



**World Health  
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REGIONAL OFFICE FOR **Europe**

# Review of the Tuberculosis Programme in Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999])

22–26 April 2013

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## ABSTRACT

The notification rate of TB cases in Kosovo<sup>a</sup> is among the highest in south-east Europe. WHO was asked to organize a review of the Kosovo Tuberculosis Programme, which took place from 22 to 26 April 2013. The reviewers provided a number of recommendations to improve the Programme and to ensure its long-term sustainability before the end, in 2016, of support from the Global Fund to Fight AIDS, Tuberculosis and Malaria. The main focus should be on: the creation of a central management unit, adoption of standard operating procedures, provision of universal access to rapid diagnosis, ensuring of effective infection control, development of a nominal electronic database, integration with family medicine, and adoption of policies for maintaining and enhancing human resources.

<sup>a</sup> In accordance with United Nations Security Council Resolution 1244 (1999).

### Keywords

BEST PRACTICES  
INTEGRATED HEALTH CARE SYSTEMS  
MULTI-DRUG RESISTANCE  
OUTPATIENT CARE  
PUBLIC HEALTH  
TUBERCULOSIS, EXTENSIVELY DRUG-RESISTANT  
TUBERCULOSIS, MULTI-DRUG RESISTANT

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## **Acronyms and abbreviations**

DOT	directly observed treatment
DST	drug susceptibility testing
KTP	Kosovo Tuberculosis Programme
MDR-TB	multidrug-resistant tuberculosis
SS+	sputum smear-positive
TB	tuberculosis
UNMIK	United Nations Mission in Kosovo
XDR-TB	extensively drug-resistant tuberculosis

## **Acknowledgements**

The members of the review team gratefully acknowledge the cooperation and hospitality of all officials, members of nongovernmental organizations and patients spoken to. Their understanding and patience allowed the team to accomplish effectively the visits and interviews planned (and some that were unplanned). We also apologize for any inconvenience our visits may have caused.

The WHO Office in Pristina provided efficient administrative and logistic support. We thank Dr Skender Sylja, Head of the Office, for his input to the discussions and the report and Dr Ardita Tahirukaj, Public Health Officer, for organizing and contributing to the visit. Thanks are also due to the health authorities for allowing the Kosovo TB Programme Manager to be part of the review team.

All the support received was highly appreciated and underlines the commitment to improve tuberculosis control in Kosovo.



## Executive summary

Kosovo<sup>1</sup> is currently undergoing a social, political, institutional and cultural transition. As a result of widespread poverty, low health budgets and ongoing health system reforms, TB remains a public health problem. The Kosovo Tuberculosis Programme (KTP) was established with the technical assistance of WHO and several other international stakeholders.

Despite its limited budget, Kosovo is firmly committed to supporting TB control. The TB strategy for 2012–2016, which is in line with the WHO Stop TB Strategy and its accompanying action plan for 2012–2016, was endorsed in December 2011. Financial support for the implementation of the strategic plan comes from the Global Fund to Fight AIDS, Tuberculosis and Malaria through a grant that started in 2011 and will end in 2016. The Country Coordinating Mechanism still has to negotiate the phase 2 disbursement of this grant.

This review is the result of a request to WHO to assess the epidemiological situation of TB in Kosovo and the features of the TB control programme with reference to the Millennium Development Goals for TB, the implementation of the Stop TB Strategy (including the grant from the Global Fund) and the linkages with the health system. The team was asked to develop specific recommendations for improving TB control and combating drug-resistant TB.

## Main findings

### *TB epidemiology*

Since 1999, TB has re-emerged as a public health problem in Kosovo. The burden of TB is among the highest in south-east Europe, with a notification rate of 46 per 100 000 population in 2012. Only the Republic of Moldova and Romania have higher notification rates.

TB control has been relatively successful: total notifications fell from 1443 cases in 2002 (69 per 100 000 population) to 968 in 2012 (46 per 100 000), a median annual decline of 3.5%. There was a decreasing trend in notified cases until 2006, since when the number of cases has remained more or less stable.

Comparing rates is difficult, as the size of the population and its evolution over the years is not accurately known. The population size used as denominator in the past was 2.1 million; however, the 2011 census showed the population to be only 1.74 million. Using this denominator would increase the TB notification rate for 2012 to 56 per 100 000. This has consequences for the targets agreed with the Global Fund.

In all age groups, notification rates among females are higher than among males. The census showed almost equal numbers of men and women, but labour migration is probably higher among men. Uneven notification rates between municipalities have been reported; the diversity suggests a weak recording and reporting procedure rather than real differences in incidence.

Treatment success rates among new sputum smear-positive cases have been consistently high, at around 90% over the past 10 years. Mortality is low and has been decreasing.

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<sup>1</sup> For the purposes of this publication, all reference to “Kosovo” should be understood/read as “Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999])”.

The efficacy of case-finding is unknown, as strategies are not standardized and algorithms for what to do, when and where are absent. In an unknown proportion of cases, diagnosis is based on chest X-ray or clinical considerations, without bacteriological confirmation. Even when sputum smears are requested, only a small proportion of them are confirmed by culture, mostly on solid (slow) media. Rapid molecular tests have recently been introduced in Kosovo and are now used for very few presumptive TB cases.

Multidrug-resistant (MDR-TB) is a relatively small problem in terms of absolute numbers with only four patients currently on treatment, but there is an unknown backlog of chronic cases. The reliability of recording of retreatment cases is uncertain, but a 2007–2008 survey showed that 11.5% of retreatment cases had MDR-TB, indicating that some resistant cases may go undetected.

The burden of co-infection with TB and HIV is unknown, because of incomplete testing for HIV among TB patients and poor linkages with the HIV surveillance system.

### ***Millennium Development Goals and Stop TB Partnership targets***

The Stop TB Partnership targets are a case-finding rate of 70% and a treatment success rate of 85%. The success of case detection is unknown, because of the uncertainty in the estimates of TB incidence and population size. Treatment success rates for the past five years were around 90%, higher than the target.

One of the targets of Millennium Development Goal 6 is to halt and begin to reverse the incidence of TB and to halve the prevalence and mortality (compared with the 1990 values) by 2015. The notification rates of new infectious TB cases (as a proxy of the actual incidence) have clearly declined, despite uncertainty about the population denominator and the efficacy of case-finding. Data for the years before 2001 are difficult to use. Mortality rates have fallen by half since 2001. The estimates of prevalence vary widely. For mortality, it can be assumed that Kosovo has already met the Millennium Development Goal 6 target for TB.

### ***Governance***

The responsibility for TB control is assigned to a clinician as part-time manager of the KTP. The KTP is mainly supported by the Global Fund grant, the principal recipient and sub-recipients of which are nongovernmental organizations. Thus, TB control activities are managed with only partial ownership by, and accountability to, the health authorities. There is no official KTP central management unit. Staff operate in a number of functions part-time under the Public Health Institute and part-time implementing TB programme activities, paid by the principal recipient of the Global Fund grant. Lines of authority are, therefore, ambiguous.

### ***Standardization of services***

Quality health care requires a high level of medical professionalism: services should be provided in a standard manner and patients should perceive them as targeted to their needs. The review team observed weaknesses in many aspects of the TB control programme that could be addressed by simple means. Guidelines, when available, are interpreted in different ways. Staff have varying levels of knowledge about aspects of TB control. A manual with clear written guidelines on all aspects of TB control would support standardization and improve the quality of service delivery.

The KTP manager has recently started to hold regular meetings with the regional coordinators, which will contribute to improving the situation. Clear guidelines, standard operating procedures and, above all, supervision with on-the-job training are, however, mostly missing. This lack of standardization has a negative influence on programme performance.

### ***Case-finding and case management***

The laboratory network is well-established, with a clear hierarchical structure. The mycobacteriology laboratory in the Institute for Public Health acts as the central reference laboratory but has not yet been officially endorsed in this function. Its stewardship is needed for the introduction of new molecular tools, with the accompanying need for new algorithms, advice on new equipment to be purchased and quality assurance.

Despite the widespread use of self-administered treatment, the success rate of treatment is high. The number of drug-resistant TB cases is still low, but expertise in the management of these patients is limited.

Involvement of primary health care services and private practitioners in case-finding and case-holding can be strengthened. This may include training and supervision schemes.

### ***Nosocomial transmission***

The stabilization in the number of TB cases since 2006 is an indication of continuing TB transmission. Transmission can take place in households, hospitals or other congregate settings, or among vulnerable population groups. Notification rates in children up to 14 years of age have declined over the years, reflecting a decrease in household transmission. TB prevalence in vulnerable groups is unknown, but is likely to be small.

Strong points are the availability of a number of specific and well-detailed consultants' reports that include many general and specific recommendations for the improvement of infection control. A Committee for the Prevention of Nosocomial Infections has been established, but TB infection control guidelines for health facilities have not been developed. US Centers for Disease Control and Prevention guidelines have been translated as interim guidelines but are not well-known. Despite the separation of patients, aerosol transmission can easily occur in a number of health facilities: engineering controls (ventilation and ultraviolet irradiation) are inadequate, personal protection measures for staff (respirators) are not available or not used, and bio-safety in laboratories is not ensured because of lack of regular maintenance.

Given the poor implementation of infection control guidelines, nosocomial transmission is the most likely explanation for the interruption in the decline of the epidemic.

### ***Drug and commodity management***

The KTP uses drugs prequalified by the Global Drug Facility, for which an import licence is granted even though the drugs are not registered with the Kosovo Medical Agency. The drug management system functions relatively well. Warehousing remains a weak point as the central warehouse is damp and in other ways is not suitable. Stock-outs have been reported.

### ***TB database and the health information system***

Reliable information is necessary to monitor the TB programme and to evaluate the efficacy of interventions. Standardization of definitions, training and supervision are essential.

The TB recording and reporting system is not optimally used. New sputum smear-negative cases are not included in the database. Retreatment cases are not divided by smear-positive and smear-negative cases, or into subcategories. Laboratory registers do not allow methodology and quality of performance to be evaluated.

Analysis of notifications is complicated. Recording at the periphery is nominal, but reporting from regional level upwards is by aggregated tables. Mistakes in recording have been noticed, which may be related to inadequate training and lack of supervision.

Kosovo intends to strengthen its health information system as part of its health sector reform. The action plan for 2011–2014 includes the creation of an adequate health information system covering all areas of health, to be pilot-tested and then expanded to the whole of Kosovo. It is not yet known if the TB database will fit into the health information system. A private company has recently been contracted to develop an electronic nominal database for the KTP.

### ***Ethnic minorities, vulnerable populations and human rights***

The Serbian minority population has its own family medicine facilities, with Serbian staff and financing from the government of Serbia and municipal authorities. Members of this population usually go to Mitrovica North Hospital for secondary care and to Serbia for tertiary care. The Roma and other groups that are difficult to reach are served by nongovernmental organizations, which also provide education and health promotion.

Poverty is the most important social determinant of TB in Kosovo: more than 30% of the population lives below the poverty line and more than 12% live in extreme poverty. Although TB care is free of charge, poor people face other obstacles to accessing health services. The use of monthly incentives and enablers is helping to overcome the problem.

Other social determinants that may directly or indirectly influence TB control are unemployment (35% of the population), substance abuse (7000–17 000 intravenous drug users) and imprisonment. TB control in prisons is in line with international standards; unlike in other parts of south-east Europe, the burden of TB in prisons is comparable to that in the general population.

TB and HIV co-infection is still a small problem, but coverage of testing is incomplete.

The Kosovo health sector strategy for 2010–2014 states that equality and non-discrimination are fundamental elements of the right to health. Kosovo has not yet introduced the Patients' Charter for Tuberculosis Care, which outlines the rights and responsibilities of people with TB.

### ***Health sector reform and family medicine***

The health sector strategy for 2010–2014 emphasizes the strengthening of primary health care, but progress has been variable. The gatekeeping role of primary care remains underdeveloped. Meanwhile, specialists often redirect patients to their private clinics, which are not overseen by

the public health authorities. Public health has been introduced and local responsibility for it has been delegated to municipal authorities.

The emphasis on expanding family medicine health services has contributed to the greater role played by primary health care in TB control, but coverage is still limited. Much more should be done in the areas of job descriptions, training and incentives to increase primary health care involvement. Training in the practical approach to lung health strategy is incomplete. The engagement of private care providers in TB control is limited.

The position of the anti-TB dispensaries is not yet clear. Given the emphasis on primary health care and the development of TB as a competency of the clinical pulmonologist, anti-TB dispensaries could become part of family medicine centres.

The health system continues to be funded out of the Kosovo consolidated budget. As taxation has generated more revenue, so the amount of money allocated to the health system has gradually increased. The budget for 2013 was €1.5 billion; €152 million (10.1%) was allocated to health, of which €43 million (28%) was for primary health care which is generally provided by municipalities. These funds remain inadequate.

### ***Human resources and capacity-building***

The action plan for 2011–2014 aims to upgrade the level of professional medical knowledge and skills through improved education and training. An assessment of future human resources needs is also included.

Several TB specialists and laboratory technicians will retire soon and adequate replacements are not available. TB control in Kosovo will no longer be able to rely on TB specialists. Fortunately, diagnosis and treatment of TB have become easier, with simple, rapid diagnostic techniques and standardized treatment regimens delivered in fixed-dose combinations. In many instances, treatment does not need hospitalization, and family medicine doctors can deal with the majority of TB cases under the supervision of a specialist. However, more complex cases, including drug-resistant TB, need specialist attention in hospital.

TB control also needs more doctors oriented to public health to monitor and evaluate progress. Nurses (of whom there is reportedly no shortage) can perform many activities, such as case-holding, treatment delivery and health education.

Analysis of the tasks in TB control could lead to job descriptions that are different from those currently in use. Kosovo has developed an education strategic plan for 2011–2016, which includes a needs assessment based on labour market needs.

### **Main recommendations**

1. The long-term sustainability of TB control should be ensured before the end of the Global Fund grant, as Kosovo may not be eligible for further funding. Alternative sources of funding should be found well before 2016.
2. If gaps in service delivery occur, the government could consider contracting out specific tasks to nongovernmental organizations that have the needed human resources with specific skills.

3. Negotiate with the Global Fund a revision of the target indicators for evaluating performance in the grant implementation, based on the population size found in the 2011 census.
4. A KTP central management unit should be established with authority, terms of reference, appropriate staff and skills and clear lines of command to be responsible for organizing and coordinating all KTP partners.
5. Programme activities should be standardized by introducing a manual with guidelines on case-finding, case management and standard operating procedures for diagnosis, infection control measures, recording and reporting to support the management of all TB patients.
6. The mycobacteriology laboratory in the Public Health Institute should be officially endorsed as the central reference laboratory.
7. Universal and more rapid access to microbiological diagnosis of TB should be ensured, in view of the introduction of new tools, according to a sustainable algorithm based on aggregate data. One of the two algorithms presented at the end of this report should be selected, the necessary equipment and consumables purchased and a routine flow of samples for testing established according to the chosen algorithm.
8. Infection control guidelines should be implemented as soon as possible. Engineering approaches to prevention of nosocomial transmission should be accompanied by regular and adequate maintenance of the equipment. Staff should be made aware of the importance of infection control, trained in the proper interventions and offered effective personal protection devices.
9. Special attention should be paid to the Dubrava Prison Hospital, where infection control is weak. The Prison Health Department will become part of the civilian sector in 2013.
10. A nominal electronic database for TB should be developed, linked to the general health information system. To save time and effort, the database already developed in Albania could be considered as a model.
11. TB control should be included in health sector reform and decentralization of services to family medicine. Job descriptions should be developed, based on a TB task analysis at all levels of care. This may facilitate the redeployment of present staff, alleviating the shortage in certain positions. Public health interventions do not necessarily have to be carried out by a specialist in pulmonology; other skills may be required, such as programme management, epidemiology, statistics, organization of training, drug management, health education and health promotion. Staff may be recruited for these duties from the Public Health Institute. Family medicine doctors can take over tasks in TB case-finding and case-holding. Further training in the practical approach to lung health strategy should be provided for family medicine doctors.
12. A career perspective or incentives to preserve TB clinical expertise in the health system should be provided. The stigma attached to TB is found among health staff as well as in the general population. TB doctors are often paid less than other specialists, and have little chance for a private income as diagnosis and treatment have to be provided free to the patient. Working in TB also carries a risk of infection that should be compensated for by a higher salary (as well as being tackled through better infection control). A career perspective, such as from local specialist to regional coordinator to KTP manager with rising salary scales, will help.
13. The advocacy, communication and social mobilization strategy should be finalized and implemented, and drug resistance, HIV co-infection, ethnic minorities and vulnerable populations included.

## Introduction

Kosovo<sup>2</sup> is currently undergoing a social, political, institutional and cultural transition. As a result of widespread poverty, TB remains a public health problem. There is a firm commitment to support TB control, as can be seen from the Kosovo TB strategy for 2012–2016 and its accompanying action plan for 2012–2016 (1).

External funding comes mainly from the Global Fund to Fight AIDS, Tuberculosis and Malaria. Kosovo received grants for TB control from the Global Fund in Rounds 4 (2006–2011) and 9 (2011–2016) and a grant for HIV/AIDS control in Round 7 (2008–2014). The Round 9 grant was for US\$ 5.8 million; the Community Development Fund, a nongovernmental organization, was the principal recipient of this grant (2).

The Round 9 grant has been implemented for almost two years, and the Country Coordinating Mechanism now has to negotiate the disbursement of the second phase of the grant. In support of that process, Kosovo asked WHO to assist in a review of the Kosovo Tuberculosis Programme. WHO therefore assigned a team to:

- assess the epidemiological situation of TB in Kosovo and the features of the Kosovo Tuberculosis Programme with reference to the Millennium Development Goals, the implementation of the Stop TB Strategy (including the grant from the Global Fund) and the linkages with the health system;
- develop specific recommendations for improving TB control and combating drug-resistant TB.

On behalf of the European Green Light Committee, part of the review was also dedicated to monitoring the Programme's interventions for preventing and controlling drug-resistant TB.

The review took place from 22 to 26 April 2013 with the financial support of the Global Fund through its Principal Recipient Community Development Fund. A team of three international and one local expert participated in the review (Annex 1), analysed available documents, conducted visits to relevant institutions and facilities and interviewed many stakeholders, both at the central level in Pristina and in a number of peripheral areas, in order to cover different TB epidemiological situations and the geographical distribution and organization of services. The programme is in Annex 2 and a list of the people met is in Annex 3.

After the visit the team, accompanied by Dr Pierpaolo de Colombani, Medical Officer for TB and M/XDR TB at the WHO Regional Office for Europe, presented its main findings and recommendations to Dr Curr Gjocaj, Director of Health Services.

## General information

Kosovo, in south-eastern Europe, is bordered by Albania, Montenegro, Serbia and the former Yugoslav Republic of Macedonia. The 2011 census showed the population to number 1.74 million, with almost equal numbers of men and women (3). The urban population is 36%. Kosovo has a young population: 28% are aged under 15 years, 35% are aged between 15 and 34 years and 7% are aged over 65 years. The median age is 27 years. Albanians form the majority ethnic group

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<sup>2</sup> For the purposes of this publication, all reference to "Kosovo" should be understood/read as "Kosovo (in accordance with United Nations Security Council Resolution 1244 (1999))".

(92%), but there are also Bosnians, Egyptians, Gorani, Roma, Serbs and Turks. About 18 000 people are internally displaced. An estimated one million people from Kosovo live abroad.

The legal system is a mixture of old laws of the former Yugoslavia, laws and regulations of the United Nations Mission in Kosovo (UNMIK) and new Kosovo laws.

Over the past few years, Kosovo's economy has shown significant progress in moving to a market-based system while maintaining macroeconomic stability, but it is still highly dependent on the international community and the diaspora for financial and technical assistance. Remittances from the diaspora are estimated to account for about 18% of the gross domestic product, and donor financing and aid for approximately 10%. The people living in Kosovo are the poorest in Europe, with an average annual per capita income of US\$ 3510. More than 30% of the population live below the poverty line and more than 12% live in extreme poverty (3). Unemployment, at around 35%, is a problem, and encourages outward migration and a significant informal, unreported economy (1).

TB re-emerged as a public health problem after 1999 and its burden is one of the highest in the South-East Europe Health Network, with a notification rate of 41 per 100 000 population in 2011 (4).

The Kosovo Tuberculosis Programme was established under the leadership of WHO and several other international stakeholders, including Doctors of the World, Fogarty International Center/National Institutes of Health (United States) and the Fondazione S. Maugeri and San Raffaele Institute (Italy). Initially, UNMIK authorized WHO to act as the executive health agency. In January 2000, the Kosovo Department of Health and Social Welfare, jointly led by local and UNMIK officials, was established to pursue the health sector reforms initiated by WHO. Programme staff participated in rebuilding the programme, in accordance with international guidelines and based on the directly observed treatment (DOT) strategy.

The WHO Office in Kosovo designated Doctors of the World as the lead partner for planning and implementing TB control activities. The DOT strategy was successfully implemented together with a five-year Kosovo TB action plan for 2000–2004. A second five-year plan was drawn up for 2005–2009, following approval of a grant under the Global Fund Round 4.

