PAL

Practical Approach to Lung Health

– Manual on initiating PAL implementation

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World Health Organization

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Foreword

In June 2005, WHO's Strategic, Technical and Advisory Group on TB approved the new Stop TB Strategy, which was endorsed by the Stop TB Partnership Coordinating Board in November 2005. The new Strategy was designed to deal with challenges and obstacles that slow the progress in achieving tuberculosis control goals. The major challenges identified are accessibility of good-quality TB care, TB/HIV co-infection epidemic, multidrug-resistant TB, weaknesses of health systems, involvement of all care providers, engagement of communities, and the development of new diagnostics, drugs and vaccines.

The Practical Approach to Lung Health (PAL) is one of the strategies intended to overcome the challenge posed by weak health systems. This initiative is aimed at managing respiratory patients in primary health care settings while expanding TB detection and good-quality TB services. PAL focuses on the most prevalent respiratory diseases at first-level health facilities – pneumonia, acute bronchitis and other acute respiratory infections, TB, and chronic respiratory conditions including chronic bronchitis, asthma and chronic obstructive pulmonary disease.

PAL uses two main approaches to achieve integrated case-management of respiratory patients in primary health care: standardization of diagnosis and treatment of respiratory conditions, and coordination among health workers of different levels.

This manual was developed by WHO to assist country institutions – health and other government ministries, social security agencies, nongovernmental organizations – that want to introduce the PAL strategy into case-management practices in primary health care. It describes a phased process of promotion, technical guideline development and adaptation, pilot testing, managerial planning and implementation. The standards and recommendations represent a synthesis of the observations and experience gathered in primary health care settings in 10 countries in all regions of the world in the past six years.

The manual provides practical guidance to health managers whose efforts are crucial to the achievement of global TB control goals and national targets for case-management of respiratory conditions. It will also be helpful for health care providers at both first-level health care facilities and the first referral level.

The overall policy and guidelines development will rest at the central level of the ministry of health as the leading agency of the country health sector. Planning and implementation will be the responsibility of the district health level and the authorities of other institutions that provide primary health care services.

The PAL strategy encompasses many managerial elements of the Stop TB Strategy in relation to training, logistics, patient education, community involvement, and information systems for monitoring and evaluation.

Health workers need to be prepared to assess patients presenting with respiratory symptoms, some of whom will have TB but most of whom will have other respiratory conditions. They also need to be familiar with the criteria for referring respiratory patients or for treating them at home; supplies for case-management of respiratory conditions; and guidance on health education activities and on recording and reporting of data.

The manual provides guidelines and tools for health managers to meet all the above-mentioned needs. Because PAL is a strategy requiring commitment and cooperation, it is important to devote time to building consensus and creating a broad base of

support during the development of guidelines and planning of activities. Countries are encouraged to follow a well-defined, stepwise process: promotion, political commitment, establishment of a PAL national working group, assessment of the local situation, adaptation of technical and operational guidelines, elaboration of training materials, feasibility testing, planning of national expansion and mobilization of funds.

Although PAL is still in the early stages of promotion and development, available information from country projects suggests that the strategy may improve TB detection and diagnosis, drug prescribing, quality of care, criteria for referral, and follow-up of patients with chronic respiratory diseases.

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Development of the manual and acknowledgements
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Acronyms and abbreviations

ADF	Asthma Drug Facility
AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
ALRI	acute lower respiratory infection
ARI	acute respiratory infection
AURI	acute upper respiratory infection
CD	chronic disease
COPD	chronic obstructive pulmonary disease
CRD	chronic respiratory disease
DOTS	a brand name for the WHO-recommended overall strategy for TB control
GARD	Global Alliance against Chronic Respiratory Diseases
GINA	Global Initiative for Asthma
GOLD	Global Initiative for Chronic Obstructive Lung Disease
HIV	human immunodeficiency virus
HMIS	health management information system
ICD-10	*International statistical classification of diseases and related health problems: tenth revision*
IMAI	Integrated Management of Adolescent and Adult Illness
IMCI	Integrated Management of Childhood Illness
MOH	ministry of health
NGO	nongovernmental organization
NTP	national tuberculosis programme
NWG	national working group
PAL	Practical Approach to Lung Health
PEF	peak expiratory flow
PHC	primary health care
PTB	pulmonary tuberculosis
TB	tuberculosis
The Union	International Union Against Tuberculosis and Lung Disease
WHO	World Health Organization

Introduction

Scope and objectives of the manual
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Scope

A strategy for effective tuberculosis control, called DOTS, was developed in the early 1990s by the World Health Organization (WHO) and the multilateral and bilateral cooperation agencies and nongovernmental organizations (NGOs) that together established the Stop TB Partnership in 2000.

The objectives of tuberculosis (TB) control as adopted by the World Health Assembly are to cure 85% of the sputum smear-positive TB cases detected and to detect 70% of the estimated new sputum smear-positive TB cases. In an effort to achieve those objectives and to provide all people with TB with access to effective diagnosis and treatment, the Stop TB Partnership developed a global plan to accelerate the expansion of the DOTS strategy and improve the quality of TB control services.

Since the inception of the DOTS strategy, achievement of the treatment target has been given priority over the case-detection target, because detecting cases makes no sense if their cure cannot be assured. Thus, expansion of case-finding should be pursued only after cure rates have improved substantially.

The DOTS strategy has been widely implemented, particularly in countries with a high TB burden. The most recent WHO report on the TB control situation indicates that the global treatment success rate among new AFB (acid-fast bacilli) smear-positive TB cases reached the 85% target under the DOTS strategy in 2005, while the case-detection rate was 61% in 2006. It is now recognized that the major deficiency in controlling TB worldwide is the lower than expected case-detection rates – and that the DOTS strategy alone is not sufficient to control and eliminate TB at the global level.

While maintaining the gains achieved in the implementation of the DOTS strategy, WHO and the Stop TB Partnership have therefore developed a new approach – the Stop TB Strategy – to address the remaining major constraints to achievement of the Millennium Development Goals and related global targets for TB control. The box below outlines this new strategy – its vision, goal, objectives, targets and six principal components.

The Practical Approach to Lung Health (PAL) is explicitly identified in component 3 as an innovation within the TB control community that can contribute to strengthening the health system as a whole.

PAL is a patient-centred approach to improving the quality of diagnosis and treatment of common respiratory illnesses in primary health care (PHC) settings. It seeks to standardize service delivery through the development and implementation of clinical guidelines and managerial support within the district health system. It is intended to achieve coordination between the different levels of health care and between TB control and general health services.

By linking TB control activities to proper management of all common respiratory conditions through PAL, four main benefits are expected:

The Stop TB Strategy at a glance	
Vision	**A world free of TB**
Goal	• To reduce dramatically the global burden of TB by 2015, in line with the Millennium Development Goals and the Stop TB Partnership targets.
Objectives	• To achieve universal access to high-quality diagnosis and patient-centred treatment. • To reduce the suffering and socioeconomic burden associated with TB. • To protect poor and vulnerable populations from TB, TB/HIV and multidrug-resistant TB. • To support development of new tools and enable their timely and effective use.

Targets	• MDG 6, Target 8 – halt and begin to reverse the incidence of TB by 2015.
	• Targets linked to the MDGs and endorsed by the Stop TB Partnership:
	  — by 2005, detect at least 70% of new sputum smear-positive TB cases and cure at least 85% of these cases;
	  — by 2015, reduce TB prevalence and death rates by 50% relative to 1990;
	  — by 2050, eliminate TB as a public health problem (<1 case per million population).

Components of the strategy and implementation approaches

1. **Pursue high-quality DOTS expansion and enhancement**
   a. Political commitment with increased and sustained financing
   b. Case-detection through quality-assured bacteriology
   c. Standardized treatment with supervision and patient support
   d. An effective drug supply and management system
   e. Monitoring and evaluation system and impact measurement

2. **Address TB/HIV, MDR-TB and other challenges**
   a. Implement collaborative TB/HIV activities
   b. Prevent and control MDR-TB
   c. Address prisoners, refugees and other high-risk groups, and special situations

3. **Contribute to health system strengthening**
   a. Actively participate in efforts to improve system-wide policy, human resources, financing, management,service delivery and information systems
   b. Share innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
   c. Adapt innovations from other fields

4. **Engage all care providers**
   a. Public–public and public–private mix approaches
   b. International Standards for Tuberculosis Care (ISTC)

5. **Empower people with TB, and communities**
   a. Advocacy, communication and social mobilization
   b. Community participation in TB care
   c. Patients' Charter for Tuberculosis Care

6. **Enable and promote research**
   a. Programme-based operational research
   b. Research to develop new diagnostics, drugs and vaccines

- increased awareness of respiratory symptoms in the community;
- motivation of patients with respiratory symptoms to seek appropriate care;
- improvement in the efficiency and quality of health services delivery, use of drugs and management of resources for respiratory conditions in PHC settings;
- improvement in the quality of TB diagnosis, increased TB case-detection and enhanced adherence to treatment by TB patients.

The PAL strategy is particularly suitable for implementation in settings with high HIV prevalence. Respiratory tract conditions are the most frequent manifestations of AIDS and often appear in the early stages of HIV infection. PAL offers guidelines on dealing efficiently with the large case-load of infectious and non-infectious respiratory conditions at first-level health facilities in these settings. In addition, because effective HIV prevention requires an increase in HIV testing, the registration of repeated acute upper respiratory infections and/or severe bacterial infections such as pneumonia will serve to identify possible HIV-infected patients who should be offered voluntary counselling and HIV testing.

General purpose of the manual

This manual is intended to assist health managers of national ministries of health (MOH), international cooperation agencies and NGOs to plan and implement the general principles and practical elements of the PAL strategy. Its general purpose is to ensure that PAL is efficiently organized and effective in improving TB case-detection and the quality of health services care through the appropriate management of respiratory diseases.

The PAL strategy contributes to upgrading the quality of TB case-detection and diagnosis as defined in the International Standards for Tuberculosis Care (ISTC). A high standard of care is essential to restore the health of individuals with TB and protect the health of communities. Experience from implementing the PAL strategy will provide a basis for the reissue or refinement of international standards for care of the most frequent respiratory conditions at first-level health facilities of low- and middle-income countries.

This manual summarizes recent international experience in promoting and supporting pilot PAL projects in different epidemiological, economic and sociocultural circumstances . While PAL is not concerned with preventive measures in the community, such as tobacco control activities and environmental health programmes, it does deal with communication on preventive activities, including counselling and assistance with stopping smoking, at the time of contact between health workers and patients and their families within the health system, particularly at district level.

Target audience

The manual is intended primarily for use in low- and middle-income countries or regions that:

- have already implemented or are successfully implementing the DOTS strategy to control TB, at least within the government health infrastructure setting; or
- have adopted a national policy to develop, expand and strengthen PHC services; or
- have a high prevalence of HIV infection (since respiratory diseases are frequent complications in HIV-seropositive individuals).

The manual's target audience thus includes consultants and health professionals involved in managing TB, HIV/AIDS and chronic diseases programmes or in organizing PHC services:

- at provincial, state, regional or national levels of MOH;
- in social security institutions; and
- within projects supported by cooperating agencies or NGOs.

The audience comprises programme managers and supervisors, epidemiologists, clinical specialists in TB, respiratory diseases, infectious diseases and HIV/AIDS, general practitioners, nurses, microbiologists, statisticians, health educators, logistics officers, and trainers.

Others who will also find the manual useful include health managers of refugee and displaced population camps, prisons and large private enterprises, such as factories and mines, where the prevalence of TB, HIV/AIDS and respiratory diseases may be high. In addition, teachers in medical, nursing and public health schools will find valuable information for training their students in effective organization of case-management of TB and respiratory diseases.

Specific objectives

The manual has been divided into 10 chapters, corresponding to the specific objectives outlined below; the chapters provide the basic information necessary for developing the skills allied to these objectives.

1. Enlisting political, academic and professional support to implement the PAL strategy in countries.
2. Estimating the epidemiological and social burden of respiratory diseases.
3. Assessing the capabilities of the health infrastructure to implement the PAL strategy.
4. Developing standard clinical guidelines for improving the case-management of respiratory diseases at PHC outpatient services and first-referral (or district) hospitals.
5. Designing communication messages as an essential part of the case-management of patients with respiratory symptoms.
6. Formulating an information system to monitor and evaluate the implementation of the PAL strategy.
7. Developing materials for training on the clinical guidelines.
8. Testing the implementation of the clinical guidelines and the information system in a pilot area.
9. Developing a national implementation plan.
10. Organizing systematic supervision and evaluation of the PAL strategy.

Chapter 1

Enlisting support to initiate the PAL strategy

Long-term development of the PAL strategy in a country depends on acceptance and political commitment on the part of the national health authorities. Political commitment can be secured through promotion documents and advocacy meetings that discuss the PAL issues; by review of WHO recommendations and approaches; and through presentation of the experience and results from several countries with PAL pilot projects or routine PAL activities. The MOH, a university or any academic or teaching institution interested in enlisting support in developing the PAL strategy can undertake production of the promotion document and convene the advocacy seminar.

PAL promotion document

A promotion document should summarize the main background information that helps people to understand the foundations of the PAL strategy and forms the basis for a decision to start its implementation. For instance, the promotion document would include the following information:

- Respiratory diseases, in particular acute respiratory infections (ARI) including pneumonia, are a frequent cause of morbidity and mortality among people of all ages. Tuberculosis and chronic respiratory diseases (CRDs) such as asthma and chronic obstructive pulmonary disease (COPD) are often frequent as well.

- Management of respiratory diseases is an essential element of PHC.

- The case-management of TB at all ages, and of ARI in children under 5 years, is very well defined for all levels of the health delivery services. By contrast, there are often no guidelines for case-management of other respiratory diseases in individuals aged 5 years and over in developing countries. Often there are specialized guidelines on some respiratory diseases (community-acquired pneumonia, asthma, COPD) issued by professional organizations. The role and conditions of PHC are often not considered in these guidelines and evaluation of their level of implementation and impact is omitted.

- There are deficiencies in the quality of respiratory disease care at first-level health facilities and first-referral hospitals.

- WHO has developed the PAL strategy, which focuses on the district health level and aims at improving the quality of care for patients with respiratory conditions.

- The quality of care can be improved through the introduction of technical guidelines defining criteria for clinical diagnosis, the need for complementary tests, and criteria for referral of patients seeking care for respiratory symptoms.

- Guidelines on case-management of respiratory diseases will standardize treatment, particularly with antibiotics, corticosteroids and bronchodilators.

- The guidelines will also deal with the appropriate content of educational messages for respiratory patients and their families.

- The guidelines will be developed in a careful and concerted process with the extensive participation of professionals concerned with clinical care, disease prevention and programme management from all institutions providing health care services.

- The experience of several countries that have adapted the WHO recommendations and approaches is testament to the benefits and effectiveness of a PAL strategy.

Box 1.1 Typical situation analysis results for inclusion in a promotion document on case-management of respiratory illnesses

- In the global population aged 5 years and older, almost one-fifth of all deaths are caused by respiratory diseases.
- The main causes of respiratory deaths in developing countries are pneumonia, TB and COPD.
- The prevalence of asthma has been increasing substantially throughout world during the past few decades, in parallel with the increasing demographic trend of urbanization.
- Tobacco smoking is the chief risk factor for COPD and lung cancer.
- HIV/AIDS is a major contributor to the morbidity and mortality from pneumonia and TB.
- Between 20% and 30% of patients over the age of 5 years attending first-level health facilities seek care for respiratory symptoms.
- There are no global management recommendations for patients aged 5 years and over with respiratory symptoms at any level of the health infrastructure, with the exception of TB.
- Although standardized procedures exist for the management of TB suspects, most such patients do not have TB and need proper diagnosis and treatment for their particular condition.
- Antibiotics are prescribed for two-thirds or more of patients with respiratory symptoms.
- Standardization of case-management of respiratory diseases is needed to improve the quality and efficiency of respiratory care within PHC.

Advocacy seminars

The promotion document can be prepared as a working document to be presented to an advocacy seminar or workshop. Participants at the meeting can be:

- programme managers and technical staff of MOH departments related to TB control, HIV/AIDS, chronic diseases and PHC services;
- other related ministries – education, social welfare, labour, industry, environment;
- pneumonologists and public health experts from professional societies and academic training establishments;
- representatives from medical and nursing associations;
- potential partners in implementing PAL activities – social security, NGOs;
- potential partners in providing technical or financial support – bilateral and multilateral cooperation agencies.

Advocacy seminars provide a forum for a large group of interested professionals to reach a common understanding of the practical concepts of the PAL strategy and its advantages and implications for strengthening the TB programme and improving the

PHC system. The meeting can review the working document and make recommendations to the MOH and other relevant health institutions in order to:

☐ start a pilot project to gain experience with the practical application of the PAL strategy;

☐ allocate initial resources for reviewing policies and planning;

☐ establish coordination mechanisms with other institutions and agencies.

Political commitment

It is essential that the MOH officially endorse the initial steps for PAL development and implementation. To demonstrate its commitment, the MOH, on the basis of the promotion document and the recommendations of the advocacy seminar, should:

- Prepare and issue an official statement announcing that PAL is a suitable strategy and will be introduced into the district health system, beginning with a pilot phase to test the guidelines and demonstrate that the quality of TB diagnosis and respiratory diseases care can be improved.

- Designate an officer as the focal point within the MOH to coordinate all concerned programmes and departments in developing a plan to start PAL activities. This coordinator may be the manager of the national TB programme (NTP), the director of the disease control department or an officer from the ministerial department of PHC services.

- Request that WHO, or a relevant technical agency, provide technical assistance with initiating the adaptation and development of the PAL strategy.

- Appoint a national working group (NWG) to assess the epidemiological situation of respiratory diseases, review current national practices in the management of respiratory illnesses and prepare technical and operational guidelines, as well as the training materials for implementing these guidelines.

- Allocate funds for the start of developmental PAL activities.

The MOH should circulate its official statement to representatives of all concerned programmes and departments within the ministry, together with a memorandum directing them to collaborate in the preparatory activities and pilot project. The official statement should be widely distributed to all agencies and institutions that deliver health services, schools that train health professionals and agencies collaborating with TB, HIV/AIDS, chronic diseases and PHC programmes.

Organizational structure

As a national health authority, the MOH provides national direction and coordination for the PAL strategy, in the framework of the Stop TB Strategy, to government programmes and agencies, social security institutions, NGOs and the private sector. The PAL strategy should be considered as a public health approach for respiratory care provision, closely linked to the NTP at central, regional and district levels and to the system of service delivery in the PHC setting.

Coordination between the programmes and departments of the MOH is described as *intra-organizational,* and is formally carried out through the mechanism of a ministerial PAL task force. Coordination between the MOH and other government ministries, the cooperation agencies, the health professional societies, NGOs and other interested parties is called *inter-organizational coordination*; its official

mechanism of action is the national working group on PAL, in which all the partners are represented.

Intra-organizational coordination

Intra-organizational coordination refers to the linkage of PAL activities to various levels and departments of the MOH and is essential for an efficient PAL strategy development. The coordination linkages are strengthened through regular meetings of an MOH PAL task force with the participation of specific and support programmes involved in prevention and control of TB and respiratory diseases. The chairperson of the task force will be the MOH focal point for all matters related to PAL. Administrative responsibilities, for instance procurement and distribution of essential drugs and collection of information from outpatient health units, can be shared by several departments.

Coordination among specific health services

Standardization of diagnosis and treatment of respiratory diseases should be considered as a natural extension of a well-established and effective TB control programme and an integral part of PHC activities relating to the appropriate treatment of common diseases and injuries. The TB and PHC services should join efforts to develop guidelines on case-management of the most common respiratory conditions and to plan integrated managerial activities for TB and respiratory diseases, within the district health system.

Coordination between PAL strategy, as an extension of TB control, and PHC services should result in:

- the issue of guidelines on diagnosis and treatment of respiratory diseases for health posts, health centres and first-referral level facilities or district hospitals;
- development of materials and organization of activities to train health workers in integrated case-management;
- an assured supply of essential drugs (anti-TB drugs, antibiotics, bronchodilators, corticosteroids) and equipment (oxygen sources, pulse oximeters, peak flow meters and spirometers);
- delivery of educational messages on prevention of respiratory illnesses and the importance of adherence to treatment for TB and CRDs;
- expansion of the information system so that it covers not only TB but also CRDs;
- monitoring activities, capable of reliably assessing progress in implementing the PAL strategy and its impact.

In countries with high prevalence of HIV infection, close coordination should be established with the HIV/AIDS programme. This will promote joint activities such as the issue of guidelines on the management of respiratory diseases in HIV-infected patients; surveys of HIV-positivity among patients with respiratory conditions; identification of HIV-positive individuals among patients with respiratory symptoms; prevention of respiratory diseases among HIV-infected persons; in some country settings, implementation of antiretroviral therapy for selected HIV-infected patients; and development of training modules and educational materials on HIV infection and associated respiratory diseases.

In countries where IMAI (Integrated Management of Adolescent and Adult Illnesses) projects are being developed, there should be close coordination and collaboration;

in other countries, PAL can be the first building block in the development of the IMAI strategy.

Where occupational lung diseases such as pneumoconiosis are prevalent, PAL activities should be closely coordinated with the occupational health programme regarding guidelines for treatment and prevention, seminars, training courses and surveys. Within its range of activities, the PAL strategy will support the activities of the tobacco control programme and of indoor air pollution control (environmental health).

In some countries, PAL can be also the first intervention of the Global Alliance against Chronic Respiratory Disease (GARD).

Coordination with support programmes

The main MOH supporting programmes, services and departments at regional and central levels should participate in PAL strategy development; these are:

- *Essential drugs programme* – which procures, stores and distributes drugs for respiratory diseases, including anti-TB drugs, antibiotics, bronchodilators, anticholinergics, corticosteroids, analgesics and antitussives.

- *Public health laboratory* – which issues guidelines for microbiological laboratory procedures, supplies materials and reagents, undertakes training, provides information on laboratory performance, undertakes quality assurance and supervision related to microbiological diagnostic techniques, and participates in surveillance of bacterial drug resistance.

- *Radiology services* – which provide X-ray equipment and training in techniques, interpretation and quality control of chest radiographs, and radiation protection for staff and patients during diagnostic procedures.

- *Essential medical equipment programme* – which can procure and distribute oxygen sources, pulse oximeters, inhalation chambers, nebulizers, peak flow meters and spirometers.

- *Human resources development department* – which collaborates in the development of materials for training on the PAL technical and operational guidelines, organizes in-service training courses and evaluates the training activities.

- *Health education programme* – which develops and produces educational materials for patients and their families.

- *Public relations department* – which develops and implements advocacy strategies.

- *Health information management system department* – which should review the information needed to monitor and evaluate the PAL strategy, consider necessary adaptations or modifications in the existing recording forms and the introduction of specific forms and registers to meet PAL needs, and ensures the collection and analyses of relevant data.

- *Nursing department* – which develops guidelines on the role of nurses in diagnosis (pulmonary function tests), treatment (inhalation techniques, oxygen therapy), follow-up of CRDs (registers of TB and CRDs) and health education.

Inter-organizational coordination

Partnership is a key element for success in public health programmes. The MOH is responsible for encouraging inter-organizational coordination, which means the linking with other agencies and institutions that are concerned with the prevention, management and control of TB and other respiratory diseases, such as other ministries, social security agencies, NGOs, international co-operation agencies, health professional associations, representatives of the private health sector, suppliers of medical equipment for management of respiratory diseases, and manufacturers and importers of drugs used in the treatment of respiratory diseases.

Coordination with related ministries and other bodies

- *Ministry of education*

    - Introduction of national PAL guidelines in the teaching curricula of health science institutions, such as medical schools, public health schools and schools for nurses, medical assistants, laboratory professionals and technicians, community health workers and other health workers.
    - Introduction of PAL messages into the health education programme of elementary and secondary schools.

- *Ministry of social welfare*

    - Agreements on prevention, diagnosis and treatment of CRDs among beneficiaries of social security agencies.
    - Care of CRDs in shelters for the homeless and old people's institutions.

- *Ministry of labour, ministry of industry*

    - Regulations on case-management of CRDs in occupational settings (mining, industry).

- *National research agency*

    - Provision of grants for technical and operational research projects related to respiratory diseases at PHC settings.

- *National public information agency*

    - Allocation of space for educational messages on respiratory diseases and lung health in public television and radio broadcasts and publications.

Coordination with NGOs and global initiatives

Linkages should be established with local and external NGOs that provide health care services. Coordination at district level is essential to consolidate information and reports.

Ideally, NGOs should follow national policy with respect to TB and respiratory diseases, introduce into their health units standard case-management as defined and formulated in the PAL strategy, produce educational materials and promote educational messages targeting patients, their families and the community in general. Seminars and training courses on the PAL strategy should therefore be organized for NGO managerial staff.

Linkages should also be established with international professional and scientific associations that formulate and update guidelines on standards of care for respiratory diseases, such as the International Union against Tuberculosis and Lung Disease (The Union) or GARD.

Coordination with external agencies

Collaboration with external allied health agencies may be critical for effective implementation of the PAL strategy in many countries. Collaboration with other multilateral organizations and bilateral cooperation agencies is also useful in securing funding (grants or loans in the case of international financial agencies) for some activities, or for implementation in specific districts or regions, in conjunction with more general health programmes supported by the agencies.

National working group on PAL

The main mechanism of inter-organizational coordination is the establishment of a national working group on PAL to guide and support the initial activities and to foster the involvement of official and private institutions and external agencies in the planning, implementation and funding of the PAL strategy as an extension of the NTP. The NWG should include members who can bring together a rich variety of experience in technical, managerial, advocacy and educational matters relating to TB, HIV/AIDS and respiratory diseases, and ensure linkages with related programmes of the MOH and with all the other agencies and institutions. The membership should include:

- programme managers and technical staff of the most relevant MOH services (TB, PHC, HIV/AIDS, essential medicines);
- pulmonologists from university departments, reference hospitals and professional societies;
- representatives from social security agencies;
- members of NGOs involved in community-based interventions;
- representatives from allied health agencies.

It would be advantageous for the NWG to organize subgroups such as:

- *technical guidelines subgroup*, committed to developing the PAL guidelines for health centres and for first referral hospitals;
- *training subgroup*, focusing on elaborating the training materials to teach the PAL guidelines to health professionals;
- *communication subgroup*, which develops messages and materials for health education of patients, families and communities on prevention and control of respiratory diseases;
- *site-piloting subgroup*, which selects the appropriate areas for site-piloting and organizes the testing of the PAL guidelines in these areas;
- *advocacy subgroup*, which promotes the objectives of the PAL strategy and helps in raising funds for its implementation.

