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Review of the Tuberculosis Programme in Bosnia and Herzegovina

11–22 November 2013

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By:
Jaap Veen, Emanuele Borroni,
Askar Yedilbayev, Aleksandar Simunovic

ABSTRACT

A review of the TB programme in Bosnia and Herzegovina was organized by the WHO Regional Office for Europe on 11–22 November 2013. The review was requested by the Minister of Civil Affairs in view of the end of the support of the Global Fund to Fight AIDS, Tuberculosis and Malaria foreseen for September 2105. The review identified the major challenges and main recommendations for improvement.

Keywords

BOSNIA AND HERZEGOVINA
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Contents

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All the support received was highly appreciated and underlines the commitment to strengthen tuberculosis control in Bosnia and Herzegovina.

Acronyms and abbreviations

ATD	antituberculosis dispensary
BSC	biological safety cabinet
DB	District of Brčko
DOT	directly observed treatment
DOTS	first component and pillar element of the WHO Stop TB Strategy
DR	drug-resistant
DRS	drug resistance survey
DST	drug susceptibility testing
ECDC	European Centre for Disease Prevention and Control
EDL	essential drugs list
ELISA	enzyme-linked immunosorbent assay
EQA	external quality assurance
FBiH	Federation of Bosnia and Herzegovina
FLD	first-line drugs
FMC	family medicine centre
GDP	gross domestic product
GDF	Global TB Drug Facility
Global	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
IC	infection control
IDA	International Development Aid
IDP	internally displaced person
IEC	information, education and communication
IQC	internal quality control
ISTC	International Standards for Tuberculosis Care
KAP	knowledge, attitudes and practice
LED	light-emitting diode
LiPA	line probe assay
LTBI	latent TB infection
M&E	monitoring and evaluation
MDG	Millennium Development Goal
MDR	multidrug-resistant
MGIT	mycobacteria growth indicator tube
NATO	North Atlantic Treaty Organization
NGO	nongovernmental organization
NRL	national reference laboratory
OHR	Office of the High Representative
PAL	practical approach to lung health
PCR	polymerase chain reaction
PHC	primary health care
PIU	Project Implementation Unit
PPD	purified protein derivative
PPN	polyvalent patronage nurse
PTB	pulmonary tuberculosis
RCC	Regional Cooperation Council
RS	Serbian Republic
SAT	self-administered treatment

SEEHN	South-eastern Europe Health Network
SFOR	stabilization force
SLD	second-line drug
SOP	standard operating procedures
SRL	supranational reference laboratory
TB	tuberculosis
TST	tuberculin skin test
UN	United Nations
UNDP	United Nations Development Programme
UVGI	ultraviolet germicidal irradiation
VCT	voluntary counselling and testing
WHO	World Health Organization
XDR	extensively drug-resistant

Executive summary

In July 2013, the Council of Ministers of Bosnia and Herzegovina endorsed the implementation plan for the second phase of the Global Fund grant for "Strengthening of DOTS strategy and improving the National Tuberculosis Programme, including multidrug resistant and infection control in Bosnia and Herzegovina". The plan proposed an external review of the national tuberculosis (TB) programme, which the Minister of Civil Affairs, in a letter dated 4 September 2013, officially asked the WHO Regional Office for Europe to organize.

From 11 to 22 November 2013, four international experts visited 30 facilities and institutions in the Federation of Bosnia and Herzegovina (FBiH), Republika Srpska (Serb Republic, RS) and Brčko District (BD) to assess the epidemiological situation of TB and the features and performance of the TB programme.

Main findings

TB is still a public health problem in Bosnia and Herzegovina. For 2012, WHO estimated an incidence of 49 per 100 000 population (range 42–56), which is more than three times the average of 14 per 100 000 population in the European Union (EU). The review team found that a number of cases are not notified, so in reality the incidence is probably even higher. The epidemiology of TB reflects access to health services and the socioeconomic conditions of a country and, as such, should be taken into account in future discussions about joining the EU community.

Bosnia and Herzegovina reports a total budget for TB control of US$12 million in 2013, of which the Global Fund to Fight AIDS, Tuberculosis and Malaria contributes a significant proportion to support essential aspects, such as procurement of drugs and other commodities, outreach activities, overall coordination and supervision. The support of the Global Fund will end in September 2015 and will probably not be renewed, which will leave the country with a significant financial gap.

Combating TB requires a countrywide strategy and cost-effective joint actions by the different entities, which – given the complexity of the current public administration – will need to be carefully designed.

Infection control and biosafety

There is no proper awareness or understanding of the importance of airborne transmission of TB, especially in congregate settings, such as hospitals. The situation in almost all health facilities favours the transmission of TB.

Health information system

The data published and used in both FBiH and RS are different from those reported to WHO and the European Centre for Disease Prevention and Control (ECDC), reflecting the occurrence of errors and unnecessary duplication of workload.

Diagnostic algorithm

There is a – sometimes considerable – delay in the diagnostic process, as well as misunderstanding about what laboratory methodology to use when.

Management of drugs and other commodities

The current drug management system is highly dependent on the Global Fund, which carries the risk that it will not be sustainable when the grant ends in September 2015. This is especially true for second-line drugs used to treat multidrug-resistant TB, but also pertains to first-line drugs for susceptible strains.

Gaps in knowledge

During the visit, the team noticed mistakes and misconceptions by different types of health professionals of all kinds about several aspects of the programme, leading to wrong conclusions about needed interventions.

Ethical issues

The review team observed at least one example where the access to TB services for internally displaced persons coming from another entity was limited, despite the existence of a bilateral agreement between the two entities to cover each other's health expenses in such a situation.

Main recommendations

1. The highest authorities at state level, as well as in FBIH, RS and Brčko District, should further increase their commitment to combat tuberculosis as a public health issue. Cost-effective interventions should receive adequate administrative and financial support.
2. The Ministry of Civil Affairs, together with the ministries of health, should use the coming two years to ensure a smooth transition from the Global Fund grant.
3. Capacity should be created at the level of the Ministry of Civil Affairs, especially in relation to interventions of international relevance, such as central procurement of drugs and commodities, and data exchange with international bodies, such as WHO and ECDC.
4. Capacity should be created at the ministries of health for a central management TB unit, with full-time staff paid from government resources. They should oversee essential TB programme features, such as development of policies and guidelines, planning, laboratory services, training, monitoring and evaluation, and supervision

5. The Government should endorse the existing properly designed State infection control plan, which will contribute to preventing further spread of TB.
6. Implementation of the State infection control plan should start as soon as possible, as some of the recommendations may need a capital investment from the Global Fund.
7. The electronic TB database developed for the country should be implemented as soon as possible once the pilot phase is over. At the same time, the monitoring and validation of recording and reporting should be further strengthened and supported by adequate supervision to avoid systematic errors. Additional training in data management and analysis may be needed.
8. The TB control programme should introduce a clear diagnostic algorithm for laboratories, incorporating the new rapid molecular tests. This may lead to a reassessment of the workload and quality assurance programme of the laboratory network.
9. The Government should develop a plan for procuring medicines and other commodities at the level of the Ministry of Civil Affairs; pooling of FBIH and RS funds for central procurement will be more cost-effective and thus sustainable.
10. On the basis of analysis of data on performance, the TB programme should organize supportive supervision visits, associated with on-the-job training; this will strengthen programme and process management by individual staff members.
11. The ministries of health should build central capacity to guide this process of supportive supervision.
12. The ministers of health should resolve as soon as possible the issue of limited access to health care for internally displaced persons. Not only is this an ethical problem contrary to human rights, it is also a public health problem, as restricting access to health services may lead to uncontrolled transmission of communicable diseases.

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1. Introduction

Despite a history of effective public health interventions and programmes, tuberculosis (TB) is still common in Bosnia and Herzegovina. TB re-emerged as a public health problem in the aftermath of the armed conflict of 1992–95 and the estimated burden is among the highest in the Balkan subregion. The estimated incidence rate in 2012 was 49 (42–56) cases per 100 000 population. The burden of multidrug-resistant (MDR) TB is low, with only 7 cases in 2012, or rates of 0.14% among new cases and 9.8% among retreatment cases.[1]

In July 2013, the Council of Ministers of Bosnia and Herzegovina endorsed the implementation plan for the second phase of a grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), "Strengthening of DOTS Strategy and improving the National Tuberculosis Programme, including multidrug resistant and infection control in Bosnia and Herzegovina".[2] The plan includes an external review of the TB programme. In a letter dated 4 September 2013, the Minister of Civil Affairs officially asked the WHO Regional Office for Europe to conduct such a review, with financial support from the Global Fund.

The review had the following objectives:

- to assess the epidemiological situation of TB in Bosnia and Herzegovina;
- to assess the TB control programme, with reference to the TB-related Millennium Development Goals (MDGs), the implementation of the Stop TB Strategy, including use of the Global Fund grant, and the linkages with the health system;
- to develop specific recommendations for improving TB control and combating drug-resistant TB;
- to prepare a comprehensive report of the review;
- to prepare a report on behalf of the regional Green Light Committee (GLC).

The review took place from 11 to 22 November 2013, with logistics support provided by the WHO and UNDP country offices. The international and Bosnian experts (Annex 1) participating in the review analysed relevant documents already available, and conducted site visits (Annex 2) and interviews (Annex 3), both at central levels and in a number of areas, selected to reflect a range of epidemiological situations as well as geographical distribution and organization of TB services. On behalf of the regional GLC, the review also monitored interventions for preventing and controlling drug-resistant TB. At the end of the mission and accompanied by Dr Pierpaolo de Colombani, Medical Officer of the TB and M/XDR TB Programme at the WHO Regional Office for Europe, the review team presented an overview of the key findings and recommendations at a formal meeting with representatives of the Ministry of Civil Affairs and the ministries of health of the Federation

of Bosnia and Herzegovina (FBiH), the Republika Srpska (Serbian Republic, RS) and the District of Brčko (DB).

2. General information

Bosnia and Herzegovina declared its independence from the former Yugoslavia on 3 March 1992. In April 1992, it was accepted as a member of the United Nations and the World Health Organization (WHO). The declaration of independence was followed by an ethnic conflict, which continued until the signing of the Dayton Peace Agreement in 1995.

The Dayton Peace Agreement established the Office of the High Representative (OHR) to oversee the implementation of the civilian aspects of the Agreement. The Agreement retained Bosnia and Herzegovina's international boundaries, while acknowledging the existence of the two entities – FBiH and RS. On 8 March 2000, by decision of the OHR, Brčko became an autonomous district.[3]

The Peace Implementation Council, at its conference in Bonn in 1997, gave the OHR authority to impose legislation and remove officials, the so-called "Bonn Powers". A stabilization force (SFOR), led by the North Atlantic Treaty Organization (NATO), currently deploys around 600 troops in Bosnia and Herzegovina in a policing capacity.

Geography and population

Bosnia and Herzegovina is situated in southeastern Europe, bordering Croatia, Montenegro and Serbia, and has a small access to the Adriatic Sea. It has hot summers and cold winters, and is mountainous and prone to destructive earthquakes.[4]

There were around 3.8 million inhabitants in July 2013 – 2.3 million in FBiH, 1.4 million in RS and 95 000 in DB. The median age is 39 years; life expectancy for the total population is 76 years (males 73 years, females 78 years). The male:female ratio is 0.95. The literacy rate among people aged 15 years and older is 99% for males and 97% for females (2011 estimate).

Approximately three-fifths of the population are urban residents. Ethnicity and religion are relevant issues in Bosnia and Herzegovina. The three main ethnic groups are Bosnians (48%, mainly Muslim), Serbs (37.1%, mainly Orthodox Christians) and Croats (14.3%, mainly Catholics). Other ethnic groups, including Roma, make up the remaining 0.6%. The official languages are Bosnian, Croatian and Serbian.

As specified in the Dayton Agreement, Bosnia and Herzegovina is one democratic, independent country, whose basic principles – respect of human rights, equality and tolerance, continuation of international legal sovereignty, and democratic transformation of its internal systems – are rooted in the constitution.

Economy, administration and health services

Bosnia and Herzegovina has a transitional economy with limited market reforms. The economy relies heavily on the export of metals, remittances from abroad and foreign aid. The high level of fragmentation of the government hampers coordination and reform of economic policy, while the excessive bureaucracy and segmented market discourage foreign investment. Government spending is roughly 50% of the gross domestic product (GDP). The real growth rate in GDP in 2012 was –0.7%, while the GDP per capita was US$ 8400. Of the total population, 18.6% live below the poverty line (2007 estimate).[4]

The World Bank classifies Bosnia and Herzegovina as an upper-middle-income country, with an average annual income of US$ 4750 per capita.[5] High unemployment remains the most serious macroeconomic problem, with an unemployment rate of 43% in the general population and 57% among 15–24-year-olds (2011 estimate).

As a consequence of its ethnic composition and the Dayton Agreement, Bosnia and Herzegovina has a complicated administration. FBiH and RS are each responsible for formulating health policies, and organizing, financing and delivering health services within their territory. FBiH is divided into ten semi-autonomous cantons, inspired from the Swiss model, and 79 municipalities. RS is divided into two main regions (north-west and east), which are subdivided into two and five subregions, respectively (but without administrative autonomy), and 62 municipalities. The District of Brčko is a single administrative unit of local government under the sovereignty of Bosnia and Herzegovina.[6]

The Law on Ministries of 2003 recognized eight ministries at state level (for all of Bosnia and Herzegovina), including the Ministry of Civil Affairs, which is responsible for the coordination of health and social welfare.[7] In addition, both FBiH and RS have their own ministries.

Entities and cantons have their own ministries of health. Services are financed through local health funds, which reportedly function inequitably and inadequately.

Health expenditure doubled from US$ 546 million in 2005 to US$ 1153 million in 2010.[3] In 2008, the total expenditure on health was 10.3% of GDP; in 2010, 2011 and 2012, it was 6.8%, 10.2%.and 11.1%.[2] The main health indicators are shown in Table 1.

Table 1. Health indicators for Bosnia and Herzegovina[8]

Indicator	Value	Year
Population aged 14 years or under (%)	15	2010
Literacy rate among people 15 years and over (%)	97.9	2010
Median age of population (years)	39.2	2012
Life expectancy at birth (male/female) (years)	73/78	2011
Fertility rate	1.27	2012
Maternal mortality ratio (per 100 000 live births)	8	2012

Crude birth rate (per 1000 population)	8.7	2011
Crude death rate (per 1000 population)	10.6	2011
Number of physicians	6443	2010
No. of physicians per 1000 population	16.4	2010
No. of hospital beds per 1000 population	3.4	2009
HIV/AIDS prevalence rate in adults (%)	<0.1	2007

3. Epidemiology of tuberculosis

Notification

The TB notification rate in Bosnia and Herzegovina is the third-highest in the south-east Europe subregion, among the countries represented in the Regional Cooperation Council (Table 2).

Table 2. Notification rates for tuberculosis, selected countries, south-east Europe[9]

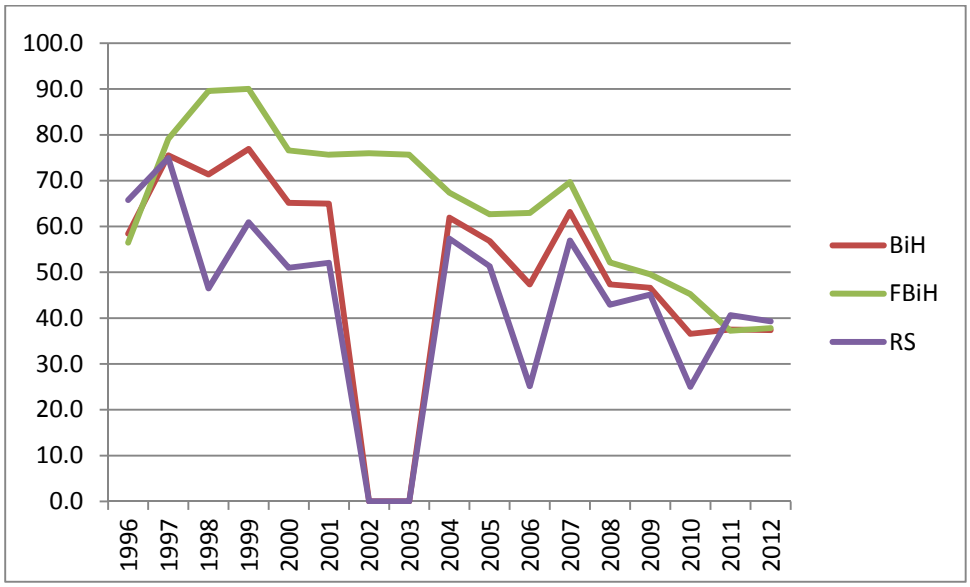
Country or area	TB notification rate (per 100 000)
Albania	16
Bosnia and Herzegovina	37
Bulgaria	29
Croatia	13
Former Yugoslav Republic of Macedonia	16
Montenegro	16
Republic of Moldova	125
Romania	74
Serbia (excluding Kosovo)	20

In 2012, the TB Programme in Bosnia and Herzegovina notified a total of 1301 (92%) new cases and 119 (8%) retreatment cases; 79% were laboratory-confirmed, mainly by sputum microscopy only. Of the new cases, 1123 (86%) were pulmonary TB (PTB). Of 1092 cases with a sputum smear result, 569 (51%) were sputum smear-positive. The review team considers this proportion acceptable, although 60% is the norm.

In 2012, the notification rate was 37 per 100 000 (37 in FBiH and 39 in RS); compared with the estimated TB incidence of 49 (42–56) cases per 100 000 population, this translates into a case detection rate of 76%. Figure 1 shows a similar decreasing trend in both entities. The annual fluctuations may be caused by variations in the quality of reporting. Since 2004, the

annual decrease is 4.8% in FBiH and 3.5% in RS, indicating that TB control efforts have been successful in both entities.

Figure 1. TB notification rates for Bosnia and Herzegovina (BiH), FBiH and RS, 1996–2012



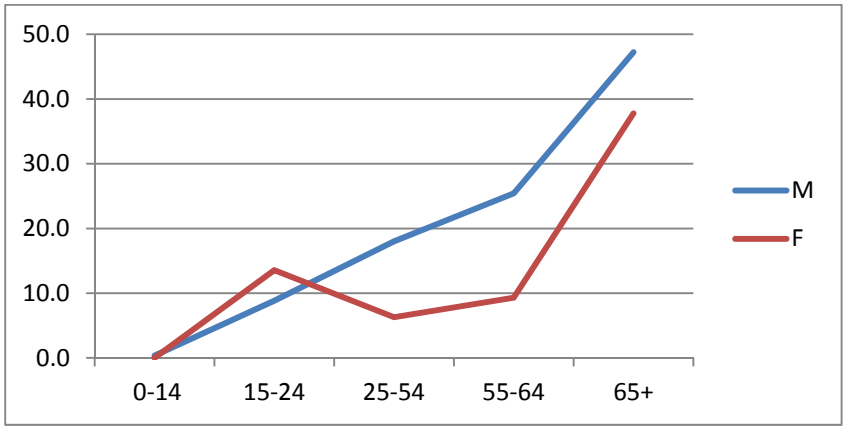
In 2012, only one child under the age of 15 years was notified as having TB. The male:female ratio for new smear-positive PTB between 2010 and 2012 was stable at around 1.5 (Table 3).

