

NATIONAL TUBERCULOSIS STRATEGY FOR 2009-2014
**“THE IMPROVEMENT OF THE TUBERCULOSIS EPIDEMIOLOGICAL
SITUATION TO SUCH AN EXTENT THAT TUBERCULOSIS NO LONGER
CONSTITUTES A PUBLIC HEALTH PROBLEM”**

ACKNOWLEDGMENTS

The need for the review of the National Strategy for Tuberculosis Control in the country, and the formulation of the new strategy stemmed from the stabilized epidemiological situation of tuberculosis, health sector reform, the change in the mission of the Shefqet Ndroqi University Hospital for Lung Diseases (UHLD), and as a result of the improvement of the living conditions of the population in general.

The formulation of the national strategy aims at improving tuberculosis control to the degree that it no longer poses a threat for the public health. The objectives are very ambitious, but the formulation of the strategy, in addition to the above mentioned factors, was also sponsored from the recommendations of the WHO, and of the Ministry of Health, and we would like to seize this opportunity to thank them for their generous support.

This strategy is the fruit of the joint work of the national staff of tuberculosis control, in cooperation with the pulmonology service in the Lung Diseases University Hospital, with the support as well of the SUSM “Shefqet Ndroqi”, whom I would also like to wholeheartedly thank on the occasion of the publication of this strategy.

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Abbreviations

AFB.....	Acid-Fast Bacilli
BCG.....	Bacil-Calmette-Guerin
BK.....	Bacillus Koch (Mycobacterium tuberculosis)
DOT.....	Directly Observed Therapy
DOTS.....	Directly Observed Therapy, Short Course Strategy
DST.....	Drug Susceptibility Testing
ECHO.....	European Community Humanitarian Office
EUROTB.....	European Region Surveillance of Tuberculosis and AIDS
GDP.....	Gross Domestic Product
GF.....	Global Fund
HIV.....	Human Immunodeficiency Virus
INSTAT.....	Institute of Statistics
IPH.....	Institute of Public Health
IUATLD.....	International Union Against Tuberculosis and Lung Disease
KNCV.....	Royal Dutch Tuberculosis Foundation
CSF.....	Cerbro-Spinal Fluid
NRL.....	National Reference Laboratory
MDR.....	Multidrug-Resistance
MoH.....	Ministry of Health
WHO.....	World Health Organization
NGO.....	Non-Governmental Organisations
NTP.....	National TB Program
PPD.....	Purified Protein Derivative
QSUT.....	Hospital University Center Tirana
AIDS.....	Acquired Immunodeficiency Syndrome
SUSM.....	Spitali Universitar i Sëmundjeve të Mushkërive
TB.....	Tuberculosis

Abbreviations of antituberculosis drugs

E.....	Ethambutol
H.....	Isoniazid
R.....	Rifampicin
S.....	Streptomycin
Z.....	Pyrazinamide

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SUMMARY

The need for the review of the National TB Strategy came as a result of rapid and significant improvement of the TB epidemiological situation in the course of the recent years, and improved TB control thanks to financings from the Government of Albania, European Community, and the Global Fund. On the other hand, the re-organization of the health care service, and the health reform, which often fail to take into account TB control in the country represent yet another challenge for TB control. A WHO publication of 2007 called “The Plan for Stopping Tuberculosis in 18 high priority countries in the European Region during 2007-2015”, which considers Albania as a low priority country in terms of stopping tuberculosis and which recommends the review of the strategy makes the formulation of this strategy even more indispensable.

The improvement of the epidemiological situation is reflected in all the key epidemiological indicators. Thus, the incidence of new tuberculosis cases for 2007 was 13 per 100,000 inhabitants, the bacterial resistance, and in particular the multi drug resistance is low, at below/under 2% at country level, thus not presenting a problem for the moment; mortality continues to remain low at approximately 5 per 100.000 inhabitants, and the results of the success of the treatment are approximately 87% for all new tuberculosis cases.

Thanks to the financial support from the project on “Raising national tuberculosis response”, during 2007 and 2008 it was made possible a rapid expansion of DOTS strategy at the country level, currently covering approximately 80% of the country, from 38% coverage before the start of the project financed by the Global Fund.

Thus, the existing strategy is no longer up-to-date, and consequently does not respond to the country’s needs for tuberculosis control in the face of this new reality. The previous Strategy is no longer appropriate or sufficient to control tuberculosis in the country, since it does not properly consider the technical potential, it does not have a very aggressive approach regarding tuberculosis control, in particular for the vulnerable groups, and does not properly harmonize the NTP with primary health care.

On the other hand, the sustainable decline of tuberculosis incidence in the country may lead to feelings of self-sufficiency among the ranks of the health professionals, and the Government representatives, as well as might create the wrong/false impression that the tuberculosis is no longer a problem, and does not pose a threat for the public health. Unfortunately, this opinion often times is prevailing among health professionals as well. Experience of other countries, even very developed countries, with very robust programs for tuberculosis control such as the United States has shown that this disease when/if neglected, the consequences are quite dramatic, difficult to be amended and represent a major economic burden.

The formulation of this strategic plan is based on the systematic analyses of the current tuberculosis situation in the country, on a detailed budget, and with the relevant responsibilities. The plan considers the options and challenges generated by the health reform underway, the potential for the inclusion/involvement of other health institutions

and programs, as well private sector involvement. The development of the new strategy is based on the fact that we already have in place a good infrastructure for TB control in terms human perspective, with trained physicians and nurses; the physical infrastructure has been rehabilitated recently, and we believe that we will have the **Government's** commitment for the implementation of the strategy.

The new Strategy has a more aggressive approach for TB control, and consists in three main pillars, which are:

- 1) ***Early tuberculosis case detection*** and its treatment until recovery, as well as prevention of TB avoidable deaths;
- 2) Reduction of infection incidence through management of risk groups, and prevention of infection transmission in the health care institutions;
- 3) Reduction of tuberculosis infection prevalence through management of outbreaks, and administration of chemoprophylaxis for specific groups and individuals.

Key issues that the new strategy should seek to address include:

- Integration of tuberculosis in primary health care service. Lung disease dispensaries in the districts should move under the primary health care;
- Enhancing the quality of laboratory examinations and TB cases confirmation through direct sputum and BK culture;
- Reinforcing the treatment and DOT implementation, according to the WHO recommendations both for the intensive phase and for the ongoing/continuity phase.
- Improvement of the procurement system, and drug management;
- Introduction of the physical infrastructure for the treatment of MDR patients, and securing second series drugs;
- Performance of chemoprophylaxis with INH in specific groups;
- Management of vulnerable groups, and high risk groups;
- Control of infection in the health institutions, and in the infection sources;
- Improving cooperation among Infectious Diseases Hospital for HIV/TB patients or meningitis TB patients, the Pediatrics Hospital, and the other specialized hospitals that confirm TB cases, which are mainly extra pulmonary cases.
- Better cooperation with the Ministry of Justice for the tuberculosis patients who are either being detained or who are doing time in the prisons;
- Active screening in the high risk groups, and contact persons;
- Social and financial support for the TB patients in financial need;
- Introduction of coverage of expenses for TB control in the health insurance scheme.

Key specific objectives that the new strategy should seek to address:

- Strengthening the health care system regarding TB control. Integration of TB control in the primary health care within five years;
- Ensuring, and maintaining 100% DOTS coverage at the national level within 2009.
- Ensuring and maintaining access to DOTS for the vulnerable groups.
- Proper case management for cases with bacterial resistance, and control of MDR spread.

Expected outcome for the period until 2013 will be:

- New cases incidence will be 10 cases less in 100,000 inhabitants by the end of 2013;
- Maintaining the high rates of treatment success for the tubercular cases with positive sputum over 90%;
- Reducing and maintaining mortality rates to figures below 0.5%;
- Detect more than 75% of new tuberculosis cases.

Albania's economic and social situation & the organization of the health care service

According to official data, the population figures for Albania in 2006 were 3.552.000.

From the administrative perspective, Albania has 12 Prefectures. Each of these prefectures includes on average 3 districts, while the country has a total of 36 districts. At the district level there are 42 Municipalities and 315 Communes.

The country's capital is Tirana, which in the recent years has grown tremendously, and today it accounts for over 700.000 inhabitants.

Approximately 46% of the population (according to INSTAT 2006) lives in the urban areas, while approximately 20 % of the population lives in the capital (2006).

Average urban population growth during 1990-2006 was 1.2%, whereas the population's growth rates were 0.529% (2007). This growth is mainly the result of migration of the population in the recent years towards the urban centers. Thus, within the last 15 years, the regions of Tirana, Durrës, and Fier are characterized from almost a doubling of their population, compared to the decline in the same size of the population in the regions of Kukës, Shkodra, and Dibra.

The major social and economic changes were accompanied by both migration and emigration of the population. Approximately 700.000 Albanians, mainly males, have emigrated from the country (INSTAT, 2005).

The Albanian population composition is: 93 % Albanians, and 7 % ethnic minorities such as: Greek, Vlah, Macedonian, Roma, and Bulgarian (INSTAT 2005).

Population Distribution according to Age Groups

Approximately 29 % of the population belong to the age group from 0-14, 42 % under 19. 70 % of the overall population belongs to the 15-24 age groups, and only 10% are above 65.

Albania has the youngest population in Europe, with average age at 29.6.

Key Health Indicators and the Health System Organization

As a result of the difficult transition period, the health status of the population is problematic. Yet the main indicators in terms of primary and hospital health care are improving.

Birth rates are 15.22 births per /1,000 inhabitants (2007), and according to gender division the ratio is 1.1 males/females.

Fertility rates are 2.1 births per every woman of 15-45 age group.

Infant mortality per 1000 births fell from 28.3 in 1990 to 20.2 in 2007(Ministry of Health).

Maternal mortality is still high compared to Western Europe, even though there is a decline from 28 to 16.7 per 100 000 births from 1994 to 2006.

For the period between 1993-2004, the general mortality structure has not changed.

There is an increase in the overall number of deaths per 100 thousand inhabitants from 465, 1 (1994) to 567.6 per 100 thousand inhabitants in 2005.

The main group of diseases causing deaths is:

Cardiovascular apparatus with 286.4 death cases per 100 thousand inhabitants (2004);

Tumor diseases with 93.1 death cases per 100 thousand inhabitants (2004);

Undetermined causes with 63.8 death cases per 100 thousand inhabitants (2004);

Traumas and accidents with 38.9 death cases per 100 thousand inhabitants (2004);

Respiratory apparatus with 30.5 death cases per 100 thousand inhabitants (2004);

Hospital mortality has maintained the levels of 11-12 % for the entire period of 1993-2004.

According to population projections, life expectancy is 75.7 years old.

Life expectancy for males is 73.8 years old, while for females is 78.4 years old (2004 INSTAT).

Infant immunization is mandatory and is administered in the Maternity Homes, while the mother and child consultories provide assistance for TB with BCG vaccine, DPT with DPT1beta vaccine, and HepB with HepB3 vaccine.

Social & Economic Data

In the course of the last 17 years, Albania has faced continuous political and social changes. The country has now embarked on the road of major economic and structural reforms.

Despite its slow, but sustainable economic progress, Albania still remains one of Europe's poorest countries.

According to the Bank of Albania, in 2007, the income per person were 3.150 \$, with a considerable increase in the course of the recent years.

According to the World Bank's Poverty Assessment Report (2005), the official unemployment level is 13.5%, while 18.5% of the population lives below the average of the poverty line.

Real GDP growth (2007) was 6% per person.

The inflation rate was 3%.

Annual average GDP per capita growth from 1990-2006 was 5.2(%), but approximately 4 % of the population spends less than 1 \$ US daily (1995-2005).

Government health expenditures (1995-2005) were 4%.

