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# **Extensive review of TB prevention, care and control services in Hungary**

22–25 May 2012

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WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR EUROPE  
EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

# Mission report

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## **Extensive review of TB prevention, care and control services in Hungary**

**22–25 May 2012**

The WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC) regularly collaborate on tuberculosis (TB) surveillance, prevention and control in the European Union. Following a request by the Ministry of National Resources of Hungary on 26 April 2012, the Regional Office and ECDC organized a joint country visit on 22–25 May 2012 to provide a comprehensive overview of TB prevention, control and care in the country and present the health authorities with key recommendations and suggested action to improve TB prevention, control and care.

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<sup>1</sup> Gaál P et al. Hungary: Health system review. *Health Systems in in Transition*, 2011, 13(5):1–266.

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## **Executive summary**

Following a request by the Ministry of National Resources on 26 April 2012, the WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC) organized a joint country visit to Hungary on 22–25 May 2012 in collaboration with Hungarian national technical counterparts. The agreed terms of reference were as follows.

### **Goals**

- To provide a comprehensive overview of tuberculosis (TB) prevention, control and care in the country.
- To present the health authorities with the key recommendations and suggested action to improve TB prevention, control and care.

### **Objectives**

- To analyse TB, drug-resistant TB (DR-TB) and TB/HIV epidemiological data and their trends.
- To assess TB prevention, diagnosis, treatment and care services in terms of quality, pertinence, access, availability and use.
- To review the social determinants of TB and the responses to them.
- To assess the links, synergies and opportunities for TB control in relation to health system strengthening and other disease-specific interventions, including management of TB/HIV coinfection.
- To assess the role and involvement of civil society organizations in TB-related activities.
- To assess partnership, coordination and collaboration on TB control with national and international stakeholders, including the Ministry of Public Administration and Justice.

With the assistance of the WHO country office and in close coordination with the Ministry of Human Resources, a team of eight international experts conducted the country visit and programme review. All technical reports, surveillance data, national reports and epidemiological data were reviewed. The review team was divided into two subteams for field visits.

The teams interviewed health authorities, health-care staff, epidemiological centres, TB laboratory services, nongovernmental organizations and patients. The site visits were suggested by the review team and agreed with the health authorities. TB prevention, control and care interventions were assessed on the basis of the six “building blocks” of the health system defined by WHO – service delivery, health workforce, information, medicines, financing and governance.

## **Key findings**

Hungary has successfully decreased its TB rate over the last two decades, with decreased notification and a low percentage of MDR-TB cases. There is close collaboration with civil society organizations (e.g. the Hungarian Maltese Charity Service) in providing TB screening for hard-to-reach populations.

Despite all these positive developments, there are key challenges, as only one third of new pulmonary TB cases were bacteriologically confirmed in 2010, and allocation of resources is disproportionate, with up to 65% of the overall budget for TB control used for active case-finding in the general population and the treatment success rate for new bacteriologically confirmed pulmonary TB patients in 2009 standing at only 57% (significantly below the target of 85%). There are discrepancies between the national guidelines for TB prevention and control and the latest international recommendations.

## **Key recommendations**

Hungary needs to maintain its commitment to the prevention and control of TB and multidrug-resistant/extensively drug-resistant TB (M/XDR-TB). The mission members suggested the following action.

- Develop a national TB action plan which reallocates financial resources in accordance with international guidelines and includes a monitoring framework with national targets for TB control (1,2).
- Improve ambulatory care of TB patients and directly observed treatment (DOT) in order to improve treatment adherence and outcomes.
- Implement the planned reorganization of the TB laboratory network.
- Establish a single coordination platform (e.g. a national StopTB Partnership forum) for tuberculosis prevention and control, involving civil society organizations, the private sector and other stakeholders.