The NWG should meet regularly so that the subgroups can update each other on their work and share information. Each subgroup needs a coordinator to schedule meetings and organize the working agenda. Some NWG members may serve on more than one subgroup.

Box 1.2 Terms of reference of the national working group on PAL

- Gather information on the magnitude of acute and chronic respiratory diseases in the community and at health facilities.
- Compile data on existing equipment and facilities for diagnosis and treatment of respiratory diseases at health posts, health centres and first-referral hospitals.
- Adapt and develop national PAL guidelines on case-management of respiratory diseases for first-level health facilities and first-referral hospitals.
- Review the adequacy of the existing health information system, and identify any gaps that can be tackled to allow the collection of essential information for monitoring and evaluating PAL activities and performance.
- Support and assist in the development of materials for training on the PAL guidelines on case-management.
- Contribute to successful organization of the PAL feasibility study at first-level health facilities, collecting information on case-management practices for respiratory diseases before and after implementation of the PAL strategy.
- Supervise the analysis of the feasibility study data collected at the pilot sites.
- Revise the PAL technical and operational guidelines, as well as the training materials, on the basis of the results of the feasibility study.
- Collaborate in the planning and implementation of the PAL strategy expansion.
- Participate in PAL advocacy activities.
- Collaborate in reviewing the performance of PAL activities.

The PAL strategy in the context of health sector reform

Reforms of the health sector are already under way in many countries. A balanced view sees health sector reform as a sustained process of fundamental change in policy and institutional arrangements, guided by the government, designed to improve the functioning and performance of the health sector and, ultimately, the health status of the population.

Appropriate objectives for health sector reform are to improve access to and use of health services (equity), upgrade the quality of health services and make better use of resources, while keeping a balance between PHC units and higher-level health facilities (major efficiency). The most relevant features of reform are decentralization of management and planning of health services to district levels, integration of essential programmes, public consultation and improved financial management. If these principles are well understood and implemented, the result should be a framework that strengthens the managerial and technical support capacity of health teams at regional and district levels and improves the overall health situation.

The PAL strategy should be adopted as an integral part of health sector reform because it can directly contribute to health system strengthening in the field of respiratory diseases. Efforts to improve the health system by well-conceived and appropriately applied health sector reform are enhanced by implementation of the PAL strategy. Any minimum package of priority health services should include an integrated approach to care of TB and the most common respiratory conditions.

Although the technical policies should be formulated by the specific control programmes at central level, the authority to plan, manage and finance implementation of the PAL strategy should be gradually delegated to the district level, with full support from regional and central levels.

Chapter 2

Estimating the burden of respiratory diseases

The growing problem of respiratory diseases

Respiratory diseases are among the most common acute and chronic diseases worldwide. They occur in all societies, regardless of their level of development, and are frequent among all age groups and sectors of the population. The overall incidence has increased in recent decades due to a rapid increase in risk factors such as:

- population growth and urbanization (more frequent close interpersonal contacts favour transmission of respiratory infections);
- economic growth and industrialization in some regions, which increase the levels of atmospheric air pollution;
- deterioration of the socioeconomic situation in many developing countries with a concomitant reduction in funding for health services;
- high levels of indoor air pollution affecting large proportions of the population living in rural and periurban areas of the world;
- increasing prevalence of tobacco smoking in developing countries;
- the HIV epidemic, with the attendant respiratory conditions that are the most frequent manifestations of AIDS.

Upper and lower ARIs, including pneumonia, are frequent at all ages but are particularly devastating in young children. Tuberculosis, asthma, COPD and lung cancer are the leading causes of respiratory morbidity and mortality among adults. The prevalence of COPD is increasing in adults of 40 years and over in developing countries. Pneumonia and TB are frequent in young adults in low- and middle-income countries, whereas pneumonia and lung cancer are important in people aged 50 years and over in high-income countries. The prevalence of asthma has been increasing in children and adults in industrialized countries and in large urban areas of developing countries over the past three decades.

Mortality

Table 2.1 shows the 2002 estimated mortality rates from all causes and from respiratory diseases, for all ages, in five groups of countries, classified by mortality strata (various combinations of child and adult mortality levels). The global mortality rate, all causes, is 9.2 per 1000, with a range from 6.8 (Group B) to 16.6 (Group E). Mortality from respiratory diseases, excluding those associated with HIV infection, is within a narrow range from 127.6 to 143.5 per 100 000 in countries of Groups A, B and C. The rate in Group D is much higher – 239.2 per 100 000 – and Group E has the highest rate, at 296.7 per 100 000. The global proportional mortality from respiratory diseases is 20.0%. This proportion is 16.5% in the high-income countries that constitute Group A and only 8.1% in Group C. In the other three groups, the proportion is between 18% and 23%.

Table 2.1 **Mortality, all ages, from respiratory diseases[a] by mortality stratum: estimates for 2002**

Mortality stratum	Population (thousands)	Total deaths: number in thousands, and rate per 1000	Deaths from respiratory diseases: number in thousands, and rate per 100 000	Respiratory deaths among all deaths (%)
A. Very low child Very low adult	904 303	7 786 8.6	1 285 142.1	16.5
B. Low child Low adult	2 670 905	18 257 6.8	3 834 143.5	21.0
C. Low child High adult	239 717	3 779 15.8	306 127.6	8.1
D. High child High adult	2 037 977	21 110 10.4	4 876 239.2	23.1
E. High child Very high adult High HIV prevalence	360 965	6 007 16.6	1 071 296.7	17.8
Total	6 213 167	56 939 9.2	11 372 183.0	20.0

[a] Excluding deaths from respiratory diseases associated with HIV infection.

Number of countries by mortality stratum:
  A. 3 in Americas, 26 in Europe, 5 in Western Pacific.
  B. 26 in Americas, 13 in Mediterranean, 16 in Europe, 3 in South-East Asia, 22 in Western Pacific (including China).
  C. 9 in Europe (including Russian Federation).
  D. 25 in Africa, 6 in Americas, 9 in Mediterranean, 7 in South-East Asia (including India).
  E. 20 in Africa (with high prevalence of HIV infection).

Source: Reducing risks, promoting healthy life. World Health Report, 2002. Geneva, World Health Organization, 2002.

The overall rates shown in Table 2.1 hide great variations in the risk of dying from respiratory diseases according to age and sex within each mortality stratum. The specific rates by age and sex are presented in Table 2.2. In general, the rates in males are higher than those in females in most of the age groups; the largest differences are observed in Group C, particularly in adults aged 15 years and over, where the rates are approximately 5 times higher in men than in women. This is due to a large difference in the mortality from TB, pneumonia, lung cancer and COPD between the two sexes. The rates in females are higher than those in males in children and adolescents of Group B. In all groups, the highest rates occur in people of 60 years and older and the lowest rates are found in school-age children. In Groups D and E, the rates in children aged 0–4 years are much higher than in adults aged 15–59 years as a result of the high death rates from childhood pneumonia in low-income countries. Mortality from respiratory diseases is more than 200 times

higher in children of Group E than in children of Group A. By contrast, the corresponding rate in persons aged 60 years and over in Group E is only 1.7 times higher than in Group A.

Table 2.2 **Death rates per 100 000 from respiratory diseases[a] by age, sex and mortality stratum: estimates for 2002**

Age group and sex	A	B	C	D	E
0–4 years					
Male	5.1	111.7	58.2	708.4	1014.1
Female	4.1	160.6	46.1	706.5	996.0
Total	4.6	136.2	52.3	707.5	1006.3
5–14 years					
Male	0.7	9.9	2.0	50.9	78.0
Female	0.64	11.0	1.8	61.5	77.2
Total	0.69	10.4	1.9	56.1	77.6
15–59 years					
Male	29.9	52.9	122.1	113.0	179.1
Female	16.5	31.3	22.1	83.0	113.2
Total	23.2	42.3	71.1	98.4	145.6
≥60 years					
Male	829.4	1234.5	877.3	1384.4	1409.9
Female	492.8	995.6	186.6	972.6	825.5
Total	638.4	1106.4	430.6	1167.9	1086.2
All ages					
Male	165.2	150.7	207.5	255.1	344.6
Female	119.7	136.2	57.7	222.8	249.9
Total	142.1	143.5	127.6	239.2	296.7

[a] Excluding deaths from respiratory diseases associated with HIV infection.

Number of countries by mortality stratum:

A. 3 in Americas, 26 in Europe, 5 in Western Pacific.
B. 26 in Americas, 13 in Mediterranean, 16 in Europe, 3 in South-East Asia, 22 in Western Pacific (including China).
C. 9 in Europe (including Russian Federation).
D. 25 in Africa, 6 in Americas, 9 in Mediterranean, 7 in South-East Asia (including India).
E. 20 in Africa (with high prevalence of HIV infection).

Source: Reducing risks, promoting healthy life. World Health Report, 2002. Geneva, World Health Organization, 2002.

A significant difference can be observed in the relative burden of mortality from communicable and noncommunicable respiratory diseases (Table 2.3). The rates of deaths from communicable diseases are increasing from about 40 per 100 000 persons in Groups A and C and almost 50 in Group B, to 182.6 in Group D and 256.9 in Group E. By contrast, the trend in death rates from noncommunicable diseases follows the reverse direction, going down from 102.8 per 100 000 persons in Group A to 39.7 in Group E. Deaths from communicable respiratory diseases account for

27.6% of all respiratory deaths in Group A but for 86.6% in Group E, because TB in adults, measles in children and pneumonia in all age groups are frequent causes of death in persons both with and without HIV infection.

Table 2.4 presents the main respiratory diseases that are causes of death, by age group and mortality stratum. For children aged 0–4 years, acute lower respiratory infections (ALRI) – mostly pneumonia, but also some bronchiolitis and acute obstructive laryngitis – are the most frequent causes in all mortality strata, although there is a broad variation in the rates from 2.5 per 100 000 in Group A to 633.9 in Group E. Measles is the second cause of respiratory deaths in children aged 0–4 and 5–14 years in Groups B, D and E. In the 15–59 age group, the first cause of death in high-income countries, all included in Group A, is lung cancer, whereas TB is the first cause in the other four groups. In the 60 years and over age group, cancer is the first cause of death for Groups A and C, COPD for Group B and ALRI (mostly pneumonia) for Groups D and E. Pneumonia and COPD are among the three top killer respiratory diseases in all five over-60 age groups; TB is also included in groups B, D and E.

Table 2.3 **Death rates per 100 000 from communicable and noncommunicable respiratory diseases,ᵃ by age and mortality stratum: estimates for 2002**

Age group	A	B	C	D	E
0–4 years					
Communicable	2.8	126.2	47.0	695.5	989.8
Noncommunicable	1.9	10.0	4.1	96.7	150.4
5–14 years					
Communicable	0.3	9.5	1.9	6.6	8.3
Noncommunicable	0.4	0.9	0.5	2.4	1.4
15–59 years					
Communicable	3.0	23.0	40.9	65.9	123.0
Noncommunicable	20.2	19.3	30.2	32.5	22.5
≥ 60 years					
Communicable	186.5	51.0	63.4	627.6	545.4
Noncommunicable	452.0	855.4	367.2	540.2	540.8
All ages					
Communicable	39.2	49.9	40.3	182.6	256.9
Percentage	27.6%	34.7%	31.6%	76.3%	86.6%
Noncommunicable	102.8	93.6	87.5	56.6	39.7
Percentage	72.4%	65.3%	68.4%	23.7%	13.4%

ᵃ Excluding deaths from respiratory diseases associated with HIV infection.

Number of countries by mortality stratum:

A. 3 in Americas, 26 in Europe, 5 in Western Pacific.
B. 26 in Americas, 13 in Mediterranean, 16 in Europe, 3 in South-East Asia, 22 in Western Pacific (including China).
C. 9 in Europe (including Russian Federation).
D. 25 in Africa, 6 in Americas, 9 in Mediterranean, 7 in South-East Asia (including India).
E. 20 in Africa (with high prevalence of HIV infection).

Source: Reducing risks, promoting healthy life. World Health Report, 2002. Geneva, World Health Organization, 2002.

Table 2.4 **Main causes of mortality from respiratory diseases,[a] by age group and mortality stratum, rates per 100 000: estimates for 2002**

Ranking	A Very low child Very low adult		B Low child Low adult		C Low child High adult		D High child High adult		E High child Very high adult	
0–4 years										
1st cause[b]	ALRI	2.5	ALRI	95.0	ALRI	35.1	ALRI	449.2	ALRI	633.8
2nd cause[b]	AURI	0.4	Measles	21.6	AURI	11.2	Measles	141.8	Measles	222.3
3rd cause	Asthma	0.2	AURI	6.2	TB	0.6	Pertussis	89.5	Pertussis	99.9
5–14 years										
1st cause	ALRI	0.3	ALRI	5.4	ALRI	1.0	ALRI	40.4	ALRI	54.1
2nd cause	Asthma	0.2	Measles	2.9	AURI	0.3	Measles	8.1	Measles	11.7
3rd cause	AURI	0.03	Asthma	0.3	TB	0.1	TB	4.1	TB	7.8
15–59 years										
1st cause	Cancer	14.8	TB	16.6	TB	23.2	TB	46.1	TB	81.4
2nd cause	ALRI	2.7	Cancer	8.6	Cancer	18.0	ALRI	19.1	ALRI	41.2
3rd cause	COPD	2.6	ALRI	5.8	ALRI	17.3	COPD	17.1	COPD	7.6
≥ 60 years										
1st cause	Cancer	204.6	COPD	597.1	Cancer	158.2	ALRI	486.6	ALRI	360.4
2nd cause	ALRI	179.5	Cancer	150.2	COPD	150.7	COPD	363.0	COPD	297.7
3rd cause	COPD	159.3	ALRI	143.5	ALRI	42.0	TB	130.9	TB	182.4
All ages										
1st cause	Cancer	50.0	COPD	60.0	Cancer	40.8	ALRI	111.6	ALRI	147.1
2nd cause	ALRI	37.6	ALRI	25.6	COPD	31.7	TB	37.1	TB	56.8
3rd cause	COPD	33.4	TB	20.5	ALRI	20.6	COPD	34.2	Measles	36.2

[a] Excluding deaths from respiratory diseases associated with HIV infection.

Number of countries by mortality stratum:

    A. 3 in Americas, 26 in Europe, 5 in Western Pacific.

    B. 26 in Americas, 13 in Mediterranean, 16 in Europe, 3 in South-East Asia, 22 in Western Pacific (including China).

    C. 9 in Europe (including Russian Federation).

    D. 25 in Africa, 6 in Americas, 9 in Mediterranean, 7 in South-East Asia (including India).

    E. 20 in Africa (with high prevalence of HIV infection).

Source: Reducing risks, promoting healthy life. World Health Report, 2002. Geneva, World Health Organization, 2002.

In summary, the following features of mortality from respiratory diseases deserve highlighting:

- Estimated global mortality among people of all ages from respiratory diseases in 2002, excluding those associated with HIV infection, was 183.0 per 100 000 population and represented 20% of all causes of death.

- Mortality rates from respiratory diseases vary widely by region, age and sex. The highest rates for all age and both sexes occur in African countries with high prevalence of HIV infection (Group E in the classification of countries by mortality stratum).

- In general, mortality rates from respiratory diseases in males are higher than in females due to a large difference in deaths from TB, pneumonia, lung cancer and COPD between the two sexes.

- Mortality rates from respiratory diseases are lowest in the 5–14 year age group and highest in people aged 60 years and over, regardless of mortality strata.

- Whereas about one-third of all deaths from respiratory causes are due to communicable respiratory diseases in mortality stratum Groups A, B and C, the proportion of deaths due to communicable respiratory diseases is 76.3 % in Group D and 86.6% in Group E.

- ALRI, mostly pneumonia, is the most frequent respiratory cause of death in the 0–4 and 5–14 year age groups throughout the world. In adults aged 15–59 years, lung cancer is the leading cause of respiratory deaths in Group A, whereas TB is the most frequent cause in the other four groups. In people aged 60 years and over, lung cancer is the first cause of respiratory deaths in Groups A and C, COPD in Group B and ALRI in Groups D and E.

Morbidity

Acute respiratory infections

Acute respiratory infections are divided into two groups according to their anatomical location:

- infections affecting the airways above the epiglottis, designated upper respiratory tract infections (AURI), which also include otitis media;
- those affecting the airways below the epiglottis, called lower respiratory tract infections (ALRI), which include laryngitis, tracheitis, bronchitis, pneumonia and, in young children, bronchiolitis.

However, upper and lower parts of the respiratory tract are often affected simultaneously or consecutively during an acute episode, and there are also disseminated forms such as the influenza syndrome. The incidence of ARIs is seasonal almost everywhere, with the highest annual peak in either the cold or the rainy season.

AURI and acute bronchitis are very common in all populations, the incidence being similar in both low/middle- and high-income countries. On average a young child has 4–6 episodes and an adult 2–4 episodes of AURI a year, counting every episode, even the mildest ones. However, there is a striking difference in the incidence rates of community-acquired pneumonia depending on the country income level (Table 2.5).

Pneumonia rates are high in very young children and decline with increasing age until age 60 years. The lowest rates are usually observed in young adults: the estimated annual incidence among young adults is 0.6% in high-income countries and 1.0–2.0% in low/middle-income countries. In persons aged 60–74 years, the rates are 1.5% in high-income countries and 3.0–4.0% in low/middle-income countries. The highest rates in adults are observed in persons of 75 years and above. Pneumonia rates in adults can double during epidemics of influenza A. People who are HIV-seropositive have an ALRI incidence almost 10 times higher than who are HIV-seronegative, a risk of bacterial pneumonia 4–20-fold higher and a rate of invasive pneumococcal infection between 40- and 1000-fold higher.

Table 2.5 **Estimated annual incidence of community-acquired pneumonia, by age, in low/middle- and high-income countries**

Age group (years)	Community acquired pneumonia incidence (%)	
	High-income countries	**Low/middle-income countries**
0–4	3.0	10.0–30.0
5–14	1.6	2.0–3.0
15–44	0.6	1.0–2.0
45–59	0.6	1.0–2.0
60–74	1.5	3.0–4.0
75+	3.2	5.0–7.0

Source: Scherpbier R, Hanson C, Raviglione M. *Basis for development of algorithms for assessment, classification and treatment of respiratory illness in school-age children, youths and adults in developing countries.* Geneva, World Health Organization, 1998 (WHO/TB/98.257).

Pulmonary tuberculosis

Pulmonary TB refers to disease affecting the lung parenchyma and is by far the most frequent type of TB. Pulmonary TB is classified as direct AFB smear microscopy positive or direct smear microscopy negative. Extrapulmonary TB tends to occur more frequently in HIV-infected than in non-HIV-infected persons, but pulmonary TB remains the most common type of TB in both groups worldwide. Smear-negative pulmonary TB is more common among HIV-positive patients than among HIV-negative TB cases. Among the extrapulmonary TB forms, pleural, laryngeal and bronchial TB are counted as respiratory TB locations.

In 2006, there were an estimated 9.2 million new cases of TB in the world, of which 4.1 million were smear-positive (Table 2.6). Eighty per cent of the cases are estimated to occur in 22 high-burden countries, which represent 63% of the world population.

Even though the DOTS strategy has been widely adopted at global level and substantial progress has been made in the implementation of effective TB control programmes in a growing number of countries worldwide, the burden of TB remains enormous. Co-infection with HIV is a major contributing factor in many countries, mainly those of sub-Saharan Africa; in 2006, for example, the estimated incidence rate in sub-Saharan Africa was 363 cases per 100 000 population. TB control has also been complicated by the emergence of multidrug-resistant TB, and to some extent extensively drug-resistant TB, in many countries, particularly those of the former Soviet Union.

After increasing at a rate of 1% per year until 2004, the incidence of TB became stable or declined in all the six WHO regions in 2005 and 2006. However, the total number of new TB cases continued to rise slowly.

Table 2.6 **Estimated TB incidence, all forms and smear-positive pulmonary TB, 2006**

Region	Population (000)	TB, all cases		TB, smear-positive cases	
		Number	Rate per 100 000	Number	Rate per 100 000
Africa	773 792	2 808 000	363	1 203 000	155
Americas	899 388	331 000	37	165 000	18
Eastern Mediterranean	544 173	570 000	105	256 000	47
Europe	887 455	433 000	49	194 000	22
South-east Asia	1 721 049	3 100 000	180	1 391 000	81
Western Pacific	1 764 231	1 915 000	109	860 000	49
22 high-burden countries	4 150 313	7 334 000	177	3 265 000	79
Other countries	2 439 775	1 823 000	75	803 000	33
Total	6 590 088	9 157 000	139	4 068 000	62

Source: *Global tuberculosis control: surveillance, planning, financing. WHO Report 2008.* Geneva, World Health Organization, 2008 (WHO/HTM/TB/2008.393).

Asthma

Asthma is a chronic, inflammatory disorder of the airways that causes recurrent episodes of wheezing, breathlessness, chest tightness and cough, particularly at night and in the early morning. The airflow limitation is variable and partially or totally reversible, either spontaneously or with treatment. The total number of patients suffering from asthma worldwide has been estimated at 300 million, most of whom live in low- and middle-income countries.

Asthma occurs at all ages in most countries, with higher prevalence rates in urban than in rural areas, in children than in adults, and in adult females than in adult males. Reports on asthma prevalence have shown huge variations within and between countries, even between high-income countries, as confirmed by surveys carried out using similar methodology and standard research protocols (Table 2.7). Some variations may be due to different interpretations of the definitions used, but the most important reasons for variation are not clearly established. They are probably linked to differences in exposure to environmental risk factors, either for the development of asthma or for exacerbations of this variable disease.

Table 2.7 **Asthma prevalence in age groups 13–14 and 20–44 years in several regions of the world**

Adolescents 13–14 years		Adults 20–44 years	
Region	Prevalence per 100 people	Region or country	Prevalence per 100 people
Oceania	25.9	Australia/New Zealand	6.8–9.7
North America	16.5	USA/northern Europe	>5.0
Latin America	13.4	Western/southern Europe	1.0–4.0
Western Europe	13.0	Algeria (Algiers)	2.4
Eastern Mediterranean	10.7	Morocco	5.1
Africa	10.4	India (Bombay)	2.6
Pacific Asia	9.4	Zimbabwe	0.3
South-east Asia	4.5	Gambia	0.0
Eastern Europe	4.4		

Source: Scherpbier R, Hanson C, Raviglione M. *Basis for development of algorithms for assessment, classification and treatment of respiratory illness in school-age children, youths and adults in developing countries*. Geneva, World Health Organization, 1998 (WHO/TB/98.257).

Since 1960, asthma prevalence has gradually risen in most high-income countries as well as in many low/middle-income countries. In several areas, there has been a 100% increase in the overall prevalence of asthma in children. Severe asthma is an emerging public health issue among the poorest people, especially minorities, living in degraded areas of big cities of both developed and developing countries. The increase is linked to changes in exposure to environmental factors that may exacerbate asthma:

   □ at home, indoor pollutants such as second-hand tobacco smoke and smoke from the combustion of solid fuels, as well as allergens;
   □ at the workplace, allergens and irritants;
   □ outdoors, allergens and air pollution.

Asthma prevalence has increased in most developing countries , particularly in Africa and Latin America. The epidemic of asthma observed in low- and middle-income countries may continue in the future with increasing urbanization and adoption of western lifestyles, which are factors that have been associated with the increasing trends.

Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease, or COPD, is a nonspecific term developed to describe chronic lung disease characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles and gases. The pathological conditions that contribute to COPD are chronic bronchitis and emphysema.

Many previous definitions of COPD have emphasized the terms "emphysema" and "chronic bronchitis"; these are no longer included in the definition. Emphysema is a pathological term and describes only one of the several structural abnormalities present in patients with COPD. Chronic bronchitis, defined as the presence of cough and sputum production for at least 3 months in each of 2 consecutive years in a

patient in whom other causes of chronic cough have been excluded, remains a useful clinical and epidemiological term. However, it may or may not be associated with airflow limitation, which is the essential characteristic of COPD.

By far the most important cause of COPD is tobacco smoking. Other important factors reported to be associated with the condition include indoor air pollution, occupational exposure to irritants, and childhood respiratory infections. Cigarette smoking continues to increase in all low- and middle-income countries and will substantially increase the global COPD prevalence, particularly among certain subpopulations in Asia, who are becoming early and heavy smokers. In addition, increasing life expectancy is likely to be followed by higher COPD prevalence. COPD is an important cause of restricted activity and chronic disability, with a consequent reduction in quality of life from adulthood to old age.

In some high-income countries, such as the United States of America, the prevalence of COPD has shown a progressive decline in men during the past decade but a progressive increase in women. Unfortunately, different survey methodologies and variable definitions for COPD make inter-country comparison of epidemiological data difficult. Available data are likely to underestimate the total COPD burden.

The estimated prevalence of COPD worldwide in 2001 was 1013 per 100 000 population – 1206 males and 810 females. These estimates include people of all ages and therefore underestimate the frequency of disease in adults, because COPD rarely occurs in young age groups. The highest prevalence (1675/100 000 population) was found in WHO's Western Pacific region, particularly because smoking is a very common habit in China (60% of the adult male population smoke). The lowest prevalence was in sub-Saharan Africa (179/100 000 population) probably because of Africa's young population (only 3.2% are over 65 years) and the low prevalence of smoking. Recently, WHO estimated that COPD affects 210 million people globally. The disease is currently the fourth leading cause of death globally and may become the third by 2030.

Lung cancer

Lung cancer was a relatively uncommon disease at the beginning of the twentieth century. Since then, its incidence in the world has been steadily growing, more rapidly after 1960 than before, in both developed and developing countries. Global incidence has been rising at 0.5% per year in recent years; a major contribution to this trend comes from eastern Europe and developing countries. Lung cancer is the most common cancer in males. There were 1.3 million new cases in 2000, of which 939 900 were in men (30.9 per 100 000) and 365 700 in women (11.9 per 100 000). The estimated incidence of lung cancer varies greatly with region and depends on age and population structure, prevalence of tobacco smoking and other risk factors, and opportunities for detection and treatment.

Table 2.8 presents the estimated age-standardized incidence rates of lung cancer by sex and mortality stratum by region. Incidence in males is highest in the countries of Europe and North America, ranging from 43.3 to 52.2 per 100 000 population. In females, the highest rate, 30.5 per 100 000, was estimated in North America. Lung cancer incidence is lowest in Africa.