Table 3. New smear-positive PTB cases by age group and sex, Bosnia and Herzegovina, 2010–2012

Year	Age group														All ages		
	0–14 years		15–24 years		25–35 years		36–44 years		45–54 years		55–64 years		≥ 65 years				
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	Total
2010	1	0	27	27	37	19	34	16	61	10	46	18	51	94	257	184	441
2011	2	3	33	17	32	27	52	17	75	13	61	25	62	128	317	230	547
2012	1	0	23	33	32	26	58	21	74	10	62	25	92	116	342	231	573

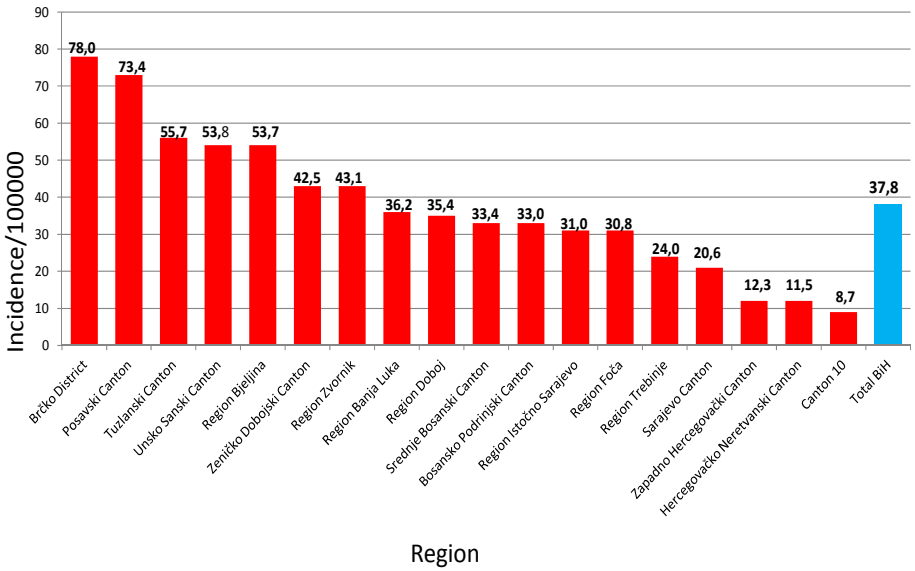
The age-specific notification rates for smear-positive PTB in 2012 (Figure 2), especially among women, reflect what would be expected in a mid-level epidemic in a country where TB control is successful. There is a small peak among teenagers, but a much higher one among those aged 65 and over. (Data for the age groups between 25 and 54 years have been aggregated, as no further breakdown of population denominator was available.)

Figure 2. Age- and sex-specific incidence of smear-positive PTB, Bosnia and Herzegovina, 2012



In FBiH, the cantonal distribution of TB notifications is rather variable, with the highest rate being in Posavina Canton (73 per 100 000) and the lowest in West Herzegovina Canton (11 per 100 000). In RS, the highest notification rate is in Zvornik Region (41 per 100 000), while the lowest rate is in Trebinje Region (26 per 100 000) (see Figure 3). This cantonal and regional variation probably reflects incorrect reporting rather than real epidemiological differences.

Figure 3. Regional and cantonal TB notifications, Bosnia and Herzegovina, 2011



Mortality

The mortality rate due to TB was 14 per 100 000 population in 1990, 9 per 100 000 in 1993 and 5.2 (4.6–5.8) per 100 000 in 2012.[9]

Drug-resistant TB

In 2012 the TB reference laboratories in both FBiH and RS performed drug susceptibility testing (DST) for a total of 790 cases (724 new and 66 re-treatment cases); only seven cases showed resistance to both isoniazid and rifampicin (4 new and 3 re-treatment cases).

TB/HIV co-infection

The general prevalence of HIV infection is very low (<0.1% of the general population); thus the occurrence of TB/HIV co-infection is even lower. However, 26 (25%) patients with AIDS have TB.[10]

Additional information on TB epidemiology can be found in Annex 4.

Recommendation

- Despite a declining trend over recent years, TB is still an important public health problem in Bosnia and Herzegovina, and it should remain a priority at State and entity level. The highest authorities at State level, and in FBiH, RS and BD, should further increase their commitment to combat TB as a public health issue. Cost-effective interventions should receive adequate administrative and financial support.

4. Tuberculosis programme

FBiH and RS have each developed a tuberculosis programme for 2013–2017. The FBiH TB Programme 2013–2017 (final draft June 2013)[11] describes the current organization and the clinical guidelines; it is essentially a manual. The RS TB Programme 2013–2017, issued in May 2013,[12] has been endorsed by the Ministry of Health. It sets four objectives and describes the activities needed to achieve them. In this sense, it is basically an action plan, but without measurable targets and indicators. Both documents are useful and provide complementary information, but neither is complete in itself. At State level, the Ministry of Civil Affairs could coordinate a similar approach for both documents, to allow each entity to have both a coherent strategic plan for the next five years and a good manual for those involved in TB control. A strategic vision on how to guarantee the sustainability of the programmes after 2015, when the Global Fund grant ends, has not been described.

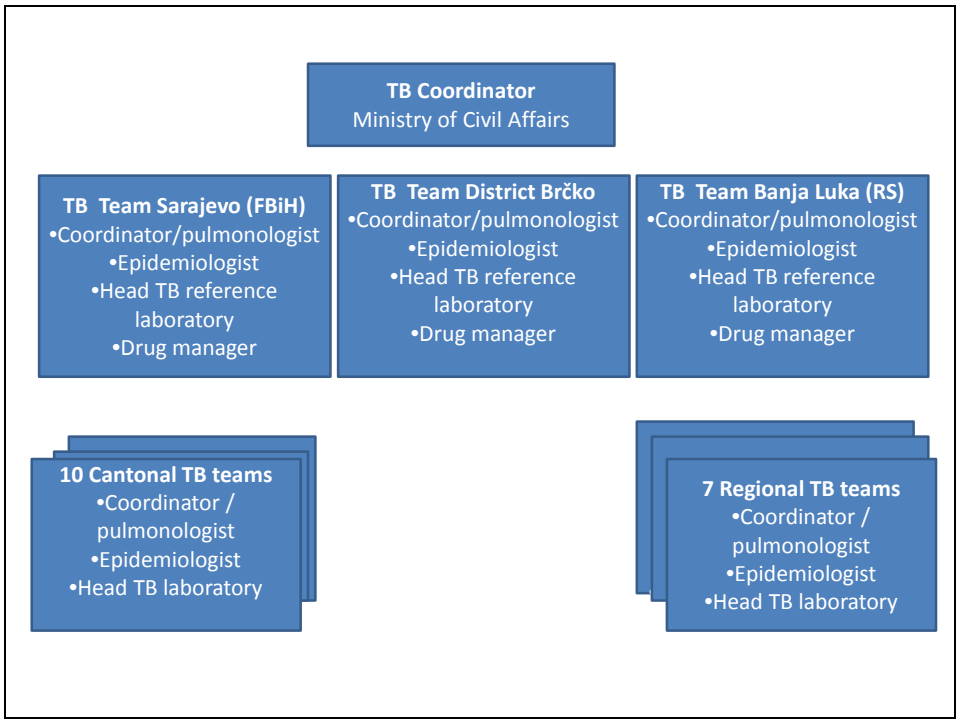
Structure

At the State level, the Ministry of Civil Affairs has set up a TB unit, whose only function is to consolidate the TB data for the country and report them to international institutions.

In FBiH, the TB unit based in Sarajevo coordinates ten cantonal TB units. The team consists of: a coordinator (pulmonologist) with overall responsibility; one epidemiologist (pulmonologist), who collects and reports data; the head of the reference laboratory (microbiologist); and a nurse, responsible for drug supply management. The RS TB unit, based in Banja Luka, has a similar team, but with a pharmacist responsible for drug supply management. Two additional staff (one medical nurse/technician and one assistant lecturer at the University of Banja Luka) can be called upon if needed. Currently, the coordinators in FBiH and RS are practising senior physicians with academic responsibilities, who have difficulty allocating sufficient time to the management of the TB programme.

In FBiH, TB control is the responsibility of each cantonal ministry of health. Despite the cantonal autonomy, these ministries have a harmonized structure and responsibilities. Each canton has a TB team, consisting of a TB coordinator/pulmonologist, epidemiologist and, if there is a functional laboratory, laboratory head/microbiologist. The RS has a similar structure at the regional level (Figure 4).

Figure 4. Organigram of TB control management



Patient flow

Health services in Bosnia and Herzegovina are organized at primary, secondary, and tertiary level. TB control is managed at all three levels. Family medicine centres (FMCs) provide primary health care to their catchment population through family doctors and polyvalent patronage nurses (PPNs). Patients suspected of having TB are referred to pulmonary disease services (previously called antituberculosis dispensaries (ATDs)), which are often in the same building. If TB is confirmed, patients are referred to a pulmonologist working in a secondary

or tertiary level hospital. As soon as the condition of the TB patient allows it, she or he is referred back to the primary health care facility for completion of treatment.

Resources

The total budget for TB control in Bosnia and Herzegovina in 2013 was US$ 12 million, a significant proportion of which was contributed by the Global Fund to support essential aspects, such as procurement of drugs and other commodities, outreach activities, overall coordination and supervision.

Bosnia and Herzegovina received TB grants from the Global Fund in round 6 (covering October 2007 to September 2012) and round 9 (October 2010 to September 2015), and HIV/AIDS grants in round 6 (November 2007 to October 2011) and round 9 (December 2010 to November 2015). The total amount approved by the Global Fund was US$ 60 million, of which US$ 20 million was for TB. The round 9 TB grant was US$ 16.4 million. The United Nations Development Programme (UNDP) is the principal recipient of the grants.

Since 2011, the overall resources of the Global Fund have been decreasing. This has led to more strict eligibility criteria, which means that, once the present grant ends in September 2015, Bosnia and Herzegovina will no longer be eligible for further Global Fund funding. The Government should therefore be looking for alternative ways of funding the TB control programme. The ministries of health of FBiH and RS should gradually start expanding their budget for TB control in 2015, to include drug-resistant TB and TB/HIV co-infection from 2016 onwards.

Achievements

The DOTS strategy was introduced in 1994, resulting in a decrease in TB incidence along with an increase in case detection (for all forms of TB).[13] WHO estimates the present case detection rate at 76%. Although the case detection rate is based on rough estimates of incidence, and its general significance as an indicator has been overestimated in the past,[14] these trends may reflect the efforts of the TB programme to achieve the MDGs in 2015. The importance of TB diagnosis and case-finding in reaching the targets has been referred to in the TB programmes of the entities.

TB targets related to MDG6 are to halve TB prevalence and TB mortality by 2015, compared with their levels in 1990. Unfortunately, data for 1990 are not available, and neither are prevalence data for Bosnia and Herzegovina. However, the notification trend is a good proxy for the prevalence trend. The baseline notification rate for all TB cases in Bosnia and Herzegovina in 2000 was 65.2 per 100 000. In 2012, it was 37 per 100 0000, which is a 40% decrease. Mortality in 2012 was one-third of that in 1990. This suggests that the MDGs have been achieved.

Treatment success rates in 2011 were given as 70%, but 24% of the cohort had not yet been evaluated. There were very few unsuccessful outcomes, indicating that the actual success rate was close to 90% (see section 6).

Recommendations

- The Ministry of Civil Affairs, together with the ministries of health, should designate a transitional mechanism for the coming two years, to ensure a smooth handover of financial support from the Global Fund grant, starting gradually in 2015, and taking full responsibility from 2016 onwards.
- Capacity should be created at the Ministry of Civil Affairs, especially in relation to interventions of international relevance, such as central procurement of drugs and commodities, and data exchange with international bodies, such as WHO and the European Centre for Disease Prevention and Control (ECDC).
- Capacity should be created at the ministries of health for a central management TB unit, with full-time staff paid from government resources. They should oversee essential TB programme features, such as development of policies and guidelines, planning, laboratory services, training, monitoring and evaluation, and supervision.

5. TB case-finding and diagnosis

Case-finding

There are no official guidelines for the TB diagnostic workflow, but both FBiH and RS have adopted the same diagnostic strategy.

Active case-finding takes place among close contacts (relatives and neighbours) of infectious cases only; there is no mass screening. Polyvalent patronage nurses interview contacts during home visits, identify symptomatic cases and refer them for chest X-ray and sputum microscopy.

Passive case-finding is through self-reporting of symptomatic individuals to FMCs with pulmonologists on their staff (in RS), ATDs (in FBiH) or the outpatient departments of general hospitals. If TB is suspected, a chest X-ray is made, and sputum is collected for laboratory analysis. Once TB is confirmed, more specific investigations take place at the hospital level. Although the team noticed a few exceptions, family doctors rarely request sputum microscopy.

Diagnostic policies and methods

The tuberculin skin test is used only on contacts of infectious cases. Quantiferon GIT is used for patients undergoing immunosuppressive therapy. Chest X-rays are done routinely on every patient with respiratory symptoms. Radiology equipment is present in most FMCs and all hospitals; prisons have no radiology equipment. Sputum analysis is the most common

laboratory method for diagnosing TB, but if the patient cannot produce sputum (spontaneously or induced), bronchoalveolar lavage (for pulmonary signs) or histology (for extrapulmonary signs) may be carried out.

Laboratory tests

Standard operating procedures (SOPs) were visibly posted in each laboratory visited. None of the laboratories visited used light-emitting diode (LED) microscopy, contrary to what has been reported to WHO. LED microscopes were found only at the national reference laboratory (NRL) in Sarajevo, but had not been used.

Sputum collection

Patients are instructed on how and when to produce sputum samples at home. Some facilities have sputum collection points, where nurses instruct patients and supervise sputum collection. A recent study by the NRL in Sarajevo showed that 26% of sputum samples were of insufficient quality in terms of volume, consistency or purulence. Although this study was not flawless (no distinction was made between adults and children or between diagnostic and follow-up examinations), it is evident that sputum collection should be improved through more training and better supervision. Poor quality sputum samples are processed and reported as negative, but without alerting the doctor about the poor quality of the sample; this leads to poor reliability of the laboratory results.

The number of sputum samples and other specimens processed varies, but in most of the TB centres visited it is common practice to examine three samples for diagnosis. Mobile units from the Red Cross Society of Bosnia and Herzegovina routinely collect sputum samples throughout the country (including prisons) at two-week intervals. The number of collected samples may range from 10 to 60 per delivery.

Sputum smear microscopy

Ziehl-Neelsen is the routine staining method for TB microscopy in Bosnia and Herzegovina; auramine is not used. The review team found that the positivity rate for smear microscopy is quite low, especially in samples collected by mobile units. The smear positivity rate in most laboratories is 3–4% (compared with a norm of 10%). This low rate can most likely be explained by the poor quality of the samples (poor collection, long storage in inappropriate conditions), and by the lack of differentiation between diagnostic and follow-up examinations.

Culture

The majority of laboratories routinely culture every sample using Loewenstein-Jensen (LJ) solid culture medium. Some selected laboratories use mycobacteria growth indicator tube (MGIT) liquid culture medium (the NRL Podhrastovi in Sarajevo for every sample, the laboratory of the clinical hospital, Tuzla, for samples coming from that hospital, and the NRL in Banja Luka on request). The proportion of positive cultures for all individuals tested

(culture positivity rate) is low, which suggests that the added benefit of culture to direct microscopy is negligible. However, this analysis may be incorrect, as the culture positivity rate cannot be calculated separately for diagnostic and follow-up samples.

Molecular techniques

Xpert/MTB Rif is not available. Line probe assay (LiPA) Genotype MTBDRplus is used in selected laboratories. Many laboratory workers have already been trained in its use by the supranational reference laboratory (SRL) in Borstel, Germany. At present, LiPAs are performed on positive cultures, but all smear-positive samples should be tested by LiPA to avoid having to wait for culture results.

Drug susceptibility testing

In Bosnia and Herzegovina, six laboratories perform DST, three in FBiH and three in RS. Sarajevo Podhrastovi uses only the liquid method (MGIT), while the Public Health Institute in Banja Luka uses both MGIT (liquid) and the proportional method on LJ (solid). Other laboratories performing DST include those in Tuzla (both solid and liquid media) and Mostar (only LiPA) in FBiH, and the University Hospital of Banja Luka and Kasindo/Sarajevo East (solid media) in RS. Turnaround time for such DST methods is variable, ranging from 2 days (LiPA) to 42 days (solid media).

Laboratory network

In order to rationalize use of resources while maintaining a good standard of TB testing, FBiH and RS established two separate laboratory networks in 2006–07. The TB laboratory at the General Hospital in Brčko is part of the FBiH network (Annex 5). Infrequently, samples from one entity may be analysed in the other entity.

The FBiH network consists of one NRL (Podhrastovi Sarajevo), two level III laboratories (Mostar[a] and Tuzla), three level II laboratories (Zenica, Travnik and Bihac) and two level I laboratories (Velika Kladusa and Tesanj). The level II laboratory in Brčko will soon be upgraded to level III. The Tuzla laboratory is officially part of the network, but it connects with the NRL only for quality control.

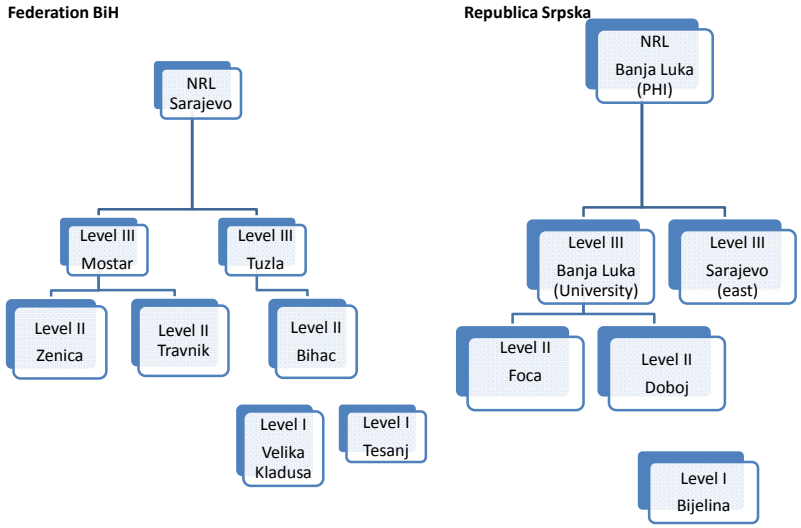
The RS network consists of one NRL (Public Health Institute in Banja Luka), two level III laboratories (University Hospital Banja Luka and Kasindo/Sarajevo East), two level II laboratories (Foca and Doboj) and one level I laboratory (Bijelina).