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## Acronyms and abbreviations

AIDS	acquired immunodeficiency syndrome
BCG	bacillus Calmette-Guerin
CXR	chest X-ray
DL	direct microscopy laboratory
DOT	directly observed treatment
DOTS	directly observed treatment, short-course – the basic package that underpins the WHO Stop TB Strategy
DRG	diagnosis-related group
DR-TB	drug-resistant TB
DST	drug susceptibility testing
ECDC	European Centre for Disease Prevention and Control
EQA	external quality assurance
EU12	the original 12 Member States of the European Union
EU15	the 15 Member States of the European Union from 2004
EU27	the current 27 Member States of the European Union
GDP	gross domestic product
HIV	human immunodeficiency virus
HUF	Hungarian forint
IGRA	interferon gamma release assay
LED	light-emitting diode
LJ	Lowenstein-Jensen medium (for recovery of mycobacteria)
LPA	line probe assay
LTBI	latent tuberculosis infection
MDR-TB	multidrug-resistant tuberculosis (i.e. resistant to, at least, isoniazid and rifampicin)
NHIFA	National Health Insurance Fund Administration
NPHMOS	National Public Health and Medical Officer Service
NRL	national reference laboratory for TB
NTM	non-tuberculous mycobacteria
OECD	Organisation for Economic Co-operation and Development
OKTPI	Korányi National Institute for Tuberculosis and Pulmonology
PDR-TB	polydrug-resistant tuberculosis
PLHIV	people living with HIV/AIDS
PPS	purchasing power standard
SLD	second-line drug
SNRL	supranational reference laboratory
TB	tuberculosis
TST	tuberculin skin test/testing
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

# **1. Background**

## **1.1 Socioeconomic situation**

### **1.1.1 Public administration**

In Hungary, there are three levels of public administration, consisting of the central government and two tiers of local government: counties and municipalities. Local government elections are held a few months after the general election. Policy-making at the national level establishes the framework within which decision-making by local governments takes place. The Hungarian Constitution guarantees the right of local governments to take decisions on local affairs; disputes in authority between the central and local governments can be settled by the Constitutional Court. Under the Government elected in April 2010, many public administration functions are currently being integrated into new central Government offices at the county level.

### **1.1.2 Economic context**

Between 2001 and 2006, the Hungarian economy grew at an annual rate of more than 4%, which resulted in a positive output gap. This was accompanied by sharp fluctuations in the fiscal deficit, which reached a peak of 9.2% of gross domestic product (GDP) in 2006. Surprisingly, the economic growth during these years did not have a substantial impact on the employment rate, which stagnated at around 57% between 2000 and 2008 for individuals between 15 and 64 years of age. Of the 27 Member States of the European Union, only Malta had a lower rate of employment in this age group in 2008 (3).

**Table 1. Macroeconomic indicators, 1995–2009 (selected years)**

	1995	2000	2005	2008	2009
GDP at market prices (millions of euros)	34 922	51 411	88 574	106 373	92 942
GDP at market prices (in millions of PPS)	78 170	107 763	143 073	162 142	153 161
GDP at market prices (euros per inhabitant)	3400	5000	8800	10 600	9300
GDP at market prices (PPS per inhabitant)	7600	10 600	14 200	16 300	14 800
Real GDP growth rate (%)	0.7 <sup>a</sup>	4.9	3.2	0.8	-6.7
Total general government expenditure (% of GDP)	55.7	46.8	50.2	48.8	50.5
Total receipts from taxes and social contributions (% of GDP)	40.9	39.0	37.6	40.1	39.6
Government consolidated gross debt (% of GDP)	85.2	55.0	61.8	72.3	78.4
Industry, value added (% of GDP)	32.3 <sup>a</sup>	32.2	30.2	29.5	n/a
Agriculture, value added (% of GDP)	7.1 <sup>a</sup>	5.4	4.2	4.3	n/a
Services, etc., value added (% of GDP)	60.6 <sup>a</sup>	62.4	65.6	66.2	n/a
Labour force (total)	4 175 464 <sup>a</sup>	4 162 578	4 268 262	4 268 267	n/a
Unemployment rate (% of labour force)	9.6 <sup>a</sup>	6.4	7.2	7.8	10.0
At-risk-of-poverty rate	n/a	11.0%	13.5%	12.4%	12.4%
Gini coefficient	n/a	26.0	27.6	25.2	24.7
Central bank interest rate (official deposit rate), annual	19.0	9.8	5.0	9.5	5.3
Euro/ECU exchange rate (HUF)	164.6	260.0	248.1	251.5	280.3

Source: (4). Notes: <sup>a</sup> data from 1996; ECU = European currency unit; GDP = gross domestic product; HUF = Hungarian forint; PPS = purchasing power standard.

