WHO/HTM/TB/2008.396

Evaluation of the Practical Approach to Lung Health

Report of meeting
held on 18 and 19 June 2007
WHO, Geneva

STOP TB DEPARTMENT
Tuberculosis Strategy and Health Systems

ACKNOWLEDGEMENTS

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We thank Rhona O'Halloran for her help and support in the organization of the meeting and in coping with the various administrative aspects.

We are grateful to the United States Agency for International Development (USAID) for their financial support.

Contents

Acronyms and abbreviations

ADF	Asthma Drug Facility
AIDS	acquired immunodeficiency syndrome
COPD	chronic obstructive pulmonary disease
DOTS	the internationally recommended strategy for TB control until 2005, and the foundation of the Stop TB Strategy introduced in 2006
GARD	Global Alliance for Respiratory Diseases
GINA	Global Initiative for Asthma
GOLD	Global Initiative for Chronic Obstructive Lung Disease
HIV	human immunodeficiency virus
IMAI	Integrated Management of Adolescent and Adult Illness
KFLHP	Kyrgyzstan Finland Lung Health Project
MOH	Ministry of Health
NTP	national tuberculosis programme
NWG	national working group
PAL	Practical Approach to Lung Health
PALSA	Practical Approach to Lung Health in South Africa
PHC	primary health care
STB	WHO Stop Tuberculosis Department
STI	sexually transmitted infection
TB	tuberculosis
The Union	International Union Against TB and Lung Disease
WHO	World Health Organization

1. Background

The Practical Approach to Lung Health (PAL) is a patient-centred approach to improve the quality of diagnosis and treatment of common respiratory illnesses in primary health care (PHC) setting. It seeks to standardize service delivery through development and implementation of clinical guidelines and managerial support within the district health system. It is intended to coordinate among different levels of health care and between tuberculosis (TB) control and general health services.

PAL was initiated by WHO in early 1998. Field experience helped to develop PAL clinical guideline models and to define a phased process to adapt, develop and implement PAL in countries. Presently, there are 31 countries worldwide at different stages of the PAL development process. Data from countries' experience suggest that PAL is likely to: (i) increase significantly TB case detection in some situations; (ii) improve care quality of acute and chronic respiratory patients at first level health facilities; (iii) decrease unwarranted drug prescription, particularly antibiotics and adjuvant drugs; and (iv) reduce drug prescription cost per patient.

The new Stop TB strategy has identified PAL as an integral part of the component addressed to strengthen the health system by linking TB control activities to proper case management of all common respiratory conditions. A network of international agencies has joined WHO in the commitment to develop PAL. Most of the funding for PAL support at global level comes from the United States Agency for International Development. PAL is also considered for funding within the TB proposals by the Global Fund against AIDS, Tuberculosis and Malaria. Collaborative links have been established with the Tobacco Free Initiative, the International Union Against Tuberculosis and Lung Disease (The Union), the Finnish Lung Health Association, the Forum of International Respiratory Societies, the Global Alliance for Chronic Respiratory Diseases (GARD) and some national academic institutions.

At the beginning of 2007, WHO launched an evaluation plan in order to:

1. Assess the current status of PAL development and implementation at global level on the basis of available technical and managerial tools, country experience, collaborating institutions and funding.
2. Identify the main weaknesses and obstacles to PAL development at international and country levels, document the strengths so far achieved and point out the challenges to be confronted.
3. Formulate recommendations to re-orient the development and implementation of the PAL strategy at global level.

The evaluation plan included the following activities: (i) an overview of the global progress in PAL development and implementation; (ii) collection of data through an evaluation survey questionnaire in countries with some PAL activities; (iii) field evaluation visits to the four countries which have reached the most advanced stage in PAL implementation, namely El Salvador, Kyrgyzstan, Morocco and South Africa.

The consultation meeting took place at WHO Headquarters in Geneva on 18 and 19 June 2007. The Agenda of Sessions is presented in Annex 1 and the List of participants in Annex 2.

2. Objectives of the consultation meeting

The objectives of the consultation meeting were:

- to review all the information collected by the 2007 PAL evaluation plan;
- to provide to WHO an independent assessment of the situation of PAL development and implementation at global and country levels, pointing out main strengths, weaknesses and challenges;
- to review and discuss PAL strategy in the frame of Stop TB Strategy; and
- to advise on ways to overcome constraints, deal properly with identified challenges, establish priorities and define further steps in the process of development and implementation of the PAL strategy.

In the opening session, Dr Mario Raviglione, Director of the Stop TB Department (STB), welcomed the participants and pointed out that it was high time for WHO to assess what happened in the field of PAL after the first and second consultation meetings held in 1998 *(1)* and 2002 *(2)* respectively. The role of PAL within the whole health system has become clearer and is now very appropriate, given the current WHO priority set up by the WHO Director-General of reviving and stressing the policies of the 1978 Alma-Ata Declaration on Primary Health Care. He asked the meeting participants to give special consideration to: the role of PAL in primary health care (PHC) of low-income and middle-income countries; the suitability of promoting a single model or alternative models of PAL case management guidelines; and the degree of commitment that the national tuberculosis programme (NTP) should assume in the development and implementation of the PAL strategy.