Kosovo applied again successfully to the Global Fund Round 9. The grant agreement was signed in October 2010, but the first funds were only disbursed in mid-2011, because of a change in the designated principal recipient. Phase 1 of this grant implementation is coming to an end. Phase 2 is expected to cover the three years until 2016.

## **Epidemiology of TB in Kosovo**

### **Recommendations**

1. Negotiations should be undertaken with the Global Fund to revise the grant targets taking into account the results of the 2011 census. For instance, the target for the Global Fund Round 9 grant was a TB notification rate for pulmonary new smear-positive cases of 12 per 100 000 population, based on an estimated population of 2.1 million. The 2011 census has, however, given a population of 1.74 million, which changes the rate for the same number of cases to 14 per 100 000 population.



## Notification

### *Incidence*

The TB epidemic in Kosovo was analysed on the basis of documents available from the Community Development Fund, the Kosovo Tuberculosis Programme, the European Center for Disease Prevention and Control and the WHO Regional Office for Europe. Summary tables of the current TB situation in Kosovo are given in Annex 4.

The uncertainty in the population figures makes the calculation of notification rates difficult. In previous years, the estimated population of 2.1 million was used as denominator; however, the 2011 census estimated the population at 1.7 million, suggesting that a large proportion of the population lived abroad, even if occasionally visiting Kosovo.

Using the population figure from the 2011 census, in 2012 the notification rate was 55.6 per 100 000 population for new TB cases (all forms), and 14.4 per 100 000 for new TB pulmonary sputum smear-positive (SS+) cases. There are no WHO estimates available to judge whether the target of 70% case detection rate has been reached, but the discussion on case detection and diagnosis in the section of TB case finding and diagnosis below indicates that case-finding needs to be strengthened.

### *Trends*

TB control has been relatively successful: total notifications decreased from 1443 cases in 2002 (69 per 100 000 population) to 968 in 2012 (46 per 100 000), a median annual decline of 3.5%. There was a decreasing trend in notified cases until 2006, after which the number of cases remained more or less stable (Table 1).

**Table 1. Number of TB cases notified in Kosovo, by sex, 2002–2012**

Sex	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Males	746	570	507	533	555	498	495	481	458	436	495
Females	697	557	502	569	567	432	453	420	460	410	473
Total	1443	1127	1009	1102	1122	930	948	901	918	846	968

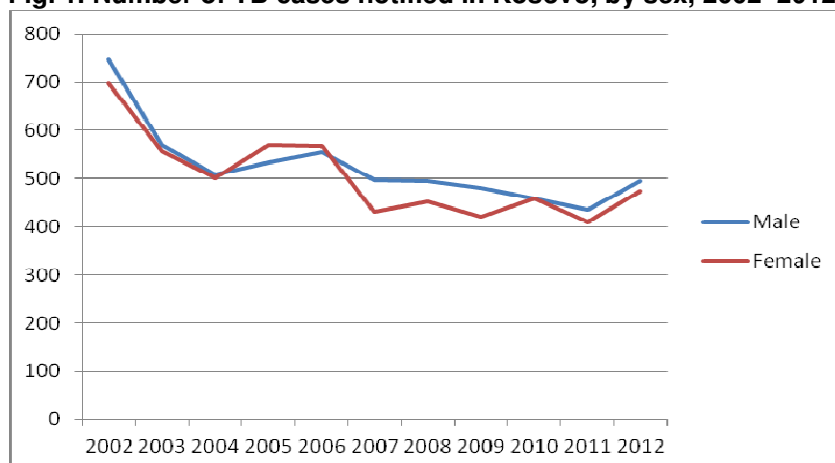
The analysis of trends in TB case notification rates is rather difficult as it is not clear for which years the lower population size should be used as a denominator. For this analysis, therefore, the trends in absolute numbers have been taken.

Fig. 1 shows clearly how the annual number of cases declined between 2002 and 2006, but that thereafter the number of cases notified remained rather stable. Annual fluctuations are seen, especially in females.

### *Millennium Development Goals*

One of the targets of Millennium Development Goal 6 is to halt and begin to reverse the spread of TB by 2015 (5). Accordingly, the reported incidence rate for all TB cases in Kosovo decreased from 83 per 100 000 in 2000 to 45 per 100 000 in 2012. The rate of new smear-positive cases decreased from 22 per 100 000 population in 2001 to 12 per 100 000 in 2012.

**Fig. 1. Number of TB cases notified in Kosovo, by sex, 2002–2012**



The target set in the Global Fund grant agreement for new smear-positive cases was 12 per 100 000 for 2012, based on a denominator of 2.1 million population. If the population estimated in the 2011 census (1.7 million) is taken as the new denominator, the target should now be 15 per 100 000.

### ***Notification by category***

There is no report on the distribution of smear-positive and smear-negative cases among new pulmonary TB cases. Smear-negative cases are aggregated, including new and retreatment cases. Moreover, pulmonary smear-positive TB retreatment cases are not divided into relapses, return after lost to follow-up and others. This makes proper analysis of categories of patient complicated, although it is possible to extract some data. New smear-positive pulmonary TB cases are reported, as are all extrapulmonary TB and all smear-positive retreatment cases. Thus, the number of smear-negative pulmonary cases can be calculated, but without being able to distinguish between new and retreatment cases.

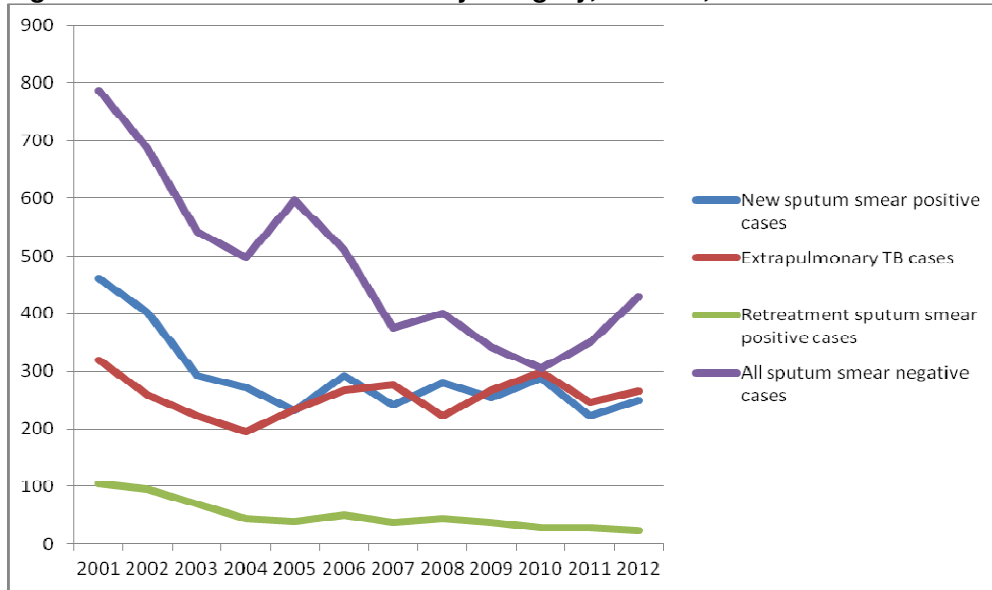
Fig. 2 shows the number of cases of TB notified by category for 2001–2012. There was a decrease in all categories from 2001 to 2006 and a more or less stable situation afterwards. The sputum smear-negative cases showed the sharpest decline, which continued until 2010. After 2010, these cases again increased, especially in 2012. Some TB specialists consider the apparent steep increase in 2012 to be due to over-notification, but it could also be argued that there may have been misclassification in 2011, when there was a decrease for most categories but an increase in smear-negative cases. Over the 12 years, the average annual decline was 3.5% overall: 3.8% for new smear-positive cases, 1.4% for extrapulmonary cases, 6.5% for retreatment cases and 3.8% for smear-negative cases.

### ***Notifications in children***

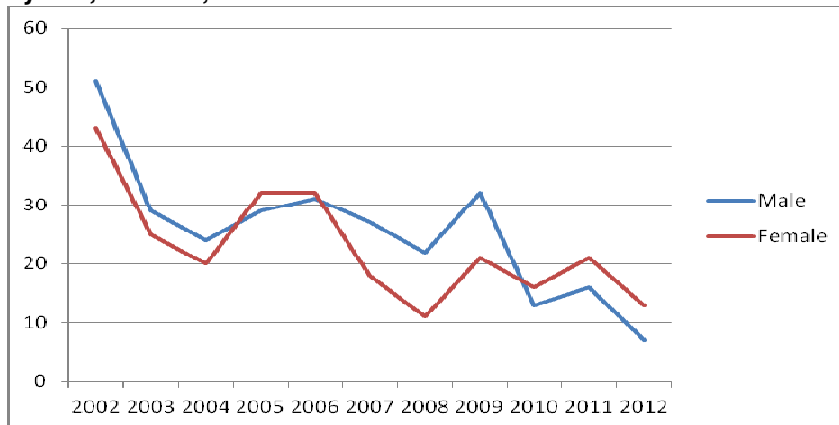
Another way of judging the success of the Programme is to look at notifications of disease among children up to 14 years of age. As shown in Fig. 3, these showed a steady declining trend, suggesting that transmission in households is decreasing (see also the section on TB in children below).

The ratio between the notifications for those aged under 15 years and those aged 15 years and over has changed very little (Fig. 4). There is, however, a clear declining trend, indicating that the decrease in household transmission is the result of an overall decrease in transmission.

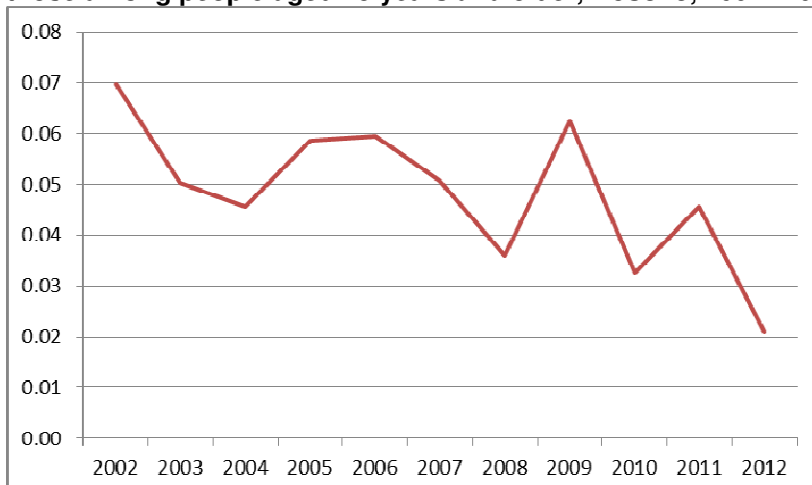
**Fig. 2. Number of TB notifications by category, Kosovo, 2001–2012**



**Fig. 3. Number of TB notifications in children aged up to 14 years, by sex, Kosovo, 2002–2012**



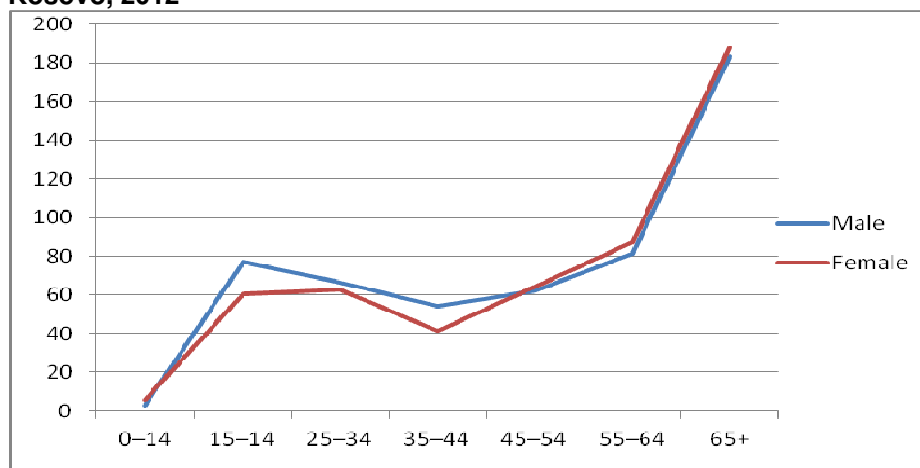
**Fig. 4. Ratio of notifications among those aged under 15 years to those among people aged 15 years and older, Kosovo, 2002–2012**



### ***Notifications in the elderly***

The age distribution of cases in 2012 (Fig. 5) was typical for a mid-level epidemic, with a peak in the young population (aged 15–34 years) and a similar peak in the group aged over 65 years. This is another indication of a declining epidemic, which is contradicted by the stable notification rate over the past six years.

**Fig. 5. Age-specific (in years) TB notifications, by age group and sex, Kosovo, 2012**



### ***Sex***

The 2011 census showed an almost equal number of men and women in Kosovo. In the population in general, however, and among young children, more TB cases are notified among females than among males. In the older population, this may be explained by the fact that men work abroad more often than women, but this cannot be the reason for children. It is possible that cultural aspects may play a role; for instance, girls may be more engaged in household chores, and thus more exposed to intra-household transmission of TB than boys are.

### ***Bacteriologically confirmed cases***

The number of new SS+ pulmonary TB cases registered decreased from 418 in 2000 (20 per 100 000 population) to 250 in 2012 (12 per 100 000).<sup>3</sup> As explained earlier, there is some uncertainty about the rates, because of the apparent change in population size. Among all cases notified, the proportion of new smear-positive cases remains around 26% (Annex 4); this is low. During the field visits, the team noticed that not all pulmonary TB cases had sputum-smear results. Doctors often relied on chest X-rays without asking for sputum smears. Confirmation by culture is not done routinely.

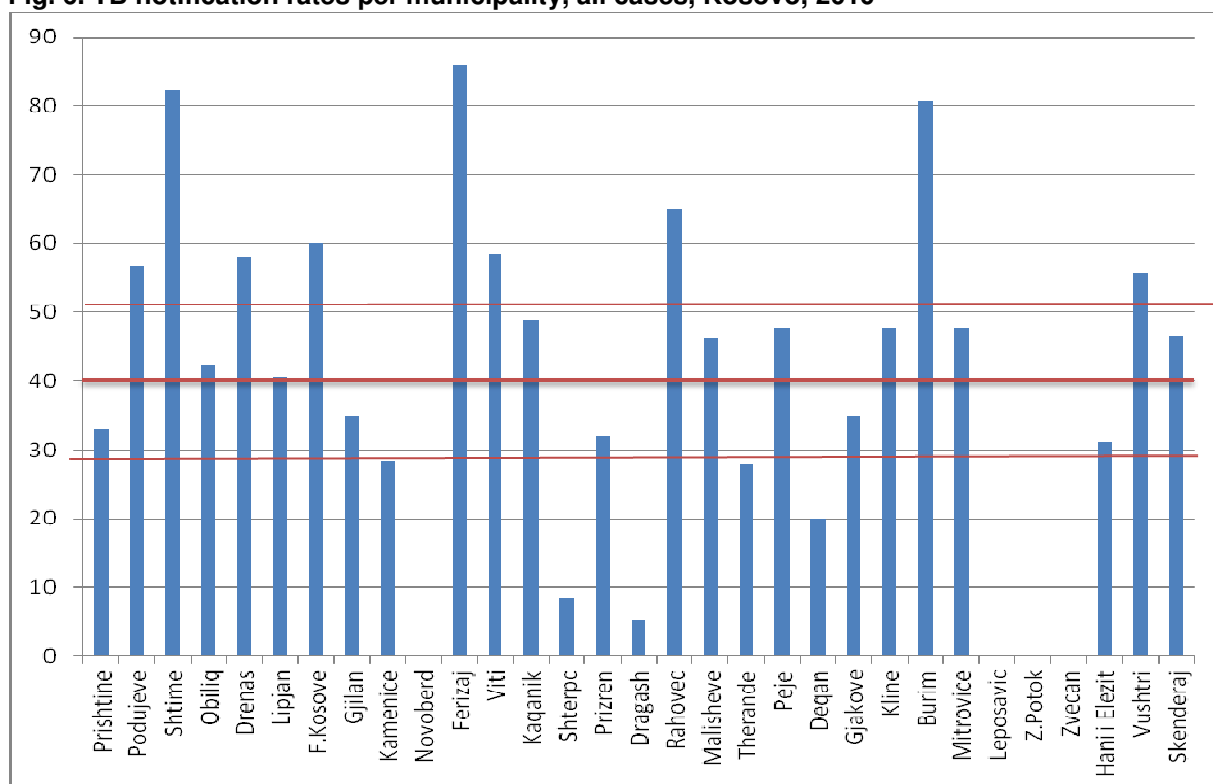
The number of retreatment cases is low. Only SS+ retreatment cases (relapses and failures together) are reported. The proportion of smear-positive retreatment cases among all smear-positive cases has decreased over the years. However, the numbers are small, and should be treated with caution. The low proportion of relapses is a good indicator of the quality of the treatment programme.

<sup>3</sup> Rates are based on an unchanged denominator population of 2.1 million.

## Regional distribution

Large differences can be seen in disease rates in different municipalities. Uneven notification rates have been reported. The figures for 2010 in relation to the populations of the municipalities (2004 estimates) show a very diverse picture. The average notification rate is 40 per 100 000 (confidence interval 37–43, median 42 per 100 000). However, some municipalities report no cases, while others report over 80 per 100 000 (Fig. 6). The diversity suggests a weak recording or reporting procedure rather than real high or low incidence rates. Pristina has a notification rate lower than the average.

**Fig. 6. TB notification rates per municipality, all cases, Kosovo, 2010**



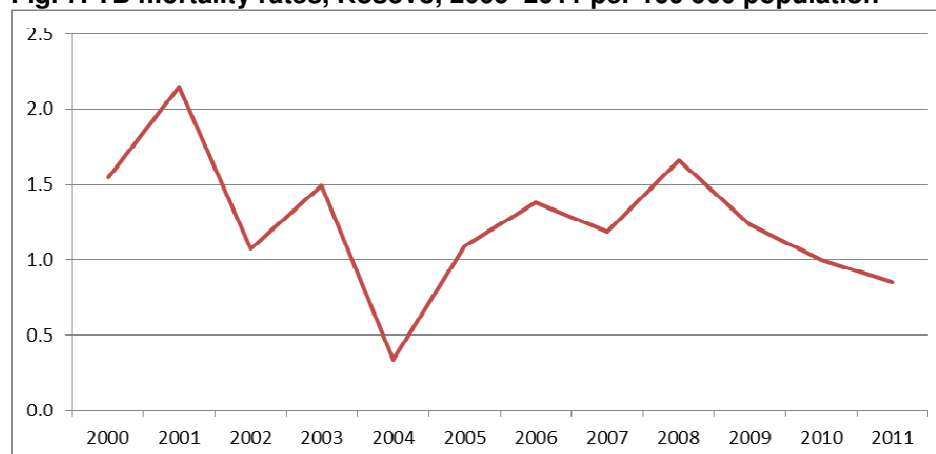
Note: the red lines show the average and confidence intervals.

## Mortality

Despite the fact that TB mortality rates reflect the effects of control efforts in the past, they are used as vital statistics and are included in the Millennium Development Goals. In Kosovo, mortality figures for years before 2001 are difficult to interpret; mortality decreased from 2.1 per 100 000 in 2001 to 0.9 per 100 000 in 2011. The relevant target in the Millennium Development Goals is to halve the mortality rate by 2015 in comparison with 1990 figures; mortality in Kosovo has been halved in comparison with 2001 figures.<sup>4</sup> However, the numbers are small and tend to fluctuate (Fig. 7).

<sup>4</sup> The Millennium Development Goals use data for 1990 as the baseline for comparison. However, in 1990 Kosovo was part of Yugoslavia and data were included in the overall data for Yugoslavia. Comparison with the data for 2001 is a good proxy.

**Fig. 7. TB mortality rates, Kosovo, 2000–2011 per 100 000 population**



### ***Treatment outcome***

Success rates of treatment of new SS+ cases have been consistently high over the past 10 years, at around 90% (Table 2). This is higher than the global target of 85%. Bacteriological confirmation of success (= cured) has also increased.

**Table 2. TB treatment outcome, Kosovo (%), 2001–2011**

Treatment outcome	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Cured	32	56	60	71	75	70	71	77	76	77	73
Completed	48	34	30	22	14	21	17	12	14	14	19
Successfully treated	79	91	90	93	90	90	88	89	90	91	91
Died	4	1	1	2	3	3	5	6	5	4	3
Failed	3	2	0	0	2	1	1	0	1	1	0
Lost to follow-up	5	5	7	3	4	1	4	2	3	3	4
Transferred out	0	0	1	2	1	3	2	3	2	1	1
Not evaluated	9	0	0	0	5	1	0	0	0	0	0

The reasons for non-successful outcome have not changed significantly over time. The case-fatality rate in 2008 was 6% but in other years remained below the 5% target. Failures are few, indicating that the proportion of multidrug-resistant (MDR) TB cases remains low. The proportion of lost to follow-up is consistently below the 5% target, despite the almost universal use of self-administered therapy during ambulatory treatment (Fig. 8).

