World Health Organization
REGIONAL OFFICE FOR Europe

GLC/EUROPE MISSION

FOR MONITORING OF THE IMPLEMENTATION

OF THE NATIONAL M/XDR-TB RESPONSE PLAN

In Albania

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1. Executive Summary

For the first time ever in recent decades Albania is without culture facilities for TB due to the lack of regular, budgeted funds from the Ministry of Health now the support from the Global Fund has stopped (2012). Albania has had a long tradition of very proficient TB control but the lack of maintenance of laboratory equipment and of finances for basic consumables during the last year and a half has reduced diagnostic capacity to simple sputum microscopy and to the level of that of some poor African developing countries.

This means that there is at present no way in which resistant TB may be timely detected and addressed. There is also now a lack of funds for proper supervision of TB diagnostic and case holding performance in the districts, leaving alone serious problems of infection control in hospitals dealing with TB.

In spite of recurrent criticism from external WHO monitoring visits and the fact that Albania signed the Berlin Declaration in 2007 there are still no available 2nd line TB drugs for the so far limited number of Multi-drug resistant TB cases (MDR-TB), who will infect others persons as they are left without treatment, and contrary to international standards of care left to themselves to look for cure outside the country. As a third of the Albanian population is thought to work abroad and some 180 000 jobless Albanians are said to have returned from the neighboring countries recently (e.g. Greece) compounding the problem of migration, the threat of TB among Albanians in the future should also be of immediate concern for the EU.

With the current economic crisis, increasing poverty in many parts of the Albanian society, and the low priority granted by the Ministry of Health for the public health problem of TB which means no resources for a maintaining a proper TB control programme the risk is real, that TB incidence may be rising. This is so much more lamentable as Albania in many ways has enjoyed a well-established National TB Programme which since 2002 has been very much improved through the external input from the Global Fund, WHO , EU and USAID and the country has seen a decreasing annual number of TB cases. So far the incidence of MDR-TB has been low compared to other places in the eastern part of Europe.

Since 2006 and with the external support the TB situation in Albania has in many ways been very favourable. Incidence of TB has gradually declined thus from 2010-2012 between 13-14/ 100 000- the lowest level ever.

Treatment outcomes have also been highly satisfactory with a treatment success rate of over 90% (92% in the last available data from 2011), and with very few defaulters and hardly any failure cases. As compared to many Eastern European countries the prevalence among infective TB cases of MDR-TB is very low: less than 1% among TB patients never treated before, and only 5.3% among the small number of re-treatment cases according to the national drugs susceptibility study finalized in 2010.

The National Reference Laboratory (NRL) is in principle well equipped and until recently (2012) with different culture methods being available although no rapid genotypic resistance test is yet being performed. The NRL has a long track record of good and reliable results being itself subject to quality control from Super-national Reference Laboratories in Italy. The low and decreasing incidence of TB on the other hand has made a reduction of the number of peripheral microscopy centres of the laboratory network logical and necessary. Only one laboratory now outside Tirana (Shkodër) can do culture (but

only on solid media), although the current problems of lacking funds has also rendered this laboratory function idle.

In 2010 the NRL performed a Drug Resistance Survey that corroborated the above mentioned low MDR-TB prevalence figures. It is thus very plausible that there have not been many undetected MDR-TB cases over the last 6 years, but only the 13 MDR-TB cases found since 2007. For the mentioned reasons now there is no longer any possibility of monitoring of drug resistance.

On this background of a very limited problem of MDR-TB with the very modest amount of money needed for treatment (perhaps at the most US $ 4-6000 per year) it is incomprehensible why so far nothing has been done to procure the 2nd.line TB drugs that might have cured the few MDR-TB cases encountered. Without treatment these patients will die eventually of their disease, but before that each single MDR-TB case may have infected on average 20 other people. This is not only a moral problem but- from a cost-effectiveness point of view- absolutely meaningless. So far there seems to be no positive development in this state of affairs that is as epidemiologically unacceptable as it is intolerable for the country.

Both in the NRL and in the TB wards in the University Lung Disease Hospital "Shefqet Ndroqi" there are substantial problems of infection control. Infection Control will have to be taken much more seriously to avoid cross infection between TB and non-TB patients in hospitals and dispensaries, and to avoid infection of health care and laboratory staff.

In the long run TB activities will have to be integrated much more in the primary health care sector, which is instrumental for identifying symptomatic patients that must be examined for TB, and also for the follow-up and the directly observed treatment of detected patients. For this reason the National Health Insurance should take upon itself to reimburse family doctors also for uninsured TB patients who need care by a family doctor.

It is for the MOH to make sure that there are budget lines in the recurrent health budget that will support an effective TB programme. Albania has achieved a very good and effective TB programme over the 10 years with external support until 2012. There is every good reason to try and protect and consolidate these achievements for the benefit of the Albanian people.

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2. Acknowledgements

This report has been made possible thanks to the valuable information from and owing to many discussions with to Dr. Hasan Hafizi (National TB manager), Dr Donika Mema, epidemiologist, and Dr. Silva Tafaj, head of the National TB Reference Laboratory, both during this and during previous visits to Albania.

As the present GLC visit has been short (2-3 days) the main focus has been on the sustainability issues after the withdrawal of external support of Global Fund support in 2011.

2. Terms of Reference

Objectives:

- to assess the implementation of the TB program, evaluate current achievements and sustainability of the program; and develop recommendations for future activities;
- to assess the National M/XDR-TB Response Plan and ensure that it complies with the European M/XDR-TB Response Plan;
- to assess the progress of the implementation of the National M/XDR-TB Response Plan

Expected outcome of the mission

- Analysis of the national plans for TB control and MDR-TB Response plans
- Impression of the role/integration of TB within the health system
- Analysis of financing of vital TB and MDR-TB activities and the situation after the discontinuation of GF support.

3. Background information

2.1.1 Country and TB summary

Albania is a south-eastern European country with a surface area of 28 000 km^2 and a geography dominated by mountains and many places with poor accessibility. The population is assumed to be around 3.1 million at present, with a growing average age in spite of an overall high positive growth rate and an unusually great proportion of citizens < 15 years of age. This is- among other conditions - due to a substantial emigration of young people to other countries. During the last 15 years there has been an important emigration also from the rural to the urban areas and thus a shift in TB epidemiology. There is a growing problem of homeless people and people living in economically very strained conditions in the

major cities in the south of the country.

The country has one of the lowest gross national incomes among the European countries, GDP of PPP int. $ 7 449 according to UNDP (2012), with the northern part of the country especially hit by poverty in rural areas. As a comparison the GPD of Bulgaria in the same region is PPP int $ 11 456, and that of Denmark is PPP int.$ 32 252. With regard to the Human Development Index Albania is number 70 of some 180 countries and at a level (0.739) which is the same as Europe on average.

2.1.2 Tuberculosis and the NTP.

The central unit of the NTP was established in 2000, and in principle the DOTS strategy has been adopted since then. A temporary financial input by ECHO-WHO and also some help from the SRL in Rome to the National Reference Laboratory was instrumental in refurbishing laboratories and district TB dispensaries, and the DOTS strategy was initially started in two populated areas of the country.

The MOH finances all expenses of the programme including staff salaries, cost of hospitalisation and OPD care of TB patients. However, at the main TB reference unit at the Shefqet Ndrogi Hospital in Tirana, where most of infectious TB patients are hospitalized for 3-4 weeks, the budget for TB activities are carved out of the hospital grants. This is also true of the money needed for procuring all 1st. line TB drugs for the entire country.