Level I laboratories do sputum smear examinations only. Level II laboratories do smear and culture, but no DST, while level III laboratories do smear, culture, and DST, on both solid and

[a] Mostar is considered as biosafety level II; each positive culture (solid media) is submitted to Sarajevo for DST. Yet in the network schedule (Figure 5) FBiH defines it as a level III laboratory.

liquid media. The NRLs additionally have the possibility of doing molecular tests and coordinating external quality assurance (EQA) (Figure 5).

Figure 5. Laboratory networks in Bosnia and Herzegovina



In both networks, a specimen referral system is in place, using vehicle transport. Vehicles have been procured for public health institutes, but the high cost of fuel, maintenance and salaries means that the system does not function well. In both FBiH and RS, the NRLs sometimes receive samples only once every two weeks. It is critical that samples are stored in appropriate conditions and analysed within seven days, since the sensitivity of microbiological tests and contamination rates may be affected by delays.

The respective ministries of health have not officially endorsed the role of the NRLs in Sarajevo and Banja Luka, but the laboratories act as such, relying on good relationships within and between the networks. The NRLs register the performance indicators of the laboratories in their network.

The University Clinic in Banja Luka does not refer cultures for DST to the NRL, because this would be more expensive. This means, however, that diagnosis is delayed as DST on solid media requires much more time.

Quality assurance

In January 2013, a joint plan for quality assurance was developed for the two laboratory networks. The document “Tuberculosis laboratory network – quality assurance monitoring and evaluation framework 2013–2015” comprises six modules that describe how to improve EQA within the networks and contain specifications related to the quality system.[15] Apart

from one doubtful part about fluorescence microscopy, which is not routinely used, the document is complete and specific.

Quality assurance is in place in the networks and in individual laboratories. Every laboratory visited has adopted at least one measure of internal quality control (IQC) for microscopy, culture, or DST. The two NRLs assure quality by sending out panels of samples for microscopy, culture, or DST twice a year. Proficiency testing is performed within a more comprehensive EQA system, which includes on-site visits by national laboratory staff.

Every year the SRL supervises the two NRLs. Both have shown an optimal level of accuracy in susceptibility testing to first-line TB drugs (FLDs). Panels of samples for EQA are sent by the SRL at least once a year to check on microscopy, culture, and DST for FLDs. The SRL also conducts training in culture, DST, and new molecular tools (LiPA), both in Bosnia and Herzegovina and in Borstel. All MDR strains are sent to Borstel for second-line drug (SLD) testing. So far, no XDR TB has been detected.

The NRLs are also involved in another international quality assurance scheme for diagnostic tests, such as culture and microscopy (Instand e.V., Germany).

Biosafety

According to the new tuberculosis biosafety manual published by WHO,[16] which is based on risk assessment, biosafety risk increases exponentially from smear microscopy to DST. Genotype MTBDRplus has no biosafety requirements, except that the first phase must be done in a containment laboratory (like DST).

Laboratory biosafety should be part of a wider infection control plan to protect TB laboratory staff during daily activities. In all sites visited, personal protective devices were available, e.g. certified respirators, laboratory gowns, and gloves. The (low-risk) microscopy laboratories visited had adequate infrastructure and ventilation systems; culture laboratories (moderate risk) had biological safety cabinets (BSCs) and maintenance schedules in place. The main concerns are related to the inadequate infrastructure of level III laboratories. In particular, laboratories performing DST (high-containment laboratories) should have at least a closed anteroom, to avoid any bacterial dispersion to the outside in case of a major accident, and an area where protective devices are stored for use in the containment laboratory only.

The NRL Sarajevo Podhrastovi is currently (2013) located in a provisional laboratory. It has one room, with direct access from the corridor, which people (health staff, visitors) could use as a recreational area. This should end as soon as possible.[a]

[a] The new containment laboratory, with adequate infrastructure, was in fact brought into use in June 2014.

Financial resources

TB laboratories carry out sputum smear microscopy and culture free of charge. The Global Fund grant at present partly covers TB diagnostic procedures and equipment (BSCs). It is planned to use the grant for procurement of LiPAs, consumables, and equipment for liquid cultures and DST (except for Tuzla laboratory, where equipment and half the consumables for liquid cultures are on the hospital budget).

Recommendations

To the ministries of health

- Include national TB programmes or transitional plans for 2015–17 in the health budget, to cover costs related to the laboratory diagnosis of TB and drug-resistant TB after September 2015. The sustainability of the entire system should be ensured through the federal and republic budgets, as the most expensive tools (liquid culture) will be needed in the two NRLs.
- Harmonize the diagnostic strategy with the ministries of justice, for presumptive TB patients in detention facilities.

To the tuberculosis programme

- Carry out sputum examination for each patient with TB symptoms, irrespective of the chest X-ray result.
- Introduce a clear diagnostic algorithm for laboratories, covering all essential steps, including the new rapid molecular tests. This may lead to a reassessment of the workload and quality assurance programme of the laboratory network (see also Annex 6).
- Supervise the implementation and harmonization of policies in each laboratory; differentiate between diagnosis and follow-up examinations.
- Strengthen the timeliness of sample referral from the periphery. Adopt a uniform transportation schedule (twice a week would be optimal) to avoid loss of sensitivity of tests and contamination of samples.
- Ensure that the EQA plan for 2013–15 is put in place, by coordinating activities between TB programmes, TB national laboratories and other actors involved.
- Before upgrading laboratories to level II or level III, consider introducing new rapid tools (i.e. Xpert/MTB Rif) as a cost-effective option; consider also the biosafety requirements.

To the National Reference Laboratories

- Revise the algorithm for the use of new rapid diagnostic tools on smear-positive biological samples.
- Test all re-treatment cases with liquid culture and liquid DST.

- Strengthen supervision of the laboratories within each network in terms of performance indicators.
- Communicate results, with their limitations, to requesting clinicians.
- Continue participating in external quality assessment by the SRL in Borstel and maintain the training schedule as in past years. Ensure that internal quality control is performed regularly.

6. TB treatment and case management

Treatment

In 2013, the TB programmes in both FBiH and RS developed treatment guidelines that are in line with WHO recommendations.[17] New patients with drug-sensitive TB are initially treated as category I or III, and re-treatment cases as category II.[a] Treatment starts at inpatient facilities, with the regimen chosen by the cantonal or regional pulmonologist. First-line drugs are available in fixed-dose combinations, procured with the Global Fund grant. During the continuation phase, patients are treated at primary health care facilities. In recent years, with the support of the Global Fund, service delivery has been significantly strengthened.

Case management

In the continuation phase, the majority of patients visit FMCs weekly to receive medicines for self-administered treatment (SAT) at home. It was explained that this is a result of longstanding practice, trust between the health providers and patients, and the stigma of TB in the community. Patients in remote areas with limited access to health services, those with disabilities, and those at high risk of developing MDR TB because of poor adherence to treatment are given directly observed treatment (DOT). This is provided by a countrywide network of 76 trained and dedicated PPNs, selected from the nurses working at primary health care (PHC) facilities. Through the Global Fund, these PPNs receive a 20% monthly allowance on top of their regular salary to perform DOT. FMCs with a high number of patients are staffed with one or two PPNs. The terms of reference for PPNs have been developed in the context of the present grant and include the provision of DOT, the identification of presumed cases with referral for diagnosis, and social support and public health education of patients and their families. PPNs report monthly on their activities to the cantonal or regional TB unit and the Global Fund project implementation unit (PIU). With the

[a] Category I or III refers to new patients (either smear-positive or smear-negative) who are treated with four drugs during a 2-month intensive phase, followed by two drugs for four months (regimen 1); category II refers to re-treatment patients, who are treated for an intensive phase of three months and a follow-up phase of five months (regimen 2).

existing funding from the Global Fund grant, a maximum of 240 patients per year can be covered by DOT.

The well developed network of primary health care services in FBiH and RS offers good access to service delivery in each municipality and provides a good basis for strengthening the involvement of PHC in TB control. The question of whether SAT is more efficacious than DOT could be a subject for operational research. With the imminent ending of the Global Fund grant in 2015, the sustainability and financing of the current system of case-holding using PPNs in each municipality, especially among vulnerable groups, will need to be examined.

Treatment outcome

Reported treatment outcomes showed a noticeable change after 2010, with a sudden drop in the reported success rate from 95–99% before 2010 (Table 4) to 70% in 2011.[18] The explanation was a change in methodology. In previous years, outcomes were based on an aggregate sample of new smear-positive cases with results extrapolated for the whole cohort. For 2011, the total cohort was evaluated on the basis of individual reporting forms. However, 24% of patients had not yet been evaluated and extrapolation suggests a high success rate also for 2012.
Case–fatality rates are low; failure rates and defaulter rates are extremely low (Table 4).

Table 4. Treatment outcomes for new sputum smear-positive PTB patients, Bosnia and Herzegovina, 2001–2011.

Treatment outcome	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Cured	95%	84%	55%	96%	93%	94%	93%	87%	97%	91%	43%
Complete	3%	11%	39%	3%	3%	3%	4%	5%	2%	7%	27%
Treatment success	**98%**	**95%**	**94%**	**98%**	**96%**	**97%**	**97%**	**92%**	**99%**	**97%**	**70%**
Died	0%	1%	1%	0%	1%	1%	1%	4%	0%	1%	5%
Failed	1%	2%	2%	0%	0%	1%	1%	1%	0%	0%	1%
Defaulted	0%	1%	2%	0%	0%	1%	1%	1%	0%	0%	1%
Not evaluated	0%	-----	0%	0%	2%	1%	1%	1%	0%	0%	24%

Latent TB infection

Latent TB infection (LTBI) is looked for only in contacts of infectious cases. The tuberculin skin test (TST) is used to diagnose LTBI. TST criteria for evaluation are clear: an induration of over 5 mm in diameter is considered as a positive result. If the first test result for a contact is negative, the test is repeated after three weeks. The results of the test(s) are weighted

according to the risk of infection and the person's condition (closeness and length of contact with the source case, diameter of induration, history of allergy). A large proportion of the population has been vaccinated with BCG at birth; however, there is very little revaccination. Interferon-gamma release assay is too expensive for routine use.

Preventive treatment is hardly ever offered for LTBI, despite previous recommendations to consider chemoprophylaxis with isoniazid, 5mg/kg of body weight daily during 6 months. Resistance to isoniazid is extremely low.

Isoniazid preventive treatment for HIV-positive persons is not used.

Recommendations

To the tuberculosis control programme

- Operational research should be conducted to investigate the efficacy of SAT, taking into consideration that PPNs are additionally remunerated for DOT, and for providing social support and health education, which may not be sustainable when the Global Fund grant ends.
- Testing for latent tuberculosis without offering preventive chemotherapy makes no sense; this strategy should be reconsidered.

7. TB in children

TB in children has received more attention in the past few years, but the diagnosis remains notoriously difficult. The TB programmes and public health authorities should give more attention to case-finding of TB among children in vulnerable groups, including refugees, migrants and the Roma population.

In 2012, there was one notification of TB in a child under 14 years of age in Bosnia and Herzegovina (see Table 3). However, the team was informed that there were 15 notifications in children up to 19 years of age; this is 1% of all notifications. In 2000–05, around 2% of all notifications in FBiH were in children under 19 years; no data are available for RS. This declining trend of TB among children indicates decreased transmission in the community. Over the past 10 years, no drug-resistant TB has been diagnosed in children.

BCG vaccination

BCG vaccination is mandatory at birth in Bosnia and Herzegovina, with coverage of almost 100%. Revaccination at the age of 5 or 6 years is currently optional, but will reportedly be withdrawn from the protocols in both FBiH and RS. National regulations recommend vaccination of foreign nationals coming from countries with a low burden of TB to take up temporary or permanent residence in Bosnia and Herzegovina. The Public Health Institutes are responsible for implementing these guidelines.

Case-finding, diagnosis and treatment

A contact register has been introduced and is being tracked by epidemiologists in the national TB units, but no aggregated information is available.

Diagnosis of TB in children is difficult. The TST has limited value in vaccinated children. Infants hardly cough, so sputum examinations are rare and are limited to gastric lavage. Chest X-rays are difficult to interpret. Sputum smear and culture are less sensitive in children than in adults. With the arrival of molecular diagnostic tools, confirmation of the diagnosis may become somewhat easier. The role of rapid diagnostics in case detection in children could be studied.

The case management strategy for children with TB is the same as for adults, and is in line with the latest WHO recommendations.[19] The TB programmes in FBiH and RS have regulated the regimens and dosages for children according to age and weight. In view of the low number of cases reported, no paediatric formulations for small children have been available, which hinders prescription of adequate dosages. If necessary, tablets are broken.

Family members deliver treatment. In some family medicine centres, nurses supervise follow-up once every 2–4 weeks. Preventive therapy with isoniazid is not given to children with a positive skin test.

Recommendations

- Update the TB programme guidelines with the latest WHO recommendations for TB case detection in children.
- Consider using molecular tools to diagnose TB in children and study its efficacy.

8. Drug-resistant TB

WHO estimates that the rate of multidrug resistance in Bosnia and Herzegovina in 2011 was 0.14% among new cases and 2.1% among previously treated cases.[9] However, the latest GLC monitoring mission in 2012 reported rates of 0.17% and 9.8% respectively. In 2012, countrywide coverage of culture and DST for FLD for all smear-positive cases was achieved. The incomplete DOT coverage will likely lead to more MDR TB in the future.

Pulmonology units at regional level, in both FBiH and RS, are responsible for enrolling MDR TB patients in treatment, designing treatment regimens, managing adverse drug reactions, and organizing patient referrals. There is no national committee of experts. All TB programme coordinators have received specific training at the WHO Collaborating Centre in Riga, Latvia, and are responsible for training doctors in their region.

Confirmed MDR TB patients start treatment with a standardized regimen containing: pyrazinamide; one injectable agent (amikacin or capreomycin); levofloxacin; ethionamide; cycloserine; and 4-aminosalicylic acid. There are no indications that empiric regimens are

being used, as patients start treatment only once there is laboratory confirmation of MDR TB. If the clinical response to MDR TB treatment is poor, or if a patient remains smear- or culture-positive four months after initiation of therapy, DST to SLD may be done at the SRL in Borstel, Germany. There are plans to introduce SLD testing in Bosnia and Herzegovina.

All SLDs are procured through the GLC/Global Drug Facility (GDF)/International Development Aid (IDA) mechanism. In the intensive phase, hospitalization in the nearest lung clinic is mandatory; this is followed in the continuation phase by ambulatory treatment at the PHC level. PPNs provide DOT to all MDR TB patients in the continuation phase.

Clinical and bacteriological monitoring of MDR TB is possible throughout treatment and meets the most recent WHO recommendations. The national guidelines on TB regulate all clinical aspects of MDR TB management, including the duration of the use of the injectable agent (minimum of 8 months) and the total duration of treatment (20 months), but they lack information on the management of mono- and polydrug-resistant TB. The development of these guidelines was supported by the Global Fund, and they were submitted for review to the GLC Europe.

Approval of phase 2 of the Global Fund grant made it possible to create specialized MDR TB wards for M/XDR TB patients (at the Clinic for Infectious Diseases in Banja Luka, RS, and the Clinic for Lung Diseases in Sarajevo, FBiH), with maximal isolation and enhanced inpatient clinical management. In the planning stage, a WHO consultant on infection control reviewed the technical documentation for reconstruction of these centres, which was thereafter submitted to the Global Fund for funding approval. It is expected that the MDR TB wards will meet the latest international standards for infection control, with modern ventilation systems and upper-level ultraviolet germicidal irradiation (UVGI) lamps.

In December 2009, the GLC approved Bosnia and Herzegovina's application to access quality-assured medicines for a cohort of 40 patients with drug-resistant TB, funded by the Global Fund grant. Since 2010, 20 patients diagnosed with MDR TB have been enrolled in the project. Seven patients started treatment in 2010, five in 2011, seven in 2012 and one in 2013. Of the seven patients enrolled in 2010, four completed treatment, two died and one defaulted.

Since the launch of the MDR TB treatment project, GLC Europe has provided continuous support for both FBiH and RS, and has conducted four monitoring missions, which have produced a set of programmatic and practical recommendations for improving programmatic management of drug-resistant TB. The GLC reports have been used to prepare phase 2 of the project. There is concern that the treatment of MDR TB patients will stop once Global Fund support comes to an end in September 2015.

Recommendations

To the ministries of health

- Ensure adequate financing of second-line drugs to sustain MDR TB treatment after the end of the Global Fund grant.

To the tuberculosis programme

- Develop strategic planning to sustain all elements of TB control and programmatic management of drug-resistant TB once Global Fund support comes to an end.

9. HIV/TB co-infection

HIV prevalence in Bosnia and Herzegovina is below 1% in the general population and below 5% in high-risk groups.[20] The first official report of HIV infection in the country was in 1986, since when a cumulative total of 245 HIV-positive cases have been registered. Of these, 126 have developed AIDS; 91 receive antiretroviral therapy (2 patients receive treatment outside of the country). In 2013, a total of 22 new cases were registered in the whole country (16 men and 6 women), of whom six developed AIDS (5 men and 1 woman). Also, four deaths were reported in 2013 (3 men and 1 woman), all related to AIDS progression.

The male:female ratio among HIV-positive persons in Bosnia and Herzegovina is 4:1. The main modes of transmission reported are heterosexual contact (57%) and men having sex with men (17%); transmission through injecting drug use accounts for 12.9% of cases.[21] Most HIV-positive individuals were infected while working outside the country, as labour migrants. The Roma population is also considered at high risk, because of their poor access to health services and high rate of unemployment.

In 2013, TB co-infection was registered in 26 (25.2%) people with AIDS (pulmonary form in 22 cases). Hepatitis co-infection (B, C or both) was registered in 24 cases (23.3%). In 2012, 53 TB patients were tested in the voluntary counselling and testing (VCT) centres; none was co-infected with HIV. In the first six months of 2013, of 37 TB patients, 3 were co-infected with HIV (one in Sarajevo and two in Banja Luka).

In 2002, with technical assistance from the United Nations, the Council of Ministers established a National Advisory Board to Fight HIV and AIDS. The Board developed the National Strategies to Fight HIV and AIDS in Bosnia and Herzegovina for 2004–2009 and for 2011–2016,[21] which were accepted at the entity level and supported for implementation in the whole country. Funded by Global Fund grants (US$ 10.9 million during 2006–11, followed by a further US$ 20 million), the National HIV Programme includes needle and syringe exchange, working with people at risk, sustaining VCT centres, various training and educational activities, and an important TB/HIV component with TB screening and management of people living with HIV.