3. Overview of PAL strategy at global level

Dr Salah Ottmani, STB Medical Officer in charge of PAL activities, presented the rationale for PAL and the progress achieved in its development and implementation. TB presents the same symptoms as most respiratory conditions but while TB patients represent a small proportion of those attending PHC units, respiratory patients account for 20–35% of them, as determined by a WHO-sponsored survey in primary care services in nine countries *(3).* The most common situation is that the PHC workers have no guidance at all for taking care of respiratory patients aged 5 years and more. PAL was designed to provide guidance on syndromic case management of all patients with respiratory symptoms of 5 years and more in PHC settings, with a major emphasis on tuberculosis, acute respiratory infections, especially pneumonia, asthma, chronic bronchitis and chronic obstructive pulmonary disease (COPD).

The main components of the PAL strategy are standardization of case management (diagnosis, treatment and follow-up) of the most common respiratory conditions and coordination among health care system components *(4)*.

WHO produced managerial guidelines for the introduction of the PAL strategy on the basis of a gradual process comprising 10 defined steps:

1. An official request from the national health authorities for WHO assistance as an expression of the government political commitment to develop and implement the PAL strategy.
2. A preliminary assessment of the situation of the case management of respiratory conditions at primary health care units and the existing facilities for diagnosis and treatment.
3. Establishment of the PAL national working group (NWG).
4. Development of the national clinical and operational guidelines.
5. Development of the training tools to teach the guidelines.
6. Baseline study on current case management of respiratory conditions at PHC units.
7. Training and provision of supplies for implementation of the guidelines in the area where the baseline survey was conducted.
8. Impact study on the implementation of the PAL guidelines.
9. Revision of the guidelines after the impact study and formulation of a national implementation plan.
10. Adoption of the national expansion plan by the health authorities.

The results of the baseline and impact studies were reported by eight countries: Guinea in Africa, Bolivia in Latin America, Kyrgyzstan in Central Asia and five Eastern Mediterranean countries: Algeria, Jordan, Morocco, Syrian Arab Republic and Tunisia.

These studies plus research conducted in South Africa and the programme experience of El Salvador indicated that PAL is likely to:

- decrease referral of non-severe respiratory patients from first level health facilities to upper health care levels;
- improve the quality of the process of diagnosis of TB;
- improve TB case detection among respiratory patients;
- decrease unwarranted drug prescription, mainly antibiotics and symptomatic medication;
- improve the quality of drug prescription for chronic respiratory conditions; and
- reduce the average cost of drug prescription per respiratory patient.

At present the PAL strategy implementation is in the expansion phase in 8 countries, in the preparatory expansion phase in 5 countries and in the feasibility stage in 2 countries. The guidelines are being discussed and adapted in 16 countries, while 7 additional countries have expressed their interest in starting PAL activities.

WHO has examined and gathered the countries' experience in adapting and testing guidelines, planning implementation and evaluating activities in a PAL Manual which has been submitted for publication *(5)*.

A gradual process of delegation of PAL responsibilities from WHO Headquarters to the Regional Offices was initiated. Three WHO Regional Offices: for Africa, the Americas and the Eastern Mediterranean have organized regional workshops to disseminate information about the PAL strategy and promote their adoption by national authorities. The workshops were held in Kampala, Uganda (January 2007), San José, Costa Rica (December 2006) and Cairo, Egypt (December 2005).

4. Questionnaire survey on PAL development

WHO designed a questionnaire to collect information about the NTP managers' perception regarding the available tools, recommended steps and technical assistance on PAL development. The questionnaire was sent to 26 countries of the African, Latin American and Eastern Mediterranean Regions which are initiating, developing or expanding PAL activities.

The replies from 10 countries highlighted the relevance of PAL as an integral part of the PHC services and pointed out the usefulness of the WHO documents on PAL development. The NTP managers agreed with the stepwise approach to introduce the PAL strategy and stressed the need for global guidance to develop national PAL guidelines and training materials.

5. PAL evaluation in countries

The same protocol was used in the evaluation of the implementation of the PAL strategy in El Salvador, Kyrgyzstan, Morocco and South Africa. The protocol was divided into two parts: information to be collected at national level and information to be collected in the field.

Almost 100 questions were designed to collect information at national level in relation to national policies, PAL NWG, guidelines on PAL and on TB, training materials and activities, educational materials, feasibility test, implementation plan, logistics, information system, monitoring, evaluation and perspectives of sustainability.

The field evaluation was focused on: determining the commitment of the local health authorities; having talks with the trained staff about the way in which the training was conducted and whether the PAL guidelines could be applied in the daily work; looking at the availability of equipment and drugs; inspecting the information forms and registries; and asking about the frequency and modality of supervision.

5.1 Kyrgyzstan

The field evaluation was carried out by Dr Liisa Parkkali.

The Republic of Kyrgyzstan is a Central Asian country with a population of 5.2 million. The TB DOTS strategy has been implemented for 10 years. TB treatment results have reached a success rate of over 82% nationwide. The case detection rate is estimated at around 50%.