Only through the GF Round 5 Grant, effective from 2007, the DOTS strategy including training of a large number of health care staff and family doctors could be expanded to the rest of Albania. During the grant, the GF has financed roughly 50% of all TB program expenses. The grant money has now finished by March 2012

TB drugs were for a while purchased through the Global Drug Facility of the WHO, but is now procured by the MOH by open tender. The TB drugs together with other hospital drugs are financed over the budget for the University Lung Disease Hospital. This introduces an unhappy competition with the hospital for funds for drugs threatening the regular provision of TB drugs, as there is no special MOH budget line for TB drugs, nor for the NTP as such. So far, luckily, there has not been any shortage of TB drugs, but the present bufferstock will only cover 3-5 month, and until this point in time of 2013 the procurement procedure has apparently been unsuccessful. The principle of having “open tendering procedures” so far has meant that the GDF has not been an option and that prices for drugs, according to Dr Hasan Hafizi has been 2 times the cost through GDF.

The **NTP** is under the Department of Public Health of the ministry of Health. The Deputy Minister of Health is chairing the advisory body, The National Committee for TB Control established in 1995 with representatives of the ministry, the National institute of Public Health, the University Lung Diseases Hospital (UHLD) in Tirana, the Tirana Tuberculosis Dispensary and the Pulmonary hospitals of Shkodër nd Korca.

However, the key institution for practical organisation of TB control is the Shefqet Ndrogi Hospital in Tirana, where also the” programme manager” over the last many years, Dr Hasan Hafizi, an unit of epidemiology, and the National TB Reference Laboratory are housed.

The Shefqet Ndroqi Hospital is also the central training institution for teaching medical students and pulmonary specialists and the majority (30) of the some 50 TB beds (down from 100 beds 3 years ago) of the country so far have been located here.

The Shefqet Ndrogi Hospital is being changed into a multidisciplinary hospital, which has meant a reduction of the number of TB beds. This is also true in Shkodër where the number of beds has already been reduced from 20 to 5 TB beds. All sputum smear positive patients and other types of severely ill TB patients are hospitalized for 1-2 weeks, and not any longer until their sputum samples become negative. Thus, the national bed capacity of some 50 TB beds seems to be adequate.

2.2 HIV situation

HIV in Albania is still not a big issue. In the 18 years from 1992 to 2011 only 485 HIV cases have been reported, In 2010 44 new HIV infections, 24 AIDS cases, and 6 deaths among AIDS cases were reported, in 2011 72 giving a rate of newly diagnosed HIV infections of 2.3 per 100 000 population in 2011. Only 145 HIV infected persons were on ART in 2010. The great majority of infected persons are MSM. Admittedly, few persons are HIV tested. Thus in 2010 only some 2900 persons out of a population of 3 million. Among TB patients the ratio of tested persons is considerably higher: in 2010 a total of 186 TB patients were tested amounting to 42% of all TB patients diagnosed. In 2011 170 TB patients were tested but only 2 found HIV positive, the figures for 2012 being 233 (60%) and 6 (1.5%) positive, respectively.

2.3 Global Fund support

Albania applied successfully in 2006 for a major Global Fund grant (ALB-506-G02-T) of a **total** of **US $ 1 263 490**.This input has been instrumental for reviving and strengthening the NTP and its activities, and the money well spent by the local GFATM office under the Ministry of Health and NTP management.

The main objectives of the Round 5 application were to strengthen health care for TB control by training primary health care staff (family doctors and nurses above all in remote areas), to ensure DOTS expansion, to achieving 70% detection rate of infectious cases and 95% (!) cure rate while simultaneously improving also recording and reporting countrywide. The plan also included the improvement of the infra-structure and equipment of the peripheral TB dispensaries and dedicated central unit was to be established with a view of improving drug procurement and distribution. DOTS should especially be assured for vulnerable groups such as Roma people and the areas of north-east Albania with least accessibility and the highest TB incidence. HIV-TB programme co-operation should be enhanced and TB control in prisons improved. The laboratory network should be reinforced, and above all, the national reference laboratory would be equipped adequately for performing culture and DST of a great part of SS+ samples. As a special point drug resistant TB should be addressed. A DSR was planned and was finally in 2010.

A MDR-TB focal point was to be established in the Central Unit in Tirana and an application made to the Green Light Committee for approval of purchase of 2nd. line TB drugs for MDR-cases. Specifically it was stipulated in the application to the GF that a MDR-TB patients would be treated in a special department of the Sefqet Ndogi Hospital providing adequate infection control measures.

The Round 5 grant has now ended in March 2012, and has been successful in as much as the rating by the GF was **A1**.

A further application for TB during Round 9 was not possible due to Albania's ineligibility.

However, with the end of the GF support, a number of activities have suffered. There has been a lack of money for laboratory reagents, and there is no more money available for the NTP supervision of the districts nor of the 16 microscopy centres.
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2.4 Current status of the National M/XDR TB Response Plan:

The brief version is, that there is no such thing as a M/XDR response plan in Albania.

There have never been written proper national guidelines for PMDT TB in Albania. The number of MDR-TB cases has been very modest - between 0-5 annually for the last many years, thus only one case registered in 2012. At present there is no way of telling how many, as DST activities in the NRL have been suspended as a regular activity. However, there has been no attempt whatsoever to secure adequate 2nd line drugs for the treatment for these few MDR-TB cases, most of whom must have died by now, leaving alone the uncertainty about the number of people they must have infected with MDR-TB before passing away.

However small the number of MDR-TB patients this lack of action is contrary to the standard of care of TB patients advocated by the StopTB and the WHO. It is also extremely counterproductive epidemiologically. Even in a successful TB programme like the Albanian with very few treatment failures and defaulters, a great opportunity has been missed in coping effectively with dissemination of MDR-TB strains, the cost of which would have been very small indeed.

Although the issue seem to have been discussed at length, still no action has been taken to build or refurbish a small unit for MDR-TB with 2-3 rooms with single beds with proper infection control facilities. It is still debated whether this isolation facility should be located at the Shefqet Ndrogi Hospital or at Infectious Disease Unit at the National Nënë Teresa Hospital also in Tirana. To compound the issue further there does not exist a national plan for infection control and nobody in the NTP has undergone training in this subject.

Back in 2008 an application was being prepared to the GLC for being granted the access to high quality 2nd. line TB drugs. Yet the plan was stalled, as in the meanwhile a collective application for the same purpose on behalf of a number of Balkan countries seemed to be under way. This initiative never materialized. Hence 2nd line TB drugs have never reached Albania. It seems that neither 1st. nor 2nd line drugs have ever been officially registered in Albania, although the pharmaceutical company that won the MOH tender for 1st. line TB drugs has encountered no difficulties in getting the drugs into Albania.

4. Follow up of the previous mission recommendations (2012).

*)Key to outcome color codes:

