STANDARDIZATION OF DISTRICT-BASED PACKAGES OF CARE
FOR THE MANAGEMENT OF TUBERCULOSIS AND
OTHER RESPIRATORY DISEASES AMONG YOUTH AND ADULTS

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Executive Summary

GTB has successfully defined and implemented effective TB control in various countries. The strategy endorsed by GTB, "DOTS", is a specialized programme which often operates in parallel to the general health services of a country. In the past, to ensure success of national TB programmes (NTPs), TB was looked at and promoted in isolation and, as a result, may have individual donors and technical support agencies which are not always sustainable. While this approach has served to introduce effective TB control, it does not address the more general priorities of many health systems - such as promoting health in general. As countries move toward more comprehensive service delivery, the specialized programmes will lose ground. A more integrated approach must be considered.

Primary health care (PHC) is recognized as key to attain health in all settings. The PHC approach addresses the main health problems in a community, of which respiratory diseases constitute a large fraction. In the statistics of many developing countries, respiratory symptoms are the first or second cause of visits to outpatient services in most developing countries. The most frequent respiratory patients are those with acute illness (60 to 80%), in which the respiratory signs disappear after 1 or 2 weeks of appropriate treatment. To reach TB patients, the PHC system must appropriately manage all respiratory symptomatics to weed out all known non-TB cases and thereby identify the TB suspects.

The suspicion in middle- and low-income countries is that primary health care facilities may provide inadequate care for respiratory diseases. With the exception of case management of tuberculosis, many health systems have no standard strategy for dealing with respiratory diseases in adults. Lack of means further complicates the problem. The absence of diagnostic algorithms may result in overdiagnosis of sputum smear-negative tuberculosis, particularly in high HIV prevalence settings and in countries relying mostly on chest radiography for diagnosis. The consequences of the absence of treatment guidelines may be excessive drug prescriptions, use of ineffective and sometimes harmful drugs, unnecessary referral of many patients and, therefore, a high cost for the individual patients and for the community whatever the source of funding.

While theoretically strong, many primary health care systems remain weak due to operational difficulties. Consequently, the problem of integrating communicable disease control programmes into the primary health care system is not one of transforming an existing specialized programme into an integrated one, but a question of how to utilize the strengths of the specialized programme to enhance/support the primary health care system. The aim, therefore, of integration is to optimize use of scarce resources and respond more effectively to the community's needs.

GTB acknowledges that, to improve TB control, the overall health care infrastructure in the country must be strengthened. GTB therefore aims to support PHC by using its comparative advantage of technical expertise and successful management strategies relating to TB. Much could be gained in PHC if standardized care management could be extended to other respiratory diseases, presently not clearly addressed. Benefits should be possible in terms of health service delivery, i.e., improved care through a logical approach responding to local needs, multipurpose use of resources, and sustainability, in addition to economies of scale.

This paper will explore the rationale for introducing a district-based package for the management of TB and respiratory disease (Part I). Based on this rationale, a project for assessing the feasibility of such a package is presented (Part II).
PART I  PAST EXPERIENCE ON SPECIALIZED AND INTEGRATED MANAGEMENT IN THE CONTROL OF COMMUNICABLE DISEASES

Historical analysis of management approaches to programmes for the control of communicable diseases

After the Second World War the health services in developing countries evolved around two separate systems: the vertical programmes and the expansion of the general health infrastructure\(^1\).

The vertical (also called categorical or specialized programmes) were established for the control or eradication of specific problems through a specialized infrastructure operating with single-purpose staff and their own lines of command from centre to periphery. Vertical programmes were developed after important discoveries of effective control technologies such as DDT against malaria and yellow fever vectors, and antibiotics plus other chemotherapeutic agents against tuberculosis (streptomycin, PAS, isoniazid), leprosy (dapsone) and yaws (penicillin).

In parallel in the late 1940s and early 1950s, the governments invested resources in expanding the general health services infrastructure with a major focus on the provision of a wide range of curative services, through multi-purpose staff, first in large urban areas and later moving gradually towards providing coverage for small towns and rural populations.

The division between preventive services (vertical programmes) and curative services (general health infrastructure) was apparent in the administrative organization of the ministries of health (Figure 1). In the 1950s, typically the ministerial structure was divided into two independent branches: Curative Medicine, responsible for the network of general hospitals, health centres and health posts, and Preventive Medicine in charge of the specific programmes such as tuberculosis, leprosy and malaria. Each vertical
programme had its own structure, independent from the curative medicine structure, to support the service delivery and to deliver the services. For instance, the tuberculosis programme operated the specialized hospitals, clinics, X-ray mobile units and BCG Teams as well as the bacteriology and BCG production laboratories.

From the early 1960s a growing sense of failure was widespread among public health experts. On one side, it became clear that vertical programmes could not provide services to the whole population throughout their specialized structure, and therefore without adequate coverage they could not bring specific diseases under control\(^2\). Although developed countries could afford vertical programmes and succeed in controlling through them difficult problems such as tuberculosis, the cost was far beyond the resources of developing countries. It was unrealistic from the organizational and financial viewpoints to set up countrywide vertical programmes with an independent single-purpose infrastructure. There were, however, some successes from vertical programmes in developing countries, like yaws eradication from most endemic areas and the global smallpox eradication. In both cases, a simple technology (penicillin injection, inoculation of freeze-dried smallpox vaccine through a bifurcated needle) applied only once to every person (one-time action) facilitated the organization and management of mass campaigns. Such technological simplicity was not available to tuberculosis, leprosy or malaria programme managers.
Figure 1

Separate management of general health infrastructure and vertical programmes

MOH

Curative Medicine

Preventive Medicine

TB Programme

Leprosy

Hospitals
Health Centres
Health Posts

TB Hospital
TB Clinics
X-Ray Mobile Units
BCG Teams
TB Laboratory
BCG Laboratory

LEP Hospital
LEP Clinics
Home Visitors Teams
LEP Laboratory
LEP Centres for Rehabilitation
The sense of failure was also arising from the very slow progress of general health structure in reaching large rural populations to provide curative services. A generalized view was that efforts and resources devoted to ineffective vertical problems hindered the strengthening and expansion of basic health services. The situation called for new directions in the organization and management of health services in developing countries. The new directions were shaped progressively during the 1960s and 1970s until they crystallized as the Primary Health Care Principles at Alma Ata in 1978\(^3\).

Two simultaneous transition processes have taken place in the last three decades and are still under way: (i) from autonomous vertical programmes to programmes integrated into the general health infrastructure; and (ii) from basic curative health services to a primary health care system capable of providing both curative and preventive health care effectively to the entire urban and rural populations. Integration of curative and preventive health services is one of the essential elements of primary health care.

This document focuses on the modalities of the first mentioned transition, that from vertical programmes to programmes integrated into general health systems. The consensus on the principles of integration was almost universal; they have gradually been adopted as the official policy for communicable diseases in most developing countries\(^4\,^5\,^6\,^7\). However there were many difficulties in the way of translating the operational philosophy into operational practice\(^8\). In the last few years, there have been renewed pressures to reform the health sector in response to the persistent poor performance of many health services and unsuccessful attempts to meet unmet demand and need with limited resources. Donors and Ministries of Health, concerned to increase efficiency, are attempting to decrease the duplication and possible distortions that may result from many vertical programmes operating from a centralized ministry and are adopting a more decentralized and integrated approach\(^9\).
Constraints to the integration process

A large number of constraints to the integration process can be mentioned. However, the following factors can be considered as the most important ones that influenced the process pace:

- Health managers, aware of the weaknesses of the general health system, desired to maintain specialized programme activities because they were more effective. There was a well founded feeling that with full integration at least some communicable disease programmes would be "watered down", i.e. oversimplified and therefore ineffective. Although an exaggeration, it was a common place to hear in specialized circles statements like "there is nothing to integrate into" and "integration means in fact disintegration". To the question "what" should be integrated into "what", the specialists were ready to provide a simplified, effective, acceptable and inexpensive technology in reply to the first "what". But then it was not easy to construct the right answer to the second "what".

- Although governmental cooperation agencies adhered to integration principles, in practice a large proportion of external support was earmarked for clearly identified single-purpose programmes which can produce tangible results in the short term. Cooperation agencies were inclined to prefer contributing to these programmes which were considered effective and well managed. There was in fact a problem of "credibility image". Specialized programme managers were seen as more dynamic and action-oriented than public health administrators dealing with development of health infrastructure.