Epidemiological studies have consistently shown that the majority of lung cancer patients have a history of cigarette smoking, and the highest mortality attributable to smoking corresponds to lung cancer. There are other risk factors, however, particularly exposure to asbestos. The falling incidence observed in developed countries in recent years seems to be related mostly to decreased cigarette smoking.

Respiratory diseases in outpatient services

The heavy epidemiological burden of respiratory diseases in the community is also reflected by the statistics of patients attending PHC facilities. Cough is one of the most common reasons for patients to seek care at first-level health facilities in both developed and developing countries. Sputum production and shortness of breath are frequently reported in these health settings.

Data on prevalence of respiratory conditions among patients seeking care at outpatient services were collected by WHO, using the same protocol, in 76 health units in nine developing countries in different world regions. The data were collected from at least three typical PHC facilities in each country for a period of 1–3 months during the rainy season or winter period.

Table 2.9 shows the data collected in Argentina, Guinea and Morocco on outpatients of all ages during the survey period. The prevalence of outpatients with respiratory symptoms varied from 46.6% to 74.4% in children under 5 years of age, and from 16.2% to 33.7% in patients aged 5 years and over.

The classification of outpatients of 5 years and over who had respiratory symptoms and attended first-level health facilities staffed with doctors is shown in Table 2.10.The data indicate that 80% of patients had an ARI, 50% of the upper respiratory tract and 30% of the lower respiratory tract. The prevalence of clinical pneumonia was 2.8%. Chronic conditions – chiefly asthma, chronic bronchitis and COPD – accounted for 20% of outpatient diagnoses. Tuberculosis was diagnosed in 1.4% of the outpatients with respiratory symptoms; 77% of the TB cases had bacteriological confirmation.

Table 2.8 **Global and regional age-standardized incidence rates of trachea/bronchus/lung cancer by sex and region: estimates for 2002**

Mortality stratum	WHO region	Incidence per 100 000	
		Male	**Female**
A	AMRO	44.8	30.5
	EURO	43.3	13.4
	WPRO	28.9	11,6
B	AMRO	20.6	8.8
	EMRO	18.9	6.7
	EURO B1	47.1	9.9
	EURO B2	20.6	5.5
	SEARO	27.5	5.4
	WPRO B1	30.8	16.0
	WPRO B2	26.4	7.4
	WPRO B3	14.7	8.4
C	EURO	52.2	7.6
D	AFRO	8.3	3.5
	AMRO	6.9	4.4
	EMRO	16.6	5.6
	SEARO	20.3	5.3
E	AFRO	12.0	5.8
Total		30.9	11.9

Number of countries by mortality stratum:

A. 3 in Americas, 26 in Europe, 5 in Western Pacific.

B. 26 in Americas, 13 in Mediterranean, 16 in Europe, 3 in South-East Asia.

   B1 11 in Europe and 4 in Western Pacific, including China.

   B2 6 in Europe and 4 in Western Pacific.

   B3 14 islands in Western Pacific.

C. 9 in Europe (including Russian Federation).

D. 25 in Africa, 6 in Americas, 9 in Mediterranean, 7 in South-East Asia (including India).

E. 20 in Africa (with high prevalence of HIV infection).

Source: Reducing risks, promoting healthy life. World Health Report, 2002. Geneva, World Health Organization, 2002.

Table 2.9 **Distribution of outpatients with respiratory symptoms by sex and age in health facilities with medical staff in Argentina, Guinea and Morocco**

Sex	Outpatients <5 years			Outpatients ≥5 years		
	Total	With respiratory symptoms		Total	With respiratory symptoms	
		Number	%		Number	%
Argentina: July–August 1998						
Male	4860	3186	65.5	3924	1415	36.1
Female	4487	2776	61.8	6376	2053	32.2
Total	9347	5964	63.8	10300	3468	33.7
Guinea: July–September 1999						
Male	5448	2462	45.2	6050	1247	20.6
Female	5321	2556	48.0	9814	1317	13.4
Total	10769	5018	46.6	15864	2564	16.2
Morocco: February 2000						
Male	1442	1057	73.3	3758	1390	37.0
Female	1409	1065	75.6	7787	2235	28.7
Total	2851	2122	74.4	11545	3625	31.4

Source: Ottmani S et al. *Respiratory care in primary care services: a survey in 9 countries*. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.333).

Table 2.10 **Distribution of diagnoses in patients of ≥5 years with respiratory symptoms attending health facilities staffed with doctors in nine countries[a]**

Diagnosis	Number	%
Acute respiratory diseases		
AURI	12 915	50.5
ALRI:		
– no pneumonia	6 886	26.9
– pneumonia	722	2.8
ARI – no specification	12	0.05
Subtotal	20 535	80.2
Tuberculosis		
Pulmonary TB:		
– smear-positive	223	
– smear-negative	66	
Subtotal	289	1.2 (1.4[b])
Chronic respiratory diseases		
Asthma	1 756	6.9
Chronic bronchitis/COPD	1 186	4.6
Other diseases	1 819	7.1
Subtotal	4 761	18.6
Total	25 585	100.0

[a] Argentina, Chile, Côte d'Ivoire, Guinea, Kyrgyzstan, Morocco (two settings), Nepal, Peru and Thailand.

[b] Peru and Kyrgyzstan did not report the number of pulmonary TB cases. If the 5642 respiratory patients of these two countries are excluded from the total, the proportion of pulmonary TB among all the respiratory conditions is 1.4%.

Source: Ottmani S et al. *Respiratory care in primary care services: a survey in 9 countries*. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.333).

Treatment practices

Measurement of the burden of respiratory diseases should also include information on current treatment practices in the case-management of outpatients with respiratory symptoms.

Table 2.11 shows the medications prescribed by doctors at first-level health facilities to patients with respiratory symptoms in eight countries of the WHO survey. The average number of drugs prescribed per patient was 1.6 (range 1.1–2.4). Antibiotics were the most frequently prescribed medication: 66.5% of respiratory patients were prescribed antibiotics, and antibiotics represented 40.8% of all drugs prescribed for respiratory patients. Antipyretics were the second most frequently prescribed medication (36% of patients and 22.5% of prescribed drugs).

Table 2.11 **Drugs prescribed for outpatients with respiratory symptoms by doctors at first-level facilities in eight developing countries[a]**

Medication	Drugs prescribed		Percentage of 23 538 respiratory patients
	Number	**Percentage**	
Total	37 728	100.0	
Antibiotics	15 406	40.8	65.5
Aspirin or paracetamol	8 492	22.5	36.0
Bronchodilators	3 173	8.4	13.5
Cough medicines	2 888	7.7	12.3
Antimalarials	1 808	4.8	7.7
Non-steroidal anti-inflammatories	1 740	4.6	7.4
Decongestants	1 505	4.0	6.4
Steroids	1 259	3.3	5.3
Vitamins	435	1.2	1.8
Other medications	1 022	2.7	4.3
Drugs prescribed/patient		1.6	
Range		1.1–2.4	

[a] Argentina, Chile, Côte d'Ivoire, Guinea, Kyrgyzstan, Morocco (two settings), Nepal and Peru.

Source: Ottmani S et al. *Respiratory care in primary care services: a survey in 9 countries.* Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.333).

The distribution of antibiotic prescriptions per respiratory illness category in the WHO survey is presented in Table 2.12. The data indicate that antibiotics are over-prescribed, particularly for ARIs. On average, two-thirds of patients diagnosed with an upper or lower respiratory infection and one-third of those diagnosed with CRD received an antibiotic prescription.

Most of the frequent causes of outpatient attendance for ARIs are self-limiting and antibiotic prescriptions may have limited or no value in their evolution. Antibiotics are not indicated in CRDs unless there are signs of infectious exacerbation.

Table 2.12 **Number of patients with a respiratory illness, excluding TB, treated with antibiotics by doctors at first-level health facilities in six developing countries[a]**

Respiratory illness[b]	Total outpatients	Patients treated with antibiotics	
		Number	Percentage (range)
AURI	10 413	7 011	67.3 (33.2–94.5)
ALRI	4 788	3 434	71.7 (49.9–83.5)
CRD	2 517	827	32.9 (12.2–63.1)

[a] Chile, Kyrgyzstan, Morocco (2 settings), Nepal, Peru and Thailand.

[b] AURI: acute upper respiratory infection
  ALRI: acute lower respiratory infection
  CRD: chronic respiratory disease.

Source: Ottmani S et al. *Respiratory care in primary care services: a survey in 9 countries.* Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.333).

Chapter 3

Assessing the capabilities of the health infrastructure to implement the PAL strategy
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Introduction

Efficient adaptation and development of the PAL strategy in a country depends upon situation analysis concerning:

  ☐ demographic, socioeconomic and epidemiological information;
  ☐ current status of the TB programme;
  ☐ burden of respiratory diseases in the country;
  ☐ health system infrastructure and resources;
  ☐ clinical practices regarding respiratory diseases.

The situation analysis should be undertaken by the MOH with the active involvement of the NWG on PAL. Technical assistance with this analysis can be requested from WHO or other international agencies.

Demographic, socioeconomic and epidemiological information

The description of the country's current demographic pattern, socioeconomic conditions and general epidemiological situation should be relevant for the assessment of the level of epidemiological transition and the relative weight of the burden of communicable and non-communicable diseases.

Demographic data:

  ☐ size of the population;
  ☐ age and sex composition of the population, proportion of the population aged under 15 years and that aged 60 years and over;
  ☐ distribution of population by health administrative jurisdiction;
  ☐ urban and rural distribution;
  ☐ birth rate;
  ☐ mortality rate, infant mortality, maternal mortality;
  ☐ population growth rate;
  ☐ life expectancy at birth.

Socioeconomic data:

  ☐ per capita gross domestic product;
  ☐ classification of country by income: low-, lower middle-, upper middle- or high-income;
  ☐ literacy rate;
  ☐ total per capita annual health expenditure, including public- and private-sector expenditures and foreign aid.

General epidemiological situation

Epidemiological transition defines the occurrence of a shift in predominance from the prevalence of communicable diseases and malnutrition to the prevalence of chronic noncommunicable and degenerative diseases. Whether or not a country is in epidemiological transition, and at what level, is determined from the current general epidemiological, demographic and socioeconomic data.

The effect of the level of epidemiological transition on patterns of respiratory diseases in the adult population of different settings is illustrated in Table 3.1.In developed countries, the epidemiological transition has been completed; in developing countries it is often incomplete or at an early stage. Although the burden of respiratory conditions is important in all settings, the relative contribution of specific respiratory conditions to the overall respiratory morbidity burden varies across settings. The respiratory conditions prevalent in post-transitional countries are mainly noncommunicable, accounting for 73.5% of the total respiratory disease burden. Transitional countries face a "double burden": a relatively high proportion (32.4%) of communicable respiratory conditions coexist with a high proportion (58.0%) of conditions with noncommunicable causes. Before, or at a very early stage of, epidemiological transition, countries present the "classical" pattern of a great predominance of communicable respiratory conditions, which amounts to 59.4% of the total respiratory burden. Settings with a high prevalence of HIV infection have the highest proportion of communicable respiratory conditions, which contribute 70.8% of the total respiratory burden.

Current status of the TB programme

Assessment of the current status of the TB problem and of progress made in TB control should include the following information:

- *Magnitude of the TB problem:*
    - total number of notified TB cases and rates per 100 000 population per year in the past 15–20 years for the whole country and across regions;
    - distribution of TB cases and trends by age and sex;
    - classification of cases by bacteriological status and disease localization;
    - prevalence and trends of HIV infection among TB cases;
    - prevalence and trends of mycobacterial drug resistance among new and previously treated patients.

Table 3.1 **Estimates of burden of respiratory disease in the population over 15 years of age (expressed as DALYᵃ rates per 100 000 population), by epidemiological profiles/socioeconomic status, for 2000** (adapted from WHO data)

Epidemiological profile	High child, very high adult mortality	High child, high adult mortality	Low child, high adult and low child, low adult mortality	Very low child, very low adult mortality
Economic profile	Low/middle-income countries	Low-income countries	Middle-income countries	High-income countries
Level of epidemiological transition	No transition High HIV prevalence	No transition	In transition	Transition completed
Total respiratory burden	4471.5	3372.3	2212.2	1541.4
Total communicable respiratory burden	3167.9	2002.8	715.9	197.9
As % of total respiratory burden	70.8%	59.4%	32.4%	12.8%
Upper respiratory infections	5.9	16.0	11.6	5.8
Lower respiratory infections	1270.7	549.8	203.8	176.1
Tuberculosis	1891.3	1437.0	500.5	16.0
Total noncommunicable respiratory burden	717.8	1031.2	1283.3	1132.5
As % of total respiratory burden	16.0%	30.6%	58.0%	73.5%
Asthma	334.7	281.6	165.1	149.9
COPD	301.9	616.2	835.0	504.1
Trachea, bronchus, lung cancers	81.2	133.4	283.2	478.5
Other respiratory diseases	585.8	338.3	213.0	211.0
As % of total respiratory burden	13.2%	10.0%	9.6%	13.7%

*DALY = disability-adjusted life year, a unit measuring the present value of the future years of disability-free life that are lost as the result of the premature deaths or cases of disability occurring in a particular year.

- *TB control programme*
  - □ government commitment to TB control;
  - □ national Stop TB Strategy implementation plan;
  - □ integration of TB control into the PHC system;
  - □ international and national partnership network for TB control;
  - □ TB programme policies, structure, staff and activities at central, regional and district levels;
  - □ population coverage by the DOTS strategy;
  - □ type of TB control activities carried out at first-level health facilities and at the referral level;
  - □ degree of achievement of the TB programme strategic targets on case-detection and pulmonary TB bacteriological confirmation rate;
  - □ treatment outcomes in smear-positive pulmonary cases – treatment success, default rates, case-fatality rates;
  - □ TB laboratory network;
  - □ TB drugs management system;
  - □ TB recording and reporting information system.

Burden of respiratory diseases in the community

Available data from routine information systems and other existing sources (morbidity surveys, research papers) should be reviewed to describe the burden of respiratory conditions in the community. The assessment should include:

  - □ total mortality and proportional mortality from respiratory conditions;
  - □ distribution of mortality from respiratory conditions by cause, age groups, sex and region;
  - □ prevalence of respiratory conditions among patients attending PHC services;
  - □ distribution of respiratory conditions by cause, age group and sex in outpatient services;
  - □ prevalence and distribution of respiratory conditions among hospitalized patients;
  - □ prevalence of risk factors for respiratory conditions – smoking, malnutrition, HIV infection, indoor air pollution, occupational risk factors;
  - □ ranking of respiratory conditions among all health problems in outpatient and inpatient health services.

Information on the health system

An important step in the early phase of PAL strategy development is to assess the capabilities of the health infrastructure to implement PAL activities. There is thus a need for information on the institutions that provide general health services, their organization, the number, type and distribution of health facilities, the available resources (equipment, drugs, human capabilities), access to and use of health services by the population. Information should therefore be gathered on:

  - □ national and regional government health infrastructure;
  - □ local health services – district or municipality or county;
  - □ social security institutions;

☐ non-profit NGOs that provide health services;

☐ private sector;

☐ others.

The description of the health infrastructure should include the same kind of information for all the institutions. The government services may have different independent administrations – MOH, ministry of education, ministry of justice, etc. Countries may have national, state (or provincial or regional) and local services.

When based on the principles of PHC, the service delivery setting in industrialized and developing countries is very similar in organizational set-up and hierarchical structure. There is increasing specialization and complexity from the periphery to the central level, in which the elements are mutually interrelated, serving a defined population in a defined geographical area (often referred to as a "district"). Commonly, the levels distinguished in a district health system are: individual, family, community, first-level facility and first referral facility. At the first-level facility, a multipurpose health worker (general practitioner, clinical officer, medical assistant or nurse) provides services of health promotion, disease prevention and case-management. At first referral level there are general practitioners, sometimes specialists, and basic laboratory and radiology services.

Several social insurance institutions may provide health services to members, such as government employees, social security programme participants and workers in large industries, mines and agricultural enterprises, who pay a monthly fee. The data collected should also include information on the network of health facilities run by non-profit NGOs.

The most relevant information to be collected from the MOH includes the following:

• Public health sector policies in relation to: programme and budget priorities, integration of programmes, management of health care, planning and financial decentralization, essential package of health services, community involvement, contribution of external financial aid to the health sector.

• Managerial organization in the form of an organizational chart of the MOH at central, regional and district levels; lines of authority; position of the TB, chronic diseases and HIV/AIDS programmes in the chart at each level, and linkages with PHC.

• Managerial activities to implement interventions, such as training and supervision. These activities are often programme-specific; they are rarely integrated among the different programmes.

The following information should be collected from all public, semi-public and non-profit institutions that provide health services:

• Structure of general health facilities: number and distribution of hospitals by level of complexity, health centres, health posts; average catchment population for district hospitals, health centres and health posts. Maps marking the location of health units and major roads.

• Categories of health workers managing patients with respiratory diseases at district hospitals, health centres and health posts: specialists, general physicians, nurses, other paramedical staff and community health workers.

• Specialized services for respiratory diseases: outpatient specialists at hospitals and health centres.

- Availability and condition of equipment and materials for diagnosis of respiratory diseases at hospitals and health centres: radiology, pulse oximetry, spirometry, peak flow meters, bacteriological laboratory and other relevant facilities.

- Availability and quantities of drugs used for respiratory diseases and smoking cessation therapy, which are included in the national list of essential drugs.

- Availability of equipment for treatment of respiratory diseases at hospitals and health centres: oxygen sources, nebulizers, spacers for inhalation therapy and other equipment.

- Usual referral practices at first-level health facilities for patients who need specialized or hospital care. Types of transportation.

- Description of health information systems at health posts and health centres: type of information collected, frequency, forms and periodic reports.

- Training needs for personnel at peripheral health units, district hospitals and laboratories.

Table 3.2 shows a format for presenting a summary of the information on type of staff and facilities available at different levels of the health services infrastructure. It is suitable for use by any institution – health and other ministries, local health services, social security or NGOs.

Clinical practices regarding respiratory diseases

In most cases, the available sources provide complete information on case-management of TB and some information on current clinical practices in the management of respiratory diseases at outpatient services, especially health centres and health posts. If the information on case-management of respiratory conditions other than TB is insufficient or inaccurate, further information can be collected through visits to health centres, health posts and district hospitals and in meetings with clinicians and nurses.

The relevant information on clinical practices should include:

- existence of guidelines on case-management of ARI for patients of all ages diagnosed with pneumonia, and for those with asthma, chronic bronchitis and COPD;
- criteria for the referral of patients with symptoms and signs of respiratory conditions;
- clinical criteria for the diagnosis of pneumonia and asthma and the possibility of COPD;
- availability of equipment for the diagnosis of respiratory conditions such as asthma and COPD;
- drugs commonly used for the treatment of ARI, pneumonia, asthma, chronic bronchitis and COPD;
- cost of drugs used in the treatment of respiratory conditions;
- availability of equipment for the treatment of asthma and COPD exacerbations;
- criteria for the follow-up of CRD cases;
- registration system for CRD cases.

Table 3.2 **Summary of available staff and facilities in different health units of the ministry of health**

Type of health unit	Health post	Health centre	Other (TB unit or chest clinic)	First-level hospital	Second-level hospital
Type of staff: – nurse – general practitioner – specialist – other					
Diagnosis: – TB laboratory – bacteriology lab. – X-ray – peak flow meter – spirometer – other					
Treatment resources: – oxygen – nebulizers – other					
Hospital beds: – general – pulmonary					
Forms: – outpatient register – TB treatment card – TB register – chronic disease treatment card – chronic disease register – other					
Observations					

Conclusions of the situation analysis

Collection of all the relevant information – demography, general epidemiology, TB programme, health infrastructure and clinical practices regarding respiratory conditions – should be followed by an analysis of whether the PAL strategy is compatible and consistent with existing health sector policies and capabilities. The outcome of the analysis should be a clear identification of existing problems and constraints in the management of respiratory diseases at PHC services, the assets that favour implementation of the PAL strategy, the challenges that PAL development needs to overcome, and the specific objectives to be achieved by the PAL strategy.

Problems and constraints

The following are the commonest problems found by situation analysis of the case-management of respiratory conditions at first-level health facilities in developing countries:

- ☐ poor-quality diagnosis of respiratory conditions;
- ☐ insufficient investigation to allow diagnosis of smear-negative pulmonary TB;
- ☐ absence of guidelines on criteria for requesting laboratory, radiology and pulmonary functional examinations;
- ☐ lack of equipment for pulmonary function examinations;
- ☐ inadequate criteria for referral of cases for further assessment or hospitalization;
- ☐ inappropriate drug prescriptions;
- ☐ limited availability of inhaled bronchodilator and corticosteroid medications and inability of patients to afford to purchase them;
- ☐ Insufficient availability of oxygen sources;
- ☐ lack of guidelines on follow-up of chronic respiratory diseases.

Assets for PAL development

The situation analysis should identify the most important assets that favour the development of the PAL strategy, such as:

- ☐ government decision to include PAL development as an integral part of the strategic plan to control TB;
- ☐ designation of a focal point in the MOH for coordination of PAL development activities;
- ☐ establishment of a national working group on PAL development, with broad representation of the interested parties;
- ☐ clear description of the magnitude of the burden of respiratory diseases at PHC level;
- ☐ effective organization of PHC services and continuing training and supervision programmes for PHC workers;
- ☐ effective organization of the DOTS strategy for TB control;
- ☐ extended health-management information system within the PHC service network;
- ☐ essential drugs list available and regularly updated;
- ☐ existing guidelines on case-management of asthma and COPD;

☐ willingness of PHC workers to improve their knowledge and skills for case-management of respiratory conditions.

Challenges of PAL development

The situation analysis should also identify the most relevant challenges that PAL strategy development will face. The following challenges were often confronted by the countries that have started implementing PAL activities:

☐ the PAL strategy should be considered and developed in line with national health priorities and within national health policies;

☐ PAL strategy inputs (training, drugs, equipment) should be clearly defined in the context of existing resources;

☐ health staff should be trained in smoking cessation and treatment of tobacco dependence;

☐ antibiotics should not be used to treat ARIs that are believed to be caused by viruses;

☐ equipment essential for PAL implementation must be available in health facilities;

☐ medications for inhalation therapy should be accessible to CRD patients;

☐ integration of smoking cessation and prevention activities within the provision of PAL services;

☐ an effective referral and counter-referral system should be organized;

☐ teaching of PAL guidelines should be introduced into existing continuous medical and nursing education programmes.

Objectives of the PAL strategy

Box 3.3 presents the objectives of the PAL strategy divided into three areas: epidemiology (impact objectives), improvement of case-management (care quality objectives) and improvement of programme management (managerial objectives). It does not include all the relevant objectives of TB control – only those that can be better achieved in the context of the PAL strategy implementation.

Expected outcomes of the PAL strategy

If properly implemented, the PAL strategy is expected to produce qualitative and quantitative benefits that contribute to strengthening the PHC system (Box 3.4), increasing the effectiveness of the Stop TB Strategy for TB control (Box 3.5), and enhancing the competence of health workers at peripheral health units (Box 3.6).

Box 3.3 **Main objectives of the PAL strategy**	
Category	**Objectives**
Managerial objectives	Improve the efficiency of PHC services in managing respiratory diseases through:
	☐ standardization of diagnostic procedures and requests for complementary examinations (laboratory, radiology, pulmonary functional tests);
	☐ standardization of drug prescription (antibiotics, bronchodilators, corticosteroids, antitussives);
	☐ formulation of guidelines on referral criteria for further assessment or hospitalization;
	☐ definition of parameters for planning and budget;
	☐ selection of monitoring and evaluation indicators;
	☐ improvement of the cost–effectiveness of the case-management of respiratory diseases as a consequence of better care quality.
Quality of care objectives	☐ Improve the selection of patients for case-detection of TB.
	☐ Reduce the proportion of smear-negative pulmonary TB among all TB cases by improving the diagnosis of pulmonary TB.
	☐ Improve TB case-holding.
	☐ Improve case-management of ARIs, particularly those caused or complicated by bacterial agents.
	☐ Improve the case-management of asthma attacks and COPD exacerbations.
	☐ Improve the follow-up of the long-term treatment of asthma and COPD prescribed by the specialist.
Impact objectives	☐ Reduce the average delay in the diagnosis of pulmonary TB by the health services.
	☐ Reduce case-fatality from pneumonia.
	☐ Prevent bacterial complications of AURIs.
	☐ Prolong the average duration of the periods between crises in asthma patients.
	☐ Prolong the average duration of the periods between exacerbations in COPD patients.
	☐ Reduce tobacco consumption among patients with respiratory illnesses.

**Box 3.4 Expected benefits of PAL implementation strategy
for the PHC system**

PAL strategy implementation will help to strengthen health services delivery and management of the PHC system through:

- ☐ Feasible and sound technical guidelines on diagnosis and treatment of common respiratory conditions among patients attending health posts, health centres and district hospitals.
- ☐ Supply of essential equipment for the diagnosis of asthma and COPD.
- ☐ Standardization of treatment of ARIs that will entail the appropriate use of antibiotics
- ☐ Increased use of inhaled bronchodilators and inhaled steroids for treatment of asthma and COPD.
- ☐ Establishment of a referral and counter-referral system for the case-management of respiratory diseases.
- ☐ Improvement of the health management information system.
- ☐ Promotion of health-education activities for the prevention of respiratory conditions.

**Box 3.5 Expected benefits of PAL strategy implementation
for tuberculosis case-detection and diagnosis**

PAL strategy implementation will help strengthen the coordination between TB control and the PHC system and will improve the process of detecting and diagnosing TB through:

- ☐ Identification of TB cases among patients who report a short duration of respiratory symptoms and among severely ill patients.
- ☐ Better quality of differential diagnosis in patients with respiratory symptoms and with smear-negative microscopy, particularly in settings of high HIV prevalence and in units with easy access to chest radiography.
- ☐ Systematic follow-up of TB suspects until a plausible diagnosis has been made.
- ☐ Clear guidelines on systematic TB diagnostic procedures in patients with chronic respiratory symptoms.
- ☐ Intensified supervision of TB and PAL case-management activities.
- ☐ Increased or sustained visibility of TB among emerging ARIs and CRDs, particularly asthma and COPD.
- ☐ Strengthening of the links between the health management information system and the TB information system.