Achieved	
Some progress	
No change	

2012 GLC mission recommendations	By whom	Time frame
TB Control Financing		
• The MOH and the NTP must elaborate agreed budget-lines in the MOH budget for all specified and necessary TB control activities (e.g. TB drugs; MDR-TB management; TB related infection control, supervision and training) , so that TB control is not jeopardized by sudden lack of fund.	MOH/NCP	ASAP
• The National Health Insurance shall reimburse family doctors for visits by even uninsured TB suspects or TB patient during their treatment to enhance full involvement of primary care in TB management and control	MOH/NHI	ASAP
MDR-TB Management		
• ASAP to register the standard 2nd.line TB drugs (Kanamycine, Ofloxacine, Ethionamide, Cycloserin, and PAS)	NTP	Before December 2012
• Procure the quantities from the GDF/StopTB of these drugs corresponding to 2-3 full courses of treatment to have a "stand by treatment" whenever necessary	NTP	Before December 2012
• Translate to Albanian language the salient chapters of the *WHO Guidelines for programmatic Management of Drug-Resistant TB*	NTP	Before April 2013
• Identify a young MDR-TB interested chest physician , who could be trained in PMDT abroad	NTP/WHO	Before April 2013
• Recruit of group of clinicians with interest in poly- and MDR-TB case management and willing to serve as a core group/ "consilium" for practical and clinical patient related issues	NTP	Before October 2013
Laboratory Issues		
• A budgeted plan must be for regular necessary maintenance / repair / replacement of all laboratory equipment and IC measures must be produced and financed by the MOH on a regular basis (= with a budget line)	NRL/NTP MOH	By December 2012
• Reagent should be available for "line probe genotyping of Rifampicin resistance mutations" (or the acquisition of a GeneXpert machine and reagents) for all SS+ MDR-TB suspect persons or their symptomatic contacts; re-treatment cases; cases not sputum converting after 2 month or obviously improving during anti-TB treatment.	NRL	BY April 2013
• The lab network structure should be revisited and laboratories with a very low work load should be closed.	NTP/NRL	By Dec. 2012
• Quality control should be enhanced by panel of sputum slides for reading being sent from the NRL to the microscopy centres, and by blinded re-reading of slides by lab technicians in the district microscopy centres.	NRL	By April 2013
• Directly observed treatment (DOT) must be maintained as the standard of care for TB patients, especially where deficient adherence is suspected.	NTP/MOH NHI	ASAP
Infections Control		
• 1-2 dedicated persons from the NTP should be sent on a IC training course •	WHO/NTP	During 2013
• Written IC guidelines in Albanian language should be produced	NTP	BY Dec.

		2013
• Health staff at the hospitals with TB patients and at the District Dispensaries should be trained in administrative, personal, and mechanical IC precautions.	NTP/MOH	From 2014 onwards
• TB patients still regarded as being infective should be isolated from other patients and wards and infective patients should not be mixed with TB suspects.	NPT ULDH "Shefqet Ndroqi"	ASAP
• TB Wards should be equipped with UV light.	NTP/MOH ULDH "Shefqet Ndroqi"	By Oct 2013
• Personal protection (Respirators) should be made available for staff caring for TB patients	ULDH "Shefqet Ndroqi"	ASAP

5A. 2013 GLC mission recommendations. **<u>Unchanged from 2012 due to incompletion of previous recommendations</u>**	**By whom**	**Time frame**
TB Control Financing		
• The MOH and the NTP must elaborate agreed budget-lines in the MOH budget for all specified and necessary TB control activities (e.g. TB drugs; MDR-TB management; TB related infection control, supervision and training) , so that TB control is not jeopardized by sudden lack of fund.	MOH/NCP	ASAP
• The National Health Insurance shall reimburse family doctors for visits by even uninsured TB suspects or TB patient during their treatment to enhance full involvement of primary care in TB management and control	MOH/NHI	ASAP
MDR-TB Management		
• ASAP to register the standard 2nd.line TB drugs (Kanamycine, Ofloxacine, Ethionamide, Cycloserin, and PAS)	NTP	Before Febr.2014
• Procure the quantities from the GDF/StopTB of these drugs corresponding to 2-3 full courses of treatment to have a "stand by treatment" whenever necessary	NTP	Before Febr.2014
• Translate to Albanian language the salient chapters of the *WHO Guidelines for programmatic Management of Drug-Resistant TB*	NTP	Before April 2014
• Identify a young MDR-TB interested chest physician , who could be trained in PMDT abroad	NTP/WHO	Before April 2014
• Recruit of group of clinicians with interest in poly- and MDR-TB case management and willing to serve as a core group/ "consilium" for practical and clinical patient related	NTP	Before April

issues		2014
Laboratory Issues		
• A budgeted plan must be for regular necessary maintenance / repair / replacement of all laboratory equipment and IC measures must be produced and financed by the MOH on a regular basis (= with a budget line)	NRL/NTP MOH	By December 2013
• Reagent should be available for "line probe genotyping of Rifampicin resistance mutations" (or the acquisition of a GeneXpert machine and reagents) for all SS+ MDR-TB suspect persons or their symptomatic contacts; re-treatment cases; cases not sputum converting after 2 month or obviously improving during anti-TB treatment.	NRL	BY April 2014
• The lab network structure should be revisited and laboratories with a very low work load should be closed.	NTP/NRL	Before Febr.2014
• Quality control should be enhanced by panel of sputum slides for reading being sent from the NRL to the microscopy centres, and by blinded re-reading of slides by lab technicians in the district microscopy centres.	NRL	Before Febr.2014
• Directly observed treatment (DOT) must be maintained as the standard of care for TB patients, especially where deficient adherence is suspected.	NTP/MOH NHI	ASAP
Infections Control		
• 1-2 dedicated persons from the NTP should be sent on a IC training course •	WHO/NTP	During 2014
• Written IC guidelines in Albanian language should be produced	NTP	Before Febr.2014
• Health staff at the hospitals with TB patients and at the District Dispensaries should be trained in administrative, personal, and mechanical IC precautions.	NTP/MOH	From 2015 onwards
• TB patients still regarded as being infective should be isolated from other patients and wards and infective patients should not be mixed with TB suspects.	NPT ULDH "Shefqet Ndroqi"	ASAP
• TB Wards should be equipped with UV light.	NTP/MOH ULDH "Shefqet Ndroqi"	Before Febr.2014
• Personal protection (Respirators) should be made available for staff caring for TB patients	ULDH "Shefqet Ndroqi"	ASAP

5B. Need for consultants for specific area

With the training abroad of dedicated TB staff in MDR-TB management and in Infection Control, there may be no additional need for the time being specific WHO-EURO consultancies, but a ***well planned and well prepared*** **GLC monitoring visit** should take place within the next year to monitor progress within the fields of recommendations and for discussion with the MOH.

6. General country/region profile

5.0 General data:

Albania has approximately 3.1 million inhabitants, and with a nominal GDP/capita of int. PPP.$ 8 820 (roughly half to two thirds of the regional average in Balkan) is a middle income country in south-eastern Europe . There have been a number of very economically difficult years especially in 1997 and 99 with the so-called pyramid investment crisis, when also public health establishments were looted, and due to the war in Kosovo, where many thousands of ethnically Albanian refugees spilt over from Kosovo, once a substantial part of Albania.

The economy has gradually improved. Health expenditure has also gradually increased from 2.3% in 1995, over 6.3% in 2005 to 6.3% in 2011(last available figure) according to WHO country data. Life expectancy is no different from the regional average. Albania has a very low HIV prevalence (0.38% - or similar to the regional average) and a remarkably low and declining incidence of new TB cases over the last 10 years from 17/100 000 (2001) to now (2011) 13/ 100 000.

The DOTS strategy has been prevailing countrywide in principle from since 2002 but only achieving national coverage during the Round 5 grant from the Global Fund. Yet, "DOT" - in its original sense of the word- (= directly observed treatment) for out-patients has never been implemented. Most patients fetch drugs once monthly. Nevertheless, **treatment success** rate (2011) for **new SM+** 180 cases (in 2010) was **93%** (!), and for 18 **re-treatment cases** the same year **83%**.

5.1 Findings

The short visit 2013 did not leave time for field visits. Below is copied the experience from last year's visit:

Experience from 2012:

During site visit to Tirana Municipal Dispensary (covering the region of Tirana, and to the district of Lushnje (about 120 km south of Tirana) impressions and finding from the two previous visits in 2008 and 2009 were corroborated.

5.1.1 Field visits to Tirana Municipal TB Dispensary

TB-wise Tirana region is being served by the TB dispensary in Tirana, covering officially a population of 800 000 but more likely around 1 million people (a third of the entire national population).
*In **2011** a total of 132 new TB patients were registered in the "district register" giving a incidence of 13 / 100 000 compatible with the national incidence figures. There were 9 relapse cases but no cases of treatment after default or due to treatment failure.*
51 cases of the total of 144 TB cases starting treatment in 2011 (35%) were sputum smear positive. Of all patients 55% were men. Only one case of paediatric TB (a child of 7) was recorded.