- Non-governmental organization, which for their very nature were devoted to specific diseases, had a mandate for supporting specialized activities and they were constrained to making contributions only in their specific fields such as tuberculosis or leprosy control.
The debate on how to translate with success the doctrine on integration into reality has remained a permanent issue in publications and the agenda of public health meetings for several decades. This was an indication of the operational difficulties surrounding the managerial approaches to integrated programmes. Many specialized programme managers felt that they could not move ahead towards full integration as long as the debate was ongoing.

In view of these difficulties, each country and each specialized programme took their own transitional path from verticality to integration. Operational realities required a step by step process and considerable time. There were notorious failures; many vertical programmes regressed considerably at early stages of integration in a large number of countries. However, the direction was not questioned because universal coverage is not possible in developing countries with vertical structures, although there may be some exceptions like eradication programmes.

In practice, most ministries of health adopted a flexible approach by integrating some specialized activities into the primary health care system (for instance health services delivery) but keeping others under a vertical management (especially training, supervision, information system and monitoring). Full integration of all elements (organizational components, management and support functions, and services delivery) was rarely achieved. Given the realities, primary health care experts have recently recognized that integration does not mean the elimination of specialized disciplines, programmes, personnel and services. Integration does not necessarily imply that all services will be provided by multipurpose workers. A rational referral system requires specialists at secondary and tertiary levels; where resources permit, some specialization may be appropriate at district and primary health care levels.
Variations in the transition from vertical to integrated programmes

Among the different approaches to shifting from vertical programmes to integrated programmes, five prototype variations can be singled out:

1. **Only administrative integration of structures**

Administrative integration or integration of organizational components is to bring the specialized structures for support (laboratory) or services delivery (hospitals, clinics, mobile teams) together with the general health facilities under the same authority. Usually administrative changes were the first decision a MOH used to take at the beginning of the integration process. **Figure 2** illustrates the changes in the ministerial organization when, for instance, the tuberculosis programme facilities were taken out from the Preventive Medicine branch and assigned to the Curative Medicine branch. Then these names were replaced by Disease Prevention and Control Technical Divisions (Science and Technology), whose functions were limited to selection of strategies, guidelines and evaluation, and Health Services Delivery Division, the directing and administrative authority responsible for delivery of all preventive and curative services.

In this integration step, services such as case management of tuberculosis or leprosy continue being provided by single-purpose workers at specialized units. There is no services delivery integration. In general, there was a period of confusion regarding the managerial responsibilities and support activities. The disease control programmes were no longer directly responsible for training, supervision and monitoring and the primary health care structure was not technically prepared to take over these functions. Administrative integration was a first step of short duration in most countries because after a while they moved to integration of services delivery (prototype 2) and other modalities of integration.
Administrative integration of vertical programmes
structure with general health infrastructure

MOH

Health Services

Disease Control Technical Divisions

General Services
- Hospitals
- Health Centres
- Health Posts

TB Services
- TB Hospital
- TB Clinics
- X-Ray Mobile Units
- BCG Teams
- TB Laboratory
- BCG Laboratory

Leprosy Services
- LEP Hospital
- LEP Clinics
- Home Visitors Teams
- LEP Laboratory
- LEP Centres for Rehabilitation
2. **Integration of services delivery without integration of managerial support**

Once the administrative integration has been put into effect, the next step in the process was the disestablishment of the specialized services delivery facilities and their integration into the general health infrastructure. **Figure 3** shows the result of the integration of services delivery functions. Specialized hospitals were transformed into general hospitals, and specialized clinics into health centres. Diagnosis and treatment of specific diseases such as tuberculosis and leprosy become an additional responsibility for multipurpose health workers throughout the primary health care system. However, the primary health care administrators rely on the Disease Control programmes for the managerial support to the health facilities; there was no managerial integration. This was the prevailing situation in most MOHs in the 1980s. While the general hospitals, health centres and health posts were in charge of taking care of tuberculosis, leprosy, diarrhoea, ARI, EPI and malaria patients, each corresponding Disease Control Programme provided the managerial support as a vertical activity: training, supervision, information system, monitoring, health education, operational research. This is still the most common situation that in practice exists in the organization of communicable disease control programmes.

3. **Integration of managerial support of two disease control programmes**

The best example of integration of the managerial support of two disease control programmes is the merger of leprosy and tuberculosis as shown in **Figure 4**. Some countries (e.g. Kenya, Rwanda, Tanzania, Zaïre) decided to put leprosy and tuberculosis programmes under a common managerial authority in view of the operational similarities between the two programmes. This managerial integration facilitated the integration of technical manuals and support activities such as training, logistics, supervision and monitoring while the services delivery was being integrated into the primary health care system.
Figure 3
Integration of services delivery without managerial integration

MOH

PHC Programme

Disease Control Programmes

TB Programme

LEP Programme

PHC Infrastructure
Hospitals
Health Centres
Health Posts

Community Level
Village Health Workers

Figure 4
Integration of managerial activities of two disease control programmes

MOH

PHC

Disease Control

TB/Leprosy Integration of:
Training
Supervision
Logistics

Other Specialised Programmes (e.g. Malaria)

PHC Infrastructure
Hospitals
Health Centres
Health Posts

Community Level
Village Health Workers
4. Integration of one managerial or support activity for all programmes

All programmes operate through the same types of managerial and support activities. Coordination and integration of the same kind of activity among all the programmes can lead to more efficient use of human and financial resources, elimination of duplication of tasks and more effective support. There are two successful examples of integration of managerial or support activities: one is the integration of drug logistics into the Essential Drugs Programme; all control programmes transferred to Essential Drugs the responsibility for procurement, storage and distribution of drugs; the control programmes, however, continued providing guidance on the selection of standard drugs, strength and pharmaceutical presentation. Another example is the integration of laboratory services; the specialized laboratories (such as tuberculosis, malaria, leprosy) were integrated into general public health laboratories under a unified structure within the MOH. Figure 5 shows these two examples: while the integration of drug logistics into the Essential Drugs Programme is within the Health Services or Primary Health Care Division of the MOH the integrated laboratory structure is kept under the Disease Prevention and Control Division.

5. Technical and managerial integration of a control strategy common to several programmes

5.1 Integration of immunization strategies

Mass immunization is a control strategy for the prevention of morbidity common to several programmes: tuberculosis (BCG), acute bacterial diseases (DPT) and viral diseases (poliomyelitis, measles). Selected immunization is recommended by other programmes, for instance, against meningitis and arbovirus diseases (e.g. yellow fever). In the 1970s a single immunization programme was established in all developing countries by integrating the immunization activities which until then were undertaken as an independent responsibility of the concerned programmes. The new programme, called Expanded Programme on Immunization or EPI, developed integrated technical
guidelines on immunization (vaccination schedules, doses, care for reactions following immunization) and integrated materials on training, cold chain logistics, supervision, communication and evaluation. However, the new programme kept a vertical managerial approach vis-a-vis the primary health care organization. The programme was put into action through specialized EPI training courses, supervision, logistics and evaluation (Figure 6). Moreover the involvement of the primary health infrastructure in routine vaccination of children attending health facilities (integration of service delivery), is supplemented by annual mass immunization days or weeks to ensure the achievement of eradication goals (poliomyelitis, measles) and high vaccination coverage for other vaccines.\textsuperscript{14}

5.2 Integration of case management strategies in children

Case management is a control strategy common to several programmes addressed to prevent mortality in children: diarrhoea, acute respiratory infections, severe malnutrition, malaria, measles. A new programme aimed at integrating the case management of these diseases, called Integrated Management of Childhood Illness or IMCI, is the most recent example of a comprehensive integration approach involving not just an activity like logistics in Essential Drugs Programme or vaccination in EPI, but 2 full-fledged programmes (control of diarrhoea and ARI) and the case management component of important programmes such as malaria and nutrition. Ten WHO programmes and units have been involved since 1992 in developing the new programme, which at the beginning was cautiously called just an initiative\textsuperscript{15,16}.