Hungary was one of the countries in the region hit hardest by the global financial crisis, experiencing a complete freeze in the Government bond market from late 2008 to early 2009, and an average depreciation of the Hungarian forint of some 30% against the major currencies by March 2009 (5). The latter had a devastating effect on the thousands of households with mortgages in foreign currencies, especially Swiss francs.

According to the TÁRKI European Social Report, Hungary was one of a large number of nations in the EU in 2005 with a Gini index<sup>1</sup> above 25% but below 30%, placing it squarely between low-inequality countries such as the Nordic States or Luxembourg and high-inequality countries such as the Baltic States, Poland, Greece and Portugal (6). In 2009, Eurostat data show that the Gini index in Hungary was 24.7%, which was lower than the averages for the current 27 European Union Member States (EU27) (30.4%), the original 12 Member States (EU12) (30.7%) and the 15 States which made up the European Union from 2004 (EU15) (30.3%) (4).

One of the stated goals of successive governments has been to promote job creation. This goal has dominated public policy since the mid-1990s. The employment database of the Hungarian Central Statistical Office shows that the employment ratio for the population between the ages of 15 and 64 years was 56.7% in 2008 (7). Thus Hungary has occupied the last-but-one place in the European Union for many years. The low level of employment makes the living conditions of the Roma population, especially, very difficult. Unfortunately, it is difficult to collect data on the working and living conditions of this group because of data protection regulations.

### **1.1.3 General health status**

Since the mid-1990s, Hungary has seen a strong and steady increase in life expectancy at birth among men and women alike (see Table 2). Half of this increase has been attributed to a decrease in cardiovascular mortality over the same period. Indeed, after three decades of declines in the population's health status due to noncommunicable diseases, this turnaround was interpreted as the beginning of a new era in population health (8). Some researchers are sceptical of this view and have pointed out that the gap in life expectancy at birth between Hungary and neighbouring Austria, the other Visegrád Group countries (Czech Republic, Poland and Slovakia) and the EU15 average has remained essentially unchanged for women and narrowed only a little for men over this period (9). Moreover, since the mid-1990s, mortality due to ischaemic heart disease in individuals younger than 65 years in Hungary has actually increased relative to the EU15 and Visegrád Group averages (9). Finally, compared with the EU15 average, the relative risk of mortality from cardiovascular disease, malignant neoplasms and respiratory disease among both women and men of all ages has continued to rise (10).

In short, Hungary is still towards the bottom of the list of European countries with regard to life expectancy at birth, trailing the EU27 average by 5.1 years and the EU15 average by 6.3 years in 2009. When overall disease burden is taken into account, this gap persists, with disability-adjusted life expectancy in Hungary reaching 65.8 years in 2007 (Table 3) compared with 73.0 years in the

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<sup>1</sup> The Gini index measures the extent to which the distribution of income or consumption expenditure among individuals or households within an economy deviates from a perfectly equal distribution. Source: World Bank. *Data* (<http://data.worldbank.org/indicator/SI.POV.GINI>, accessed 11 April 2013).

EU15, 71.7 years in the EU27, 71.3 years in Slovenia, 69.9 years in the Czech Republic and 67.1 years in Poland (11).

**Table 2. Mortality and health indicators, Hungary, 1970–2009 (selected years)**

	1970	1980	1990	1995	2000	2005	2009
Life expectancy at birth, total (years)	69.3	69.1	69.5	70.1	71.9	73.0	74.5
Life expectancy at birth, male (years)	66.4	65.5	65.2	65.5	67.6	68.8	70.3
Life expectancy at birth, female (years)	72.2	72.8	73.9	74.8	76.3	77.2	78.5
Crude death rate per 1000 population, total	11.6	13.6	14.0	14.1	13.3	13.5	13.0
Crude death rate per 1000 population, male	12.5	14.8	15.4	15.7	14.5	14.6	13.9
Crude death rate per 1000 population, female	10.8	12.4	12.8	12.6	12.2	12.5	12.1

Source: (11).

**Table 3. Disability-adjusted life expectancy in years, Hungary, 2000–2007 (selected years)**

	2000	2001	2002	2007
Male	57.9	58.0	61.5	62.3
Female	65.4	65.5	68.2	69.3
Total	61.6	61.8	64.9	65.8

Source: (11).