Treatment outcomes were available for all 144 cases of TB minus 4 patients still being evaluated: 46 were cured (meaning 90% of the SS+ cases). Treatment success rate for the entire group was 85%, with 11 defaulters (8%) and 0% failure cases, 6 patients (4%) died.

The general impression from the Tirana district dispensary is one of perfect and meticulous order in registration and recording. As Tirana TB dispensary has "regional status", they are linked to the national computer data system for TB, and the nurse enters all relevant data on the computer. The system was checked looking up specific patients and seems to be functioning and operated well. Computerized data handling is found at (12) regional level only, but not on district level.

The laboratory was visited, and the lab register was found well kept. The lab technician demonstrated two AFB positive slides on a fairly good microscope. One was recorded as "scarce", the consultant being unable to find any AFBs, yet the culture result was cross checked and found to be positive. The other slide was qualified as a " 2+" and of a good quality with visible AFBs.
All positive, but none of the negative, samples are sent to the NRL for confirmation and culture. The district lab is not subject to other quality control nor blinded re-reading.

5.1.2 Field visit to Lushnje
Lushnje district has approximately 200 000 inhabitants (equal to a sample of 6-7% of the whole population). For the last two years an annual number of registered TB cases has been between 26 (2011) and 23 (by September 2012), reflecting very well the national incidence of 13 / 100 000.

Only 6 patients of the 26 (23%) TB patients in the district registered in 2011 were referred by their general practitioner, the rest had come to the TB dispensary by their own initiative. This may reflect, on one hand, that TB patients are poor, have no health insurance for the same reason, and cannot afford to go to a general practitioner. On the other hand, it does not seem very appropriate that patients should come directly to specialized care and jump over a rational referral system in the primary health sector.

Only 9 of 26 TB patients in 2011 were sputum smear positive, 12 were pulmonary leaving a somewhat surprising majority of 14/26 (54%) of extra-pulmonary cases (according to the doctor in charge TB cases of TB lymphadenitis.

All patients in 2011 were categorized as "new". In 2012 there have been 2 relapse cases so far among a total of 23 cases.

All 26 patients were sent to the University Hospital of Lung Diseases in Tirana, where 11 stayed for less than a month a few for more than 2 month and the majority for approximately one month, the delay between registration and start of treatment being a few days on average.

Surprisingly, none of the 26 patients in 2011 were < 15 years of age, 14/26 were > 45 years of age.

Treatment results were good, 8/26 (30%) were cured, 16/26 completed their treatment, and two patients were unaccounted for, thus a success rate of 92%.

The visit to the small laboratory also confirmed previous findings. No supervision had taken place since March 2012, no panels of slides for quality control are sent from the NRL, but all sputum smear positive slides are "copied" and sent to the NRL together with the sputum sample for culture.

The small laboratory, with a microscope that asked for replacement, had done 70 slide examinations during the whole of 2011 (!) and of those 57 were on new patients for diagnosis resulting in 5 new sputum smear positive cases. This detection of 1 out of 10 symptomatic patients is the kind of ratio one

would expect.

5.2 Summary of discussion

Impression during the field visits corroborates the national data TB data with an incidence of 13/ 100 000 and highly satisfactory treatment outcomes. There is only a modest proportion of re-treatment cases (6% in 2011), no failure cases and a modest rate of absconders (8%).
On a general note case holding, registration and recording is good. There is no "DOT", as practically all patients get a provision of one month of drugs. Only when the nurse judges that the patient may not stay adherent, the patient will be asked to come more frequently.

The fact that in Tirana only 88/141 (62%) patients have pulmonary TB and of those only 51/88 (58%) were SS+ may indicate an element of over-diagnosis of TB. On the other hand, the incidence of TB is falling and there is no increase in the proportion of SS+. Thus, it is unlikely that many TB patients are detected too late. Thus case finding is probably at an acceptable level.

Although it is ideologically correct to insist on "Directly Observed Treatment" it is unlikely that "DOT" would improve treatment results substantially in Albania. Yet, in individual cases it is vital that treatment is supervised to prevent the appearance of defaulting and failure cases with resistant TB.

To avoid delay in patients coming forward to be diagnosed with TB it would be instrumental that initial diagnostic services and follow-up TB cases at the family doctor will be covered by the National health insurance. This could motivate family doctors and the primary sector to be more involved in TB control and in the long run create a more cost-effective and rational system than seeing TB suspects finding their way directly to the secondary health system.

Recommendations:

- **The National Health Insurance shall reimburse family doctors for visits by even uninsured TB suspects or TB patient during their treatment to enhance full involvement of primary care in TB management and control**
- **Directly observed treatment (DOT) must be maintained as the standard of care for TB patients, especially where deficient adherence is suspected.**

7. MDR -TB Response Plan and its alignment with the European M/XDR Response Plan.

The present "National Tuberculosis Strategy" for 2009-2014 outlining a new strategy for Albanian TB control addresses all issues that concerns conventional TB control, including HR management and the need for training, supervision and monitoring. The strategy follows the policy lines of WHO and StopTB, and indicates overall summary running costs per year of € 335 500 annually, out of which expenses for the TB drugs would amount to € 30 000, the NRL € 100 000, and "MDR-TB management" € 20 000. There are no specifications of the kind and quantity of TB drugs that will be procured.

It is fair to say that the "National Tuberculosis Strategy" expresses the good intentions of the NTP but so far there has been no major political will to finance nor to sustain the achievement made during the GF support.

As stated above (**chapter 2.4**) there does not exist any concrete M/XDR Response plan for Albania,

leaving alone that there are no national guidelines for PMDT TB either, nor has there at any time ever been procured MDR-TB 2nd. line drugs by the MOH/NTP.

The closest the NTP in Albania has been to consider the issue of treating the 12 MDR-TB patients during the last 5 years was the intention of a sending a "fast track" GLC application at the time of the GLC consultant visit in 2008. However, that application was never finalized. The explanation offered in December 2009 on the follow up visit by the same GLC consultant, who has now again visited Albania in 2012 and 2013, was that a "collective" Balkan application was under way making a separate application for the very few Albanian MDR-TB patients redundant. However, the proposal for a collective Balkan application which was raised at a meeting in Banja Luca on behalf of WHO Euro by Dr. Lucica Ditiu never materialized, leaving Albania with no access to 2nd.line drugs from the GLC, as the original "Fast Track" application was never taken up again.

With reference to the second of the "***Strategic Directions of the WHO consolidated response plan"*** formulated in **"The Consolidated Action Plan to Prevent and Combat M/XDR TB in the European Region 2011-15",** there are at present, after the discontinuation of GF means no special provision for help to the most vulnerable and poor TB patients (no social support for incapacity) nor any incentives/enablers for patients to endure and complete the long treatment of TB or even less that of MDR-TB.

Looking at the 7 ***Areas of Intervention*** of the mentioned "**Consolidated WHO Action Plan"** the situation of Albanian TB control needs direction and input that will demand a much more convincing political will and financial support on behalf of the MOH.