The TB/HIV co-infection components include: establishment of stronger links between HIV and TB programmes to increase the level of HIV testing in TB facilities; counselling and referral of HIV-positive people to TB services for TB diagnosis and treatment; development of a model for joint TB/HIV programmes, with a particular focus on prisons; training in stigma reduction for TB and HIV clinicians; and development of educational materials to be shared by TB and HIV facilities.

The ministries of health of RS and FBiH are responsible for organizing and coordinating the HIV/AIDS programmes in each entity. Two clinics for infectious diseases in FBiH (Sarajevo and Mostar) and one in RS (Banja Luka) coordinate the process. The country has established 22 centres for VCT, which provide free, confidential HIV testing for all. There are also ten drop-in centres, where intravenous drug users can receive free medical assistance and kits containing syringes, condoms and information on HIV prevention. Finally, support mechanisms exist in 12 prisons, with a network of 60 peer-educators aiming to prevent the spread of HIV and sexually transmitted diseases.

The diagnosis of HIV is based on the results of Western blot, enzyme-linked immunosorbent assay (ELISA), and polymerase chain reaction (PCR) methods, as well as clinical stage of infection, and is free of charge. Antiretroviral therapy is available free of charge for all patients with clinical stage 3 or 4 disease and a CD4 count of less than 350/mm^3. Appropriate medical care, including antiretroviral treatment, is available for those living with HIV/AIDS. Individuals are also provided with psychosocial counselling, as well as food and nutrition supplements.[22] It is not mandatory for TB patients to be screened for HIV, but it is mandatory for HIV-positive persons to be screened for TB (chest X-ray; no purified protein derivative (PPD), but QuantiFERON-TB Gold test; and physical examination). The results of this testing are reported to the ministries of health every six months. The majority of lung clinics in both FBiH and RS do not cooperate with VCT centres, which means that not every TB patient is screened for HIV.

Although the prevalence of HIV/AIDS in Bosnia and Herzegovina is low, there is a strong focus on its prevention. Early identification of the infection enables individuals to take actions that benefit both their own health and public health, and early treatment of those infected substantially reduces the risk of HIV transmission to others. This can be achieved only through effective treatment and adherence to antiretroviral therapy.

Recommendations

To the ministries of health

- Ensure the sustainability of the programmes currently supported by the Global Fund, once the funding runs out in 2015.

To the tuberculosis control programme

- TB patients should be tested for HIV, to allow diagnosis of co-infection as early as possible, so that appropriate interventions, such as antiretroviral therapy, can be started promptly. Collaboration between TB and HIV services is essential.
- Information on VCT should be included on TB treatment forms and registers.

10. TB control in prisons

The execution of criminal sanctions is distributed across three levels of government (national, entity and regional/cantonal), under the responsibility of the Ministry of Justice of Bosnia and Herzegovina and the Ministries of Justice of FBiH and RS.[a] There are 15 penitentiary institutions in Bosnia and Herzegovina, which in 2011 accommodated a total of 2580 prisoners.[23] The prison population rate is 64.5 per 100 000 population, which is low by European standards. FBiH has three pretrial centres and five prisons; RS has three pretrial centres and three prisons; and DB has one pre-trial detention centre.

Prisons in Bosnia and Herzegovina are classified as closed or semi-open, according to their level of security and execution regime (closed institutions are for prisoners who have committed more serious crimes). There are two closed facilities in RS (Foca and Banja Luka) and one in FBiH (Zenica).[23]

The Ministry of Justice has plans to improve the prison system, including reducing the prison population density and ensuring health protection for all inmates. In general, the living conditions in the prisons are reasonable, with a limited number of prisoners in each cell. Overcrowding was not observed; sanitary conditions are simple but adequate.

The ministries of justice pay for health services provided by their own medical staff, but it is unclear if services provided by the ministries of health are always paid for. In principle, the Health Insurance Fund will pay for those who are insured.

All detainees undergo a medical examination on entry into the penitentiary system. They have to see a doctor within 24 hours; the doctor can then order X-ray examinations or laboratory tests from the civil services, if needed. Twice a year, volunteers from the Red Cross screen prisoners using a questionnaire and ask those with a cough to produce sputum. During detention, case-finding depends on prisoners presenting with symptoms. There is 24-hour access to medical services.

Sputum smears are examined in the nearest public health laboratory. However, even when the result is positive, there is no routine confirmation by culture, as the Ministry of Justice

[a] Brčko District has no prison facility for execution of criminal sanctions. The pronounced sanctions are executed in prisons in FBiH or RS, on the basis of a Memorandum of Understanding between Brčko District and the entities.

does not pay for this. The results of the smear examinations are reported back to the prison facilities in a reasonable time (estimated turnaround time 5 days).

After diagnosis, the intensive phase of treatment is given in a Ministry of Health hospital. The team found that, in the few cases mentioned, the full course of treatment was given in hospital.

A study in 2011 done in four prisons in FBiH and six in RS found that one-third of respondents had used drugs before being imprisoned; of those, about one-fifth had used intravenous drugs.[24] The prison services have harm reduction programmes (methadone substitution and condom provision, both under medical supervision). Substitution therapy is provided in six prisons – Sarajevo, Zenica, Tuzla, Busovaca, Bihac and East Sarajevo. However, in Sarajevo prison, it is provided only for detained persons under investigation. In Zenica, the prison cooperates with a drug addiction centre. In other prisons, substitution therapy is provided only sporadically on an individual basis.[25]

Surprisingly few TB cases have been identified in prisons. This may be under-diagnosis, as one would expect some cases to develop. An overall estimate of TB incidence among prisoners could not be obtained. In 2013, four cases – one new and three re-treatment cases – were notified. Prison staff reported anecdotal cases. In one prison visited, no case of TB had been registered for 20 years. In another prison with over 700 inmates, one presumed TB patient was in hospital for investigation, while another had been admitted to hospital for TB treatment. One case found was an elderly man, whose diagnosis after onset of symptoms took over 14 months to be established. Nevertheless, it was claimed that no satellite cases had occurred. The patient had fully susceptible TB and was cured.

Recommendations

To the prison health services and the tuberculosis control programme

- Sputum samples should be cultured as well as being microscopically examined. The ministries of justice should arrange cost remittance with the ministries of health.

11. Other vulnerable populations

People living with HIV, prisoners, immigrants, refugees and ethnic minorities are at increased risk of developing TB. The main determinants for developing TB include poverty, homelessness, unemployment and substance abuse. Often these determinants are inter-related. Most of the people in the vulnerable groups have no health insurance. Municipal social services help them to get health insurance, financial support, and free meals or food packages. The recently updated TB notification form includes questions on certain socioeconomic and other risk factors, which makes it possible to analyse the burden of TB

among vulnerable groups. In 2013, of 1373 registered cases, 379 (28%) were young[a] and poor, 351 (26%) were elderly, 24 (1.7%) were internally displaced, 11 (0.8%) were Roma, 4 (0.3%) were prisoners and 48 (3.5%) had other conditions. Certain vulnerable populations should be described in more detail.

Internally displaced persons

Bosnia and Herzegovina still hosts 103 000 registered internally displaced persons (IDPs), of whom 8600 live in collective centres, often under undignified conditions and without access to basic socioeconomic rights. The United Nations High Commissioner for Refugees (UNHCR) monitors the regional housing programme and the Bosnia and Herzegovina social housing project for residents of collective centres, which has spurred the national authorities to seek sustainable solutions for the most vulnerable. To overcome the administrative and bureaucratic hurdles of registering birth and citizenship, UNHCR supports the provision of free legal aid for people at risk of statelessness. Some 4500 people belonging to the Roma minority group still have an unresolved status and are unable to enjoy basic rights.[26]

There is no special screening for infectious diseases among IDPs. If not insured, IDPs in principle have free access to health services: the entities have agreed to pay the cost of medical care of inhabitants of one entity who are treated in another entity. However, the team was shown a letter from a health insurance fund, which stated that only emergency care would be paid for, and for no longer than three days. All other costs had to be borne by the facility. Such a letter creates a barrier to access to health facilities, which is not only denying the right to health of the individual, but is also creating a public health risk in the case of an infectious disease like TB.

Asylum-seekers

Asylum-seekers are housed in a centre near Sarajevo. In 2013, this centre accommodated 70 people, of which 49 were from Syria. Asylum-seekers have free access to health care. There is no systematic screening for TB among them, and no cases of TB have been reported in recent years. However, the risk of infectious diseases is always present, as a recent outbreak of poliomyelitis among Syrians showed. A new centre for asylum-seekers, with 155 beds, is under construction. Border police in charge of security have been trained to recognize infectious diseases.

Ethnic minorities

According to WHO, 80% of TB cases in Europe are concentrated in 16 countries, many of which have substantial Roma populations.[1] However, there is no comprehensive overview of the available data on the prevalence of TB in Roma communities in Bosnia and Herzegovina

[a] The definition of “young” in Bosnia and Herzegovina is up to 30 years of age; “poor” means an adjusted income of less than 340 convertible marks (KM) per family member.

or other European countries. The timely detection and adequate treatment of TB cases among the Roma community would contribute to decreasing the incidence and prevalence of TB in Bosnia and Herzegovina. The estimated size of the current Roma population in Bosnia and Herzegovina (76 000) is 8.5 times that reported in the census of 1991. Some of these Roma have been in Bosnia and Herzegovina since independence; others have returned from other countries where they had been refugees, and still others came to Bosnia and Herzegovina seeking refuge from other parts of the former Yugoslavia. In general, poverty, marginalization, low educational attainment, and poor living conditions characterize the Roma in Bosnia and Herzegovina, as in many other countries in the region. The unemployment rate is about 98%. Most Roma in Bosnia and Herzegovina lack personal identification documents, which exacerbates their marginalization.

The Roma are a minority group that is difficult to reach. Although they live in communities that are easy to target, they have difficulties in accessing health services. Under the Global Fund grant, two subrecipients (Red Cross and World Vision International) support sputum collection in at-risk populations, provide food packages, and engage in health education and community involvement.

Other marginalized people

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 estimates that 14% of the population of Bosnia and Herzegovina lives below the national poverty line (2007 data).[27]

A large proportion of the population in Bosnia and Herzegovina is unemployed. Among adults, the unemployment rate is 43%, while among 15–24-year-olds it is 58% (2011 data).[28] There are no separate data on the risk of TB among the unemployed.

In recent years, alcohol abuse among young people has been increasing; around 1% of adults have symptoms of alcohol dependence. Indirect indicators suggest that there are currently 10 000–15 000 opiate addicts in Bosnia and Herzegovina and that 3000–8000 of them are intravenous drug users.[29] Regular services are offered through networks of outreach workers and drop-in centres. In 2012 (until November), 3119 intravenous drug users used needle and syringe exchange services in low-threshold programmes across the country.

Four NGOs work in the area of harm reduction, employing low-threshold and outreach approaches: two cover FBiH (PROI and MARGINA) and two the RS (Viktorija and Poenta).

Recommendations

To the Government

- The ministers of health should resolve as soon as possible the issue of limited access to health care for IDPs. Not only is this an ethical problem contrary to human rights, it is also a public health problem, as denying access to health services may lead to uncontrolled transmission of communicable diseases.

To the tuberculosis programme

- Asylum-seekers often come from countries with a high prevalence of TB; the TB programmes should consider whether active screening mechanisms are needed.

12. Infection control

Strategy

Infection control (IC) for TB involves a combination of measures aimed at minimizing the risk of TB transmission within populations. Unfortunately, the existing guidelines in both entities do not correspond to international criteria and are an obstacle to the effective prevention of TB transmission. This comment applies to all three aspects of infection control (administrative, environmental measures and personal protection). A State infection control plan,[30] developed in 2012 with the assistance of an international consultant, has not yet been endorsed by the Government.

Administrative measures

According to the State infection control plan, MDR TB patients should be separated from other patients. In RS, the MDR TB department will be housed on a separate floor of the Clinic for Infectious Diseases in Banja Luka (in two rooms containing four beds). In FBiH, the specialized TB department will be on the third floor of one of the wings of the Clinic for Lung Diseases in Sarajevo, with two rooms containing four beds for MDR TB patients, and 24 beds for regular TB patients. However, at the time of the review mission, both departments were under construction and scheduled to be completed in 2014.[a] The Global Fund grant has provided funding and technical assistance to the governments of RS and FBiH for refurbishment and installation of negative pressure systems in both departments. Administrative separation of patients with different DST status is possible and seems to be adequately designed in both technical plans, with separate toilets and shower rooms. The specialized wards will allow proper isolation of MDR TB patients.

However, infection control measures in other inpatient facilities visited by the review team have not been adequately implemented. TB patients share rooms with patients suffering from chronic obstructive pulmonary disease (COPD), cancer and other pulmonary disorders. Considering that all TB patients are hospitalized for the duration of the intensive phase (or until they have had at least two consecutive negative smears), non-TB patients are at high risk of being infected with TB. The absence of guidelines means that staff have insufficient knowledge of modern requirements for infection control and contributes to ongoing transmission.

[a] The MDR TB ward at the Clinic for Infectious Diseases in Banja Luka was completed in September 2014.

The case of the Sveti Vraveci General Hospital, Bijeljina (RS)

In Bijeljina, a new well designed hospital has been built, with 230 beds and 120 staff, serving a population of 150 000. It has been divided into three functional areas: technical (electricity, water, heating), functional (laboratory, radiology) and clinical (all specialities).

One wing of the third floor has been designated for pulmonology and neurology. The pulmonology ward has 19 beds, six of which are for TB patients. At the time of the visit, there were two TB patients, but a week earlier ten TB patients had been discharged. If there are more than six TB patients, rooms designated for other lung diseases are used. It is expected that the number of cases will increase now the laboratory has started to work properly.

Infection control

In the ward are two sputum smear-positive TB patients in one room (adequate administrative measure). However, the door to the corridor is wide open. Neither patients nor staff wear masks. The available masks are not adequate (not being N95/FPP2). During visiting hours, there is free traffic of visitors back and forth through the corridor.

There is no way of separating the flow of air from the room with infectious TB patients from the rooms of other pulmonology patients (some of whom may be immunocompromised).

It is pity that such a well designed hospital did not consider better separation of infectious patients from other patients. This should be a warning for other hospitals that are considering reconstruction.

In Bijeljina, a relatively easy solution would be to put a glass sliding door between the corridor and the entrance to the two TB rooms, and to install UVGI appliances.

Environmental measures

None of the facilities in Bosnia and Herzegovina have adequate environmental infection control measures (ventilation and continuous upper-level UVGI lamps). Patient segregation and cough etiquette are the only IC measures in inpatient facilities.

Sputum collection points in the health facilities visited were usually ventilated rooms (mainly toilets with open windows). However, in a few cases (Brčko, Travnik), sputum samples were collected in rooms in which other people, such as nurses, technicians or patients (TB or other), were present.

Considering the current budget constraints, the installation and maintenance of modern ventilation systems in TB departments should not be a priority. However, investing in an

adequate number of UVGI lamps will significantly contribute to decreasing the risk of nosocomial transmission of TB.

Personal respiratory protection

Respirators were not available for health personnel in every setting; doctors and nurses wore surgical masks even in wards with smear-positive patients. However, no cases of hospital-acquired TB have been reported over the past three years in the facilities visited. Recently, a laboratory technician in the Podhrastovi NRL in Sarajevo developed tuberculosis that was probably laboratory-acquired.

Recommendations

To the Government

- The Government should endorse the existing and properly designed State infection control plan. It will contribute to preventing further spread of TB.
- Implementation of the State infection control plan should start as soon as possible, as some of the recommendations may need a capital investment from the Global Fund.

To the tuberculosis programmes

- TB programmes should pursue the administrative separation of TB and non-TB patients, as well as investing in environmental measures of infection control, such as UVGIs, which will significantly decrease the risk of nosocomial transmission of infection.
- TB programmes should conduct a comprehensive risk assessment regarding infection control in each facility involved in the management of TB and drug-resistant TB.

13. Management of medicines and other commodities

In 2009, the parliaments of FBiH and RS agreed to create the Agency for Medical Products and Medical Devices, which is responsible for the registration, importation and quality control of medicines.[31]

Procurement, product selection and registration

An essential drugs list (EDL) is available in RS and FBIH. The EDL contains a basic list of generic medicines commonly prescribed by primary care practitioners at FMCs, and funded by the republican (RS) or cantonal (FBiH) health insurance.

Since 2011, first-line anti-TB drugs are procured through the UNDP Procurement Support Office, while second-line drugs are available through the GDF/GLC/IDA mechanism. All procurement is based on a protocol describing the type, quantity and cost of the first- and second-line TB drugs needed and the procedures for their quality control.[32] All drugs are paid for by the Global Fund, while the ministries of health provide ancillary medicines that are on the EDL.

All medicines for TB and drug-resistant TB are free of charge for all TB patients in Bosnia and Herzegovina. Procurement of first- and second-line drugs is centralized and the drugs are imported under a waiver on registration for humanitarian donations (Annex 7). Permission to import the drugs is obtained in cooperation with the Ministry of Civil Affairs, and takes up to one month.

Storage

GDF drugs arrive at the airport in Sarajevo, from where they are transported to the different parts of the country. Drugs for FBiH cantons go to the TB clinic of Sarajevo, which has no climate control. Drugs for RS are stored for free in the warehouse of a private company (Krajinalijek) in Banja Luka, which has climate control. In Brčko, the drugs are stored in a small hospital room.

Distribution

In FBiH, drugs are distributed quarterly to cantonal TB facilities (except those with a very small patient load, which are given drugs for one year). In RS, drugs are distributed quarterly to local pharmacies in cities and towns where TB facilities exist; patients receive their TB drugs on presentation of a doctor's prescription.

Forecasting and stock

The respective TB programmes have never reported any shortage of first-line drugs. In general, most pharmacists order reserve stock – either 30% more than needed or for three months extra. No shortages of second-line drugs have occurred over the past year. However, in 2012 Bosnia and Herzegovina had to borrow SLDs from a neighbouring country for five MDR TB patients, when a shipment took 11 months to arrive after it had been ordered and paid for by the PIU. Delays in procurement are possible, especially for SLD. When preparing orders, drug managers should include possible shipment delays in their forecasts.

At present, there is insufficient urgency in considering the next order for drug procurement. How will drug procurement be dealt with after the Global Fund grant ends? The assumption seems to be that there are still two years to find a solution; however, the procurement process itself takes one year, so only one year is left to find a solution.

Monitoring

Mandated by the ministries of health of FBiH and RS, TB unit coordinators supervise drug estimation, forecasting, monitoring and reporting to the ministries and PIU, as well as drug distribution to cantonal and regional levels. Requests from cantons and regions are usually submitted monthly by fax or email to the entity TB unit coordinators, who have transport available for delivering the drugs.