Health care expenditure as % of the GDP (2005): 6.5

Per capita health expenditure (Int \$,2005): 353

Recently, the Government of Albania has drafted a new Strategy for the Poverty Elimination and Economic and Social Development, which aims at poverty reduction and the country's economic and social development. The strategy gives an important role to the efforts for TB and HIV prevention and control in Albania. The Government of Albania is signatory of the Declaration of the Millennium, which expresses the commitment for the achievement of the Millennium Development Goals (MDGs)

The Organization of the Health Care System

The health system in Albania is mainly public. The state accounts for the majority of service delivery for the population in terms of promotion, prevention, diagnosis, and treatment. The private sector is still in its first steps, and covers the majority of the pharmaceutical service, dental services, and accounts for some of the specialized diagnosis clinics. These clinics are mainly located in Tirana.

The Ministry of Health plays the key leading role in the public sector. This Ministry is responsible for the formulation of policies and strategies for the health care system, for its regulation, and for the coordination of all actors within and outside the system. The diagnosis and treatment system is organized in three layers/levels: primary health care,

secondary hospital service, and tertiary hospital service. Public health and promotion services are delivered in the context of primary health care, and with the support and supervision of the Institute of Public Health (IPH).

There are 406 Primary Health Care Centers in the country. Health care centers deliver all types of primary health services- disease prevention, health promotion, diagnosis, treatment, rehabilitation and other health care services.

Currently, the primary health care service is responsible for the employment of 1617 physicians and 6640 nurses/midwives. In the cities, a general practitioner (GP) provides services to approximately 2000 inhabitants for the adults, and one pediatrician services to 1000 children.

In the villages, a physician provides services for all age groups to approximately 1700 inhabitants. Currently, there are remote mountainous areas in the country where due to absence of physicians, one general practitioner has to provide services up to 5000 inhabitants.

Secondary health care is represented by the district and regional hospitals.

The country has 34 hospitals (22 district hospitals, and 12 regional hospitals). The current number of hospital beds in Albania is 8874 (14,000 in 1992; 12,000 in 1993) with a ratio of 28.2 beds/10000 inhabitants; most of them fall under the category of acute care beds.

Tertiary health care is represented by the University Hospital Center.

Tertiary health care in Albania is delivered in the Tirana University Hospital Center (TUHC), which is a national center of referral and diagnosis.

Health care financing sources are:

The State budget: public health; primary health care; and hospitals.

Health insurance funds cover: key drugs, general practitioners, some specialized services, and very expensive diagnosis procedures in the Tirana University Hospital Center (TUHC) and in the Durrës hospital.

Health insurance in the Republic of Albania is sanctioned in the Law “On Health Insurance in the Republic of Albania” (No. 7870, 13.10.1994.) Health insurance covers approximately 45 % of the population.

The Organization of Tuberculosis Service in Albania

Government’s Political Commitment

Tuberculosis has continuously been considered as a priority by the Government of Albania, and the legislation for tuberculosis control has been subject to frequent changes.

Decision no. 161 of the Council of Ministers contains important improvements regarding tuberculosis control in terms of the re-organization of the fight against tuberculosis. Some of the most important measures in this context included: free of charge treatment,

strengthening of active screening, and vaccination. Hence, this was a **law** which gave priority to active screening, and prophylaxis, thus substantially strengthening, for the time, the fight against tuberculosis.

In 1993, the legislation regarding control of infectious diseases, in the Parliamentary acts on “Prevention and Fight against Infectious Diseases” included also Law No. 7761 “On the fight against tuberculosis.”

Tuberculosis has been classified under the infectious diseases category through Order no. 189 of the Ministry of Health, an order which was issued in 1995.

In line with the recommendations of WHO/IUATLD for the implementation of DOTS in Albania, in 1996 was established the National Committee for Tuberculosis Control. **In its first meetings, this Committee decided in principle in favor of the implementation of DOTS in Albania.**

In 1996, the Ministry of Health accepted the start of the implementation of DOTS in the pilot areas, and to this end the Albanian staff received training abroad. Later on, training courses were launched in Albania with the financial support of WHO. In 2001 DOTS implementation began in two pilot areas, in Tirana and Shkodra, which represented less than 30% of the population nationwide.

In 1998, Order No. 105 of the Minister of Health specified some additional measures that were needed to be taken in the fight against tuberculosis.

Specific regulations regarding tuberculosis control in Albania have been included in the National Tuberculosis Control Program, drafted and published in 2002, under the technical guidance of WHO through the Representation Office of ECHO/WHO Albania.

The National Strategy for Strengthening the Fight against Tuberculosis was drafted in 2006. This strategy received financial support from the Global Fund in the amount of 1.2 million US\$ for the period of 2007-2011.

But, there are many cases when the current legislation is not respected. Despite the fact that the out-patient service has one single regulation at the national level regarding its reporting arrangements under the District Pulmonology Services, in some districts, the pulmonology services are under the Hospital Directorates, whereas in some others they are under the Primary Health Care. This is often done in an arbitrary fashion, according to the wishes of the local managers/directors.

In the recent years, the National Program has not been receiving any financial, or logistical support for the conduct of supervision and monitoring, and sometimes due to the negligence of the Ministry, this has led to major problems. Thus, for instance as a result of the failure to purchase the PPD for several years no chemoprophylaxis could be conducted. Also, we have had problems with the purchase of anti TB drugs. Lack of commitment on the side of the Government is expressed in the absence of a dedicated budget line for anti TB drugs, and for maintaining some of its basic activities.

In our view, the biggest ignorance to tuberculosis control in Albania was expressed in the decision of the Government of Albania for changing the mission of University Hospital for Lung Diseases “Shefqet Ndroqi” from a lung diseases hospital into a general services hospital. Of course, we are not against this decision, but the fact that there have been no

preliminary consultations, or that no feedback was required from the staff of the hospital and NTP for TB patients does not bode well.

Therefore, we might conclude that the political commitment of the Ministry of Health, despite seemingly correct in appearance, in these recent years has been declining.

The last two decades may be divided into two distinct periods. The first period from 1990 -2000 coincides with the first decade of the democracy, where Government commitment though not lacking, was more focused in the areas of legislation and reforms, without being accompanied with concrete measures, and financial support. Consequently, most of the physical infrastructure of the dispensaries in the course of this period started to dilapidate and by the end of 2000, none of the bacteriological laboratories in the dispensaries was operational, whereas the physical conditions of the dispensaries were deplorable. The second period starts during 2000. In this period, technical and financial support was provided by international organizations such as: WHO, European Community, and the Global Fund. During this period, all dispensaries were reconstructed; the network of bacteriological diagnosis in the districts is now operational; the DOTS strategy has already started and is being expanded; there are many publications available, which have helped in improving tuberculosis control; many training courses have been organized for the specialized health professionals and physicians and nurses in the out-patient service.

TUBERCULOSIS SERVICES IN ALBANIA

Tuberculosis services include a broad range of services such as: diagnosis, treatment, and prophylaxis. With the exception of the BCG vaccination, all of the above mentioned services have been integrated under the pulmonology service since 1982. In the out-patient service, this service is delivered by the lung diseases dispensaries, which are in general a continuation of structures of former anti TB dispensaries and have one or several pulmonologists; several nurses who used to be vaccinators and one technician for the bacteriological laboratory.

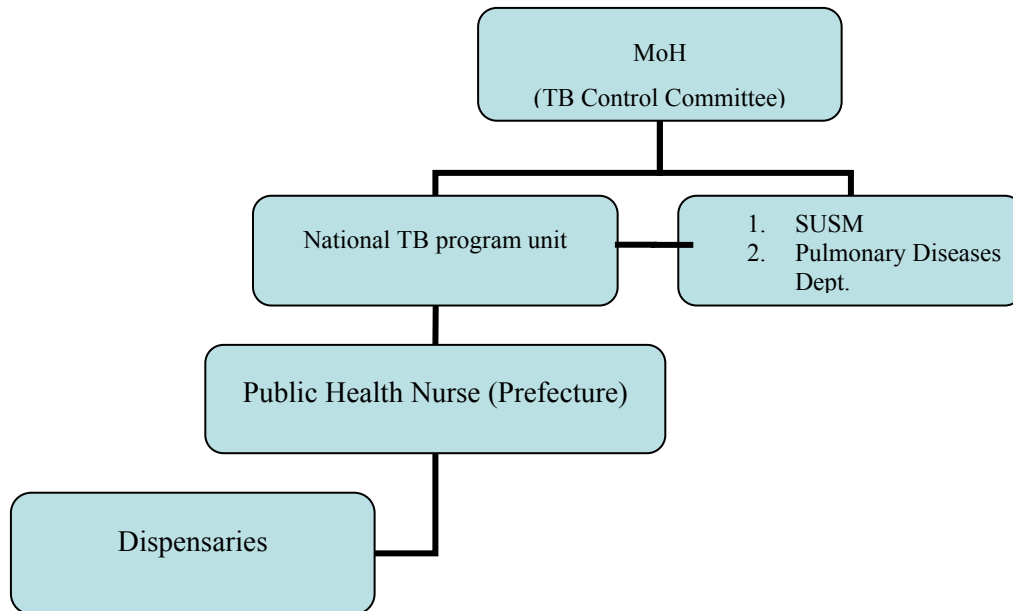
The organization of tuberculosis control in Albania is organized vertically, i.e. it is a closed system within the pulmonology service. Despite few efforts to integrate it within the primary health service, they have been to no avail.

The Ministry of Health is the main responsible institution for the control of tuberculosis. In this Ministry there is a National Tuberculosis Control Committee, which was established in 1996. The Ministry of Health is responsible for the legislation and the budget for TB control. There is no dedicated tuberculosis budget, but the Ministry of Health allocates the budget of hospitals and districts as a grand total for all services comprehensively. Only the budget for anti tuberculosis drugs is separate, and this budget is allocated to the University Hospital for Lung Diseases, which is responsible for managing it.

The University Hospital of Lung Diseases “Shefqet Ndroqi” is the main health institution engaged in the fight against tuberculosis. Integral parts of this hospital are the NTP and the national tuberculosis reference laboratory. Also all the students of Medicine, post-

graduate physicians, and the technicians of the laboratories receive their training in this hospital.

The following chart represents in broad lines the organization of tuberculosis in Albania:



At the national level there are 150 beds for the treatment of tuberculosis patients, but this a theoretical number, and it has kept declining gradually in a spontaneous manner in favor of other lung diseases. Thus, in Tirana there are 100 beds, but actually less than 50 are available for tuberculosis patients. Whereas in Shkodra and Korça there are less than 50 beds available, and therefore the actual number of beds for tuberculosis patients is not known, but it is however less than 100 nationwide.

There are also some beds in the Vlora Psychiatric Hospital for the mental health patients (approximately 5 beds), but that number is not accurate.

CASE DETECTION, DIAGNOSIS AND THE ORGANIZATION OF THE LABORATORY SERVICE

Lung Diseases Dispensaries

As a rule, General Practitioners should refer patients with respiratory complaints such as: cough or other types of complaints, when they are of the opinion that these patients need complementary, further examinations, to the pulmonologists, either in the out-patient clinics or in the hospitals. But often patient themselves go to dispensaries without any recommendation for doing so. Dispensaries which are in the policlinics or located within the set up of the hospitals can make use of their X ray equipments, but in most of the

cases they are not allowed by the local managers, and the X-ray examination is more and more being performed by the radiologists, rather than by the pulmonologists. In the instances when the physician of the dispensary either suspects or diagnosis the patient to have tuberculosis, he refers him/her for further hospital treatment in one of the three lung hospitals. These hospitals treat also cases of patients with other pulmonary diseases, which can not be treated in the out-patient clinics, or in the district hospitals, as well as patients with unclear diagnosis, which are in need of further examinations in order to determine the diagnosis.