- ***Prevent the development of cases of M/XDR-TB***
  - Case holding of sensistive TB must guarantee that patients are adherent and finish their whole treatment without interruption nor defaulting
  - Cases of MDR-TB must be diagnosed and treated adequately to interrupt the chain of transmission
- ***Scale up access to testing for resistance to first- and second line anti –TB drugs***
  - DST for all SS+ were being being done, but is now suspended.
  - It is still very relevant to insist on availability of rapid molecular diagnosis when MDR-TB is suspected.
- ***Scale up access to effective treatment for all forms of Drug-resistant TB***
  - Guidelines and appropriate 2nd.line drugs should be made available for management of *poly- and multi resistant TB cases*
- ***Scale up infection control***
  - There must be designed a national plan for infection control in institutions handling TB patients, a focal person(s) appointed to organize the area, and further staff training performed; TB ward (in Tirana) should have appropriate infection control equipment and personal protection devices; a ward with at least two rooms must be constructed/refurbished where a MDR-TB patient could be treated without the risk of cross infection with MDR-TB in hospital
- ***Strengthen surveillance including recording and reporting***

- MDR-registers and special format for reporting and recording must be produced

- ***Expand the countries capacity to scale up the management of drug-resistant TB, including advocacy, partnership and policy guidelines***
  - For the time being there seem to be no need for any grand scale initiative, but that should be no argument for not doing everything to cure the few diagnosed MDR-TB patient
- ***Address the need of special population***
  - TB incidence tend to be 3-4 times higher in the most poor northern part of Albania and there will be other vulnerable groups like the Roma people, HIV positive persons, the very poor, where MDR-TB will be more likely to present itself and spread more easily if appearing.

8. Epidemiology, Case finding and Program performance data

Epidemiology

TB incidence has been in Albania seems to have been rather steady over the last 10 years. According to the current official WHO figures (website 2012) case detection rate is 97% (??) Below the data provided by the national epidemiological unit (by Dr. Donika Bardi)

Case finding strategies for TB,

Case finding of TB patients in Albania is in essence passive apart from cases detected through contact tracing, which is being done at district level and registered meticulously in the district registers.

Many poor patients do not pay money to the National Health Insurance scheme and would have to pay money in cash if they went to a family doctor with their symptoms. The majority of TB patients registered in the district of Lushnje had come *directly* to the TB dispensary, where investigations (CXR and sputum examinations) are free of charge. Family doctors were trained during the GF grant period to become more aware of TB (GF Round 5 until March 2012). No family doctors were seen during the present monitoring visit, so there is no clear idea of their contribution to TB case finding at present.

Year	New cases	Relapse	Others	Failure	Defaulter	P	EP	SS+	SS-	SS not done	C+	C-	C not done	Total
2001	530	26	16	0	0	355	217	196	305	71	140	264	168	572
2002	571	41	0	0	0	410	202	253	273	86	233	181	198	612
2003	529	32	0	0	0	362	199	232	251	78	237	198	126	561
2004	544	30	6	0	1	357	224	220	251	110	201	224	138	581
2005	497	15	23	1	4	360	180	215	210	115	194	6	340	540
2006	467	13	18	0	4	321	181	199	207	96	166	149	187	502
2007	423	15	7	0	2	292	155	182	191	74	193	189	65	447
2008	**392**	**25**	**17**	**0**	**0**	**282**	**152**	**195**	**229**	**10**	**214**	**147**	**73**	**434**
2009	416	19	**10**	**0**	**2**	**305**	**142**	**192**	**199**	**56**	**209**	**174**	**64**	**447**
2010	415	16	**10**	**3**	**1**	**275**	**170**	**165**	**248**	**32**	**205**	**198**	**42**	**445**
2011	416	11	**3**	**0**	**0**	**301**	**129**	**190**	**191**	**49**	**205**	**146**	**79**	**430**
2012	391		**0**			**285**	**106**	**185**	**99**	**1**	**183**	**208**		**391**

Table 1. Annuall TB incident cases divided into categories (NTP- Epidemiological Unit)

Graph of all new TB cases, all SS+, Re-treatment cases including relapses, and all culture positive and culture negative patients from 2001 (1) to 2011(11) (made based on the table above)

Table 2. Incidence, and mortality rates of TB (2001,2010, and 2011)

Year	Incidence**	Prevalence	Mortality***
2001	17/ 100 000	?	4.6
2010	13/ 100 000		2.7
2011	13/ 100 000		3.6
2012	12/ 100 000		?

Case finding of DR-TB cases

Only SS+ sputum samples are sent to the NRL for culture. *Here in principle- until the beginning of 2012- ideally* all samples were grown in parallel on L-J solid media and on Batec fluid media, and a DST made on the Bactec machine on all positive cultures. Now November 2013, no reagents for Bactec / MGIT are available. It has also proved difficult to prepare Löwenstein-Jensen media containing calibrated contents of antibiotics. At this moment in time (November 2013) only sputum microscopy is performed. To complicate matters further the essential centrifuge for spinning down the NaOH decontaminated and later buffered sputum samples has been out of order due to lack of maintenance on –off in 2012 and is now not working at all.

Where some 3 000 cultures annually on Bactec were performed in 2010, now there has only been bought reagents for 50 in 2013.

The laboratory used to have a budget for consumables of some € 100 000 which this year was cut to € 10 000. Line probe assay reagents for genotypical Rifamapicin and INH resistance would cost some € 8 per test, but is at present unavailable. Previously all resistant samples were forwarded to the "Istituto di San Rafaele" in Milan.

Case holding results

The DOTS strategy in Albania is short of performing "DOT" and all patients after the initial approximately 1-4 weeks of hospitalization. Patients are normally only seen / controlled on a monthly basis. Yet the "case holding" results are excellent. Thus, looking at the group of smear positive TB patients the rate of default is below 3%, no failure cases was detected in 2010 nor in 2011 indicating that so far drug resistance cannot be a major issue, and the mortality rate during the three last years of available data (2009+2010+2011) has come down to 2.4, 2.7%, and 2.6% respectively.

Below given in absolute numbers and percentages the national treatment outcomes of **new smear positive TB cases 2001-2011.**

Year	Cured	%	Completed	%	Success %	Died	%	Failed	%	Defaulted	%	Transferred	%	Unknown	%	Total
2001	73	42,7	66	38,6	81,3	8	4,6	4	2,3	6	3,5	0	0	14	8,3	171
2002	98	43,5	91	40,4	83,9	3	1,3	2	0,9	15	6,6	1	0,4	15	6,9	225
2003	115	54,2	71	33,5	87,7	8	3,8	0	0	14	6,6	1	0,5	3	1,4	212
2004	97	41,6	89	38,2	79,8	12	5,1	0	0	11	4,7	0	0	24	10,4	233
2005	85	43,5	69	35,2	78,7	8	4,1	3	1,5	10	5,1	0	0	21	10,6	196
2007	**90**	**49.7**	**63**	**34.9**	**84.6**	**8**	**4.4**	**3**	**1.6**	**8**	**4.4**	**9**	**5**	**0**	**0**	**181**
2008	88	**51.8**	66	**38.8**	90.6	6	**3.5**	1	**0.6**	3	**1.8**	**0**	0	6	**3.5**	**170**
2009	110	**64.3**	43	**25.1**	89.4	4	**2.4**	2	**1.2**	6	**3.5**	**0**	0	6	**3.5**	**171**
2010	71	**49**	61	**42.1**	91.1	4	**2.7**	0	**0**	4	**2.7**	**0**	0	5	**3.5**	**145**
2011	117	**65**	51	**28.3**	93.0	3	**1.6**	0	**0**	7	**3.9**	**0**	0	2	**1.1**	**180**

Table 3. Treatment outcome for new cases of sputum smear positive TB cases 2001-2011.

Paediatric TB:
The group of paediatric patients with TB seems to be very small indeed indicating little transmission in society at large: Among children < 15 years there were 3 and 2 cases in 2011 and 2012 respectively

Individuals living with HIV/AIDS

Please see chapter 2.2

9. Coordination of the program and financing

Organization of the TB programme

Please see chapter 2.1.2 for details.

The **NTP** is under the Department of Public Health of the ministry of Health. In principle the Deputy Minister of Health is chairing the advisory body, The National Committee for TB Control established in 1995 with representatives of the ministry the National institute of Public Health, Shefqet Ndogi Hospital in Tirana, the Tirana Tuberculosis Dispensary and the Pulmonary hospitals of Shkodër and Korca. However, the advisory board has to be revived, and is at present not functioning.