Kyrgyzstan was one of the pioneering countries to introduce the PAL strategy under the Kyrgyzstan Finland Lung Health Project (KFLHP) and in close collaboration with WHO. The project started in two pilot areas (Bishkek and Toctogul) in 2003. The ministry of health (MOH) established a PAL NWG, based in the National Hospital. The local staff developed the PAL guidelines, consistent with WHO recommendations, with the assistance of local and foreign experts. The guidelines are addressed to health workers who deliver case management services at PHC settings. Specific training materials to teach the guidelines were prepared. The quality of the training materials is excellent. After the WHO-recommended feasibility test was completed in the pilot areas, the implementation of the PAL strategy was expanded to the whole PHC infrastructure of the country with KFLHP technical and financial support. A PAL focal point was designated in each district. The most critical activity was the organization of 5-day training courses for 4407 health workers in four years: 2508 doctors, 606 feldshers and 1293 nurses. After training, each staff member was provided with a basic medical kit for case

management of respiratory diseases. Each kit included a stethoscope, a tensiometer, a thermometer, a watch, tongue depressors, a calculator and a pen. The national essential drugs list includes the drugs recommended for respiratory diseases by the PAL guidelines. The PAL guidelines were introduced in the curricula of the medical and nursing schools.

The programme evaluation showed that the PAL strategy resulted in better quality in the case management of asthma and significant reduction in unwarranted referral to upper health care levels and in unwarranted prescriptions of antibiotics, symptomatic medicines and clinical laboratory examinations. In only the Bishkek district the TB case detection clearly improved in a period of four years.

The strategy was very well accepted by the managerial and service delivery staff and strongly supported by the high authorities of the MOH. The strategy was included in the national policies for health reform. The major recommendations made by the external WHO evaluation were to: increase the commitment and participation of the NTP in the PAL strategy implementation, develop guidelines and organize training for staff at reference levels; schedule regular supervision and monitoring of the trained staff; organize the maintenance and repair of equipment for case management of respiratory diseases; revise criteria for referral of respiratory patients, and supply sufficient copies of educational materials.

5.2 South Africa

The field evaluation was undertaken by Dr Marina Erhola.

The Republic of South Africa has a population of 44.3 million. It ranks in the 7th place among the 22 TB high burden countries of the world and has one of the most severe AIDS epidemic with no evidence of decline so far. The TB treatment success rate is 70% and the case detection rate is more than 80%. In recent years South Africa is confronting a very serious problem of emergence of extensively drug resistant TB.

The development of the PAL strategy in South Africa (Practical Approach to Lung Health in South Africa, PALSA) has been undertaken by a research team of the Lung Institute of the University of Cape Town. The Department of Health was not fully involved at the beginning. The PAL team carried out high quality work in the development and testing of the PAL guidelines and in the elaboration of training materials to teach the guidelines. The guidelines were carefully adapted to the existing epidemiology of respiratory diseases and the structure and human resources of the PHC services. A major focus was placed on training of nurses who are the main health care providers at peripheral levels.

PAL strategy development was initiated in 2000 when there was no global experience in this area. A systematic process of adaptation and testing of guidelines and training materials was carried out, which included several

revisions, identification of barriers and constant feedback from trainers and trainees. Randomized controlled trials were carried out. Implementation started in 2005 in the provinces of the Western Cape and Free State, with the involvement of the Provincial Departments of Health. Training of trainers was planned and conducted by the Lung Institute. Training was based on adult learning methodologies. Use of key messages was highlighted throughout the training. A training cascade process was put into effect from trainers to nurse managers and from nurse managers to clinical nurse practitioners at health facilities. Routine monitoring and supervision in the two participating provinces are carried out by the PALSA trainers who visit the health facilities.

The results of the programme evaluation and the related research activities have shown that the PAL strategy was effective in increasing TB case detection, improving the care of HIV/AIDS patients, upgrading the quality of asthma case management, empowering nurses in dealing with respiratory diseases, and strengthening the PHC services in general.

Further developments of PALSA include the expansion of the guidelines to include the diagnosis and management of HIV infection and STIs, and the case management of common chronic diseases such as diabetes and hypertension. All the PAL drugs are included in the national list of essential drugs and are provided free of charge to patients. A plan for national expansion was prepared and has been submitted to the MOH authorities for endorsement and approval. So far no national working group on PAL has been established.

The major recommendations made by the external WHO evaluation were to: increase the commitment and participation of the national MOH and the NTP in the PAL strategy development, include PAL in the National Health Plan, establish the PAL NWG as well as provincial PAL Focal Points and include PAL guidelines in the curricula of medical and nursing schools.

5.3 Morocco

The field assessment was carried out by Dr Pierre Norval and Dr Samiha Baghdadi.

Morocco has a population of 31.5 million population. The National TB Programme is very well organized, with an estimated 100% in case detection and 87% in treatment success. The MOH is fully committed to the implementation of the PAL strategy as an integral component of the Stop TB strategy and under the managerial responsibility of the NTP.