Pharmacovigilance

Pharmacovigilance is government-regulated in both entities. Adverse drug reactions in TB hospitals are managed, but are not recorded or monitored. In outpatient settings, tracking of adverse reactions is not possible, since the majority of patients are self-administering treatment and come to the FMCs only to collect their drug supply. Thus, pharmacovigilance in the TB programmes is insufficient.

Ancillary medicines are available in the majority of inpatient facilities, but ambulatory settings only have those listed on the EDL. The EDL is renewed annually by the ministries of health of RS, FBiH and the cantons. Stronger coordination is needed at State level to define a standardized minimum list of ancillary medicines to be used for treating adverse reactions to anti-TB drugs.

Recommendations

To the Government

- The Government should develop a plan for procuring medicines and other commodities at the level of the Ministry of Civil Affairs; pooling of FBiH and RS funds for central procurement will be more cost-effective and thus sustainable.

To the ministries of health

- The ministries of health of both entities should plan how to pay for a procurement order of TB drugs to be placed in the first half of 2014 (which may take a year to arrive), to avoid stock-outs once the Global Fund grant ends in September 2015. The procurement plan should be based on realistic forecasting of the expected number of TB and MDR TB patients.

To the TB programme of FBiH

- The TB programme of FBiH should try to ensure that climate control is installed in the warehouse in Sarajevo.

14. Monitoring and evaluation

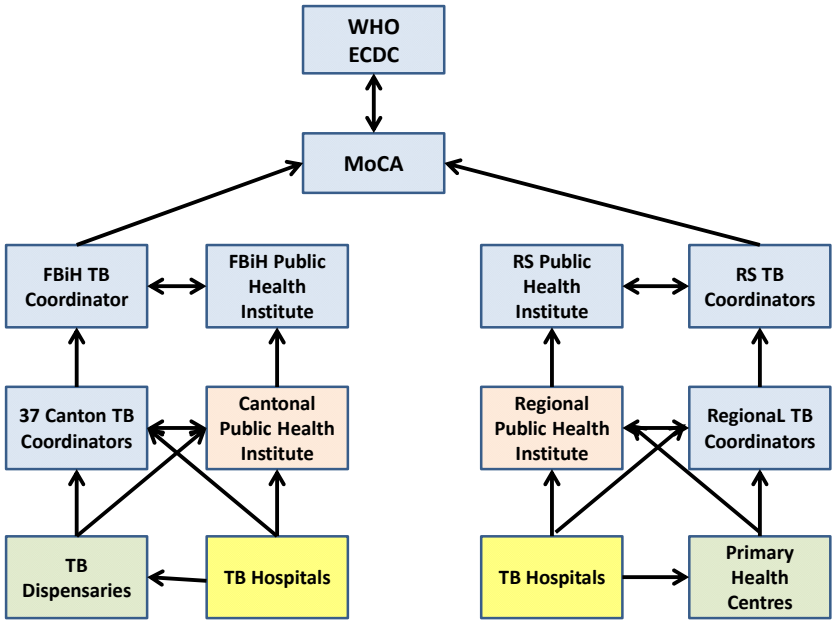
Flow of information

Patient data are recorded on standard WHO-compatible documents and entered into registers. The pneumophthisiologist who diagnoses the patient and starts treatment completes three copies of the patient card: one remains at the dispensary or hospital, one goes to the cantonal or regional TB coordinator, and one goes to the cantonal or regional public health institute.

Monthly aggregate reports are sent by the regional and cantonal coordinators to the entity TB unit coordinator and PIU. Each laboratory sends monthly reports to its NRL and the PIU.

Reports from the peripheral public health institutes are sent to the FBiH and RS public health institutes. At State level, the Ministry of Civil Affairs produces an aggregate national report, which is shared with international organizations, such as WHO and ECDC. There is little analysis of the collected data.

Figure 6. Flow of information on TB patients



Recording and reporting

In 2012, the Global Fund assessed the TB recording and reporting system in Bosnia and Herzegovina[33] and found that registers and forms were out of date, treatment outcome results for new smear-positive cases were reported together with all cases, data checking was late and incomplete, and the flow of information was ineffective for proper data management.

In 2013, FBiH and RS adopted a new recording and reporting system, based on the latest WHO revised definitions. While definitions and records have been updated, procedures have remained the same, which leads to late reporting of some cases that are necessarily excluded from the cohort analysis and consolidation in WHO and ECDC annual reports. Eventually, the PIU team corrects the mistakes made and produces a second set of official data. Moreover, there are errors in applying definitions: some TB centres (Zenica and Mostar in FBiH, Foča and Doboj in RS) report a high proportion of smear-positive extrapulmonary cases.

In most of the TB laboratories visited, the request form for sputum examination did not indicate the purpose of the test (diagnosis or follow-up), or at what stage of treatment

monitoring follow-up samples were taken. Missing data on request forms can affect final reports, statistics, and evaluation of trends; the 2012 laboratory report shows some unlikely numbers because of mistakes in reporting. There is also confusion about the calculation of laboratory indicators (Annex 8).

The Global Fund is supporting the development of a unique electronic information system for each entity, which will contain nominal data on all presumptive and diagnosed cases of TB. The system has four modules (programme management, epidemiology, laboratory and drug management). This new electronic system ("King ICT") is in its initial testing phase and is expected to be pilot-tested from February 2014.

Supervision

Theoretically, supervision visits have to be organized at different levels: from central to cantonal or regional level (hospitals) by the entity TB coordinator; and from cantonal or regional level to primary care level (FMCs/ATDs) by the TB cantonal or regional coordinator. However, in practice there is little supervision because of the low capacity at central levels, and the fact that the additional workload is not properly financially compensated.

Recommendations

To the ministries of health

- The electronic TB database developed for the country should be implemented as soon as possible once the pilot phase is over. At the same time, the monitoring and validation of recording and reporting should be further strengthened and supported by adequate supervision, to avoid systematic errors. Additional training in data management and analysis may be needed.
- The ministries of health should build central capacity in monitoring and periodic programme evaluation for decision-making.

To the tuberculosis programme

- Based on analysis of programme performance, organize supportive supervision visits in association with on-the-job training; this will strengthen programme and process management of individual staff members.
- Train or retrain staff in WHO definitions (including the new ones of May 2013) to ensure that reliable information is produced via adequately completed forms, cards and registers.
- Strengthen recording and reporting. Collected data should be analysed at all levels of aggregation, but certainly by entity TB unit coordinators.
- Make sure that quality assurance systems are in place when the nominal electronic database is introduced.

- Only one set of consolidated data should be prepared. Coordinators should be urged to send in their reports before a certain date (e.g. end of January). Monitoring visits aimed at improving data quality should be completed before that date.
- Develop a checklist to improve supervision. Findings and recommendations need to be recorded in a monitoring and evaluation form. Recommendations made should be followed up during the subsequent visit. Identification of good practices and communication of these to a wider audience will help.
- Improve the quality of laboratory data by disaggregating diagnostic and follow-up results and by reporting on individuals examined rather than samples tested. For laboratory managers, it is important that indicators are sample-based to allow the quality of results and reliability of indicators to be judged. For the TB units, indicator**s** must be case-based to allow epidemiological trends to be analysed.

15. Human resources development

As principal recipient of the Global Fund TB grant, UNDP helped develop the human resources plans for the tuberculosis programmes in both entities. The report issued in October 2012[34] documented a total of 1729 staff working in TB services (Table 5).

Table 5. Number of staff employed by level of TB service, 2012.

TB service	Doctors	Nurses	Other staff	Total
Hospital pulmonology departments	91	314		405
FMC	450	129+17[a]		596
Laboratories (microbiology)			303	303
Epidemiology at Public Health Institute			394	394
NGO mobile units			29	29
Total				1727

[a] 17 additional patronage nurses.

Source: ref 34.

On average, there is one doctor (pulmonologist) per 10 patients. However, there are important differences in the distribution of pulmonologists in different parts of the country

(Table 6), with ratios as high as 1 pulmonologist per 144 patients in Zenica (FBiH) and 1 per 54 patients in Foca (RS).

Table 6. Number of pulmonologists by entity and age, 2012

Entity	Total TB patients reported in 2012[a]	Total pulmo-nologists	Patients per pulmo-nologist	Pulmonologists aged >55 years		No. of pulmonology trainees
				No.	%	
BD	35	3	11.6	2	67	1
FBiH	850	109	7.8	43	39	11
RS	535	34	15.7	8	24	5
Total	1420	146	9.7	53	36	17

[a] In the national statistics DB is not mentioned. For calculation purposes, the 35 patients recorded in DB in 2012 have been subtracted from the FBIH (20) and RS (15) data for 2012.

The patient:pulmonologist ratio is unbalanced, with RS having twice as many patients per pulmonologist as FBiH. Of the total of 146 pulmonologists (including those at FMCs), 53 (36%) are aged over 55 years, while only 17 doctors are currently training to become pulmonologists (Table 6).

The number of clinical pulmonologists seems sufficient to deal with the current declining TB incidence. The UNDP report[30] advised the TB programmes in both entities to consider integrating dedicated TB clinical services and staff into general pulmonology services starting from 2015. The postgraduate training in tuberculosis has been merged with training on respiratory diseases, although the TB part currently represents one-third of the total curriculum. FBiH has three medical schools (in Sarajevo, Tuzla and Mostar) while RS has two (East Sarajevo and Banja Luka).

Family medicine has become a postgraduate course of 3 years, with its own medical curriculum, which includes some training in TB diagnosis and treatment. The Global Fund round 9 grant included among its objectives the implementation of the practical approach to lung health (PAL) strategy, to improve the management of respiratory patients by family doctors.

The two NRLs have laboratory staff dedicated to TB work only; this is justified by the workload. All other laboratories have multifunctional technicians. In general, the number of staff is sufficient.

The tasks of clinical nurses will shift from specific TB care to more generalized pulmonary disease care (e.g. for COPD, asthma and lung cancer). The number of patronage nurses may need to increase, as there will be a shift towards more chronic disease care as part of the more integrated ambulatory health services.

Analysis of the tasks in TB control could lead to the development of new job descriptions for staff at all levels. Such a task analysis should preferably be done before human resources needs are assessed, since it will have repercussions on the allocation and education of human resources.

Recommendations

- Task analysis should be undertaken before a new human resources plan is developed, as such an analysis will lead to new job descriptions, which will affect the needs assessment.

16. Operational research

The strategic documents from FBiH and RS reviewed by the team[11,12] do not consider operational research; there is no research agenda in either TB programme.

The review team considers that priority areas for future operational research are case-finding (diagnostic algorithm, the use of rapid diagnostic tools, drug resistance) and infection control (prevention of nosocomial transmission).

Case-finding

One of the areas that needs to be investigated is the delay in diagnosis. This may be caused by patient-related factors (poor recognition of symptoms, difficult access to health facilities) or service-related factors (no timely recognition of symptoms, inadequate diagnostic procedures, long turnaround time for diagnostic investigations). Procedures related to source detection and contact-tracing could also be studied. These studies may be done in the general population (priority) or in vulnerable groups (e.g. prisoners and asylum-seekers).

Infection control

The best indicator of poor infection control leading to nosocomial transmission is the occurrence of TB cases among health care staff. The LTBI status of all staff should therefore be registered at the start of employment (baseline data). Outbreaks may occur. At present Bosnia and Herzegovina has no way to set up a bacterial DNA database but – especially if cases of drug-resistant TB accumulate – contact-tracing is important and the role of nosocomial transmission is one of the issues to be studied.

Diagnostic algorithm

The introduction of the LiPA Genotype MTBDRplus in the country diagnostic algorithm, and its comparison with phenotypic standard diagnostic tests, could be considered as a preliminary step for evaluating its efficacy in reducing the turnaround time, long-term costs for the health systems and disability-adjusted life years (DALYs).

The planned change to using LiPA Genotype MTBDRplus directly on biological samples rather than on positive cultures could be a good opportunity to set up an operational research study with assistance from international institutions, such as the SRL in Borstel.

Xpert/MTB Rif

The global upsurge in drug-resistant TB cases (primary or acquired) could pose great challenges for surveillance, particularly of individuals belonging to risk groups (HIV-infected people, prison inmates and vulnerable populations) and those for whom routine diagnostic tests are less sensitive (children, patients with extrapulmonary TB). However, new WHO-endorsed molecular tools (e.g. Xpert MTB/Rif) could be used to diagnose cases that were overlooked or missed in the past. The introduction of such assays should be based on a stepwise approach, to determine whether these new tools lead to more efficient TB case-finding. So far in Bosnia and Herzegovina, the absolute number of TB cases reported in prisons and in children is too low to justify the introduction of new tools for diagnosis of TB/MDR TB only in these groups.

Drug resistance survey or surveillance

To determine the level of drug resistance, there should be either a drug resistance survey (DRS) or a system of surveillance. The cost of a DRS is typically at least €0.5–1 million.[35] Currently, given the sample referral system in the FBiH and RS, and the high DST coverage (93.5%, estimated in 2012 by UNDP), the existing surveillance system is a better solution for studying the level of drug resistance.

Recommendations

To the tuberculosis programme

- Develop an operational research agenda for TB, outlining the priority topics to be studied, identifying key investigators, and providing an adequate study budget. Priority areas for operational research are case-finding and infection control.
- Standardize guidelines and operating procedures before engaging in operational research.
- Seek assistance from national and international institutions to carry out operational research.
- Analyse and disseminate results of the research in a workshop; consider changing policy if the findings indicate that this is needed.

To heads of national reference laboratories and TB programme managers

- Conduct operational research to measure the potential benefits of introducing rapid testing directly on biological specimens; develop a study protocol in a workshop with external technical assistance.

17. Ethics and human rights

Accessibility and affordability

In theory, health facilities in Bosnia and Herzegovina are equally accessible to all inhabitants, including ethnic minorities. Access to services for TB and other infectious diseases is, in principle, free of charge. However, patients with symptoms first have to pay for the initial clinical and laboratory examinations. Once TB has been diagnosed, the patient is entitled to claim the money back. This is a lengthy administrative process, which does not always result in complete reimbursement. As a result, there is underdiagnosis of cases. Where patients have direct access to TB services, this problem does not exist.

People who are employed have health insurance, for which 17% of their salary is deducted. Voluntary insurance is also possible, but the coverage of this insurance scheme is unknown. Both entities have an agreement to treat patients from the other part of the country. In general, this agreement is respected, although infringements have been noted. People with insurance will have few barriers to overcome, compared with those without insurance. Unfortunately, the latter are often the poor people, who are prone to more illness and who encounter financial barriers to private practices and most clinical specialists.

Closely related to access to health professionals is the issue of access to essential drugs. Adequate financing, management and monitoring mechanisms are crucial. A core obligation of states is to provide essential drugs, as defined by WHO, to their population.[36] Bosnia and Herzegovina has an essential drugs list, which includes first- and second-line anti-TB drugs.

Availability

Bosnia and Herzegovina has a sufficient number of physicians to serve the population. However, an inequitable health financing system, which relies on inadequate state revenues 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 broad 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 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.

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".[36]

There has been significant progress in Bosnia and Herzegovina in ensuring that health providers are respectful of minorities, particularly the Roma.

Quality

Bosnia and Herzegovina has a successful nurse education initiative and family medicine training programme. There is a continuing medical education programme for physicians. However, the review team encountered individual health professionals who had made mistakes or had misconceptions about certain aspects of TB, leading to wrong conclusions about interventions needed. Quality suffers because of a lack of supervision and on-the-job training.

Recommendation

- Consider how presumptive TB patients could avoid having to pay initially for diagnostic services and then facing a difficult and lengthy procedure for reimbursement.

18. Advocacy, communication and social mobilization

The fifth objective of the Global Fund round 9 proposal is to empower TB patients and their communities 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 the knowledge of the public about early signs and symptoms of TB and to reduce associated stigma, in order to increase case-finding, early diagnosis and adherence to treatment. The grant proposal states that to ensure access to TB and respiratory medicine services, a supportive environment involving the Roma community has to be created, and guidelines on TB control developed and published in the Roma language.

Community involvement

An Action Plan for Roma Health aims to improve the health of the Roma population in Bosnia and Herzegovina. The plan includes: sensitization of health workers on Roma issues; education of Roma health community workers with the highest priority on TB; awareness-raising campaigns on health among the Roma communities; the creation of access to the health system for the Roma population (health insurance); and coordination with the international community and local government.

World Vision, a subrecipient of the round 9 grant, has established four regional TB-oriented centres within the Roma network in Bosnia and Herzegovina. About 60% of the Roma population have no health insurance, but at the time of the visit, EuroROM (one of the Roma organizations contracted by World Vision) had provided health insurance to some 500 Roma people. Members of the community have been trained as champions of education, and are used as peer educators to help overcome the stigma of TB. In cooperation with World Vision, workshops have been held on tuberculosis and health education. EuroRom claims that about ten deaths have been prevented and that stigma is already reduced, but both claims are difficult to prove. In fact, knowledge, attitudes and practice (KAP) studies indicate that stigma among the Roma population has increased.

The Bosnian Red Cross, another subrecipient of the Global Fund grant, has given workshops and provided patient education in communities and schools and initiated media campaigns.

KAP studies

Three KAP studies took place between 2008 and 2012, involving 1354 participants. The main goal was to determine changes brought about by information, education and communication (IEC) interventions in knowledge of symptoms and mode of transmission of tuberculosis, and in stigma associated with the disease. The target groups were the Roma population, elementary and high school students, and refugees and internally displaced persons.

The baseline study in 2008 aimed to measure the level of knowledge of the target groups, while the follow-up studies showed the results of the education interventions. The results are summarized below.

- In the baseline study, a high proportion of participants recognized cough and expectoration as symptoms of TB; among the Roma no change was seen after education, while among refugees, IDPs, and students knowledge decreased.
- Knowledge that TB is transmitted by air increased among the Roma population, did not change among refugees and IDPs (who had high initial knowledge), and decreased among students. This last observation is unexpected and suggests that the IEC intervention was poor.
- Stigma increased among the Roma, who are ashamed to be diagnosed with TB; it decreased among students and did not change in the other groups.

The conclusion was that an educational campaign can be useful but is not sufficient to make a difference in the three areas studied. Education designed specifically for each population would probably give better results.

World TB Day

World TB Day and the Bosnian TB Week are two occasions when TB is discussed and presented to the public. The actual situation in terms of TB burden is highlighted.

Educational material prepared for these occasions is distributed in health centres, schools and other settings, by health workers, Red Cross volunteers and Roma outreach workers.

In 2013, a press conference was organized with the participation of the entity TB coordinators, staff from TB hospitals and public health institutes, and other stakeholders.