As can be seen from Table 4 below, the main causes of death in Hungary are diseases of the circulatory system, malignant neoplasms, diseases of the digestive system (including liver disease) and external causes (including suicide). This pattern has remained essentially unchanged since 2000, and mortality from each of these causes continues to be higher than the EU27 average and, in the case of malignant neoplasms and digestive system disease, the EU12 and WHO European Region averages (11).

Communicable diseases play a subordinate role in Hungary, with the incidence and mortality rates for most childhood infectious diseases continuing to be lower than the EU12 average (11) and the mortality rates for viral hepatitis and HIV remaining lower than the EU15 average (4).

**Table 4. Main causes of death (standardized death rates, all ages, per 100 000), Hungary, 1980–2009 (selected years)**

	1980	1990	1995	2000	2005	2009
<b>Communicable diseases</b>						
Infectious and parasitic disease	13.4	8.5	7.2	5.6	4.1	3.8
Tuberculosis	10.9	6.1	5.5	3.3	2.1	1.4
HIV/AIDS	n/a	n/a	0.1	0.2	0.1	0.1
<b>Noncommunicable diseases</b>						
Diseases of circulatory system	688.7	643.9	592.0	521.0	502.4	421.2
Ischaemic heart disease	229.4	239.7	248.7	226.9	261.3	214.8
Cerebrovascular disease	218.0	177.2	158.6	141.7	108.2	90.8
Malignant neoplasms	239.9	266.7	276.2	268.2	237.4	243.2
Trachea/bronchus/lung cancer	44.5	61.2	65.0	65.0	60.8	65.9
Malignant neoplasm female breast	29.0	32.2	32.7	32.5	27.4	28.1
Cancer of the cervix	11.0	9.6	8.4	7.3	6.5	5.9
Diseases of the digestive system	62.9	81.4	106.4	87.0	70.6	65.6
Chronic liver disease and cirrhosis	27.4	50.6	79.0	60.1	44.5	41.3
Diseases of the respiratory system	89.4	57.1	52.5	40.3	47.7	44.3
Mental disorders and diseases of the nervous system and sensory organs	12.1	19.4	25.5	22.2	22.3	29.6
Diabetes	16.9	16.2	14.8	17.3	25.6	17.9
<b>External causes</b>						
External cause injury and poison	114.3	121.1	100.9	82.2	67.9	59.0
Suicide and self-inflicted injury	44.4	38.1	30.5	29.2	23.2	21.8
Motor vehicle traffic accidents	15.8	24.4	16.2	12.0	12.1	8.5

Sources: (4, 11).

Table 5 shows selected findings of the General Practitioners' Morbidity Sentinel Stations Programme (GPMSSP) for 2009. Hypertension and diabetes mellitus are clearly important sources of disease burden in the Hungarian population. Moreover, looking at men and women separately reveals that acute myocardial infarction was almost twice as common – and chronic liver disease almost four times as common – among men as among women in 2009. Other data from the GPMSSP show that the prevalence of chronic liver disease was especially high in men aged 35 years and above (University of Debrecen Faculty of Public Health, unpublished data, 2011).

**Table 5. Prevalence of selected noncommunicable diseases in Hungary, 2009 (adults aged 20+ years, per 1000 population)**

	Hypertension	Diabetes mellitus	Chronic liver disease	Acute myocardial infarction	Stroke
Men	273.0	74.0	13.2	12.5	20.4
Women	339.7	73.5	3.5	6.9	17.0
Total	308.9	73.7	8.0	9.5	18.6

Source: University of Debrecen Faculty of Public Health, unpublished data, 2011.

The Hungarian immunization system is well-organized and serves the public health needs of the population. Among children, measles immunization coverage was 99.8% in 2009, which is an outstanding result among the countries of the Organisation for Economic Co-operation and Development (OECD) and also in the WHO European Region. Coverage for immunization against diphtheria, pertussis and tetanus is equally high (11).

## 1.2 Epidemiology of TB and HIV in Hungary

With an estimated 1500 (1300–1700) incident TB cases and 130 (120–160) deaths from TB every year (12), Hungary with its 10 million population is defined as a country with a low TB incidence (2). The national focal point reported 39 deaths with TB as the underlying cause out of 152 TB deaths that were reported by the country in the Vital Registration System, which also includes cases in which the primary cause of death was something other than TB. Of a total of 1741 TB cases registered in 2010, 1543 cases (89%) were reported as new and relapses.