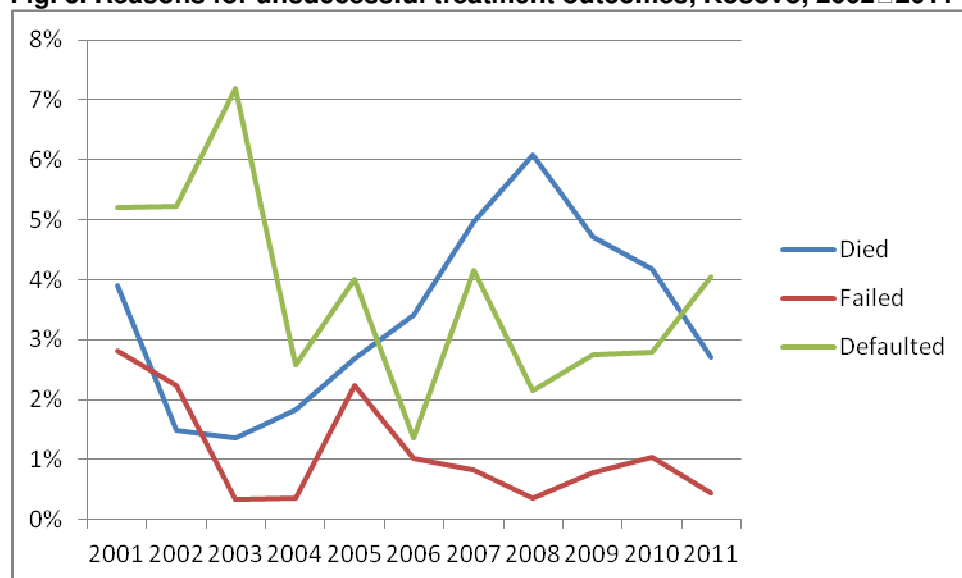
### ***Drug-resistant TB***

There is no routine surveillance for drug resistance in Kosovo. A drug resistance survey in 2007–2008 found no MDR-TB among new patients. Among retreatment cases, 11.5% were MDR-TB (Annex 5).

### ***TB/HIV co-infection***

No reliable data are available on the rates of co-infection with TB and HIV, since HIV testing is incomplete. Co-infection is, however, rare.

**Fig. 8. Reasons for unsuccessful treatment outcomes, Kosovo, 2002–2011**



## Kosovo Tuberculosis Programme

### Recommendations

1. The Kosovo Tuberculosis Programme (KTP) management unit should be officially endorsed, preferably with full-time employees, and the ambiguity in lines of authority addressed.
2. A budget line for TB control should be introduced to increase sustainability and limit dependence on the Global Fund.

### Introduction

In 1999, staff of the TB Programme participated in the building of a new programme that was in accordance with international strategies, guidelines and definitions. TB control in Kosovo was implemented in three phases:

- (i) a newly established advisory body of TB specialists (the TB Technical Commission) drafted a five-year TB action plan for 2000–2004, based on the DOT strategy;
- (ii) a sound DOT strategy was established, selected elements of the Stop TB Strategy were implemented and preparations were made for phase 3 (2005–2009);
- (iii) the Stop TB Strategy was established in the strategic plan for 2010–2015 (now updated to cover 2012–2016).

### Strategy

The Kosovo TB Strategy for 2012–2016 has the same six general objectives as those in the WHO Stop TB Strategy:

- to pursue high quality DOT expansion and enhancement
- to address MDR-TB and prevent TB/HIV

- to implement the practical approach to lung health
- to engage all care providers
- to empower people with TB and the community
- to promote operational research.

## Structure

The health care system is based on family medicine centres and secondary- and tertiary-level hospitals. Family medicine has been introduced, but job descriptions are still being developed. There is a private health sector, with growing investments from neighbouring countries such as Turkey. Most doctors working in public facilities also have their own private practice. Out-of-pocket expenditure is common. The combination of working in a public and a private practice may lead to conflicts of interest.

Kosovo has seven regional hospitals and anti-TB dispensaries (Ferizaj, Gjakova, Gjilan, Mitrovica, Peja, Pristina and Prizren) (Annex 6). All the regional hospitals, except Ferizaj, have beds for general patients, and all the regional hospitals, except Mitrovica, have a pulmonology ward or unit with beds for TB patients. Pristina University Clinical Centre contains a hospital for lung diseases with 18 beds for TB patients. Anti-TB dispensaries do not have beds. In areas where there are no beds, patients are referred to Pristina. In addition to the seven regional anti-TB dispensaries, there are six satellite anti-TB dispensaries (Klina, Lipjan, Malisheva, Podujeva, Shtimje, Skenderaj), each located close to a family medicine centre and administered by the municipality. The anti-TB dispensary in Pristina is also administered by the municipality.

There is a microscopy laboratory in each regional anti-TB dispensary and in Klina, Malisheva and Podujeva.

Each region has a TB coordinator. Since the second half of 2012, the coordinators have been meeting the KTP manager each month to discuss programme issues. Once every three months, the six pulmonologists working in satellite dispensaries join these meetings.

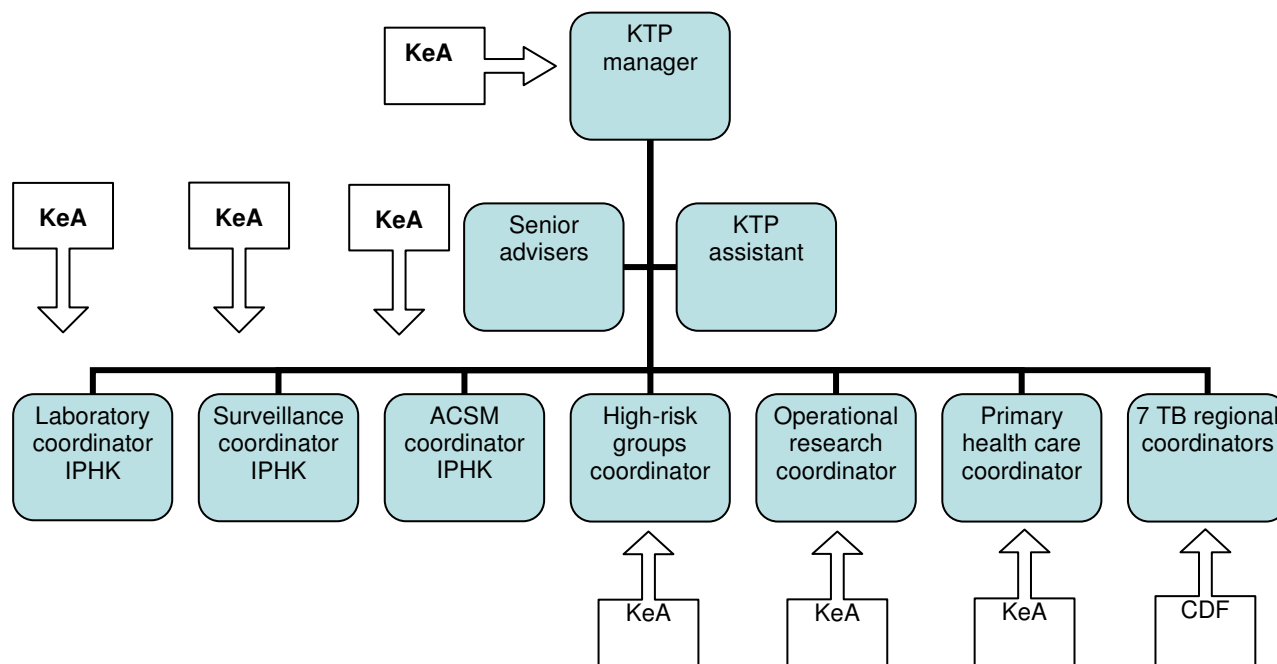
At central level, the KTP manager is assisted by five coordinators dealing with laboratories, surveillance, high-risk groups, operational research, and advocacy, communication and social mobilization. Fig. 9 shows the KTP organigram that became official after the approval of the KTP strategy and plan. A primary health care coordinator has not yet been nominated. At most levels of the structure, support is provided by the nongovernmental organizations that are recipients of the Global Fund grant.

The actual lines of authority are unclear.

- Kasnecet e Ardhmerise supports most of the coordinators assisting the KTP manager.
- The coordinators for the laboratories (and the head of the central TB reference laboratory), surveillance and advocacy, communication and social mobilization are staff of the Institute of Public Health of Kosovo and are accountable to the Director of the Institute.
- The chairperson of the Kosovo Committee on the Prevention of Nosocomial Infection has been nominated as infection control coordinator within the KTP but is also a staff member of the Institute of Public Health of Kosovo.



Fig. 9. KTP organigram as envisaged in the Kosovo strategy, 2012–2016



KeA: Kasnecet e Ardhmerise  
 IPHK: Institute of Public Health of Kosovo  
 CDF: Community Development Fund  
 ACSM: advocacy, communication and social mobilization  
 Shaded boxes: employees of KTP

- The KTP manager is a staff member of the lung diseases clinic of Pristina University Clinical Centre and is employed only half-time as KTP manager.
- There is no coordinator assigned to the essential KTP function of drug supply and management.
- There is no official designation of a KTP management unit, and there is no separate budget line for TB control in the Kosovo health budget.

It is a pity that the professional knowledge and experience available, especially within the Community Development Fund and Kasnecet e Ardhmerise, is not being used to build the capacity of the KTP central management.

## Policy

Patients with respiratory symptoms may go to a primary health care facility or a private practitioner. Many patients who suspect that they have TB go directly to an anti-TB dispensary. Diagnosis must be bacteriologically confirmed, but there is still a heavy emphasis on chest X-rays. A TB specialist initiates the treatment. The programme tries to keep admissions to a minimum and prefers ambulatory treatment, often at the family medicine centre. In theory, the quality of services is guaranteed by supervision and quality assurance, but in practice, this still has to be developed.

Tracing of household contacts has been strengthened since 2012. Bacillus Calmette–Guérin vaccination takes place at birth; there is no revaccination. If MDR-TB is diagnosed, treatment takes place in Peja Pulmonology Hospital, which has been designated as the MDR-TB hospital for Kosovo. All TB patients should be tested for HIV co-infection, but for various reasons this is rarely done.

## **Resources**

External funding for the KTP comes mainly through the Global Fund (see first section above). The agreement for the Round 9 grant of US\$ 5.8 million was signed in December 2011. Phase I of the grant, which had a two-year budget of US \$ 2.9 million, ended in September 2013.

The Community Development Fund, a local nongovernmental organization, is the principal recipient of this grant. Implementation is through five sub-recipient nongovernmental organizations:

- Kasnecet e Ardhmerise, which covers laboratory services, surveillance, operational research, MDR-TB, vulnerable groups, and advocacy, communication and social mobilization;
- The Organization Against Alcoholism, Narcotics, Smoking and AIDS, which covers TB/HIV;
- the Kosovo Health Foundation, which deals with the practical approach to lung health;
- the Association of Health Education and Development, covering community DOT; and
- the Health Agency for Development, covering drug management.

The Country Coordination Mechanism that made the application to the Global Fund was disbanded because of potential conflicts of interest of some of its members, and reinstated with a revised membership.

The KTP strategy and action plan for 2012–2016, approved in December 2011, and the Global Fund grant work plan are very similar. The KTP receives only a limited budget to cover the costs of facilities and staff; all other costs are covered by the grant. The delay in the grant negotiation caused a serious shortage of laboratory consumables, which forced the KTP to limit culture and drug susceptibility testing mainly to TB retreatment cases.

The resources of the Global Fund are decreasing, as donor countries have reduced their pledges since 2011. This has led to more strict selection criteria for grants. Kosovo may not be eligible for further funding once the present grant ends, jeopardizing the long-term sustainability of the KTP, and should, therefore, be looking for alternative ways of funding the Programme.

## **TB case-finding and diagnosis**

### **Recommendations**

1. The mycobacteriology laboratory in the Public Health Institute should be officially endorsed as the central reference laboratory.

2. A plan should be urgently developed and funding provided for maintenance to improve biosafety at all levels, with the emphasis on laboratories performing high-risk procedures (culture and DST).
3. The current quotation for Xpert MTB/Rif cartridges should be negotiated according to the internationally agreed price.
4. Clear guidelines should be provided and a quality-assured microbiological diagnostic workflow standardized at all levels, specifying the number of samples to be tested at diagnosis and follow-up in each facility (peripheral laboratories, anti-TB dispensaries, the TB laboratory in Peja and the Institute of Public Health of Kosovo). A routine referral flow should be established of all samples to be tested by culture (see new WHO definitions) (6).
5. Universal and more rapid access should be ensured to microbiological diagnosis of TB, and consideration given to introducing new (molecular) tools according to a sustainable algorithm based on aggregate data (see Annex 7 for two suggested algorithms).
6. A centralized information system should be created for nominal reports on microbiological confirmation of TB, based on smear microscopy, culture and resistance patterns.
7. One of the suggested new algorithms should be adopted, although both will have the following consequences:
  - DST in liquid will only be done in Pristina; DST will be stopped in Peja;
  - in Peja, cultures should be kept on solid media, or culture should be done only on solid media for follow-up;
  - a new Xpert should be purchased, with sufficient capacity for Pristina and Peja;
  - samples from all retreatment cases should be delivered to Pristina for liquid testing;
  - the workload in Pristina will increase.
8. Whichever algorithm is chosen, the workload will increase, both on the technical side and the administrative side.
9. Clear standard operating procedures should be developed for automated liquid cultures and DST according to international standards, as well as new standing operating procedures for molecular assays.
10. External quality assurance should be strengthened by:
  - developing and implementing an adequate supervision scheme, including on-the-job training; the Institute of Public Health of Kosovo should provide prompt feedback on external quality assurance findings and be involved in problem-solving;
  - including a positive and negative control in the daily workload of diagnostic facilities at each level.
11. MDR isolates should be sent to the supranational reference laboratory for testing against second-line drugs, to monitor the need for modification of the treatment regimen.

## **Case-finding**

The private sector may be the first stop for patients. Symptomatic patients may also go to family doctors, who refer presumptive TB patients (formerly called TB suspects) for diagnosis to a specialist, or directly to an anti-TB dispensary.

Chest X-ray was previously the usual diagnostic method used by clinicians. When the DOT strategy was introduced in 2000, priority was given to microbiological diagnosis (smear microscopy and culture).

Active screening for TB is done only among household contacts of infectious cases and in the penitentiary sector. There is no population-based X-ray screening.

## **Diagnosis**

Even if the patient goes first to a private practitioner or family doctor, diagnosis and initiation of treatment are the domain of the pulmonologist. Initial diagnosis is by sputum smear microscopy and chest X-ray. X-rays (chest and other) are widely used. The larger family medicine centres have X-ray equipment, including automatic developing machines, but family medicine doctors are not supposed to request sputum examinations. If TB cannot be confirmed, broad-spectrum antibiotic treatment is given. If this is unsuccessful, patients are referred to the pulmonologist at the nearest anti-TB dispensary with a laboratory for sputum smear examination. Confirmation is by culture, predominantly on solid media, although in practice very few patients have a culture test.

Extrapulmonary TB can be diagnosed by radiology, histology of tissues or chemical analysis of body fluids. This is the domain of specialized secondary or tertiary services.

## **Laboratory network**

Kosovo has ten smear microscopy centres: seven within the regional anti-TB dispensaries (Ferizaj, Gjakova, Gjilan, Mitrovica, Peja, Pristina, Prizren) and three in peripheral health centres (Klina, Malisheva, Podujeva).

Although the microbiology laboratory in the Institute of Public Health in Pristina acts as the central reference laboratory, it has not been officially endorsed in this function. Even so, all members of the network accept its role. Its activities include performing daily routine diagnostics for its own catchment area, acting as the referral centre for anti-TB dispensaries, developing procedures, ensuring external quality assurance for sputum smear microscopy, carrying out visits to peripheral laboratories and acting as a training centre.

TB culture services are available at the central reference laboratory in Pristina and in the TB culture laboratory in Peja.<sup>5</sup>

It is intended that anti-TB dispensaries in Ferizaj, Gjilan, Mitrovica and Pristina send samples to the central reference laboratory in Pristina, while anti-TB dispensaries in Gjakova, Peja and Prizren send samples to Peja. The flow of samples does not necessarily coincide with the flow of referred patients.

According to international standards and based on the recent population census, Kosovo should have 17 smear microscopy laboratories (one per 100 000 people), one culture laboratory (one per 5 000 000) and one DST laboratory (one per 5 000 000). These standards are meant for high-

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<sup>5</sup> A third TB culture laboratory has been under consideration for Prizren in southern Kosovo (since most cases are notified in Peja, Pristina and Prizren), but the two existing laboratories can handle cultures for all presumptive TB patients.

burden countries. For Kosovo, the present laboratory infrastructure is a rational one, given the number of specimens to be examined and the area to be covered.

## **Bacteriological confirmation**

### ***Sputum smear***

Peripheral laboratories perform direct smear with Ziehl-Neelsen staining, according to recognized protocols. Fluorescence microscopy is also available at the central reference laboratory in Pristina.

Smears and staining of slides at the laboratories visited were of good quality. However, sample data from the laboratory registers showed that the positivity rate for smear microscopy is low, and even fluctuates within a laboratory, indicating a weak supervision system. The following are possible causes for the low positivity rates of smear microscopy observed.

- Many samples in the laboratory registers are indicated as “saliva”, suggesting that sputum collection was inadequate or that the patient was not a presumptive TB patient.
- Some laboratories do not distinguish between new and follow-up examinations in their registers.

Additional causes could include the following:

- smear microscopy may be poor
- reagents may have expired
- reagents may be out of stock (although there were no stock-outs in 2012)
- sputum collection may be inadequate
- the selection of presumptive TB cases may be too broad
- TB cases for which no sputum smear is performed are reported as smear-negative.

The number of samples collected for diagnosis and follow-up was not uniform in the different sites visited. Not all laboratories tested the required number of samples. Too few samples lead to suboptimal case detection.

### ***Culture***

Cultures are not done for all presumptive TB cases and culture confirmation is still quite low (39% in 2011). The sample referral system is not uniformly applied: some doctors send all samples for culture confirmation to Peja or Pristina, others only when there is a high suspicion of TB. This amounts to a prior selection of samples. Samples are sent by car to culture facilities two or three times a week, according to a specific timetable.

At the Peja and Pristina laboratories, culture samples are first decontaminated using international standard procedures (N-acetylcysteine-sodium hydroxide). Until recently, both the Peja and Pristina laboratories used exclusively solid media (Lowenstein-Jensen), as liquid media were unavailable because of procurement limitations. This problem has been resolved, and the central reference laboratory now inoculates each sample (about 20 per day) in both solid and liquid (mycobacteria growth indicator tube) media. The Peja laboratory still uses only solid media.

In 2012, there was a shortage of both mycobacteria growth indicator tubes and Lowenstein-Jensen media, causing an interruption of culture confirmation of cases. Administrative procedures slow down procurement. The central reference laboratory cannot negotiate directly with the supplier but must refer to domestic distributors.

Identification of *Mycobacterium tuberculosis* strains is done by immunochromatographic assay if available, otherwise by the niacin test.

### ***Molecular techniques***

New molecular tools for rapid detection of TB and MDR-TB have been introduced at the central reference laboratory: Xpert MTB/Rif (maximum capacity eight samples per day) and Hain Genotype MTBDR*plus*. There is no clear algorithm for the use of these WHO-approved rapid diagnostics.

Xpert MTB/Rif is only used at the request of a clinician. In 2012, about 50 Xpert tests were performed. The cases included extrapulmonary samples and samples from children with presumptive TB. The limited number of tests in 2012 was due to budget constraints: in Kosovo a single Xpert MTB/Rif test costs €90, which is unsustainable. The internationally negotiated price is about €10 per test.

The Xpert MTB/Rif apparatus in Pristina has insufficient capacity. It is a two-module model, which is a sort of prototype. A four-module model, which can handle 16 samples per day, would be better (16- and 48-module machines are also available). Peja should also have a four-module Xpert MTB/Rif. Discussions should be started with the company (Cepheid) to change the two-module model for a four-module one without cost.

The Genotype MTBDR*plus* is not used in routine diagnostics, but the central reference laboratory considers that it has potential as a new tool for future use.

### **Drug susceptibility testing**

Drug susceptibility testing (DST) of positive cultures is done on Lowenstein-Jensen media using the proportional method, both at the central reference laboratory and in Peja. The BacTec MGIT960 system has not been used for DST so far. First-line drugs tested include streptomycin, isoniazid, rifampicin and ethambutol but not pyrazinamid. There is currently no DST for second-line drugs. For testing of second-line drugs, the central reference laboratory is linked to an supranational reference laboratory in Milan. There have been no shipments of MDR strains in the past two years.

### **Recording**

Kosovo plans to adopt the revised WHO definitions for TB, including the culture-based definition of TB. This means that sputum samples from all presumptive TB cases should be tested by culture, regardless of the microscopy results. This will increase the workload for the central reference laboratory and the Peja laboratory, as well as complicating the logistics of transporting the samples.