Physical status of the dispensaries and laboratories

All dispensaries and laboratories have been reconstructed and refurbished with the necessary equipments for the tuberculosis bacteriological diagnosis. Reconstruction and refurbishment took place during 2000-2002, in the framework of the ECHO program, with European Community funds. The project financed by the Global Fund began in 2007. This project helped refurbish the laboratories with microscopes and reagents, thus contributing substantially in improving the laboratory diagnosis. Today, all dispensaries are in very good physical shape, equipped with microscopes and reagents for the direct sputum diagnosis.

At the national levels there are two models for the organization of dispensaries. One part is a direct continuation of the structures of anti-TB dispensaries and have inherited the premises with ample space, which have been refurbished recently. These dispensaries have more than one pulmonologists, several nurses who used to be vaccinators, and one bacteriological laboratory, whereas the other part has one physician and one or two nurses. The hospital service is delivered in three hospitals, namely the Lung Diseases University Hospital “Shefqet Ndroqi” in Tirana and the lung diseases hospitals in Shkodra and Korça.

Recently, several mainly retired pulmonologists have opened their private practices in Tirana, Gjirokastra, Fier, Durrës, Shkodra, Saranda, Fier, Lushnja, and Burrel. These physicians may assist in the diagnosis of TB cases, but they do not have the right to treat them, and should refer them to the dispensaries.

Children who are tuberculosis patients receive treatment in the Mother Teresa University Hospital Center, alongside with cases of meningitis or other extra pulmonary TB forms, according to the specializations.

During 2007, a new position opened up, and that was the position for the public health nurse, which serves for ensuring tuberculosis control at the Prefecture level. Opening up of this position was meant to strengthen the role of nurses in tuberculosis control, but in practical terms it did not have this desired effect. The nurses were selected from the pool of staff of the dispensaries of the prefectures, but this was not received very well from the heads of the dispensaries and their nurse colleagues who were in equal positions in their districts.

The medical staff of the dispensaries

The medical staff of the dispensaries has been trained and re-trained in the implementation of DOTS. In general, there is strong commitment of the staff of the dispensaries for the implementation of DOTS.

The problem remains with the distribution of the pulmonologists at the national level. In the districts with high incidence of tuberculosis and other pulmonary diseases such as in: Tropoja, Kukës, and Dibra there are staffing shortages for pulmonologists, whereas in the districts with low incidence there is an overload with physicians, not to speak of instances where there are more physicians than tuberculosis patients.

Often there are personnel changes in the dispensaries, and nurses without the necessary experience or training are appointed as heads of dispensaries.

The most concerning problem remains the failure to include/involve former vaccinators in the routine control of treatment. In the majority of the cases, the DOT can not be performed due to the physical distance of the tuberculosis patients from the dispensaries. But even in the cases when such a thing is possible, such as for instance within the cities, the DOT is not administered properly.

Case Detection and Treatment

TB case detection in the dispensaries is based on clinical, X-ray (radiological) and bacteriological examination of direct sputum. In most of the cases, the diagnosis continues to be based on fluoroscopic examination, despite the fact that this examination is more and more falling under the domain of the radiologists, and not of the pulmonologists.

However, the basic examination for the tuberculosis diagnosis remains the X-ray examination, while the bacteriological examination in the districts continues to be bypassed.

As a rule, TB patients, and in particular those with pulmonary tuberculosis get hospitalized in one of the three lung diseases hospitals for the duration of the first two months, or rather until their conversion from sputum BK positive into sputum BK negative.

If the diagnosis is performed in the dispensaries, the latter have to notify the NTP according to the notification form drafted in 2003. If the diagnosis is either given, or confirmed in the lung diseases hospital, the dispensary is notified by the NTP.

For the last two decades, active case screening is not working, except for some screenings for the detection of cases in sources with tuberculosis patients. PPD control for the relatives of the tuberculosis patients has resumed last year, after several years of interruptions due lacking of PPD. The percentage of individuals from the members of the families screened for TB with PPD and fluoroscopy is approximately 70%.

In the recent years, Global Fund financing has made possible the start of active screening for vulnerable groups of population such as: inmates/prisoners and Roma. Active screening is no longer performed for particular professions, which might present added

risk for the infection of the population, even though there is the appropriate legislation for the terms of their employment.

DOT (Directly Observed Treatment)

As a rule, tuberculosis patients, and in particular those with direct BK positive sputum get hospitalized for treatment during the intensive phase in the lung hospitals. Over 90% of the cases with direct positive sputum are treated in the hospitals of Tirana, Shkodra, and Korça. The DOT in the hospitals is properly administered because the treatment takes place in the presence of the nurses.

Thus, usually the DOT for the intensive phase of the treatment is performed in the lung diseases hospitals, whereas the treatment for the continuity phase can be performed in the out-patient clinics, and the DOT in most of the cases is not done under medical control every day. In the cities, the DOT for the continuity phase takes place once a week, whereas in the villages, drug administration usually is performed once a month.

DOTS implementation

The implementation of DOTS began in 2001, following a preparatory period and training sessions in the course of 1998 – 2000. Initially, it started in two pilot areas, respectively in Tirana and Shkodra, covering only 30% of the country. Later on, it was expanded to other districts, but at a very slow pace, due to absence of political commitment of the Government for expanding the DOTS. Last year, thanks to the financial support from the Global Fund, qualitative expansion of DOTS in all its elements was made possible in approximately 80% of the country. We believe that in the course of 2008, the DOT will be available nationwide. All indicators for the measurement of the activity of the dispensaries, and in particular the treatment data have constantly been better in the DOTS areas.

Recording and reporting system

Albania has a good information system. Recording is administered by the pulmonologists. In the hospitals, the bacteriological laboratory can notify the NTP or the pulmonologists. There is no double reporting system that can include the laboratory staff and the pulmonologists, but the reporting is done only by the latter. However, we have double control from the NTP for the clinicists and the laboratories, and consequently the possibility for losing/missing the reporting of cases with sputum or BK positive culture is almost inexistent. All data are aggregate and individual, in compliance with the EuroTB and WHO requirements.

Recorded and used variables are suitable for monitoring TB control performance and DOTS strategy.

LABORATORY SERVICES IN TUBERCULOSIS CONTROL

Laboratory services play a key role in the diagnoses, treatment methodology and epidemiological investigation of tuberculosis. They constitute but one of the elements of the DOTS strategy, and deserve particular attention regarding quality control.

The bacteriological diagnosis has improved after 2000. Following a period where in the districts there were almost no laboratorial services, in 2000 there was a reconstruction and refurbishment of the majority of the district laboratories, and of the three lung hospitals.

Currently, thanks to Global Fund financings, 17 laboratories are in good physical conditions, and equipped with binocular microscopes and sufficient reagents for the bacteriological diagnoses of the TB patients. The sputum is collected outside the premises of the dispensaries or in the patient's home. The network of TB laboratories in Albania includes 17 periphery laboratories that perform direct microscopy (Berat, Vlora Lushnja, Durrës, Pogradec, Lezhe, Elbasan, Burrel, Kukës, Rrëshen, Kavaje, Gjirokastra, Fier, Peshkopi, Shkodra, Korça and Tirana), and one National Reference Lab (NRL) at the University Hospital for Lung Diseases in Tirana, which is in charge of the culture and sensitivity testing against anti-TB (DST) of the first line. Two of the above mentioned laboratories (those of Shkodra and Korça) used to perform also the culture for *M. tuberculosis*, but due to lack/absence of reagents during a given period, they stopped with the cultures, and today they perform only direct microscopy.

The level of skills the laboratory staff is good. The records of the laboratories are filled in properly. forms and smear positive slides are preserved for quality control, but in general there is no sustainable quality control system for the laboratories, and for this purpose some efforts have been under way last year.

The percentage of detected cases with direct sputum is high, at approximately 62% of the cases with pulmonary tuberculosis, and it is considered as good.

The number of laboratories in Albania is relatively high, and varies from one district to the other. There are districts that cover 200,000 inhabitants, but there are others that cover less than 50,000 inhabitants. There is a large variation in the number of examinations, and this depends not only on TB case incidence, but also from the pulmonologists, who usually continues to base his work more on the X-ray diagnosis. There are laboratories that detect only 3-4 cases annually, and it is understandable that for the majority of the laboratories it is very difficult to ensure good quality levels.

The National Reference Laboratory (NRL)

The National Reference Laboratory on average handles 20 samples per day. Every sample is examined directly by microscope, and is cultivated at the same time in solid and liquid terrain/ground. Every strain isolated for the first time goes through sensitivity testing for anti-TBs of the first line anti TB drugs.

The NLR is supplied with one fluorescent microscope, and 4 binocular microscopes. Since 2000 there is 1 biosafety cabinet of the first class for the performance of sensitivity testing. There has been no maintenance service for this cabinet. 3 biosafety cabinets of

class II, type B2 have been purchased through GFATM (Global Fund for AIDS, TB, and Malaria), and consequently, the laboratory currently meets the international biosafety standards. Maintenance services should be provided once a year for these cabinets in order to ensure quality and safety at work. UPS equipments are very important for ensuring uninterrupted power supply because in the event of a sudden power cut while a lab technician is working in the cabinet can prove to be very dangerous for the health of the medical staff.

Solid terrain of Lowenstein-Jensen is prepared in the laboratory. The reagents of BACTEC MGIT 960 have been purchased by the Ministry of Health. Sensitivity testing is performed for four anti-TBs (Isoniazid, Rifampicin, Ethambutol and Streptomycin) through the proportions method.

Identification at the type level is performed with conventional methods (sensitivity to TCH and PNB). Niacin and Nitrate testing have also been used. Currently, the laboratory is implementing the identification through molecular methods (Hain GenoType Mycobacterium CM kit, a molecular genetic test for the identification of the most important mychus bacteria from the cultures. This test will be used for the identification of *M. tuberculosis* complex and the atypical muchus bacteria). The types will be further differentiated through Hain GenoType Mycobacterium AS kit, if this will be necessary for clinical purposes. For further differentiation within *M. tuberculosis* complex, the GenoType MTBC kit will be used). This will be made possible during the DRS (Drug Resistance Survey), which will be conducted for the first time in Albania during 2008-2009, and will be financed by GFATM, the US Agency for International Development, and the TM-REST project financed by the EC (European Commission) in the context of FP 7 (Seventh framework programme).

The samples get recorded, and the outcome of the direct microscopy (IUATLD scale), culture, and sensitivity are recorded in the registry and the computer database.

Regarding the quality control, since 1999 NLR is linked (is an network) with the Reference Laboratory (Rome- Milan) Supranational Refernce Laboratory. In 2002 there was 90% compliance for each drug. In 2005 and 2008, compliance is 100%.

Diagnosis of HIV Infection

The NLR is equipped with the Abbott AxSYM System, which operates with the **Microparticle Enzyme Immunoassay (MEIA)** methodology.

The test AxSYM HIV Ag/Ab Combo kit is a MEIA for the qualitative concomitant detection of HIV-1 and/or HIV-2 antibodies and of Ag HIV p24 in IV (**serum**) or human plasma. It helps in the diagnosis of the HIV infection.

Currently efforts are being made for testing all patients with tuberculosis, but this has often proved to be cumbersome due to technical problems, and absence of reagents. Thus, the routine testing that started this year is usually being performed in the Institute of Public Health.

The performance indicators in most of the periphery laboratories are low. Many of these labs conduct a very small number of examinations annually, which makes it impossible

for sustaining a high level of expertise for the performance of direct microscopic examination of the sputum. These laboratories will be supervised for a period of two years. Further training courses will be provided to the technicians of the laboratories in order to increase the number of examinations. This will be done in close cooperation with the pulmonologists of the respective dispensaries. If still there will be no changes in the situation, the NTP will be forced to close down these laboratories due to inefficiency, and to concentrate the case load in a smaller number of laboratories that will be selected based on performance indicators.

The General Practitioners

General practitioners (GPs) are considered as important actors in TB control, even though so far they have not been involved either in practical terms, or by legislation in the control of tuberculosis. They contribute in the diagnosis of TB cases, when they suspect it, and then refer the patient to the dispensary. But, their contribution in the diagnosis of TB cases is practically low, despite the fact that these are not confirmed data. During 2007, and up to September 2008, thanks to Global Fund financings, 1375 general practitioners and nurses received training on basic TB knowledge, and DOTS implementation.