Despite the fact that Hungary has common southern and eastern borders with countries such as Romania, Ukraine, Serbia and Croatia, where notification rates are significantly higher (85.6 and 74.5 per 100 000 population) or slightly higher (19.3 and 15.6 per 100 000 population), TB epidemiology shows a decreasing trend since 2000, after a plateau during the period 1992–2000 when migration increased significantly. Western and northern neighbours such as Slovenia, Slovakia and Austria have much lower notification rates – 8.3, 7.2 and 4.3 per 100 000 population. A similarly wide range of TB notification is observed among 19 counties of Hungary, from 4.9 to 25 cases per 100 000 population, with the highest rates in the north-eastern areas, Miskolc, Nyíregyháza and Debrecen, as well as in Budapest and Szekszard (see Annex 4, TB epidemiological country profile).

The treatment success rate among new pulmonary laboratory-confirmed TB cases, new laboratory-unconfirmed/extrapulmonary cases and previously treated cases was 57.1%, 77% and 61%, respectively. These low success rates are mostly due to the rates of failed treatment (22.4%), death (9.7%) and loss to follow-up (10.7%). The death rate and loss to follow-up may be explained by the age of the TB population (25.4 and 22.3 cases per 100 000 population, or 60% of all TB cases, are notified among people over 44 years of age), and by poor observation of treatment, respectively: however, high treatment failure rates (22.4% among new laboratory-confirmed TB patients) are difficult to explain and call for operational research based on available case-based data.

Out of 13 MDR-TB patients notified in 2008, all on second-line drug (SLD) treatment, the treatment success, death and failure rates were 31%, 23% and 46%, respectively.

While the routine DR-TB surveillance system in Hungary in 2010 shows the percentage of MDR-TB among new and previously treated patients (2.4% and 8.8%, respectively) to be close to the estimated figures (3.3% for new patients (range 1.9%–5.3%) and 7.3% for previously treated patients (range 2.0%–18.0%)), the system has been classified as a Class B DR-TB surveillance system, mainly because of the low rate of culture confirmation of TB.<sup>1</sup>

By 2011, the cumulative number of people living with HIV/AIDS (PLHIV) was 2115, of whom 656 (30%) had AIDS. In 2011, there were 162 new HIV infections (1.6 incident cases per 100 000 population). Men having sex with men was identified as the main path of HIV transmission (85%); the remaining 15% were classified as heterosexual transmission, according to the 2011 data. Thirty-eight TB cases were detected among these PLHIV, of whom 22 died (case-fatality rate 58%). Pulmonary TB among TB/HIV coinfecting cases stood at 79%, and among non-HIV-infected cases at 95% (source: Korányi National Institute for Tuberculosis and Pulmonology and National Public Health and Medical Officer Service, unpublished data, 2012).

The percentage of HIV infection among TB incident cases was estimated at 1.0% (range 0.6–1.6%) or 15 (range 9–24) cases, among whom only one TB/HIV coinfecting case was detected. HIV testing coverage was difficult to determine owing to poor documentation.

### **1.3 Health system structure**

#### **Overview of the health system and health reforms**

##### *Organization and governance*

The Hungarian Constitution assigns overall responsibility for social welfare and health-care provision to the central Government, but other actors are also involved in decisions related to the organization and functioning of the health system. In the single-payer system, recurrent expenditure on health services is funded primarily through compulsory, non-risk-related contributions made by eligible individuals or by the Government (from the State budget) and through general taxes. Entitlement to benefits is based on these contributions. The contributions themselves are pooled in the Health Insurance Fund (HIF), which is administered by the National Health Insurance Fund Administration (NHIFA). The latter is the sole payer in the system. It is under the direct control of the State, has no discretion over revenue collection or budget-setting, and has only very limited discretion over purchasing decisions.

Prevention and health promotion are not adequately funded, and the coordination of intersectoral activities is lagging behind. Growing inequities have yet to be addressed in an appropriate manner. Some indicators of avoidable mortality, however, paint a more positive picture, as does Hungary's excellent immunization record, with virtually 100% coverage against childhood diseases.