Box 3.6 Potential benefits of PAL strategy implementation for health workers

Implementation of the PAL strategy should bring benefits for health staff working at first-level health facilities and first referral hospitals. The potential benefits for health workers are:

- ☐ Increased motivation and competence in the management of respiratory diseases.
- ☐ Application of experience gained in case-management of TB to the management of CRDs.
- ☐ Strengthened connections between workers at first-level health facilities and professionals at first referral level.

Chapter 4

Developing standard PAL clinical guidelines

Working methods

Who develops the technical guidelines?

The NWG has the responsibility of developing the PAL guidelines. The guidelines should be based on international standards for clinical care of respiratory diseases that have gained general acceptance because they are founded on sound evidence. They cannot cover every clinical situation but should address those most frequently encountered in PHC services. They should be adapted to national conditions and health policy priorities, bearing in mind the organization of district health services and the skills of the health staff (general practitioners, medical assistants, nurses) who will use them.

The guidelines should be field-tested for feasibility and acceptability before they are officially approved. To facilitate its task, the NWG on PAL may establish a subgroup to draft the technical guidelines.

Why develop new guidelines?

New guidelines are needed because existing documents usually do not allow the standardized, integrated case-management of patients who attend first-level health facilities with respiratory symptoms. In first-level health facilities, simple guidelines and algorithms are needed for rapid triage of patients, appropriate decision-making and effective coordination with the referral services.

An integrated approach to certain respiratory diseases in children under 5 years of age (mainly ARIs but also asthma) has been developed in the programmes on integrated management of childhood illness (IMCI). However, children older than 5 years and adults are included in existing technical guidelines only in the context of vertical programmes or academic statements, in which each disease is presented as a separate entity (community-acquired pneumonia, tuberculosis, asthma, COPD). In general, first-level health facilities are ill-prepared to deal with the large number of cases of respiratory disease other than TB. Far too few people with asthma or COPD are receiving appropriate care in many developing countries, particularly at this level. Inappropriate management of these conditions is common. Meeting the demand for lung health care requires standardized guidelines and managerial support for case-management at first-level and first-referral health facilities .

The PAL strategy focuses not on the disease but on the patient who attends first-level health facilities or the first referral level because of respiratory symptoms. That is, PAL is a patient-centred, rather than a disease-centred, approach.

Are the clinical guidelines useful?

From a clinical perspective, guidelines are useful aids in appropriate decision-making by PHC professionals working in outpatient services. Scientifically valid and reliable guidelines help to improve outpatient outcomes and make the process of care more efficient. The introduction of standardized guidelines requires active educational interventions such as training courses, frequent supervision and close monitoring. The PAL guidelines should:

- describe the standardized case-management of the most frequent respiratory conditions;
- improve qualitatively the selection of patients identified as respiratory cases whose TB status should be assessed (i.e. TB suspects);
- provide guidance on case-management of TB suspects with sputum smear-negative microscopy to reduce the false diagnosis of bacteriologically negative pulmonary TB, particularly in health units with facilities for chest radiology and in settings with high HIV prevalence;
- lead to prescription of appropriate drugs and discourage the use of ineffective drugs;
- define precise criteria for referral of cases to a higher level for hospitalization, further clinical assessment or complementary investigations;
- establish criteria for counter-referral of patients and follow-up of ambulatory treatment for TB and the most frequent CRDs (asthma, chronic bronchitis, COPD).

From a public health point of view, guidelines can help to reduce both inappropriate clinical practices and inequities and inefficiencies in the health system. The guidelines on integrated case-management of respiratory diseases will:

- help health workers to meet the needs and expectations of patients and thus contribute to increased confidence in the health system;
- establish a definitive list of the equipment necessary to carry out the directives described in the guidelines;
- specify a list of drugs, including smoking cessation drugs, needed to provide care to patients as formulated in the guidelines;
- clearly describe the tasks to be carried out by health workers at different levels, particularly within the district health system;
- improve the use of resources and staff time by establishing clear criteria for drug prescriptions, referral for complementary investigations and referral for hospitalization;
- facilitate coordination between the first-level health facility and first referral services within a district;
- contribute to improving management of the health resources available within the district health system.

To whom are the guidelines addressed?

These guidelines are addressed to health staff working in district health services. To facilitate their development and presentation, the guidelines might be divided into two separate, but fully consistent, manuals:

- A manual for general practitioners, medical assistants and nurses working at first-level health facilities (health posts, dispensaries, health centres) without laboratory and radiology services. At this level, the guidelines should be based on a minimum number of clinical signs and symptoms to determine the correct action: urgent referral to a hospital of patients who have severe respiratory conditions; referral of patients who need further assessment or complementary investigations for purposes of diagnosis or modification of their treatment; home treatment with specific medications or with supportive measures.

- A manual for general practitioners and specialists (pulmonologists, paediatricians, ear, nose and throat physicians) at referral health services associated with the

district hospital (emergencies, specialized outpatient services, inpatient services), with access to clinical laboratory, radiology and respiratory function tests. The health staff should determine a precise diagnosis in patients with severe ARIs, TB suspects and patients with CRDs and prescribe a treatment and follow-up plan for those who require prolonged care. In addition, the referral staff should treat respiratory emergencies, hospitalize severely ill patients, and refer to a second referral level those patients who require more specialized investigations or care.

On what principles should the guidelines for first-level health facilities be based?

First-level health facilities are the link between the health system and the community, and the success of the health system depends largely on their performance. The tasks of the health workers at this level are:

- ☐ *technical*, directly related to the interaction between patients and healthy individuals in the community; and
- ☐ *managerial,* related to the running of the facility (e.g. drugs stock maintenance, management of the information system).

The demands for health services made on the multipurpose health worker at these facilities is complex, implying important decisions on referral or local treatment for all types of illness of all degrees of severity. When health workers have neither laboratory nor X-ray facilities on site, their decisions on respiratory diseases should be based on a syndromic approach to cases.

To ensure their usefulness, the guidelines on respiratory diseases for first-level health facilities should therefore be based on the following principles:

- Integrating the case-management of the most frequent respiratory conditions.

- Providing details on performance of activities (task-oriented guidelines).

- Promoting affordable and feasible directives by taking into account:

  - ☐ the diagnostic and treatment limitations of first-level health facilities; and
  - ☐ the qualifications and competence of the health workers at those facilities.

- Adopting an algorithmic or semi-algorithmic format in which the grouping of signs and symptoms is used to define syndromes and determine the action to be taken (referral for hospitalization, further assessment or complementary investigations, specific treatment at home, supportive measures at home).

- Ensuring that the signs and symptoms included in the clinical guidelines are sufficiently sensitive and specific. There is widespread consensus that standard clinical algorithms, based on experience, research, expert clinical opinion and proper validation in field-testing, are more effective than individualized case-management at first-level health facilities with limited diagnostic resources;

- Selecting the most cost-effective therapeutic measures. The directives should not offer several alternatives for treatment but focus as much as possible on a simple decision; if an alternative is proposed, the circumstances in which it should be used should be explained.

- Specifying the prescription of drugs that are, or can be, included in the national list of essential drugs.

- Giving practical treatment recommendations to patients who will be treated at home, including how to take oral drugs and how to use inhalers.

- Stressing communication of key health messages on signs that indicate that the patient should return immediately to the health unit, and on when to return for scheduled follow-up.

- Promoting preventive measures, particularly advice on why and how to stop smoking.

What documents are needed to prepare the technical guidelines?

The NWG – or the subgroup charged with developing the technical guidelines – should gather background documents containing:

- the main international technical references (see Annex);

- country documents: national technical guidelines on TB control, HIV/AIDS programme, control of respiratory infections; recommendations on the use of antibiotics; guidelines on case-management of asthma and COPD; national list of essential drugs; list of medical equipment available at first-level health facilities and first-referral services; existing register of the health management information system.

It is important that the technical guidelines take into account existing national guidelines in order either to refer to them in the PAL guideline or to ask the programmes or departments concerned to update them in accordance with the most recent international technical recommendations.

Technical guidelines for first-level health facility staff

Depending on the organization of general health services, first-level health services are delivered by general practitioners, clinical officers, medical assistants or nurses. The PAL guidelines for these personnel should address the essential elements of care for the respiratory conditions most frequently encountered at this level. Various country models of PAL guidelines exist that can be adapted to the health environment of other countries (see examples in the Annex).

The action of the first-level health facility should be effectively supported by:

- The first referral level facilities, where:

  - specific diagnoses can be reached with the help of radiology, clinical laboratory and pulmonary function tests; and
  - severe cases can be managed appropriately.

- The district (or regional) health management level, which is responsible for training, supervision, management of equipment, materials and drug supplies, monitoring, evaluation and budget support.

In assessing any patient with a respiratory problem, the first step is to determine whether this is an acute problem, or whether the patient is making a first visit or a follow-up visit for a chronic problem.

The guide can be structured in different practical ways and may include such components as:

- assessment and classification of an acute problem;
- clinical respiratory signs of possible HIV infection;
- treatment guidelines for acute problems;
- case-management of respiratory diseases that need prolonged care.

Assessment and classification of an acute problem

Assessing a patient means obtaining information about the patient's illness by asking questions, making simple measurements (e.g. temperature) and, at times, listening to the patient's chest. For respiratory diseases, it is practical to present the guidelines divided into two closely inter-linked sets – one for patients presenting with cough and/or difficult breathing (as the key entry points for assessing diseases of the lower respiratory tract) and another for patients with symptoms and signs of upper respiratory tract involvement.

At first-level health facilities, an action-oriented classification should be used rather than specific disease diagnosis. Each illness is classified according to whether it requires urgent referral for hospitalization or for further assessment, specific ambulatory medical treatment and advice, or simple advice on supportive measures and home care.

If the patient has an acute problem, the health worker should look immediately for the presence of danger symptoms or signs suggesting a threat to the vital prognosis and calling for urgent measures as well as referral for hospitalization, if feasible. If the patient has no symptoms or signs of severity, the guidelines should direct the health worker to three alternatives on the basis of the presence or absence of the following characteristics:

- patient with no wheeze and no known COPD;
- patient with known COPD without wheeze; and
- any patient with wheeze.

Patients with no severity symptoms, no wheeze and no known COPD

If the patient has no severity symptoms or signs, no wheeze and no known COPD, the next step is to assess whether there are symptoms or signs suggesting non-severe pneumonia, such as rapid breathing, fever, chest pain associated with breathing (pleuritic chest pain), and localized crackles at auscultation (if the health worker has been trained to use a stethoscope).

If there are no symptoms or signs of non-severe pneumonia, other possible diagnoses should be considered depending on the duration of symptoms.

- If the duration of symptoms is less than 2 (or 3) weeks, the assessment should be based on the presence and characteristics of expectoration (bloody, purulent or mucoid), the presence of symptoms of the upper respiratory tract, the presence of nonspecific symptoms (such as fever, tiredness, myalgia), or the existence of influenza epidemic context. The guide should specify whether the patient needs to be referred to a higher level of health care for further assessment or can be locally managed and treated with clearly identified procedures.

- If the symptoms are of 2 (or 3) weeks' duration or more, at least two samples of sputum should be systematically examined for AFB in view of a possible diagnosis of TB. The patient may be locally managed or referred to a higher level of health care depending on the presence or absence of symptoms such as difficult breathing, weight loss, haemoptysis, and recurrent or severe episodes of wheezing.

Any patient with dyspnoea and wheeze

Any case with dyspnoea and wheeze should first be classified and then treated to alleviate dyspnoea. The case may be a patient with known asthma who has a recurrent episode of wheeze (asthma exacerbation), a patient with COPD who

wheezes (COPD exacerbation), or a patient with an episode of wheeze with no clear diagnosis. Wheeze is a clinical manifestation common in most patients with an asthma exacerbation and in many, but not all, patients with COPD exacerbations. COPD patients with acute dyspnoea and wheeze should be managed initially in the same way as patients with asthma exacerbations. With treatment, patients usually improve quickly.

There are three possible classifications for an episode of dyspnoea with wheeze – severe, moderate or mild; these correspond to three of the four grades of severity of asthma exacerbations – severe, moderate and mild (the fourth grade being imminent respiratory arrest in which there is no wheeze). The key clinical signs for classifying severity of asthma attack are described in various international guidelines (see Annex). If the health facility is equipped with a peak flow meter and the health worker has been trained in its use, the classification should also be based on the results of peak flow measurements. The use of peak expiratory flow (PEF) measurement to classify asthma attack is described in many international guides (see Annex).

If the episode is severe, the patient needs immediate and continuous treatment and may require urgent referral to a hospital.

The guidelines should clearly describe how the patient should be treated, assessed and followed locally in the health facility and in what circumstances she or he should be referred to higher-level health care.

Known COPD patients with an acute episode

If a known COPD patient has an acute episode with cough or difficult breathing (with or without wheeze), the PAL guidelines should indicate how the severity of this episode should be assessed on the basis of clinical signs and symptoms specified in international recommendations. The guidelines should also clearly describe the management procedures for each severity category.

Clinical respiratory signs of possible HIV infection

The PAL guidelines for first-level health facilities should indicate when HIV infection should be suspected in a patient with respiratory symptoms, particularly in settings of high HIV prevalence. As HIV infection progresses and immunity declines, patients become more susceptible to infections in general. These infections can occur at any stage of progression of HIV infection and immunosuppression. Some patients may develop constitutional symptoms (unexplained fever and weight loss); some patients develop chronic diarrhoea; and some patients have respiratory infectious diseases such as TB, pneumonia, bacterial sinusitis or recurrent respiratory infections. If HIV infection is suspected, the health worker should refer the patient for HIV testing and counselling. This section of the PAL guidelines should be developed in collaboration with the national HIV/AIDS programme and should include the relevant directives of that programme.

Treatment guidelines for acute problems

Practical details regarding the standard treatment for acute conditions that will be managed at the first-level health facility should be included in the PAL guidelines. The guidelines should be consistent with:

  ☐ international recommendations on the use of antibiotics for ARI and the treatment of pneumonia;
  ☐ the Stop TB Strategy for control of TB;

- international recommendations for management of asthma, such as those of the Global Initiative for Asthma (GINA);
- international recommendations for management of COPD, such as those of the Global Initiative for Chronic Obstructive Lung Disease (GOLD).

The guidelines should specify the presentation, doses, route of administration and time interval between doses for antibiotics, anti-TB drugs, inhaled bronchodilators, oral and inhaled corticosteroids, and analgesics. All the specified drugs should be included in the national list of essential drugs. The guidelines should also specify the urgent treatment to be given, if needed, to severely ill patients before and during referral to hospital.

Practical instructions should be given to health workers about advising patients on compliance with prescribed medication, self-management of asthma, use of metered-dose inhalers, choice of safe, soothing remedies for colds and coughs, protection against exposure to risk factors (with major emphasis on smoking cessation and triggers for asthma exacerbations) and about providing support to patients and families.

The guidelines should also indicate, for every condition, when patients must return to the health facility for follow-up, including routine follow-up of patients with known asthma or COPD and directly observed treatment of TB.

Case-management of respiratory diseases that need prolonged care

The PAL guidelines should describe how to deal with respiratory illnesses that are often encountered in first-level health facilities and that need prolonged care. Besides TB, the most frequent such diseases are persistent asthma and COPD. Other CRDs, such as bronchiectasis, pneumoconiosis or lung cancer, which are less frequent at this level but which also need prolonged care, might be considered in the guidelines in terms of appropriate referral and for palliative care at PHC level when indicated.

Management of tuberculosis

The section of the guidelines concerned with management of TB should be in line with the DOTS strategy and developed in close collaboration with the NTP. The TB case-management described in the PAL guidelines must reflect the directives of the NTP regarding:

- identification of patients who needs to be investigated for TB;
- definitions of TB cases and criteria for establishing the diagnosis of, for example, smear-positive and smear-negative pulmonary TB;
- role of medical staff at first-level health facilities in establishing the diagnosis of TB;
- categories of standardized TB treatment regimens and the forms of TB in which they are indicated;
- the roles of medical and non-medical staff in prescribing TB drugs and providing them to patients, directly observed treatment, TB patient follow-up and treatment, and tracing of defaulters;
- procedures used in the NTP recording and reporting system and the role of staff at first-level health facilities in monitoring TB patients, including assessment of bacteriological status at the various stages of treatment.

In countries with a high prevalence of HIV infection, a significant proportion of patients have TB/HIV co-infection. In these countries, the national TB and HIV/AIDS programmes should establish clear directives, based on international

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recommendations, for managing co-infected patients. Depending on country-specific factors, these directives may be included in the guidelines for managing TB, HIV or both. In high-burden HIV settings, such directives need to be considered in the PAL guidelines.

PAL guidelines should include practical instructions for staff in charge of TB case treatment. For example, health workers should:

- give educational advice to the patient together with a relative; explain the disease, its transmission, necessary examination of contacts;
- emphasize that the disease can be cured only if anti-TB drugs are taken regularly;
- organize the administration of drugs under direct observation in the initial phase and, if possible during the continuation phase;
- organize the investigation of TB contacts, targeting as priorities contacts under 5 years of age and those with an underlying condition such as HIV-positive status or diabetes;
- organize control of patients' adherence to treatment;
- organize tracing of patients in case of default/delay in attending a scheduled visit;
- when indicated, explore the possibility of community support for TB patients;
- check the results of bacteriological examination of two sputum samples at the end of the 2nd month, the 5th month and the last month of treatment;
- complete TB treatment cards and report the information on treatment outcomes to the district TB register.

Management of asthma

Demand for care from asthma patients is very common in first-level health facilities. The PAL guidelines should therefore include the key elements of asthma treatment and clearly highlight the role of the first-level health facility in case-management. In some countries, specific guidelines on managing asthma may already have been developed by a professional medical society, university hospitals or a department of the MOH, usually based on international recommendations such as those provided by GINA and usually targeting specialist doctors. Any such guidelines should be taken into consideration during development of PAL guidelines on asthma management.

The PAL guidelines for first-level health facilities should describe the procedures for establishing a diagnosis of asthma and classifying asthma severity. An explanation of the use of PEF measurements to determine asthma severity may also need to be included. Guidelines should:

- describe the treatment plan according to the degree of asthma severity and in line with international guidelines;
- highlight preventive measures for avoiding factors that trigger asthma attacks in each patient, according to their environment;
- define the role of first-level health facility staff in the management of asthma according to the degree of severity;
- clarify the process of referral and counter-referral of asthma patients between the first-level and referral health facilities;
- describe the organization of long-term follow-up for the purpose of regularly assessing the patient, increasing his or her adherence to treatment and adapting the treatment according to the assessment results.

In addition, the medications specified in the PAL guidelines must be clearly identified under their generic names and registered in the national list of essential medicines.

Management of chronic bronchitis and COPD

Patients with chronic bronchitis, with or without airway obstruction, are recurrent care-seekers in PHC facilities. The PAL guidelines should include a section on the management of chronic bronchitis and COPD and the role of the first-level health facility. As for asthma, specific guidelines for managing COPD may already have been developed by national professional societies and/or university hospitals, usually on the basis of international recommendations (such as those from GOLD) and usually targeting lung specialists. The section of the PAL guidelines on chronic bronchitis and COPD management should take account of the content of any such existing guidelines.

The PAL guidelines should highlight the major features of the management of chronic bronchitis and COPD and may include the following elements, which are extensively described in various international guidelines:

- the definition and description of chronic bronchitis and its close relation with airway obstruction;
- the definition of COPD, based on international standards;
- a description of the procedures for establishing the diagnosis of COPD and the various degrees of severity;
- procedures for the management of chronic bronchitis and COPD, using pharmacological and non-pharmacological measures in line with international recommendations (see Annex).

As for asthma management, the PAL guidelines should also cover:

- measures for managing patients according to the severity of COPD;
- use of the referral/counter-referral system in the management of chronic bronchitis and COPD;
- the role of first-level health facility staff in case-management, according to the severity of COPD;
- identification of exacerbations in patients with COPD;
- advice that should be given to COPD patients, including smoking cessation;
- organization of the long-term follow-up of COPD patients in coordination with the higher health care levels.

The medicines recommended by the PAL guidelines for the management of COPD should be identified under their generic names and registered in the national list of essential medicines.

Other chronic respiratory diseases

Patients may seek care in PHC facilities for other chronic respiratory conditions, for example:

- bronchiectasis or sequelae of cured pulmonary TB, which can predispose to repeated infections or lead to haemoptysis;
- pneumoconiosis, which can present as respiratory insufficiency during episodes of bronchial infection;
- lung cancer, which requires palliative care when inoperable.

The PAL guidelines should provide appropriate directives for the management and follow-up of patients with these conditions, involving collaboration and coordination between first-level facilities and the other health care levels, as required.

Model plan of PAL guidelines for first-level health facilities

Box 4.1 presents a model of the contents of PAL guidelines for first-level health facilities that can be adapted to the technical competence of the health workers concerned and to the local resources.

Technical guidelines for the first referral level

First-referral health services are located within or near to district hospitals and should have facilities for clinical laboratory, radiology and pulmonary function tests. Technical guidelines addressed to health staff at the first referral level may deal with the problems faced by doctors at:

- emergency services;
- outpatient services (clinical medicine, TB control unit and other disciplines such as paediatrics, otorhinolaryngology, pulmonology);
- inpatient (hospitalization) services.

The guidelines should consider the respiratory conditions that are encountered in each of these health settings and describe procedures for their management. The following sections of this chapter describe the various components that may be included in PAL guidelines for the first referral level.

Technical guidelines for doctors in the emergency service

The guidelines should consider that doctors in the emergency services have a crucial role in the case-management of severely ill patients, immediate follow-up and future therapeutic orientation. The main functions of the emergency service with respect to patients with respiratory conditions are to:

- hospitalize severely ill patients with cardiovascular or respiratory diseases;
- treat patients with asthma exacerbations according to the degree of severity;
- treat patients with COPD exacerbations;
- identify signs of life-threatening conditions in patients with community-acquired pneumonia;
- identify signs of imminent respiratory arrest in patients with asthma attacks;
- refer patients, after brief follow-up observation, either for hospitalization or to specialized outpatient services for long-term treatment.

Box 4.1 **Model plan of PAL technical guidelines for first-level health facilities**

1. **Introduction**
    - To whom the guide is addressed
    - Magnitude of respiratory diseases at first-level health facilities
    - PAL objectives at first-level health facility units
        - Meet the demands of respiratory patients for care in a standard manner
        - Improve the registration of health care services delivery
        - Identify respiratory patients to be sent to a referral service or hospital

2. **Assessment and classification of a patient with respiratory symptoms**
    - Role of the general practitioner, medical assistant or nurse
        - Assess the patient's condition: identify signs of severity; ask; listen; examine
        - Classify the patient according to the diagnosis made
        - Identify patients to be investigated for TB

3. **Case-management of patients with upper airways symptoms**

4. **Case-management of patients with cough and/or difficult breathing**
    - Patients to be referred urgently to the district hospital (emergency)
    - Patients to be treated in the facility with no need for hospitalization
    - Patients to be referred to a district hospital physician for diagnosis or modifications to a prolonged treatment plan

5. **Respiratory infections in HIV-positive individuals**

6. **Follow-up of patients with TB or CRD**
    - Tuberculosis, asthma, COPD, other

7. **Guidelines on health education**

8. **Essential medications, devices and materials**
    - Medical supplies and equipment
    - Wall posters and materials for health education
    - Essential medicines (short list of 20–30 drugs): presentation, doses, indications

9. **Information system**
    - Register of outpatient services
    - TB treatment card
    - List or register of chronic respiratory patients
    - Monthly report of activities on respiratory outpatients

Annexes
   I.   Criteria for severity in ALRI patients (pneumonia cases)
   II. Case-management of TB: diagnostic decision tree and prescription of anti-TB drugs according to the patient's weight
   III. Case-management of asthma exacerbation and asthma according to the degree of severity
   IV. Case-management of COPD
   V.   How to measure peak expiratory flow (PEF)

Referral for hospitalization of severe cases

Some emergencies require diagnostic measures or treatments that exceed the capabilities of an emergency service. The guidelines should therefore stress that

urgent hospitalization is critical for patients who have severe respiratory conditions such as:

- severe toxic infectious syndrome, with or without alterations of consciousness;
- acute respiratory insufficiency;
- imminent respiratory arrest;
- sudden, very acute, localized chest pain that could indicate a myocardial infarction, pulmonary thromboembolism, acute pericarditis, or pneumothorax;
- severe haemoptysis;
- abundant pink and frothy expectoration in a patient with dyspnoea (sign of acute pulmonary oedema);
- recent chest trauma, with or without an open wound;
- aspiration of a foreign body.

For all such cases, the guidelines should specify the first therapeutic measures that should be taken in the emergency room before patients are referred to a hospital ward or an intensive care unit (if available).

Asthma exacerbation

An asthma exacerbation – either a first manifestation of the disease or an attack in the course of the disease – should be classified by the degree of severity and treated accordingly, as recommended in the various international guidelines. The PAL guidelines should specify both the circumstances in which patients must be hospitalized and when and how they should be referred to an outpatient health care setting where a medical officer will organize follow-up.

COPD exacerbation

Clinical assessment of a COPD exacerbation should be rapid and the best therapy should be selected on the basis of simple criteria. The guidelines should describe evaluation of exacerbation level and management according to international standards. The process of patient follow-up should be specified. As for asthma exacerbations, the indications for hospitalization and the organization of patient follow-up, including an action plan for recurrent exacerbations, should be clearly explained.

Life-threatening factors in patients with community-acquired pneumonia

Patients with severe pneumonia should be hospitalized. The PAL guidelines should specify the symptoms and signs for assessing the severity of pneumonia in line with international recommendations on community-acquired pneumonia.

The guidelines should also specify the criteria for hospitalizing patients with non-severe pneumonia, again in accordance with international recommendations.

Case-management of respiratory diseases by doctors at first referral level outpatient services

The tasks of doctors at first referral level outpatient services are:

- urgent identification and hospitalization of patients with signs of severe disease (as described above for doctors in emergency services);

- referral to the emergency service of patients with asthma attacks whose symptoms persist after bronchodilator treatment and of patients with pneumothorax;
- establishment of a diagnosis, even if it is provisional;
- requests for complementary investigations, if necessary;
- prescription of initial treatment and scheduling of follow-up visits;
- case-management of respiratory diseases that need prolonged care (mainly TB, persistent asthma, COPD and other CRDs);
- referral to the emergency service or for hospitalization of patients who cannot be followed-up as ambulatory patients.