The positivity rate of cultures compared with that of smear microscopy cannot be judged, as the results of the smear test for samples coming from anti-TB dispensaries are not written on the

laboratory request form. The central reference laboratory does not repeat microscopy unless specifically asked to do so by the physician. The laboratory has no nominal register of sputum and culture results.

The contamination rate according to the TB register is 0.8–1% on solid media. This is a low rate, which might indicate a harsh decontamination protocol possibly contributing to false-negative results.

## **Human and financial resources**

There are not many laboratory staff experienced in mycobacteriology and they are relatively old. Previous consultancy visits have noted that there will be a shortage of competent staff in the near future.

There is a danger that laboratory confirmation of diagnosis will not be sustainable once the Global Fund grant runs out.

## **Drug resistance survey**

The first survey aimed at detecting drug resistance in Kosovo dates back to 2000.

A standardized and reliable drug resistance survey/surveillance protocol was developed in 2007–2008. During a period of one year all smear-positive TB cases were enrolled and tested. Because of delays at the start, the survey/surveillance was not completed until early 2010. There was a small prevalence of isoniazid resistance among retreatment cases (2.9%) and a large prevalence of resistance to streptomycin, both in new (16.9%) and retreatment cases (20.0%). Among new cases no MDR was found, while among previously treated cases 11.5% showed an MDR-TB pattern (Annex 5). Routine surveillance for drug resistance has not yet been implemented.

## **Quality assurance**

For at least the past two years, the seven anti-TB dispensary laboratories have undergone some external quality control for smear microscopy by the central reference laboratory, although this does not appear to be consistent with international standards. The three peripheral centres have only recently been included in the external quality assurance scheme.

In October 2012, a first version of an external quality assurance manual for smear microscopy was drafted. It includes protocols, forms, flow charts and timetables of visits and rechecking of slides, according to an internationally recognized scheme (7). The central reference laboratory was designated as the institution to lead the external quality assurance scheme. When doing external quality assurance for smear microscopy, prompt feedback on findings should be given and the central reference laboratory should be involved in problem-solving. Each diagnostic facility should keep positive and negative control sputum smears for daily use. So far, few activities have been put in place.

Every year the central reference laboratory undergoes proficiency testing by the Italian supranational reference laboratory. It has shown an optimal level of accuracy in susceptibility testing to first-line TB drugs. The central reference laboratory sends out the same testing panel to the laboratory in Peja and checks the results according to those of the supranational reference

laboratory. Although an archive of results is not available, results are apparently also excellent for the Peja laboratory.

## **Bio-safety**

According to the new WHO TB bio-safety manual (8), which is based on risk assessment, bio-safety risk increases exponentially from smear microscopy to DST. Xpert MTB/Rif requires the same bio-safety measures as smear microscopy. Genotype MTBDRplus has no bio-safety requirements, except that the first phase must be done in a containment laboratory (in the same way as cultures).

At all sites visited, sputum collection and smear microscopy were done in rooms that are adequately ventilated for such procedures. Gloves were available at all sites. While the general layout of the laboratories could be improved, no immediate risk of infection was recorded.

The laboratories performing culture (the central reference laboratory and Peja), which is considered an intermediate bio-safety risk procedure, had the main containing devices, such as personal protective devices and biological safety cabinets.

The biological safety cabinets were not ducted out but re-circulated air inside the laboratory. This is not uncommon in TB laboratories, and is acceptable provided that maintenance is carried out and high-efficiency particulate air filters are checked at least once a year. The biological safety cabinets in Peja and Pristina were not well-maintained and the filters had not been checked or replaced for years. It must be concluded that this constitutes an unacceptable occupational risk for the staff.

DST procedures are considered the most at risk for laboratory staff. Different safety situations were found at the central reference laboratory and Peja laboratory. The central reference laboratory uses three rooms separated by window-doors; this would be acceptable, if the biological safety cabinet were regularly maintained and the doors kept closed. The Peja laboratory has only one room. This layout is inadequate for performing DST, although the rapid Xpert molecular technique can be done safely.

Renovation of the central reference laboratory has been agreed, including a new ventilation system which should lead to an acceptable rate of air change.

## **TB treatment and case management**

### **Recommendations**

1. Guidelines should be developed for the programmatic management of TB and MDR-TB, including a case management manual for different groups of health care workers.
2. Private providers should be formally engaged in TB control and involved in training activities and supervision schemes so as to improve the quality of care and adherence to guidelines.
3. Guidelines should be finalized on chemoprophylaxis for latent TB infection in contacts and HIV-positive people and incorporated into the overall guidelines.



4. The hospitalization period should be shortened, when possible. To prevent super-infection through nosocomial transmission, smear-negative patients should not be admitted.

## Introduction

Treatment activities are in line with the Kosovo TB strategy for 2012–2016. However, this strategy has not been translated into a TB control manual that can be used by family medicine doctors, pulmonologists and other health care workers.

Specialists working in pulmonology departments of general hospitals or in anti-TB dispensaries carry out TB diagnosis and deliver treatment. Each month, ambulatory patients are supplied with anti-TB drugs without any DOT scheme. Sometimes, nurses in a family medicine centre take over supervision of treatment (patronage teams).

## Case management

Patients may go directly to a TB service or may be referred by a primary health care worker. A pulmonologist will then manage the diagnosis and initiate treatment. Pulmonologists work in hospitals, anti-TB dispensaries or private practice (often in combination with a public position). Since TB care is provided free, the number of patients seen by private practitioners is thought to be small. Nevertheless, some patients are diagnosed in the private sector, and some of these diagnoses may be based on questionable procedures. The treatment provided may also be non-standard.

Patients are usually hospitalized for the intensive phase of treatment. There are two treatment regimens:

- regimen I for category one (new smear-positive) patients and category three (new smear-negative and extrapulmonary) patients: two months isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E), followed by four months isoniazid and rifampicin (2HRZE/4HR);
- regimen II for category two (retreatment) patients: two months streptomycin (S), isoniazid, rifampicin, pyrazinamide and ethambutol, followed by one month isoniazid, rifampicin, pyrazinamide and ethambutol, and the continuation phase with isoniazid and rifampicin is extended to five months (2SHRZE/1HRZE/5HR).

WHO guidelines (9) suggest that hospital care should be based on the patient's condition. The present approach in Kosovo is to shorten hospitalization from the previous routine of two months inpatient care. In Pristina, patients with pulmonary TB are admitted for four weeks if sputum conversion occurs; those with extrapulmonary TB are admitted for three to four weeks. Originally, the two months admission also depended on the socioeconomic situation of the patients. In view of the poor infection control in many institutions, shorter hospitalization periods may help to avoid nosocomial transmission.

After discharge, the ambulatory phase continues at the anti-TB dispensaries or at family medicine centres with a pulmonologist (at least part-time). Although Kosovo has adopted the DOT strategy, DOT is rare after the patient has been discharged from hospital. Most patients receive drugs for one month at a time and administer them themselves daily. Drugs are available in fixed-dose combinations. Despite the fact that most treatment is self-administered, the

treatment success rate is high. The centres visited showed that they were quite capable of managing continuation of care.

Follow-up of treatment is by clinical observation and regular chest X-rays. Routine sputum examination is carried out at two months and five months.

## **Case-holding**

Rates of case-holding depend largely on the health education provided to the patients. At the sites visited, patient education was routine. In several family medicine centres, primary health care nurses trace lost to follow-up cases. They occasionally make home visits to check that patients are taking their tablets regularly, and retrieve patients if treatment is interrupted. These activities have presumably contributed to the low failure and treatment interruption rates.

As an added incentive, patients receive food and hygiene packages once a month.

## **Latent TB infection**

Latent TB infection, as indicated by a positive tuberculin skin test without TB clinical disease, is treated with isoniazid for six months, although there are reports that some doctors use a combination of isoniazid and rifampicin for three months. The Kosovo Pulmonology Association is developing guidelines on the treatment of latent TB infection. Overall, partly because of a shortage of tuberculin, pulmonologists rarely prescribe prophylaxis.

Tuberculin was available in private clinics and apparently 64 people were put on full treatment based on a positive skin test without further diagnostic examinations. No further details are known.

## **TB in children**

### **Recommendations**

1. An uninterrupted supply of tuberculin to support skin-testing in children should be ensured.
2. Paediatric drug formulations should be procured so that drugs can be prescribed on the basis of body weight.
3. Guidelines should be developed for the treatment of latent TB infection.
4. Training should be provided for better detection and treatment of TB in children.

## **Epidemiology**

TB in children aged up to 14 years has been declining over the years and has become a relatively small problem in Kosovo (Fig. 3).

Using the latest census data, in 2011 and in 2012 the age-specific notification rate per 100 000 population was 6.3 and 2.7, respectively, for boys and 8.9 and 5.5, respectively, for girls. The decreasing trend in general is an indication of lower transmission in households. The numbers are, however, small and fluctuations in case-finding influence the trend. Between 2006 and 2011,

the median decrease in TB among children was 2.6%. Stock-outs of tuberculin for skin-testing in the past year may have contributed to fewer cases being reported, but did not influence the overall trend.

## **Prevention, case-finding and diagnosis**

All newborn babies are given bacillus Calmette-Guérin vaccination. This is the responsibility of the obstetric services. Coverage reported by the KTP manager is almost 100%.

In 2012, from 468 contact examinations, 20 children with TB were identified (4.3%). This relatively low number of cases may be the result of the unavailability of tuberculin for seven months. Contact-tracing has been stepped up since 2012. A contact register has been introduced.

Bacteriological confirmation of TB in children is notoriously difficult. Infants hardly cough, so sputum examinations are rare. There are, however, indications that not enough sputum samples are requested. The tuberculin skin test has only limited value in vaccinated children. Diagnosis is, therefore, mostly based on symptoms and chest X-ray. Chest X-rays in small children are difficult to interpret. A new algorithm, using molecular tools for identification of bacilli in gastric lavage or body fluids, may change that.

## **Treatment**

Children are treated with the same regimens as adults, with dosages adjusted according to body weight. No paediatric formulations for small children have been available, which hinders prescription of adequate dosages. If necessary, tablets are broken.

No drug-resistant TB has been diagnosed in children.

Family members deliver treatment. In a number of family medicine centres, nurses supervise follow-up once every two to four weeks.

## **Drug-resistant TB**

### **Recommendations**

1. A physical separation should be constructed in the corridor of the pulmonology hospital in Peja to prevent nosocomial transmission of drug-resistant bacilli. Staff should be made aware of the risk of nosocomial transmission. Infection control measures for drug-resistant cases are even more important than for susceptible cases.
2. The pulmonology hospital in Peja should negotiate the sharing of equipment with the regional hospital, taking the necessary precautions to prevent contamination and thus transmission of TB.
3. The Ministry of Health should consider how to persuade at least one more pulmonologist to build up expertise in MDR-TB. Having only one pulmonologist dealing with MDR-TB in Peja makes the system vulnerable. Written guidelines on case-finding, case management and standard operating procedures should be developed to support the clinical management of patients with drug-resistant TB.

4. Culture by liquid media and DST should be limited to the central reference laboratory in the Institute of Public Health in Pristina. The laboratory in Peja is not suitable to function as a level 2 plus or level 3 reference laboratory.
5. A realistic forecast of the number of MDR-TB cases to be expected in the next few years is needed. Given the low failure rate and the small number of reported retreatment cases, it is likely that few new MDR-TB cases will emerge. The size of the backlog of chronic cases is unknown. Technical assistance may be needed.

## **Introduction**

The Regional Office organized three technical missions (in 2007, 2009 and 2010) to assist Kosovo to establish a system for the management of MDR-TB.

## **Size of the drug resistance problem**

The drug resistance survey finalized in 2010 found no MDR-TB among new patients and 11.5% among retreatment cases (Annex 5). At present, there are four patients with confirmed MDR-TB in Peja pulmonology hospital. The KTP management knows of a fifth patient who may soon start treatment.

There is only a small number of treatment failures. In 2010, 29 smear-positive relapses and 17 smear-negative retreatment cases were reported. Assuming that 11.5% of these retreatment cases have an MDR-TB strain, five new MDR-TB cases per year can be expected from this pool of patients. There is no chronic TB case register but the KTP staff know of 25–30 chronic patients who probably had drug-resistant TB; most of them have died.

The establishment of routine surveillance would indicate the real extent of drug resistance in Kosovo.

The size of the MDR-TB burden seems relatively small but may increase when molecular tools are more widely used for rapid diagnosis. This will increase the financial burden of MDR-TB accordingly.

## **MDR-TB centre**

A new building has been built within the regional general hospital complex in Peja, 80 km north of Pristina, to provide adequate treatment for patients with MDR-TB. The two-storey building is designed for 56 beds. The major construction was completed by December 2010, but because of budget constraints it could not be finished during 2011. In August 2012, it was decided to complete the work and procure equipment for the first floor of the building. The official opening was 28 November 2012. There is still a shortage of funds for routine maintenance.

The new hospital building has 27 pulmonology beds (five for MDR-TB, nine for TB, four for daily treatment and nine for other pulmonary cases). One corridor has single rooms for patients with MDR-TB, each with its own bathroom. The corridor has access to the garden and could have a separate entrance for visitors. There are no doors in the corridor separating the susceptible TB cases from the drug-resistant cases. Separating the two parts of the corridor would greatly diminish the risk of nosocomial transmission. It is a pity that during reconstruction, little attention was given to infection control measures.

The regional hospital has equipment that the pulmonology hospital occasionally needs. Since there is no formal collaboration between the two hospitals, the TB coordinator is considering procuring his own equipment. One obstacle to sharing equipment is the perception that TB patients could contaminate the equipment. Since funds are scarce, health authorities should look into the conditions in which sharing of equipment by the two hospitals is feasible.

The University Hospital for Pulmonology Diseases in Pristina does not admit patients with drug-resistant TB. Patients found to have drug-resistant TB during admission are transferred to Peja.

## **Policy**

There seems to be no awareness of the need to set up a sustainable system for treatment of MDR-TB that goes beyond the management of the present four patients. It is not clear if an additional application to the Green Light Committee will be made to expand the current patient treatment cohort. The size of the expanded cohort should be estimated on the basis of the number of chronic patients already known, the number of resistant cases last year, and the estimated number of newly emerging MDR-TB cases.

The strategic plan for 2012–2016 states that:

- all patients with pulmonary TB should have a culture examination and the possibility for rapid DST;
- no case of MDR-TB should remain undetected and untreated;
- DOT should be organized for all MDR-TB patients during the intensive and continuation phases;
- the ambulatory component of TB care should be further strengthened;
- infection control measures should be improved.

## **Clinical management**

Until recently, it was difficult to diagnose and treat drug-resistant cases, as second-line anti-TB drugs were scarce and of unknown quality and had to be paid for by the patient. This changed at the end of 2012 with the arrival of second-line drugs from the Global TB Drugs Facility. Four patients then started treatment free and are currently hospitalized in the Peja pulmonology hospital for the intensive phase. The continuation phase of treatment will be in ambulatory health facilities near to the patients' homes, which have already been contacted.

An expert group (consilium)<sup>6</sup> has been established to decide on the treatment regimen. There are no written clinical guidelines for MDR-TB, and physicians seem to rely on the advice of a WHO consultant. The regimen used for MDR-TB cases includes capreomycin, levofloxacin, cycloserine, ethionamide and 4-aminosalicylic acid. No DST has been performed for the second-line drugs (which are not available in the Institute of Public Health).

The patients do not have audiometric or optometric tests before starting treatment. There is no clear (written) protocol regarding tests to be done before and during treatment. The expert group follows up treatment progress by monthly sputum smear and culture examinations. During the

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<sup>6</sup> A specialized team or panel of experts with medical professionals covering complementary aspects of care (clinical (for adults and children), surgical, radiological, public health, psychological and nursing).

ambulatory phase, second-line drugs will be delivered to the regional TB coordinators. Ancillary drugs to cope with adverse reactions have not been procured by the KTP. None of the MDR-TB patients has been tested for HIV co-infection.

Patients with drug-resistant TB should receive the same incentives as those with susceptible TB after hospital discharge (a food and hygiene package once a month), but increased support is planned as part of the workplan for the Global Fund grant.

## **Human resources**

Of the eight pulmonologists in Peja pulmonology hospital, only the TB coordinator is willing to take care of MDR-TB patients. His expertise in the clinical management of MDR-TB is still limited. The review team is concerned that, as regional TB coordinator, he will find it difficult to combine the clinical care of patients with supervision of the TB programme. In addition, having only one doctor who is building up competence in the clinical management of MDR-TB makes the system very vulnerable. At least one more doctor should be trained to work with drug-resistant cases.

Staff of the Peja laboratory will need additional training if and when new equipment is installed.

## **Green Light Committee**

Second-line drugs for 20 MDR-TB patients were approved by the Green Light Committee in 2010. The first shipment arrived in October 2012 and the next shipment is due in July 2013. Given the limited capacity to do DST, it is questionable if enough MDR-TB patients will be identified during the shelf-life of some of these drugs.

A number of the recommendations of this review mission repeat the recommendations of the Green Light Committee consultant, indicating that implementation of the recommendations has been slow. The main reason for this seems to be inadequate human and financial capacity.

## **TB and HIV co-infection**

### **Recommendations**

1. Consideration should be given to developing an advocacy, communication and social mobilization strategy that covers TB/HIV co-infection.
2. The KTP and the Kosovo HIV/AIDS Committee should meet regularly (twice a year) to discuss common obstacles and joint interventions.
3. Information on HIV status should be included in the TB treatment card or a system of anonymous reporting developed so as to estimate the prevalence of TB/HIV co-infection.
4. Voluntary HIV counselling and testing should be expanded to cover all TB patients.
5. The guidelines on TB/HIV should be finalized.
6. The Kosovo HIV/AIDS Committee should be involved in the development of TB treatment guidelines, where these are of importance for people living with HIV.

## Introduction

The situation regarding sexually transmitted infections, HIV and AIDS in Kosovo is uncertain because of a lack of reporting accurate information and prevention programmes. Although HIV prevalence probably is low, particular elements are present that may lead to a rapid spread of the epidemic if it is not addressed in the early stages:

- a large young population with high rates of unemployment (over 50%);
- an environment characterized by poverty;
- recent rapid social changes;
- increased drug use (up to 0.3% of the total population);
- a thriving sex industry connected with human trafficking and organized crime;
- a highly stigmatized group of men who have sex with men;
- high mobility of the population to and from European countries with higher HIV prevalence rates; and
- approximately 40 000 international development, civil and military personnel, including many unaccompanied workers (10).

These findings were reported in 2007, but the situation has not changed substantially since then.

## Burden of HIV

Based on the limited data available and the classification system of the Joint United Nations Programme on HIV/AIDS, the HIV epidemic in Kosovo is categorized as low-level. Until December 2012, a cumulative 85 HIV infections had been diagnosed. In 2010 the nongovernmental organization Kosovo Association for People with HIV/AIDS reported the annual incidence of HIV infection as relatively low. The average age of HIV-infected persons is 30–45 years (11).

Given Kosovo's history of conflict and human trafficking and high rates of emigration and immigration, it can be assumed that the HIV burden is underestimated. Routine surveillance is not carried out. The prevalence of HIV infection among pregnant women is not known.

## Strategy

The Global Fund Round 7 grant for HIV/AIDS aims to maintain HIV prevalence among key at-risk groups at the currently low level of less than 5%, and to prevent HIV from spreading to other groups.

Screening of people living with HIV for TB is routine under the strategy for HIV/AIDS for 2009–2013.

The Kosovo HIV/AIDS Committee coordinates the HIV/AIDS programme. The principal recipient for the Global Fund grant is the Community Development Fund. The nongovernmental organization Anti-DANS is a sub-recipient of the Global Fund Round 9 grant and provides HIV testing for TB patients. The public sector has only one voluntary counselling and testing centre, in Pristina, which tests 400 people a year, indicating that the majority of people tested are TB

patients. The Global Fund grant allowed for testing of 200 people in the first year and 160 people in the second year. Anti-DANS decided to increase the number for the second year to 200. It plans to set up seven voluntary counselling and testing centres in the next three years in TB services with the target of testing 1400 people for HIV, although this would still not cover all TB cases detected. Training of staff to provide voluntary counselling and testing will also take place and the goal is to make these services sustainable with public funding.

In 2012, an external consultant developed TB/HIV guidelines and conducted a two-day workshop for pulmonologists and infectious disease specialists to discuss them. These guidelines have apparently not been finalized and they were not available at facility level or in the KTP (although 500 copies are reported to have been distributed). The consultant also discussed point-of-care testing for TB infection among HIV-infected people.

## **Voluntary counselling and testing**

A proportion of TB patients are offered HIV testing free of charge. Testing is voluntary and formal consent is required for the test. However, the uptake is low for various reasons. In Peja pulmonology hospital, none of the MDR-TB patients had been tested for HIV.