The general practitioners do not have information regarding the tuberculosis TB patients that they cover, and for the moment they are not involved in the control of the source, or in the treatment of the patients. But, in general, general practitioners, are aware of their future role in TB control, and are willing to cooperate for the diagnosis and treatment of the tuberculosis.

Anti-tuberculosis Drugs

Albania has never been in a situation of drugs absence, despite the fact that there is not as yet a sustainable procurement, storage/conservation and distribution system. The latter has often been the cause of being almost on the brink of drug absence.

Drugs are procured and purchased by the Ministry of Health through the Drug Facility. The pharmacies do not have the right to either keep, or sell anti-tuberculosis drugs. Thus, we have a centralized system for drug purchase and management. But, their purchase is still problematic since there is not as yet in place a sustainable and qualitative system for the purchase and management of anti TB drugs. Despite consecutive recommendations from WHO experts, purchase transactions are carried out on behalf of the Lung Diseases University Hospital and not of the NTP. Consequently, the NTP can not be in charge of drug administration and distribution. What is even worse, there is no space/facility for the conservation/storage and management of drugs.

Drugs are purchased by the Ministry of Health, and then it is the responsibility of the University Hospital for Lung Diseases to properly manage them. The drugs are kept in the pharmacy of the hospital, and are distributed by the head of the pharmacy facility, according to the requests of the dispensaries.

According to the Albanian legislation, the out-patient pharmaceutical network does not have anti TB drugs, except for rare cases of Rifampicin, which is a drug used for other purposes as well.

Management of High Risk Groups

The high risk groups in Albania include: Roma population; the inmates; the homeless; the population that lives in mountainous areas. Thanks to the financings from the Global Fund, for the first time these segments of the population are going through active screening. We have trouble in determining the tuberculosis incidence in these high risk groups since often we do not know the denominator like for instance in the case of the Roma population, or of the homeless etc. Active screening has already started in two population samples: the inmates and the Roma.

The migrants & the emigrants

The number of migrants in Albania is small, and there is still no policy in place for controlling migration. But, even more problematic is the case of the Albanian emigrants abroad and in particular in Greece. Albanian emigrants who are illegal emigrants in Greece are forced to hide their disease because this way they risk to be expelled, and do not benefit from the anti-tuberculosis treatment. Efforts are underway to establish a data exchange system for the tuberculosis patients with the neighboring countries.

The inmates/prisoners

Registration of tuberculosis patients among inmates, as a stand alone group, began in 2005. The data get reported to the NTP, and are recorded in the national register.

Drug Users & HIV patients

HIV prevalence is still low among drugs users, and consequently concomitant TB & HIV infections are rare. However, despite the small number of cases, this group should be considered among high risk groups. Outbreak

Outbreak Management

Cases/instances of contacts with tuberculosis patients, as a rule, are notified to submit to examination in the lung diseases dispensaries. This is done through clinical examination, PPD, and X-ray examinations.

In general, the family of the patient is notified either through the patient, or through another member of the family. In other instances, a nurse of the dispensary goes in the house of the TB patient, and invites the contact persons to submit to an examination. The nurse also explains to them the importance of screening, and uses the visit as an opportunity for health awareness regarding the tuberculosis disease.

The data for the contact persons found to suffer of tuberculosis during the visits of the source are recorded separately.

In most of the cases, the pulmonologists are in charge of managing the screening of the source, but now, the pulmonologists are getting more and more involved in other clinical areas/matters.

Source screening in other contact cases such as: working place, schools etc. leaves to desire.

Infection control

The check-ups for the tuberculosis patients take place in the same premises with other patients, and disease transmission may occur also during the diagnosis phase. This may occur in the waiting halls, in the check-up rooms or in other premises/facilities of the health institutions. We do not have special regulations/guidelines for prevention of infection transmission in the facilities/premises of the dispensaries or in the out-patient clinics. Once the patient is diagnosed to have TB, he gets hospitalized in one of the lung diseases hospitals. As a rule, in these hospitals, TB patients are kept in separate rooms, with usually 5-6 patients in one room. There are no special wards for the treatment of the tuberculosis patients, and often the latter move from one room to the other. There are few spontaneous measures for controlling tuberculosis infection, and for the prevention of infection from TB patients to other patients in the lung diseases hospitals. The masks are not being utilized, except in the cabinet of bronchoscopy, but even in these instances they are not special masks. More often during warm weather, natural ventilation is used, by leaving the windows open, which can not be done during the cold months of the year.

BCG

BCG vaccination is done once, in the first week of the infant's life, and for the cases which have not been vaccinated they can be vaccinated without having to submit to PPD within the first year. If vaccination should be done once the infant is 1 year old, first should be applied the PPD.

Financing sources

Even though in theory Government commitment regarding control of tuberculosis is not lacking, in practice, the level of political commitment is low. Albania began DOTS implementation since 2001, but the preparatory phase, the reconstruction of the physical infrastructure, and the refurbishment are being taken care by foreign funds. Here we can mention a fund of 2 million US\$ during 2000-2002 from the European Community ECHO program, and a fund of 1.2 million US\$ from the Global Fund for 2007-2011. Also, technical assistance and training for the implementation of DOTS and the formulation of the national policies of TB control have been financed by international organizations, mainly WHO. Policy formulation, surveillance activities, and other support activities are being developed and implemented by the National Tuberculosis Program, which currently is part of the University Hospital of Lung Diseases "Shefqet Ndroqi".

There are approximately three decades where there is no specific TB tailored fund. Furthermore, the funds which are indirectly allocated for tuberculosis control have kept continuously declining after the 90s. This is reflected in particular in the redundancies in the number of staff of the dispensaries, lack of funds for purchasing PPD, lack of funds for travel and per diem for monitoring from the center at the basic level, and within the district.

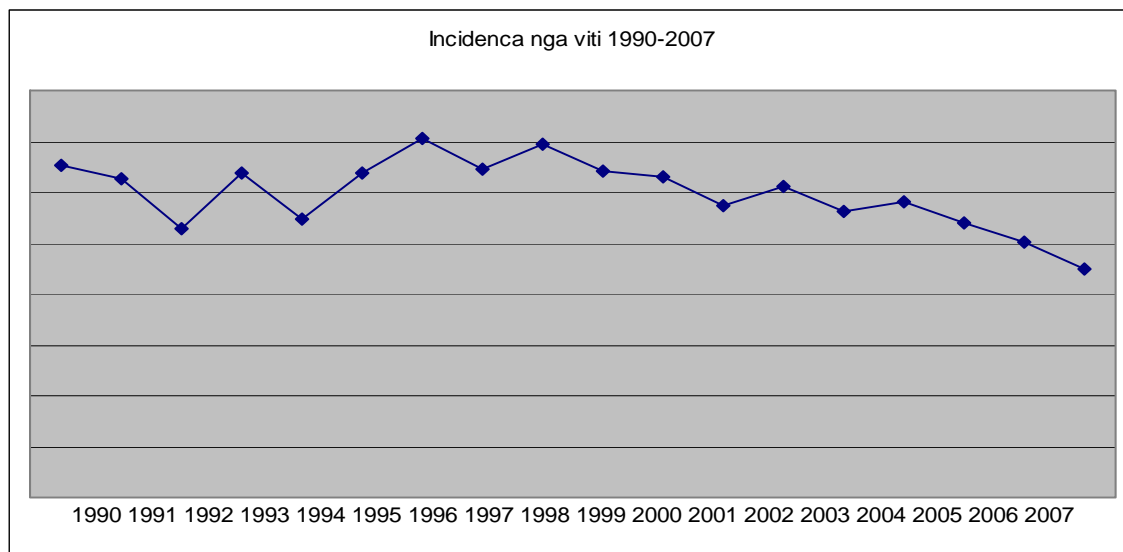
Tuberculosis treatment is free of charge, but it is not covered by the health insurance. A concerning issue is lack of payment of the tuberculosis patients as invalids during the treatment period. This is the same for the employment active age groups, who can work, but are not insured, as well as for uninsured youngsters and children.

THE EPIDEMIOLOGICAL SITUATION OF TUBERCULOSIS IN ALBANIA

The epidemiological situation of tuberculosis in the recent years has kept improving, and all epidemiological indicators speak for a stabilized and improving situation. The situation is characterized by a low incidence of 13 new cases per 100.000 inhabitants, a low number of recidives under/below 6%, low bacterial resistance under 2%, low mortality at approximately 0.5 per 100.000 inhabitants and high treatment outcomes at 90%.

During the first years of democracy there was a slight tendency of tuberculosis aggravation, and for many years it went on with slight fluctuations only to get stabilized in the recent years.

The following graph reflects the epidemiological situation in Albania during the last decades.



As regards incidence, Albania is ranked among the low and medium incidence countries. During 2007 were reported a total number of 447 tuberculosis cases, with the following break down:

New cases (not treated before)	422 cases (94.6%)
Recidives	16 cases (3.4%)
Interruptions	2 cases (0.4%)
Others	7 cases (1.6%)

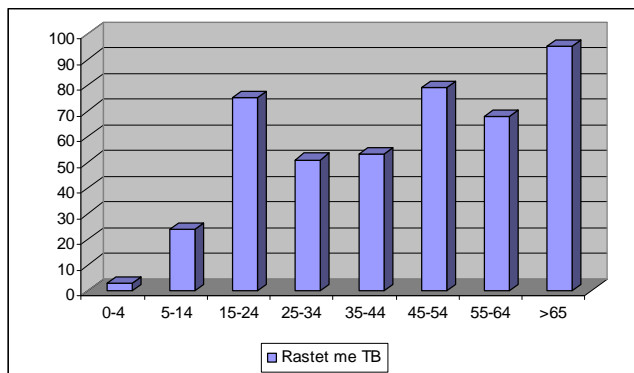
Total pulmonary cases:	292 cases (65.3%)
New pulmonary cases:	270 cases
Extra pulmonary:	155 cases (34.7%)

Positive sputum:	183 cases or 65% of pulmonary caseload
Negative sputum:	190 cases
Positive culture:	194 cases
Negative culture:	189 cases
Urban	212 cases (47.9%)
Rural	235 cases (52.1 %)

Tuberculosis structure according to age groups and gender

In 2007, the most affected age groups were 15-24(17%), 45-54(17.7%), and > 65 years old (21.3%). If we analyze age groups during the last five years, there is a marked stability for adult age groups and most of the cases are shifted over over 65 years old. Also, the structure of age groups is similar in the Central Europe countries, or groups with low or average incidence.

Figure 2 illustrates distribution according to age groups for 2007.

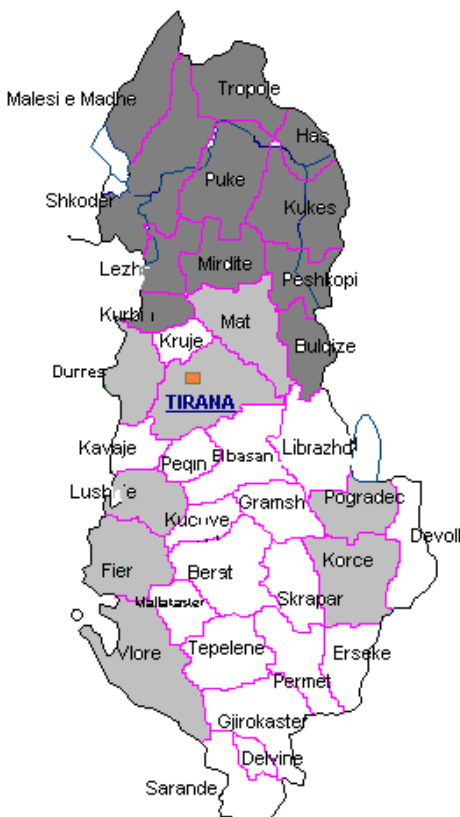


Males are more prone than the females for all types of tuberculosis. In 2007, this ratio was respectively 63.3% and 36.7 %.