##### *Financing*

The issue of health-system financing has dominated the health-care agenda of consecutive governments since the fall of the communist regime. The first wave of reforms (1989-93)

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<sup>1</sup> In a Class B system, there is (i) nationwide coverage of 100% or culture results available for 90% of all cases; (ii) at least 35% of all cases are culture-positive; (iii) drug susceptibility testing (DST) results are available for 50% of culture-positive cases; and (iv) external quality assessment (EQA) results are available for 95% of cases.



transformed the system from one financed primarily through taxes to one based on compulsory health insurance. In 2009, Hungary spent 7.3% of its GDP on health, with public expenditure accounting for 69.6% of total health spending. Health spending has fluctuated over the years, with several waves of short increases followed by longer periods of cost containment and budget cuts. The share of total health expenditure attributable to private sources has been increasing, most of it accounted for by out-of-pocket expenses. Voluntary health insurance, on the other hand, amounted to only 7.4% of private expenditure and 2.7% of total health expenditure in 2009.

Public expenditure on health care is financed mainly through a combination of contributions and general-tax-revenue transfers to the health insurance scheme. There has been increasing reliance on the latter in recent years. Participation in the health insurance scheme is compulsory for all citizens living in Hungary, and opting out is not permitted. Based on the current legal framework, coverage should theoretically be 100%, but the health insurance status of approximately 4% of the population is unclear. The benefits package is comprehensive but not exhaustive. Both a positive and a negative list are currently in place.

The provider payment system has become output-based, and payment mechanisms are geared to the type of service provided, rather than the type of institution responsible for provision. Family doctor services are paid through capitation, outpatient specialist care through a fee-for-service point system, acute inpatient services through a payment system based on diagnosis-related groups (DRGs) and chronic care through per-diem rates. Special rules apply to certain services, such as emergency patient transfers. Physicians are either salaried employees or private entrepreneurs contracted by NHIFA, whereas other health professionals are mostly salaried.

### *Physical and human resources*

In 2011, the Government started to nationalize the hospitals, which were previously owned by local governments, in order to improve the allocative efficiency of the system, partly by reallocating hospital beds among the providers and also by changing the service profile. Since the mid-1990s, Hungary has also followed the general European trend of reducing the number of acute hospital beds, both through real reductions and through bed reallocations to different types of service. The capacity for long-term nursing care in both the inpatient and the outpatient setting is still considered insufficient to meet the needs of the ageing population. In general, the average length of stay and hospital admission rates have decreased since 1990, as have bed occupancy rates.

With regard to human resources in the health-care sector, Hungary had 3.1 active physicians per 1000 population in 2008, which is slightly below the OECD average. The number of physicians has dropped substantially since 2003, and increased professional mobility may lead to a further decline in this ratio in the near future. Physicians are unevenly distributed in terms of both geography and specialties. A similar trend can be observed for associated health-care personnel. Given that (a) Hungary is also a net donor country in respect of health-care worker migration and (b) on the whole, health-care personnel are ageing, the current health workforce crisis is easily explained.

### *Provision of services*

Health-care delivery is based on the constitutional obligation of the State to make health services available to all eligible residents. Municipalities are responsible for providing primary care while, following the nationalization of the hospitals, the central Government has become the main actor responsible for providing specialist health-care services since the beginning of 2012.

Public health services in Hungary also fall within the remit of the central Government, in particular the Ministry of Human Resources, which provides these services through the National Public Health and Medical Officer Service (NPHMOS). NPHMOS is responsible for public health; social medicine and health administration; supervising health service delivery; monitoring and evaluating sanitary conditions, epidemiological issues and changes in the population's health status; and health promotion and prevention.

## 2. Service delivery

### 2.1 Structure of TB prevention, control and care services

#### 2.1.1 Routine screening by chest X-ray

##### *Observations*

In Nyíregyháza, among 60 000 persons screened in 2011, 2618 had a chest X-ray (CXR) abnormality requiring a medical visit and examination. TB was diagnosed in 27 cases (five confirmed by culture), some 33% had another disease, and 66% were normal. The proportion of cases confirmed by culture was the same in all groups for whom CXR was performed (5/27 for cases detected by routine X-ray screening and 3/18 for cases visiting the clinic because of symptoms), meaning that the cases detected by routine screening were probably **not** different from the cases who visited the dispensary because of their symptoms.