During a five-year period, Anti-DANS tested 920 TB patients for HIV in Gjilan, Peja, Pristina and Prizren. Of all cases tested, only one was positive, which may reflect the small number of people living with HIV in Kosovo. Routine testing in Peja is planned to start in the second half of 2013.

Immediately after an HIV infection has been diagnosed, testing for TB by tuberculin skin test or chest X-ray takes place. The Kosovo Association for People with HIV/AIDS keeps the register.

Voluntary counselling and testing is available in the penitentiary system but the uptake of the test is very low, despite the presence of information materials.

## **Treatment**

Antiretroviral treatment is available in Kosovo, purchased with domestic resources. Cotrimoxazole preventive treatment is also available. Isoniazid preventive treatment is not routinely given to HIV-positive people with latent TB infection.

Post-exposure prophylaxis was discussed at the TB/HIV workshop in September 2012, but no information is available about its implementation.

## **Recording and reporting**

Data on HIV are not reported on the TB treatment cards (the HIV status is considered to be confidential) to they are not included in the aggregated reports. Only through annual cross-checking of Pristina hospital treatment cards and Anti-DANS records is it possible to assess the coverage of testing.

## **Advocacy, communication and social mobilization**

Stigma is still an issue in Kosovo, but information campaigns are trying to reduce it. It is especially important to know the HIV status of TB patients. Keeping such information confidential precludes adequate knowledge of the problem and hampers clinical management.



The Red Cross Society of Kosovo has a programme to raise awareness about the risk of HIV and AIDS among young people. Project activities will be implemented at 13 Red Cross branches. A training of trainers session has been conducted for peer educators. As part of the celebration of World AIDS Day in 2012, in addition to awareness campaign rallies, a workshop entitled “0 to discrimination” was conducted in collaboration with the Institute of Public Health. The Red Cross has no activities directly targeted at TB/HIV co-infection, although raising awareness indirectly contributes to preventing and reducing the problem (12).

## **TB control in prisons**

### **Recommendations**

1. Infection control in the penitentiary system should be improved, especially in the prison health service in Dubrava. Probably the easiest way is to provide upper-room ultraviolet germicidal irradiation appliances in the TB patient rooms and open windows for ventilation.
2. Prison staff in contact with, or possibly exposed to, infectious cases should be provided with adequate N95 masks. The wearing of masks should be compulsory.

### **Structure of the penitentiary system**

The medical services in the penitentiary system are being transferred from the penitentiary to the civilian authorities.

There are six pre-trial detention centres in six regions. For convicted prisoners, there are three correctional prisons for:

- 200 males serving short sentences in Mitrovica
- 100 juveniles and 100 women in Lipja
- 1449 males serving long-term sentences in Dubrava.

A high-security prison for 400 inmates is under construction in Gërdovc.

### **Epidemiology**

From 2004 to 2012, 59 cases of TB were detected in prison. Only five occurred during incarceration, the others were detected on entry. Unlike in many countries, the notification rate for TB in prisons is comparable to that in the general population.<sup>7</sup>

### **Case-finding and diagnosis**

All detainees undergo a medical examination on entry in the system. They have to be seen by a doctor within 24 hours, who can order X-ray examinations or laboratory tests if needed. During detention, case-finding depends on prisoners presenting with symptoms. There is 24-hour access to medical services and a doctor visits all inmates at least once a week.

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<sup>7</sup> A total of five cases in nine years for a system with a capacity of 1850 prisoners gives a case rate of 30 per 100 000. The denominator of the prison population is, however, uncertain as it varies depending on turnover and the length of incarceration.

Sputum smear examinations are performed in the nearest public health laboratory.

Leaflets on voluntary counselling and testing and TB are offered to all prisoners, and HIV testing and general blood tests are available. If the front-line rapid HIV test is positive, blood samples are sent to Pristina for western blot confirmation. Only 27 prisoners have been tested so far. No HIV-positive cases have been registered.

## **Treatment**

TB patients can be treated in prison. A pulmonologist from the nearby anti-TB dispensary initiates and regularly supervises treatment. The prison nurse ensures DOT.

Patients with serious illness needing hospital care are sent to a civilian health facility. The regional hospital in Peja has two detention rooms. If a prisoner needs to be admitted to the TB ward, prison staff will guard him or her. In this situation, consideration needs to be given to prevention of transmission.

## **Infection control**

In the Dubrava prison hospital, the cells for TB patients are in the same area as the staff rooms. Since these cells may house prisoners with infectious TB, transmission of TB infection to prison staff is a risk. The staff rooms can be ventilated by opening the windows, but transmission can only be prevented by constructing a physical barrier or by finding alternative cells for infectious cases. Personal protection for the staff is poor: there are no adequate respirators, and those respirators that are available are not used. Staff occasionally wear paper surgical masks, which are inadequate to protect against TB.

## **Harm reduction**

The team was told that among 165 randomly selected prisoners, 4.1% had used intravenous drugs. No relationship with TB or HIV infection was found.

Methadone is available for drug users (there are an estimated 15 000 in Kosovo). Condoms are distributed but not syringes and needles.

## **Resources**

The medical department of the penitentiary system seems to be well-organized and no shortages of staff, food, drugs or other commodities were reported. Under the Global Fund Round 9 grant, Kasnecet e Ardhmerise address high-risk groups, including prisoners, but diagnostic and treatment costs are borne by the civil hospitals.

## **Ethnic minorities**

### **Recommendations**

1. Respect should be shown and trust built up in dealings with ethnic minorities.
2. Treatment/red cards should be analysed to measure the size of the TB problem among ethnic minorities in order to judge whether targeted interventions are needed.

According to the 2011 census, there are about 120 000 members of ethnic minorities in Kosovo. The largest groups are the Bosnians (27 500), Serbs (25 500), Turks (18 700), Gorani (10 200), Ashkali (15 400), Egyptians (11 500) and Roma (8800). The last three groups are related.

The Serbian minority lives primarily in two small enclaves in Gracanica and Shterpshe in the north. They have their own family medicine facilities. For second-level care they go to Mitrovica North Hospital, and for third-level care they go to Serbia. Although in some areas this distinction is less clear-cut, the same holds for TB. The Serbian health facilities take care of diagnosis and treatment of TB and report data to the Serbian authorities. The TB burden among the Serbs in Kosovo is unknown, but is likely to be similar to that in Serbia (16 per 100 000).

The Roma are a minority group dispersed through the territory. The Ashkali and Egyptians are related to the Roma. Ashkali are predominant in the regions of Ferizaj, Fushe Kosovo and Lipjan. Egyptians live in western Kosovo (Burim, Decan, Gjakova and Peja). The Association for Health Education and Development works in the Gjakova region, mostly with Roma. It trains community leaders and community health workers and tries to erase the stigma of TB.

There used to be a refugee camp for Roma in north Mitrovica, which closed after the municipality, with help from international donors, rebuilt the Roma Mahalla district on the banks of the river Ibar. Now approximately 2500 people live there with their own family medicine clinic (13).

Gorani, or “highlanders”, can be found in the triangle between Kosovo, Albania and the former Yugoslav Republic of Macedonia. Bosnians are predominant in Dragas and Prizren. The Turkish minority also lives primarily in and around Prizren. In general, these minorities live in communities that are easy to target.

Ethnicity is recorded on the red (identity) card but is not included in TB reports, so the burden of TB is unknown among these minority groups. They have the same access to health services as other inhabitants, but because of their cultural background they often do not use the services. In general, there is insufficient case-finding and diagnosis and reportedly less adherence to treatment.

In 2004, Doctors of the World published a study of TB control among ethnic minorities (14). A number of their conclusions are still valid:

- health providers should build trust with minority counterparts;
- improving access to services has two elements:
  - improvement of access to facilities
  - establishment of minority-focused services in minority communities;
- culturally sensitive health education is important.

## **Other vulnerable populations**

### **Recommendation**

1. Social determinants should be routinely recorded to help identify groups at high risk for TB.

## **Introduction**

The social determinants of developing TB include poverty, homelessness, unemployment and substance abuse. People living with HIV, prisoners, immigrants, refugees and ethnic minorities are also at risk. Often these categories overlap. People living with HIV, prisoners and ethnic minorities have been dealt with above.

## **Poverty**

All over the world, poor people and those from disadvantaged social groups suffer more illness and die younger than the more privileged. The World Bank rates Kosovo as lower-middle-income, having an average annual income of US\$ 3510 per capita with 34.5% of the population living below the Kosovo poverty line.

## **Unemployment and homelessness**

A large proportion of the Kosovo population – between 34.5% and 45% – is unemployed (3,15). Because the proportion is so large, unemployment can hardly be considered a risk factor for TB in Kosovo. No data are available on homelessness.

## **Substance abuse**

Estimates of the number of people who inject drugs in Kosovo range from 7000 to 17 000. The burden of TB in this group seems to be small.

A study undertaken in 2008 interviewed 100 intravenous drug users aged 19–49 years, 85 male and 15 female. The median age was 24 years; 98% reported that they had used drugs in the previous three months, 47% had been in a drug treatment or detoxification programme (almost all of them (94%) in Pristina) and 34% had undergone residential rehabilitation (16).

Of those surveyed, 16% had never been tested for HIV, 72% knew their status to be negative, 6% were uncertain if they had been tested and 8% did not know. TB was not explored.

## **Infection control**

### **Recommendations**

The recommendations of the previous infection control missions are exhaustive and detailed. Here only the most urgent requirements for action are mentioned.

1. The infection control activity plan should be endorsed and a central TB infection control coordinator nominated in the KTP management unit.
2. The interim guidelines of the US Centers for Disease Control and Prevention should be endorsed as a basis for further implementation of infection control activities, until the Kosovo guidelines have been developed.
3. The TB infection control plan should be finalized and a focal person designated to be responsible for infection control at each facility.

4. Infection control should be improved in all facilities dealing with pulmonary and TB patients based on a risk assessment at facility level.
5. Once interim guidelines have been put in place, intensive training should be organized on infection control at each level of the health system (peripheral and referral centres) so as to change incorrect behaviour.
6. All staff (including doctors) should wear respirators in all risk areas. Adequate respirators for personal protection of staff are available, but their use is haphazard.
7. Bio-safety measures should be improved in all laboratories practising high-risk procedures and the staff trained.
8. Consideration should be given to a triage system for fast-tracking coughing patients in reception areas.
9. Surveillance for TB infection and disease should be established among health care workers (14).
10. Health care workers in the prison system should be included in infection control training.
11. Prisons should be included in supervision visits by the TB infection control coordinator (once this person has been established).
12. Infection control in the MDR-TB ward in Peja should be dealt with by improving the layout through small reconstructions and positioning of upper-room, shielded ultraviolet germicidal irradiation lamps.
13. There should be a budget for regular maintenance of equipment and ventilation systems, as they lose their effectiveness when not working properly.

## **Introduction**

TB infection control involves a combination of measures aimed at minimizing the risk of TB transmission within populations. The foundation of infection control is early and rapid diagnosis and proper management of TB patients. It should be part of overall infection prevention and control policies, in particular those that target airborne infections (17).

A number of specific and detailed consultants' reports are available that include many general and specific recommendations for improving infection control.

## **Strategy**

Service delivery area 2.2 of the Global Fund Round 9 TB grant is entirely dedicated to improving infection control. Six health facilities or congregate settings (settings where a number of people gather) should have implemented infection control measures by April 2012 and another eight by October 2012.

## **Previous infection control assessments**

The fact that three WHO missions dedicated to infection control have taken place since 2010 underlines the importance of infection control policies and clear guidelines in Kosovo. The 2010 recommendations were mostly strategy-oriented: to nominate someone to be responsible for infection control in Kosovo and to develop an infection control activity plan, including a budget for implementation of specific recommendations and maintenance. In 2011, a visiting consultant

helped to draft the TB infection control activity plan and introduced a facility-based infection control plan, illustrated by doing a risk assessment in the University lung diseases hospital in Pristina. A 2012 mission noted that TB infection control guidelines had been developed. All three missions contained detailed recommendations for the main pulmonology hospitals in Peja and Pristina. The Peja pulmonology hospital, having been designated for the treatment of MDR-TB, was also critically analysed for implementation of infection control guidelines in two more general Regional Office reports. The first found that the Kosovo infection control plan was still in draft form and included specific recommendations for the Peja MDR-TB ward. Six months later, the second report found that, apart from having procured respirators, the infection control plan in Peja Hospital was not yet functional.

## **Administrative issues**

At the central level, there is a Committee on the Prevention of Nosocomial Infections, composed of 11 members from different backgrounds; the chairman is the representative of the KTP. The Committee has been working on developing general guidelines for infection control. Priority was given to methicillin-resistant *Staphylococcus aureus*, antibiotic resistance, surveillance of nosocomial infections, and sterilization, disinfection and decontamination. The Committee started to collaborate with the KTP in 2012 to develop guidelines on TB prevention and transmission. This work is planned to be completed in 2–3 years. For the moment, TB infection control guidelines of the US Centers for Disease Control and Prevention have been translated into Albanian.

In line with earlier recommendations, a draft TB infection control action plan has been developed but not yet endorsed. A TB infection control coordinator should be nominated at the KTP management level to supervise implementation of the infection control measures.

Regional facilities do not have focal persons to coordinate TB infection control measures, and there are no standard operating procedures on infection control.

In the Pristina University pulmonology hospital and Peja pulmonology hospital this mission found that infectious patients were separated from non-infectious patients and MDR-TB cases were separated from drug-susceptible cases.

There is a general tendency to shorten the time of hospitalization, which is an important contribution to reducing nosocomial transmission.

The central reference laboratory has standing operating procedures available regarding action in case of an emergency or major incident. Laboratory staff at the central reference laboratory have received training on bio-safety in the past as part of more comprehensive training (culture and DST training). Two training courses have been held and questionnaires and checklists regarding infection control measures have been developed, which the staff of the central reference laboratory use during external quality assurance visits. These checklists include general questions on the use of personal protection devices, layout of the facility and disinfection. External quality assurance visits do not, however, specifically focus on infection control, but aim to obtain a general overview of the current situation. This could be an area for operational research but no plans have been made yet.

Since infection control has been recognized as important in the Global Fund grant, there is an opportunity to make improvements in the next few years.

## Engineering

The layout of the health facilities visited was not adequate for infection control. In some facilities, this was clearly the result of infrastructure limitations. In others, there was either limited awareness of the consequences or simply resistance to changing habits. In the University hospital in Pristina, old windows have been replaced by new windows with an extraction fan.

Some of the recommendations of the previous infection control missions have been implemented, but many important ones are still pending. For instance, in Peja hospital TB patients share a corridor with other respiratory disease patients and there are no ultraviolet germicidal irradiation shielded lamps. A ventilation system is under construction. The programme should introduce a triage system to fast-track presumptive TB patients in waiting areas.

Some laboratories do not meet the bio-safety requirements for performing hazardous procedures. Although the necessary equipment is available, no maintenance has occurred in recent years, rendering the equipment itself hazardous (see the section on TB case-finding and diagnosis above).

## Personal protection

The availability of personal protective devices (respirators and surgical masks) does not necessarily mean that they are used. It has been noted that at some sites, health care workers do not regularly and correctly wear the supplied respirators, while in some other health facilities (such as Dubrava prison), health care workers use surgical masks instead of respirators.

Personal protective devices are available in TB laboratories (respirators, gloves and laboratory gowns). The laboratory staff seem to be aware of when to use them.

## Management of drugs and other commodities

### Recommendations

1. Conditions in the central warehouse should be improved.
2. Interruptions in laboratory supplies resulting from delayed agreements between the various parties, including domestic distributors, should be avoided. Tuberculin for skin-testing should be available.
3. Second-line drugs should be ordered in good time. The second tranche of Global Drug Facility second-line drugs was supposed to be in Kosovo at the end of April 2013, but at the time of the mission it was expected to arrive in July 2013.
4. The stocks of drugs for MDR-TB should be monitored monthly and distributed in strict accordance with the “first expiring, first out” principle.

Detailed recommendations were given by Wehrens in 2012 (18).

## Introduction

This section cites many findings of the drug management consultant who visited Kosovo just a few months before the review, in November 2012 (18). The present mission looked critically

into the shortcomings noted in the report of that visit and discussed some of them with the acting head of the Pharmaceutical Department.

## **Product selection**

First-line anti-TB drugs (streptomycin, isoniazid, rifampicin, pyrazinamid and ethambutol) and second-line drugs for MDR-TB are available (Annex 8). Ancillary drugs are available through the regular supply of essential drugs ensured by the health authorities.

## **Stock**

In 2012, there was a brief period of shortage of some first-line drugs, which was overcome by re-distributing drugs between facilities. There were no shortages of laboratory reagents in 2013, although in the recent past culture media (both liquid and solid) were not available at the central reference laboratory. Some intravenous fluids were also out of stock in October–November 2012. Tuberculin has been out of stock for over one year.

It is official policy to keep a three-month buffer stock, but the drug management consultant doubted if this was done in practice.

## **Forecasting**

First-line anti-TB drugs are free in Kosovo. They are entirely procured through the Global Drug Facility, thus from prequalified sources, and the selection of drugs is based on international standards of treatment.

The calculation for first-line drugs is done using the Global Drug Facility forecasting tool, based on the assumption of 800 category one patients, 100 category two patients, and 36 paediatric patients. A buffer stock of 30% for adult formulations and 20% for paediatric formulations is added.

The procurement forecast for the MDR-TB patients was done with the assistance of the Green Light Committee consultant.

The data for forecasting the need for anti-TB drugs come from health facilities that provide TB treatment. They report monthly to their regional TB coordinators, who send aggregated monthly reports to the KTP, including separate reports on consumption and remaining stocks of drugs.

## **Procurement (resources, process, registration)**

All anti-TB drugs used in the TB programme are procured through the Global Drug Facility. Procurement requires an import licence, which takes a long time to process.

The Kosovo Medicine Agency requires imported drugs to be registered and labelled with the Kosovo medicinal import permission number. Although none of the Global Drug Facility anti-TB drugs have been registered with the Kosovo Medicine Agency, special permission has been granted for their import. All formulations are in the WHO Essential Medicine List 2012. This List contains two fluoroquinolones: ciprofloxacin and levofloxacin. However, ciprofloxacin should not be used in the treatment of TB.



The first delivery of second-line drugs arrived on 28 October 2012; the second delivery, which was scheduled for April 2013, was delayed until July 2013. Private pharmacies do not seem to have any anti-TB drugs.

Laboratory supplies follow a different route. Quotations for and purchases of consumables pass through the Community Development Fund, which is under contract for the import of laboratory supplies and other consumables. Every year, the Fund has to prepare an agreement with domestic distributors. In 2012, a shortage of certain laboratory consumables occurred because of delays in the negotiations.

## **Storage**

Products are stored in the central warehouse and distributed monthly to health facilities.

In August 2012, flooding in the central warehouse led to the loss of about 20 000 tablets (ethambutol, isoniazid and rifampicin). Additionally, the storage conditions at the warehouse in general do not offer sufficient protection against moisture and leakages. The limitations of the warehouse were well addressed in the report by the pharmaceutical consultant (18).

The acting head of the Pharmaceutical Department was not aware of the consultant's report, since she had only recently been appointed. A company had been contracted to refurbish the present building.

## **Distribution**

Hospitals are supplied from the central warehouse on a monthly basis. Additional orders may be submitted and are filled as long as they are approved by the Pharmaceutical Department. Distribution is outsourced to a private company.

TB patients are supplied monthly with drugs after discharge from the hospital.

## **Monitoring**

In 2010, a locally developed electronic pharmaceutical inventory control system (18), referred to as System Management Stock Pharmaceutical, was introduced. This Web-based system can be accessed from the Pharmaceutical Department, the warehouse, all the public hospitals and some of the lower-level health facilities. The staff at the warehouse only use the system to print picking lists for orders that have been approved. They cannot see the stock levels, but depend on their paper stock cards.

## **Drug management and pharmacovigilance**

The nongovernmental organization Health Agency for Development is the Global Fund grant sub-recipient in charge of TB medicine management. Some of the Agency's staff have been trained in drug procurement in the Netherlands.

The Health Agency for Development has two main areas of intervention:

- developing tools and training materials for drug management, conducting training and supervision, supporting the registration of pharmaceuticals;

- conducting training on pharmacovigilance.

The roles of international organizations, such as the Global Fund, Global Drug Facility and Green Light Committee, are currently crucial for the supply of anti-TB drugs.

## **Destruction of pharmaceutical waste**

The destruction of expired, obsolete and damaged drugs involves a number of public authorities, including those for the environment, health, agriculture and internal affairs. It is a lengthy and bureaucratic process, which has only been undertaken once since August 2011.

It appears that health facilities dispose of their pharmaceutical waste via, for example, their own incinerators. The volumes of pharmaceutical waste generated within the TB programme are fairly small, and this is not a major issue for the KTP.

## **Monitoring and evaluation**

### **Recommendations**

1. A supervision coordinator in the KTP management unit should be nominated to coordinate regular supervisory visits at all levels and in all areas of TB control and to support on-the-job training.
2. Staff should be trained or retrained in WHO definitions (including the latest definitions from May 2013) to produce reliable information through adequately completed forms, cards and registers.
3. A nominal electronic database should be started.
4. Monitoring and evaluation should be strengthened to allow periodic evaluation of the performance of the KTP for decision-making purposes, and the KTP's capacity for monitoring and evaluation should be enhanced.