IMCI is a valuable precedent for any project addressed to integrate case management strategies in the adult. For this reason some details related to IMCI development are given in Annex 1.
Figure 5
Integration of one managerial or support activity common to all programmes

MOH

PHC Programme

Disease Control Programmes

Essential Drugs, including all disease control

Tuberculosis Programme

Laboratory Support, including all disease control programmes

PHC Infrastructure
Hospitals
Health Centres
Health Posts

Community Level
Village Health Workers

Figure 6
Integration of a control strategy (immunization) common to several programmes

MOH

PHC Programme

Disease Control Programmes

Tuberculosis Programme

EPI Programme
BCG vaccine
DPT
Polio, Measles
Yellow fever

PHC Infrastructure
Hospitals
Health Centres
Health Posts

Community Level
Village Health Workers
Is there any lesson from the past experience for integrating programmes addressed to adult health?

The review of past experience concerning specialized and integrated management in the control of communicable diseases provides lessons which are useful to bear in mind if an attempt is made to integrate programmes addressed to adult health.

1. Integration is a right administrative and managerial approach in public health.

Among the many reasons the theory and practice of integration can put forward, the most compelling ones are those related to efficient use of limited resources in developing countries. The aim of integration is to optimize use of scarce resources and respond more effectively to the community’s needs. In the current environment of Health Reform, the integration process may be strengthened by measures of decentralization of all government services where these measures result in the development of health care services which are fully integrated under the management of a district health team, lead by a district health manager, in order to:

- bring together resources and activities;
- allow multipurpose use of resources such as personnel;
- facilitate integration of training programmes, supervision, information system and monitoring;
- mobilize sustained political and community support; and
- set priorities to respond to local needs.

However, integration and decentralization are not the panacea for everything. A local health service can continue to have vertical or specialized programmes where and when the situation requires, for instance, in the case of eradication programmes or programmes addressed to diseases which are of low prevalence at peripheral units and, therefore, are best dealt with by specialized services at
district level. The affordability of such a vertical or specialized service is of course the limiting factor for its presence.

Within the same programme, integrated and vertical approaches are not at all mutually exclusive\textsuperscript{10,17}. Probably the best administrative and managerial decisions for most communicable disease control programmes are those addressed to reach a right combination of integrated services and vertical or specialized activities. Both are necessary parts of the same effort to reach the disease control objectives. This is the approach adopted with success by many developing countries at present for tuberculosis control. It is an eclectic organization combining a strong specialized central unit and specialized regional management in charge of training, supervision and monitoring, with the full participation of primary health care in case finding and treatment activities. Generally there is a full integration of tuberculosis drugs logistics with the Essential Drugs Programme and full integration of tuberculosis microscopy and culture services with the Public Health Laboratories responsible for all diagnostic laboratory activities.

2. At country level, integration is more effective when the disease control programme has achieved a high degree of implementation and the primary health care system is well developed

The technical policies and managerial needs of a programme have to be well defined and some experience has to be available about the effectiveness of the control strategy. The better the control programme is defined and tested, the easier its incorporation into an integrated system. On the other side the primary health care system, as recipient of vertical programmes, should have reached a reasonable level of development to implement and sustain such programmes. Despite widely held expectations of the primary health care approach, progress towards health systems based on primary health care has been slow, plagued with problems of conceptual confusion and operational uncertainty\textsuperscript{10}. 

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Because of the weaknesses of the primary health care system and the operational difficulties, often the problem of integrating communicable disease control programmes is not one of transforming an existing vertical programme into an integrated one, but a question of how to utilize the strengths of the specialized programme to enhance/support the primary health care system.

3. Integrated programmes into primary health care often require specialized support from intermediate and central levels

This lesson is closely linked to lesson number 1. There is a need to define precisely the appropriate linkages between technical units responsible for policies and the integrated system responsible for services delivery. The questions to answer for each programme and in each country are the following: how much specialized support to integrated programmes is appropriate? How much towards the periphery should such a support be extended? What are the measures of accountability and to whom are programmes/systems accountable?

4. Integration should not lead to a complete loss of visibility of a key disease control programme

An integration process may result in the loss of visibility of important control programmes within the MOH structure. For instance the introduction of the new programme on Integrated Management of Childhood Illness may result in the disestablishment of the ARI and CDD programmes at central level as happened within WHO where ARI and CDD are no longer listed in the programme nomenclature. The loss of organizational visibility may lead to a gradual loss of expertise if specialists are being replaced by generalists as programme staff at central level. For visibility reasons (and to preserve expertise), any process aimed at combining tuberculosis with other programmes should lead to a
Tuberculosis and other Respiratory Diseases Programme rather than a Respiratory Disease Programme.

5. All concerned technical and support programmes must be involved in and take ownership of the integration process

The transition towards integration should be the combined effort of all concerned programmes; the teamwork will facilitate the commitment to a shared vision and goals of the new programme, pooling resources and increase joint ownership. All parties should be involved in the decision on integration and participate in the formulation of integrated guidelines and development of managerial tools. For instance, obvious partners in the combined case management of tuberculosis and other respiratory diseases in adults would be those involved in AIDS, asthma, viral diseases (influenza), acute bacterial diseases (pneumonia), chronic diseases, radiology, public health laboratories and essential drugs.

6. The objectives and scope of an integrated programme or a combination of programmes must be clearly defined

A clear definition of the objective of an integrated programme or a combination of programmes is essential to guide the development of appropriate technical guidelines and managerial tools. The central objective of integrating immunization strategies into EPI was defined as prevention of morbidity; the main objective of integrating case management strategies of several programmes related to children was reduction of mortality. It appears that neither morbidity prevention nor mortality reduction (except for tuberculosis) can be a realistic objective for a programme combining tuberculosis with other respiratory diseases in adults. The primary objectives of this project will be to a) improve the quality of case management of TB and other respiratory diseases; b) increase
ownership of TB control by health services; and c) increase cost-effectiveness of case management of key respiratory diseases at PHC level.

7. It is not enough to define what to do through formulation of guidelines; it is essential to give orientations on how to do it

One of the strengths of WHO is the production of managerial tools to assist national managers and district-level health care workers to translate policies into realities through programme planning and implementation. If WHO develops guidelines on combined management of tuberculosis and other respiratory diseases (a clinical algorithm on combined case management), the resulting package to support its implementation will include training tools, diagnostic and treatment algorithms, etc. which will be targeted to the district-level health worker. This package will only focus on tuberculosis and the other most prevalent respiratory diseases for which such a management strategy will improve the cost-effectiveness and quality of services provided. In addition to introducing district-based tools for improved management of TB and respiratory diseases, existing tuberculosis managerial materials should be revised to make them compatible with the guidelines and orient countries in their implementation. The tuberculosis training courses and supervision checklists should incorporate the combined case management for both tuberculous and non-tuberculous respiratory conditions; the list of necessary drugs and equipment should be expanded (antibiotics, bronchodilators, nebulizers); the information system should be modified to collect some data on diagnosis and treatment of non-tuberculous respiratory diseases at outpatient services (this is a difficult area of negotiation to reach a compromise between a simple information system, and yet able to provide key information to monitor the programme); the tuberculosis programme review manual should include also a review of other respiratory diseases; the advocacy materials should enlarge their scope beyond tuberculosis; the laboratory activities might include some diagnostic bacteriological investigations and surveillance of bacterial drug resistance in
relation to most common agents of pneumonia and acute exacerbations of chronic bronchitis. All these developmental implications must be taken into account in the process of making a decision on combining case management of tuberculosis with other respiratory diseases.

8. **It is necessary to determine whether an Adaptation Guide should be issued together with the WHO generic guidelines and managerial materials**

The WHO guidelines and other materials are made as "generic" as possible to make them widely applicable, in such a way that most countries can use them. However, in practice countries need to introduce changes to adapt the WHO generic materials to local situations. If countries have no guidance on how to introduce changes they may commit mistakes which impair or lower the technical quality of the WHO generic materials.

When the IMCI guidelines were developed it was foreseen the need for each country to make some essential adaptations at least in the selection of standard drugs and the food advice recommendations to reflect the national policies on essential drugs and nutrition. Any change in the guidelines implies many changes in the training and other managerial materials. To facilitate the right adaptation work at country level, WHO issued an IMCI Adaptation Guide. The need for such a guide should be considered in the development of guidelines and managerial materials on the combined case management of tuberculosis and other respiratory diseases.
PART II

ASSESSMENT OF THE FEASIBILITY OF COMBINED PACKAGES OF CARE FOR TUBERCULOSIS AND OTHER RESPIRATORY DISEASES AMONG YOUTH AND ADULTS

A. Objectives

The combination and standardization of case management (including diagnostic and treatment strategies) of tuberculosis and other respiratory diseases has three main objectives:

1) To improve the quality of case management of TB and other respiratory diseases;
2) To increase ownership of TB control by health services; and
3) To increase the cost-effectiveness of case management of respiratory diseases and TB at PHC.