Geographical Spread/distribution of Tuberculosis

In Albania there is an impressively uneven geographical distribution with major differences among various geographical regions. This change is more pronounced between North-East and Southern areas. Highest incidence for 2007 continues to be same as in the previous years in Mirdita 47.3/100000 inhabitants, Kukës 31.4/100000, Bulqiza 30.9/100000, Dibra 27.4/100000, Tropoja with 28.3/100000 (the incidence for Tropoja has marked a considerable decline from 48 new cases which was in the past) and in Lezha with 22.3/100000. The districts with the lowest incidence are in the South, such as in: Gramsh 4/100000, in Gjirokastra 8.7/100000, in Fier and in Lushnja with 10.4/100.000 inhabitants.

Incidence: in dark color > 20, gray >10, white <10



Whereas the ratio between the TB patients according to residence, rural or urban is continuously changing in favor of urban, and it is gradually getting even/equal and this is explained with the major demographic moves of the population in our country. Thus for 2007, we have 212 (47.9%) urban and 235 (52.1%) rural patients.

Vulnerable groups

The vulnerable groups represent a particular segment of the population, whose morbidity is significantly higher than the rest of the population. In 2007, for the first time, we

considered the Roma population under the vulnerable groups category, and we have identified 5 TB cases from this population, 1 case from among the prisoners, and 5 cases from among the emigrants. Under the vulnerable population category we have also included the population living in the mountainous areas, and mainly in the North-East.

Mortality

In 2007, we have had had 7 deaths or 0,5 per 100,000 inhabitants. However, if we compare the data of the civil status offices with our data, we will observe a larger number being recorded by the civil status offices.

Data regarding anti-TB Drugs Resistance

Drug resistance for M. tuberculosis is done with the proportions method of Cannetti & Grosset in Lowenstein-Jensen, according to WHO recommended protocol.

Results of a study show that for the last five years, 9.2% of all strains are mono-resistant. The prevalence of mono-resistance varied from 5.6% per STM (median value) and 2.4% per INH to 1% per RIF.

REVIEW OF THE NATIONAL STRATEGY FOR THE CONTROL OF TUBERCULOSIS AND FORMULATION OF THE STRATEGY FOR 2009-2014 “FOR IMPROVING THE EPIDEMIOLOGICAL SITUATION OF TUBERCULOSIS TO THE EXTENT WHERE IT NO LONGER POSSES A THREAT FOR PUBLIC HEALTH”

The need for the review of the National Strategy for TB control came as a result of the rapid and substantial improvement of the TB epidemiological situation in the course of the last years, due to improved control of tuberculosis thanks to Global Fund financings, and in the light of the health system reform which often fails to take into consideration TB control in the country. Furthermore, a publication of WHO in 2007 of the “Plan for stopping TB in 18 countries of high priority in the region of Europe in 2007-2015”, which considers Albania as a low priority country for stopping TB, and recommends the revision of the strategy makes the formulation of this strategy even more important. The ambitions for formulating such a strategy would be easier achieved if we would have again the support of the Global Fund, where we will apply again this year.

The formulation of this strategic plan is based on the systematic analyses of the current situation of tuberculosis in our country, on a detailed budget and the relevant responsibilities. This strategic plan takes into account the options and challenges as a result of the reform underway in the health sector, the possibilities for the involvement/inclusion of other health institutions and programs, and the possibilities for the involvement of the private sector.

In the formulation of the strategy have been taken into consideration the publications and recommendations of WHO and KNCV for the European countries of low and average

incidence such as: “Plan for stopping TB në 18 high priority countries in the European region for 2007-2015”; the document published by ECDC “ A Draft action plan for the fight against tuberculosis in the European Union” published in 2008; a publication of WHO, IUATLD and KNCV “The European Draft for the Control and Elimination of Tuberculosis in countries with low incidence” and the “Tuberculosis Handbook” published by the WHO in 1998.

The previous strategy is no longer adequate for the control of TB in our country since it does not properly take into consideration the technical potential; it does not have a very aggressive approach towards TB control, in particular for the vulnerable groups, and it does not properly link the NTP with the primary health care.

On the other hand, sustainable reduction of tuberculosis incidence in our country may lead to self-gratification for the health professionals, and the government and it may create the impression that tuberculosis is no longer a problem, and it does not pose a threat for public health. Unfortunately, this opinion is often prevailing among health professionals as well. Experience of other countries, even countries with more solid programs for TB control, such as the United States, has shown that when this disease is neglected, the consequences can be dramatic, difficult to repair and a major economic burden.

Often times, the health professionals themselves support this view point, and this is related to the fact that Albanian health professionals and other health employees have insufficient knowledge regarding tuberculosis.

The tendency for reducing the number of treatment days during the intensive phase in the hospital would have dramatic adverse impacts if measures are not taken to ensure controlled treatment, and with social support during the intensive phase. Furthermore, the change in the mission of the Lung Diseases University Hospital “Shefqet Ndroqi” without a coordination with the NTP, may compromise the control of tuberculosis if proper measures are not taken. Therefore it is urgent that the change in the traditional manner for the treatment of tuberculosis in the hospital with that in the out-patient facilities should be properly planned, and to this end the work should start for guiding the control of tuberculosis towards primary public health. But this can not happen within one night, and it requires its own preparatory phase, which can last from three to five years.

Some of the goals of the new strategy include:

- Strengthening of the political commitment of the Government regarding TB control, in the formulation of the policies and priority of activities;
- Incorporation and adoption of elements of the WHO, KNCV recommendations, in compliance with the epidemiological situation, and the social and economic conditions of our country.
- Support for education programs for the physicians, public health, nurses, and other health professionals in the fight against tuberculosis, in the country’s new stage.

The most important elements for a more aggressive approach towards TB control are:

- Early TB cases detection and their treatment until cured, and prevention of TB avoidable deaths.

- Reduction of infection incidence through management of risk groups, and prevention of transmission of infection in the health institutions.
- Reduction of TB infection prevalence through management of outbreaks in the sources and administration of chemotherapy for particular groups and individuals.

The commitment of the Government for the current stage of TB control

The commitment of the Government should be expressed through provision/securing of the necessary infrastructure for TB control, which consists in financial support, human resources, and other services. The Government should ensure an effective leadership at the national level, and the introduction of the adequate legislation in support of the strategy for improving the TB situation to the degree that this does not pose a threat to public health.

Guidelines for the management of risk groups, outbreak management, prevention of infections in the health institutions, and delivery of preventive therapies should be formulated within this year. Also, there must also be put in place guidelines for personnel protection and professional risks, while their implementation must be monitored.

The TB, even though sustainable declining should be considered as a disease that presents a threat for the public health, if neglected.

The national scheme for TB control during the stage of the consolidation of incidence reduction up to the degree where the TB no longer presents a threat for public health

With the constant decline of TB incidence, the existing “vertical” system for its control is no longer credible. In the majority of the European countries, the existing TB control programs have been replaced since the 70s with an integrating approach in the primary health care service. It is now high time that in Albania we adopt such approaches for TB control. But, on the other hand, it is important that the key activities be planned, coordinated, and monitored and evaluated by the NTP staff, which should be represented by a group of professional experts. With the decline of TB incidence there is also a shrinkage in the expertise for the management and control of tuberculosis, in particular at the dispensary level.

The National Program for TB control should be a stand alone unit, under the Ministry of Health, with staff approved by the latter, and with separate funds.

The NTP should have a dedicated and consolidated budget for the basic activities for TB control and treatment. New phenomena for TB control, which are characteristic for the Central European countries shall also be present in our country. Thus, some of the characteristics for our country could be: less information/knowledge on the side of the GPs and other specialized physicians about the tuberculosis disease; TB concentration in vulnerable groups, which will be very difficult to have access to such as: the homeless, Roma population, the alcoholics, drug users.

Therefore, the delineation of a responsible group for TB control, with properly defined activities in the NTP is indispensable. The renewal of a national scheme for the new stage should include a National Coordinator and a group of experts to guide/lead and support

the medical personnel and other organizations, directly or indirectly involved in TB control.

National Policies for TB Control

The re-activation and re-launch of the National Committee for TB Control is indispensable for ensuring an ongoing consensus, and for the coordination of TB policies among different stakeholders. This Committee should be operational on permanent bases, and must convene at least once in 6 months. The Committee must have representatives from different organizations that have a stake in the vulnerable groups and individuals who possess the necessary professional and policy expertise. Whereas the NTPs require individuals with professional expertise. The Committee must ensure a balance among the technical, policy and administrative needs.

The legislation framework

There is need for review and amendment of important parts of the legislation such as: mandatory/compulsory denouncement of TB cases by the physicians and the laboratories; mandatory treatment under supervision for cases of pulmonary tuberculosis, mandatory control of contacts, free of charge service and treatment for all patient categories; coverage of expenses from health insurance; issuance of invalidity for at least one year for the TB patients, irrelevant from their age; restricting trading of Rifampicine in the pharmaceutical market.

Furthermore, another element to be addressed is what should be done with those cases when patients either interrupt their treatment, or refuse to submit to the treatment, in particular for those patients who pose a threat for public health.

Development of Human Resources

Adequate education of medical staff and others directly involved in TB control, but also of those indirectly impacted by it such as: education of inmates, vulnerable groups etc. should take place in cooperation with other governmental and non-governmental organizations. To this end, the National Program should appoint a contact person in charge of planning, coordination and monitoring the training activities. The purpose of the training programs in addition to providing basic knowledge regarding TB and DOTS is to inform the process of decision-making, communication, community management and to ensure continuous training regarding TB.

Also, the curricula in the Faculties of Medicine and Nursery should include sufficient information regarding TB and the national policies for its control.

Tuberculosis control as an essential element of primary health care

Tuberculosis control from public health view means the establishment of regional units for TB control, which should have a good cooperation with the clinical sector. This orientation is valid for countries bigger in size than Albania. This would also be valid for Albania as well, but the cost for the moment would be unaffordable. However, this

structure may become operational in a couple of years by the Global Fund, and later by the Government of Albania. These services should entail:

- Regional surveillance;
- Support of TB patients during out-patient treatment;
- Risk groups management;
- Management of contact groups and source outbreaks;
- Ensuring of TB expertise at a time when knowledge about the disease and the number of patients in the clinics is declining.

TB control and primary health care are inter-dependent. In the new stage where the country is, TB control is not possible without its integration in the primary health care service. Effective TB control does not solely depend on access to diagnosis and treatment services, but also on the active participation of the community, which can not take place without the help of primary health service.

The whole range of tuberculosis services, either diagnosis, or treatment, should be provided free of charge by the health insurance.

The General Practitioners should be part of TB control both during diagnosis, as well as during treatment and profilacy.

There is need for a change in the traditional methods of TB treatment in the hospitals, to move instead in the out-patient clinics, launching the control of TB by the public health. With regard to the above mentioned, training of medical personnel and nurses in the out-patient service for the TB disease and DOTS is very important, as is the introduction of the necessary legislation and the establishment of the appropriate infrastructure. This period may last from two to three years, and initially out-patient treatment will be delivered only for those patients who DOT is provided every day by medical staff.. Otherwise, the treatment should continue to be administered in the relevant health institutions.

The General Practitioners, with properly defined Terms of Reference shall be responsible for treatment during the continuation phase, and will also assist in the control of the source and in the administration of the chemoprofilacy.

The National Objectives of the Strategy for 2009-2013

Objectives for the impact on the population:

- To reduce TB transmission and incidence to the extent where tuberculoses is no longer a threat for public health;
- To prevent the occurrence of anti-TB multi drug resistance.
- To reduce human sufferance caused by TB, in particular among the vulnerable groups of the population.