Patients with respiratory symptoms without signs of immediate severity

For patients with respiratory symptoms but with no signs of immediate severity on physical examination, doctors may establish a first, provisional, diagnosis while waiting for the results of complementary investigations or observing the evolution of symptoms.

The PAL guidelines may include a simplified table for case-management of the most frequent respiratory infections such as common cold, acute pharyngotonsillitis, acute rhinosinusitis, acute otitis media or influenza. During the subsequent follow-up visit, the doctor should designate a treatment plan for patients who need prolonged therapy and follow-up, based on clinical evolution and the results of complementary investigations, even for patients who are usually managed by first-level health facilities.

The doctor at the referral outpatient service who designs the appropriate treatment plan should provide complete information to the patient and his or her family on the disease and its treatment, advise on preventive measures, and schedule follow-up visits in coordination with the first-level health facility.

The doctor at the first referral level should refer complex cases to a second referral level for diagnosis and treatment.

Technical guidelines for doctors in the hospital service

In many cases, hospitalization is necessary to provide medical care that cannot be delivered in outpatient services or the emergency room, to establish a diagnosis or to monitor the evolution of respiratory disease under treatment.

The main tasks of doctors responsible for hospitalized patients are usually to:

- provide urgent respiratory therapy if necessary (laryngotracheal aspiration and/or intubation and ventilation, oxygen administration, pleural drainage);
- establish the most likely diagnosis that can be reached with the available facilities;
- prescribe appropriate treatment;
- refer patients who need more specialized investigations or care to the second referral level;
- refer patients to a specialized outpatient service for long-term treatment, if needed, and for follow-up after discharge.

Complete clinical examination and chest radiography will supplement the syndromic diagnostic approach and indicate what complementary investigations are needed.

The possibility of pulmonary TB or HIV infection should always be considered. Microscopic examination for TB should be done in every patient with chest X-ray

abnormalities; HIV testing should be considered in every patient with symptoms or signs suggesting possible HIV infection.

The presumptive diagnosis should always take into account the most frequent differential diagnosis.

Organization of the patient's discharge

When the patient is ready to be discharged the doctor at the first referral hospital ward may have to deal with any of the following four situations:

- *The patient is cured and requires neither home treatment nor follow-up.*
  If the patient has a health card, the doctor should record the diagnosis and the duration of hospitalization.

- *The patient appears to be cured but he or she should be followed up for a short period.*
  This is the situation of patients who had severe pneumonia, non-tuberculous pleurisy, purulent pleural effusion or lung abscess. Follow-up requires a regular assessment by the hospital outpatient doctor or specialist in order to confirm the cure or detect a relapse or, if symptoms persist, investigate the possibility of other illness such as TB or lung cancer. The patient is given a report explaining the cause and duration of the hospitalization and the dates for follow-up visits. This information is also recorded on the patient's health card.

- *The patient requires long-term treatment.*
  A patient with TB or a CRD (persistent asthma, COPD, bronchiectasis, or sequelae of TB) should be informed about the treatment. If required, he or she should be trained in taking medications using the metered-dose inhaler, advised on smoking cessation, and taught to recognize the signs of worsening or exacerbation. The patient is given a letter to take to the treating physician who will provide follow-up treatment.

- *The patient requires referral to a second-level referral service.*
  For many patients hospitalized with respiratory diseases, a precise diagnosis can be established and appropriate treatment administered. In some cases, however, patients should be sent to a second-level referral facility for more specialized investigations or care and for a final diagnosis. The patient is given a report to be presented to the second-level referral service, which should state the reason for, and duration of, hospitalization. The report can be accompanied by a confidential letter with detailed information about the patient's disease and the reason for referral to a higher level for specialized examinations (echography, computed tomography, bronchoscopy, mediastinoscopy, pulmonary function tests, bronchoalveolar lavage, pleural biopsy) or specialized treatment (surgery, radiotherapy, cancer chemotherapy, pleural drainage, rehabilitation).

Model plan of PAL guidelines for the first referral level

Box 4.2 presents a model plan of the contents of PAL guidelines for first referral level health services that can be adapted to the technical competence of the staff concerned and to the local resources.

Essential medical supplies

Technical guidelines should include a list of the equipment needed by medical and non-medical health staff to carry out the activities described in the guidelines. In

addition to the basic equipment that should be available at any health facility (thermometer, sphygmomanometer, lamp, otoscope, stethoscope, weighing scale, an instrument to measure the patient's height), specific equipment should be provided for case-management of respiratory diseases.

The minimum specific medical equipment for a first-level health facility must include sputum containers. A first-level health facility staffed with doctors should be supplied with the following equipment:

- peak flow meter with disposable (cardboard) or re-usable (washable plastic) mouthpieces;
- pulse oximeter;
- spacers with masks for children and mouthpieces for adults;
- sources of oxygen (cylinders with appropriate accessories and/or concentrators);
- nebulizer with masks of different sizes.

This equipment should be also be available at referral outpatient services and in emergency rooms. However, other equipment should also be considered for these facilities; a list is proposed in Box 4.3 but is only an example – it should be adapted to the local context and to available human and financial resources.

Choice of essential medicines

Each technical guide should contain an annex listing the essential medicines from the national list that can be used in the treatment of respiratory diseases, according to the indications given in the guide. Each drug should be mentioned with its generic name, the recommended daily dosage (in mg/kg per day or by number of tablets or injections per unit of time). As an example, Box 4.4 presents a list of the main essential medications; those that are marked with an asterisk (*) could be administered under the control the first referral services.

One of the main barriers to the implementation of PAL in low- and middle-income countries is the high cost of essential medicines for patients, particularly inhaled corticosteroids for asthma and COPD. To increase the accessibility to, and affordability of, these essential medicines, The Union created the Asthma Drug Facility (ADF). The ADF is a mechanism, based on the successful model of the Global Drug Facility of the Stop TB Partnership, for making good-quality essential asthma medicines affordable in low- and middle-income countries. It aims to promote standard case-management practices according to international recommendations and should be an important mechanism for facilitating the implementation of PAL in many countries.

Box 4.2 **Model of contents of PAL technical guidelines for staff at first referral health services**

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1. **Introduction**
   - To whom the guide is addressed
   - Role of doctors and nurses in the case-management of respiratory diseases

2. **The emergency service in respiratory diseases**
   - The tasks of doctors and nurses
   - Patients who require urgent hospitalization
   - Case-management of asthma exacerbations by degree of severity
   - Case-management of COPD exacerbations
   - Referral of chronic patients to a specialized outpatient service after emergency

3. **The first referral level outpatient service**
   - The tasks of doctors and nurses
   - Urgent identification and hospitalization of patients with symptoms and signs of severe disease
   - Assessment and classification of patients with respiratory symptoms and signs
   - Case-management of patients with upper airway symptoms
   - Case-management of patients with cough or difficult breathing
   - Respiratory conditions in HIV-infected individuals
   - Case-management of patients who need prolonged care and follow-up by the first-level health facility units: TB, asthma, COPD, and other
   - Common measures in the case-management of CRD

4. **The inpatient (hospital) service**
   - The tasks of doctors and nurses
   - Establish a diagnosis as precise as possible
   - Prescribe an appropriate treatment for severe respiratory infection, severe asthma exacerbation, severe COPD exacerbation, pleural diseases
   - Organization of discharge from hospital:
     - cured patient without need for follow-up
     - cured patient to be followed-up up for a maximum of 3 months
     - patient needing prolonged care at the district level
     - referral of patient requiring specialized care or investigations to a second referral hospital

Annexes
   I. Essential equipment for case-management of respiratory diseases
   II. Information system on case-management of respiratory diseases
   III. Main respiratory diseases to be registered
   IV. Essential medicines for treatment of respiratory diseases
   V. Normal curves of PEF measurement in adults and children
   VI. Spirometry
   VII. Pulse oximetry

Box 4.3 **Example of medical equipment needed at the referral outpatient service, the emergency room and the hospital ward**

At the referral outpatient service:

☐ Source of oxygen and accessories for oxygen administration
☐ Pulse oximeter
☐ Peak flow meter
☐ Spacers with masks
☐ Metered-dose inhalers for bronchodilators
☐ Spirometer

In the emergency room:

☐ Peak flow meter
☐ Spacers with masks
☐ Metered-dose inhalers for bronchodilators
☐ Pulse oximeter
☐ Mask with manual ventilation system
☐ Material for tracheal intubation
☐ Aspiration equipment
☐ Catheters for nasopharyngeal or tracheal aspiration
☐ Source of oxygen and accessories for oxygen administration

In the hospital ward:

☐ Pulse oximeter
☐ Equipment for pleural drainage
☐ Source of oxygen and accessories for oxygen administration
☐ Aspiration equipment
☐ Instruments for pleural biopsy
☐ Sterile tubes, screw-capped, to collect pleural liquids
☐ Bronchoscope (operated by a specialist)
☐ Spirometer
☐ Access to clinical and microbiological laboratories, measurement of blood gases, electrocardiograph and radiology facilities

Box 4.4 **Example of selected essential medicines for case-management of respiratory symptoms and diseases**	
Analgesics, antipyretics	acetylsalicylic acid, tablets 100–500 mg paracetamol, tablets 100–500 mg
Antiallergics, antihistaminics	promethazine, tablet 25 mg chlorphenamine, tablet 4 mg
Anti-inflammatory steroids (systemic)	prednisolone, tablets 5 mg and 25 mg hydrocortisone, ampoule 100 mg for IV injection dexamethasone, ampoule 4 mg/ml
Antibacterials	amoxicillin, tablet 500 mg amoxicillin + clavulanic acid, tablets 500 mg + 125 mg benzathine benzylpenicillin, ampoule 2.4 million IU for IM injection benzylpenicillin, ampoule 1 million IU for IM injection cloxacillin, tablet 500 mg or ampoule 1 g for IM injection erythromycin (or equivalent), tablet 250 mg, 500 mg gentamicin, ampoule 10 mg and 40 mg/ml phenoxymethylpenicillin, tablet 250 mg procaine benzylpenicillin, ampoule I million IU for IM injection sulfamethoxazole + trimethoprim (co-trimoxazole), tablets 400 mg + 80 mg, 800 mg + 160 mg

Drugs for asthma, COPD and chronic rhinitis	beclomethasone, nasal aerosol 50 µg/dose
	beclomethasone, metered dose inhaler 250 µg/dose
	epinephrine (adrenaline), 1-ml ampoule 1 mg for SC or IM injection
	ipratropium bromide, metered dose inhaler 20 µg/dose
	salbutamol, metered dose inhaler 100 µg/dose
	  * solution for nebulizer 5 µg/5 ml
	  * ampoule for injection 0.5 µg

Anti-TB drugs (administered under the control of the referral service)	Separate drugs: ☐ * ethambutol, tablet 400 mg ☐ * isoniazid, tablets 100 mg and 300 mg ☐ * pyrazinamide, tablets 400 mg and 500 mg ☐ * rifampicin, capsules 150 mg and 300 mg ☐ * streptomycin, vial 1 g for IM injection Fixed drug combinations (for daily administration for adults): ☐ * isoniazid + rifampicin, tablets 75 mg/150 mg or 150 mg/300 mg ☐ * isoniazid + rifampicin + pyrazinamide, tablet 75/150/400 mg ☐ * isoniazid + rifampicin + pyrazinamide + ethambutol, tablet 75/150/400/275 mg
Other	purified tuberculin (PPD), vial with 5 or 10 test doses influenza vaccine, ampoule for SC injection furosemide, 2-ml ampoule 10 mg/ml for IV injection

Chapter 5

Communication activities in a PAL strategy

Who is responsible for health education of patients and their families?

Communicating health education messages to patients and their families is an integral part of health services delivery at all levels of the health system. Health workers should give advice at each contact with patients attending a health facility for any reason – medical consultation, medical intervention (physical examination, pleural puncture), complementary examinations (sputum collection, chest radiography), or nursing care. It is the responsibility of health personnel to relieve the anxieties of patients and their relatives, answer their questions and explain, in clear and suitable language, the diagnosis, the necessary investigations, treatment, follow-up and preventive measures.

Health education messages should be adapted to the particular situation, including the cultural background and educational level of patients and families, the type and stage of respiratory disease, and the professional level of the health worker. The messages should be repeated at each contact with patients receiving long-term treatment.

The principal skills needed to communicate effectively with patients are summarized in Box 5.1.

Box 5.1 **Main skills for effective communication with patients**	
Skills needed	**In order to:**
1. Ask questions and listen	☐ understand the patient's medical history; ☐ understand the patient's current knowledge about his or her disease; ☐ identify and help to solve any problem the patient may have with treatment.
2. Demonstrate a caring, respectful attitude 3. Praise and encourage the patient	☐ motivate the patient to comply with treatment.
4. Speak clearly and simply 5. Encourage the patient to ask questions 6. Ask questions to check the patient's Understanding	☐ ensure that the patient understands and remembers important messages about the disease and its treatment; ☐ ensure that the patient knows exactly what to do about treatment and preventive measures.

Advising and counselling patients and their families on immunization

- Check the vaccination status of children and adolescents – diphtheria, pertussis (whooping cough), measles, BCG – and administer whatever is needed in line with the directives of the national expanded programme of immunization.

- Recommend annual vaccination against influenza in accordance with international recommendations and the national health policy.

Advising and counselling patients with acute respiratory infections

- Recommend a healthy diet and appropriate hydration in patients with acute respiratory infections.

- In young patients, find out about previous respiratory problems, particularly repeated acute bronchiolitis in the first year of life, recurrent acute bronchitis, recurrent or seasonal rhinitis and wheezing episodes.

- If an oral antibiotic is prescribed, teach the patient how to take it at home:
  - explain why the antibiotic has been prescribed;
  - clearly show the patient the correct dose to take;
  - ask the patient to take the first dose;
  - carefully explain to the patient how many times a day he or she should take the antibiotic; label and package the tablets;
  - explain that all the tablets must be taken, even if the patient feels better before the course of treatment is finished;
  - check the patient's understanding of all these points before he or she leaves the health centre.

Advising and counselling TB patients and their families

First meeting in which the patient is informed of having TB

The health worker should give the patient essential information about TB and its treatment. The most important initial messages for new TB patients (and their families, if present) are the following:

- What TB is, how it is transmitted and where in the body it develops; who can be contaminated; what can happen to TB patients if they are not appropriately treated.

- TB is a curable disease. Powerful anti-TB drugs are now available and TB can be easily cured with appropriate treatment regimens provided that key rules are respected.

- Treatment of TB. For each patient's treatment regimen, the following should be explained:
  - daily dosages of anti-TB drugs;
  - the need to take all prescribed anti-TB drugs together;
  - the importance of strict compliance with anti-TB treatment;

- □ duration of treatment;
- □ the necessity of directly observed treatment;
- □ the risks associated with irregular TB treatment;
- □ the place where the patient will receive treatment (e.g. health centre, with treatment supporter);
- □ frequency of visits for taking treatment;
- □ the availability to the patient of the anti-TB drugs for the entire period of treatment.

- How TB spread can be prevented. Being appropriately treated and then cured helps prevent the spread of TB bacilli to community and family members. It should be stressed to the patient that it is necessary to:

  - □ cover the mouth and nose when coughing or sneezing; and
  - □ open windows and doors to allow fresh air to flow through the home.

- The need to screen close contacts of the patient in order to identify unknown TB cases. Children under 5 years of age living in the patient's household should be screened for TB as a priority, as should other close contacts with underlying conditions, such as HIV infection.

Subsequent meetings with a TB patient throughout treatment

- After the initial meeting with a TB patient, the health worker should continue to pass on health education messages. At each encounter, earlier messages should be reinforced or new ones taught, but the health worker should not try to teach too much at one time. During the early visits, there may be a need to reinforce messages about TB and how it spreads. It may also be necessary to remind patients to bring family members for TB screening.

- Messages about the side-effects of anti-TB drugs are also important during the early stages of treatment: patients often need to be reassured in order to continue taking the drugs.

- As treatment continues, health workers should explain the need for follow-up sputum examinations. They should explain to the patient the importance of bringing up sputum from deep in the lungs, how to cough it up and collect it in a container for testing.

- At every encounter, the health worker should discuss with the patient, and identify, any minor or major side-effects of anti-TB drugs. These conditions should be managed in line with the directives of the NTP.

- Once the patient feels better, it may be necessary to convince him or her of the importance of continuing treatment, explaining that stopping treatment is dangerous not only for the patient but also for family and community members.

Advising and counselling about HIV for patients with respiratory infections, particularly pneumonia or TB

- Health workers should give patients and their families basic information about the possible risk of HIV, about the relationship of HIV to pneumonia and TB, and about preventing its transmission. Patients should be encouraged to seek HIV counselling and testing.

- Any woman of childbearing age with pneumonia or TB should be asked whether she is pregnant. If a woman is pregnant, she should be referred for HIV counselling and testing, if this is the national policy established by the MOH.

- The messages that should be conveyed about HIV infection should be in line with the national health policy and the HIV/AIDS programme.

Advising and counselling asthma patients and their families

Self-management at home

Health worker should explain the asthma treatment plan to patients and their families.

- Explain control and quick-relief treatments clearly, using the prescribed medications.

- Tell the patient about the importance of having an adequate supply of the prescribed medications and the need to take them regularly without interruptions in the case of persistent asthma.

- Check both the patient's and the family's understanding of the self-administration of asthma medications and of when and where to seek care.

Maintaining well-being

- Stop smoking and avoid exposure to second-hand smoke.

- Avoid triggers of asthma attacks.

- Use insecticides to eliminate cockroaches from the house (if the patient can stay away for some time).

- Shake mattresses, pillows, bedspreads and blankets and expose them to the sun as often as possible.

- When cleaning the house:
  - sprinkle the floor with water before sweeping to avoid raising dust;
  - clean furniture with a damp cloth;
  - avoid piling up books, toys, clothes, shoes and other items that accumulate dust, in the bedroom.

- Lead as active a life as possible, including practising physical exercise.

Use of the metered-dose inhaler

- If available, use a placebo (distilled water, for example) to teach and check the use of metered-dose inhalers.

- Use a commercial spacer with a mouthpiece. If the patient cannot tolerate a spacer or cannot use it because of breathlessness, use a spacer with a mask.

- Ask each patient to show how she or he takes the inhalations.

- Check whether the patient coordinates inhalation with activating the inhaler.

- If the patient is not using the inhaler correctly, demonstrate the correct technique and then ask the patient do it.

Advising and counselling COPD patients and their families

Chronic obstructive pulmonary disease develops and progresses slowly. Smoking and indoor air pollution are the major risk factors: it is essential that COPD patients stop smoking and avoid inhalation of smoke and of irritants. The following measures should be promoted:

- An appropriate treatment plan, and good compliance with that plan, including knowledge of when to return to the health centre for medical follow-up.

- Smoking cessation.

- Regular and progressive aerobic exercise, according to individual capacity.

- Adequate nutrition.

- Effective psychological and family support.

Returning to the health centre before the date of a scheduled visit

The patient with COPD should know the circumstances in which he or she should return to the health centre in advance of a scheduled visit; these are summarized in Box 5.2.

Box 5.2 **Circumstances that should prompt immediate return to the health centre**

The patient should return to the health centre immediately if he or she becomes aware of any of the following:

- **Exacerbation of symptoms**
  - ☐ breathing becomes worse
  - ☐ fever
  - ☐ increase in sputum
  - ☐ change in sputum colour (from colourless to yellow or green).

- **New symptoms**
  - ☐ swollen ankles
  - ☐ inability to lie flat to sleep
  - ☐ confusion
  - ☐ increased shortness of breath while walking
  - ☐ chest pain (possible pneumothorax)
  - ☐ haemoptysis or blood-streaked sputum.

- **No response to regular prescribed medication**
  - ☐ need for more medication than that prescribed in the treatment plan, such that the number and frequency of inhalations needs to be increased.

Advising regular exercise

- Physical deconditioning (being "out of shape") makes breathlessness occur with less and less exertion.

- Patients should stay active, gradually building up to an exercise regimen.

- Success with the recommended exercises requires the encouragement of family members.

- A patient with severe COPD should be referred to a respiratory rehabilitation service if available. Otherwise, patients should be instructed to take regular exercise as appropriate to their environment.

- Wherever possible, the patient should consult a rehabilitation professional about exercises to improve thoracic movements, tolerance to physical activities and health-related quality of life.

Nutrition

- Weight loss generally, and muscle-wasting in particular, contributes significantly to disability and mortality in patients with COPD.

- Good nutrition helps prevent weight loss and infections and keeps respiratory muscles strong. If possible, refer the patient to a nutrition specialist.

Indoor and outdoor air pollution

- Always keep the kitchen – or other room where meals are cooked – well ventilated by opening windows and doors.

- If possible, cooking with wood or carbon should be done outside the house; otherwise, build an indoor oven with bricks and a chimney that vents the smoke outside.

- Stop working in areas with occupational irritants.

Smoking cessation

- Tobacco smokers must be urged to stop smoking. Brief counselling sessions should be organized and repeated at frequent intervals. The measures to help patients stop smoking should follow national directives and/or international recommendations.

Chapter 6

Formulating a PAL information system

 Any health intervention needs to be guided by, and adjusted on the basis of, appropriate information if it is to generate evidence that will help optimize the performance of this intervention. As highlighted in the WHO framework for health information system, producing information and evidence involves:

- data generation,
- data compilation,
- data analysis and synthesis, and
- dissemination and use of findings for decision-making.

 To improve respiratory care and health services through the PAL strategy, an optimal information support system is needed. The PAL activities need to be integrated into the daily practice of health services delivery at outpatient facilities. Information for monitoring ongoing PAL activities is more easily and more efficiently obtained through routine data collection and reporting, with adaptation – if needed – of the existing information forms and reports that are completed by the health personnel.

The existing information system, which is presumably used on a routine basis, should allow the collection of relevant data for analysis of information about outpatients attending PHC facilities for respiratory symptoms as well as about the types of care provided by the health personnel to the outpatients.

In places where there are no instruments for collecting and reporting on patients attending first-level health facilities, the implementation of PAL activities may serve as an incentive for the development of an information system for case-management services in general.

The information needed to evaluate the impact of PAL activities is best collected through special sample surveys or by sentinel units (as described later in this manual), rather than through routine methods.

Essential information : the outpatient register

Different countries use different types of outpatient registers – there may even be several kinds in use within a single country. In countries with established health management information systems (HMIS), the outpatient register is standardized and is the fundamental element of the HMIS. All the data registered should fulfil particular monitoring or surveillance needs.

Outpatient registers help health professionals to assess the activities at their own particular level. Further, they provide information for surveillance analysis, help to set health priorities, and contribute to monitoring the performance of health care services. In many country settings, the outpatient registers form the main database for managerial functions. Information collected in these registers is compiled in reports and transmitted to the district level; the district consolidates the health services reports, which are then submitted to the upper health levels. However, data included in the reports should be analysed at all levels and feedback provided to the units that generated the reports. A mechanism should be established for disseminating the analysis results to inform those who need the information, particularly the health workers who contribute to the data collection process.

Periodic feedback of this kind to the health units is essential if staff are to be motivated to improve the regularity and quality of data collection.

By reviewing the data on respiratory patients in the existing outpatient register, measures can be recommended, in the framework of PAL implementation, to correct two possible inadequacies in the design of the register:

- The register may not record sufficient information for meaningful analysis and subsequent appropriate action regarding respiratory diseases.

- The register may include excessive information, much of which may be irrelevant for measuring the selected indicators and for sustaining adequate respiratory care services.

A model of an outpatient register (see Box 6.1) used during preliminary surveys in the development of the PAL strategy has proved useful in some country settings for meeting the information objectives. This model may be taken into consideration when the existing outpatient register is reviewed and will help to reveal whether the register requires revision to include all the information needed for monitoring implementation of the PAL strategy. The model includes the following data:

- identification of each patient attending the health service;
- symptom(s) reported by each patient as the reason for his or her visit;
- initial diagnosis made by the doctor or medical assistant;
- type of visit: first time or follow-up;
- reason for any referral: hospitalization, emergency service, examination by a specialist, complementary investigations;
- drug prescription: essential drugs, preparation, dosage, number of days;
- observations (final diagnosis, prognosis or other)
- the ICD-10 morbidity code.

The register is useful for monitoring overall outpatient activities. It records the number of visits, not the number of patients; because one patient can attend a health service several times in a short period, the register helps in assessing the demand for care within PHC.

Box 6.1 **Model of outpatient register**

Left page of register

(1) Date	(2) No.	(3) Full name	(4) Sex	(5) Age	(6) Full address	(7) Reason for visit		(8) Initial diagnosis	(9) Type of patient[a] (Fi, Fo, CD)
						Symptoms	Duration		

Right page of register

(10) Referral		(11) Drug prescription			(12) Observations	(13) ICD-10 code
Hospital	Specialist / Complementary examinations	Drug(s)	Presentation Dosage	Number of days		

[a] Fi = first visit for the current disease, Fo = follow-up of acute or chronic disease, CD = chronic disease.

Note: It is preferable to design a double-page book, with enough space to register the required information and to register 10 patients per double page.

Completing and using the model outpatient register

The outpatient register should be used at every medical outpatient service at PHC units as well as at the referral services (e.g. TB and chest clinic, emergency room, hospital outpatient department). The register is filled in by the doctor or the medical assistant who takes care of the attending patients and patients are registered individually.

Column   Information

1   Date of visit

This column allows the number of days of outpatient services to be counted and compared with the number of working days. It also allows the number of people who attended the service per doctor, per day, per week and per month to be counted.

2   Number

All individuals attending the outpatient service (for health care or control of symptoms, for interpretation of the results of prior examinations, or for advice from a specialist) are registered in chronological and consecutive order. Thus the register shows the number of persons who attended the outpatient services in a given period; it is not used to identify patients.

Each person, regardless of whether he or she attends several times in a week, a month or a year, is registered with a new number on each visit. Each year the number 1 is given to the first patient seen on the 1 January, and the last consecutive number is given to the last patient registered on the 31 December.

3   Name

The name entered in the register should be the same as that which appears on the patient's identity card or in the family booklet (or any other official document).

4   Sex

Enter "F" if the patient is female or "M" if the patient is male.

5   Age (in years)

For infants (under 1 year) the age in months should be recorded followed by the word "month".

6   Address

The address should be as precise as possible, in order to be able to locate the patient – if necessary – in the quarter or municipality where he or she lives.

7   Reason for the visit

The main symptoms reported by the patient (or the patient's parents) or elicited through questions, which are the reason for the visit to the health service (for instance, fever + cough; headache; dyspnoea at night), are recorded. It is essential to register the duration of symptoms, particularly of cough, since this helps identify patients who need to be screened for TB (i.e. TB suspects).