B. Rationale

1) TB tends to be promoted in isolation from the general health system
Over the recent years, GTB has successfully defined and started to implement TB control in various countries of the world. The strategy endorsed by GTB, "DOTS", is a specialized programme which often operates in parallel to the general health services of a country. In the past, to ensure success of national TB programmes, TB has been looked at and promoted in isolation and, as a result, may have individual donors and technical support agencies which are not always sustainable. While this approach has served to introduce effective TB control, it does not address the more general priorities of many health systems - such as promoting health in general. As countries move to promote more comprehensive service delivery, the specialized programmes will lose ground, and a more integrated approach must be considered and studied.
2) A syndromic approach to the management of TB and respiratory illness may improve TB diagnosis

The suspicion in middle- and low-income countries is that the primary health care facilities may provide inadequate care for respiratory diseases. With the exception of case management of tuberculosis and acute respiratory infections in children (ARI programme), many health systems have no standard strategy for dealing with the large number of respiratory diseases in youth (defined as over 5 years old) and adults. Lack of means further complicates the problem. The absence of diagnostic algorithms may result in overdiagnosis of sputum smear-negative tuberculosis, particularly in high HIV prevalence settings and in countries relying mostly on chest radiography for diagnosis. The consequences of the absence of treatment guidelines may be excessive drug prescriptions, use of ineffective and sometimes harmful drugs (antibiotics, corticosteroids, antihistamines), unnecessary referral of many patients to upper level facilities for specialized investigations or to the private sector and, therefore, a high cost for the individual patients and for the community whatever the source of funding (government, social security, or cost recovery schemes).

To improve tuberculosis control, the overall health care infrastructure in the country must be strengthened. Much could be gained if the technical expertise and successful management strategies of tuberculosis could be applied to case management of other respiratory diseases, presently not clearly addressed. The goal is to better define needs and opportunities and, eventually, to test the feasibility of a combined approach to the care of adult respiratory diseases and HIV-related respiratory complications. Ultimately, based on the results of the assessment, GTB will derive strategic policy recommendations mostly focusing on district health systems.

3) Strengthen PHC services

While theoretically strong, many primary health care systems remain weak due to operational difficulties. Consequently, the problem of integrating communicable disease control programmes into the primary health care system is not one of transforming an existing specialized programme into an integrated one, but a question of how to utilize the strengths of the specialized programme to enhance/support the...
primary health care system. The aim, therefore, of integration is to optimize use of scarce resources and respond more effectively to the community's needs.

GTB acknowledges that, to improve TB control, the overall health care infrastructure in the country must be strengthened. GTB therefore aims to support PHC by using its comparative advantage of technical expertise and successful management strategies relating to TB. Much could be gained in PHC if a standardized care management could be extended to other respiratory diseases, presently not clearly addressed. Benefits should be possible in terms of health service delivery, i.e., improved care through a logical approach responding to local needs, multipurpose use of resources, and sustainability, in addition to economies of scale.

The combined approach falls within the scope of the health reform process under way in many countries. Since 1980, the budgetary constraints (a consequence of economic structural adjustment) and the need to curb the health expenditures in all countries called for the participation of all interested parties (stake-holders) in the health reform process: political authorities, planners, researchers, case management operators, non-governmental organizations, donor community, teachers and service consumers. The health reform looks for influencing the use of human, material and financial resources at central, intermediate and peripheral levels, organizing the delivery of health services across the whole population and enlisting the participation of the communities to express their needs and to control the management of health services.

The need to expand the WHO tuberculosis control strategy (DOTS) is recognized. Whether the impact of control programmes can be enhanced by combining case management of tuberculosis with case management of other respiratory diseases needs to be explored.
4) Absence of an information system for respiratory diseases is a serious deficiency for planning

To appropriately treat TB and other respiratory illnesses, treatment facilities must be equipped with adequate diagnostic materials and a regular drug supply. In the absence of a management system which ensures accurate categorization and tabulation of cases, it is impossible for health facilities to predict their needs and to order/maintain adequate and appropriate stocks.

5) Respiratory diseases are frequent in PHC

Primary health care (PHC) is recognized as key to attain access to health in all settings. The PHC approach identifies and addresses the main health problems in the community, of which respiratory diseases constitute a large fraction. Tuberculosis, other communicable respiratory diseases (pertussis, diphtheria, measles, HIV/AIDS opportunistic respiratory complications, other respiratory infections in youth and adults) and non-communicable respiratory diseases (asthma, chronic bronchitis, chronic obstructive pulmonary disease, lung cancer) represented in 1990 about one fifth of the global burden of disease measured in disability-adjusted life years (DALYs). In the statistics of many health facilities in most developing countries, respiratory symptoms are the first or second cause of visits to outpatient services. The most frequently encountered respiratory patients are those with acute illness (60 to 80%), in whom the respiratory signs disappear after 1 or 2 weeks of appropriate treatment.

Tuberculosis, other communicable respiratory diseases (pertussis, diphtheria, measles, HIV/AIDS opportunistic respiratory complications, other respiratory infections) and non-communicable respiratory diseases (asthma, chronic bronchitis, chronic obstructive pulmonary disease, lung cancer) represented in 1990 almost one fifth (18.7%) of the global burden of disease measured in disability-adjusted life years or DALY\textsuperscript{18}. There are large inter-regional differences as can be seen in Table 1.
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<th>Cause</th>
<th>World</th>
<th>SSA</th>
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<th>China</th>
<th>OAI</th>
<th>LAC</th>
<th>MBC</th>
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<td>850</td>
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<td>683</td>
<td>444</td>
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<td>Communicable diseases, perinatal and maternal causes</td>
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<td>71.2</td>
<td>50.5</td>
<td>25.3</td>
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<td>42.2</td>
<td>51.0</td>
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<td>9.7</td>
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<td>18.9</td>
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<td>4.7</td>
<td>3.7</td>
<td>2.9</td>
<td>5.1</td>
<td>2.5</td>
<td>2.8</td>
<td>0.6</td>
<td>0.2</td>
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<tr>
<td>Respiratory infections</td>
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<td>10.8</td>
<td>10.9</td>
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<td>11.1</td>
<td>6.2</td>
<td>11.5</td>
<td>2.5</td>
<td>2.6</td>
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<td>Pertussis</td>
<td>0.9</td>
<td>1.6</td>
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<td>1.1</td>
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<td>Diphtheria</td>
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<td>0.01</td>
<td>0.04</td>
<td>0.0</td>
<td>0.02</td>
<td>0.02</td>
<td>0.01</td>
<td>0.0</td>
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</tr>
<tr>
<td>Measles</td>
<td>2.5</td>
<td>5.5</td>
<td>3.2</td>
<td>0.15</td>
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<td>0.4</td>
<td>2.7</td>
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<td>HIV</td>
<td>2.2</td>
<td>6.3</td>
<td>1.4</td>
<td>0.0</td>
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<td>4.3</td>
<td>0.2</td>
<td>0.3</td>
<td>1.7</td>
</tr>
<tr>
<td>Maternal and perinatal</td>
<td>9.5</td>
<td>9.9</td>
<td>11.8</td>
<td>6.4</td>
<td>9.9</td>
<td>10.9</td>
<td>13.8</td>
<td>3.2</td>
<td>2.8</td>
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<td>Noncommunicable diseases</td>
<td>42.2</td>
<td>19.4</td>
<td>40.4</td>
<td>58.0</td>
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<td>42.8</td>
<td>36.0</td>
<td>74.8</td>
<td>78.4</td>
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<td>Lung cancer</td>
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<td>0.06</td>
<td>0.2</td>
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<td>0.3</td>
<td>0.3</td>
<td>2.6</td>
<td>3.3</td>
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<td>COPD</td>
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<td>0.2</td>
<td>0.6</td>
<td>5.5</td>
<td>0.5</td>
<td>0.7</td>
<td>0.5</td>
<td>1.6</td>
<td>1.7</td>
</tr>
<tr>
<td>Asthma</td>
<td>0.9</td>
<td>0.6</td>
<td>0.6</td>
<td>1.8</td>
<td>0.8</td>
<td>1.1</td>
<td>0.8</td>
<td>0.9</td>
<td>1.2</td>
</tr>
<tr>
<td>Injuries</td>
<td>11.9</td>
<td>9.3</td>
<td>9.1</td>
<td>16.7</td>
<td>11.3</td>
<td>15.0</td>
<td>13.0</td>
<td>16.6</td>
<td>11.9</td>
</tr>
<tr>
<td>Total Respiratory Diseases (excluding HIV infection)</td>
<td>18.7</td>
<td>23.5</td>
<td>20.2</td>
<td>18.0</td>
<td>21.0</td>
<td>11.8</td>
<td>19.7</td>
<td>8.4</td>
<td>9.0</td>
</tr>
<tr>
<td>Total Burden of Disease</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