## **Introduction**

The Kosovo health sector strategy 2010–2014 (19) cites the European Commission Handbook of Monitoring, which defines monitoring as "... the systematic and continuous collecting, analysing and using of information for the purpose of management and decision-making. The purpose of monitoring is to achieve efficient and effective performance of an operation." In TB control, information is produced by recording and reporting that allows the programme to be monitored and evaluated and, through supervision, performance to be strengthened, where necessary.

## **Strategy**

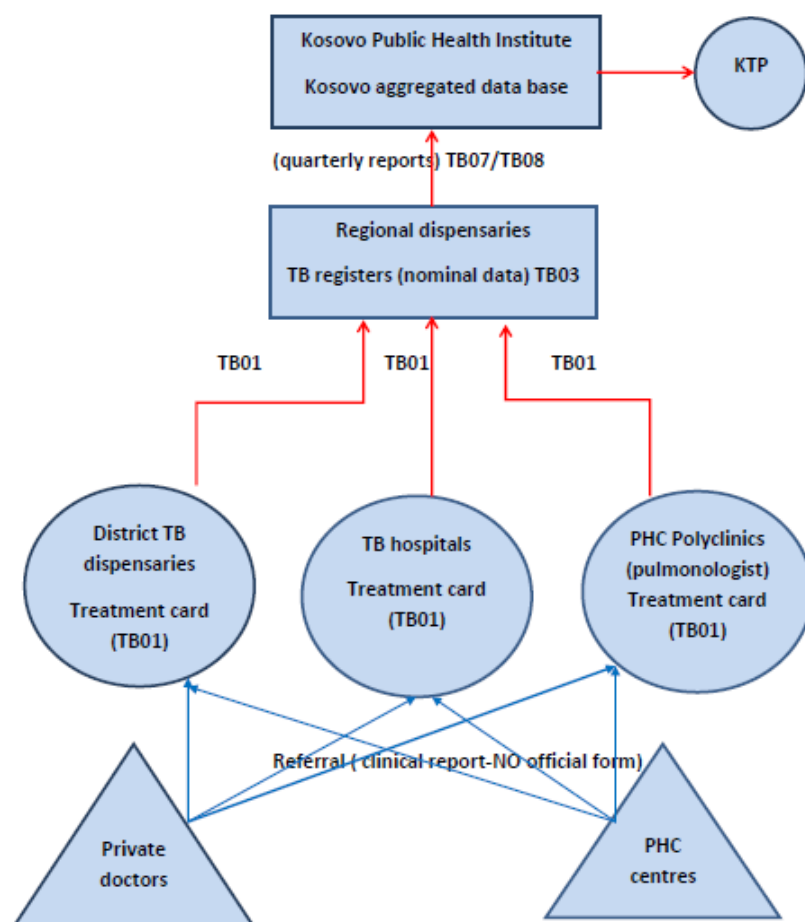
As part of the TB strategy for 2012–2016, a modern surveillance system compatible with the requirements of WHO and the European Center for Disease Prevention and Control will be put in place. In addition, a comprehensive monitoring and evaluation plan will be developed that deals with recording and reporting and includes a supervision plan.

## Recording and reporting

WHO-recommended cards, forms and registers are in use but there are many inaccuracies in recording. The system has not been updated since 2008 and its use is far from standardized. Errors are being made in, for instance, the categorization of patients as new or retreatment cases. A nurse or the TB coordinator fills in the registers. Initial training is being given and refresher training takes place twice a year. This might be one reason for the low number of retreatment cases reported (together with the high treatment success rate). The system is paper-based. Under the present Global Fund grant, a private company has been hired to develop an electronic recording and reporting system.

Treatment cards from peripheral centres are sent to the regional TB coordinator, who compiles quarterly reports. The TB registers are kept by the coordinator (Fig. 10).

**Fig. 10. Recording and reporting flow, KTP, 2013**



Note. TB01 or TB03 indicates a specific recording form.  
PHC = primary health care.

The TB coordinator sends the quarterly reports with aggregated data to the central database at the Institute of Public Health, where Kasnecet e Ardhmerise supports a focal point. The epidemiologist at the Institute “cleans” the reports, but this is limited to checking for major

inconsistencies and calculation errors as there is no way to change registration errors. The epidemiologist then puts the reports into an Excel database, which is shared with the KTP manager, the Community Development Fund and Kasnecet e Ardhmerise.

Data management at primary care level is not the same as in the KTP. In 2009, the Kosovan statistics recorded 1267 cases of pulmonary TB while the KTP reported 901 cases of all TB. The reason is that the primary health care system reports as TB every patient referred for TB diagnosis. This parallel reporting to the Institute of Public Health naturally leads to over-reporting. There is, however, no evidence that these data are used for decision-making.

Kasnecet e Ardhmerise has introduced a contact register to evaluate the performance of contact screening. It carries out supervisory visits to check whether the registers are filled in, and to calculate the proportion of contacts screened and the number of cases detected among contacts. Reports are generated, but their epidemiological meaning is unclear; they serve as evidence that contact-tracing takes place.

The KTP manager receives the reports after they have been processed and commented on by the Institute of Public Health. This delayed reporting may mask situations that need immediate attention. Some data are used for decision-making, but this is not routine. The current monitoring system does not capture indicators related to TB-HIV co-infection, MDR-TB and drug management.

In 2012, the Health Agency for Development assessed the TB supervision system in Kosovo. It recommended the adoption of the WHO definitions (updated in May 2013), development of training materials to improve the quality of recording and reporting, and consideration of the implementation of computer-based software, while maintaining the paper-based system. This should result in a health information system for monitoring purposes and possibly for drug management. The Agency suggested that monitoring and evaluation capacity should be developed to support the evaluation of the KTP and allow evidence-based adaptations to the TB control strategy. The capacity for supportive supervision at all levels should also be enhanced and adequate resources made available for the nomination of a monitoring and evaluation coordinator in the KTP management unit. None of these recommendations have yet been implemented.

## **Supervision, monitoring and evaluation**

Under the Global Fund Round 9 grant a new information system will be put in place, linking all TB laboratories in a single system from which patient and epidemiological data can easily be extracted. This will allow data to be checked at any time to allow correct patient management or changes in existing strategies. Access to this tool will be limited to specific people selected from each laboratory or office after dedicated training (20).

Since the end of 2012, coordination meetings at central level have been taking place quarterly attended by the KTP managers, the Global Fund Project Implementation Unit and the main sub-recipients. The KTP manager and the regional coordinators have been holding monthly meetings to review the performance of the KTP.

The regional coordinators routinely visit all TB centres in their region every three months. Cars and funds for this are provided through the Global Fund grant. There are no clear terms of reference for supervisory activities. Supervisors have not been trained in supervision and they

use standard checklists that have not been revised since the adoption of the Stop TB Strategy. The supervision schedule from the central level to the regional centres and dispensaries is unclear.

The Health Agency for Development supports supervisory activities financially, and provides specific support to the drug management component, checking for inconsistencies between reported cases and drugs requested and distributed.

## **Human resources development**

### **Recommendations**

1. A task analysis in TB control should be carried out urgently, as there will be shortages of TB specialists, microbiologists and laboratory technicians in the near future. Innovative thinking would enable tasks to be diversified and new job descriptions created, which could help alleviate the imminent shortages.
2. An educational programme should be created for public-health-oriented doctors on the programmatic approach to infectious diseases, strategy development, supervision, statistical analysis and reporting.
3. Some traditional tasks of TB specialists should be moved to family medicine doctors and nurses, who would require additional training, including in the practical approach to lung health.
4. Initiate a human resources development plan based on the above recommendations.
5. Consider filling the gaps by contracting out services to nongovernmental organizations that have the necessary capacity.

### **Introduction**

Kosovo aims to strengthen education at all levels. It has calculated future needs, including for medical education, based on the needs of the labour market (21). Quality health care requires a high level of medical professionalism. Services should be provided in a standard manner, and patients should perceive them as targeted to their needs. Improving the quality of the health system depends on the provision of continuous education, establishment of clinical protocols and guidelines, and establishment of structures for regular monitoring and evaluation of quality of care. These issues are addressed in the updated health action plan for 2011–2014 (22).

### **Strategy**

The first priority of the action plan is “to improve the health status of the population and the quality of health care services”. For human resources development, the main objective is to upgrade the level of professional medical knowledge and skills through improved education and training. This will require future human resources needs to be assessed, an educational plan to be established, and the capacities of family medicine and maternal and child health care to be strengthened.

## **Human resources in TB**

### ***TB specialists***

The University of Pristina has a medical faculty covering general medicine, dentistry, physiotherapy and nursing. Training in family medicine has become part of the medical curriculum. The University hospital offers postgraduate training in a number of specialities, including pulmonology. This is likely soon to develop into pulmonology, with a subspecialization in TB. Most such specialists already consider themselves as pulmonologists, rather than TB doctors.

Several specialists will retire soon and there are apparently no replacements available. TB control thus faces an imminent human resources shortage.

### ***Family medicine doctors***

Although their job descriptions do not officially include TB case-finding and case-holding, family doctors and nurses at the sites visited by the review team were fully involved in TB control issues. It is intended to use primary health care doctors more in the TB programme, which will necessitate an adequate job description and additional training. About half of the primary health care doctors have been trained in TB control or the practical approach to lung health strategy.

### ***Public health doctors***

The Institute of Public Health has students but it is not clear if they have an opportunity to study infectious disease programmes, in the sense of a set of coherent public health interventions that can be monitored, analysed and evaluated. These doctors could assist in strategy development, supervision, statistical analysis and reporting. Technical assistance may be needed to develop a postgraduate curriculum.

### ***Laboratory staff***

The Institute of Public Health provides training for microbiologists and laboratory technicians. A staff shortage will occur in the next few years as existing staff retire. Mycobacteriology will remain a subspecialty of microbiology; the number of positions to be filled will depend on the workload, the chosen methods and algorithms and the size of the laboratory network. A needs assessment is the first step; this should be done soon.

### ***Nurses***

No shortages in nursing staff are expected. Nurses should be trained in sputum collection, treatment delivery, recording and reporting, TB health education and interpersonal communication. Special skills are needed for the nursing of MDR-TB patients. All nurses should be trained in general and TB-oriented infection control.

## **Task analysis and job descriptions**

TB control in Kosovo cannot continue to rely on TB specialists. Fortunately, diagnosis and treatment of TB have become easier, with simple, rapid diagnostic techniques and standardized treatment regimens delivered in fixed-dose combinations. Family medicine doctors can deal with

the majority of TB cases, under the supervision of a specialist consultant. In many instances, patients do not need to be hospitalized. Cases that are more complex, including those with drug-resistant TB, will need specialist attention in hospital.

In addition, more public-health-oriented doctors are needed to monitor and evaluate programme performance and progress. Nurses can carry out many activities, such as case-holding, treatment delivery and health education.

Analysis of the tasks in TB control could lead to the development of new job descriptions. Such an analysis should be done before human resources needs are assessed, since it will have repercussions for the educational plan envisaged in the action plan.

## **Contracting out**

If the public authorities cannot provide enough staff with specific skills, it could consider filling the gaps by contracting out services to nongovernmental organizations that have the necessary capacity.

## **Operational research**

### **Recommendations**

1. An operational research agenda should be developed for TB, outlining the priority topics to be studied, identifying key investigators and providing an adequate study budget. Case-finding and infection control are priority areas for operational research.
2. Guidelines and operating procedures should be standardized before operational research is started.

## **Introduction**

The organization of health services, their accessibility, patterns of service delivery, availability of equipment, competence of the staff and other service determinants influence the efficacy of TB control interventions. Operational research can help to determine which interventions are most cost-effective. Topics for research need to be prioritized. In setting an operational research agenda, it is also necessary to take into account who, or which institutions, can perform a particular study, how much time will be involved and how much it will cost. While operational research often uses routinely collected data, the dissemination of findings costs time and money. The outcomes of these studies are important for improved policy-making and better service delivery.

## **Research agenda**

Scientific research activities in the field of medicine are carried out in a number of institutions, including the University of Pristina Faculty of Medicine, the University Clinical Centre, the Institute of Public Health and the Centre for Development of Family Medicine.

Kosovo has an overall health research agenda, within which infection control and infectious diseases are mentioned as research priorities. Various topics within these disciplines may be supported, including prevention and diagnosis of TB and patient safety (23).

For operational research to be possible, interventions have to be standardized with consistent definitions and recording procedures. The review team suggests the following priority areas for research:

- improved case-finding, both programme-oriented (involvement of primary health care) and process-oriented (sample flow, rapid testing using molecular tools, turn-around time from onset of symptoms to first contact with health services to the start of treatment involving delays on the part of both patients and doctors);
- nosocomial transmission (contacts in aggregate settings and occupational hazards).

## **Ethics and human rights**

### **Recommendations**

1. The Patients' Charter for Tuberculosis Care should be introduced.
2. Ancillary drugs should be provided to combat adverse reactions to anti-TB second-line drugs, in accordance with human rights.
3. Staff should be protected from occupational hazards, including nosocomial transmission of TB.

### **Introduction**

Two fundamental elements of the right to health are equality and non-discrimination. The right to health is an inclusive right, which extends to both medical care and the underlying determinants of health such as adequate sanitation, safe water, adequate food and access to health-related information. It contains the interrelated and essential elements of available, accessible, acceptable and affordable health facilities, goods and services that are appropriate and of good quality. Good-quality health facilities require skilled health workers, who receive domestically competitive salaries and whose own human rights are protected (for example, through a safe working environment and freedom of association, assembly and expression) (24).

### **Accessibility and affordability**

#### ***Poverty***

Health authorities must ensure that the health system is accessible to all without discrimination, including those living in poverty. Poor people will, however, encounter monetary barriers to private practices and most clinical specialists.

In Kosovo, a family medicine consultation costs €2 and a hospital consultation costs €4. These fees are paid to the facility, not to the physician. Poor people have a special identity card which entitles them to free health services.

Some public health services, such as for the diagnosis and treatment of TB, HIV/AIDS and sexually transmitted infections services, and opioid substitution therapy, are free for everyone. However, identification of drug-resistant TB cases is not optimal and treatment is not available for extensively drug-resistant TB (XDR-TB) or for treating adverse reactions to second-line anti-



TB drugs. In many facilities, the staff are not well protected from nosocomial TB transmission because infection control measures are poorly implemented or equipment is not well maintained.

Spending on health is comparable to that in countries with a similar gross domestic product to that produced by the people in Kosovo, but 40% of all health expenditure comes from out-of-pocket payments. Households pay about the same amount for health care regardless of their income, which means that people with the lowest incomes spend a much higher proportion of their income on health than those with a higher income.

Health financing is the most important mechanism that policy-makers have to influence the access, efficiency and equity of the health system. A new law on health insurance has been drafted, which would make health services more widely available to the poor.

## **Availability**

### ***Human resources***

A sufficient number of health care facilities and a sufficient quantity of goods must be made available to meet the preventive and curative health needs of the population, including the specific needs of subgroups of the population. This obligation encompasses the provision of enough trained medical and other personnel to meet the identified needs of the health service. The health system should ensure that health professionals are given appropriate incentives and infrastructure support to permit them to use their skills. These necessary inputs range from acceptable salaries to adequate facilities, supplies, equipment and pharmaceuticals.

There are enough physicians to serve the population. However, an inequitable health financing system, which relies on inadequate funding for the public sector and out-of-pocket payments for the private sector, has driven many of the most competent and experienced physicians into the private sector. The result is that skilled health professionals are not available to the general population. Moreover, salaries in the public service are low, which discourages doctors and nurses from participating if they have other options. At the same time, private services are well beyond the reach of most of the population. This leads to serious infringements of the right to health in the use and distribution of human resources for health.

### ***Essential drugs list***

Closely related to access to health professionals is the issue of access to essential drugs. Adequate financing, management and monitoring mechanisms are crucial. Essential drugs, as defined by WHO, must be available to the population.

Kosovo has an essential drugs list, which includes first- and second-line anti-TB drugs.

## **Acceptability**

Health services need to be acceptable in the sense that “all health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.” (22) This means that physicians, nurses and others must respect cultural and ethnic differences.

There has been significant progress in Kosovo in ensuring that health providers are respectful of minorities, particularly the Roma. Although there are some indications of continuing discrimination, poverty appears to be a greater barrier than lack of respect for culture or ethnicity.

## **Quality**

Quality requires: attention to medical education at all levels of training and professional development; availability of supplies and equipment for appropriate medical practice, including diagnosis and treatment; health information systems to ensure that health resources are allocated appropriately to meet needs and priorities; and mechanisms to ensure that appropriate care is given to individual patients and applied to specific conditions.

Kosovo has a successful nurse education initiative and family medicine training programme but the elements needed to ensure quality of care are not in place. There is a continuing medical education programme for physicians but it is not linked to the identified needs of the health system. Quality also suffers because of the lack of an appropriate health information system which can provide reliable information on how resources (including human resources) are being accessed and used as well as patterns of use or outcome parameters. Finally, quality suffers because of inadequate salaries for doctors and nurses in the public sector and a lack of tools, supplies and equipment needed to provide adequate care.

## **International Standards for Tuberculosis Care**

The International Standards for Tuberculosis Care describe a widely accepted level of care that all practitioners, public and private, should seek to achieve in managing patients who have, or are suspected of having, TB (26).

The basic principles of such care are the same worldwide. An accurate diagnosis should be established promptly, standardized treatment regimens of proven efficacy should be used with appropriate support and supervision, the response to treatment should be monitored, and the essential public health actions should be carried out. All providers who evaluate and treat patients with TB should recognize that they are not only delivering care to an individual, they are also assuming an important public health function that entails a high level of responsibility to the community.

The Kosovo TB Strategy for 2012–2016 is in line with the requirements of the International Standards for Tuberculosis Care although there are weaknesses in its implementation.

## **Patients' Charter for Tuberculosis Care**

The Patients' Charter for Tuberculosis Care outlines the rights and responsibilities of people with TB (27). The Charter sets out the ways in which patients, the community, health providers and policy-makers can work as partners in a positive and open relationship, with a view to improving TB care and enhancing the effectiveness of the health care process. It allows for all parties to be held more accountable to each other, fostering interaction and a positive partnership. Developed in tandem with the International Standards for Tuberculosis Care to promote a patient-centred approach, the Charter is in line with the health and human rights principles of the United Nations and other international organizations.

Kosovo has not yet implemented the Charter.

## **Advocacy, communication and social mobilization**

### **Recommendation**

1. The strategy on advocacy, communication and social mobilization should be finalized.

### **Introduction**

The fifth objective of the Global Fund Round 9 proposal deals with empowering TB patients and their community by improving knowledge and awareness of TB among the general population, TB patients and their family members and health staff. The ultimate aim is to increase knowledge among the public about early signs and symptoms of TB and to reduce the associated stigma in order to increase case-finding, early diagnosis and adherence to treatment.

### **Strategy**

The KTP wants to produce and disseminate more culturally appropriate information, education and communication materials, and to reach the general public through radio and television spots on TB, MDR-TB and TB/HIV.

A consultant provided technical assistance and helped with the drafting of an overall advocacy, communication and social mobilization strategy in August 2012 (28). The strategy has not yet been finalized.

### **Workplan**

A five-year workplan for 2012–2016 has been set out, detailing the activities to be put in place. Advocacy, communication and social mobilization activities are shared between two nongovernmental organizations.

- Kasnecet e Ardhmerise is responsible for the main advocacy, communication and social mobilization activities, including developing the overall strategy, producing advocacy, communication and social mobilization guidelines, training, organizing the World TB Day activities, and carrying out a survey of knowledge, attitudes and practice. The main target audiences for advocacy activities are journalists, media groups and decision-makers, including political, faith and opinion leaders. Informing these audiences about TB control should lead to increased and more accurate reporting in the media, greater attention and more funds allocated to TB control.
- The Association of Health Education and Development, based in Gjakova, is in its second year of activity and is mostly involved in community TB care. Its activities target community-based DOT interventions, such as identification of cases, referrals, collection and transport of sputum, monitoring of treatment, tracing of patients lost to follow-up and strengthening community awareness. A training curriculum for community health workers will be updated.

Continuous health education is given to TB patients and their families in all lung departments of all hospitals and in all TB dispensaries. The health education rooms are equipped with video and DVD machines and all have produced health education materials.

## **World TB Day**

World TB Day 2013 was marked by several activities, starting with a central event in which all key stakeholders participated, including pulmonologists and public health authorities, the KTP, the Global Fund, nongovernmental organizations and the Institute of Public Health. Some 50 people participated in this event, which was held in the newly built pulmonology hospital in Peja. Participants visited the MDR-TB unit within the hospital and presentations were given on achievements and challenges in TB control. The event ended with a conference for the media.