International Standards for Tuberculosis Care

The International Standards for Tuberculosis Care (ISTC) describe a level of care that all practitioners, public and private, should seek to achieve in managing patients who have, or are suspected of having, tuberculosis.[37] The FBiH and RS strategic plans are in line with the requirements of the ISTC, but their implementation still has weaknesses.

Patients' Charter for Tuberculosis Care

The Patients' Charter for Tuberculosis Care[38] outlines the rights and responsibilities of people with tuberculosis. The Charter sets out the ways in which patients, the community, health providers and governments can work as partners in a positive and open relationship, to improve tuberculosis care and increase the effectiveness of the health care process. It allows all parties to be held more accountable to each other, fostering interaction and a "positive partnership". Bosnia and Herzegovina has not yet implemented the Charter.

Recommendation

To the tuberculosis programme

- Education designed specifically for each target group would give better results than general education campaigns.
- Adopt the International Standards for Tuberculosis Care and introduce the Patients' Charter for Tuberculosis Care.

19. Health system reform and TB control

In 1995, the Government of Bosnia and Herzegovina began a health reform programme to restructure its health system. The reform aimed to develop a new model of primary health care and a basic health programme comprising: (1) primary health care based on family medicine; (2) a shift from an emphasis on large hospitals and polyclinics towards more decentralized outpatient facilities and home-based care; and (3) a greater emphasis on cost-effectiveness and public health measures for disease prevention and control.[39]

Governance

Organization, financing, and delivery of health services are the responsibilities of FBiH and RS; Brčko District runs an independent health care system.

Ministries of health were created at the entity level in RS and in each of the ten cantons in FBiH. Since 2003, the Ministry of Civil Affairs has a coordinating and harmonizing role.

Financing

The global objective of the strategies adopted at the entity level is "to establish a modern, rational, fair, efficient, and sustainable financing of health care, adapted to the needs of the population and economic capabilities of the entity, which provides universal coverage of solidarity".[40] A mixed financing system has replaced budget funding, with the introduction of health insurance to complement budget transfers from the state and local government. Provider payment systems for primary health care changed from budget to per capita funding.[40] The health insurance system is decentralized to 13 health insurance funds: the Federal Bureau of Health Insurance and Reinsurance, the ten cantonal health insurance funds in FBiH, the RS Health Insurance Fund, and the DB Health Insurance Fund. Autonomous family medicine units (comprising a family physician and one or two family medicine patronage nurses) have been formed. These are allowed to contract directly with the municipality health centres or through them with the health insurance organizations to provide health care services.

The financing of health care is directly dependent on the economic strength of the entities and cantons, and there is no aggregation of risk. Health insurance is acquired by applying to the appropriate fund and providing the required documentation. The base rates for mandatory health insurance depend on income.[41] Because of the economic problems in Bosnia and Herzegovina, an estimated 20% of employers do not contribute to the mandatory health insurance, resulting in low coverage of employees and their families. This influences access to health care, especially among vulnerable populations.

Human resources

Public employees are paid a fixed salary, which is not affected by the quality or quantity of work done; this results in reduced motivation. As a result, a large number of public employees also work in private practice, or use public resources for private purposes (e.g. referring patients to their own private practice). Moreover, staff tend to prefer not to work in rural areas and are concentrated in major centres. The Ministry of Civil Affairs has a plan to develop human resources, and a university faculty has been established to train nurses as physician assistants, so that they can replace doctors where necessary. Under the World Bank-supported Health Sector Enhancement Project, there are plans to improve services for detection and management of chronic diseases, such as diabetes and heart disease. Patronage nurses are pivotal in these plans, which offer an opportunity to integrate services, including TB. The recently initiated Swiss Development Cooperation project on the roles and scope of practice of primary care nurses could also serve as a vehicle for collaboration. In addition, human resource plans are being developed with technical assistance from the Canadian Government.

Service delivery

Health care in Bosnia and Herzegovina is delivered through both a public and a private sector. The European Union (EU) supported a project[41] in 2011–13 to strengthen public services and harmonize them with public health legislation in the EU. This is expected to result in a more effective use of information to control public health threats and reduce the burden of communicable diseases. The private health sector is emerging, and mainly offers specialized services to the affluent section of the population.[42] Establishing clear standards for both the public and the private health sector requires a well functioning accreditation system.

In addition to diagnosis and curative care, family medicine centres are responsible for minor surgery, drug management, emergency care, maternal and child health care and reproductive health services, including family planning and treatment of sexually transmitted diseases. They also carry out prevention activities (health education, immunization, home visits and palliative care). At PHC level, users have the right to choose their family physician. Private practitioners may be the first point of contact with the health system for some patients, especially for pharmaceutical and dental services, and some specialized diagnosis.

In 2012, a survey in primary health care facilities showed that the majority of patients had respiratory symptoms, mainly due to infection of the upper respiratory tract (34%), infection of the lower respiratory tract (18%) and COPD (14%). TB was rarely diagnosed (2%). To improve the quality of TB diagnosis at this level, the adoption of the practical approach to lung health strategy is appropriate. Based on this survey, algorithms and guidelines for PAL are currently under development.[43]

General hospitals provide secondary health care. There is a wide network of general hospitals and several psychiatric institutions. Hospitals have wards for respiratory diseases where TB patients are diagnosed and treated. University hospitals provide tertiary care and deal with the more serious and drug-resistant cases of TB (Annex 9).

Public health offices are present in all municipalities. There are higher-level public health institutes in all cantons, and at the entity level, with overall supervision by the Ministry of Civil Affairs. The FBiH Public Health Institute has departments of hygiene and environmental health, social medicine, epidemiology, health statistics, health promotion, and radiation protection. The RS Public Health Institute has departments of epidemiology, hygiene, microbiology, sanitary chemistry, social medicine and organization of health economics, and a school of public health.

South-eastern Europe Health Network

The South-eastern Europe Health Network (SEEHN), established in 2001, is a multigovernmental forum for regional collaboration on health, health systems, and public health, working on social determinants of health. It comprises Albania, Bosnia and

Herzegovina, Bulgaria, Croatia, Israel, Montenegro, the Republic of Moldova, Romania, Serbia and the Former Yugoslav Republic of Macedonia. The WHO Regional Office for Europe lends technical support to SEEHN's various health projects, after having supplied its secretariat, along with the Council of Europe, from 2001 to 2009.

On 1 January 2010, SEEHN took over ownership of regional cooperation for health and development under the auspices of the Regional Cooperation Council (RCC) and the South-eastern Europe Regional Cooperation Process. RCC's main purpose is to provide leadership, sustain ownership by the member countries and maintain the concerted health development action launched with the Dubrovnik Pledge (2001), and maintained through the Skopje Pledge (2005) and the Memorandum of Understanding (2008).[44]

In all, eight regional health development centres have been or will soon be established; they include one dealing with strengthening of public health services in the Former Yugoslav Republic of Macedonia and one for communicable diseases in Albania. These initiatives may contribute to cross-border TB control in the region.

Recommendations

To the Government

- A system of more coordinated central financing should be developed to allow control of infectious diseases, including TB, to be harmonized.
- The Ministry of Civil Affairs could explore whether the RCC in Sarajevo could be a channel for EU funding, e.g. for cross-border financing of control of infectious diseases, including TB, among the Roma population.

To the TB programmes

- Extend training in PAL, as this will contribute to better and faster case-finding for TB.

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Annex 1. Participants in the review

International experts

Dr Jaap Veen	Independent Senior Tuberculosis Control Advisor, The Netherlands (Team Leader)
Dr Emanuele Borroni	WHO Collaborating Centre in Tuberculosis Laboratory Strengthening, San Raffaele Scientific Institute, Milan, Italy
Dr Askar Yedilbayev	Medical Officer, Partners in Health, Boston, MD, United States of America
Dr Aleksandar Simunovic	TB Epidemiologist, Croatian National Institute of Public Health, Zagreb, Croatia

Bosnian experts

Dr Rankica Bahtijarevic	TB expert, UNDP Tuberculosis Project Office

Other experts

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

Annex 2. Timetable for review of tuberculosis programme in Bosnia and Herzegovina

Sunday, 10 November 2013		
Arrival of team members at Sarajevo International Airport	Jaap Veen, ETA: 15.30, flight from Zagreb OU344 Emanuele Borroni, ETA: 14.15, flight from Vienna OS757 Askar Yedilbayev, ETA: 12.40, flight from Munich LH1730 Aleksandar Simunovic, ETA: 22.00, flight from Zagreb OU342 Transport to hotel by WHO official car	
	Accommodation: Hotel Sarajevo, Dzemala Bijedica 169 A, Sarajevo, http://www.sarajevohotel.ba/	
Monday, 11 November 2013		
07:30	Departure	Transport to UN building, approx. 20. min
08.00 – 09.00	Briefing at the WHO Country Office for Bosnia and Herzegovina	
09.00 – 11.00	Meeting with health authorities and counterparts	• Ministry of Civil Affairs of Bosnia and Herzegovina • Ministry of Health of FBiH, • Department of Health of Brčko District)
11.30 – 16.30	Hospital for lung diseases Podhrastovi, Sarajevo (FBiH)	• TB registry (*Professor Hasan Zutic and Dr Aida Ustamujic)* • TB drug management (*Begajeta Catovic*) • TB laboratory (*Dr Jasminka Maglajlic*) • MDR department (*Professor Hasan Zutic*) • HIV/AIDS – TB (*Dr Vesna Hadziosmanovic tbc)*
13.00 – 14.00	Lunch break	Team split
13.00 – 14.00	Public Institution Cantonal Centre for Social Care Sarajevo	• *(Ms Mirsada Poturković)* • *(Ms Fatima Čalkić)*
17.10 – 18.30	Pulmonary service Omer Maslic, Sarajevo (FBIH)	• TB services at PHC level *(Dr Edin Arslanagic)* • Polyvalent patronage nurse (community nurse) *(Senada Fejzic*)
19:00	Regional Cooperation Council	Holiday Inn, meeting was forwarded till next day
20:00 – 22:00	Dinner and debriefing	
	Accommodation: Hotel Sarajevo, Dzemala Bijedica 169 A, Sarajevo, http://www.sarajevohotel.ba/	

Tuesday, 12 November 2013		
07:30	Departure	Travel to Kasindo, approx. 20 min.
08.00 – 10.00	Punishment and rehabilitation prison Kula, Sarajevo East (RS)	• TB services for incarcerated individuals *(Boris Zivak)*
10.30 – 12.00	General hospital Kasindo, Sarajevo East (RS)	• TB department *(Dr Anita Kovacevic)* • TB laboratory *(Dr Spomenka Janjic)*
12.00 – 13.00	Lunch break	Team split
12:15 – 13:30	Regional Cooperation Council	• *Mr Nand Shani* • *Ms Chris Brown*
13:45 - 14:45	PIU HIV/AIDS	• *Dr Nesad Seremet* • *Ms Ariana Drin*
15:00 – 15:45	Assistant Minister of Health	• *Dr Aida Pilav*
13.30 – 15.30	Asylum Centre, Ministry of Security of Bosnia and Herzegovina	• Department of admission and accommodation for asylum-seekers *(Mustafa Pasalic tbc)*
15:30 – 16:00		Travel to Pale, approx. 30 min
16.00 – 18.00	Primary health care centre, Pale (RS)	• TB services at PHC level *(Dr Dobrinka Granzov-Kozlina)* • Polyvalent patronage nurse (community nurse) *(Milanka Veselinovic)*
18:00 - 21:00	Travel to Mostar, dinner and debriefing on the way	
	Accommodation: Hotel Ero, Dr Ante Starcevica Dzemala Bijedica, Mostar, http://www.ero.ba/	
Wednesday, 13 November 2013		
07:45	Departure from hotel	
08.00 – 10.00	Punishment and rehabilitation prison Mostar, Mostar East (FBiH)	• TB services for incarcerated individuals *(Tahir Djulic)*
10.15 – 11.45	Primary health care centre Mostar West (FBIH)	• TB services at PHC level *(Dr Davor Pehar, Director)* • Polyvalent patronage nurse (community nurse) *(Kristina Peric)*
12.00 – 14.00	University Clinical Hospital, Mostar West (FBiH)	• TB laboratory *(Dr Maja Ostojic)* • TB department *(Dr Ljiljana Cupac)* • TB drug manager *(Verica Miljko)*
14.00 – 15.15	Lunch break	
15.30 – 17.00	Hospital Dr Safet Mujic, Mostar	• TB department (Dr Hasan Custovic)

	East (FBIH)	
17:00 – 19:30	Travel to Sarajevo Accommodation: Hotel Sarajevo, Dzemala Bijedica 169 A, Sarajevo, http://www.sarajevohotel.ba/	
20:00 – 22:00	debriefing and dinner	
Thursday, 14 November 2013		
07:15	Departure	Travel to Zenica
09:00 – 10.00	Cantonal Hospital, Zenica (FBIH)	• 2nd level laboratory *(Dr Dijana Saric)*
09:00 – 10.00	Social protection services Zenica	*Ms Nurka Babović*
10.00 – 11.00	Primary health care centre Zenica (FBiH)	• TB coordinator *(Dr. Dzevad Balta)* • Polyvalent patronage nurse (community nurse) *(Merima Hadzic)* • Drug manager *(Delibasic Saliha)*
11.15 – 13.00	Punishment and rehabilitation prison Zenica (FBiH)	• TB services for incarcerated individuals *(Hidajet Jabandzic)*
13:00 – 15:00	Travel to Tesanj	
15.00 – 17.30	General hospital, Tesanj (FBiH)	• TB department *(Dr Rifat Sejdinovic)* • TB laboratory, first level *(Dr. Kadrija Abduzaimovic)*
17:30 – 19:30	Dinner with hospital management	
19:30 – 22:00	Travel to Brčko Accommodation: Hotel Nea, Jovana Ducica 3, Brčko, http://www.garnihotel-nea.com/	
Friday, 15 November 2013		
07:45	Departure	
08.00– 09.30	General hospital Brčko, TB department	• TB coordinator *(Dr Velimir Beres)* • TB drug management *(Ika Trakic)* • TB laboratory *(Dr Danica Lazic)*
09.30 – 10.00	Department of Hygiene and Epidemiologic Services Brčko (Brčko District)	Epidemiologist *(Dr Mirjana Kuzmanovic)* *Alternative programme: other team members stay in the hospital and JV goes to the DPH*
10.15 – 11.30	Primary health care centre Brčko (Brčko District)	• TB dispensary *(Dr. Sadikovic)* • Polyvalent patronage nurse (community nurse) *(Ruza Matanovic)*
11:30 – 13:00	Travel to Bijenjina	
13:00 – 14.00	Lunch break	

14.00 – 16.30	General Hospital Sveti Vracevi, Bijeljina (RS)	• TB coordinator*(Dr Sladjana Trifkovic)* • TB laboratory *(Dr. Sanda Lazic)*
16.00 – 16.30	Primary health care centre Bijeljina (RS)	• TB coordinator *(Dr Sladjana Trifkovic)* • Polyvalent patronage nurse (community nurse) *(Dragana Savic, Jadranka Markovic)*
	Departure of Askar Yedilbayev – transfer to Sarajevo by car	Accommodation: Etno selo Stanisici, Bijeljina, http://www.etno-selo.com/
Saturday, 16 November 2013		
09:00 – 12:00 12:30 – 14:00 14:00	Team meeting Lunch Data analysis and drafting of the report	Accommodation: Etno selo Stanisici, Bijeljina, http://www.etno-selo.com/
Sunday, 17 November 2013		
09:00 – 13:00 12:30 – 13:30 13:30 - 14:30 14:30 -	Data analysis and drafting of the report Lunch Travel to Tuzla Data analysis and drafting of the report	Accommodation: Hotel Senad od Bosne, Prokosovici, Lukavac, http://www. http://hotelsenadodbosne.com/
Monday, 18 November 2013		
08.00 – 09.30	Primary health care centre Tuzla (FBiH)	• TB dispensary *(Dr Munevera Osmic)* • Polyvalent patronage nurse (community nurse) *(Sidika Fazlic, Zlata Golos)*
10.00 – 11.30	Clinical hospital Tuzla (FBiH)	TB laboratory *(Dr Alma Imamovic)*
10.00 – 13.00	Clinical hospital for lung diseases and tuberculosis Tuzla (FBiH)	• TB clinic *(Dr Sead Jamakosmanovic)* • TB drug management *(Raza Gulanovic)* • HIV/AIDS – TB *(Dr Sana Sabovic tbc)*
13.00 – 14.00	Lunch	
14.15 – 16.00	NGO roles and activities, meeting at Clinical hospital for lung diseases and tuberculosis Tuzla (FBiH)	• Bosnia and Herzegovina Red Cross Society *(Emina Omerbegic)* • NGO EuroRom Tuzla (FBIH) *NGO roles and activities (Nedzad Jusic)*
16:00 – 19:00	Travel to Banja Luka, approx. 2h 50 min.	Accommodation: Hotel St Georgije, Krajiskih brigada 2, Banja Luka, http://www.hotelstgeorgije.com/