8   Initial medical diagnosis

The initial diagnosis made by the doctor after the first assessment is recorded. If the diagnosis is provisional or probable (confirmation requires

examination by a specialist or complementary investigations), a question mark (?) should be added.

If the patient is known and is returning for follow-up or because of a chronic disease, the precise diagnosis is recorded. In cases of co-morbidity, several diagnoses can be registered in this column.

The diagnosis of the disease whose symptoms prompted that particular visit is written down first, followed by associated diagnoses, for example: 1) acute bronchitis; 2) diabetes.

9   Type of patient

Health workers should only mark the appropriate column.

Fi – first visit to the health unit because of the current health condition.

Fo – follow-up visit for an acute or chronic health condition, or a visit for information about the results of complementary investigations or the report by a specialist.

CD – if the visit is related to a chronic disease (diabetes, hypertension, heart disease, asthma, COPD, epilepsy, etc).

10   Referral

The health professional may refer the patient to:

- □ an emergency service (indicate where); or to
- □ a specialized medical outpatient service (indicate which – psychiatry, gynaecology, pulmonology, etc.); or to
- □ a laboratory for complementary investigations (indicate the requested complementary investigations; avoid general terms).

11   Drug prescription

At the end of the visit, the doctor issues a prescription, if needed, and gives the patient all necessary explanations. The doctor records three sets of information in the register:

- □ the names of the prescribed drugs, preferably the generic names as they appear in the national list of essential medicines;
- □ the dosage of the drugs and the form in which they are provided – tablets (tab), injections (SC, IM, IV), suppository (supp), syrup (sp), inhalation (inh);
- □ the duration of the prescribed treatment in days.

12   Observations

This column provides space for information on the impact of the health intervention and the outcome for patients who have been referred.

For patients who do not return, "not returned" is recorded

For those who come back (or whose parents come to inform the doctor), the following information is entered in column 12 of the line corresponding to the first visit, as appropriate:

- □ cured, or
- □ still has symptoms, or
- □ change of diagnosis, or
- □ died.

When the initial diagnosis is no longer valid and needs to be changed, the final diagnosis should be added in the line corresponding to the first visit for the current disease. Depending on the health services level, the diagnosis (initial or after referral or observation) should be more or less precise..

First-level outpatient services (health centre, dispensary) should have a list of diagnoses to be registered before the referral is indicated.

13   ICD-10 code

ICD-10 refers to the *International statistical classification of diseases and related health problems*, tenth revision, of the World Health Organization. The code is a 3-digit code that allows the classification of the causes of morbidity, provides an analysis of the demand for health care (297 causes), and permits international comparisons. This column is not usually filled by the clinical doctor but by an officer at the health unit acquainted with ICD-10 or by the person responsible for supervising the registered medical diagnoses.

Lists of respiratory disease diagnoses

List of respiratory disease diagnoses based on symptoms and signs, for first-level health facilities

Coryza, acute rhinitis, acute rhinopharyngitis, chronic rhinitis

Acute sinusitis

Pharyngitis, pharyngotonsillitis, presumptive streptococcal pharyngotonsillitis (4–20 years of age, depending on local criteria)

Otitis externa

Acute otitis media

Acute laryngitis

Acute bronchitis, purulent acute bronchitis

Influenza

Simple chronic bronchitis, purulent chronic bronchitis

Asthma exacerbation

Intermittent or persistent asthma

COPD exacerbation

Pneumonia without signs of severity (non-severe)

List of suspected diagnoses that require confirmation at a referral service or by laboratory investigation

The initial provisional diagnoses should be marked with a question mark (?) and the patient should always be referred to a better-equipped service where a more precise diagnosis can be made.

Presumptive diphtheria pharyngitis

Foreign body in the airways

Chronic rhinosinusitis

Pleurisy

Pneumothorax

Pulmonary TB

Persistent asthma

COPD

Bronchiectasis

Severe pneumonia

Lung abscess

Lung cancer

Hydatid cyst

Occupational respiratory disease

Acute pulmonary oedema, pulmonary thromboembolism, pulmonary hypertension, cor pulmonale, etc.

List of respiratory disease diagnoses that can be made only at a referral outpatient service on the basis of appropriate investigations

Persistent asthma classified by degree of severity

COPD classified by stage of severity

Bronchiectasis

Pulmonary TB, smear-negative

Extrapulmonary TB (pleural effusion or mediastinal adenopathy)

Sequelae of TB

Pleurisy (non-tuberculous, viral, purulent)

Occupational asthma, pneumoconiosis

Lung cancer

Heart disease (to be specified)

Register of TB suspects

The register of TB suspects is a complementary support information instrument on case-management of patients with respiratory symptoms attending first-level health facilities. A TB suspect is any patient who presents with symptoms or signs suggestive of TB, in particular cough of long duration (more than 2 weeks).

This register complements the information recorded in the outpatient register regarding patients identified as TB suspects. Monitoring the TB case-detection activities of the health facility is useful: it provides information on how many patients identified as TB suspects in health facilities are actually screened for TB by sputum smear microscopy and how many of them are confirmed as positive cases of pulmonary TB. The information on sputum-positive results should be confirmed by comparing the register of TB suspects with the TB laboratory register. In addition, linking the information on duration of symptoms among respiratory patients recorded in the outpatient register with the list of patients included in the register of TB suspects will help establish, among the respiratory patients who meet the definition of TB suspect, the exact proportion of those who were requested to submit sputum samples for microscopy examination.

WHO has recently proposed a model of a register of TB suspects in the new recording and reporting system (see Annex).

Information instruments on treatment of respiratory diseases

First-level health facilities provide long-term care to many patients, under the guidance of the referral services. In relation to respiratory diseases, services are provided to:

- TB patients, who should be followed on treatment for 6 or 8 months until they are cured;
- patients with chronic respiratory diseases, who often need to be followed for life.

To ensure good care of these patients, a standard individual clinical record should be filled in, as recommended by the health authorities. Two different treatment cards are necessary, for:

- TB cases with a limited follow-up (maximum 8 months);
- chronic respiratory diseases in which the end of follow-up cannot be foreseen.

Tuberculosis treatment card

The TB treatment card is the record of the patient's diagnosis and TB treatment. It is used by all the TB programmes that have adopted the Stop TB Strategy for TB control, although its format may vary somewhat from country to country. Whenever a patient is classified as having TB or is transferred in from another health facility, a treatment card is opened and then kept up to date throughout treatment. Instructions on how to fill in the TB treatment card are included in the NTP manual.
The card should record relevant data regarding each TB patient in first-level health facilities. The data should be transferred on a quarterly basis to the district TB register.

In addition to the TB treatment card, it is useful for health units to keep a notebook with the list of TB patients under treatment together with critical information such as address, diagnosis and date of starting treatment. This may be useful if a patient's TB treatment card is misplaced or lost.

Register for the follow-up of chronic diseases

The register for follow-up of chronic diseases records – by name or date of diagnosis – all patients who need long-term care and follow-up. The CRDs are mainly asthma, COPD, bronchiectasis and extensive sequelae of TB. Every patient who starts treatment for a CRD should be logged in this register.

To avoid multiple registers, a single register for chronic diseases should be kept in each first-level health facility. If a chronic disease register already exists, it should include CRDs. Scheduled control visits and the therapeutic decisions for each case are recorded in this register. If there are no chronic disease registers, the PAL strategy advocates their introduction into the practice of health units, starting with the register of CRDs. The register can take the form of individual cards arranged in alphabetical order of name or by chronological order of the dates on which patients have been instructed to return to the health unit for a follow-up visit. The register can also be in the form of a book, with each patient registered in a single line. A model register book for CRDs is proposed in Box 6.2; the same items of information should be recorded if a programme opts for the use of individual cards rather than a register book.

Summary of forms for registering information in PHC services

Box 6.3 provides a summary of the forms required to register information, adapted from the Morocco PAL guidelines for PHC services.

Box 6.2 **Follow-up of chronic respiratory diseases at the primary health care unit**						
Left page						
Date of diagnosis	Number/ Year	Full name	Sex/ Age	Main address	Diagnosis of chronic respiratory disease	Number of clinical record at the referral service

Right page				
Essential drugs initially prescribed	Follow-up			
	Date Decision	Date Decision	Date Decision	Date Decision

Box 6.3 **Summary of forms for registering information**		
In all health units	• General outpatient register • Individual health card	
At first-level health facilities	*Tuberculosis*	*Chronic respiratory diseases*
	• Register of TB suspects • TB treatment card • Form for the control of TB cases • Register of TB contacts	• Individual card for follow-up of CRD
At first referral level	• Register of TB suspects • TB treatment card • Form for the control of TB cases • TB contacts' registration system • Clinical history record • TB cases register	• Individual card for follow-up of CRD • Clinical history record • Follow-up card to be given to the patient • Register of CRD

Information that can be collected during supervision of the PAL strategy implementation in PHC units

If the unit has no staff trained in ICD-10 classification, the medical supervisor at district level should check and complete the outpatient register (at least for respiratory diseases) by entering in column 13 the ICD-10 code for cause of morbidity. (The diagnoses included in the list of causes of respiratory disease morbidity are presented in Box 6.4.)

During a supervisory visit, the supervisor together with the unit staff should analyse the information registered in the outpatient service on the number and proportion of respiratory diseases among all outpatient visits and their distribution by age group. The data can be summarized either on the simplified form shown as an example in Box 6.5 or in an expanded form, which includes distribution by sex as shown in Box 6.6. The form can be completed for each health unit every month or for one month per trimester or per semester (always the same month) for surveillance of the demand for services by respiratory patients.

Depending on the work burden of the medical supervisor and the skills of the personnel at PHC units, and after discussion among them, it may be possible to collect more detailed data during supervisory visits. The data can be analysed according to one of the three diagnostic groups presented in Box 6.7.

Based on the data recorded in the outpatient register, the supervisor prepares a list of patients, by name, who have been referred to the district outpatient service and the report received on each of them (Box 6.8). The report can be prepared quarterly; it allows monitoring of the participation of first-level health units in TB case-finding and in the diagnosis of CRDs.

Finally, at the first-level health facilities that supervise TB treatment and provide long-term follow-up of CRDs under the guidance of the referral services, the medical supervisor verifies that all patients under treatment and follow-up have been registered in the district TB register and the district CRD register.

Box 6.4 **Selection of causes of respiratory morbidity included in the List of 297 Causes of Morbidity (ICD-10)**	
Code	**Diagnosis**
007	Tuberculosis of the respiratory system
008	Other forms of tuberculosis
014	Diphtheria
015	Pertussis
048	Echinococcosis
054	Sequelae of tuberculosis
066	Malignant larynx tumour
067	Malignant tumour of trachea, bronchi, lungs, respiratory organs and intra-thoracic
069	Other malignant tumours of respiratory organs and intra-thoracic
140	Otitis media, mastoiditis
165	Acute pharyngitis and tonsillitis
166	Acute laryngitis and acute tracheitis
167	Other infections of the upper airways
168	Influenza
169	Pneumonia
170	Acute bronchitis and acute bronchiolitis
175	Chronic bronchitis, emphysema and other chronic obstructive pulmonary diseases
176	Asthma
177	Bronchiectasis
178	Pneumoconiosis
179	Other diseases of the respiratory system

Box 6.5 Simplified model of monthly report on distribution of outpatients with respiratory diseases by age				
Age group	**0–4 years**	**5–14 years**	**15–49 years**	**≥ 50 years**	**Total**
Total outpatients (all symptoms)					
Outpatients with respiratory symptoms (all causes)					
New cases All cases					
Acute respiratory infections					
New cases All cases					
Chronic respiratory diseases					
New cases All cases					
Pulmonary tuberculosis					
New cases All cases					
Other respiratory diseases					
New cases All cases					

Box 6.6 **Expanded model of monthly report on distribution of outpatients with respiratory diseases by age and sex**										
Age group	**0–4 years**		**5–14 years**		**15–49 years**		**≥ 50 years**		**Total**	
Sex	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**
Total outpatients (all symptoms)										
Outpatients with respiratory symptoms (all causes)										
New cases										
Follow-up cases										
All cases										
Acute respiratory Infections										
New cases										
Follow-up cases										
All cases										
Chronic respiratory diseases										
New cases										
Follow-up cases										
All cases										
Pulmonary tuberculosis										
New cases										
Follow-up cases										
All cases										
Other respiratory diseases										
New cases										
Follow-up cases										
All cases										

Box 6.7 **Models of report on outpatient activities**		
Simplified model	**Intermediate model**	**Complete model**
Acute respiratory infections (ARI)	Acute upper respiratory infections (AURI)	Acute otitis media, mastoiditis Rhinitis, sinusitis Acute pharyngitis, tonsillitis Acute laryngitis, acute tracheitis Other AURI
	Acute lower respiratory infections (ALRI)	Influenza Pneumonia Acute bronchitis (acute bronchiolitis)
Chronic respiratory diseases (CRDs)	COPD Asthma Other	COPD Asthma Bronchiectasis Pneumoconiosis Other CRDs
Tuberculosis	Pulmonary tuberculosis Pleural tuberculosis Other	Smear-positive pulmonary TB Smear-negative pulmonary TB TB pleurisy TB primary infection with symptoms
Other respiratory diseases	Suspicion of lung cancer or hydatid cyst	Cancer Hydatid cyst Other intra-thoracic tumours
Other	Other non-respiratory causes with respiratory symptoms	Hyperventilation Heart diseases Other

Box 6.8 **List of patients referred by the first-level health unit to a district outpatient service**			
Part A: Patients suspected of having pulmonary TB, referred for TB investigations			
Identification no. in outpatient register	Full name	Date and reason for referral	Date and report by referral service
Part B: Patients with a chronic respiratory disease (persistent asthma, COPD, other)			
Identification no. in outpatient register	Full name	Date and reason for referral	Date and report by referral service

Information to be collected at first referral health services (emergency rooms, district hospital, specialized or non-specialized outpatient service)

The main task of the medical supervisor is to ensure satisfactory coordination of activities between the PHC units and the referral services.

With regard to the *TB programme*, the supervisor verifies that all suspected cases of TB that have been referred by the PHC units have actually been registered by the laboratory and in the district TB register. The supervisor should check:

- whether the patients reported in the TB suspect register actually meet the criteria for TB suspects in the outpatient register of PHC facilities;
- whether all the patients reported in the TB suspect register actually underwent sputum smear examinations; this is done by comparing the TB suspect register with the TB laboratory register;
- the quality of information in the TB laboratory register;
- the district TB register in which the names of all the TB patients are recorded.

The supervisor also ensures that TB patients who have been sent for treatment follow-up to the PHC units are correctly recorded on the TB treatment cards of these units.

With regard to case-management of CRDs, the supervisor should verify that all CRD patients followed up in different PHC units have been examined and diagnosed by the referral outpatient services. The supervisor should check:

- the outpatient register of the first referral services (for instance paediatrics, ear, nose and throat, pulmonology, emergencies, etc);
- the register of chronic (respiratory) diseases at the district level;

and identify the health care units or services where the patients with CRDs (asthma, chronic bronchitis, COPD, bronchiectasis) are treated and followed up.

Specific information instruments at district level

In relation to *tuberculosis*, two information instruments are used for the supervision and evaluation of the programme activities:

- the district TB register;
- the TB laboratory register.

Models for these registers are available in the guides issued by NTPs.

For CRDs, as well as for other chronic noncommunicable diseases, it would be convenient to have a register in which all cases of chronic, noncommunicable diseases (including CRDs) are recorded and followed-up, usually for many years. The model proposed in Box 6.2 can be adapted to or used at district level since the same information on follow-up of chronic patients should be transferred from the health units to the district managerial level.

All the information on chronic respiratory patients included on the health unit card or register for these patients should be transmitted to the district register of CRDs (or chronic diseases). There is no separate form for transferring information from the health facility card or register to the district register, but there are several ways of effecting this transfer:

- A health facility worker takes the information to the district level each month or every three months.

- The district supervisor copies the information into the district register during supervisory visits to the health units.

- A copy or photocopy of the card or the register page is sent each month to the district to be copied into the district register.

PAL reports by the district level

District information to be reported to regional and central levels is based mainly on the data gathered and recorded at first-level health facilities and first referral level services. Several district TB reports are specified in NTP guidelines, including:

- quarterly report on TB case registration;
- quarterly report on sputum conversion;
- quarterly report on treatment outcomes;
- quarterly report on programme management.

The following reports can be used for PAL activities:

- *Monthly report*, by age (simplified format), or by age and sex, of outpatients with respiratory symptoms who attended first-level health facilities and first referral level services. The reports from the several units are consolidated using the selected formats shown in Boxes 6.5 and 6.6.

- *Quarterly report* on the cases registered in the CRD register. A model of this kind of quarterly report is shown in Box 6.9.

Box 6.9 Classification of the main chronic respiratory diseases in patients aged 5 years and over at outpatient services				
Chronic respiratory diseases (CRDs)	No. of CRD cases still followed at the start of quarter[a] (1)	New CRD cases registered during quarter (2)	CRD cases excluded during the quarter[b] (3)	Number of CRD cases at the end of the quarter (1) + (2) – (3)
Intermittent asthma Persistent asthma: mild moderate severe				
COPD, stages: I Mild II Moderate III Severe IV Very severe				
Other (depending on the country)				

[a] CRD patients should be categorized according to the results of their last assessment.
[b] Deaths, defaulters or transferred; these patients should be categorized as reported in (1) or (2).

Chapter 7

Developing PAL training materials

The national working group on PAL, which will already have developed the first version of the PAL technical guides and the related information system adapted to country conditions and priorities, is also responsible for developing the training materials.

Why develop training materials?

Experience has shown that dissemination of written guidelines, either as printed publications or in electronic form, has little impact on health personnel practices, because the health workers concerned do not feel that the guidelines are useful in their daily work.

To whom are training materials addressed?

The training materials are addressed to:

- *Health personnel* at first-level health facilities and first referral services who will be convened to participate in training workshops by district or provincial groups according to the scheduled plan for PAL strategy implementation.

- *Workshop facilitators* who have been identified among the members of the NWG on PAL, the officers of the NTP central unit and national consultants in respiratory diseases and TB.

What are the objectives of a PAL training workshop?

The main objectives of a PAL training workshop are to provide the knowledge and skills essential for delivery of standard case-management of TB and respiratory diseases and to comply with the recording and reporting procedures of the information system (Box 7.1).

The PAL training workshop also provides a good opportunity to remind participants about the NTP guidelines that relate to criteria for TB diagnosis, treatment categories, treatment follow-up, and the TB recording and reporting system.

The optimal duration for a workshop is between 3 and 4 days. The content of the workshop programme should be adapted to the skills and knowledge of the health personnel in the concerned country.

What documents are needed?

Three documents are needed for the training workshop:

- A *participant's module*, which: explains the training objectives and activities, step by step; presents clinical cases as problems to be solved (diagnosis and therapeutic decisions); and describes necessary communication skills. The problem-solving approach should cover all components of the PAL guidelines.

- A *facilitator's module*, which: presents the training objectives and activities, step by step, gives the expected answer(s) to each clinical case and exercise and refers to the corresponding specific paragraphs of the PAL technical guidelines.

- A *workshop director's module*, which provides guidance in the administrative and logistic requirements for effective conduct of the workshop.

Box 7.1 **Purpose and objectives of a PAL training workshop**
General purpose At the end of the workshop, the participants should be able to deliver integrated case-management of outpatients aged 5 years and over who have one of the main respiratory diseases or TB. **Objectives** At the end of the workshop, participants should: ☐ be able to provide adequate care, using standard guidelines for the diagnosis and treatment of patients with respiratory symptoms attending first-level health facilities and first referral level services; ☐ be familiar with the system for collecting and reporting essential data for monitoring and evaluating PAL activities; ☐ be competent in interpreting the results of peak flow and spirometric measurements for the classification and follow-up of asthma and COPD; ☐ evaluate the results of their own activities related to the integrated case-management of the main respiratory diseases and TB.

In the elaboration of the clinical cases included as exercises, the participation of both the specialists or experienced medical officers who were responsible for the technical guidelines and clinicians with teaching experience is essential in order to answer all questions and to provide any necessary information about the clinical cases. The expected answers should be clearly documented in the technical guidelines.

Participant's module

The participant's module should explain the training objectives (by day of the workshop and by step) and should include a list of the activities involved in achieving these objectives. The activities comprise:

- review of theoretical cases that are to be solved by small working groups and that cover all the situations included in the technical guidelines;
- role-playing by the participants;
- demonstrations of TB sputum smear microscopy and practical exercises, use of the peak flow meter, and use of the spirometer;
- practice in filling in outpatient registers, TB treatment cards and treatment cards (or the register) for CRDs (for the documentation of case-management activities, their supervision and their evaluation).

The training workshop programme may differ from country to country in the light of the knowledge and skills acquired by local health personnel in their basic training, and/or in previous in-service training (for instance on the NTP, the integrated management of childhood illness, or the case-management of asthma).

Step 1

In Step 1, the training activities review the technical guidelines on ARIs, TB control and the main CRDs at first-level health facilities. Specific training objectives are presented in Box 7.2 and the proposed activities in Box 7.3.

Box 7.2 **Step 1 training objectives**
At the end of Step 1, the participant should be able to: select, from the information supplied, the elements that help in making an initial diagnosis in patients who present with respiratory symptoms and when to suspect TB or a chronic respiratory disease; adopt a pragmatic and realistic approach to: giving advice or therapeutic prescriptions, requesting complementary investigations, using specialized outpatient referral services or an emergency service, communicating with patients and their families; fill in the outpatient register.

Box 7.3 **Step 1 training activities**
Reading the technical guidelines for first-level health facilities. Working groups: solving problems presented in exercises on acute and chronic cases, followed by plenary sessions for discussion and clarification. Practical work: use of the peak flow meter (measurement of peak expiratory flow in all working group participants); bronchodilator test. Role-playing, examples: advising a 12 year-old child and the mother on the treatment of asthma; explaining the treatment and follow-up plan for pulmonary TB to a 35-year-old patient.

The problems presented by the clinical cases should be designed in such a way that, based on the content of the technical guidelines, the working groups of participants can reach a diagnosis and propose an adequate management plan for the various respiratory conditions, for example:

presumptive streptococcal pharyngotonsillitis, to be treated with antibiotics;

viral pharyngotonsillitis, acute laryngitis, acute bronchitis or simple chronic bronchitis, for which antibiotics should not be prescribed;

acute otitis media and pneumonia, for which antibiotics should be prescribed;

suspected pulmonary TB, which needs at least two AFB sputum smear examinations;

suspected pleurisy, which needs further investigation at first referral level;

asthma exacerbation, which must be urgently assessed and treated with inhaled salbutamol and, if indicated, corticosteroids, oxygen and/or referral;

intermittent asthma that needs inhaled salbutamol only;

suspected persistent asthma or COPD, which needs assessment and then appropriate treatment according to its level of severity as judged by monitoring.

Step 2

During Step 2, the training activities are concerned with practical teaching of the technical guidelines concerning TB and CRDs, in particular the coordination between the first-level health facilities and first referral services. The training objectives of this step are described in Box 7.4 and the proposed activities in Box 7.5.

Box 7.4 **Step 2 training objectives**
At the end of Step 2, the participant should be able to:

- select, from the information supplied, the elements that contribute to suspicion of a CRD (asthma, COPD, sequelae of TB, bronchiectasis);
- assess the severity of an asthma or COPD exacerbation, and take the appropriate course of action;
- identify and refer designated respiratory emergencies;
- follow-up any treatment prescribed by a referral service for cases of TB, persistent asthma, COPD;
- register all examined patients in the outpatient register and all cases of TB or CRD in their corresponding registers.

Box 7.5 **Step 2 training activities**

- Complete the reading of technical guidelines for first-level health facilities and start reading the technical guidelines for referral services.

- Working groups: solve the problems presented in exercises on chronic cases, followed by plenary sessions for discussion and clarification.

- Practical work: demonstration (film or slides) on TB microscopy, followed   by a discussion on sputum collection requirements and the transport of sputum specimens.

- Role playing (examples):
    - explaining to a stage 1 COPD patient the need to stop smoking;
    - providing treatment for tobacco dependence;
    - explaining to a pulmonary TB patient the need for examination of close contacts and for other preventive measures.

The problems presented by the clinical cases should be designed in such a way that the working groups of participants can reach a diagnosis (even presumptive) and propose an adequate management plan or prescribe the treatment recommended by the outpatient referral service, for the following cases as examples:

- moderate and severe asthma exacerbations;
- hyperventilation syndrome;
- worsening of a patient classified as "moderate persistent asthma" by the referral outpatient service;
- exacerbation in a known COPD patient;
- treatment for smear-positive pulmonary TB;
- treatment for TB relapse;
- treatment for presumptive tuberculous pleurisy;
- suspected spontaneous pneumothorax.

Step 3

In Step 3, the training activities are concerned with the decisions that can be taken only at the referral services, for making a precise diagnosis and starting treatment (even if treatment will be continued and supervised in first-level health facilities). The training objectives of this step are described in Box 7.6 and the proposed activities in Box 7.7.

Box 7.6 **Step 3 training objectives**
At the end of Step 3, the participant should be able to: identify, for relevant clinical cases, the tasks that should be undertaken at first-level health facilities and those that belong to referral services; classify TB cases by both diagnostic category and treatment category; classify asthma exacerbations, and asthma itself, by degree of severity, and prescribe the corresponding treatments; classify COPD cases by stage of evolution and decide on appropriate therapeutic measures; identify patients who should be referred to a second referral service for more specialized investigations or treatment; register the precise diagnosis and the decision taken for each case in the outpatient register; complete both the TB register and the CRD register.

Box 7.7 **Step 3 training activities**
Careful reading of the technical guidelines for referral services (hospital outpatient service, emergency room, hospital ward). Working groups: solving all problems presented in exercises on chronic cases, followed by plenary sessions for discussion and clarification. Practical work: demonstration of the use of the spirometer, with some participants acting as patients (measurement of forced expiratory volume in one second (FEV1) and forced vital capacity (FVC), calculation of the FVE1/FVC index, comparison with expected values). Role playing: explaining the importance and features of directly observed treatment to a patient who should receive TB re-treatment; explaining the treatment and preventive measures to a patient who suffers from severe persistent asthma.