In 2001, the MOH issued technical and operational guidelines for case management of TB and respiratory diseases at PHC facilities and at first referral health care. A PAL NWG and a team of trainers were established. On the basis of the experience of a PAL feasibility test, national expansion of PAL implementation started in 2002. By the end of 2004 the strategy was

operational at the MOH PHC units and first level referral facilities of 11 out of 16 regions, representing 75% of the country's population. During that period more than 3200 health workers (general practitioners and nurses) were trained in 3-day PAL courses. Excellent training materials were used. All the participating health facilities were supplied with essential equipment for case management of respiratory diseases. The monitoring and supervision activities are carried out by the regional TB managerial staff.

One of the main weaknesses of the programme is the lack of adequate funding. The supply of free drugs for chronic respiratory diseases is irregular and very limited in the public health facilities. The existing information system does not meet the essential requirements to monitor the PAL activities.

The major recommendations made by the external WHO evaluation were: prepare a multiyear PAL work plan and budget, including drug supply for chronic respiratory diseases; procure sufficient funds from national and external sources; reactivate the functioning of the PAL NWG; update the PAL guidelines and training materials; develop educational materials for patients; promote the rational use of antibiotics; and identify a minimum number of key indicators that can be measured through information registered in the national health information system.

5.4 El Salvador

The field evaluation was carried out by Dr Marina Erhola.

El Salvador is a Central American republic with a population of 6.6 million and a density of 332 inhabitants per km^2. The DOTS strategy was adopted by the NTP in 1997 and coverage of the whole country was attained in 2000. The treatment success rate is 88% and the estimated case detection rate is 53%. The control of TB is fully integrated into the PHC services.

The MOH is fully committed to develop and implement the PAL strategy under the managerial responsibility of the NTP. The official decision to start the PAL activities was taken in 2005. A PAL NWG with broad representation was established. The initial task was to develop the technical and operational guidelines with the collaboration of a consultant of the Pan American Health Organization. The guidelines are not fully consistent with the WHO recommendations; for chronic diseases they follow the traditional format of disease specific guidelines, with separate flow charts for each clinical entity. The guidelines are not integrated with the TB control guidelines.

The PAL guidelines were not tested in a feasibility study. They were gradually introduced in 36 health centres from the 5 health regions of the country, which amount to 10% of all health centres. Training was carried out by NTP managers with the assistance of paediatricians, pulmonologists and local health managers. No special materials were developed for use in the training courses. The duration of the training courses was limited to between 4 and 6 hours.

The programme did not issue materials for health education of patients. The most prominent PAL educational activity is teaching patients on how to inhale drugs with spacers. All basic PAL drugs, with the exception of inhaled corticosteroids, are included in the list of essential drugs and provided free of charge by the MOH.

The monitoring and evaluation activities have shown that the introduction of the PAL strategy in the health centres resulted in a dramatic decrease in the use of drugs for nebulizations and the use of nebulizers, an increase in sputum examinations for diagnosis of TB, a reduction in the referrals for hospitalization and a better quality in the case management of asthma.

A plan to expand the strategy to all the PHC services was prepared and approved by the MOH. The plan includes the involvement of the social security health units.

The major recommendations made by the external WHO evaluation were: revise the technical guidelines in line with the syndromic approach recommended by WHO; integrate the guidelines for TB and respiratory diseases; develop training materials to teach the revised guidelines; organize training for trainers; and involve the referral level in the implementation of the PAL strategy.

6. Strengths, weaknesses and challenges of the PAL development and implementation experience

In the analysis and discussion of the reports of the WHO PAL activities and PAL implementation in four countries the consultation meeting identified important ***strengths*** and achievements that fully justify the investment in human and financial resources devoted to the strategy and were encouraged to pursue the effort. At the same time the consultation meeting pointed out ***weaknesses*** that should be overcome to prevent serious failures and ensure a satisfactory progress in further development and implementation. The consultation meeting considered that some special situations are ***challenges*** that should be faced with creativity and innovative approaches.

6.1 Strengths

- The PAL strategy is fully consistent with the ongoing health sector development process in many countries because: it integrates case management programmes; contributes to upgrading the quality of health care; makes better use of resources; and provides criteria for coordination between the PHC units and the upper level health facilities. The strategy has attractive features for health policy-makers and planners interested in decentralizing the managerial functions and strengthening the support capacity of district health teams. PAL offers practical ways of integrating programmes for the control of communicable and non-communicable diseases and for organizing the PHC involvement in the control of chronic conditions.

- The recommended phased implementation through 10 steps allows the gradual strengthening of coordination among condition-focused programmes (TB, HIV, chronic diseases, tobacco control) and support programmes (health information systems, human resources, logistics, health education). Site-piloting through the feasibility test is an effective mechanism for the validation of the technical guidelines and operational procedures before the national expansion is undertaken. Therefore, these features are favourable for a political commitment and decision to undertake PAL activities within the framework of the PHC and with the active involvement of the TB control programme.

- The standardized integrated PAL guidelines are attractive to PHC workers because with them they are empowered to make appropriate decisions on the basis of key clinical signs and provide effective treatment to patients with respiratory symptoms. The health workers

accept and welcome the PAL guidelines as a tool that facilitates and improves their daily work.