Key specific objectives:

- Strengthening of the health system to control TB. Integration of TB control in the primary health service within five years;

- Ensuring and maintaining 100% DOTS coverage at the national level within 2009;
- Ensuring and maintaining access to DOTS for the vulnerable groups;
- Proper management of cases with bacterial resistance, and control of MDR spread.

Expected outcome until end of 2013:

- Incidence of new cases: less 10 cases per 100,000 inhabitants by the end of 2013;
- Maintaining the high success rates of treatment for TB cases with positive sputum (over 90%);
- Reducing and maintaining mortality under 0.5%;
- Ensuring detection of over 75% of new TB cases.

In our view, these objectives are entirely doable, in compliance with the recommendations of WHO, IUATDL, KNCV and they even go beyond the thresholds/targets of the Millennium Goals in the “Global Fight against Tuberculosis.”

In order to expand the DOTS implementation at the national level, so that by 2009 we can ensure 100% coverage, the DOTS strategy should be modified, and adopted in line with the WHO recommendations.

The expansion of the strategy shall entail strengthening of five essential elements of DOTS strategy. It also includes issues related to HIV and treatment of MDR cases.

5 expanded elements of the DOTS strategy to be implemented by Albania are the following:

1. Continuous political commitment of the Government for strengthening human and financial resources, and for making TB control a nationwide activity integrated in primary public health care.
2. ensuring qualitative diagnosis of the sputum through direct microscopy for the detection of cases among patients complaining of respiratory problems or patients who during examination were found to have signs of tuberculosis. Special attention should be paid to detection of HIV infected cases as well as other high risk groups.
3. short-term standardized treatment for all TB cases, with a clear case management policy, and under direct orientation treatment (DOT) –case management shall also entail the presence of support medical and social units.
4. uninterrupted supply with qualitative drugs with a credible drug procurement and distribution system.
5. a recording and reporting system, which enables evaluation of treatment outcomes for each and every patient, as well as overall program performance evaluation.

The budget

Basic activities such as: salaries of physicians, nurses and other health personnel costs directly related to TB control will continue to be covered from the state budget. Also, the purchase of anti TB drugs will be covered by the state.

The rest of activities, which are described below, we hope to be covered by the Global Fund, since we will apply again for the 9th round.

Budget division according to main items shall be according to the following table:

Nr	Budget break down	In Euro
1	Budget for drugs	30,000
2	Budget for PPD	15,000
3	Buxheti për monitorim diete	15,000
4	Periodical meetings with the physicians of the dispensaries	6,000
5	Budget for training of the Primary Health Service staff	100,000
6	Budget for cooperation activities for TB+HIV	3,000
7	Budget for training of NTP personnel	15,000
8	Budget for publication of an Annual Bulletin	1,500
9	Budget for TB World Day	10,000
10	Budget for MDR-TB management	20,000
11	Budget for the laboratory	100,000
12	Budget for active screening	20,000
	Grand Total	335,500

In order to strengthen active screening of high risk groups it is necessary to purchase a digitalized X-ray equipment, and a mobile vehicle which could be worth 250,000 Euro. This can be made possible only with the support of the Global Fund.

Main activities:

The activities are inter-related, despite different financing sources. The five year program will have two financing sources: the “Global Fund” will cover approximately 56% of the needs of the total budget for strengthening TB control during the next five years, whereas the rest of the budget will be covered by the Government of Albania.

Main activities that will be covered by the Global Fund shall include:

- Integration of TB services in the general health service;
- Improvement of TB infrastructure;
- Training and establishment of capacities, enhancing health awareness and information; enhancing communication with the broad population, and the vulnerable groups;
- The implementation of all activities with the view to increasing access of the poor population and of the vulnerable groups towards all types of TB services, in order to make an assessment of the number of cases in the community, in order to increase case detection and treatment compliance.
- Evaluation and monitoring of the quality of work in the labs, and introduction of a quality control system;
- Improvement of drug management system;

- Improvement of the standard recording and reporting system;
- Introduction of a permanent system for monitoring and evaluation of all implemented activities;
- Conduct of studies.

REVIEW OF TECHNICAL POLICIES

The review of the technical policies should be based on a close cooperation and coordination of the NTP with the Ministry of Health, Institute of Public Health, pulmonologists and the primary health care physicians. Ongoing training of the health personnel, and ongoing evaluation of the application of the NTP and adjustments in order to achieve maximum effectiveness should be considered as permanent activities.

Tuberculosis disease monitoring may be conducted through:

- Study of the tuberculin index;
- Early case detection (case finding)
- Treatment of patients up to full recovery;
- Treatment of risk groups;

Case detection

Definition of the criteria for the identification of suspicious TB cases

Special importance should be paid to early detection, and application of treatment of cases with pulmonary tuberculosis, either with cases positive sputum culture, or those with direct negative sputum. All procedures for the diagnosis and treatment should be free of charge. The staff should be both qualified, and motivated.

Case detection shall include all activities related to the identification case referral. Case detection, in the current epidemiological situation shall be mainly passive, which means that it shall involve only detection of cases that have complaints. This includes also the cases that will be presented complaining of coughing that has lasted for over three weeks, weight loss, fever, sweating during the night, chest pain, hemoptizi etc. The health professionals should be familiar with, and competent in the evaluation/assessment of the symptoms, and should refer on time the patients with these types of complains for an examination/check-up at the dispensaries.

Active detection of TB cases should take place in increased/added risk population group samples.

Diagnosis and classification

The diagnosis algorithm should be based on the anamneses and the physical examination, three examinations of the sputum for BK direct and culture, and the X-ray of the thorax.

If the patient is BK positive, then the testing of the tuberculin reaction is not necessary.

The TB diagnosis is based on direct bacilloscopy and whenever possible also on the confirmation with the culture for BK.

Bacteriological diagnosis

The bacteriological diagnosis in the pulmonary cases with positive sputum may be performed through the conventional diagnosis method of viewing the sputum directly with the microscope. However, other methods as well can be used.

Case Definition

The tuberculosis diagnosis is the recognition of active cases i.e. patients with symptomatic diseases due to lesions caused by M. Tuberculosis. The TB diagnosis should be followed by the specification of the TB type (i.e. case definition.)

Case definition is necessary for:

- accurate registration of the patient, and for reporting purposes;
- establishment of the trend of the structure of case type;
- administration of treatment according to the standard categories;
- analysis of the patients groups.

Case definition is based on four parameters:

- anatomic localization of the disease;
- seriousness of the disease;
- bacteriological outcome;
- anamnesis of previous treatment.

Age and HIV infection may also be required for a more comprehensive case definition.

Treatment

The purpose of the anti TB therapy (*for the patient*) is achieving as rapidly as possible full sterilization of the lesions in order:

- To cure all infection carriers and non-carriers;
- To prevent recidives and selection of resistant bacillus in carrier patients.

The purpose of the therapy (*in terms of collective health*) is:

- reducing infection sources;
- transforming the patient in non-carrier mode in the briefest time possible;

- preventing other individuals from becoming carriers

The treatment is considered effective if it leads to “rapid” **negativization of the mycobacterium tuberculosis in the sputum and there are no recidives**. Treatment regime are based on the DOTS strategy of the WHO and IUATLD, and we have adopted them into two categories to tailor them to the circumstances of the country. These categories are:

- 2 HRZE/4 HR for all new cases (irrelevant from the form of the tuberculosis). In the forms of serious tuberculosis, such as disseminated tuberculosis, treatment is recommended to last up to 12 months.
- 2 HRZES/1 HRZE/5 HRE for all cases of renew-treatment.
- Also, there are other regimen of the second series of drugs for the resistance cases in the University Hospital of Lung Diseases, which for the moment are not, and have not been available. MDR treatment is envisaged to start in 2009, if the necessary physical infrastructure is established.
- The basic element in the “short term treatment” is the fact that the drugs have bactericide and sterilization, and prevent resistance, if *administered under direct supervision*. That is why the intensive phase of treatment should take place under direct supervision of the medical personnel, both for the hospitalized patients, as well as for specific cases, which in this stage receive out-patient treatment.

MONITORING OF THE TREATMENT

Direct supervision in the treatment of the patients with tuberculosis is essential to ensure an effective control program. In order to ensure good compliance, in particular among patients from remote mountainous areas, treatment during the continuity phase should be possible in the closest/nearest health center.

In order to make sure that over 92% of the overall number of cases under treatment complete the necessary cycle of the treatment within the assigned time it is necessary to introduce a tracking/monitoring system for those patients that stop/interrupt the treatment. Primary health care personnel should be involved in order to ensure cooperation for following the treatment, as well as for case detection.

The effect of the treatment for Bk direct positive cases should be monitored via direct bacilloscopy every month during treatment, whereas the culture upon termination of the intensive phase (in the second month for Category I, and in the third month for Category II), 5 and 8th of treatment. *Monitoring of sputum examinations in the 5th month is important to identify the failures, and by the end of the treatment for the evaluation of the treatment outcomes (in order to determine the frequency of recovery.)*

X-ray examination monitoring takes place every 2 months.

MONITORING OF DRUG ADMINISTRATION

During the intensive phase of the treatment, the patient gets hospitalized. Hospitalization is mandatory for all pulmonary forms with positive sputum until their conversion into negative sputum. Hospital treatment may be performed in all those hospitals that respect infection control measures, and administer treatment under supervision.

In the cases of patients with forms of pulmonary tuberculosis with negative sputum or culture, who have good economic and social conditions, and when we are sure that the patient receives out-patient treatment every day under strict medical control, then this treatment can also be administered in out-patient clinics. In both cases, the health personnel are in charge for giving the patient the drugs every day, and the patient should take them in the presence of the health professional.

For the patients who live in the city, treatment should be controlled every day from the dispensary, whereas in the rural areas, treatment should be controlled by the health personnel of the health care center and of the dispensary.

During the continuity phase of the treatment, almost all patients stay at home, and take the drugs from the nearest health care unit. In the continuity phase, treatment should be controlled by the General Practitioner or the nurse, in cooperation with the staff of the dispensary.

The health personnel follow proper administration of drugs for the patients in the continuity phase.

The staff of the dispensaries in the cities, and that of the nearest health care centers in the villages will be responsible for following the treatment in the continuity phase. The health personnel should immediately track those patients who do not show up for treatment, and make them resume treatment. The health personnel should also be responsible for the continuous health awareness related to the risk of interrupting the treatment and that failure to take the proper dosage of drugs reduces recovery chances.

PREVENTIVE CHEMOTHERAPY

Preventive treatment should be applied with cautiousness. The effectiveness of preventive treatment increases substantially, if it is delivered in high risk groups for developing TB

- Persons with fibrotic lesions, for e.g.: (i) migrants from areas with high TB prevalence, and who have not been treated properly;
- Persons with fresh TB infection such as: contacts with active cases;
- Persons with hyperalergy, but without signs of former or recurrent tuberculosis;
- Persons with HIV infection.

It is recommended that the preventive treatment scheme should be 6 up to 12 months with isoniazid (6H gjer 12H), 5 mg/kg for adults, and 8-10 mg/kg for children. Before starting with preventive treatment, it is important to carefully exclude active tuberculosis

cases. Alternatively, the National Committee for Tuberculosis may make recommendations for the scheme of preventive treatment 4HR.

Recommendations for the Organization of the National Reference Laboratory, and the Laboratory Service

Every procedure related to the tuberculosis (microscopy, bacterial culture, identification, sensitivity testing (DST), molecular diagnosis) should be performed by properly trained staff, who work with standard operating procedures (SOP) in laboratories which are adequately equipped, and in high levels of security/safety vis-à-vis national and international quality standards.

Quality rather than cost should be of prime importance.

❖ Accreditation

The NLR should follow an internal quality control program, and should participate in important schemes of proficiency testing. The NLR should not perform procedures, which have failed to demonstrate the appropriate level of performance through quality control schemes.