Tuesday, 19 November 2013		
07:15	Departure hotel	Travel to Gradiska, approx. 40 min.
08.00 – 09.30	Primary health care centre Gradiska (RS)	• TB services in family medicine *(Dr Gordana Bozic Ilic)* • Polyvalent patronage nurse (community nurse) *(Jasmina Spahic)*
09.30 – 11.00	General hospital Gradiska (RS*)*	• TB department *(Dr Milutin Djilas)*
11:00 _ 11:40	Departure	Travel to Banja Luka, approx. 40 min
12.00 – 13.00	Lunch	
13.00 – 14.30	Clinical center Banja Luka, Clinic for lung diseases and tuberculosis (RS)	• TB department *(Dr Mladen Duronjic, Dr Krsto Jandric, Dr Sinisa Gajic)* • HIV/AIDS – TB *(Dr Zdravka Kezic tbc)*
15.00 – 16.00	Primary health care centre Banja Luka (RS)	• TB services in family medicine *(Dr Nevena Todorovic)* • Polyvalent patronage nurse (community nurse) *(Gordana Kovacevic, Slobodanka Udovicic, Milena Savic)*
		Accommodation: Hotel St Georgije, Krajiskih brigada 2, Banja Luka, http://www.hotelstgeorgije.com/
Wednesday, 20 November 2013		
07:45	Departure hotel	
08.00 – 10.00	Public Health Institute of the Republika Srpska, Banja Luka (RS)	• RS referral laboratory *(Dr Pava Dimitrijevic, Dragana Beronja)* • Epidemiologist (*Dr Janja Bojanic)* • Epidemiologist *(Dr Jela Acimovic)* • TB drug management *(Nikolina Spiric), may include visit to warehouse Krajinalijek*
10.00 – 11.00	Social protection services Banja Luka	*Borka Vukailović, vd director*
11:00	Departure	Travel to Travnik, approx. 2h
13.00 – 14.00	Lunch break	
14.00 – 15.30	TB Hospital Travnik (FBiH)	• TB coordinator *(Dr Nenad Delic, Dr Safija Bojic)* • TB laboratory *(Gordana Pinjo)*
16.00 – 17.00	Visit to primary health care centre Travnik	• TB dispensary *(Dr Jelica Markunovic)* • Polyvalent patronage nurse (community

		nurse) *(Almir Leko, Enisa Zolota)*
17:00 – 19:00	Travel to Banja Luka, approx. 2 h Accommodation: Hotel St Georgije, Krajiskih brigada 2, Banja Luka, http://www.hotelstgeorgije.com/	
	Arrival of Pierpaolo de Colombani, Zagreb – transfer to Banja Luka by car	
Thursday, 21 November 2013		
09:00 – 12:00 12:00 – 13:00 14:00 – 18:00	Key findings Lunch Recommendations	Data analysis and drafting of the report Accommodation: Hotel St Georgije, Krajiskih brigada 2, Banja Luka http://www.hotelstgeorgije.com/
Friday, 22 November 2013		
10.00 – 11.30	Debriefing at WHO Country Office for Bosnia and Herzegovina	
12.00 – 14.00	Debriefing in Banja Luka with health authorities and counterparts	• Ministry of Civil Affairs • Ministry of Health of FBiH, • Ministry of Health and Social Welfare, RS • Department of Health of Brčko District
14.00 – 15:00	Lunch	
15:00 - 18:30	Departure of Dr Pierpaolo de Colombani, Dr Aleksandar Simunovic and Dr Jaap Veen to Zagreb – transfer from Banja Luka by car	
	Travel to Sarajevo, approx. 3h 20 min. Accommodation: Hotel Sarajevo, Dzemala Bijedica 169 A, Sarajevo, http://www.sarajevohotel.ba/	
Saturday, 23 November 2013		
	Departure of Dr Emanuele Borroni from Sarajevo International Airport, ETD: 15.05 hours, flight from Vienna OS758	

Annex 3. List of persons met

Monday, 11 November 2013			
Dr	Aida Pilav	Assistant Minister for Public Health, Monitoring and Evaluation	Ministry of Health FBiH
Dr	Haris Hajrulahovic	Head of Office	WHO
Ms	Jasmina Islambegovic	TB Project Manager	UNDP
Dr	Rankica Bahtijarevic	TB Expert	UNDP
Ms	Snjezana Brckalo	Senior expert associate for projects	Ministry of Civil Affairs of Bosnia and Herzegovina
Dr	Jasminka Maglajlic	Head of NRL	Hospital for lung diseases Podhrastovi, Sarajevo (FBiH)
Dr	Velimir Beres	TB Programme Coordinator	Hospital Brčko
Dr	Hasan Zutic	TB Programme Coordinator	Hospital for lung diseases Podhrastovi, Sarajevo (FBiH)
Ms	Marina Mujezinovic	TB M&E Data Collection Clerk	UNDP
Ms	Sanja Vukobrat	TB M&E Data Collection Clerk	UNDP
Dr	Seila Cilovic Lagarija	Department of Health Statistics and Informatics	Public Health Institute FBiH
Dr	Hasan Zutic	TB Programme Coordinator FBiH, MDR TB Department	Hospital for lung diseases Podhrastovi, Sarajevo (FBiH)
Dr	Aida Ustamujic	Epidemiologist and TB specialist	
Ms	Begajeta Catovic	Drug Manager	
Dr	Jasminka Maglajlic	Microbiologist, Head of NRL	
Dr	Jasmina Mornjakovic	Microbiologist	
Ms	Marija Omerovic	Laboratory Technician	
Ms	Nizama Hujdur	Social Worker	Centre for Social Care Novo Sarajevo (FBiH)
Ms	Meliha Prolaz	Social Worker	
Dr	Edin Arslanagic	TB Coordinator	Pulmonary Service Omer Maslic, Sarajevo (FBiH)
Ms	Senada Fejzic	Polyvalent Patronage Nurse (community nurse)	
Tuesday, 12 November 2013			
Dr	Dragana Obradovic	Medical Doctor	Punishment and rehabilitation prison Kula, Sarajevo East (RS)
Dr	Anita Kovacevic	TB Department	General hospital Kasindo, Sarajevo East (RS)
Ms	Miloranka Radonja	Laboratory Technician	

Mr	Mustafa Pasalic	Department of Admission and Accomodation for Asylum Seekers	Asylum Centre, Ministry of Security of Bosnia and Herzegovina
Dr	Dobrinka Granzov-Kozlina,	TB Coordinator	Primary health care centre, Pale (RS)
Ms	Milanka Veselinovic	Polyvalent Patronage Nurse (community nurse)	
Wednesday, 13 November 2013			
Mr	Tahir Djulic	Head of Security	Punishment and rehabilitation prison Mostar, Mostar East (FBiH)
Ms	Veldina Podro	Nurse	Punishment and rehabilitation prison Mostar, Mostar East (FBiH)
Dr	Davor Pehar	Director, Epidemiologist	Primary health care centre Mostar West (FBIH)
Dr	Zdenko Klaric	Assistant Director, Family Doctor	
Ms	Kristina Peric	Nurse and TB coordinator	
Mr	Juijan Cunjak	Department of Hygiene Epidemiology	
Dr	Maja Ostojic	Microbiologist, Head of TB laboratory	University Clinical Hospital, Mostar West (FBiH)
Ms	Ivana Pavlovic	Laboratory Technician	
Dr	Ljiljana Cupac	Pneumophthisiologist	
Ms	Verica Miljko	TB Drug Manager	
Dr	Hasan Custovic	TB Department	Hospital Dr Safet Mujic, Mostar East (FBiH)
Dr	Adisa Feriz	TB Department	
Ms	Snjezana Custo	Head Nurse of Pulmonology	
Thursday, 14 November 2013			
Dr	Dijana Saric	Microbiologist, Head of Laboratory	Cantonal Hospital, Zenica (FBiH)
Dr	Sabina Sestic	Microbiologist	
Ms	Sabina Lagumdzija	Laboratory Technician	
Ms	Nurka Babovic	Legal assistant	Social Protection Services, Zenica (FBiH)
Dr	Dzevad Balta	TB Coordinator	Primary Health Care Centre Zenica (FBiH)
Ms	Merima Hadzic	Polyvalent Patronage Nurse (community nurse)	
Ms	Delibasic Saliha	Drug Manager	
Dr	Faruk Hamidovic	Family Doctor	Punishment and rehabilitation prison

Mr	Ivica Dujmovic	Deputy Director	Zenica, Zenica (FBiH)
Mr	Semir Redzic	Engineer of Medical Radiology	
Mr	Amel Bajramovic	Head Medical Technician	
Dr	Besim Prnjavorac	Head of TB Department	General Hospital, Tesanj (FBiH)
Dr	Kadrija Abduzaimovic	Head of TB Laboratory	
Ms	Zejna Huremovic	Professional Nurse	
Dr	Rifat Sejdinovic	TB Department	
Dr	Kadrija Abduzaimovic	Microbiologist, Head of TB Laboratory	
Ms	Sadija Krdzalic	Laboratory Technician	
Ms	Subhija Kunalic	Laboratory Technician	
Ms	Nermina Mujcic	Laboratory Technician	
Ms	Semsa Skula	Laboratory Technician	
Friday, 15 November 2013			
Dr	Velimir Beres	TB Coordinator	General Hospital Brčko, TB Department
Dr	Nihad Sibonjic	General Director	
Dr	Dusan Stokic	Director	
Ms	Ika Trakic	TB Drug Management	
Dr	Mirela Suljkanovic Kovacevic	TB Laboratory	
Mr	Nijaz Fezic	Laboratory Technician	
Ms	Nevenka Simic	Laboratory Technician	
Dr	Mirjana Kuzmanovic	Epidemiologist	Department of Hygiene and Epidemiologic Services Brčko (Brcko District)
Dr	Sadikovic	TB Dispensary	Primary Health Care Centre Brčko (Brčko District)
Ms	Ruza Matanovic	Polyvalent Patronage Nurse (community nurse)	
Dr	Sladjana Trifkovic	TB Coordinator	General Hospital Sveti Vracevi, Bijeljina (RS)
Ms	Ljiljana Vujanovic	Polyvalent Patronage Nurse	
Dr	Milan Trifkovic	Assistant Director for Health Field	
Dr	Sanda Lazic	Head of Laboratory	
Dr	Sladjana Trifkovic	TB Coordinator	Primary Health Care Centre Bijeljina (RS)
Ms	Dragana Savic	Polyvalent Patronage Nurse (community nurse)	

Ms	Jadranka Markovic	Polyvalent Patronage Nurse (community nurse)	
Monday, 18 November 2013			
Dr	Munevera Osmic	TB Dispensary	Primary Health Care Centre Tuzla (FBiH)
Ms	Sidika Fazlic	Polyvalent Patronage Nurses (community nurse)	
Ms	Zlata Golos	Polyvalent Patronage Nurses (community nurse)	
Dr	Alma Imamovic	Head of TB Laboratory	Hospital Tuzla (FBiH)
Dr	Nijaz Tihic	Head of Microbiology	
Dr	Hanka Kikanovic	Microbiology Specialist	
Mr	Emir Halilovic	Laboratory Technician working on LiPA	
Ms	Jadranka Petrovic	Main Laboratory Technician	
Dr	Sead Jamakosmanovic	Tb Clinic	Hospital for Lung Diseases and Tuberculosis Tuzla (FBiH)
Ms	Raza Gulanovic	TB Drug Management	
Dr	Sana Sabovic	HIV/AIDS – TB (Tbc)	
Ms	Emina Omerbegic	General Secretary	Bosnia and Herzegovina Red Cross Society Tuzla
Ms	Jadranka Durakovic	Secretary	
Dr	Sead Jamakosmanovic	President	
Mr	Nedzad Jusic	Director	NGO EuroRom Tuzla
Tuesday, 19 November 2013			
Dr	Tihomir Mihajlovic	Director	Primary Health Care Centre Gradiska (RS)
Dr	Vesna Kovacevic	Assistant Director in Health Field	
Dr	Sanja Kezic	Replacing Head Pulmonologist	
Ms	Jasmina Spahic	Polyvalent Patronage Nurse (community nurse)	
Dr	Milutin Djilas	TB Coordinator	General Hospital Gradiska (RS*)*
Dr	Marinko Lučić	TB Department	Clinic for Lung Diseases and Tuberculosis, Banja Luka (RS)
Dr	Mladen Duronjic	TB Department	
Dr	Sinisa Gajic	TB Department	
Dr	Zdravka Kezic	HIV/AIDS – TB (Tbc)	
Dr	Nevena Todorovic	Assistant Director; TB Services in Family Medicine	Primary Health Care Centre Banja Luka (RS)
Ms	Gordana Kovacevic	Polyvalent Patronage Nurse	

		(community nurse)	
Ms	Slobodanka Udovicic	Polyvalent Patronage Nurse (community nurse)	
Ms	Milena Savic	Polyvalent Patronage Nurse (community nurse)	
Wednesday, 20 November 2013			
Dr	Janja Bojanic	Epidemiologist	Public Health Institute of the Republika Srpska, Banja Luka (RS)
Dr	Jela Acimovic,	Epidemiologist	
Dr	Sladjana Siljak	TB Coordinator	
Dr	Radovan Bradic	Collection and Analysis of Data	
Dr	Mladen Duronjic	TB Coordinator	
Dr	Pava Dimitrijevic	Head of NRL	
Ms	Dragana Beronja	Head Technician	
Ms	Nikolina Spiric	TB Drug Management	Krajinalijek
Ms	Borka Vukailovic	Director	Social Protection Services
Dr	Nenad Delic,	TB Coordinator	TB Hospital Travnik (FBiH)
Dr	Safija Bojic,	TB Coordinator	
Ms	Gordana Pinjo,	TB Laboratory	
Friday, 22 November 2013			
Dr	Boris Rebac	Project Manager	WHO
Ms	Jasmina Islambegovic	TB Project Manager	UNDP
Ms	Nikolina Spiric	Drug Manager	Clinical Center Banja Luka (RS)
Dr	Jelena Djakovic Devic	Associate for Public Health	Ministry of Health and Social Welfare of the Republika Srpska
Dr	Mladen Duronjic	TB Programme Coordinator	Clinical Centre Banja Luka (RS)
Dr	Rankica Bahtijarevic	TB Expert	UNDP
Ms	Snjezana Brckalo	Senior Expert Associate For Projects	Ministry of Civil Affairs of Bosnia and Herzegovina
Dr	Jasminka Maglajlic	Head of NRL	Hospital for Lung Diseases Podhrastovi, Sarajevo (FBiH)
Ms	Sanja Vukobrat	TB M&E Data Collection Clerk	UNDP
Dr	Velimir Beres	TB Programme Coordinator	Hospital Brčko
Dr	Hasan Zutic	TB Programme Coordinator	Hospital for Lung Diseases Podhrastovi, Sarajevo (FBiH)
Dr	Jela Acimovic	Epidemiologist	Ministry of Health of FBiH

Dr	Pava Dimitrijevic	Head of NRL	Public Health Institute of the Republika Srpska, Banja Luka (RS)
Mr	Denis Dedic	TB M&E Assistant	UNDP
Mr	Edin Telalagic	TB Project Associate	UNDP

Annex 4. Epidemiological data for Bosnia and Herzegovina

Table A4.1. Age structure of the population of Bosnia and Herzegovina (2013 estimates)

Age group	Proportion of population (%)	Male	Female
0–14	14.0	279 293	262 552
15–24	13.0	260 430	243 589
25–54	46.8	910 266	905 184
55–64	13.2	243 936	268 614
≥ 65	12.9	194 743	307 116

Table A4.2 Number of TB cases notified in Bosnia and Herzegovina, FBiH, and RS, 1996–2012.

Year	Bosnia and Herzegovina	FBiH	RS
1996	2220	1299	921
1997	2869	1820	1049
1998	2711	2060	651
1999	2923	2070	853
2000	2476	1762	714
2001	2469	1740	729
2002	no report	1747	no report
2003	no report	1740	no report
2004	2353	1550	803
2005	2160	1441	719
2006	1800	1448	352
2007	2400	1603	797
2008	1800	1199	601
2009	1772	1140	632
2010	1390	1040	350
2011	1425	856	569
2012	1420	870	550

Table A4.3 Distribution of notified TB cases by age group and sex, Bosnia and Herzegovina, 2010–12

	0–14		15–24		25–35		36–44		45–54		55–64		≥65		Total		Total
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	Male	Female	
2010	1	0	27	27	37	19	34	16	61	10	46	18	51	94	257 (58%)	184 (42%)	441
2011	2	3	33	17	32	27	52	17	75	13	61	25	62	128	317 (58%)	230 (42%)	547
2012	1	0	23	33	32	26	58	21	74	10	62	25	92	116	342 (60%)	231 (40%)	573

Table A4.4 Number of TB cases in children, by age, FBiH, 1998–2005

Age (years)	1998	1999	2000	2001	2002	2003	2004	2005	Total	Average
0–4	12	22	18	14	7	5	6	4	88	11
5–14	43	34	34	25	31	29	19	24	239	29.9
15–19	2005	2014	1710	1701	1709	1746	1525	1413	13823	1727.9
Total	2060	2070	1762	1740	1747	1780	1550	1441	14150	1768.7
Incidence among 0–14-year-olds (per 100 000)*	13.1	13.3	12.4	9.3	9.1	8.1	6.0	6.9	-	9.8

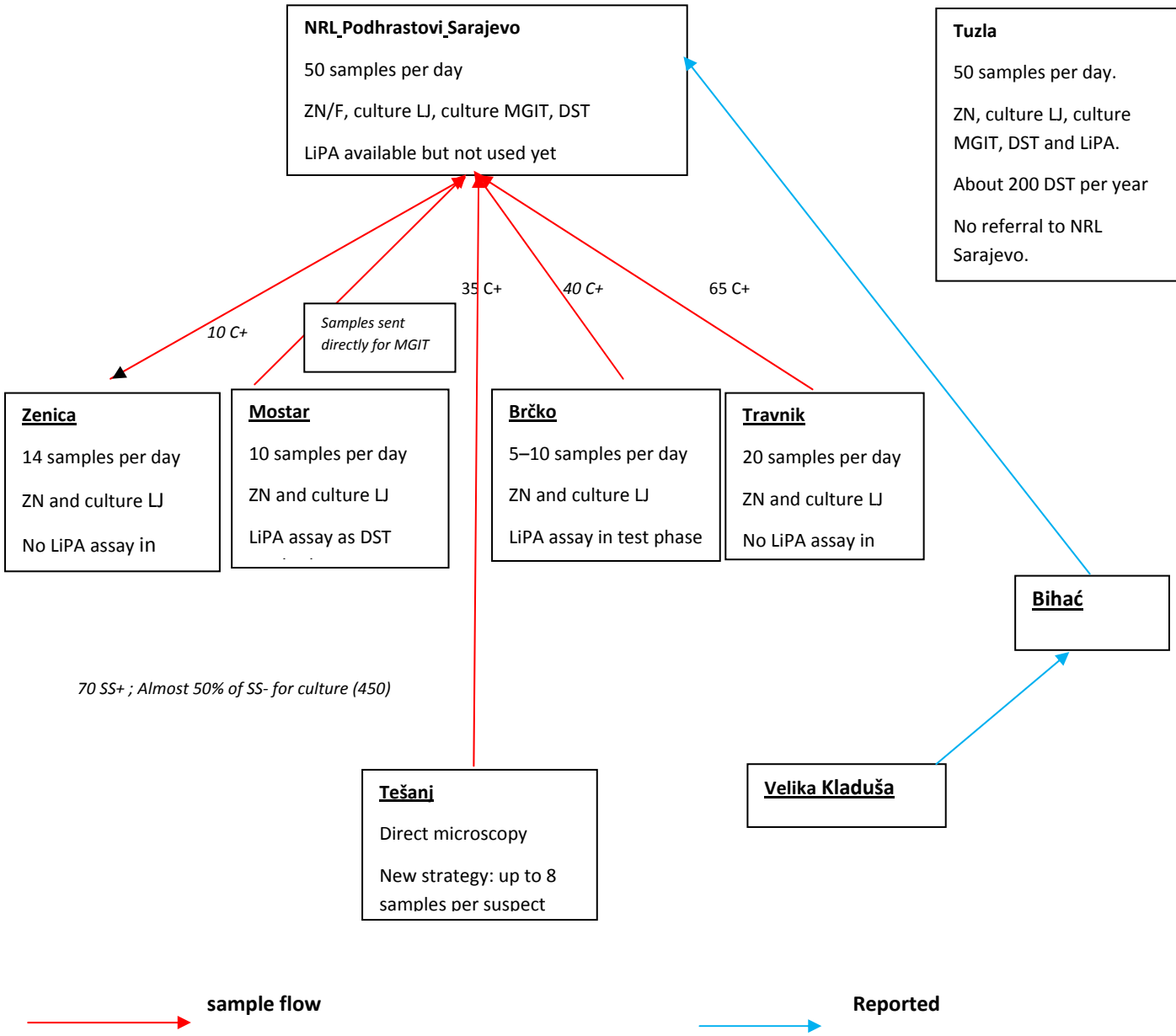
* Denominator 420 580 children under 14 years in FBiH (Statistical Yearbook FBiH 2004).