- PAL guidelines mean a strong patient-centred approach because they shift the clinical focus from the question "is it or is it not TB?" to the question "which respiratory condition is present?". In this connection the most relevant feature is the combination issue. The urgent public health need to control TB is taken care of together with the medical and humanitarian need to provide quality health care to all patients presenting respiratory symptoms. PAL contributes to increasing people's confidence and credibility in PHC services.

- A common finding throughout the many country experiences is a significant reduction in drug prescriptions and in the average per patient cost of prescribed drugs. In particular, the guidelines were effective in changing the habit of prescribing ineffective symptomatic medications in general and antibiotics, particularly for acute respiratory.

- The PAL guidelines establish a method for the systematic monitoring and follow-up of patients whose sputum examination is negative for TB leading to a more careful decision on whether the patient has TB or any other respiratory condition. The quality of TB diagnosis can be improved either by reducing the number of false pulmonary TB cases, especially in high HIV-prevalence areas or by increasing the number of diagnosed TB cases in areas with rather low case detection rates.

- In low TB prevalence countries, the PAL strategy provides an incentive to expand the professional scope of the managers and clinicians specialized in TB and at the same time to maintain their interest in TB control.

- Although PAL is essentially a case management intervention, the guidelines include health education messages on preventive measures that health workers should communicate to patients and their families as an integral part of PHC delivery services. The health education guidelines include advice on immunizations, HIV testing, avoiding exposure to allergens for asthmatic patients, quitting smoking and prevention of indoor air pollution.

6.2 Weaknesses

- The relationships between PAL and other global initiatives dealing with respiratory conditions are weak and unclear. Although PAL has adopted the recommendations on case management of asthma and COPD issued by the Global Initiative for Asthma (GINA) and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) there are no links of collaboration with these initiatives. Potential conflicts can be foreseen at country level among PAL, the Integrated Management of

Adolescent and Adult Illness (IMAI) and GARD if each one acts independently in promoting policies and supporting implementation.

- PAL advocacy needs were not sufficiently met owing to an unavoidable vicious circle: a wide political and financial support to adopt PAL policies and gather evidence on their merits was not secured in the absence of a well-founded advocacy programme, and the foundation for an advocacy programme could not be established without political and financial support. Therefore the global funds available to promote the strategy have been very limited. The financial constraints prevented the development of expertise and so far the number of consultants who can collaborate with national authorities in the planning and implementation of the PAL strategy is very limited. Moreover, the WHO follow-up and monitoring of the country projects was quite insufficient because of the lack of consultants.

- Although the country experiences have provided valuable information on the feasibility, acceptability, health care quality and cost reduction benefits of the PAL strategy, there is no information on epidemiological impact and cost-effectiveness.

- The benefits of PAL implementation for the NTP were not consistently documented in the existing country experiences. Apparently, in a very well organized and effective NTP it is difficult to achieve an increase in case detection through the implementation of the PAL guidelines. However, the country reports have not analysed adequately the quality of the diagnosis, in particular whether there are settings where the guidelines are able to reduce the number of cases wrongly classified and treated as TB cases.

- The visibility of the PAL strategy is rather low among experts in public health, tuberculosis and respiratory diseases since the dissemination of the WHO PAL documents has been quite limited, very few papers have been published in the scientific journals, and presentations on PAL have rarely been included in the agenda of international, regional and national conferences held in low and middle income countries.

- The preparation of sound and effective training materials is a difficult task that requires competent professionals with experience in development of human resources. The task of preparing training materials can be facilitated to a large extent if the national authorities could be provided with generic training modules and guides that can be adapted to the local PAL guidelines. Such generic materials have not yet been issued by WHO.

6.3 Challenges

- There is a natural resistance in many places against accepting new working programmes that convey changes in well rooted concepts and practices. The promotion of the PAL strategy should be developed in such a manner that can gradually overcome managerial and technical objections and find a way to be included within the national health policies and financial mechanisms of the ministries of health.

- The local adaptation of WHO and other international guidelines may be a difficult task in many places. The local guidelines should be the result of a consensus among a large number of concerned professionals from different MOH programmes, the universities, the professional societies and important institutions that provide health services. Often, it takes time to reach a consensus and the final local adaptation introduces modifications that mean technical mistakes or reduce the technical value of the generic guidelines. Advisory services are important to help in building up a wide consensus and ensure the technical soundness of the adapted guidelines.

- WHO has established the managerial, care quality and impact objectives of the PAL strategy implementation and proposed a list of indicators to measure the progress in achieving such objectives. There is no reported experience in the use of the recommended indicators for the evaluation of the PAL projects. The challenge is to test the use of the proposed indicators to determine whether measurement is feasible and useful in evaluating the achievement of the PAL objectives.

- The development and testing of guidelines and the start of the PAL implementation is quite well defined in the WHO documents. It remains to be developed how to maintain the expansion and follow-up of the programmes, regular reports, uninterrupted funding and periodic evaluation.

7. PAL as a component of the Stop TB Strategy

Since respiratory conditions are very frequent everywhere, PAL is an essential integral part of PHC services whatever the level of national economic income. Therefore the focus of the discussion cannot be on whether PAL is less suitable for low income countries than for middle income countries. The right focus of the discussion is whether the NTP should assume the responsibility for developing and implementing PAL everywhere.