The problems illustrated by the CRD cases described are concerned mainly with the organization of treatment in coordination with first-level health facilities and the organization of follow-up by the referral outpatient service. The cases presented in the exercises should provide information on clinical, bacteriological and radiological findings, PEF and spirometry results, and some information on the patient's clinical evolution, in such a way that participants can make a precise diagnosis and propose a plan of appropriate treatment.

As examples, the cases to be presented in the exercises could include:

moderate persistent asthma (airway obstruction reversible after bronchodilator);

hyperventilation syndrome (differential diagnosis with asthma exacerbation);

- moderate COPD (smoking or occupational risk factors), with spirometry results;
- respiratory symptoms associated with angina pectoris;
- suspected occupational asthma (as it can be observed in the local situation, e.g. flour industry, leather industry);
- management of asthma exacerbation, proper differentiation between intermittent and persistent asthma and its degree of severity, with prescription of a treatment and an action plan for exacerbations;
- indications for re-treatment of pulmonary TB in three clinical cases:
  - i. a failure of initial Category I treatment,
  - ii. relapse of a patient cured by Category I treatment,
  - iii. a defaulter of Category I treatment returning after more than 2 months;
- bronchiectasis as a sequela of symptomatic primary TB infection;
- suspected bronchogenic cancer (to be referred to a second referral level).

Step 4

In Step 4, the training activities are concerned with how the information system reports on outpatients at every level, and how the additional available registers and documents (follow-up of CRDs at first-level health facilities; register of CRDs at district level) can be helpful for the implementation, supervision and evaluation of the PAL activities.

As an exercise, 10 outpatient form sheets, with 10 patients per sheet, are each filled in with concise data from 10 hypothetical patients seeking care (i.e. 100 cases in total); 30 patients present respiratory symptoms – made up of 15 cases with ARIs, 10 with CRDs (5 asthma, 2 COPD, 3 chronic bronchitis) and 5 with TB.

Copies of these forms should be made for each participant in the workshop and put together in an exercise booklet.

Two other registers, also filled with hypothetical cases, should be prepared:

- a district TB register, showing about 20 cases of TB (pulmonary and extrapulmonary);
- a district register of CRDs, showing about 20 cases (10 of asthma, 5 of COPD, 3 of severe bronchiectasis or extensive sequelae of cured TB, and 2 other cases).

A copy of both registers should also be made for each workshop participant and should be used for the exercises specified in the training activities.

The training objectives of Step 4 are described in Box 7.8. The training activities in Box 7.9 are based on the selected information system, the checklists to be filled in during the supervisory visits, and the PAL strategy objectives formulated at the national level.

Box 7.8 **Step 4 training objectives**
At the end of Step 4, the participant should be able to:
☐ explain the importance of the proposed information system for supervising the implementation of the PAL strategy and evaluating its impact;
☐ identify the register(s) that should be filled in at first-level health facilities (register of outpatient visits; register of TB suspects; list of TB and CRD cases under treatment);
☐ identify the register(s) that should be kept up to date at the district level (district TB register; chronic diseases register);
☐ use the information in the registers to complete the monthly reports and the report of the supervisory visit;
☐ evaluate the outcomes of the PAL activities.

Box 7.9 **Step 4 training activities**
Using the outpatient register forms distributed during the exercises:
☐ Fill in column 13 of the outpatient register using the 3-digit ICD-10 code.
☐ Fill in the register of TB suspects.
☐ Complete, by name, the list of patients sent by first level health facilities to first referral service.
☐ Complete the lists of patients who need long-term care and are followed-up by first-level health facilities (TB and CRD cases).
☐ Fill in, using the outpatient forms on which 100 hypothetical cases have been registered, the monthly report of outpatient activities related to respiratory diseases and the distribution of respiratory patients aged 5 years and over by age and sex.
☐ Evaluate the degree of integration of the TB and respiratory disease diagnostic activities at first-level health facilities and first referral outpatient services.

Facilitator's module

The general objective of the training workshop is to prepare doctors (or medical assistants) for implementation of the PAL strategy. The strategy should be:

- ☐ integrated into the doctors' own daily activities,
- ☐ implemented with close coordination between the first-level health facilities and the first referral services.

Working methods

The proposed method for the workshops emphasizes self-training in small groups of participants. The participants are asked to find solutions to the exercises (clinical cases and role-playing) in the technical guidelines through an active exchange of views in each group.

The facilitator's role is to follow the progress in the discussions of each group and suggest rereading of specific parts of the guidelines in order to help the group reach

a consensus within the time allowed for each exercise. As their title suggests, facilitators "facilitate" – they do not give lectures, they do not provide solutions.

The plenary sessions are scheduled for clarifications, for providing concise answers to questions posed by the participants and reaching agreement on the usefulness of the proposed solutions.

Content of the facilitator's module

The facilitator's module follows the steps of the training workshop. The content includes:

- general objective of the workshop;
- description of the working methods used in the workshop;
- allocation of the workshop time;
- training objectives, step by step, and activities for achieving these objectives;
- answers to the hypothetical clinical cases, identified by number, pointing out in each case the expected answer, the decision(s) to be taken, the usefulness of the proposed decision(s), and the corresponding reference to the technical guidelines;
- instructions for role-playing and criteria for its evaluation (evaluation of the explanations expected by the "patient" as well as those expected from the "doctor");
- the final workshop evaluation form (to be distributed during the last day to each participant who should fill it in anonymously).

Chapter 8

Testing the clinical guidelines and operational procedures

Before the PAL strategy is introduced into the practice of the health services, a feasibility study can be undertaken.

Objectives of the feasibility study

The general objective of the feasibility study is to evaluate the short-term impact of PAL implementation on the practices of the health personnel regarding the case-management of patients who present with respiratory symptoms. Also, this study aims to:

- test and validate the technical guidelines drafted by the NWG for health personnel responsible for case-management in the field;
- document improvements in the efficiency of health personnel in their daily work;
- collect local data in order to enlist the support of authorities for the progressive expansion of PAL in the country.

Establishment of a central-level coordination group for the feasibility study

A group of coordinators/trainers should be established at central level; it should include members of the NWG that drafted the technical guidelines and contributed to designing the information system for PAL activities. This group will help develop and review the feasibility study protocol initiated by the NWG; it will be responsible for organizing, conducting and facilitating the training sessions, as well as for ensuring the monitoring and supervision of the various phases of the feasibility test.

The coordination group should:

- prepare the agenda for each training session and the practical exercises;
- organize the printing and distribution of the protocol, the information forms and the technical guides; and
- collect the data and reports from the districts, and check, complete and correct, if necessary, the tables for data analysis, with the collaboration of participating doctors and relevant staff from the districts, such as TB control coordinators, PHC key staff or TB laboratory personnel.

The chairperson of the coordinating group should supervise the secretarial and computer personnel. Computer technicians should be specially trained to take charge of the electronic management of data collected in the two surveys of the feasibility study.

Development of the study protocol

The NWG should ensure the development of a study protocol adapted to the country in question, and the coordination group should be involved in the formulation and finalization of this protocol. The protocol should clearly define the study methodology,

specify the successive phases of the feasibility study, identify the study sites and the health worker categories to be involved, explain the process of data collection, and clarify procedures for data coding and analysis. It should also highlight the resources and budget needed for the study. An annex to the protocol should identify the health facilities where the feasibility study will take place as well as the health professionals who will be involved.

Models of study protocols used in various countries are available on request from the Stop TB Department, WHO, Geneva. The following sections of this chapter outline all the various components that should ideally be considered for inclusion in a county's feasibility study protocol.

Selection of the study method

The feasibility study is based on the hypothesis that the training of district health workers on the PAL strategy has an impact on their attitudes and practices (assessment and classification of cases, request for complementary investigations, drug prescriptions and referral of patients). There is no intention to make a concurrent comparison between districts with specially trained personnel and districts with no such special training. Rather, the study aims to measure the short-term impact of the PAL strategy on the clinical practice of the health workers involved, observing the same personnel at the same study sites during the same season of the year, before and after training on PAL procedures (before-and-after comparison). To this end, the feasibility study compares the findings of two surveys: the baseline survey, carried out before the training on PAL, and the impact survey, carried out after this training.

The feasibility study should be conducted in appropriate pilot areas involving:

- ☐ 80–100 health professionals practising in the first-level health units of some districts;
- ☐ 10–20 medical officers practising in the first referral outpatient facilities of the same districts.

The informed consent of the health personnel (doctors and medical assistants) responsible for the examination, treatment and orientation of patients attending the selected health units should be ensured in order to secure their participation in carrying out the feasibility study.

Selection of study sites

If possible, the sites for the feasibility study should be selected from different provinces or regions. The most important requirement is to ensure comparability between the data sets of the baseline and impact surveys. For this, the two surveys should involve the same health facilities and the same health personnel and should be carried out in the same season. In the context of this feasibility study, internal validity is more important than representativeness. Criteria for selection of the study sites include the following:

- Districts where the system for the referral of TB patients is well organized and the doctor responsible for the TB control programme or the coordinator of the district's first-level health facilities can be responsible for implementation of the PAL feasibility study. To facilitate monitoring of the feasibility study activities, these districts should be easily reachable . There should also be a TB laboratory that is easily accessible for respiratory patients referred for sputum smear microscopy.

- First-level health units where a doctor or medical assistant provides care to, on average, 20 outpatients per working day; these units should be linked with the referral outpatient facilities of the selected districts.

Given that the observation unit is the respiratory patient, the duration of data collection should be as short as possible and the number of health personnel involved as high as possible in order to reduce the bias associated with clustering. Clustering is related to the number of respiratory patients examined per health worker involved in the study (Box 8.1).

Health personnel should be asked to record accurately all information on patients' identity, diagnoses, prescriptions and other decisions during the baseline and impact surveys. Box 8.2 shows information that can typically be collected on 5000 patients aged 5 years and over who visit PHC setting for any reason.

Country experience suggests that a sample size including 3000 patients aged 5 years and over with respiratory symptoms (roughly, 1500 in the baseline survey and 1500 in the impact survey) is reasonably adequate for the study objectives.

Box 8.1 Issues associated with clustering
First situation
10 doctors work for 2 weeks and see 2000 patients; the ratio is therefore 2000/10 = 200 patients per doctor. Every doctor examines on average 200 patients. It is important to highlight that patient management is influenced by doctors' behaviour. A clustering effect in patient management will therefore be reflected in every cluster of 200 patients.
2nd situation
100 doctors work for 1 week and see 3000 patients; the ratio is therefore 3000/100 = 30 patients per doctor. Every doctor examines on average 30 patients. Therefore, the clustering effect will be reflected in every cluster of 30 patients.
Question: Is the bias associated with clustering similar in the two situations?
Answer: In the first situation there are 10 practice behaviours related to 10 doctors; in the second situation there 100 practice behaviours related to 100 doctors. Bias associated with clustering is therefore likely to be lower in the data set of the second situation.

Box 8.2 Relevant information on 5000 patients initially involved in a survey of the feasibility study	
Outpatients, 5 years and older:	5000
With respiratory symptoms	1500
Pulmonary TB suspects	75–150
Identified pulmonary TB cases	7–15

Selection of the season

 The two surveys to be carried out in the feasibility study must be conducted in the same season of the year because of the seasonal influence on the occurrence and distribution of respiratory conditions. Ideally, they should take place in the cold season during which the number of patients with respiratory symptoms usually

increases. Further, the survey period should not coincide with any major local, national or international events (religious, cultural, sporting, etc): such events may influence the care-seeking behaviour of patients.

Phases of the feasibility study

The feasibility study can be completed over 4-6 months if it is carefully planned. It is divided into five phases (Box 8.3):

- *Phase 1*

  Phase 1 is the preparatory phase in which the study protocol is reviewed and discussed with the coordination group. At least 10 coordinators/trainers should be involved; some of them should be members of the NWG on PAL, the others should be chosen from among senior staff of key departments, such as PHC, HIV/AIDS or HMIS, and teaching institutions. Staff from the NTP must be involved in all phases of the feasibility study. The methods and materials to be used in the various training sessions inherent to the feasibility study must be carefully reviewed, discussed and standardized with the coordinators/trainers. Clear assignments must be specified for each of the coordinators/trainers, some of whom may be involved only in the training on data collection in the two surveys only, others only in the training sessions on PAL, and others only in the monitoring of data collection and computer entry. Experience in countries, however, has shown that some of the coordinators/trainers are involved in all the phases of the feasibility test. Each training session, either on data collection or on respiratory care using PAL guidelines, should be overseen by at least two coordinators/trainers.

- *Phase 2*

  Training sessions for health personnel from the selected sites on data collection should be undertaken. Each training session should be organized for a maximum of 30 persons. For instance, if 100 health professionals need to be involved in the process of data collection, four simultaneous or consecutive sessions are necessary to train all of them.

- *Phase 3*

  Data collection for the baseline or "before" survey is undertaken. Information concerning all the patients who attend for care during five consecutive working days, with detailed information about those with respiratory symptoms, should be registered at the selected sites.

- *Phase 4*

  Training sessions on PAL technical guides should involve the same health personnel. Each session should also have a maximum of 30 participants. Four simultaneous sessions are necessary to train, for example, 100 health professionals. After training, the health personnel should use the PAL guidelines in their daily practices during the following week; this will help familiarize them with the content and use of the PAL guidelines before the second survey is carried out. The computer technicians, who will be in charge of the data entry using a computer program, should also be trained through simulation exercises of data collection and entry.

- *Phase 5*

  Similar to the baseline survey, the impact or "after" survey involves registration of data on all patients who attend for health care during five consecutive working

days at the same selected sites, with detailed information on those with respiratory symptoms. In this second survey, the health personnel must use the PAL guidelines on which they were trained two weeks earlier.

The baseline or "before" survey

This initial survey includes Phases 2 and 3 of the study:

- ☐ Phase 2: training on the data collection process;
- ☐ Phase 3: registration of data.

Phase 2: Training on the data collection process

Training on data collection for 25–30 health workers who have agreed to participate in the feasibility study is carried out during one working day. The objectives of the session are:

- ☐ to explain the survey protocol;
- ☐ to fill in, without errors, the special study form on registration of outpatients;
- ☐ to fill in the other information instruments:
    - ☐ distribution of outpatients by age and sex groups;
    - ☐ list by name of patients sent to referral specialists for assessment of a chronic respiratory disease or suspected TB;
    - ☐ list by name of patients cared for by referral specialists according to their diagnosis and the therapeutic decision (TB, CRD).

Programme for the training session

The training session is attended by general practitioners or medical assistants working at first-level health facilities and by doctors working in referral services. The participants should be made familiar with the information system that will be used during the survey by everyone at the selected health facilities according to their individual functions. A model of the agenda for the training course is given in Box 8.4.

- For health personnel at first-level health facilities, the proposed information system comprises:

    - ☐ the outpatient register existing in the survey facilities; this register is used if it is appropriately designed to collect the required information (the model is shown in Box 6.1 of Chapter 6). However, in some country settings, the existing outpatient register is not designed in this way; in such cases, a special register that will provide the information needed on patients seeking care for respiratory symptoms should be used during the survey period only.
    - ☐ the list by name of patients sent to referral services because of possible CRD (to be assessed) or suspected TB;
    - ☐ the list of TB cases who were followed up and their treatment regimens;
    - ☐ prescriptions for every patient who was prescribed medications.

- For doctors at the referral services, the information system comprises:

    - ☐ the general register of outpatient visits;
    - ☐ the TB laboratory register;
    - ☐ the register of chronic respiratory diseases.

During the week in which the doctors are trained, a workshop on data entry will be held for computer technicians. The process of data entry using a computer program

such as Epi-Info should be thoroughly explained, and technicians should carry out simulation exercises.

Phase 3: Registration of data

One week after the end of the final training on the data collection process, Phase 3 on data registration starts at survey sites and takes place over five consecutive working days. During these five days, the study coordinators should visit each study site once or twice. Participants should complete the data collection within one month following the end of the five-day registration period, particularly for patients who were referred.

Protocol for data registration during the baseline survey

The baseline survey, carried out in advance of training, collects information about the demands for outpatient services in general – and for care of patients with respiratory symptoms in particular – and the ways in which first-level health facilities and referral services respond to these demands.

Box 8.3 Example: Schedule of a feasibility study		
Phase	**Date**	**Content**
1	10 – 30 January	• Identification of at least 10 coordinators/trainers. • Review and discussion of the study protocol with the coordinators/trainers. • Standardization of the methods and training material to be used in the training sessions. • Clear assignments for each of the coordinators/trainers. • Review the timetable of the feasibility study with coordinators/trainers and the NWG on PAL.
2	2 – 6 February	• Four one-day sessions to train doctors on the collection of the survey data. • Training of computer technicians who will be in charge of electronic management of the data.
3	16 – 20 February (baseline survey)	• Registration of data at all study sites before the training on the PAL guidelines
4	20 – 24 March (training)	• Four simultaneous sessions, 3–4 days each, to train doctors and nurses on the PAL technical guidelines.
5	27 – 31 March (impact survey)	• Registration of data at all study sites (as for the baseline study), after PAL training.

Box 8.4 **Agenda for the training session on the data collection process to use in the baseline survey**	
08:00	Registration of participants and distribution of working documents
08:30 - 10:30	Objectives of the baseline survey. Presentation and discussion of the survey protocol: methodology of enrolling the study participants and eligibility criteria, presentation of the forms to be used in the survey, data collection process, disease categories to be used in data collection, data analysis procedures to be used, role of study coordinators, role of the central-level coordination group for the feasibility study and other.
10:30 - 11:00	Break
11:00 - 12:00	Discussion and provision of clarifications on some components of the protocol Constitution of 4 to 5 working groups for the simulation exercises; then presentation of the exercises to be carried out.
12:00 - 13:00	Exercise on the registration of 30 patients with respiratory symptoms or defined respiratory diseases.
13:00 - 14:00	Break
14:00 - 15:30	Continuation of working group exercise on registration of 30 respiratory patients
15:30 - 16:30	Working groups: filling in the complementary information forms (using the same 30 patients)
16:30 - 17:30	Plenary session: correction of the exercise and clarification
17:30	Closure

At each survey site one staff member is responsible for the survey – a doctor or medical assistant at first-level health facilities, and a general practitioner or specialist at the referral services. The study coordinators should ensure the coordination among the different sites during the feasibility study.

Working methods

Period of the survey

The initial survey takes place over five consecutive precisely defined working days.

Criteria for selection of patients

All children aged 5 years and over and adults who seek health care at one of the selected first-level health facilities during the survey period are eligible for inclusion in the survey.

Classification of patients attending with respiratory symptoms

Some of these patients will be attending the first-level facilities because of respiratory symptoms. On the basis of the data collected through clinical questions and examination, the doctor makes an initial diagnosis (or presumptive diagnosis if complementary investigations or consultations are considered necessary). The list of possible respiratory diagnoses should be included in the protocol.

Registration of data by the doctor or medical assistant

During the five days of the survey, all patients attending the selected sites (including those with respiratory symptoms) will be registered in the existing outpatient register if the latter is appropriate for the data to be collected for the survey (see Box 6.1, Chapter 6); if not, a register needs to be specifically designed to fulfil the survey requirements and implemented in the study sites. For each patient, the doctor or medical assistant will record in the register the precise data as explained in the survey protocol.

For respiratory patients needing medications, the medical prescription form should be written in duplicate; the original is given to the patient and the duplicate is kept by the doctor. The prescription should include the patient's full name, age and outpatient register order number. The cost of the drugs should be established for each patient given a prescription.

At each survey site, the outpatient register should be maintained for one month after the five survey days and should be completed for respiratory patients who were registered during those five days. Respiratory patients who return for the results of any complementary investigations or reports by specialists within the 30 days following the week of their initial examination will be registered again with a new order number on the usual outpatient register; however, information relating to follow-up of visits made during the survey period should be added to the study register in the line corresponding to this visit (i.e. column 12, Observations, of the model outpatient register in Box 6.1).

Control of data by the study coordinator

The study coordinator supervises and monitors the quality of registered data:

- During the survey period, the study coordinator visits each site twice. For instance, if the survey starts on Monday, he/she will visit the study sites on Monday (first day of data collection) or Tuesday (second day) and again on the following Monday (eighth day, three days after the data collection is over). During these visits, the coordinator checks the filling in of the outpatient form for each patient and the initial diagnosis. At the end of the second visit, the coordinator, with the help of the local participating doctor, completes the data forms and collects the duplicate copies of drug prescriptions given to respiratory patients.

- One month later, the coordinator again visits the study sites to collect the outstanding data on the diagnostic follow-up of patients and fills in column 13 with the ICD-10 code for the final diagnosis (see Box 6.1, Chapter 6). The coordinator also visits the TB control unit and the microscopy laboratory to complete the data on pulmonary TB suspects and on the final diagnosis in patients with CRDs (Boxes 8.5 and 8.6).

- The coordinator then tabulates the data on all visits by outpatients with respiratory symptoms during the study period and the distribution of these patients by age, sex, and diagnosis.

- Depending on the study protocol, the coordinator may be asked to use duplicate prescription forms to establish the cost of the prescribed drugs as if each respiratory patient had to pay for his or her medicines. The protocol may specify that the cost should be established for each drug category, e.g. antibiotics or corticosteroids; Box 8.7 shows a model form used in the Bolivia feasibility study. The methods of establishing these costs should be the same for all respiratory patients; for instance, the prices fixed by ministries of health have been used to assess drug prescription costs in some countries where the feasibility study has been carried out.

Management of data from the baselinel survey

After local compilation, all the data collected during the survey (including copies of the register covering the survey period), control forms and duplicates of drug prescription forms should be sent to the secretariat of the central-level coordination group for the feasibility study The computer technicians should then enter the data into the study computers using a coding system from the chosen software package (e.g. Epi-Info). After data entry is complete, the data set should be checked and cleaned by the relevant members of the central-level coordination group who, at this stage, can also carry out some preliminary analysis to assess the quality of the data set.

Box 8.5 **Collection of data: Form No. 1**										
Distribution of outpatients by age and sex										
Health care unit : ………………………………….. District :………..…………………………… Period from …………….. to ………………..										
Age group	0–4		5–14		15–49		50 and older		Total	
Sex	M	F	M	F	M	F	M	F	M	F
All outpatients										
Outpatients with respiratory symptoms										

List by name of pulmonary tuberculosis suspects			
List by name of patients (name and order number)	Date of patient's referral		
	Tuberculosis centre	Microscopy laboratory	Hospital

List by name of patients referred with chronic respiratory symptoms for diagnosis (TB excluded)		
List by name of patients (name and order number)	Date of referral to a specialized service	
	Pulmonary	Other

Box 8.5 Collection of data: Form No. 1[a]				
Diagnosis and treatment of patients sent to a referral service				
Pulmonary tuberculosis suspects				
List by name of TB suspects	Diagnosis		Treatment	
	Diagnosis	Date	Category	Date
Patients with chronic respiratory symptoms referred for diagnosis				
List by name of referred patients	Diagnosis		Treatment	
	Diagnosis	Date	Prescribed drugs	Date

[a] To be filled in within the month after the end of the first period for the registration of data at the referral service.

The impact or "after" survey

The impact survey includes Phases 4 and 5 of the feasibility study:

- Phase 4 for training health personnel on the technical guides;
- Phase 5 for registering the data after training.

Phase 4: Training on PAL technical guidelines

The training courses on the PAL technical guidelines are delivered to all the health personnel who participated in the baseline survey, at the same selected study sites. The duration of these courses is three to four days, depending on the knowledge and skill levels of the participants. The objectives and training activities are described in detail in Chapter 7. The courses should be organized as planned by the NWG on PAL and the central-level coordination group for the feasibility study and should take place in the fourth week after the baseline survey. After training, the health workers should use the PAL guidelines during the fifth week to further familiarize themselves with their content and their use in daily practice.

Phase 5: Registration of data

In the sixth week after the baseline survey, Phase 5 on data registration starts at all the survey sites and continues for five consecutive working days; during this phase the trained health workers should use the PAL guidelines whenever they are needed. During these five days, and again a month later, the district coordinator visits the sites at first-level health facilities, as in the baseline survey, and completes the data from the second registration period.

The data collected during the impact survey should be collated, entered into the study computer and cleaned in the same manner as the data collected in the initial survey.

Box 8.7 **Model of drug prescription form used in the feasibility study carried out in Bolivia**

Republic of Bolivia Ministry of Health and Sport

Practical Approach to Lung Health Study

Date: PHC centre:

Code of the medical officer: Name of the medical officer: :

Patient study number: Name of the patient:

<div align="center">DRUG PRESCRIPTION</div>

Antibiotic cost	Total bronchodilator cost	Inhaled bronchodilator cost	Total steroid cost	Inhaled steroid cost	Other drug cost	TOTAL COST

Analysis of data

The data collected in both surveys should be included in the same data set using the same coding system and the same software program. Models of data entry programs on Epi-Info used in various countries can be requested from the Stop TB Department, WHO, Geneva.

The data analysis will compare the distribution of the information between the baseline and impact surveys for each variable. This will help to assess the effect of training the health personnel on case-management of patients with respiratory symptoms in the following areas:

- improvement in the quality of TB diagnosis;
- improvement in the management of CRDs;
- reduction in the number of unnecessary referrals and requests for complementary investigations;
- reduction in the overall prescribing of drugs, particularly of antibiotics;
- rationalization in prescribing drugs for respiratory diseases in general;
- reduction in the cost of drug prescriptions and complementary investigations.

The results of the feasibility study should be presented to all the participants in an evaluation meeting. At the end of this meeting, the comments of the participants about the contents of the technical guidelines should be carefully taken into account in order to introduce improvements in the guidelines before undertaking further expansion of the PAL strategy in the country.

Funding the feasibility study

It is important to mobilize the necessary resources to carry out the feasibility study of PAL. Funds are needed to cover the inherent costs of the study for:

- reproduction of the technical guides and the information instruments;
- training courses;
- transport, accommodation and daily allowances for participants and facilitators;
- activities of the central-level coordination group and computer services;
- supervisory visits by the study coordinators to the first-level health facilities.

The NWG should estimate the budget needed to carry out the feasibility study and secure financial backing from national sources (government, NGOs, public and private sponsors) or international sources (bilateral and multilateral cooperation agencies and institutions such as WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria).

Report of results

Results of the feasibility study should be compiled and analysed by the NWG on PAL in close collaboration with the central-level coordination group for the feasibility study. The study conclusions should be submitted, in a report, to the national health authorities by the NWG together with a plan for PAL expansion to all districts of the country.