❖ Biosafety and infrastructure

The staff of the lab should work in a safe environment. The staff who works with the patient samples and live mycobacterium cultures should work in the appropriate biosafety conditions, with the appropriate measures of infection control, including periodical health control.

❖ Laboratory procedures

It is recommended that the microscopy and culture for the diagnosis of new cases should be performed before commencing the treatment through a limited number of high quality samples.

1. Microscopy

Direct microscopy should be performed within one working day from the moment that the sample is brought in the laboratory. The AFB presence in a single sputum sample may be considered as the most plausible diagnosis, but there is always need for the final identification as TB.

Other extra pulmonary samples such as the LCS should be examined within one working day.

2. Bacterial culture

For patients who are clinical suspects for TB, the samples for microscopy and culture examination should be taken before starting the treatment. In practice, it is not recommended taking of more than three samples of sputum for the diagnosis of pulmonary TB, and as a rule two samples of high quality are sufficient.

3. Identification

Positive cultures should be identified as *M. tuberculosis* within 1-2 days. The purpose is to cultivate and identify the *M. tuberculosis* from the sputum within 21 days from receipt of the sample, in at least 90% of the cases.

In practice, this means utilization of liquid terrain/ground, and/or utilization of new methods of molecular diagnosis.

4. Sensitivity testing (DST)

The DST is recommended for all new TB cases; when the patient continues to be culture positive even after 2-3 months, and if he has an anti-TB treatment history (a major risk factor for resistance to occur). Individual circumstances may dictate additional testing.

5. Quality assurance

Quality assurance in the bacteriology of tuberculosis is a system designed to ensure continuous improvement of credibility, efficiency, and utilization of laboratory services related to tuberculosis. The purpose of the quality assurance program is to improve the efficiency and credibility of laboratory services. This program has three components, which are the following:

- Quality control;
- Quality improvement;
- Proficiency testing;

7. Laboratory certification

Laboratory certification is necessary for ensuring:

1. appropriate engineering control for the proper functioning of the equipments;
2. specific administrative control;
3. appropriate protective measures for the types of manipulations performed;
4. proper decontamination of waste and materials;
5. appropriate procedures for general lab safety, including physical, electrical, and chemical safety.

PLANNING OF SUPPLIES AND LOGISTICS

Anti TB drugs and other supplies should be procured on time and in the appropriate quantities.

Difficulties encountered regarding procurement, storage/preservation, and distribution in the districts should be eliminated.

Logistics at the central level

Logistics at the central level should comprise: anti TB drugs, lab materials and reagents, PPD and the records and forms for the registration and reporting.

Drugs Supply

In order to ensure qualitative anti- TB drugs, and with low prices, Albania, through its Ministry of Health has entered into an agreement with the Global Drug Facility, since 2003.

Some of the problems that need to be addressed in the area of drugs and logistics are:

- The NTPs should have a person in charge for the management of drugs and other logistics.
- Drugs and other supplies should be deposited in specific places, which are appropriate for their conservation/storage.
- The NTP should be responsible for the preservation of drugs and other materials, and other related issues.
- Anti TB drugs should continue to be purchased with combined doses and blister, but in addition there is need also for a small quantity of special doses and injectable forms for specific patients.
- Drug planning and purchase should take place 9 months prior to the arrival of the supplies, as well as planning of other supplies, with a stock for at least 6 months.
- There is always need to have a stock of drugs for one year.
- Drug inventory at the center and in the dispensaries should be known at any time, and should be checked continuously.
- Distribution of anti TB drugs, and laboratory consumption materials from the center in the peripheries should take place twice annually, considering the stock situation and its utilization.
- Drug distribution should be handled by the center, according to the relevant documentation.
- Drugs are given to patients free of charge, but with the relevant documentation.
- At the dispensary level, the stock should be checked regularly during supervision visits, also in terms of storage and distribution of anti TB drugs.

Ensuring regular drug supply in the dispensaries

- Dispensaries should have the necessary drug supply stock for at least 3-6 months.
- They should store the drugs in appropriate places, and according to the relevant rules.
- Drugs should be stored and distributed by the head nurse of the dispensary, who is responsible for keeping the necessary documentation for their storage and distribution.
- The supply of the dispensaries is done based on a written request, according to the relevant documentation signed by the head nurse, and the doctor of the dispensary.
- Administration of drugs for the patients during the intensive phase, in case they are receiving out-patient treatment, should be done daily, and taking of drugs should be supervised by the staff of the dispensary. For the ongoing phase, drugs may be administered once a week.
- If the dispensary is in no position to ensure drug administration daily for the intensive phase, the patient should be hospitalized.
- In the ongoing phase, if the dispensary can not control the treatment, drugs may be deposited in the nearest health care center, and the personnel of the health care center should be responsible for the control of the treatment.
- The 2006 WHO regulation for drugs storage should be respected in every place, and whatever level of storage of anti TB drugs.

The Logistics for lab supplies

- It should ensure the appropriate number of plastic and transportable containers for storing the sputum.
- It should ensure regular supply and in the appropriate quantities with slides, reagents, and other supplies for performin of direct sputum and culture.
- The assessment of the number of containers for holding the sputum and other materials will be done based on the expected prevalence of TB patients, or based on the number of cases of the proceeding year.

Logistics for the registration and reporting forms

- Given that the strategy and reporting is being changed frequently, the information system also should be reviewed periodically;
- The registers and forms should be provided by the NTP.
- Their distribution shall take place based on the number of patients of the previous year.

TRAINING, COMMUNICATION and ADVOCACY

The reform of the health sector in many countries, like in our country as well, presents opportunities, as well risks related to activities of TB control and the performance of medical staff. With increased experience in the implementation of training programs for TB control there is increased awareness for strengthening the quality of trainings, the need for better management of training programs, and the need for the continuity of training. The training strategy should describe planning and implementation of training as part of the interventions in the health system, interventions which should be endorsed and where “the geographical limit” is the entire country, whereas the “time limit” is “all the time”. The long-term goal related to the development of human resources for TB control is achieving and maintaining a situation where “the medical staff of all levels should possess the skills, knowledge, and conduct necessary for the implementation and successful pursuit of the activities for TB control, including implementation of strategies and other new and processed means, as well as activities related to HIV management.” Without achieving and maintaining this objective it will not be possible to achieve national objectives for TB control. Thus, the quality of training is particularly important for the successful implementation of the strategy of the fight against TB.

The purpose of training, communication, and advocacy is to convey knowledge and to foster improvement of tuberculosis control. In more specific terms:

- **The scope of Training** are the health professionals that handle tuberculosis issues and those that handle case management at all levels, both for public and private health;
- **The scope of Communication** are health service users, such as: the community in general, and in particular TB patients and their families;
- The purpose of **advocacy** is to influence utilization of health resources and practices in the community, such as: to influence politicians, senior officials who handle health policy making, professional associations, the mass media, heads of institutions, community leaders, and the broad public.

Training

Training and re-training for the staff who deal and will deal with tuberculosis control becomes even more important in the conditions of the review of the national strategy, and of the policy changes of case control and management. Training activities will continue with the support of the Global Fund, Directorate of Public Health, and the WHO.

Planning training courses on time, training before the start of the new strategy, and keeping training as a permanent activity are all important elements for the successful implementation of the strategy. This will go through two stages:

- The establishment of a national center for training of the staff, and appointment of a contact person in the NTP, who will be responsible for the preparation and planning of trainings, compilation and adoption of training documents, coordination with programs or other institutions, and assessment of other training activities;
- Expanding training for the revised strategy in all the regions.

Training Strategy at the National Level

- Establishment and review of the organizational structure for the human resources management of the NTP at the national level;
- Formulation of short-term and middle-term plans for the development of human resources for control of TB at different levels of the health system;
- Development of post-training surveillance systems, and ensuring linkages for the overall monitoring of the tuberculosis program;
- Management of human resources involved in the control of TB and exploitation of information related to this process;
- Formulation of short-term and medium-term plans for strengthening skills for conveying basic knowledge regarding tuberculosis control, in line with the relevant categories participating in the training sessions, i.e.: physicians, nurses and other health professionals involved in tuberculosis control;
- Implementation and monitoring of the human resources development plan;
- Evaluation and review of the implementation of the human resources development plan based on the data obtained during the process of Monitoring and Evaluation;
- Continuity of the implementation of human resources development plan, i.e. the continuity of the Program.

Materials and Methods to be used during the training sessions

For the trainings at the district level:

- Information regarding the revised national strategy, its objectives and goals, and the reasons for supporting it;
- How to use the registration and reporting method, definitions, filling in of the reporting forms;
- Acquiring TB knowledge and skills;
- identification of TB cases;

- methodology for taking the sputum, and for transporting it;
- description of tuberculosis treatment, and side effects of anti TB medication;
- description of DOT methodology;
- ensuring health awareness for the patients and their relatives
- data recording and reporting
- examination of contacts and identification of new cases

Training of Nurses and Paramedics

- Knowledge and skills regarding the following:
 - o identification of TB cases;
 - o referral of TB cases;
 - o DOT implementation;
 - o Health awareness for the patients and their relatives;
 - o Assistance in the examination of contacts.

Assessment of training costs is provided in detail in the plan approved by the Global Fund under the category of “për diem”, travel expenses of participants, of the trainers, cost of different materials, transportation of the training unit, overhead projectors etc.

Each activity will be monitored for:

- Participation of different categories;
- Health units and laboratories
- Comparison of performed activities with the planned deadlines for training
- training quality through questionnaires at the end of each training

Communication

The main goal of communication in the fight against TB is conveying the right messages to encourage people to actively participate in improving their health attitude.

The communication methods shall be:

1. personal: individual with individual; physicians; paramedics, patients, patient’s relatives;
2. through printed documents, posters, leaflets etc;
3. through the Mass Media, such as radio and TV

Personal communication shall mainly involve the health professionals, the patients and their relatives. The main goal is increasing patients compliance in completing the treatment, and source screening.

KAP survey carried out last year were interviewed a considerable number of people and TB patients and the conclusions are taken in consideration in the formulation of national strategy.

Public communication through posters, printed materials and the Mass Media has a broader “target”, and its objectives include:

- Promotion of human rights and gender equity;
- TB is a totally curable disease;
- Fighting the stigma that the TB is an inherited disease;
- TB is a disease that depends a lot from the social and economic factors;
- Its detection is “passive” – individuals should go to seek medical assistance the soonest possible;
- Improving awareness in the hospitals

Organized communication is of special importance since it helps in enhanced/increased case detection through passive screening.

Communication shall be the responsibility of staff trained for this purpose, and which shall include professionals, representatives of the Mass Media, public health, NGOs etc.

Personal Communication

Personal communication is the most important element of NTP communication activities. Personal communication is very important since it is concrete, it helps establish personal relations between the health or non-health professionals and the patients.

The objective of the training courses should be to supply training of medical personnel with sufficient knowledge in terms of communication and consultation techniques.

Personal communication has the following components:

- the first contact with the patient to provide data about recognition of the causes of the disease, stigma, explanation of what is the TB, anamnesis, treatment, the need for DOT, tuberculosis communication routes etc;
- further meetings with the TB patient, where we should focus more on the treatment and examination of the sputum for monitoring the treatment
- meetings with groups of patients.

Utilization of the Mass Media and printed materials

Same like with any other infectious disease, the TB is of interest for the whole community, and it is not the problem of one individual. That is why the success of TB control depends largely also on the level of awareness of the population regarding this disease, and on the participation of the community in the implementation of the recommended measures.

Whereas printed materials that will be made available to the health personnel should help improve and update knowledge regarding TB and its treatment, as well as regarding the changes in the national program.

The preparation of the materials will take into consideration the conclusions of the KAP of the last year.

Advocacy (efforts made to influence state and private entities, whose policies in turn influence the health of the community)

The advocacy is related to the initiatives, which focus on the TB disease, and on the creation of an atmosphere whereby TB is not underestimated, but is rather considered as a public threat, if proper measures to address it are not taken. The purpose of the advocacy is to point out that if Albania properly implements the new strategy, after several years the TB will no longer pose a threat for public health.