PAL is a component of the Stop TB strategy and has been developed by the WHO Stop TB Department. These circumstances do not necessarily mean that PAL should be developed and implemented by the NTP in each country. Nevertheless, it is desirable that the NTP takes over the responsibility for PAL because its structure, experience and active presence at any level of the health system, even the most peripheral one, are likely to facilitate PAL implementation. The objectives and technical issues of PAL and TB are very closely related. In settings with a high prevalence of HIV infection, the unified management of TB and the other respiratory illnesses through PAL may provide better ways to deal with the high burden of respiratory conditions at PHC services. The NTP has the responsibility to ensure that a diagnosis is pursued for patients with respiratory symptoms who do not have TB. Probably, everywhere the NTP is the best suited programme to promote and start the initial steps of the PAL strategy. If this is the case, the political commitment would be credible if additional staff were assigned to the NTP to deal with the additional responsibilities of planning and implementing PAL.

However, there may be important organizational and operational reasons to justify that the PHC Department or other MOH programme assumes the main responsibility for PAL development and implementation. As the country reports indicated, the NTP was responsible for PAL in Morocco and El Salvador, but not in Kyrgyzstan and South Africa. It can be argued that PAL may overburden the NTP and have a detrimental effect on the TB control effort, especially in low income countries with a very high TB prevalence. In any case, it is essential that the NTP is actively involved in the adaptation and development of the guidelines and training materials, the drug management, the information system and every managerial function.

The PAL NWG should encompass a broader range of technical expertise than the expertise included in the TB national technical advisory group. Therefore, the PAL strategy can be the objective of one specific subgroup under the umbrella of the TB group or the objective of an independent NWG, which has to maintain frequent communication and close collaboration with the TB group. As matter of fact, there is mutual interdependence between PAL and the NTP. If the PAL working group is a subgroup of the national TB advisory technical group, PAL should also be included within the scope of the TB Inter-Agency Coordinating Committee.

8. PAL essential elements

The consultation meeting identified four essential technical elements and six essential managerial elements that should be included in any PAL programme as *sine qua non* conditions to meet the expected objectives.

8.1 Essential technical elements

a. Classification and diagnosis of cases through standardized locally adapted protocols on the basis of key symptoms and signs for outpatient services. The protocols should include criteria for referral of patients to specialized higher levels and standardized approaches for diagnosis of smear-positive and smear-negative pulmonary TB. Guidance should be provided for the use of laboratory, radiology and lung functional tests in the diagnosis of respiratory diseases at first referral hospitals.

b. Treatment using standardized regimens of proven efficacy and drugs included in the national list of essential drugs.

c. Minimum equipment for diagnosis and treatment of respiratory diseases defined for each level of the health structure.

d. Health education of patients and their families on compliance with treatment and preventive measures such as immunization, quitting smoking, avoiding asthma-triggering factors and reducing indoor air pollution.

8.2 Essential managerial elements

e. Political commitment by the national health authorities. The political commitment should be translated into decisions such as the designation of a department or officer as responsible for the PAL strategy, the nomination of a PAL NWG, and the allocation of budgetary funds to start activities.

f. Training of managerial and health care providers in the use of the PAL technical and operational guidelines. Validation of training materials in pilot areas.

g. A regular supply of affordable drugs for managing respiratory diseases should be ensured and the minimum equipment defined in the guidelines should be supplied to the health units.

h. Adaptation and utilization of the existing information system in order to provide minimum information for measuring essential indicators to monitor and evaluate PAL activities. A register of chronic respiratory diseases should be set up at first level referral facilities wherever possible.

i. Pilot testing of the technical and operational guidelines in areas representing average conditions of the health infrastructure of the country.

j. National plan for PAL implementation taking into account the experience of the pilot area.

9. Conclusions and recommendations

9.1 Planning, advocacy and coordination

By its Constitution, WHO has a leadership role in international health which has been maintained and strengthened since its foundation 60 years ago through consistent stimulation of policies and action in the field of public health. The PAL strategy is one of the most recent examples offered by WHO of its commitment to develop pioneering and innovative approaches to new and difficult health problems.

With the collaboration of international agencies and national institutions, WHO developed and tested the PAL strategy as an integral component of the Stop TB strategy as well as an essential element to strengthen PHC services. The progress in this developmental process has reached the critical point of moving from the experimental phase to worldwide promotion and implementation. In order to succeed in the transitional effort, the Consultation Meeting recommends to WHO the following actions:

a) Develop a multi-year global work plan and budget for PAL implementation in a phasewise manner on the basis of the established evidence and taking into account country-specific health system situations.

b) Issue guidelines to conduct pilot testing of the PAL guidelines for countries which decide not to conduct the feasibility test because it requires two comparative surveys to measure the changes in the case management of respiratory patients in PHC settings before and after PAL implementation.

c) Launch advocacy activities addressed to governments, international cooperation agencies, stakeholders and potential donors. The advocacy programme should be an integral part of the global PAL work plan and should emphasize the technical and managerial benefits of the PAL strategy for the PHC functioning and the TB control programme.

d) Build up a close coordination in technical policies and PAL promotion between the Stop TB Partnership and the international agencies or initiatives mostly concerned with respiratory diseases such as The Union, GINA, GOLD, GARD and the international associations of professional societies on lung diseases.

e) Establish links within WHO between the PAL strategy and other programmes such as those dealing with the control of chronic diseases and IMAI in order to reach a clear understanding of their overlapping

scopes and eliminate factors for confusion or concern in the technical assistance to the national authorities.