The key institution for practical organisation of TB control is the Shefqet Ndogi Hospital in Tirana, where also the ad hoc programme manager through the last many years, Dr Hasan Hafizi, an TB epidemiologist, and the National TB Reference Laboratory are housed.

The major problem for the NTP is a varying degree of political will to support the program, which in its own vertical structure has tended to get lost in the turmoil of health sector reform and the creation of a National Health Insurance, that does not cater for poor TB patients, that do not pay Insurance fees.

There seems to be no clear MOH budget lines for procurement of TB drugs, but procurement is

through the Shefqet Ndoqi hospital with a not very transparent procurement mechanism. At present after the discontinuation of GF money vital TB programme elements are suffering from the lack of regular MOH funds, e.g. notably supervision, and continued health staff education (among other things in infection control, and continued education of general practitioners in TB management).

For time being the budget for TB drugs and especially the TB laboratory consumables must be negociated in competition with all the other clinical activities of the Shefqet Ndroqi hospital, paralyzing TB culture activities.

Recommendations:

- **The MOH and the NTP must together elaborate an agreed budget for all specified TB control activities including all TB drugs; cost for MDR-TB management; and for TB related infection control**
- **Accordingly a budget line for the NTP must be created by the MOH for these expenses, so that TB control is not jeopardized by sudden lack of fund.**
- **This would mean securing a budget independent from the Shefqet Ndroqi hospital for TB activities and procurement of essential consumables and drugs for TB control.**

10. TB Laboratory

Dr. Tafaj, director of the NRL, has been head of the laboratory for many years, has been trained in Italy and is maintaining good connections with both the" Istituto Superiore di Sanitá", Rome, and the SRL at "Sant Raffaele" in Milan. As of this year Dr Tafak has also been appointed the head of the general microbiological laboratory.

Last time, in 2010, when she received a panel of sputum samples for 1st. line DST the result was one of 100% concordance.

The laboratory network still consists of 16 microscopy centers. Some of these centers have a very small work load, for example Lushnja (population 200 000) with only 57 persons having been investigated in 2011 of whom 5 were SS+. This gives on average less than one slide to examine a day and only one SS+ Slide per 2-3 months. It may well be questioned whether quality/proficiency can be maintained under these conditions. For the time being there is no other kind of QC than that of all positive slides being sent "in duplo" to the NRL. Now, as supervisory visits cannot be performed in the periphery due to lack of funds from the MOH the element of "on site" inspection by the NRL has stopped.
It may be added that distances in Albania are relatively short and transport of sputum to the MRL is not a great issue.

The main laboratory issues since the last visit in 2012 have been:

- Break down of an indispensable centrifuge and no replacement in sight.
- Lack of Falcon centrifuge tubes compounding the procedures of sample preparation for DST

- Lack of reagents for the Bactec machine, limiting culture and DST activities
- Problems even with respect to quality antibiotics powder for preparing solid media DST.
- **Still no maintenance arrangement**. **For example the lab has 3 biosafety hoods but they have never been checked, the filters never changed etc.**
- No kits for rapid resistance mutation genotyping
-

A DSR proper was performed in 2010. For a comparison find below a table showing the results of all cultures between 2001- 2006.

Table 3. Drug resistance to first line drugs in Albania 2001-2006
(data provided by Dr Silva Tafaj, head of the NRL)

	Previous anti-TB treatment status							
	Never treated		**Previously treated [B]**		**Unknown**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Total patients with DST results (H+R) [A]	1,062	100%	76	100%	0	0.0%	1138	100%
I [C]Any resistance to isoniazid (H)	32	3.0%	28	36.8%	0	0.0%	60	5.3%
Any resistance to rifampicin (R)	12	1.1%	20	26.3%	0	0.0%	32	2.8%
Any resistance to ethambutol (E)	9	0.8%	8	10.5%	0	0.0%	17	1.5%
Any resistance to streptomycin (S)	81	7.6%	9	11.8%	0	0.0%	90	7.9%
II Resistance to H only	19	1.8%	9	11.8%	0	0.0%	28	2.5%
Resistance to R only	9	0.8%	2	2.6%	0	0.0%	11	1.0%
Resistance to E only	0	0.0%	2	2.6%	0	0.0%	2	0.2%
Resistance to S only	62	5.8%	6	7.9%	0	0.0%	68	6.0%
Total mono-resistance	**90**	**8.5%**	**19**	**25.0%**	**0**	**0.0%**	**109**	**9.6%**
III H + R	1	0.1%	10	13.2%	0	0.0%	11	1.0%
H + R + E	0	0.0%	6	7.9%	0	0.0%	6	0.5%
H + R + S	0	0.0%	2	2.6%	0	0.0%	2	0.2%
H + R + E + S	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Multi-Drug Resistance (MDR) [D]	**1**	**0.1%**	**18**	**23.7%**	**0**	**0.0%**	**19**	**1.7%**
IV H + E	1	0.1%	0	0.0%	0	0.0%	1	0.1%
H + S	10	0.9%	1	1.3%	0	0.0%	11	1.0%

H + E + S	1	0.1%	0	0.0%	0	0.0%	1	0.1%
R + E	0	0.0%	0	0.0%	0	0.0%	0	0.0%
R + S	1	0.1%	0	0.0%	0	0.0%	1	0.1%
R + E + S	1	0.1%	0	0.0%	0	0.0%	1	0.1%
E + S	6	0.6%	0	0.0%	0	0.0%	6	0.5%
Total poly-resistance other than MDR [E]	**20**	**1.9%**	**1**	**1.3%**	**0**	**0.0%**	**21**	**1.8%**

It is obvious that neither in 2001-05 nor in the DSR in 2010 (see table below) are MDR-TB nor poly-resistant cases a prominent phenomenon. At present it seems that the prevalence of MDR-TB among patients never treated before is below 15 (0.6%), and among re-treatment cases the level is higher, 5.3%, yet much lower than those indicated by the lab data from 2001-2006. However, even in the DRS the number of re-treatment cases is very low (19), but the 2 cases of MDR-TB is compatible with the experience during the last 5 years (see table 5. below)

Table 4. DRS results 2010

DSR 2010 Albania		**Never treated**		**Previously treated**	
		N	**%**	**N**	**%**
Total patients with DST results (H+R) [A]		**155**	**89%**	**19**	**11%**
I [C]	Any resistance to isoniazid (H)	5	3,2%	7	36,8%
	Any resistance to rifampicin (R)	2	1,3%	2	10,5%
	Any resistance to ethambutol (E)	0	0,0%	0	0,0%
	Any resistance to streptomycin (S)	5	3,2%	0	0,0%
II	Resistance to H only	3	1,9%	6	31,6%

	Resistance to R only	1	0,6%	1	5,3%
	Resistance to E only	0	0,0%	0	0,0%
	Resistance to S only	4	2,6%	0	0,0%
	Total mono-resistance	8	5,2%	7	36,8%
III	H + R	1	0,6%	1	5,3%
	H + R + E	0	0,0%	0	0,0%
	H + R + S	0	0,0%	0	0,0%
	H + R + E + S	0	0,0%	0	0,0%
	Total Multi-Drug Resistance (MDR) [D]	1	0,6%	1	5,3%
IV	H + E	0	0,0%	0	0,0%
	H + S	1	0,6%	0	0,0%
	H + E + S	0	0,0%	0	0,0%
	R + E	0	0,0%	0	0,0%
	R + S	0	0,0%	0	0,0%
	R + E + S	0	0,0%	0	0,0%
	E + S	0	0,0%	0	0,0%
	Total poly-resistance other than MDR [E]	1	0,6%	0	0,0%
Total Mono (H+R+E)		5	3,2%	7	36,8%
Total MDR		**1**	**0,6%**	**1**	**5,3%**
Total Other poly R		0	0,0%	0	0,0%
Sensitive H+R+E		149	96,1%	11	57,9%

Table 5. Number of detected MDR-TB cases in Albania from 2007 -2012 cases:

2007 = 3
2008 = 2
2009 = 2
2010 = 0
2011 = 5
2012 = 1
2013 = 1

Recommendations for the NRL:

- **A budgeted plan must be for regular maintenance / repair / replacement of all laboratory equipment and IC measures must be produced and financed by the MOH on a regular basis (= with a stable budget line) so that Culture and DST is not interrupted due to lack of funds as is the case at present.**
- **Reagent should be available for "line probe" genotyping of Rifampicin resistance mutations" and INH (or alternatively a GeneXpert machine and reagents should be purchased) with**

testing of all SS+ MDR-TB suspect persons or their contacts; re-treatment cases; cases not sputum converting after 2 month or obviously improving during anti-TB treatment.

