- Supervise like you would like to be supervised.

The consultant should constantly keep in mind that an important element of the visit is for training and demonstration purposes and her/his attitude and behavior sets an example.

4.3 How is progress reported?

A written report is prepared following each visit. IUATLD consultants use a standardized reporting format for the sake of completeness and continuity.

An executive action document is written where the main findings, conclusions and recommendations are summarized. This is followed by a detailed report as presented in the annex.

An emphasis is put on rapid reporting. It is obvious that with frequent regular visits the report has to be dispatched without delay in order to give the program management time to act on the recommendations before another visit arrives.

A draft report should be completed within one working week following the visit. Depending on collaboration with other consultants, they need to review the report before distribution. The final report should be ready for distribution within a month from the visit. The report is dispatched immediately to the program manager and according to a distribution list. The program manager takes the responsibility for any further distribution of the report within her/his country and the report is kept on file in the IUATLD for distribution upon request unless decided that the report or some parts of it are to remain confidential.

4.4 What happens between visits?

In between visits, the technical consultant should be available to the central program management for any reasonable request concerning the program or

ongoing operational research projects.

If all is well there are not many problems to be solved between visits. If there are constantly unexpected problems this is likely to be a sign of mis-management.

In case the technical organization / agency takes responsibility for procurement of equipment and / or materials there will be continuous communication in this respect.

5. How is technical support evaluated?

When a consultant repeatedly visits a program, the consultant may gain increasing understanding of the conditions and operations of the program. On the other hand, the consultant loses objectivity. Therefore it is important that occasionally, an independent assessment is made by other experts. Such an assessment will help to further strengthen the functioning of the program at the same time as it provides feed-back to the consultant. Preferably, such a periodical evaluation (program review) is conducted by more than one expert to guarantee an unbiased assessment.

6. Is there a time frame for technical support?

Intensive technical support should be provided for several years. There should be continuity to the process. A designated consultant should stay with the program otherwise the appreciation of a slow but consistent progress and consistency in recommendations will be lost.

When the program has been successfully implemented, is fully expanded, is well managed and the epidemiological situation has been stabilized, continued intensive technical support should not be needed. Periodic, ad-hoc, external support on demand becomes more appropriate in this situation.

Thus, intensive technical support should not be indefinite. If the advice provided is sound and there is political commitment for tuberculosis control, progress towards increasing self-sufficiency should become evident. If, after a prolonged period of intensive technical support the program is not able to manage on its own, then something may have gone wrong. It may be that the consultancy has been of poor quality or that the program has not been capable of becoming sustainable by its own merits. In either case, continued intensive technical support becomes increasingly questionable.

However, unexpected problems may emerge, creating obstacles in the way of

getting the situation under control. A recent example is the HIV pandemic which in some countries, threatens to take the situation back to square one, destroying the effort of years of tedious and demanding control work. In such a situation new challenges may justify prolonged intensive technical support.

Finally, there are situations that require continued external input, but less in the sense of technical support than in the sense of control. This is the case where donors provide a large proportion of the funds required by the program and where the donors insist that an entrusted technical consultant supervises the use of the funds provided. This should no longer be labeled as technical support, but rather as external supervision of a program.

Note page

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Annex

Technical support - report format

A. General aspects of the tuberculosis program

A-1. The management structure

A-2. Supportive activities

2.1. Training
2.2. Supervision
2.3. Supplies
2.4. Transport

A-3. Finances and planning

B. Diagnostic services

B-1. Microscopy network

B-2. Culture

B-3. Susceptibility testing

B-4. Radiology

C. Tuberculosis control

C-1. Case-finding

C-2. Treatment results

2.1. Patients with no history of previous treatment
2.2. Patients eligible for a re-treatment regimen

2.2.1. Relapses
2.2.2. Failures
2.2.3. Return after default

C-3. BCG vaccination coverage

D. Evaluation

D-1. National Reference Laboratory

1.1. Quality assessment of peripheral microscopy services
1.2 Surveillance of drug resistance

D-2. Other

2.1 Surveillance of HIV infection among tuberculosis patients
2.2 Tuberculin / tuberculosis surveys

E. Visits to health facilities

F. Acknowledgments and distribution

G. Tables

H. Figures

I. Appendices