Chapter 9
Developing a national expansion plan
_____

On the basis of the feasibility study results and the recommendations of the NWG, the health authorities should make a decision regarding integration of the PAL strategy into the general health policies and its implementation in the framework of TB control activities.

 This decision is an essential prerequisite for expanding the PAL strategy throughout the country but must be supported by a realistic plan for national expansion formulated by the NWG. This chapter provides the general outline for such a plan.

Establishment of a central subunit for coordination of the extension plan

A PAL central subunit, at the MOH, needs to be established within the central unit of the TB control programme. This subunit should work in priority in close collaboration and coordination with the department of PHC. It should be supported by an advisory committee of national experts, senior members of the NWG and representatives of the health personnel (doctors and nurses) from the districts that have participated in the feasibility study.

The central subunit is responsible for providing technical guidance, planning and evaluating implementation of the PAL strategy, and ensuring coordination with the national TB control policy, PHC policy, HIV/AIDS and essential medicines programmes, the HMIS, the supply services and the finance department of the MOH.

The central subunit should prepare a budget for the progressive implementation of the PAL strategy, including the purchase of essential equipment. It should also check whether the drugs that are specified in the guidelines for use in PAL services, such as drugs for inhalation use, are included in the national programme of essential drugs.

In coordination with the HMIS, the central subunit should propose a plan for the supervision and monitoring of activities at intermediate level (province, region). The intermediate level should collect and analyse the local data in order to evaluate the quality of the activities and the performance of the PAL strategy and submit periodic reports to the central subunit.

Revised technical guidelines and the information instruments

Expansion of the PAL strategy can be carried out only after comprehensive information has been made available to all relevant health personnel. It is therefore essential to ensure that the revised technical guidelines and the newly adopted information instruments are produced in adequate quantities for distribution to all health staff.

Technical guidelines

The technical guidelines prepared by the NWG before the feasibility study should be revised, taking into account the comments and recommendations of the health personnel who used them in the feasibility study. Revised versions should be prepared and printed for general distribution.

Information instruments

The information instruments that will be adopted at national level should be discussed with PHC and HMIS officers. It is important that the number of information forms to be filled in by the health workers, as discussed in Chapter 6, is not increased without strong justification.

The best solution is to integrate the necessary data into a *standard register for outpatient visits*, by expanding or modifying the existing register. If this is not possible, the specific information proposed in the feasibility study for evaluating the performance of PAL activities can be collected in special periodic surveys by sentinel units at representative sites.

Reports on the recorded data on respiratory diseases can be submitted quarterly, together with the reports required by the NTP.

In countries where the same unit is responsible for the TB control programme and for case-management of respiratory diseases, the procedures are simplified. In other situations, it is necessary to review with the officers in charge of the national health information system and disease control division – such as communicable diseases (ARIs and TB) and noncommunicable diseases (asthma, COPD, cancer, pneumoconiosis) – the data to be collected, the instruments, the periodicity for the reports, and the units to which the reports should be submitted. In these cases, the central-subunit should harmonize the recording and reporting methods.

Training of trainers for implementation of the PAL strategy

The central unit should organize the training of trainers who will be responsible for the process of expanding the PAL strategy.

At existing health services

The feasibility study is conducted with the assistance of trainers, many of whom will have been selected from among NWG members and senior staff of health departments and academic institutions. Additional potential trainers may therefore also be identified among the participants in the feasibility study.

The PAL central unit should plan the training of a team of trainers in each province or region, according to the expansion plan, who will then be responsible for the training of health personnel who will be involved in the different districts (cascade training).

The trainers should be familiar with the contents of the technical guidelines and the health information system to monitor TB control and PAL activities. They have the task of training:

- the district coordinators;
- the doctors working at referral outpatient services and in emergency rooms of each district;
- health personnel at first-level health facilities.

At the training institutions

Simultaneously, the central subunit should plan the integration of the PAL strategy into the curricula of the institutions that provide basic training of health workers: medical schools, nursing and paramedical workers schools, and public health schools.

Equipment and essential drugs for implementation of the PAL strategy

Generally speaking, the basic equipment needed for implementation of the PAL strategy is available at district-level facilities (hospitals, outpatient departments and emergency rooms). In facilities outside hospitals (clinics, health centres, dispensaries), however, the availability of equipment is variable and often there may be none. This results in frequent referrals to the district hospital for complementary investigations or simple therapeutic procedures that could be performed at the first-level health facility if it were adequately equipped.

Equipment

In planning national expansion of the PAL strategy, the central subunit should, with the support of the supply and finance departments, allow for procurement of the necessary equipment for districts in which health staff have been or will be trained.

The equipment should be procured gradually, ensuring its good quality and the ability of the health personnel to use it appropriately. A typical list of necessary equipment is given in Box 9.1 (see also Chapter 4, Box 4.3).

Essential drugs

Only drugs that are included in the national list of essential medicines should be used for PAL services. An uninterrupted and reliable system for procurement of essential medicines and their distribution to PHC services is therefore essential.

Plan for the expansion programme

Expansion of the PAL strategy starts after the results of the feasibility study have been presented and the authorities are willing to fully support the implementation of PAL strategy.

The duration of the expansion process depends on the size of the country and the number of districts. It also depends on the capabilities of the health personnel, especially in the implementation of adequate TB control activities: PAL should preferably be initiated in districts where DOTS services are functioning well along with other components of the Stop TB Strategy. This contributes to expanding the various activities of the Stop TB Strategy within districts.

The plan for expansion can be developed in three phases:

- *Phase 1*

    The main activities in this phase are: the training of trainers in each province, selecting at least one pilot district per province or region; completing the supply of necessary equipment to the selected districts, once the health workers have been trained.

- *Phase 2:*

    Each provincial/regional group of trainers trains the health personnel from four districts in one year (one district each quarter). The central unit organizes the supply of the necessary equipment to the selected districts and monitors the availability of the essential drugs needed for PAL activities. Depending on the number of districts, the size of the health professional population to be trained and the availability of the funds, this phase can take 2–4 years or more.

- *Phase 3:*

   After the start of the first year of the PAL strategy implementation, a national seminar should be convened, with the participation of PAL district coordinators, to evaluate progress made in the expansion plan; to discuss the difficulties and constraints encountered and their possible solutions; and to set the objectives to be achieved in the future, particularly the permanent supervision of activities and a more profound evaluation of PAL strategy implementation.

   Representatives from the districts where PAL will be implemented in the coming year should also be invited to attend this seminar. The process of implementation should be reviewed and discussed with these participants on the basis of experience in the districts where PAL has been already implemented. Donors who are already supporting PAL implementation in the country, plus those who may be supporters in the future, should also be invited to the seminar.

Box 9.1 **Equipment needed for implementation of the PAL strategy**

☐ At first-level health facilities:
  – sputum containers
  – peak flow meters with mouthpieces
  – inhalation chamber with masks (for children)
  – pulse oximeter
  – oxygen sources (cylinder and/or concentrators and accessories)
  – nebulizer with mask.

☐ At district referral outpatient services or laboratories:
  – binocular microscope
  – centrifuge and incubator (if cultures for TB are performed)
  – basic radiology equipment
  – spirometer
  – pulse oximeter
  – equipment for tracheal aspiration
  – oxygen sources
  – equipment for pleural drainage
  – needles and instruments for transthoracic pleural biopsy
  – blood gas analyser.

☐ At second referral level:
  – bronchoscope (if there is a chest specialist trained to use it).

Budget for the expansion plan

The budget for PAL activity expansion and the required resources should be included in the ordinary budget for health services and provided as a discrete budgetary item, independent from the budget for TB and PHC programmes. In this way, permanent integration of the PAL strategy into the country's national health policies can be ensured.

PAL is not a new "programme" that has to be supported from abroad. It is a way of delivering case-management services more efficiently, often with existing means that

have not been well utilized. Thus PAL is not a new "appropriate" technology, but a new manner of organizing the work, in line with the objectives of integrating vertical health care programmes into the delivery of case-management.

The budget for the expansion plan should provide for:

- establishment of well-equipped offices for central subunit and district – and eventually provincial – coordinators;
- wages and benefits for central subunit staff and coordinators;
- cost of training courses (preparation of guidelines and information instruments; logistics; daily allowances and transport for participants and facilitators);
- costs of supervisory missions by members of the central subunit, the advisory committee and district coordinators;
- cost of specific equipment for first-level health facilities.

Training will account for most of the cost of the expansion plan. Some countries have sufficient resources to purchase drugs and equipment but no budgetary line for training; accordingly, external support will be needed to overcome this problem.

The lack of funds in some countries will mean that external support will be needed to support the PAL expansion plan. A national review meeting on PAL activities should be convened with representatives of key health departments, academic institutions and potential national and international (multilateral and bilateral) donors. At this meeting, the NWG and the PAL central subunit of the MOH should present the progress that has been made so far: development of PAL guidelines and training materials, the final results of the feasibility test, and the expansion plan for implementation and the required budget. The intention is to strengthen political commitment and to involve potential donors in the funding of the plan.

Chapter 10

Organizing systematic supervision, monitoring and evaluation

Implementation of the information system proposed in Chapter 6 ensures close monitoring of PAL activities, including surveillance of the demand for care of respiratory diseases at PHC units. This system implies an adaptation process, which should be compatible with the organization of the general health services and the existing health information system (Chapter 3).

The adaptation process should take into account the experience gained by each country in the supervision and evaluation of their NTPs, the PHC organization and the case-management of chronic diseases.

Organization of PAL supervision

Supervision is a systematic activity for increasing the efficiency of health workers through direct contacts. It is an extension of training that serves to increase the knowledge, perfect the skills, improve the attitudes and strengthen the motivation of involved health personnel.

Supervision is completed by monitoring, which entails the observation of programme performance to ascertain that activities are accomplished in quantity and quality as planned. Monitoring is carried out at the health facility through direct contact with health workers and through the examination of periodic reports.

Who supervises and who is supervised?

Supervision of PAL activities is carried out at three levels.

- Activities at first-level health facilities and first referral services are supervised by the district coordinator for the PAL strategy, who can also be the coordinator for the TB programme, for PHC services or for the disease control programme. The district – sometimes termed area, municipality, *rayon,* etc. – is the most peripheral managerial level within the PHC system, usually with responsibility for a population of 100 000 to 500 000.

- PAL district activities are supervised by a coordinator from the intermediate level (province, region, state or *oblast).*

- Intermediate-level management is supervised by the MOH central subunit responsible for the PAL strategy (see Chapter 9).

What is supervised?

The overall PAL strategy aims to integrate the standardized case-management of TB and respiratory diseases into the first-level health facilities and to ensure good coordination (referral and counter-referral) between these facilities and the first referral level services.

Supervision of the first-level health facilities is carried out monthly or every three months, depending on the local situation, through a visit by the district coordinator who:

- Examines the outpatient registry and adds any data that were not registered by the doctor or the medical assistant (Chapter 6).

- Completes, if necessary, the column of the outpatient register concerning the ICD-10 code for each patient's disease and checks that each patient has been properly classified as attending a first visit (Fi) or a follow-up visit (Fo).

- Determines, by comparing the lists of patients in the two registers, how many TB suspects registered in the outpatient register were included in the register of TB suspects, and how many were requested to submit sputum samples for microscopy examination (a TB case-detection indicator).

- Prepares two lists, by name, of patients with respiratory symptoms: one of those suspected of having pulmonary TB and referred for TB investigations and the other of patients with symptoms of CRD and sent to a referral facility for diagnostic assessment (persistent asthma or COPD) according to the model proposed in Chapter 6 (Box 6.8).

- Prepares a list of TB suspects who submitted sputum samples for microscopy investigation to check against the TB laboratory register.

- Checks the treatment cards and/or individual clinical records of respiratory patients who require supervised treatment or prolonged follow-up care, such as TB cases and CRD cases classified by the referral service and followed up by the first-level health facility (Chapter 6).

- Tabulates (if not regularly done by the health unit), data concerning outpatient visits to complete the report of outpatient activities carried out in one month according to the model proposed in Chapter 6 (Box 6.5 or Box 6.6) , for analysis of:

  ☐ proportion of patients with respiratory symptoms among all outpatients;
  ☐ classification into four groups of patients who attend for the first time because of respiratory symptoms: ARIs, CRDs, pulmonary TB and other respiratory diseases;
  ☐ distribution of patients by age or by age and sex, depending on the setting.

- Identifies the problems raised in the delivery of the PAL services and proposes realistic solutions.

Supervision of outpatient services at the first referral level is done by the district coordinator and the intermediate-level coordinator, on the occasion of the quarterly visit of the latter to the district. During this visit, the coordinators:

- Check the outpatient registers of all the referral services to which patients with respiratory symptoms could have been referred (TB centre, pulmonology, otorhinolaryngology, HIV/AIDS).

- Check whether all the patients referred by the first-level health facilities have been registered and examined.

- Verify whether the referral service has produced a report on the diagnosis and treatment of each patient with respiratory disease who has been referred by a first-level health unit and who should be followed up by that referring unit.

Supervision of the district level is done by the intermediate-level coordinator, at least every three months. During this visit, the coordinator checks the following registers:

  ☐ the district TB register
  ☐ the TB laboratory register
  ☐ the CRD register.

At the end of this visit, the quarterly reports filled in by the district coordinator should be validated by the intermediate-level coordinator:

- ☐ quarterly report on the register of TB cases;
- ☐ quarterly report on the register of chronic respiratory disease cases;
- ☐ quarterly report on the outpatient visits of respiratory patients, consolidating the reports from the first-level health facilities of the district and those on activities in the referral outpatient services.

Why supervise?

Supervision of the completeness and accuracy of data is necessary for the monitoring of PAL activities, and, in the long term, for surveillance of the community demand for care of respiratory diseases. Without basic data from the first-level health facilities and first referral services, it impossible to identify priority health problems, plan training of health personnel and provide a regular supply of essential drugs.

The supervisory activities should therefore be carried out after the health personnel have been trained on the PAL technical guidelines, and should be expanded gradually, by stages, as the PAL plan is expanded throughout the country.

Experience gained during the feasibility study has proved useful in establishing, within each national context, the most realistic and efficient methods of collecting the needed information.

Evaluation of PAL implementation results

Routine evaluation of PAL implementation is designed to measure progress in achieving the programmatic objectives of the PAL strategy, detect performance problems and plan future programme priorities. Adequate and precise planning is a prerequisite for meaningful evaluation. The evaluation is based on indicators that are measurable, valid, reliable and easy to interpret.

Evaluation of the NTP has been well defined and is described in detail in NTP guidelines. It is a permanent and recurring activity in all districts in which the Stop TB Strategy has been introduced. This chapter refers mainly to the evaluation of activities related to respiratory diseases other than TB.

The evaluation of PAL activities covers a large number of patients (between 100 and 200 or more times larger than the number of TB cases), and it therefore cannot be exhaustive and should be complemented by data collected at sentinel sites, over the whole year or for a limited period every year, or by regular surveys.

Selection of districts and sentinel sites

The selection of districts and sentinel sites is made on the basis of the performance of the health teams involved in the feasibility study and those participating in progressive expansion of the national plan (Chapter 9). At the end, at least two sentinel districts must have been selected – ideally, one predominantly rural and the other predominantly urban – in each province/region; they must be representative of the country's various geographical and climatic situations.

The objective is not to have an epidemiologically representative sample, but to evaluate the changes resulting from implementation of the PAL strategy in optimal conditions in places with effective health personnel who master the use of the information instruments, bearing in mind local constraints such as urban or rural population, season and access to care services.

Since there should be repeated evaluations in order to measure the changes in clinical practices as well as long-term changes in demographic and epidemiological variables, the central subunit must decide which indicators should be measured by the sentinel units for short periods of each year and which should be measured throughout the year.

For indicators to be measured for short periods, it is best to select 1–3 weeks during the cold season, avoiding the periods of annual holidays. Data should be collected from at least 3000 outpatients of age 5 years and over (30% of whom would have respiratory symptoms). Evaluation of the PAL indicators can thus be repeated each year, during the same season and over the same period, at the same sites, even if the evaluation criteria are progressively modified as priority objectives change.

Selection of evaluation indicators

Evaluation indicators are quantitative measures that are meaningful in terms of determining whether the programme is achieving its objectives. They may be different according to the country, to public health priorities and to the development of the health services. A few key indicators that are practical and can be measured with a reasonable degree of accuracy are sufficient to address the main evaluation questions and assess the programmatic situation: measuring too many indicators can detract from the purpose of the evaluation.

The evaluation priorities can be operational, technical or epidemiological and may evolve depending on the extent to which the corresponding objectives are achieved.

Phase 1: Evaluation of the managerial objectives of decentralization and integration

In Phase 1 of the PAL strategy implementation, the priorities are the managerial objectives of decentralization and integration of diagnostic and treatment activities into first-level health facilities and the coordination between these facilities and the first referral services. The evaluation indicators are those that permit the measurement of the progress in achieving the following managerial objectives:

- The number of first-level health facilities that have trained the personnel and acquired the supplies essential for implementing the PAL guidelines on case-management of respiratory diseases. The guidelines recommend standard procedures for classification of patients, drug prescriptions, requests for complementary investigations and referral of patients for further assessment or hospitalization (Box 10.1). The data collected during supervisory visits and the monthly or quarterly reports on outpatient respiratory diseases and on drug stocks are important ways of measuring the degree of decentralization and integration of the diagnostic and treatment activities.

- Coordination between activities performed at first-level health facilities and those performed at the first referral level. Using the data collected in the outpatient registers and the clinical records of all health units in a district, the degree of coordination in diagnosis and treatment between first-level health facilities and first referral services can be evaluated. For this purpose, it would be helpful for districts to tabulate the data, using as a model the following two quarterly reports for all the health units participating in PAL implementation:

  - First, a report that includes the number of patients referred by first-level health facilities to the referral services and the number of patients sent by the referral services to first-level facilities as counter-referrals or for follow-up of

treatment of cases who attended the referral unit directly. Box 10.2 illustrates how these data can be tabulated.

☐ Second, a report that documents the distribution of outpatients with respiratory symptoms, classified by diagnosis and by the place where they attended. Box 10.3 provides an example of how this evaluation can be presented using a simplified classification of the respiratory conditions as recommended in Chapter 6 (Box 6.7). Box 10.4 shows the same table with an expanded classification of the respiratory conditions.

Box 10.1 **Examples of evaluation indicators for priority objectives at first-level health facilities** **Phase 1: Managerial objectives on decentralization and coordination**		
Indicators to be measured and analysed by the district coordinator	**Where**	**When**
1. Proportion of first-level health facilities that have at least one staff member trained in the PAL guidelines on standard case-management	All units	End of each year
2. Proportion of staff at first-level health facilities who are trained in the PAL guidelines on standard case-management	All units	End of each year
3. Proportion of first-level health facilities in which respiratory patients have access to standard antibiotics for treatment of acute bacterial respiratory infections, particularly pneumonia.	All units	End of each quarter
4. Proportion of first-level health facilities in which patients with asthma and COPD have access to bronchodilators for inhalation treatment.	All units	End of each quarter
5. Proportion of first-level health facilities in which CRD patients have access to corticosteroids for inhalation use.	All units	End of each quarter
6. Proportion of first-level health facilities in which asthma patients have access to corticosteroids for oral administration.	All units	End of each quarter
7. Proportion of the population with access to first-level health facilities that are staffed and equipped to deliver standard case-management of respiratory diseases	All units	End of each year

Box 10.2 **Referral of patients with respiratory conditions between first-level health facilities and referral services**	
Type of referral	**Number of patients**
Patients referred from first-level health facilities to referral services for: ☐ emergency care ☐ complementary investigations ☐ assessment by a specialist ☐ hospitalization ☐ other reasons *Total*	
Patients referred from referral services to first-level health facilities: ☐ cured patients require neither home treatment nor follow-up ☐ cured patients cured who require brief follow-up, maximum 3 months ☐ patients who should be followed up for long-term treatment for: 　☐ tuberculosis 　☐ asthma 　☐ COPD 　☐ other chronic respiratory disease ☐ other patients *Total*	

Box 10.3 **Distribution of outpatients aged 5 years and over at district health units by diagnosis: simplified model**						
	First-level health facilities		**Referral outpatient services**		**Total**	
	First visit	**Follow-up visit**	**First visit**	**Follow-up visit**	**First visit**	**Follow-up visit**
All patients attending outpatient services for care						
All patients attending because of respiratory symptoms						
Acute respiratory infections						
Chronic respiratory diseases						
Tuberculosis						
Other respiratory diseases						

Box 10.4 **Distribution of outpatients aged 5 years and over at district health units by diagnosis: expanded model**						
	First-level health facilities		**Referral outpatient services**		**Total**	
	First Visit	**Follow-up visit**	**First visit**	**Follow-up visit**	**First visit**	**Follow-up visit**
All patients attending outpatient services for care						
All patients attending because of respiratory symptoms						
Acute respiratory infections: ☐ upper airways ☐ lower airways, excluding pneumonia ☐ pneumonia ☐ unknown						
Asthma						
COPD						
Other chronic respiratory diseases						
Patients with tuberculosis: ☐ smear-positive ☐ smear-negative ☐ other TB						

Phase 2: Evaluation of the technical objectives of care quality

If integration and decentralization of health activities and coordination between peripheral and referral levels have already been achieved, the priority objectives to be evaluated are those concerning care quality. Possible indicators for this evaluation are presented in Box 10.5.

As regards indicators 2 and 3 of Box 10.5, acute upper and lower respiratory infections represent the most frequent reason for attendance at outpatient services. Most of these infections are viral. It is therefore important to evaluate the overall prescription of antibiotics for acute respiratory infections, and the standardization of antibiotics in accordance with the national list of essential medicines and the recommendations of the PAL guidelines. Box 10.6 presents a model for evaluating the prescription of antibiotics.

Box 10.7 is proposed as an example of how to evaluate the frequency of drug prescriptions for asthma, COPD and other CRDs in patients aged 5 years and over. This evaluation should be done only in sentinel units or by surveys.

Box 10.5 Examples of evaluation indicators for priority objectives at first-level health facilities Phase 2: Technical objectives on care quality		
Indicators to be measured and analysed	**Where**	**When**
by district coordinators		
1. Proportion of bacteriologically confirmed pulmonary TB cases among all notified cases of pulmonary TB	All units	At the end of each quarter
by coordinators of sentinel units or the central-level coordinator		
2. Proportion of acute upper respiratory infection cases who receive an antibiotic prescription[a]	Sentinel units	1–3 weeks a year
3. Proportion of acute lower respiratory infection cases who receive an antibiotic prescription[a]	Sentinel units	1–3 weeks a year
4. Proportion of asthma cases who are classified by degree of severity by a specialist	Sentinel units	At the end of each year for the whole year
5. Proportion of COPD cases who are classified by degree of severity by a specialist using spirometry	Sentinel units	At the end of each year for the whole year
6. Proportion of persistent asthma cases who receive inhaled bronchodilators[b]	Sentinel units	At the end of each year for the whole year
7. Proportion of persistent asthma cases who receive inhaled corticosteroids[b]	Sentinel units	At the end of each year for the whole year
8. Proportion of COPD cases who receive inhaled bronchodilators[b]	Sentinel units	At the end of each year for the whole year

[a] A more detailed way to measure this indicator is shown in Box 10.6.

[b] A more detailed way to measure this indicator is shown in Box 10.7.

Box 10.6 **Frequency and nature of antibiotics (excluding those against TB) prescribed for acute respiratory infections in patients aged 5 years and over at first-level health facilities**			
	Total number of patients with ARI (1)	**Prescription of antibiotics**	
		Number of patients (2)	**Percentage [(2)/(1) x 100]**
Acute respiratory infections: ☐ upper airways ☐ lower airways ☐ unknown *Total*			
Prescription of antibiotics: ☐ one only ☐ two or more			
Type of antibiotic: ☐ co-trimoxazole ☐ amoxicillin ☐ phenoxymethylpenicillin ☐ other (to be specified) ………………………. ……………………….			

Box 10.7 **Frequency of drug prescriptions for the main chronic respiratory diseases in patients aged 5 years and over followed up at first-level health facilities**											
Chronic respiratory disease	**Drug prescription**[a]										
	Bronchodilator			**Corticosteroid**			**Theophylline**			**Ipratropium bromide**	
	inj	tab	inh	inj	tab	inh	inj	tab	supp.	inh	tab

Intermittent asthma
Persistent asthma
  ☐ mild
  ☐ moderate
  ☐ severe											

COPD
  ☐ Stage I Mild
  ☐ Stage II Moderate
  ☐ Stage III Severe
  ☐ Stage IV											

Other chronic respiratory diseases											

[a] inh = metered-dose inhaler; tab = tablets; inj = injection (IM or IV); supp = suppository

Phase 3: Evaluation of the epidemiological objectives of morbidity and mortality

Once the managerial and quality of care objectives have been achieved, the priority indicators to be measured are those intended to evaluate the epidemiological impact of the PAL strategy. The indicators presented in **Box 10.8** can be measured for this purpose.

Box 10.8 **Examples of evaluation indicators for priority objectives in primary health care settings** **Phase 3: Epidemiological objectives**		
Indicator to be measured and analysed	**Where**	**When**
by district coordinators		
1. Proportion of respiratory cases among all hospitalized cases	All first-referral hospitals	At the end of the year for the whole year
2. Proportionate mortality rate due to respiratory conditions among hospitalized patients	All first-referral hospitals	At the end of the year for the whole year
3. Case-fatality among hospitalized pneumonia cases	All first-referral hospitals	At the end of the year for the whole year
4. Number of asthma attack cases who visited emergency room or intensive care unit	All first-referral hospitals	At the end of the year for the whole year
5. Number of COPD exacerbation cases who visited emergency room or intensive care unit	All first-referral hospitals	At the end of the year for the whole year
by coordinators of sentinel units or the central-level coordinator		
6. Average delay in the diagnosis of pulmonary TB by the health services (delay between the date of first visit and the date of starting treatment)	Sentinel units	At the end of the year for the whole year
7. Case-fatality from non-severe pneumonia treated on outpatient basis	Sentinel units	At the end of the year for the whole year
8. Proportion of AURI and ALRI cases (excluding pneumonia) who develop a complication after the first visit	Sentinel units or Special surveys	2–4 weeks a year
9. Average interval between crises among intermittent and persistent asthma cases	Sentinel units or Special surveys	At the end of each year
10. Average interval between exacerbations among COPD cases	Sentinel units or Special surveys	At the end of each year
11. Outcome cohort analysis for asthma and COPD patients	Special Surveys	At the end of each year

Annex

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