**ABBREVIATIONS:**
- SSA: Sub-Saharan Africa
- OAI: Other Asia and Islands
- LAC: Latin America & the Caribbean
- MBC: Middle Eastern crescent
- FSE: Formerly socialist economies of Europe
- EME: Established market economies

**Note:** The three main groups in the global burden of disease estimates consist of: I. communicable diseases, maternal and perinatal causes; II non-communicable diseases; III injuries. For the purpose of deriving an estimate of burden of respiratory disease first the maternal and perinatal causes were isolated from group I. Then, the diseases presenting with respiratory symptoms (tuberculosis, respiratory infections, pertussis, diphtheria, measles, lung cancer, chronic obstructive pulmonary disease and asthma) were grouped. Cardial diseases presenting with respiratory symptoms are not included because no accurate estimates could be derived from the original WDR estimates. Likewise, HIV is excluded from the burden of respiratory disease estimates. (Not all HIV cases present with respiratory symptoms, though eventually 40% of the HIV infected patients die of a respiratory cause.) Therefore, the presented estimate of burden of respiratory disease represents the minimum burden.
On one side, respiratory diseases made up approximately 23% of the burden of disease in Sub-Saharan Africa because of the large morbidity from tuberculosis and respiratory infections. On the other side, the smallest proportion, about 9%, was estimated in the established market economies (developed countries) and the formerly socialist economies of Europe, mostly due to non-communicable diseases (lung cancer and obstructive pulmonary diseases). The differences in the relative frequency of tuberculosis and other respiratory diseases in different parts of the world are due to a complex and large number of risk factors, in particular:

- age structure of the population;
- socio-economic development (population access to health services, education);
- nutrition situation (susceptibility to infections);
- air pollution (indoor, atmospheric, occupational);
- smoking (active, passive smoking).
- prevalence of HIV-infection

In the morbidity projections of WHO, World Bank and Harvard School of Public Health for the year 2020, the respiratory diseases will still make a very large contribution to the total burden of disease \(^\text{19}\). As shown in Figure 7, chronic obstructive pulmonary disease, lower respiratory infections and tuberculosis will occupy the 5th, 6th and 7th place, respectively, in the ranking of global disease burden.

Although it remains the most important infectious cause of death in adults worldwide, tuberculosis is not the most frequent respiratory morbidity in the population. As shown in studies carried out in Algeria in the period 1980-1990, acute respiratory infections, asthma and chronic bronchitis are more frequent causes of observed or reported morbidity than tuberculosis (Table 2).
Change in the rank of disease burden, measured in Disability-Adjusted Life Years (DALY), for 15 leading causes in the world, 1990 - 2020

1990

Disease or injury 1
Lower respiratory infections
2
Diarrhoeal diseases
3
Conditions arising during the perinatal period
4
Unipolar major depression
5
Ischaemic heart disease
6
Cerebrovascular disease
7
Tuberculosis
8
Measles
9
Road traffic accidents
10
Congenital anomalies
11
Malaria
12
Chronic obstructive pulmonary disease
13
Falls
14
Iron-deficiency anaemia
15
Protein-energy malnutrition
16
17
19
28
33

2020 (Baseline scenario)

Disease or injury 1
Ischaemic heart disease
2
Unipolar major depression
3
Road traffic accidents
4
Cerebrovascular disease
5
Chronic obstructive pulmonary disease
6
Lower respiratory infections
7
Tuberculosis
8
War
9
Diarrhoeal diseases
10
HIV
11
Conditions arising during the perinatal period
12
Violence
13
Congenital anomalies
14
Self-inflicted injuries
15
Trachea, bronchus and lung cancers
16
17
19
28
33
<table>
<thead>
<tr>
<th>Respiratory Diseases</th>
<th>District 100,000</th>
<th>HC 20,000</th>
<th>HP 5,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute respiratory infections(^{20}) (annual incidence)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- All forms</td>
<td>20,375</td>
<td>4,075</td>
<td>1,018</td>
</tr>
<tr>
<td>- Severe forms: pneumonia, bronchiolitis, obstructive laryngitis</td>
<td>611</td>
<td>122</td>
<td>30</td>
</tr>
<tr>
<td>Asthma (prevalence)(^{21,22})</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- All forms</td>
<td>800</td>
<td>160</td>
<td>40</td>
</tr>
<tr>
<td>- Severe, persistent forms</td>
<td>80</td>
<td>16</td>
<td>4</td>
</tr>
<tr>
<td>Chronic bronchitis in persons &gt;40 years(^{23,24}) (prevalence)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- All forms</td>
<td>500</td>
<td>100</td>
<td>25</td>
</tr>
<tr>
<td>- Chronic obstructive bronchitis</td>
<td>125</td>
<td>25</td>
<td>6</td>
</tr>
<tr>
<td>Tuberculosis (annual incidence)(^{25})</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- All forms</td>
<td>40</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>- Pulmonary, smear-positive</td>
<td>20</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Other respiratory diseases(^{25})</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Spontaneous pneumothorax (annual incidence)</td>
<td>1-5</td>
<td>0-1</td>
<td>...</td>
</tr>
<tr>
<td>- Pulmonary hydatid cyst (annual incidence)</td>
<td>1-3</td>
<td>0-1</td>
<td>...</td>
</tr>
<tr>
<td>- Lung cancer (annual incidence)</td>
<td>1-3</td>
<td>0-1</td>
<td>...</td>
</tr>
</tbody>
</table>

In the health facilities statistics, respiratory symptoms are the first or second cause of visits to outpatient services in developing countries. The most frequent respiratory patients (60 to 80%) are those with acute illness, in which the respiratory signs disappear after 1 or 2 weeks of appropriate treatment. **Tuberculosis cases represent a small proportion of all patients with respiratory symptoms attending first level**
health facilities. Certainly care for respiratory patients with acute illness takes a large proportion of health workers time and a large share of drug consumption.

Table 3 shows the outpatient statistics of Morocco, Mali and Djibouti. Patients classified as pulmonary tuberculosis suspects, i.e. those with cough for more than 2 weeks, represent from 7.3% to 20.0% of all patients with respiratory symptoms. The prevalence of pulmonary tuberculosis cases with positive microscopy is from 1.1% to 1.6% among patients with respiratory symptoms. If identification of the contagious cases with tuberculosis is considered to be important, the health systems’ response to all other patients presenting with respiratory symptoms should be appropriate. This group, which represents 98% to 99% of the patients presenting with respiratory symptoms, includes both patients not suspected of pulmonary TB at all and patients suspected of pulmonary TB, but who are sputum smear negative.

It seems appropriate to expect that, to detect the maximum number of infectious tuberculosis cases among patients attending first level health facilities, it is necessary to take care of all patients who suffer from acute and chronic respiratory symptoms. Much could be gained in both tuberculosis control and primary health care if standardised case management could be extended to other respiratory diseases, presently not effectively addressed. Benefits should be expected in improving the specificity of the diagnosis of tuberculosis among smear-negative patients, in particular in areas with high prevalence of HIV-infection using mostly radiology as a screening method. Benefits should also be possible in terms of health service delivery, i.e., improved care through a syndromic approach of respiratory diseases in general responding to local needs, multipurpose use of resources and sustainability. This approach will contribute to building up the people’s confidence in the health services.