For this reason, the “target” of the advocacy are those individuals that influence the formulation of health and social policies. It must be pointed out that TB is not just an infectious disease, but it is first of all a social disease, which is why taking complex measures is essential for putting it under control.

The planning of an advocacy campaign includes four phases:

- An analysis of the situation;
- Choosing the right strategy;
- Formulating and presenting effective messages;
- Mobilization of financial resources.

From the analyses of the situation, we want to point out that the main obstacles for the implementation of the new strategy remain in:

- Implementation of the DOT by the dispensaries, and the need for involving primary health care; review of the Job Descriptions of the staff in the dispensaries, and of the General Practitioners.
- In the current new phase, it is necessary to ensure increased performance of diagnosis through bacteriological culture, which should be accompanied with the necessary funding. Strengthening of the existing network of direct examination, by strengthening first of all transportation of all samples for direct examination and culture
- Qualitative training of General Practitioners, nurses and non-medical staff by qualified people, and in sufficient time
- Taking measures for prevention of infection transmission in the health institutions; putting this in a law.
- Management of vulnerable groups through active screening and provision of social support.

Media will be the main instrument of the advocacy, and in particular we will make use of the TB World Day, there will be printed materials, leaflets, posters, publication of articles regarding TB in the press, and conferences, involvement of other organizations, such as NGOs etc. in awareness raising campaigns.

PLANNING OF SUPERVISION, TRACKING AND EVALUATION

Theoretically, planning, tracking and evaluation are distinct activities from each-other, but in practice there is an over-lapping of these activities.

Supervision is a systematic process of increasing efficiency of health personnel through enriching their knowledge, mastering of skills, and increasing their motivation. Therefore, it is one step beyond the training.

Supervision takes place at two levels:

1. supervision of the dispensaries and health centers by the central TB Unit;
2. supervision of health care centers by the district

Supervision will begin and will be further intensified upon completion of the training of the health personnel, in order to:

1. to make sure in practice of the efficiency of the training;
2. to ensure assistance for the issues that might have come up during the practical activities.

Supervision visits will take place according to a plan agreed before hand. Before paying any visit, the supervisor will review the reports of the unit, the exchanges with this unit regarding the reports, the data of the last supervision visit, and the measures taken to address the issues raised.

The health units and the health personnel will be notified well in advance about supervision visits, giving them an opportunity to be better engaged and to ensure a better cooperation with the supervisors.

The frequency of supervision visits will vary according to different districts, and will mainly depend on the number of patients, and treatment results.

Supervision visits in districts with a large number of patients will be take place once in three months, whereas for districts with limited number of patients, supervision visits will take place once in six months. The same applies for the treatment results.

The Activities:

1. routine checking of documentation of patient treatment;
2. supervision of their daily TB related activity;
3. discussing with health professionals (nurses and physicians) about the work done, the issues that have come up, and what has been done to address them;
4. checking the consumption materials, their administration, absence of drugs and the expiry date.
5. discussing with TB patients to check their knowledge regarding TB and the treatment.

The purpose of supervision visits at the regional level is to detect the number of TB cases for which there has been no examination of the sputum; the number of cases with positive sputum; number of cases with negative sputum; the linkages between the laboratories and microscopy; the negativization rates and the outcomes of treatment.

MONITORING

It is the monitoring of the program performance to find out whether the activities have been implemented according to the plan.

Monitoring will take place through direct contacts, as well as through control of periodical reports.

The main objective of monitoring will be:

- identification and addressing of issues as soon as possible.
- Identification of the new staff in need of training.

Monitoring is an ongoing process, which began thanks to funding from the Global Fund.

The target of monitoring will be the key program activities, such as:

1. in terms of diagnosis

- a. Number of patients over 12 years that have gone to the health units, and the number of TB suspect cases;
- b. Number of examinations for BK for suspect cases;
- c. Number and ratio of samples of BK negative and positive presented in the health unit;
- d. Numbers and proportion of each category of cases.
- e. Ratio of new BK positive and negative cases;
- f. Ratio of cases with risk factor; HIV, diabetes, refugees, alcoholics.

2. In terms of treatment

- a. Number and ratio of cases under DOTS
- b. Number of examinations of sputum for control of the treatment;
- c. Rates of conversion in the 2nd and 3d months;
- d. Treatment outcomes;
- e. Number of chronic cases.

3. Training

- a. Number of trained staff;
- b. Training quality (duration, practical training time etc)

4. Logistics

- a. Stock of drugs, supplies related to the treatment, sputum vessels and forms.
- b. Quantity of expired drugs, and which should be destroyed

5. Communication

- a. Number of produced posters and leaflets, publications;
- b. Number of awareness sessions held in the health units with the patients and their families;
- c. Activities carried out for conveying awareness messages regarding the tuberculosis through the media.

6. Monitoring

- a. Number of supervision visits;
- b. Frequency of supervision visits;

- c. If the visits are in compliance with the plan;
- d. If the supervision visits have led to corrective actions for addressing the problems that come up; /

7. Organization of the laboratory

- a. Number of trained technicians, stock of reagents, slides
- b. Status of microscopes maintenance;
- c. Number of supervision visits performed in the laboratories of the districts.

Monitoring methodology

Monitoring will take place every three months, and the identification of the issues will be followed with measures for addressing them.

Monitoring will take place through the information system of the national tuberculosis program, mainly through the records of the dispensaries, laboratories, ratios of supervision visits, ratios of control of quality in the laboratories, documentation of the hospitals and mortality statistics.

Another monitoring methodology will consist of the direct supervision of the job performance.

Interviews with the health personnel will be another means for obtaining information.

The interviews with the patients will also help in understanding the effectiveness of communication and the impact it has on the patient and their families.

At the end of the year, after collection, processing and analysis of the data of TB cases, each dispensary should receive feedback in the shape of an informative report, and a summary annual report.

Evaluation

The evaluation of the program is an indication of the implementation of the planned objectives and goals of the program in a given moment. This requires that the objectives should be properly defined and with epidemiological and operational indicators in place for the measurement of these objectives.

Some of the epidemiological indicators that will be measured are:

- Number of detected cases, age, gender, residence;
- Prevalence of chronic cases;
- Annual infection risk;
- Bacterial resistance prevalence;
- HIV prevalence in the TB cases

Some of the operational indicators that will be measured are:

- Training indicators;
- Drug and other supplies indicators;
- Indicators for supervision of dispensaries and health care centers;
- Indicators for assessing TB knowledge;
- Indicators for DOTS access;
- Indicators for patients diagnosis;

- Patient treatment indicators.

Analyses and Interpretation of Outcomes

Analysis and interpretation of the data should include not only evaluation of achievement of indicators, but also should take into consideration more qualitative information which is obtained during supervision and monitoring visits.

The analysis also entails comparison with previous data, and the data among different dispensaries.

The Budget

The contribution of the NTP in strengthening the health system, and in the coordination of TB control activities

If we will achieve the integration of the tuberculosis program in the overall health system, then we will manage to contribute in strengthening the health system, in particular in the segments of service delivery. This contribution in strengthening the health system is expressed in the infrastructure of the laboratories, establishment of the capacities of the health personnel, improvement of the routine utilization of health data. Furthermore, the contribution in strengthening the health system can be expressed in the development of innovative strategies in answer to the problems and specifics of the system such as: development of the strategies for a practical approach regarding pulmonary diseases; cooperation with the HIV program; cooperation with the pediatrics association; cooperation with the private system; services in the cross-border areas; and community-based services.

The NTP should take into consideration the fact that cooperation and coordination actions with other organizations and the FSSH should strike a balance among three key objectives:

- Assist in improving the capacities of the general health system for ensuring effective service delivery for the control of the tuberculosis;
- Optimization of the positive impact in the general health system regarding specific TB activities through the adequate and harmonized coordination of funds, planning and delivery of the services;
- Protection of key TB control functions.

In terms of human resources development, the cooperation should focus in:

- (a) using a systematic approach based on the Job Descriptions, and
- (b) clearly determining the human needs for a comprehensive TB control;
- (c) developing long term strategic plans, and
- (d) developing a medium term implementation plan that will enable a merger/unification with the strategies and plans for the development of general human resources;

- To cooperate and coordinate the actions with other programs of public health and with other departments and services, in particular with diagnosis and treatment services, and the administrative units in the prefectures and districts in order to ensure cooperation and continuity with the local structures.
- To exchange experience for the engagement of the health professionals in other sectors as well, outside the public system with other organizations and other financial sources;
- Adequate education in the universities and post-university degrees for the staff who will be directly involved (public health professionals, pulmonology experts, nurses, bacteriology experts) and indirectly involved (physicians and nurses who work in residential centers for the elderly, prisons etc.)

Coordination with specific programs:

Despite the fact that HIV prevalence in Albania is not high there is still need for ensuring close linkages with the national HIV Program. These linkages began last year, and should be further consolidated. The main obstacle in the integration of the diagnosis and treatment of TB/HIV is the traditional division/classification of the TB and HIV.

Tuberculosis has a public health approach and with stabilize algorithm and standardizes treatment outcomes, whereas HIV rely on individual with human right and rapid development of treatment. Therefore it is necessary that these activities should be better adjusted with each-other.

To this end, the following activities should be undertaken:

A. Introduction of cooperation mechanisms:

1. establishment of a coordination unit for TB/HIV activities at all levels;
2. surveillance of HIV prevalence among patients with tuberculosis;
3. joint/common planning;
4. monitoring and evaluation;

B. Reducing burden of TB in the PLĚH

1. Intensification of detection of cases with TB;
2. Treatment of latent infection (preventive therapy for TB)
3. control of tuberculosis infection in the health institutions; common planning.

C. Reducing HIV burden in the tuberculosis patients

1. HIV testing and counseling of all TB patients;
2. HIV preventive method;

3. preventive treatment with Cotrimoxazole
4. support and care for HIV/AIDS

Introduction of a cross-referral system among separated TB and HIV services

- HIV clinics
 - Should ensure screening for TB patients(ekz. radiol, PPD)
 - Implement measures for control of tuberculosis infection;
 - TB suspects should be referred to at the dispensaries;

Coordination with Programs for Control of Respiratory Diseases among Children

Coordination with the Pediatrics Department has not been in the appropriate terms. The diagnosis of the tuberculosis among children is difficult, and therefore it is necessary to develop protocols for the pediatricians for the treatment of the latent infection, and for the diagnosis of the treatment of tuberculosis in our country.

Coordination with the Department of the General Practitioners

Treatment of the respiratory diseases should be considered an important part of the work of the General Practitioners. Coordination for the formulation of Guidelines and the algorithms for the diagnosis and treatment of pulmonary diseases of out-patient patients with respiratory signs is indispensable for the differential diagnosis with the tuberculosis patients.

The role of the General Practitioner in the diagnosis and the treatment of tuberculosis will be essential for our country, thus appropriate training and clear definition by law of the duties of the General Practitioner in the control of tuberculosis is very important during this stage.

The coordination mechanisms among organizations

As a rule, the MoH is in charge of introducing the mechanisms for the coordination of activities. Thus, in the Committee for Control of Tuberculosis there are participants from different departments (hospital department, primary health care, HIV program, pediatrics department, and pharmacies etc) to ensure coordination of all activities. Also, participants from the NTP are members of the immunization committee.

In addition to the above mentioned there should also be programs for horizontal coordination, such as: coordination with the HIV program, and it should also include the department of Pediatrics and different NGOs, representatives of the Roma population, prisons etc.

Organization's Internal coordination

The NTP is responsible for encouraging the involvement of the state and private institutions, as well as external agencies in the planning, implementation and funding of TB control activities. Regarding the above mentioned it is necessary to organize regular meetings, depending on the circumstances, at least once in six months.