9.2 Technical assistance

The Consultation Meeting is impressed by the progress achieved by WHO in the development of the PAL strategy despite scarce financial resources, absence of previous field experience and very limited public health expertise in this area. One of the most relevant WHO functions in global PAL development is to provide technical knowledge and support action at country level. In order to succeed in the technical assistance function, the Consultation Meeting recommends to WHO the following actions:

a) Generate and mobilize resources intended to organize workshops and seminars to train PAL consultants.

b) Expand the experience and capabilities of the TB consultants in order to enable them to provide technical and managerial assistance on PAL implementation as an integral component of the Stop TB strategy.

c) Collaborate with the national authorities in the introduction of PAL activities within the TB control proposals to be submitted for funding to the Global Fund against AIDS, TB and Malaria.

9.3 Training

Training is one of the most time and resource demanding activities in any public health programme. WHO recommends a systematic approach for developing PAL guidelines and testing their implementation. However, dissemination of properly developed and tested guidelines is not effective in changing clinical or managerial practices. Therefore, at the start of PAL implementation countries should plan training activities to provide adequate knowledge and induce changes in the managerial and technical behaviour of health workers. Models of training materials issued by international agencies are very useful if they are appropriately adapted to national situations. However, adaptation is not a straightforward issue and care should be taken that they do not result in an oversimplification to the point of ineffectiveness. Countries should know what elements of the generic materials are minimum standards that should not be changed. Countries should also plan the sustainability of the PAL strategy by introducing the teaching of the PAL guidelines in the pre-graduate health schools. In order to assist countries in the organization of effective training, the Consultation Meeting recommends to WHO the following actions:

a) Produce three sets of generic training materials for the teaching of PAL guidelines to:
   - district health managers
   - health workers at first level of PHC facilities
   - professional staff at district or first referral hospitals

b) Produce a guide on adaptation of the WHO PAL guidelines and the generic training materials with clear indication of what can be modified as required by local conditions and what cannot be modified to preserve the soundness of the guidelines and effectiveness of training materials.

c) Elaborate directives on how to introduce the teaching of the PAL guidelines into the curricula of the medical, paramedical and nursing schools.

9.4 Availability of drugs

The Consultation Meeting recognizes that one of the major obstacles for a successful implementation of the PAL strategy is the cost of essential drugs for the treatment of chronic respiratory diseases such as asthma and COPD. Inhaled corticosteroids that are essential for the treatment of persistent asthma are either not available or not affordable in many settings, especially low income countries. It is not realistic to assume that the essential drugs for management of asthma and COPD can be supplied free of charge to all patients everywhere. A more realistic approach is to guarantee the supply of low cost drugs that can be affordable for most patients in all countries.

The Union has established an Asthma Drug Facility (ADF) which is a mechanism to ensure, for qualifying programmes, the supply of good quality drugs to treat asthma at the lowest possible price. The ADF has links with other international agencies interested in asthma management, including WHO. The ADF initiative also provides technical assistance and monitoring of the use of asthma drugs to assure quality of care. In order to assist countries in ensuring accessibility and affordability of essential PAL drugs, the Consultation Meeting recommends to WHO the following actions:

a) Provide technical assistance to countries for the revision of the national list of essential drugs to ensure that it includes the essential drugs for the management of the most common respiratory diseases.

b) Collaborate with The Union ADF programme in the supply of good quality asthma drugs for PAL projects.

c) Collaborate with The Union in the analysis of the possibilities of extending the ADF to the supply of good quality and low price drugs for treatment of COPD.

9.5 Information system

The Consultation Meeting commends the valuable information that WHO collected through PAL feasibility tests in a number of countries. Since WHO has not yet disseminated information on the indicators that were selected to measure progress in achieving PAL targets of activities and epidemiological objectives, the country reports presented in the meeting did not provide a clear picture on how the necessary data for monitoring and evaluation are being collected through the health information system. The Consultation Meeting is aware of the importance of using existing registry and reporting forms as much as possible without introducing additional specific forms for the collection of PAL data. In order to assist countries in the use or adaptation of the PHC information system for the monitoring and evaluation of the PAL strategy, the Consultation Meeting recommends to WHO the following actions:

a) Design protocols for testing the feasibility and effectiveness of the indicators recommended to measure the level of achievement of the clinical, managerial and epidemiological objectives of the PAL strategy.

b) Promote protocols designed for testing the feasibility and effectiveness of selected PAL indicators.

c) Issue directives on the collection and analysis of data on respiratory diseases at first referral or district hospitals.