If patients with respiratory symptoms are not treated effectively as outpatients, they will often attend the district or provincial hospital where they can unnecessarily be treated as inpatients for long periods.
<table>
<thead>
<tr>
<th></th>
<th>Morocco\textsuperscript{26}</th>
<th>Mali\textsuperscript{27}</th>
<th>Djibouti\textsuperscript{28}</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of visits at public outpatient facilities</td>
<td>9,534,760</td>
<td>1,105,790</td>
<td>445,000</td>
</tr>
<tr>
<td>Patients with respiratory symptoms:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- number</td>
<td>760,850</td>
<td>188,297</td>
<td>171,000</td>
</tr>
<tr>
<td>- % among all visits</td>
<td>8.0</td>
<td>17.0</td>
<td>38.0</td>
</tr>
<tr>
<td>Tuberculosis suspects (respiratory symptoms for more than 2 weeks):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- number</td>
<td>152,810</td>
<td>19,878</td>
<td>12,500</td>
</tr>
<tr>
<td>- % among all visits</td>
<td>1.6</td>
<td>1.8</td>
<td>2.8</td>
</tr>
<tr>
<td>- % among respiratory symptomatics</td>
<td>20.0</td>
<td>14.0</td>
<td>7.3</td>
</tr>
<tr>
<td>Smear-positive pulmonary tuberculosis:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- number</td>
<td>12,300</td>
<td>1,740</td>
<td>1,953</td>
</tr>
<tr>
<td>- % among all visits</td>
<td>0.13</td>
<td>0.15</td>
<td>0.4</td>
</tr>
<tr>
<td>- % among respiratory symptomatics</td>
<td>1.6</td>
<td>1.2</td>
<td>1.1</td>
</tr>
</tbody>
</table>
C. Project outline

Through the assessment of the feasibility of combined packages of care for TB and other respiratory diseases among youth and adults, GTB aims to:

1) Evaluate the current demand and health system response to respiratory disease;
2) Identify the needs of PHC systems to improve the management of respiratory disease;
3) Explore the need and feasibility of introducing a comprehensive package for diagnosis and treatment of TB and respiratory diseases; and
4) Develop standardized algorithm and accompanying tools to be introduced at the district level to promote lung health and strengthen the PHC system.

The combined case management of tuberculosis and other respiratory diseases is not a second class clinical recipe for health facilities with limited resources. It is a rational and pragmatic approach which is suitable for any situation:

- countries with established market economies, those with economies in transition and those with less advanced economies;
- public and private services;
- health facilities with free services, social security systems and private clinics;
- family doctors, generalists and specialists.
- countries with high or low prevalence of HIV infection

The outline, however, is addressed to meet first the needs of district level health services in developing countries, i.e. those with middle- or low-income where tuberculosis prevalence is intermediate or high. In these countries, the population access to health facilities ranges usually from 30% to 60%; very rarely it is above 90%. For them, integration of control activities into the primary health care system is one of the key policies for tuberculosis control.

The combined case management will focus on the most prevalent respiratory diseases at the different levels within a district: outpatient services (community, health posts
without a doctor, health centres with doctors) and first referral or district hospitals. In general, the most frequent respiratory diseases in adults are:

- acute respiratory infections: these infections can be divided into five categories:
  . healthy individuals;
  . individuals with HIV infection;
  . individuals with other concomitant predisposing conditions: diabetes, long-term corticosteroid therapy, alcoholism;
  . individuals with a pre-existing respiratory handicap: occupational respiratory conditions, bronchiectasis, asthma, chronic bronchitis;
  . elderly adults (more than 60 years);
- asthma;
- chronic, non-specific pulmonary diseases: chronic obstructive bronchitis, chronic obstructive pulmonary disease (COPD), emphysema.

In some countries or some geographical areas of one country, special attention must be given to particular problems because of their high prevalence, for instance: HIV/AIDS, occupational respiratory diseases, parasitic diseases (hydatid cyst, paragonimiasis, helminthiasis) and lung cancer.

D. Workplan for the assessment of the feasibility of combined packages of care for tuberculosis and other respiratory diseases

1. Coordination of concerned WHO programmes

A Working Group should be established for the development of the project with the participation of the divisions and programmes concerned with case management of respiratory diseases such as AIDS, acute respiratory infections, asthma, chronic respiratory diseases and lung cancer, and the support programmes such as those concerned with essential drugs, radiology and laboratory, and those programmes related
to health systems and to the organization of the primary health care infrastructure. GTB will be the focal point for the coordination of the development activities. Programmes dealing with preventive aspects of respiratory diseases (EPI, tobacco, environmental health) will be kept informed and requested to provide comments and technical inputs.

2. **Situation analysis**

The first step in the development of the project is to make a situation analysis to determine the community needs for services on respiratory diseases and the facilities provided by the health services to meet such needs. The analysis will focus on the advantages and disadvantages of standardizing the combined case management of tuberculosis with other respiratory diseases in adults. The analysis will be made through two activities:

a. A thorough review of the literature about the concepts of integration of programmes into the general health system and the experience accumulated in previous efforts to integrate case management strategies of different programmes. The analysis will identify the *pro et contra* of a combined approach to care of respiratory diseases as well as to review examples and lessons learned from similar projects.

b. A rapid assessment of the problem in various settings, including low and high HIV prevalence areas in Africa, Asia, Latin America and Eastern Europe. The assessment will include:

- numbers and proportions of adults presenting at first level health facilities and first referral hospitals with respiratory symptoms;

- assessment of the proportions of the various illnesses by age and sex;

- current case management practices for diagnosis and treatment of respiratory diseases in adults;
political, financial and operational policies for delivery of primary health services to determine appropriate mechanisms for introducing the combined package of respiratory care.

3. Development of the technical guidelines on combined case management of tuberculosis and other respiratory diseases

Based on the finding of the situation analysis, technical guidelines on combined and efficient approaches on case management of tuberculosis and other respiratory diseases will be developed. The technical guidelines will define the clinical algorithm, the essential equipment and the essential drugs for each level of the health system for implementation of the combined case management. A referral system will be proposed to ensure the continuum of care between the community and the health system. Annex 2 presents an outline of the topics to be considered in the guidelines. In a first stage four technical sub-groups will be established to develop guidelines for four categories of respiratory diseases:

- Acute respiratory infections in youth and adults.
  Previous experience: guidelines issued by the WHO programme for the control of acute respiratory infections in children\(^\text{29}\) and technical guide developed in Algeria in 1984\(^\text{30}\).

- Asthma in children and adults
  Previous experience: guidelines on management of wheezing issued by the WHO programme for the control of acute respiratory infections in children\(^\text{29}\); guidelines from Global Initiative for Asthma NHLBI/WHO Workshop Report\(^\text{31}\); guidelines from the International Union against Tuberculosis and Lung Disease\(^\text{32}\); national guidelines from several high-income (France, United Kingdom) and middle-income countries (Algeria, Morocco).

- Chronic obstructive pulmonary disease
Previous experience: guidelines for high-income countries issued by the European Respiratory Society, the American Thoracic Society and the French Society of Pneumology.

- Tuberculosis

Once the specific guidelines for each condition have been defined bearing in mind the conditions of low- and middle-income countries, the process of combining the guidelines on case management of tuberculosis and other respiratory diseases will be initiated in order to produce a decision clinical algorithm for each level: community, health post, health centre and district hospital.

4. Revision of tuberculosis training materials

Some modules of the training course on Managing Tuberculosis at District Level will be revised to introduce the teaching of the combined case management.

The combined clinical algorithm will be introduced into the module "Ensuring Identification of Tuberculosis Suspects". A simple recording and reporting system on non-tuberculous respiratory diseases will be proposed to be integrated into the general information of the first level health facilities and district hospital. The forms will be included in the modules on “Quarterly Reporting on Case Finding”. The possibility of establishing a “District Register of Chronic Respiratory Diseases” will be reviewed and tested. The guidelines on supervision of the combined case management will be introduced into the module “Conducting Supervisory visits”.

5. Operational research to field test the combined approach

During the development of the policies and revision of training materials, several studies will be carried out with the aim to:

- measure the prevalence of perceived and observed respiratory morbidity in the community and at first level health facilities;
determine the sensitivity and specificity of the clinical algorithm for the case management of tuberculosis and other respiratory diseases in several epidemiological and cultural settings.