Table A4.5 Percentage distribution of TB patients by age, FbiH, 1998–2005

Age (years)	1998	1999	2000	2001	2002	2003	2004	2005
0–4	0.58	1.06	1.02	0.80	0.40	0.28	0.38	0.28
5–14	2.08	1.64	1.92	1.43	1.77	1.62	1.22	1.66
≥ 15	97.42	97.30	97.06	97.77	97.83	98.70	98.40	98.06

Annex 5. TB laboratories visited, links and referral system in Bosnia and Herzegovina

FBiH



DST: drug susceptibility testing; F: fluoroscopy; LiPA: line probe assay; LJ: Loewenstein-Jensen; MGIT: mycobacteria growth indicator tube; NRL: national reference laboratory; ZN: Ziehl-Neelsen.

Tešanj (microscopy)

In 2012–13, the number of samples tested increased remarkably. The laboratory adopted a new strategy for high-risk suspects of collecting up to 8 samples to be tested by direct microscopy. In 2013, the positivity rates of direct smears was 3% for diagnosis and 0.9% for treatment follow-up. The catchment area is about 420 000 people. In the future, the laboratory would like to introduce culture and DST within the laboratory algorithm.

Zenica (microscopy and culture solid)

A very high proportion of samples to be tested are reportedly for follow-up rather than diagnosis. More sputum smear-positive samples than culture-positive samples. In absolute figures, the number of positive cultures is extremely low (about 10 per year). In some cases, doctors can request liquid culture (MGIT) directly from Podhrastovi Sarajevo NRL. The total number of these requests is unknown.

Mostar (microscopy, culture solid, LiPA)

Catchment area is about 400 000 people. In 2012, the positivity rate on microscopy was very similar to the culture positivity rate (6.4% vs 7.7%). LiPA (Genotype MTBDR plus – Hain Lifescience) is used on positive cultures as a DST method for rifampicin and isoniazid. Some 60% of samples for analysis are non-respiratory specimens.

District of Brčko (microscopy and culture solid)

Positivity rate on microscopy reportedly higher than culture positivity rate (C+). Reported number of samples for diagnosis very similar to that for follow-up. LiPA (Genotype MTBDR plus – Hain Lifescience) is in initial phase of testing. It is intended to use it on positive cultures to test for resistance to rifampicin and isoniazid. For geographical reasons, the laboratory sometimes processes smear-positive samples from the laboratory of the General Hospital Sveti Vracevi in Bijeljina (RS).

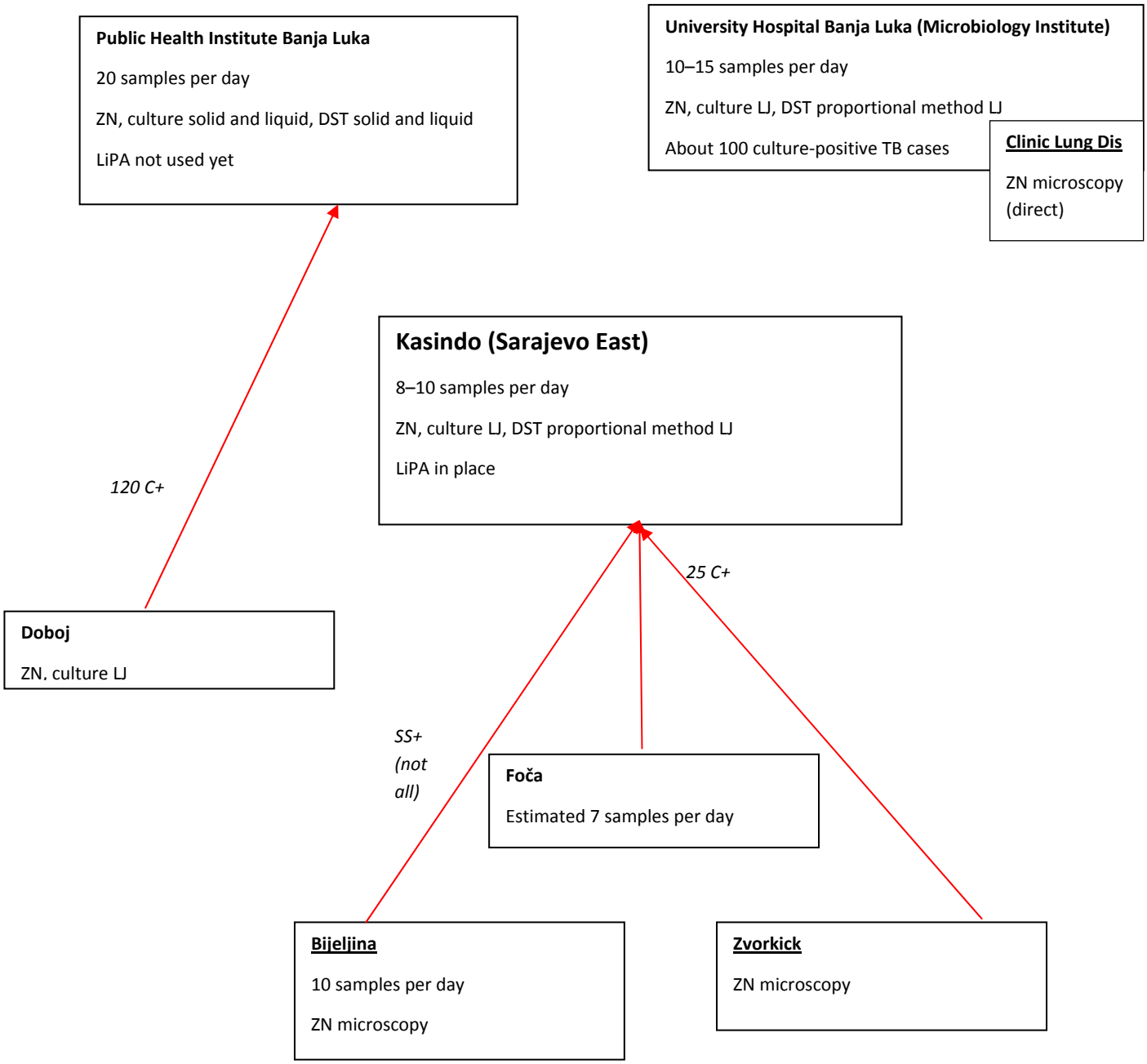
Travnik (microscopy and culture solid)

Very low contamination rate (0.2%) reported. Method of decontamination is Petroff's 4%. The laboratory has been renewed and was inaugurated in March 2013. Identification of *M. tuberculosis* by detection of chords at microscopy.

Tuzla (microscopy, culture solid, culture liquid, LiPA)

Catchment area is about 500 000 people. A very high proportion of samples to be tested are reportedly for follow-up rather than diagnosis (9200 vs 3100). Cepheid Xpert is available in the general microbiology department for diagnosis of other bacteria. There is a high contamination rate in MGIT for samples coming from peripheral sites because of delay in the referral system. Liquid cultures (MGIT) are done most of the time on request. LiPA available and used on positive cultures

RS



Kasindo Sarajevo East (microscopy, culture, DST solid , LiPA)

Catchment area about 150 000 people

The positivity rates for smear microscopy and culture are very similar

University Hospital Banja Luka (ZN, culture solid, DST solid)

While culture is done on all samples, ZN microscopy must be requested by doctor. Within the university, there is already a separate laboratory for microscopy.

DST is not performed on positive cultures unless expressly requested.

The Public Health institute is at walking distance from the University Hospital.

Bijeljina (microscopy)

Catchment area 35 000 people. Laboratory is in a general hospital. A new laboratory is to be constructed.

At present only smear microscopy is performed. Management is willing to introduce culture test on solid medium.

Not all smear-positive samples are referred for culture testing – only if expressly requested by doctor.

Public Health Institute Banja Luka (microscopy, culture solid, culture liquid, DST solid and liquid)

There are plans to reconstruct the laboratory.

Annex 6. Algorithm for improved case-finding of TB

Possible strategies to increase TB and MDR TB case-finding in Bosnia and Herzegovina

Background

The laboratory network in FBiH and RS is unbalanced in terms of the number of culture laboratories (level II). The majority of level I TB laboratories have a low daily workload. Human resources seem not to be a problem at this moment. Some laboratories would like to upgrade from level I to level II, regardless of recommendations they received from internal and external sources.

Rationale

The major obstacle to an increase in case-finding is the first screening at peripheral level. Smear-negative samples are not analysed further. Direct smear microscopy has a very low sensitivity, and some TB cases almost certainly go undetected at this stage. In Bosnia and Herzegovina, many laboratories are able to perform high-level testing (culture solid, liquid and DST) and some of them are underused.

Expected outcome

To improve case-finding, the following outcomes should be pursued:

- 100% of samples should be tested for culture, whether or not requested by the doctor;
- 100% of positive cultures should be tested for sensitivity to first-line drugs, whether or not requested by the doctor.

Initial steps

Level I laboratories

Laboratories that perform only direct smear microscopy should:

- concentrate the sputum sample after liquefaction using a centrifuge (this is routinely done in general microbiology) to increase the sensitivity of the test;
- refer for culture all sputum smear-positive samples and at least 50% of smear-negative samples from patients for whom there is a high suspicion of TB or who belong to a high-risk group; assess results after 6 months to determine if the positivity rate has increased; consider introducing new rapid tools (Xpert MTB/Rif) for use on smear-positive samples and on smear-negative samples from individuals belonging to risk groups, re-treatment cases, and those with a high suspicion of TB; positive samples should be referred for liquid culture and susceptibility testing to first-line drugs.

Level II and III laboratories

- All re-treatment cases should be tested by MGIT. Their total number is not so high as to overburden the reference laboratories in the two entities (in 2012, 55% of 119 such cases were tested).

Where LiPA is available (Genotype MTBDR*plus*), the test should be performed directly on smear-positive samples. Positive cultures should be referred for DST for confirmation only if mono-resistant or MDR.

Annex 7. Management of drugs and other commodities

The Law on Medicinal Products and Medical Devices[a]

Article 66 of this law specifies how the import of finished pharmaceutical products that have not been granted marketing authorization is to be handled. It is treated as urgent import of medicinal products for humanitarian purposes; the ministries of health of FBiH and RS and the health department of DB are responsible for issuing the import approvals.

Article 85 deals with medicinal products for humanitarian purposes and specifies that these products shall be imported to and used in Bosnia and Herzegovina only with the prior consent of the health authorities and shall not be subject to trade.

Article 86 defines import authorization for medicinal products for humanitarian purposes. Health authorities must give priority to products on the list of essential drugs for Bosnia and Herzegovina.

Article 80 specifies that quality control of medicinal products shall be carried out by the laboratory of the Regulatory Drug Agency.

TB drugs that have been approved (for humanitarian reasons)

The following first-line drugs have been approved:

- rifampicin 150 mg/isoniazid 75 mg/pyrazinamide 400 mg/ethambutol 275 mg (RHZE);
- rifampicin 150 mg/isoniazid 75 mg (RH);
- rifampicin 150 mg/isoniazid 75 mg/ethambutol 275 mg (RHE);
- streptomycin 1 g (S);
- isoniazid 300 mg (H);
- pyrazinamide 400 mg(Z);
- ethambutol 400 mg (E);
- isoniazid 100 mg (H).

The first three are fixed-dose combination (FDC) drugs, while the others are single-drug formulations.

The following second-line drugs have been approved:

- capreomycin (1 g vial);
- cycloserin (250 mg tablet);
- ethionamide (250 mg tablet);
- kanamycin (1 g vial);
- levofloxacin (250 mg);
- PASER (4-amino salicylic acid) (4 g sachets);

[a] Official Gazette of Bosnia and Herzegovina, no.58/08.

- protionamide (250 mg tablet);
- moxifloxacin (400 mg);
- linezolid (600 mg).

Annex 8. Laboratory performance in Bosnia and Herzegovina

Table A8.1. Number of TB cases detected by each laboratory, 2012

Laboratory	No. of sputum samples analysed	Approx. daily workload (250 working days)	TB suspects sputum	Diagnosis* (all samples)	Follow-up* (all samples)	Total no. of smear-positive	Smear-positive samples (%)	Total no. of culture-positive samples	Culture-positive samples (%)	No. of samples from mobile units	Smear-positive samples (mobile units)**
NRL Sarajevo Podhrastovi	10 721	50	3215	11 383	1104	82	2.6	176	3.9	--	--
Mostar	1135	10	375	1973	312	24	6.4	29	7.7	0	0
Travnik	3849	16	1191	3692	461	24	2.0	61	5.1	163	1 (0.6)
Zenica	2497	14	1114	835	2507	17	1.5	8	0.7	186	2 (1)
Bihac	4344	20	1186	4370	544	76	6.4	98	8.3	60	0
Tuzla	10 045	50	4459	3093	9128	122	2.7	167	3.7	448	3 (0.6%)
Tesanj	1686	7	804	1562	133	32	3.9	NA	NA	26	0
Velika Kladusa	391	2	130	98	293	16	12.3	NA	NA	0	0
District of Brčko	1054	5	326	733	506	41	12.8	40	12.8	34	1 (2.9%)
NRL Banja Luka	3469	20	1152	3568	243	57	3.2	71	4.0	1021	0
Banja Luka University	1738	10	585	565	1695	14	2.3	91	15.5	--	--
Kasindo (Sarajevo East)	1713	8	560	1884	89	35	4.9	40	5.7	53	3 (5.6%)
Foca	1103	7	478	1287	123	16	3.4	22	4.6	248	3 (1.2%)
Doboj	1227	6	691	1291	227	91	13.1	118	17	--	--
Bijeljina	1170	6	604	1050	618	52	8.6	NA	NA	234	1 (0.4%)

*Data on diagnosis and follow-up cannot be complete since in many cases the request form does not indicate the purpose of the test.

**Not all sputum smear-positive samples are sent for culture confirmation.

NA: not applicable.

The data have been provided by the PIU, and compiled by the team's laboratory expert..

- The approximate daily workload for TB has been calculated on the basis of all samples, not only sputum samples.
- Positivity rates for smear microscopy and culture are not differentiated between diagnosis and follow-up.
- In 2013, there was a huge increase in the number of samples tested in Tesanj (FBIH) as a result of the adoption of a new strategy of collecting up to 8 samples per suspect.
- Zenica (FBiH), Mostar (FBiH), Foca (RS) and Doboj (RS) have a high proportion of extrapulmonary samples compared with the rest of the network.

Table A8.2 Drug susceptibility tests performed in 2012*

Laboratory	No. of positive cultures	DST performed (in laboratory or on referral)	
		No.	%
NRL Sarajevo Podhrastovi	177	177	100
Tuzla	176	176	100
Zenica	9	8	88.9
Travnik	54	51	94.4
Mostar	35	33	94.3
Bihac	80	79	98.85
District of Brčko	35	31	88.6
NRL Banja Luka	66	66	100
Banja Luka University	89	88	98.9
Doboj	90	80	88.9
Kasindo (Sarajevo East)	44	43	97.7
Foca	18	13	72.2

*Data reported do not coincide with those reported in Table A8.1. Delays in reporting could be a reasonable explanation. The differences are not so big as to cause concern.

Infomation provided by the PIU.

Table A8.3. Indicators of performance in quality assessment by NRL Sarajevo, 2013

Indicator	Sarajevo NRL	Mostar	Travnik	Bihac	Zenica	Tuzla	District Brčko
1. % of smear-positive samples that are cultured	100	94.1	100	94	80	--	81
2. Smear-positive samples as % of culture-positive samples	54	80.9	74.7	67	62.5	--	81
3. Culture-positive samples as % of smear-positive samples	248.5	--	--	--	160	--	**5.8**
4. %of smear-positive samples that are culture-negative	0	5.5	0.2	1.5	20	--	11.6

5.	Contamination rate	6.84 (liquid)	1.5	**0**	4.95	**0**	--	2.7
6.	% of culture-positive samples that are subject to DST	100	100	100	100	100		100

Source: NRL Sarajevo.

- Some values for indicator 5 are unreliable, especially that for Travnick.
- Zenica has a very high rate of culture-positive samples, which may be related to too harsh decontamination or the reporting system.
- Indicator 3 for Brčko is too low. It means that about 95% of smear-positive samples give culture-negative results. This cannot be explained by the fact that half of the samples in Brčko are for follow-up.
- Indicator 2 for Sarajevo NRL seems to be too low. It means that the added value of culture to microscopy is 54%, which is a very high increment. If this is correct, smear microscopy in NRL should be investigated.

Annex 9. Health infrastructure in Bosnia and Herzegovina

Entity	Canton/region	Name	No. of beds	No. of TB beds	Sex	
					M	F
Federation Bosnia and Herzegovina	Sarajevo	University clinic for lung diseases (level 3)	106	34		
	Mostar	University clinic for lung diseases (level 3)		10		
	Zenica-Doboi	General hospital Tesanj (level 2)		20		
		Cantonal hospital Zenica (level 2)	60			
	Middle Bosnia	Lung hospital Travnik (level 2)	120	40		
	Una-Sana	Cantonal hospital Bihac (level 2)	35	30		
	Tuzla	University clinic for lung diseases (level 3)	60	40		
	Herzegovina-Neretva	University clinic for lung diseases		10		
	Subtotal			184		
District Brčko		General hospital	60	5–10		
Republika Srpska	Banja Luka	University clinic for lung diseases (level 3)		30	24	6
	East Sarajevo	University clinic for lung diseases (level 3)		10	6	4
	Foca	University clinic for lung diseases (level 3)				
		Kasindo clinical hospital (level 2)		20	10	10
		Trebinje clinical hospital (level 2)		6	3	3
	Bijeljina	Bijeljina clinical hospital (level 2)		8	4	4
		Gradiska clinical hospital (level 2)		8	4	4
	Doboi	Doboi clinical hospital (level 2)		10	6	4

	Prijedor	University clinic for lung diseases				
	Subtotal			92		
Total				281–286		

Source: GLC report 2008, Kai Vink.

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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World Health Organization
Regional Office for Europe

Marmorvej 51, DK-2100 Copenhagen Ø, Denmark
Tel.: +45 45 33 70 00 Fax: +45 45 33 70 01 E-mail: contact@euro.who.int
Website: www.euro.who.int