- **The lab network structure should be revisited and laboratories with a very low number of examined slides should be closed.**
- **Quality control should be enhanced by panel of slides for reading being sent from the NRL to the microscopy centres, and by blinded re-reading of slides by lab technicians in the district microscopy centres.**

11. TB Infection Control (IC)

Impression from the field visit:

The TB wards of the University Lung Diseases Hospital "Shefqet Ndroqi" , Tirana, are located along the main floor of the lung department with no separation from the rest of the ward with patients with different pathologies. The TB-rooms contains 3-4 beds that on the day of the visit were only 50% occupied. The TB-rooms have no UV light. During the warm season of the year there is plenty of natural ventilation through open windows, but no other means of ventilations. The matron last year, 2012, told that the staff did not use respirators for personal protection, but that they spent much time educating the patients about infection control.

According to the TB epidemiologist there is a great need for someone to be trained in IC, and a lot of uncertainty, how best to deal with the subject of IC.

Previously, it has been discussed at length to establish a small unit for MDR-TB patient, with at least two separate rooms with negative pressure, but so far no conclusion has been reached as to in which hospital, nor how. Some money is supposed to be left from the Round 5, GF grant to cover the building/refurbishment costs.

Recommendations:

- **1-2 dedicated persons from the NTP should be sent on a IC training course abroad**
- **Written IC guidelines in Albanian language should be produced**
- **Health staff at the hospitals with TB patients and at the District Dispensaries should be trained in administrative, personal, and mechanical IC precautions.**
- **TB patients still regarded as being infective should be isolated from other patients and wards and infective patients should not be in the same ward as TB suspects.**
- **TB wards should be equipped with UV light.**
- **Personal protection (Respirators) should be made available for staff caring for TB patients**

12. Treatment strategies and Second line anti-TB drug management

(For information on 1st.line TB drugs please see chapter 2.1.2)

Treatment Strategies

As mentioned on several occasions, there do not exist formulated strategies for poly-or MDR-TB

treatment in the Albanian NTP.

Isoniazid resistance is obviously a problem among 30% of the few re-treatment cases, but among TB patients never treated before the last prevalence figures for INH resistance were only 3-4%.

Fortunately, in the sputum samples of MDR-TB cases, that were examined for 2nd.line drug resistance in Italy, so far **no XDR cases were observed**.

This means that a feasible strategy for Albania would be to register and procure standard regimens 2nd. line drugs for 2-3 patients so as to have a "stand by" treatment available.

Recommendation :

- **ASAP to register the 2nd.line TB drugs listed below**
- **Procure the quantities from the GDF/StopTB of these drugs corresponding to 2-3 full courses to have a "stand by treatment" when necessary**
- **Translate to Albanian language the salient chapters of the *WHO Guidelines for programmatic Management of Drug-Resistant TB***
- **Identify a young MDR-TB interested dedicated chest physician , who could be trained in PMDT abroad**
- **Recruit of group of clinicians with interest in poly- and MDR-TB case management and willing to serve as a core group/ "consilium" for practical and clinical patient related issues**

Recommended "Stand by" MDR-TB regimen :

Intensive Phase: 6 (-8)months (Kanamycine (1g daily im/iv 6 days a week); levofloxazin 750 mg daily; Ethionamide 750mg daily; Cycloserine 750 mg daily or PAS 8 g daily; Pyrazinamide 2 g daily)

Continuation Phase: 12-18months (levofloxazin 750 mg daily; Ethionamide 750mg daily; Cycloserine 750 mg dailyor PAS 8 g daily, Pyrazinamide 2 g daily)

13. Information system and data management

Findings and summary of discussion:

Registration of TB cases in Albania follows along broad lines the recommended format of the WHO, with a District TB register, which is updated by the district TB dispensary staff from treatment cards and laboratory register (and data from the NRL in Tirana). Neither treatment cards, nor the TB register, have any information on DST, HIV status, and often no weight is registered on the treatment card. There seems to be an effective sharing of patient data between hospital and district TB clinic that receives the patient cards sent by mail once the patient is discharged from hospital for follow-up treatment in her/his district.

At regional level (12 regions) computers are available for electronic TB data entering and where it has been seen (Tirana this time, previously in Skodër in 2009) it seems to function very well.

At district level (36 districts) there is no electronic system of communication of patient data are forwarded on paper to the epidemiological center, where the national TB statistics is produced. The paperwork and CXR material as seen during the field visit for example in Lushnje are of a fine quality apart from the mentioned minor shortcomings.

14. Drugs

Although the procurement of TB drugs through the MOH with open tender happen, it seems, always in the last moment, stock out of drugs so far has not occurred. The government policy of open tenders imply that GDF drugs are not used and prices for the drugs procured according to Dr. Hasan Hafizi, are at a level 2-3 times higher than it would cost to procure via DGF, leaving alone the question of quality.

For the last years the wholesaler company Megapharm has won the procurement contract for TB drugs, and the producer is Svizera™.

The epidemiologist claims that out in the districts there are buffer stock amounting to some 3-5 months. In the hospital pharmacy there were the following stock on Nov. 15th. 2013:

	Tabl. in stock	No. of Tabl. Needed to treat 1 patient	Patient Tx. courses
Rifampicin/ INH (150/75mg)	60 000	720 tabl	83
Pyrazinamide 500mg	30 000	240 tabl.	166
Ethambutol 400mg	30 000	180 tabl.	125

If it is true that there would be 3-5 months buffer stock in the districts the situation is not dangerous, although apparently no procurement has been started yet (turn-around time 2-3 months) but with some 330- 400 patients staring treatment every year there is at present only a total national buffer stock of 5-7 months, which may become a later headache, if procurement is not being re-organized with its own ministerial budget line.

15. Ethics of TB prevention, care and control

Also in Albania the gender distribution among TB patient is the well-known 1 woman to 2-3 men diagnosed. There is no indication of any gender bias in access to services or treatment.

During this visit it has not been possible to get any idea about TB treatment in prisons nor in special population groups (refugees, Roma people etc.)

16. Itinerary and people met

GLC/Europe Monitoring Mission to Albania performed by Dr. Sören Thybo, International Consultant on behalf of the WHO Regional Office for Europe

14-16 November 2013

Thursday 14 Nov. 2013

13:00-16:00 **Visit to Shefqet Ndoqi Hospital**

- Dr Hasan Hafizi, National TB Manager (NTP)
- Dr. Donika Bardi, Epidemiologist (NTP)
- Dr. Silva Tafaj, Head of the NRL (NTP)

Friday 15 Nov. 2013

11:00-12.00 **Visit to WHO country Office**

- **Conversation and with the Country-Representative Dr. Vasil Miho and discussion of the Debvriefing note to presented to the deputy minister**

14:00-15:00 **Visit to the Shefquet Ndoqi Hospital**

- **Inspection of Hospital drug store**

16:00-17:00 **Debriefing with the deputy health minister, Ms. Milva Ekonomi**

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Annex 1.