After the policies and the clinical algorithm have been well established, the combined approach will be field tested in pilot districts in several regions of the world to determine the feasibility and evaluate the benefits of the combined approach for the purposes of the tuberculosis programme (case detection rates, compliance with DOTS) and for the primary health care system (for instance, savings in use of antibiotics and bronchodilators, reduction of referrals to district hospital).

The field test will provide information to define the functions of different levels in the delivery of the combined case management. A tentative description of such functions, the supply requirements and an outline of expected benefits from combined case management are presented in Annex 3.

Health workers should be trained and supervised in the use of the clinical algorithm to decide whether the patient with respiratory symptoms will be treated at home or referred to an upper level. The algorithm simplifies and makes more rational the work to deliver a minimum effective package of essential clinical services at outpatient settings. Training and supervision of doctors is very important to rationalize the referral of patients with respiratory diseases outside the district and limit the use of specialized services.

The access of patients to reference services (laboratory, radiology, pulmonary functional tests, specialists) must be facilitated (for instance through subsidized transport) and at the same time limited to those patients for whom referral is actually necessary.

The quality control of laboratory, radiological and pulmonary functional tests should be ensured through technical guidelines, training and supervision; this is an area in which resources are often wasted and diagnostic errors are often made.
The improvement of case management of respiratory diseases at first level health facilities and district hospitals through training, supervision and performance assurance provides a reliable support to the process of decentralization and combination of programmes and enhances the credibility of primary health care services.

6. Development of training materials for medical schools

The experience on teaching the combined management of tuberculosis and other respiratory diseases at medical schools will be reviewed. The project will develop materials focused on clinical management of the patient's problems rather than on the separate study of each disease. The training modules will combine the basic knowledge, clinical and therapeutic practices and public health approaches. The methodology will stress the practical training. The project will be included in the agenda of the GTB/NPS meeting on Teaching Tuberculosis in Medical Schools which will be held in Geneva in September 1997.
INTEGRATED MANAGEMENT OF CHILDHOOD ILLNESS

The Integrated Management of Childhood Illness (IMCI) approach was justified because it promotes important case management improvements leading to reduction of case fatality and mortality in children from 1 week up to 5 years old. The reasoning was that IMCI:

- Leads to more accurate identification of illnesses in outpatient settings using a clinical algorithm.

The health worker first assesses the sick child by asking questions and examining the child, and checks the child’s immunization status. All children are checked for general danger signs which are not disease specific. Following this, the health worker asks about four main presenting symptoms: cough or difficult breathing, diarrhoea, fever and ear problems. Each child presenting these signs is fully assessed for serious diseases and the most frequent conditions which manifest themselves through such symptoms. All children are assessed for malnutrition and anaemia.

- Ensures more appropriate and, where possible, combined treatment of all major illnesses.

Then the health worker classifies the child's illnesses according to whether it requires: urgent referral, specific medical treatment and advice, or simple advice on home management. Since most children have more than one illness classification, an integrated treatment plan is developed. After classifying, specific treatments are identified. For example, the outpatient management of
the conditions for which home treatment is appropriate requires 8 oral drugs and 2 topical drugs for external application.

**Speeds up referral of severely ill children.**

Urgent referral is indicated when the classification is severe pneumonia or very severe disease, some cases of severe dehydration, very severe febrile disease (cerebral malaria or meningitis), severe complicated measles, mastoiditis and severe malnutrition or severe anaemia. Four intramuscular preparations are necessary for pre-referral treatment before the child leaves for the hospital. Other conditions require referral for assessment such as chronic cough (tuberculosis, asthma), severe persistent diarrhoea and presence of fever every day for more than 7 days (typhoid fever). The guidelines provide detailed instructions on how to manage severely ill children at home when referral is not feasible.

**Stresses communication of key health messages to mothers.**

The health worker gives practical treatment instructions to the family of a child who will be treated at home, including how to administer oral drugs, increase fluids during diarrhoea, and treat local infections. The family is advised on the signs which indicate the child should immediately be brought back to the clinic and when to return for scheduled follow-up. Feeding is assessed and counselling on feeding problems is provided.

The IMCI developmental work has focused in 1992-1993 on the formulation of integrated technical guidelines for outpatient services and the research to validate the guidelines. An integrated clinical algorithm was developed, based on a minimal number of clinical signs and symptoms, without laboratory tests, to choose the correct illness classification and on a minimal number of essential drugs for treatment. It is the
simplest possible expression of what needs to be done to treat children in order to reduce mortality or to avert significant disability.

The next step, undertaken during 1994-1995, was to develop and test training materials to teach the guidelines to doctors and paramedical staff who take care of children at outpatient services. The result was an 11-day course in which 50% of time is devoted to clinical practice.

The course cannot be used at country level without local adaptation to make it compatible with the national guidelines, at least on standard drugs, terminology to use in talking with mothers and child feeding advice. Therefore the course is accompanied by a Planning Guide for the Introduction of the IMCI Training Course into a Country and an Adaptation Guide. To monitor the case management practice in health units after the staff training (performance quality assurance), WHO has prepared a Guide on Health Facility Quality Review.

The adaptation of IMCI guidelines and training materials was accomplished in a few countries in 1996; implementation of staff training started in 1997. WHO advises countries considering the introduction of IMCI training in two or three districts during an initial one year period, and expansion after careful review of the first-year experience to cover more districts in other areas of the country. WHO has organized a detailed close monitoring of the experience in the use of the IMCI materials in the "early use" countries. At the same time other managerial materials are being developed to assist programme managers in the full range of activities needed to implement IMCI: guidelines and training materials on inpatient care of the sick child, a planning guide for community interventions to change family behaviours in relation to child health and training materials for medical schools.
The IMCI programme is based on full integration of services delivery into the primary health care system, but it is not yet clear whether the managerial activities will be fully integrated into the primary health structure or whether features of verticality from the former ARI and CDD programmes will be preserved (for instance for training, supervision and evaluation) like in present EPI programmes. Training poses a special problem because it requires a large number of sick children with a broad range of pathologies for the clinical practice; many of the pathologies cannot usually be found at district hospitals in a period of 11 days; therefore, training should be organized in large towns like provincial or regional capitals to ensure the availability of patients for the clinical practice.
Technical guidelines on combined case management of tuberculosis and other respiratory diseases

The technical guidelines will provide instructions on case management of tuberculosis and other respiratory diseases in outpatient settings and at first referral or district hospitals.

Guidelines for outpatient services

Tuberculosis
- Identification of tuberculosis suspects at community level and at any outpatient facility: health post, health centre, hospital outpatient department.
- Microscopy smear examination at peripheral laboratory.
- Clinical and radiologic diagnosis of primary tuberculosis (children) and extrapulmonary tuberculosis at hospital outpatient department.
- Direct Observed Treatment - Short Course Chemotherapy at all levels, including the community through community health workers and volunteers under close supervision.

Acute Respiratory Infections
- Identification of severe cases which require hospitalization.
- Identification and treatment of probably bacterial respiratory infections which require antibiotics at home (non-severe pneumonia, otitis media, streptococcal pharyngitis, sinusitis).
- Symptomatic treatment of viral acute respiratory infections.
Asthma
- Identification of severe asthma (wheeze in children) which requires inpatient care.
- Identification and treatment of non severe persistent asthma.
- Identification and treatment of intermittent asthma.

Chronic bronchitis
- Treatment of acute exacerbations of chronic bronchitis as acute bacterial respiratory infections.
- Treatment of chronic obstructive bronchitis, as persistent asthma.

Chronic obstructive pulmonary disease, generalized bronchiectasis
- Identification of severe cases for referral to hospital
- Treatment of non severe cases as persistent asthma

Lung cancer
- Palliative care: psychological support and pain relief for patients who return to home after radiotherapy/chemotherapy or non-operable patients.
- Control of medication for pain relief at hospital outpatient department.

Cardiac condition presenting with respiratory symptoms
- Identification of cases for referral to hospital.

Guidelines for first referral or district hospitals

Tuberculosis
- Management of complications: haemoptysis, spontaneous pneumothorax, pleurisy, meningitis, ascites, CNS complications.
- Management of tuberculosis chemotherapy toxicity complications.
- Adaptation of chemotherapy because of concomitant diseases: chronic renal failure, liver failure.

Acute Respiratory Infections
- Management of severe pneumonia, lung abscess, pleurisy, empyema.