The KTP manager and her team gave interviews to all the main mass media (newspapers, radio and television). The most popular radio station broadcast a radio jingle about TB for three weeks. Children wearing T-shirts and hats with TB messages visited all the main centres of Kosovo and distributed TB leaflets and calendars. Some 3000 TB posters, 20 000 leaflets and 1500 desk calendars were distributed in health facilities and schools.

## **Community involvement**

Developing community involvement and awareness in order to reduce the stigma associated with TB is one of the main activities of the Association of Health Education and Development. The Association is currently active only in Gjakova region, mostly with Roma communities, training community leaders and community health workers. The intention is to expand the area of intervention geographically and to address schoolchildren, sexually abused women and marginalized groups.

Since 1999, four knowledge, attitudes and practice surveys have been conducted, but information from these surveys was not accessible.

## **Health system reform and TB control**

### **Recommendations**

1. Disease-specific databases that can exchange information for evidence-based decision-making should be developed. An overall health information system cannot comply with the specific requirements of monitoring TB control. This is probably true for other infectious diseases as well. The health information system should, therefore, be a matrix into which specific diseases will fit.
2. A system should be developed to supervise and guarantee quality care in the private sector. This is especially important for diseases that are public health threats.

### **Introduction**

Previously the health system in Kosovo, as elsewhere in eastern Europe, was largely based on the Semashko model of health care delivery with centralized decision-making and emphasis on specialization of services.

In 1999, the Kosovo health system was in need of improvement. External actors initially shaped the reforms, their scope and timing. Between 1999 and 2002, donors gave approximately €80 million for the health sector, which represented the second biggest amount (after education) in the Kosovo consolidated budget (29).

To ensure that donor funds were coordinated and sustainable, in September 1999 WHO produced interim health policy guidelines, informally known as the “blue book” (30). Consultations with major local and international stakeholders resulted in the publication of Kosovo’s health policy document, informally known as the “yellow book” (31). This document outlined the basic components of an ambitious vision for the health system in Kosovo (Annex 9).

## **Strategy**

The current Strategy of Health Care in Kosovo 2005–2015 (32) is in accordance with the Millennium Development Goals. Moreover, the Health Sector Strategy 2010–2014 has the mission “to develop a sustainable health system that provides quality services for all residents with the aim of achieving European Standards” (19). The strategic objectives for 2014 are:

- to reduce morbidity and mortality in the overall population;
- to improve the management of existing resources and quality of services;
- to bring the functioning, organization and infrastructure of the health care system, and the procurement of medical equipment, into line with European standards;
- to implement and further develop a health information system;
- to develop a sustainable funding system for the health sector.

The Action Plan for the Health Sector Strategy 2010–2014, launched in 2011, has five strategic objectives combined in three priority courses of action:

- improve the health status of the population and the quality of the health care services;
- improve management and leadership at all levels of the health care system;
- implement the health sector strategy and make the health sector ready for EU accession.

The Swiss Agency for Development and Cooperation, the Luxembourg Agency for Cooperation in Development and the World Bank support this health sector reform

## **Structure**

Both the public and private sectors in Kosovo deliver health care services. Establishing clear standards for the private sector, and for public as well as private health institutions, requires a well-functioning accreditation system. This is essential to ensure that the population experiences each health institution as part of a comprehensive health system.

### ***Primary care***

The yellow book committed Kosovo to a health system focused on primary care. Family medicine teams operating in primary care centres provide initial diagnoses and curative care, with the objective of treating 80–90% of patients. The location of health clinics is based on population size, with each facility having a catchment population of approximately 10 000 individuals. Larger communities have more extensive primary care facilities, known as family medicine centres, while smaller communities have small clinics (*punctas*).

In addition to diagnosis and curative care, family medicine centres are responsible for minor surgery and drug management, emergency care and stabilization of emergency patients,

maternal and child health care, and reproductive health services, including antenatal and postnatal care, family planning and treatment of sexually transmitted diseases. Prevention activities, such as health education and immunization, are also carried out by these centres, as are services such as home visits, palliative care, community rehabilitation and community mental health services.

The private primary health care sector may be the first stop for patients; it includes most of the pharmaceutical service and dental services, and some of the specialized diagnosis clinics.

### ***Secondary care***

The yellow book outlined a system in which patients would receive specialist care and be admitted to hospital only upon referral, except in emergencies. Specialists not working in family medicine are hospital-based. Hospitals in larger municipalities (Ferizaj, Gjakova, Gjilan, Mitrovica, Peja, Pizren, Vushtrri) provide secondary care. Some polyclinics in the private sector also provide specialist services.

Professional mental health services are also provided at secondary level through community-based mental health centres, community integrated houses and the Centre for Integration and Rehabilitation of Chronic Psychiatric Patients in Shtime.

### ***Tertiary care***

The University Clinic Centre, with several clinics and institutes, and the University Clinic Centre for Dentistry provide tertiary care. Tertiary care also includes central institutes, such as:

- the Kosovo Transfusion Centre, which manages the blood bank;
- the Kosovo Institute for Occupational Health, which is concerned with the health care of workers;
- the Medical Centre for Sport and Recreation; and
- the Institute for Public Health, which organizes programmes of health education, promotion, prevention and protection, as well as being the main centre for medical data collection and analysis.

These health institutions also serve as secondary-level institutions for the Pristina region.

### ***Public and environmental health***

The Institute of Public Health consists of one central institute with six regional institutes. These institutes are not well-connected with the rest of the health system, much of their equipment is obsolete and their health information systems function poorly. Under the health policy, the Institute of Public Health will be modernized and will concentrate on three areas: communicable disease control, health promotion, and water and food safety. The Institute provides information on public health issues. It should also guide and supervise public health activities at the district and municipal levels.

Public health is now a municipal responsibility and municipal public health inspectors have been recruited. Responsibility for immunization has been transferred to primary care facilities. A health information system has been put in place, but concerns remain regarding the ability of the

Institute of Public Health to provide reliable information and evidence-based policy advice to the health authorities.

## **Governance**

The yellow book outlines the responsibilities of the public health authorities, namely to monitor the health situation and implement appropriate measures to prevent and control health care problems, develop policies, implement legislation, coordinate activities in the health sector (including the management of the health care infrastructure), develop and implement norms and standards, and oversee adherence to these standards.

Overall capacity was not enhanced by the activities of donors, who generally had short time horizons and dispersed most of their programme funds in the first two years (1999–2001). While this ensured that immediate humanitarian needs were met, it undermined efforts to achieve longer-term development goals. Donors often focused on quantitative outputs, such as the number of health clinics re-equipped and nurses trained. Projects that were intended to contribute to the broader reform process, such as establishing standardized training and building the capacity of the civil service, were given secondary importance. While donors did coordinate their activities, they did not engage in a sector-wide approach. Most of their funds went to hundreds of nongovernmental organizations which did not report to the health authorities.

A new law dealing with health reform was enacted in April 2013. A law on health insurance reform is under discussion.

The health authorities are concerned about the position of the anti-TB dispensaries. The review team sees this as an aspect of health systems reform that should not be addressed as an isolated issue. Given the emphasis that will be put on primary health care and the development of TB care as a competency of the clinical pulmonologist, anti-TB dispensaries may become part of family medicine centres.

## **Human resources**

In 2012, 2546 physicians and 7184 nurses/midwives worked in the health care services; 472 doctors are working in primary health care. Family medicine centres usually have several family doctors and nurses and often have paediatricians, gynaecologist/obstetricians and other specialists attached as clinical consultants. In the cities, a general practitioner provides services to approximately 1200 adult inhabitants, while each paediatrician deals with up to 2000 children. In the villages, a physician provides services for all age groups to approximately 3000 inhabitants. In some remote mountainous areas, one general practitioner may have to provide services for up to 5000 inhabitants. The target is to have 1 family doctor for 2500 inhabitants. This would require 680 primary health care doctors, indicating that there is still 30% understaffing.

In September 2002, the Centre for the Development of Family Medicine was established in Pristina, along with eight regional centres for family medicine training. Family medicine was introduced into the curriculum of undergraduate medicine.

Since 1999, WHO has helped develop an education programme to improve the knowledge and skills of general practitioners. A course was developed, financed by the European Community Humanitarian Office and covering family medicine, child health, reproductive health, mental

health, common illness in primary care and common emergencies in primary care. One hundred doctors attended the first course, of whom 50 were selected to attend a course to become trainers. A family medicine centre for practical training was established in each of the seven regions, each with a clinical skills laboratory.

This WHO programme became the first year of a two-year fast-track specialization programme in family medicine. The second year covered management of the main health priorities (maternal and child health, prevention of heart and lung disease, TB, mental health and quality of care), patient presentations, and the learning domains of family medicine (doctor-patient relationship, applied professional knowledge and skills, professional and ethical roles, organizational and legal aspects and population health).

The Association of Family Physicians of Kosovo is responsible for continuing medical education. Doctors are assessed every five years, on the basis of their continuing medical education points and a personal portfolio containing a clinical audit and a personal development plan (34).

In 2012, specialization training started for 370 young doctors, dentists and pharmacists. The pharmaceutical sector in Kosovo is just beginning; there are three licensed producers.

## Financing

The health system continues to be funded out of the Kosovo consolidated budget (Table 3). As taxation has generated more revenue, the amount of money allocated to the health system has gradually increased. According to the health authorities,<sup>8</sup> the 2013 budget was €1.5 billion, of which €152 million (10.1%) was to be spent on secondary and tertiary health care in that year.

**Table 3. Total health budget (in €) by source, including allocation of capital expenditure, 2013**

Areas of health care	Central	Municipality	Total	%
Primary health care	90 616	42 658 541	42 749 157	28
Secondary health care + mental	30 776 710	2 809 707	33 586 417	22
Tertiary health care	36 946 508		36 946 508	24
Other	37 798 028		37 798 028	25
Administration	1 191 283		1 191 283	1
Total	106 803 145	45 468 248	152 271 393	100
Percentage	70%	30%	100%	

Primary health care is funded by the municipalities (€43 million for 54 family medicine facilities). The inadequacy of these funds is undermining the sustainability of the reform process. Private expenditure on health (out-of-pocket expenses for private services and pharmaceuticals, co-payments, and under-the-table payments) is higher than public expenditure. These additional costs for individuals create barriers to health care and undermine the equity of the system (33).

To build capacity, the Health Care Commissioning Agency has been developed as a forerunner to an insurance fund. The plan is for it to become an independent entity and to function as the basis for contracting services, which is necessary in order to split the purchaser and provider functions. The intention is to sign performance contracts with municipalities for primary care

<sup>8</sup> Professor Ferid Agani, personal communication, 23 April 2013.



and with hospitals for secondary and tertiary care. Essentially, the Agency should buy the services that these institutions provide, stipulating the type and quality of service.

Progress in establishing the Agency has been hampered by the absence of key inputs, such as accurate data, information and management systems and reward systems. A health insurance law has been presented to Parliament, providing for a mandatory contribution for a basic package of care and a voluntary contribution for additional care (35). It also envisages the existence of one public fund that will collect premiums from the citizens and contract services both to the public and private health care sectors. The law has not yet been passed (March 2014).

Private insurance companies are already functioning in Kosovo, and roughly 10% of the population is registered with them.

## **Achievements**

Progress has been mixed. The concept of family medicine has become part of the health system lexicon. The Kosovo Health Law enshrined family medicine as the “essential form for provision of overall health care services at the primary care level for individuals and their families” (36). Training programmes for both physicians and nurses have been initiated and include management of Kosovo’s health priorities – maternal and child health, prevention of heart and lung disease, TB, mental health, quality of care and patient prescriptions (33).

The gate-keeping role of primary care remains underdeveloped. Family medicine has faced resistance from specialists, who often believe that they are in competition with family doctors. These specialists often redirect those arriving at hospitals to their private clinics. Efforts to ensure that physicians do not abuse their ability to practise in both the public and private sectors have proved difficult. There is a limited regulatory capacity to oversee the private clinics. Stakeholders indicate that the quality of health care in the private sector is of serious concern because regulations are not respected.

Reform of the secondary and tertiary levels of the health system has received significantly less attention and financial support than primary health care reforms. Stakeholders believe that the public still perceive primary care as a stopping-point on the road to specialist care, not as a place to receive treatment. As a result, the specialist and tertiary levels remain significantly oversubscribed. Despite continued public reliance on hospitals, and the dysfunctional referral system, the health sector budget in Kosovo is evenly split between primary and secondary care services, even though secondary and tertiary care are much more expensive. This leaves hospitals underfunded for their level of activity, with few resources available to maintain the hospital infrastructure. While hospital master plans have been developed, the funding to implement these plans has consistently been lacking.

## **The impact of health sector reform on TB control**

### ***Strategic implications***

The emphasis on expanding family medicine services has contributed to a greater involvement of primary health care in TB control. Coverage is, however, still limited and much more should be done to increase its involvement (for example, in the areas of job descriptions, training and remuneration).

The action plan for 2010–2014 envisages the development of a human resources plan but areas of specialization have not been identified. Pulmonology will certainly be one area to consider, but specific attention to TB expertise is needed. The estimated cost for the implementation of the action plan is €43.9 million.

Objective 1.6 of the first priority action in the action plan (Improve the health status of the population and the quality of the health care services) is “Healthy lifestyles of the most vulnerable groups of the population improved”. Result 1.6.3 mentions “implementation of the HIV/AIDS strategy”, but TB is not mentioned in the action points, which is remarkable given its epidemiological importance compared with HIV/AIDS.

Under objective 1.8 (The burden of communicable diseases reduced), 1.8.2 is “Implement the Kosovo Programme for Prevention and Control of Communicable Diseases”. It can be assumed that TB control comes under this heading.

The fact that TB is not specifically mentioned may indicate that its impact on public health and social well-being have not yet been fully understood by policy-makers.

### ***Burden of respiratory diseases in Kosovo***

Respiratory diseases account for 3.6% of all diseases reported in Kosovo. However, reporting in general is incomplete, partly because the reporting system is still being developed. Of the respiratory diseases, TB is the second most common at 18.2%. TB accounts for 8% of all admissions to the University pulmonology department.

In a 2012 study, practical approach to lung health guidelines on respiratory diseases were present in 80% of the primary health care centres in the Giljan region, while in and around Pristina 80% of family doctors were unaware of them. Overall, 61% of family doctors do not know of their existence.

### ***Monitoring and evaluation: the need for a functioning health information system***

The action plan mentions the creation of an adequate health information system covering all areas of health, which is to be pilot-tested before being expanded to the whole of Kosovo. The budget is €2.8 million. Experience with TB recording and reporting indicates that an overall health information system cannot meet the specific requirements of TB control monitoring. This is probably true for other infectious diseases as well. The health information system should thus be designed as a matrix into which specific diseases will fit. However, this may be so complicated that it may be better to develop disease-specific databases that can exchange information with each other and with the health information system.

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## *Annex 1*

### PARTICIPANTS IN THE REVIEW

#### *International experts*

Dr Jaap Veen, Independent Senior Tuberculosis Control Adviser, Netherlands (team leader)

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Dr Emanuele Borroni, WHO Supranational Reference Laboratory for TB, San Raffaele Scientific Institute, Milan, Italy

#### *Kosovo expert*

Dr Rukije Mehmeti, Manager, Kosovo TB Programme, Pristina, Kosovo

#### *Other expert*

Dr Pierpaolo de Colombani, Medical Officer, TB and M/XDR-TB Programme, WHO Regional Office for Europe, Copenhagen, Denmark

## *Annex 2*

### PROGRAMME

#### **Monday, 22 April 2013**

08:30–09:15	Briefing meeting at WHO Pristina office	Dr Skender Sylja (WHO Representative, Kosovo)
09:30–10:45	Visit to the pulmonology clinic, Pristina University clinical centre	Dr Rukhya Mehmet (Head, KTP)
11:00–12:30	Visit to the Institute of Public Health, Pristina	Dr Gjyle Mulliqi (Head, Central Reference Laboratory) Dr Ariana Kalaveshi (Head, Communicable Diseases Surveillance)
13:00–14:30	Meeting	Professor Ferid Agani
14:45–16:45	Meeting with the Project Implementation Unit of the Global Fund Project (TB) (at Community Development Fund Office)	Dr Bahri Tigani (Project Manager)

#### **Tuesday, 23 April 2013**

09:30–13:00	Visit to Peja TB hospital and TB dispensary	Dr Brahim Beqiri (Director of the TB hospital)
14:30–15:30	Visit to the Dubrava detention centre (Gurrakoc)	Mr Ramiz Selmani (Director, Dubrava prison) Dr Milazim Gjocaj (Head, Prison Health System)
17:00	Departure for Pristina	

#### **Wednesday, 24 April 2013**

9:30–12:00	Visit to Ferizaj Family Medicine Centre	
12:30–13:00	Visit to Institute of Public Health	Professor Lul Raka (infectious diseases specialist)
13:15–14:45	Visit to Central Reference Laboratory	Dr Gjyle Mulliqi (Head, Central Reference Laboratory)
16:00–17:30	Project Implementation Unit Manager (Community Development Fund Office)	Dr Bahri Tigani (Manager, Project Implementation Unit)

#### **Thursday, 25 April 2013**

08:30–10:30	Visit to the anti-TB dispensary, Pristina	
10:45–12:00	Meeting, health authorities	Dr Curr Gjocaj (Director, Health Services Department) Dr A Turjaka (Centre for Development of Family Medicine) Dr G Ymerhalili (Head, Pharmaceutical Department)

13:15–16:30	Round table with nongovernmental organizations (at Institute of Public Health)	Ms F Hasani (Centre for Continuous Development of Nursing) Ms Lindita Avdyli (Acting Head, Pharmaceutical Department) Dr Xhevat Kurhasani (Kasnet e Ardhmerise) Dr Elmir Tarani (Association of Health Education and Development) Mr Shaip Krasniqi (Health Agency for Development) Dr Izet Sadiku (Anti-DANS) Ms Jehona Shalqini (Kosovo Health Foundation) F Kosova (Health for All)
16:30–17:30	Meeting with United Nations Office for Project Services Local Fund Agent (at Institute of Public Health)	Mrs Jehona Bajraktari (Local Fund Agent, Country Coordinator) Mrs Linsey Cole (Global Fund Portfolio Manager) Ms Jo-Angeline Kalambo (Global Fund Senior Programme Officer)
18:00	Arrival of Dr Pierpaolo de Colombani	Discussion of review findings

**Friday, 26 April 2013**

08:30–11:30	Preparation for debriefings	Team + Dr de Colombani
11:30–12:30	Debriefing meeting with WHO and Global Fund at WHO office, Pristina	WHO staff Global Fund staff
14:00–15:00	Debriefing	Dr Curr Gjocaj (Director, Health Services Department)

### *Annex 3*

#### LIST OF PERSONS MET

Dr Afrim Abazi, Director, Ferizaj anti-TB dispensary  
Dr Albina Ponosheci Bicaku, Acting Director, Organization Against Alcoholism, Narcotics, Smoking and AIDS  
Dr Arberesha Turjaka, Acting Head of Quality Control Unit and Coordinator for Development of the Health Sector Strategy  
Dr Ardita Tahirukaj, Public Health Officer, WHO Office, Pristina  
Ms Argjira Belegu Shuku, United Nations Office for Project Services, Local Fund Agent  
Dr Ariana Kalaveshi, Head, Division for Communicable Diseases Surveillance, Institute of Public Health of Kosovo  
Dr Bahri Tigani, TB Programme Manager, Project Implementation Unit, Global Fund to Fight AIDS, Tuberculosis and Malaria  
Dr Brahim Beqiri, Chief, Pulmonology Department, Peja Hospital  
Dr Curr Cjocaj, Director, Health Services Department  
Ms Drita Dauti, Nurse, Ferizaj anti-TB dispensary  
Dr Elmir Taraku, Director, Association of Health Education and Development  
Mr Fatmir Bislimi, Laboratory Technician, Institute of Public Health of Kosovo  
Ms Fekrije Hasani, Head, Centre for Continuous Development of Nursing,  
Professor Ferid Agani  
Dr Gazmend Zhuri, Chairperson, Kosovo Association of Pulmonologists  
Dr Gjyle Mulliqi Osmani, Head, Microbiology Laboratory, Institute of Public Health of Kosovo  
Dr Hilki Berisha, Director, Kosovo Health Foundation  
Ms Jehona Bajraktari, United Nations Office for Project Services, Local Fund Agent  
Dr Jehona Shalqini, Kosovo Health Foundation  
Ms Jo-Angeline Kalambo, Senior Programme Officer, Global Fund  
Ms Lindita Avdyli, Acting Head, Pharmaceutical Department, Ministry of Health  
Ms Lindsey Cole, Portfolio Manager, Global Fund  
Dr Lul Raka, Head, Committee on the Prevention of Nosocomial Infections  
Ms Luljeta Qerimi, Laboratory Technician, Ferizaj anti-TB dispensary  
Dr Milazim Gjocaj, Chief, Health Services, Penitentiary System  
Dr Naim Qerkini, Family Physician, Ferizaj anti-TB dispensary  
Dr Naza Kamberi, Lung diseases specialist, University Hospital, Pristina  
Mr Ramiz Selmani, Director, Dubrava prison  
Ms Sebahate Demi, Nurse, Ferizaj anti-TB dispensary  
Dr Shaip Krasniqi, Director, Health Agency for Development  
Dr Shekndije Kursani, TB Regional Coordinator Pristina, Pristina anti-TB dispensary  
Dr Skender Sylja, Head, WHO Office, Pristina  
Dr Xhevat Kurhasani, Director, Kasnecet e Ardhmerise



*Annex 4*

EPIDEMIOLOGICAL DATA FOR KOSOVO

**Table A4.1. Number of TB notifications, by category, Kosovo, 2001–2012**

Year	New SS+ cases	Extrapulmonary TB	Retreatment SS+ cases	All SS- cases <sup>a</sup>	All cases
2001	461	320	105	788	1674
2002	402	259	95	687	1443
2003	292	223	70	542	1127
2004	272	195	44	498	1009
2005	232	234	40	596	1102
2006	293	267	51	511	1122
2007	241	277	37	375	930
2008	280	223	44	401	948
2009	254	267	38	342	901
2010	287	299	29	305	920
2011	222	246	29	349	846
2012	250	266	23	429	968

<sup>a</sup> Calculated by subtracting the new SS+ cases, extrapulmonary cases and SS+ retreatment cases from the total number of notified cases.