Debriefing Note
GLC TB monitoring Visit September 2012 / WHO Euro

Tirana 2013.11.15

For the first time ever in recent decades Albania is without culture facilities for TB due to the lack of regular, budgeted funds from the Ministry of Health now the support from the Global Fund has stopped (2012). Albania has had a long tradition of very proficient TB control but the lack of maintenance of laboratory equipment and of finances for basic consumables during the last year and a half has reduced diagnostic capacity to simple sputum microscopy and to the level of that of some poor African developing countries.

This means that there is at present no way in which resistant TB may be timely detected and addressed. There is also now a lack of funds for proper supervision of TB diagnostic and case holding performance in the districts, leaving alone serious problems of infection control in hospitals dealing with TB.

In spite of recurrent criticism from external WHO monitoring visits there are still no available 2^{nd}. line TB drugs for the so far limited number of Multi-drug resistant TB cases (MDR-TB), who will infect others persons as they are left without treatment, and contrary to international standards of care left to themselves to look for cure outside the country. As a third of the Albanian population is thought to work abroad and some 180 000 jobless Albanians are said to have returned from the neighbouring countries recently (e.g. Greece) compounding the problem of migration, the threat of TB among Albanians in the future should also be of immediate concern for the EU.

With the current economic crisis, increasing poverty in many parts of the Albanian society, and the low priority granted by the Ministry of Health for the public health problem of TB which means no resources for a maintaining a proper TB control programme the risk is real, that TB incidence may be rising. This is so much more lamentable as Albania in many ways has enjoyed a well-established National TB Programme which since 2002 has been very much improved through the external input from the Global Fund and the country has seen a decreasing annual number of TB cases. So far the incidence of MDR-TB has been low compared to other places in the eastern part of Europe.

Since 2006 and with the external support the TB situation in Albania has in many ways been very favourable. Incidence of TB has gradually declined thus from 2010-2012 between 13-14/ 100 000- the lowest level ever.

Treatment outcomes have also been highly satisfactory with a treatment success rate of over 90% (92%

in the last available data from 2011), and with very few defaulters and hardly any failure cases. As compared to many Eastern European countries the prevalence among infective TB cases of MDR-TB is very low: less than 1% among TB patients never treated before, and only 5.3% among the small number of re-treatment cases according to the national drugs susceptibility study finalized in 2010.

The National Reference Laboratory (NRL) is in principle well equipped and until recently (2012) with different culture methods being available although no rapid genotypic resistance test is yet being performed. The NRL has a long track record of good and reliable results being itself subject to quality control from Super-national Reference Laboratories in Italy. The low and decreasing incidence of TB on the other hand has made a reduction of the number of peripheral microscopy centres of the laboratory network logical and necessary. Only one laboratory now outside Tirana (Skodër) can do culture (but only on solid media), although the current problems of lacking funds has also rendered this laboratory function idle.

In 2010 the NRL performed a Drug Resistance Survey that corroborated the above mentioned low MDR-TB prevalence figures. It is thus very plausible that there have not been many undetected MDR-TB cases over the last 6 years, but only the 13 MDR-TB cases found since 2007. For the mentioned reasons now there is no longer any possibility of monitoring of drug resistance.

On this background of a very limited problem of MDR-TB with the very modest amount of money needed for treatment (perhaps at the most US $ 4-6000 per year) it is incomprehensible why so far nothing has been done to procure the 2nd.line TB drugs that might have cured the few MDR-TB cases encountered. Without treatment these patients will die eventually of their disease, but before that each single MDR-TB case may have infected on average 20 other people. This is not only a moral problem but- from a cost-effectiveness point of view- absolutely meaningless. So far there seems to be no positive development in this state of affairs that is as epidemiologically unacceptable as it is intolerable for the country.

Both in the NRL and in the TB wards in the University Lung Disease Hospital “Shefqet Ndroqi” there are substantial problems of infection control. Infection Control will have to be taken much more seriously to avoid cross infection between TB and non-TB patients in hospitals and dispensaries, and to avoid infection of health care and laboratory staff.

In the long run TB activities will have to be integrated much more in the primary health care sector, which is instrumental for identifying symptomatic patients that must be examined for TB, and also for the follow-up and the directly observed treatment of detected patients. For this reason the National Health Insurance should take upon itself to reimburse family doctors also for uninsured TB patients who need care by a family doctor.

It is for the MOH to make sure that there are budget lines in the recurrent health budget that will support an effective TB programme. Albania has achieved a very good and effective TB programme over the 7 years with external support until 2012. There is every good reason to try and protect and consolidate these achievements for the benefit of the Albanian people.

2013 GLC mission recommendations (summary). **<u>Unchanged from 2012 due to incompletion !</u>**	**By whom**	**Time frame**

TB Control Financing		
• The MOH and the NTP must elaborate agreed budget-lines in the MOH budget for all specified and necessary TB control activities (e.g. TB drugs; MDR-TB management; TB related infection control, supervision and training) , so that TB control is not jeopardized by sudden lack of fund.	MOH/NCP	ASAP
• The National Health Insurance shall reimburse family doctors for visits by even uninsured TB suspects or TB patient during their treatment to enhance full involvement of primary care in TB management and control	MOH/NHI	ASAP
MDR-TB Management		
• ASAP to register the standard 2nd.line TB drugs (Kanamycine, Ofloxacine, Ethionamide, Cycloserin, and PAS)	NTP	Before Febr.2014
• Procure the quantities from the GDF/StopTB of these drugs corresponding to 2-3 full courses of treatment to have a "stand by treatment" whenever necessary	NTP	Before Febr.2014
• Translate to Albanian language the salient chapters of the *WHO Guidelines for programmatic Management of Drug-Resistant TB*	NTP	Before April 2014
• Identify a young MDR-TB interested chest physician , who could be trained in PMDT abroad	NTP/WHO	Before April 2014
• Recruit of group of clinicians with interest in poly- and MDR-TB case management and willing to serve as a core group/ "consilium" for practical and clinical patient related issues	NTP	Before April 2014
Laboratory Issues		
• A budgeted plan must be for regular necessary maintenance / repair / replacement of all laboratory equipment and IC measures must be produced and financed by the MOH on a regular basis (= with a budget line)	NRL/NTP MOH	By December 2013
• Reagent should be available for "line probe genotyping of Rifampicin resistance mutations" (or the acquisition of a GeneXpert machine and reagents) for all SS+ MDR-TB suspect persons or their symptomatic contacts; re-treatment cases; cases not sputum converting after 2 month or obviously improving during anti-TB treatment.	NRL	BY April 2014
• The lab network structure should be revisited and laboratories with a very low work load should be closed.	NTP/NRL	Before Febr.2014
• Quality control should be enhanced by panel of sputum slides for reading being sent from the NRL to the microscopy centres, and by blinded re-reading of slides by lab technicians in the district microscopy centres.	NRL	Before Febr.2014
• Directly observed treatment (DOT) must be maintained as the standard of care for TB patients, especially where deficient adherence is suspected.	NTP/MOH NHI	ASAP
Infections Control		
• 1-2 dedicated persons from the NTP should be sent on a IC training course •	WHO/NTP	During 2014
• Written IC guidelines in Albanian language should be produced	NTP	Before Febr.2014
• Health staff at the hospitals with TB patients and at the District Dispensaries should be	NTP/MOH	From 2015

trained in administrative, personal, and mechanical IC precautions.		**onwards**
• **TB patients still regarded as being infective should be isolated from other patients and wards and infective patients should not be mixed with TB suspects.**	**NPT ULDH "Shefqet Ndroqi"**	**ASAP**
• **TB Wards should be equipped with UV light.**	**NTP/MOH ULDH "Shefqet Ndroqi"**	**Before Febr.2014**
• **Personal protection (Respirators) should be made available for staff caring for TB patients**	**ULDH "Shefqet Ndroqi"**	**ASAP**

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