9.6 PAL as a component of the Stop TB Strategy

The Consultation Meeting acknowledges and commends the WHO Stop TB Department decision to promote and develop the PAL strategy as an integral part, probably the most important one, of the component called Contributing to Health System Strengthening of the Stop TB strategy *(6)*. Many countries may also choose the same organizational option since the objectives and technical issues of PAL and TB are very closely related. A good NTP facilitates implementation of PAL. However, the PAL strategy does not always have to be implemented at country level by the NTP. It is quite clear that the NTP is better suited than any other programme to the start-up phase. Later, PHC might be appropriate to ensure the nationwide sustainability of PAL and avoid the danger that PAL overburdens the NTP. Whatever the managerial decision, it is always necessary to have a very close collaboration between the PHC and the NTP in the planning, implementation and evaluation of PAL. The role of the NTP in PAL is enhanced in places with high prevalence of HIV infection. In order to clarify the issues related to the managerial responsibility for planning and implementing PAL at country level, the Consultation Meeting recommends to WHO the following actions:

a) Issue a policy document presenting the alternatives that the MOH should consider in choosing the national programme that will be responsible for

the planning, implementation and evaluation of the PAL strategy, and the coordination links that should be established with all the concerned national programmes. Although the NTP has the structure and experience to implement work plans, the PHC system is responsible for the health system where PAL will be implemented. Each country should decide the most suitable managerial structure for introducing the PAL strategy into the PHC system. In any case, the role of the NTP should be well visible.

9.7 Essential technical elements

The Consultation Meeting fully supports the technical and managerial framework developed by WHO for the planning and implementation of the PAL strategy. WHO could greatly enhance the impact of this work and increase its visibility by identifying the key elements of the strategy that should be highlighted in the communication activities addressed to a wide global audience. In order to determine the list of key elements of the PAL strategy, the Consultation Meeting recommends that WHO identify the key elements of the PAL strategy taking into account the four technical elements listed under item 8.1 (diagnosis, treatment, equipment and health education) and the six managerial elements listed under item 8.2 (political commitment, training, logistics, information system, pilot testing and national work plan).

References

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2 World Health Organization. *Report of the First International Review Meeting: Practical Approach to Lung Health Strategy*. Rabat, Morocco, 4-6 September 2002. Geneva, WHO Stop TB (Publication WHO/CDS/2003.324).

3 Ottmani S, Scherpbier R, Chaulet P et al. *Respiratory care in primary care services. A survey in 9 countries*. Geneva, World Health Organization, 2004 (Document WHO/HTM/TB/2004.333).

4 World Health Organization. *PAL: A primary health care strategy for integrated management of respiratory conditions in people of five years of age and over*. Geneva, World Health Organization, 2005 (Document WHO/HTM/TB/2005.351-WHO/NMH/CHP/CPM/CRA/05.3).

5 World Health Organization. *Practical Approach to Lung Health. Manual for introducing PAL within Stop TB Strategy activities*. Geneva, World Health Organization (in press).

6 World Health Organization and Stop TB Partnership. *The Stop TB Strategy - Building on and enhancing DOTS to meet the TB-related Millennium Development Goals.* Geneva, World Health Organization and Stop TB Partnership, 2006 (Document WHO/HTM/TB/2006.368).

Annex 1

Agenda

Monday 18 June

08:30	Registration	
09:00	Opening session	M. Raviglione / D.Weil
09:15	Introduction of the participants and objectives of the meeting	S. Ottmani / A.Pio
09:25	Evaluation process of PAL	S. Ottmani / M. Erhola
09:35	Overview of PAL strategy at global level	S. Ottmani
10:00	Discussion – clarifications	
10:15	Coffee	
10:30	Session on PAL evaluation in countries,	Chairman: P. Chaulet

- 10:45 PAL evaluation in Kyrgyzstan — L. Parkkali
- 11:05 Discussion
- 11:30 PAL evaluation in South Africa — M. Erhola
- 11:50 Discussion

12:15 Lunch

- 13:15 PAL evaluation in Morocco — P.Y. Norval
- 13:35 Discussion
- 14:00 PAL evaluation in El Salvador — M. Erhola
- 14:20 Discussion
- Results of the survey on PAL development in 10 countries — S. Ottmani/ M. Erhola

14:40 Constitution of the three work groups — S.Ottmani / N.Aït Khaled

15:00	Group work Question to discuss: "based on the country evaluation findings, what are the strengths and weaknesses of PAL? How to address these weaknesses?"	
16:45	Working groups' reporting and discussion	
17:30	Summary and close	

Tuesday 19 June

09:00	Presentation on Asthma Drug Facility	N. Ait-Khaled
09:30	Group work Question to discuss: "Should PAL Strategy be always developed by NTP in any countries? How to implement PAL through NTPs? What is the added workload when implementing PAL?"	
10:45	Working groups' reporting and discussion	
11:45	Group work Question to discuss: "What are the essential (non negotiable) elements in PAL which should be always involved in any country setting? Is there any missed component in the development of PAL?"	
12:30	Lunch	
13:30	Continuation of group works	
14:30	Working groups' reporting and discussion	
15:15	Coffee	
16:00	Final recommendations and discussion	S. Ottmani / A. Pio
17:00	Closing session	L. Blanc

Annex 2:

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