**Table A4.2. Notifications of new SS+ cases as a proportion of all notified cases, Kosovo 2000–2012**

Year	All cases	New SS+ cases	
		No.	%
2000	1776	418	24
2001	1674	461	28
2002	1443	402	28
2003	1127	292	26
2004	1009	272	27
2005	1102	232	21
2006	1122	293	26
2007	930	241	26
2008	948	280	30
2009	901	254	28
2010	920	287	31
2011	846	222	26
2012	968	250	26

**Table A4.3. Proportion of SS+ relapses among all SS+ cases, Kosovo, 2001–2012**

Year	All SS+ cases	Retreatment SS+ cases	
		No.	%
2001	566	105	18.6
2002	497	95	19.1
2003	362	70	19.3
2004	316	44	13.9
2005	272	40	14.7
2006	344	51	14.8
2007	278	37	13.3
2008	324	44	13.6
2009	292	38	13.0
2010	316	29	9.2
2011	251	29	11.6
2012	273	23	8.4

**Table A4.4. TB mortality, Kosovo, 2000–2011**

Year	No. of TB deaths	Death rate per 100 000 population
2000	32	1.5
2001	46	2.1
2002	23	1.1
2003	32	1.5
2004	7	0.3
2005	23	1.1
2006	29	1.4
2007	25	1.2
2008	35	1.7
2009	26	1.2
2010	21	1.0
2011	18	0.9

*Annex 5*

**SURVEILLANCE OF DRUG RESISTANCE IN KOSOVO, 2008**

**Surveillance of Drug Resistance in Tuberculosis: Kosovo**

**SDRTB4 Summary of antituberculosis resistance as of: 12/15/2008**

**For: All Males & All Females (00 to 99 years of age)**

	New Cases		Previously Treated Cases	
	N	Pct	N	Pct
Total Tested	172	100.0%	35	100.0%
Fully Sensitive	136	79.1%	19	54.3%
Any Resistance	36	20.9%	16	45.7%
Mono Resistance				
H	1	0.6%	1	2.9%
R	1	0.6%	0	0.0%
E	1	0.6%	0	0.0%
S	29	16.9%	7	20.0%
H+R Resistance				
HR	0	0.0%	2	5.7%
HRE	0	0.0%	1	2.9%
HRS	0	0.0%	0	0.0%
HRES	0	0.0%	1	2.9%
H other Resistance				
HE	0	0.0%	1	2.9%
HS	1	0.6%	1	2.9%
HES	0	0.0%	0	0.0%
R other Resistance				
RE	0	0.0%	0	0.0%
RS	1	0.6%	0	0.0%
RES	0	0.0%	1	2.9%
Other Multiresistance				
ES	0	0.0%	1	2.9%
Any H Resistance	2	1.2%	7	20.0%
Any R Resistance	2	1.2%	5	14.3%

Source: Mycobacteriology laboratory (central reference laboratory). Pristina: Institute of Public Health of Kosovo; 2012.

*Annex 6*

**STAFFING AND BEDS IN TB FACILITIES**

<b>Facility</b>	<b>No. of doctors</b>	<b>No. of nurses</b>	<b>X-ray technicians</b>	<b>Laboratory technicians</b>	<b>Total beds</b>	<b>TB beds</b>	<b>MDR-TB beds</b>
Pristina hospital	10	31	1	2	68	18	
Pristina anti-TB dispensary <sup>a</sup>	2	6		2	0	0	
Podujeve	2	2	0	1	0	0	
Lipjan	1	1	0	0	0	0	
Shtimje	1	1	0	0	0	0	
Ferizaj <sup>a</sup>	3 (1)	2	2	1	0	0	
Kaqanik	0	1	0	0	0	0	
Malisheve	0	1	1	1	0	0	
Prizren <sup>a</sup>	9	16+3 <sup>b</sup>	0	1	42	20	
Klin	1	2	0	1	0	0	
Peja <sup>a</sup>	8	14+2	0	2	32	9	5
Gjakove <sup>a</sup>	3	2+5	1	1	24	12	
Skenderaj	1	1	0	0	0	0	
Gjilan <sup>a</sup>	6	9+4	2	1	32	14	
Mitrovica <sup>a</sup>	1	2+4	0	2	10	0	
<b>TOTAL</b>	<b>48 (1)</b>	<b>91+15</b>	<b>7</b>	<b>15</b>	<b>208</b>	<b>73</b>	

<sup>a</sup> Location of TB coordinator.

<sup>b</sup> Nurses in the hospital + nurses in the dispensary.

## Annex 7

# SUGGESTED ALGORITHMS FOR THE USE OF RAPID MOLECULAR TESTS IN KOSOVO

### Premises

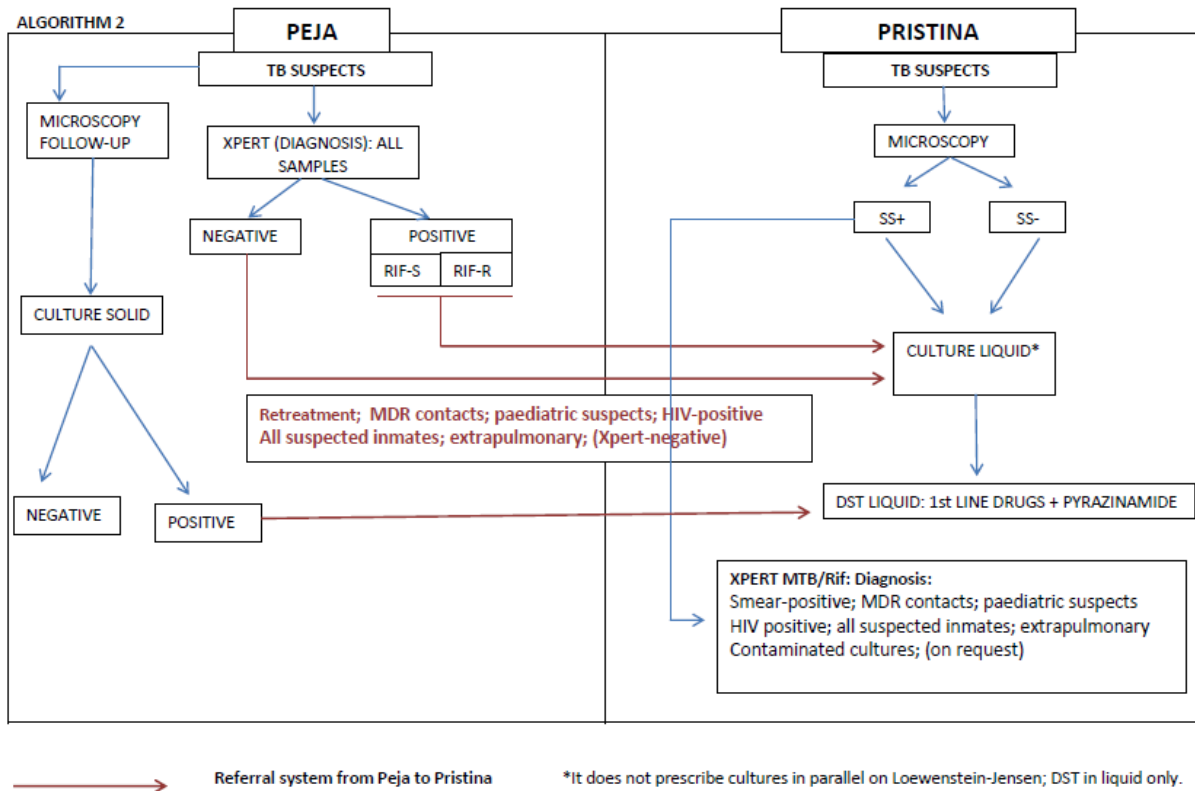
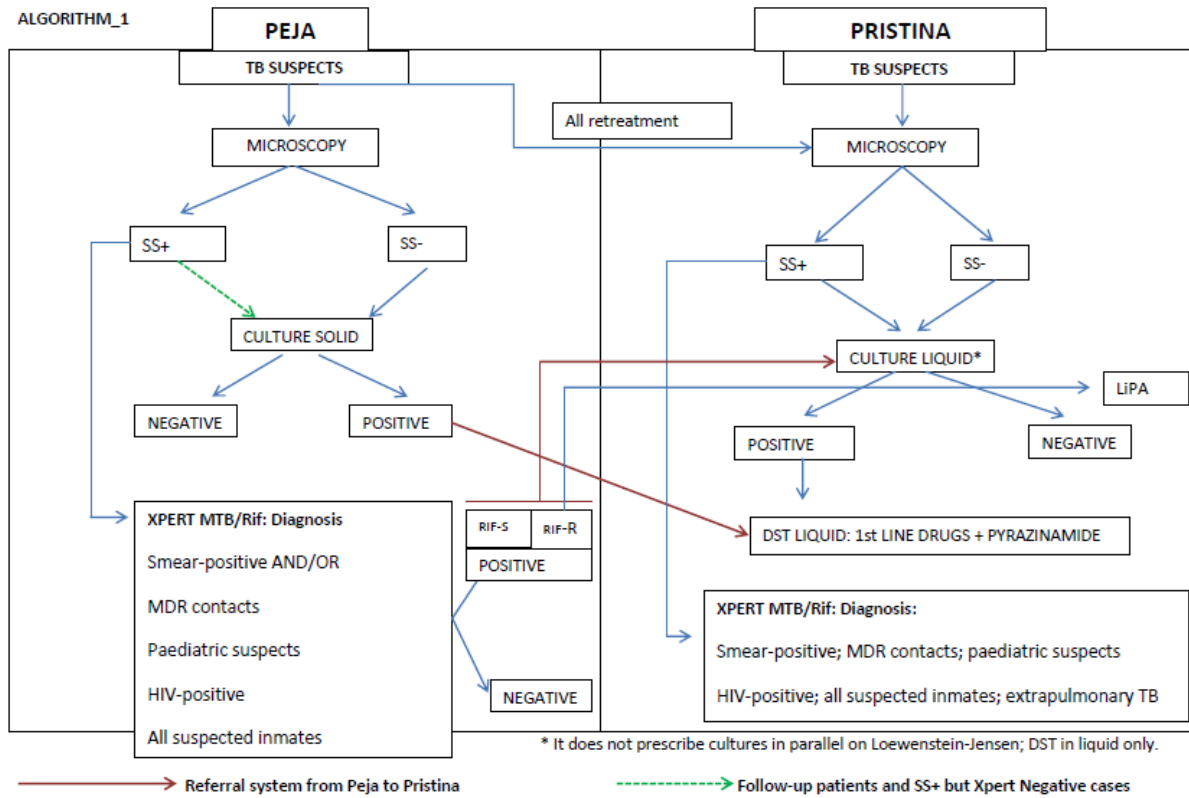
- Human resources plan for at least the central reference laboratory in Pristina. Need for additional laboratory staff.
- Bio-safety requirements fulfilled in both Pristina and Peja laboratories.
- Negotiated prices for new commercially available tools.

Algorithm 1	Algorithm 2
<p><b>Biological samples</b></p> <p><b>All</b> biological samples tested by culture (for both diagnosis and follow-up):</p> <ul style="list-style-type: none"> <li>- in Pristina: mycobacteria growth indicator tube liquid medium</li> <li>- in Peja: Lowenstein-Jensen solid medium</li> </ul> <p><b>Selected</b> samples tested by Xpert, in Pristina and Peja, for diagnosis only:</p> <ul style="list-style-type: none"> <li>- all retreatment cases</li> <li>- contacts of MDR cases</li> <li>- suspected TB in children</li> <li>- HIV-positive cases</li> <li>- all prison inmates with suspected TB</li> <li>- extrapulmonary cases</li> <li>- contaminated cultures (test the sediment)</li> <li>- smear- positive cases</li> <li>- on request</li> </ul> <p><b>Referral system</b></p> <ul style="list-style-type: none"> <li>- Positive cultures (at diagnosis and follow-up) in Peja sent to Pristina for DST in liquid</li> <li>- Biological samples from all retreatment cases sent to Pristina for culture in liquid (regardless of Xpert result)</li> <li>- Positive Xpert (at diagnosis): biological sample sent to Pristina for culture in liquid and DST if culture is positive</li> </ul> <p><b>Practical implications</b></p> <ul style="list-style-type: none"> <li>- Stop doing DST in Peja</li> <li>- Keep cultures on solid in Peja</li> <li>- DST in liquid only in Pristina</li> <li>- Purchase a new Xpert</li> <li>- Change the two-module Xpert in Pristina for a new Xpert</li> <li>- Increased workload in Pristina</li> </ul>	<p><b>Biological samples</b></p> <p>Biological samples tested by:</p> <ul style="list-style-type: none"> <li>- in Peja: Xpert (all samples received; diagnosis only, not follow-up)</li> <li>- in Pristina: mycobacteria growth indicator tube liquid culture (all samples received)</li> </ul> <p><b>Selected</b> samples tested by Xpert in Pristina, for diagnosis only:</p> <ul style="list-style-type: none"> <li>- all retreatment cases</li> <li>- contacts of MDR cases</li> <li>- suspected TB in children</li> <li>- HIV-positive cases</li> <li>- all prison inmates with suspected TB</li> <li>- extrapulmonary cases</li> <li>- contaminated cultures (test the sediment)</li> <li>- smear- positive cases</li> <li>- on request</li> </ul> <p><b>Referral system</b></p> <ul style="list-style-type: none"> <li>- Positive Xpert in Peja (at diagnosis): biological sample sent to Pristina for culture in liquid and DST if culture is positive</li> <li>- Negative Xpert in Peja: at risk suspects</li> </ul> <p><b>Practical implications</b></p> <ul style="list-style-type: none"> <li>- Stop doing DST in Peja</li> <li>- Do cultures in Peja for follow-up only</li> <li>- DST in liquid only in Pristina</li> <li>- Purchase a new Xpert</li> <li>- Change the 2-module Xpert in Pristina for a new Xpert</li> <li>- Increased workload in Pristina</li> </ul>

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<b>Algorithm 1</b>	<b>Algorithm 2</b>
<b>Budget implications</b> <ul style="list-style-type: none"><li>- New Xpert to buy (1 + 1 to change)</li><li>- Increased costs for liquid culture</li></ul>	<b>Budget implications</b> <ul style="list-style-type: none"><li>- Buy new Xpert (1 + 1 to change)</li><li>- Increased costs for liquid culture</li><li>- Higher costs for Xpert in comparison with algorithm 1</li></ul>
<b>Technical implications</b> <ul style="list-style-type: none"><li>- Xpert performed on decontaminated samples</li><li>- Keep the sediments for future tests, including retesting</li></ul>	<b>Technical implications</b> <ul style="list-style-type: none"><li>- Xpert performed on fresh samples</li><li>- The second biological sample of the suspect must be used</li><li>- If only one sample per suspect, the algorithm stops at Xpert test. Request a new sample.</li></ul>
<b><u>Points common to the algorithms</u></b> <ul style="list-style-type: none"><li>- Stop doing DST in Peja</li><li>- DST in liquid in Pristina only (including for pyrazinamide)</li><li>- All samples tested for either cultures or Xpert (100% testing of samples from TB suspects)</li><li>- Increased workload in Pristina</li><li>- Purchase of a new Xpert for Peja</li><li>- Change the Xpert in Pristina</li><li>- Purchase a new BacTEC MGIT960 for Pristina laboratory</li></ul>	
<b>Potential use of line probe assays (Hain) in Pristina</b> <ul style="list-style-type: none"><li>- Confirmation of rifampicin-resistant cases from biological samples or positive cultures</li><li>- In case DST contaminated, Hain from positive cultures</li></ul>	
<b>Rationale</b> <ul style="list-style-type: none"><li>- Peja hospital is the centre for MDR treatment, so it is important to have a TB laboratory performing at least culture</li><li>- Having two centres performing cultures would not overburden the laboratory in Pristina</li></ul>	<b>Rationale</b> <ul style="list-style-type: none"><li>- Xpert has almost the same sensitivity as solid culture. Its use in Peja for all suspects at the time of diagnosis would not decrease the detection rate</li><li>- Use of Xpert in Peja for all suspects at diagnosis would decrease rate of "unknown" results due to culture contamination</li><li>- Combination of liquid cultures and Xpert in Pristina would speed up and increase case-detection</li></ul>

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## *Annex 8*

### ANTI-TB DRUGS AVAILABLE IN KOSOVO

#### First-line preparations for adults:

- rifampicin + isoniazid, 150 mg + 75 mg tablets, in blister packs
- ethambutol, 400 mg tablets, in blister packs
- isoniazid, 300 mg tablets, in blister packs
- pyrazinamide, 400 mg tablets, in blister packs
- streptomycin 1 g, + water for injection + disposable syringes (auto-destruct).

#### First-line formulations for children:

- rifampicin + isoniazid + pyrazinamide, 60 mg + 30 mg + 150 mg tablets, in blister packs
- rifampicin + isoniazid, 60 mg + 30 mg tablets, in blister packs
- rifampicin + isoniazid, 60 mg +60 mg tablets, in blister packs
- ethambutol, 100 mg tablets, in blister packs
- isoniazid, 100 mg tablets, in blister packs.

#### Drugs for MDR-TB:

- capreomycin, 1 g, vial
- cycloserin, 250 mg tablets
- ethionamide, 250 mg tablets
- levofloxacin, 250 mg tablets
- 4-aminosalicylic acid, 4g sachet.

## Annex 9

### OUTLINE OF PROGRESS IN HEALTH REFORM

Reform objectives	Progress of reform
<b>Primary care</b> Location and services offered by family medicine centres would be based on population. Family doctors would have patient lists and be responsible for diagnoses and curative care, reproductive, maternal and child health, and emergency care and stabilization. Also responsible for coordinating specialist and tertiary care services. Private practice would be allowed, and physicians would be allowed to practise in both the public and private sectors, but institutions must be approved and regulated.	WHO established a facility master plan based on capitation, which guided rehabilitation and staffing. In minority areas, some facilities were opened that were not included in the master plan. Training in family medicine has been established. Serious impediments exist: patient registration is not universal, gate-keeping role of primary care is underdeveloped, and specialists resist primary care role. The health authorities lack the capacity to regulate the private sector, and there are accounts of physicians redirecting patients from the public sector to their private clinics.
<b>Secondary and tertiary care</b> Patients would receive specialist care and hospitalization only upon referral, except in emergencies. Hospital master plans will establish a vision for increasing the efficiency of hospitals.	Patients often bypass the primary care level to go directly to specialists. Hospitals are overburdened and under-resourced. While hospital master plans are being developed, the health authorities lack the resources to implement these plans.
<b>Public health</b> The Institute of Public Health would focus on communicable disease control, health promotion, and water safety. The Institute would operate as the technical arm of the Department of Health, providing it with information on public health issues.	Oversight of public health transferred to municipalities, public-health inspectors operate at the municipal level. Immunization transferred to primary care. A health information system has been established, but the ability of the Institute of Public Health to provide timely and accurate analysis is questioned.
<b>Health care financing</b> No commitment was made to any financing system, but a pledge was made to study the merits of various alternatives. Some form of prepayment system would be established through compulsory or voluntary insurance. Co-payments would be maintained.	Equity marred by significant private expenditure (including under-the-table payments). System funded out of the Kosovo consolidated budget. Precursor to a social insurance system, the Health Care Commissioning Agency, established. Establishment of the Agency and performance-based contracting have been undermined by the absence of accurate data and information and management systems. The failure to establish a transparent accounting system prior to the Health Care Commissioning Agency slowed efforts to implement health financing.
<b>Organization and governance</b> The central health authorities would be responsible for policy, strategic planning, regulation and standard setting. Responsibility for primary care would be decentralized to municipal level.	The senior health management was initially undermined by political turmoil, including changes and controversy surrounding the appointment of senior civil servants. Oversight for primary care became the responsibility of the municipalities in 2001. Municipalities slow to establish oversight structures, and their capacities vary.