Asthma
- Management of severe acute exacerbation
- Management of severe persistent asthma

Chronic obstructive pulmonary disease
- Management of acute respiratory insufficiency

Spontaneous pneumothorax
- Treatment at the facility

Cardial condition presenting with respiratory symptoms
- Treatment at the facility

The first referral or district hospital will have specific guidelines on criteria to refer patients to second referral level (provincial or regional) hospitals, for instance, patients requiring respiratory resuscitation, or surgical treatment (lung cancer, hydatid cyst), or medico-legal expertise (occupational pulmonary diseases).
Tentative description of case management functions and supplies required at various levels of the district health system

Four levels can be identified in the delivery of the combined case management of tuberculosis with other respiratory diseases within the district health system:
(a) the community level (community health workers); (b) the health post without doctor or medical assistant; (c) the health center with doctor or medical assistant; and (d) the district hospital with an emergency room, an outpatient department and inpatient wards.

In developing a project for the combined case management of tuberculosis with other respiratory diseases, the MOH has to define for each of these levels the functions, skills required and logistics (drugs, equipment and materials). The following scheme for a minimum package of essential clinical services would cover 90% of cases of respiratory diseases at various levels within a district.

(a) Community level

Functions and skills
The community health worker (or similar health worker, who generally has a formal health training of six months or less) should be able to:
- take the body temperature;
- take the pulse;
- measure the breathing rate;
- recognize signs of severity: severe difficult breathing, cyanosis, dehydration, unconsciousness:

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- refer cases meeting the referral criteria defined by the national guidelines for community level, for instance, fever > 39°C for more than 3 days, cough for more than one week;
- administer direct observed treatment of tuberculosis as prescribed by the health center or the district hospital;
- refer household contacts of smear-positive tuberculosis cases for examination;
- treat acute upper respiratory infections and acute bronchitis;
- demonstrate to asthma patients the use of metered dose inhaler for salbutamol nebulization as prescribed by the health center or the district hospital.

**Equipment**
- thermometer
- timer to take the pulse and measure the breathing rate

**Essential drugs**
- analgesics and antipyretics: aspirin, paracetamol
- cough remedies (with and without codeine)
- herbs for traditional teas and vapour inhalation
- topical anaesthetic and antiseptic agents for the throat

(b) **Health post without doctor or medical assistant**

**Functions and skills**
The health worker (auxiliary nurse or similar staff who generally has from 1 to 2 years of formal health training) should be able to:
- recognize severe cases who need urgent referral as defined by the national guidelines for health posts, for instance, temperature above 39°C for more than 3 days, unconsciousness or coma, severe difficult breathing, acute chest pain;
- recognize and treat acute upper respiratory infections, acute laryngitis, acute bronchitis, acute exacerbations of chronic bronchitis, crisis of intermittent asthma;
- identify and refer tuberculosis suspects;
- administer direct observed chemotherapy to tuberculosis patients and bronchodilator treatment to persistent asthma patients, as prescribed by the health center or the district hospital;
- interview household contacts of smear-positive tuberculosis cases and decide preventive measure to take (BCG, referral)

**Equipment** (in addition to community level equipment)
- sputum containers
- tongue depressors
- syringes and needles
- sterilizer

**Essential drugs** (in addition to community level drugs)
- injectable antibiotics: procaine benzyl penicillin, benzathine penicillin
- oral antibiotics: amoxycillin, cotrimoxazole, oral penicillin
- salbutamol (oral, inhalation)
- corticosteroids (injectable, oral, inhalation)
- antihistamins
- antituberculosis drugs

(c) **Health center with doctor or medical assistant**

**Functions and skills**
The doctor or medical assistant should be able to:
- Diagnose cases who need urgent hospitalisation: acute obstructive laryngitis or epiglottitis, severe bronchiolitis in young children, severe pneumonia, risk of acute respiratory insufficiency in patients with persistent asthma or chronic respiratory insufficiency, severe pleurisy, total spontaneous pneumothorax, heart insufficiency.

- Diagnose and treat complications of acute upper respiratory infections (otitis media, sinusitis, purulent pharyngitis), non-severe pneumonia, pulmonary and extrapulmonary tuberculosis, minor side effects of tuberculosis chemotherapy, intermittent and persistent asthma, chronic obstructive pulmonary disease.

**Equipment** (in addition to health post equipment)
- stethoscope
- sphygmomanometer
- (pneumatic) otoscope
- respiratory peak flowmeter
- inhalation chamber
- nasal and ear speculum
- laryngoscope

**Essential drugs** (in addition to health post drugs)
- ibuprofen
- codeine
- pethidine
- epinephrine
- antibiotics: chloramphenicol, erythromycin, gentamicin
(d) **District hospital**

The district hospital provides outpatient and inpatient care, and should have a minimum of support laboratory, radiology and pulmonary functional tests services.

**Functions and skills**

The district hospital should be able to:

- diagnose and treat all the acute obstructive laryngitis, severe acute respiratory infections (bronchiolitis, pneumonia) and their complications (lung abscess, pleurisy), severe asthma, acute complications of chronic obstructive pulmonary disease, spontaneous pneumothorax and severe complications of antituberculosis chemotherapy.

- identify cases which require immediate care by a second referral level (regional or provincial hospital): restrictive respiratory insufficiency, suspicion of lung cancer, expertise in occupational respiratory diseases and patients requiring resuscitation with assisted ventilation.

**Equipment** (in addition to health center equipment)

- basic radiology equipment for chest radiographs (depending on availability of electricity)
- spirometer or spirograph
- bacteriological laboratory for microscopy and culture for tuberculosis and respiratory bacteria
- clinical laboratory
- oxygen cylinders or oxygen concentrators, with accessories for oxygen administration to children and adults
- electric or footpump aspirator for respiratory airways
- equipment for pleural puncture and pleural biopsy (depending on available expertise)
- equipment for skin and lymph glands biopsy (depending on available expertise)
- standard electrocardiograph (depending on availability of electricity)

**Essential drugs** (in addition to health center drugs)
- major analgesics (morphine)
- antibiotics: oxacillin or cloxacillin, metronidazole
- separate presentations of antituberculosis drugs (isoniazid, rifampicin, pyrazinamide) to use in cases of drug hypersensitivity
- cancer chemotherapeutic agents (as prescribed by the regional or provincial level)
How can the combined case management approach improve the tuberculosis programme?

a. Quantitative improvement of case detection and treatment

The quantitative improvement of tuberculosis case detection depends on two factors: increasing the population access to health facilities and increasing the capacity of the microscopy laboratory network.

The definition of population with access to health facilities differs from country to country; it can be defined in terms of distance, less than 5 to 15 km from home to the nearest health facility, or in terms of time needed (less than 2 or 3 hours) for people to reach the health facility, depending on the means of transport and the geographical and climatic conditions.

The optimum number of microscopy laboratories can be estimated as at least one laboratory and a full time microscopist per 100,000 population in rural areas and one per 200,000 population in urban areas.

The two above-mentioned factors which influence the tuberculosis case detection rates are the same factors which contribute to improving the delivery of essential clinical services: an extensive network of primary health care services and an effective support system for diagnostic tests.

The quantitative improvement of tuberculosis treatment is based on decentralization of treatment activities through training and regular supervision of health workers at peripheral facilities and at community level. The same approach is effective for the delivery of essential clinical services, especially for acute conditions and chronic non-communicable diseases.

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b. **Qualitative improvement of case detection and treatment**

The quality of tuberculosis detection and treatment activities is enhanced through training, supervision, transport logistics and performance assurance systems.

Through training and supervision, health workers acquire the necessary skills to identify tuberculosis suspects for further investigation (decision algorithms adapted to local working conditions), to provide direct observed chemotherapy - DOTS - and to control contacts.

Through transport logistics, the access of patients to microscopy laboratories is facilitated either by funding the transport expenses for patients to attend the laboratory or by organizing the transport of sputum specimens.

Through performance assurance, a regular and permanent quality control system for microscopies and for chest radiographs interpretation will be organized. With good quality microscopy and radiology, the proportion of smear-negative among pulmonary tuberculosis cases should be around 20%.

The above mentioned conditions are also necessary to improving the quality of case management for respiratory diseases.
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9. Berman, PA; Health Sector Reform: Making health development sustainable; in Health Sector Reform in Developing Countries (PA Berman, Harvard 1995)


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