### 2.2 Prevention

#### 2.2.1 Contact tracing

##### *Observations*

Investigations are performed among the contacts of TB cases (no clear definition of source case and contacts). Children <14 years have a tuberculin skin test (TST), contacts >14 years have TST and CXR. Interferon gamma release assay (IGRA) is not used (not available or too expensive). The indications for preventive treatment are unclear, also the time before repetition of screening if the first examination is negative. Rifampicin seems to be used for preventive treatment in children.

##### *Suggested action*

- Update contact investigation guidelines with clear definitions of index case and contact and following the WHO guidelines (13).
- Assess whether IGRA can be used in special situations, especially immune-compromised contacts.

#### 2.2.2 Vaccination

##### *Observations*

Age-related childhood vaccination is mandatory in Hungary. Bacillus Calmette-Guerin (BCG) vaccination has been mandatory since 1953. Since 2001, BCG vaccination has been mandatory only for infants under one year of age (Annex 5, The Hungarian Childhood Vaccination Schedule). BCG vaccination of infants is performed at maternity wards and/or within six weeks of birth. Delayed BCG

vaccination does not affect the infant vaccination schedule. At six months of age, infants who have no infiltration or scar at the BCG vaccination are vaccinated again without undergoing TST. Infants who remain scar-negative after BCG revaccination are not vaccinated a third time.

#### *Suggested action*

- Continue BCG vaccination as described in the current guidelines and reassess whether general BCG vaccination should continue in five years' time.

### **2.2.3 Chemoprophylaxis**

#### *Observations*

Children detected with latent tuberculosis infection (LTBI) during contact investigation (by TST) receive preventive treatment. It seems that rifampicin is frequently used for this. The indications for preventive treatment of adults with LTBI are not clear. Adults with abnormal CXR detected during contact investigation are evaluated for TB and treated if TB is confirmed (which is the case for about half of the cases diagnosed with TB among contacts).

#### *Suggested action*

- Reinforce the use of preventive treatment in infected children and eligible adults (immune-compromised persons including HIV-infected, those under tumour-necrosis-factor-alpha (TNF-alpha) medication, possibly others).
- Discontinue the use of rifampicin monotherapy for preventive treatment in children and replace it by nine months of isoniazid therapy. Consider the use of chemoprevention with rifampicin in adults for increasing adherence rate in suitable cases.

### **2.2.4 Infection control**

#### *Observations*

Overall, airborne infection control in the facilities visited is weak. There is no infection control plan to control nosocomial infection. In one facility visited, children with TB are admitted to the same ward as children with other diseases. Natural ventilation with open air can only help when the weather permits: however, in the reference centres where patients are admitted with severe forms of the disease, particularly M/XDR-TB, there is no upper-room ultraviolet germicidal irradiation or other engineering control (e.g. negative-pressure ventilation). Recently admitted patients are housed with those who have been in the hospital for a while.

In the outpatient centres visited, waiting areas often had insufficient air circulation in cold seasons. The mission members observed a few ultraviolet lamps, but could not verify their dose or efficacy.

There are no respirators available for staff working with infectious and DR-TB patients.

#### *Suggested action*

- Update, implement and monitor the infection control guidelines and ensure availability of an infection control plan and an infection control designated person in all health-care facilities that receive patients suspected of TB.

- Provide filtering face piece (FFP) II or N95 certified (FFPII/N95) or equivalent respirators for staff working with sputum smear-positive TB patients.
- WHO to send an infection control expert to provide technical assistance.

## 2.3 Diagnosis

### Observations

Laboratory services in Hungary consist of one national reference laboratory (NRL) for mycobacteriology and 12 direct microscopy laboratories (DL). In 2011, the laboratory network received a total of 65 871 samples, including 3179 samples verified with Xpert MTB, of which 874 TB cases were culture-confirmed. The NRL and all DL perform smear examination using the Ziehl-Neelsen method. However, the smear-positivity rate remains low: only 19% of the cases were reported as having a positive smear in 2010. The NRL has capacity for routine use of the more sensitive and less labour-intensive fluorescent light-emitting diode (LED) microscopy.

For recovery of mycobacteria, the conventional Lowenstein-Jensen (LJ) method is widely used. The rapid and more sensitive liquid culture systems are available in four DL. There were seven DL in 2011 processing fewer than 3000 mycobacterial cultures per year, which is not enough to maintain the level of expertise needed (14). Identification of *M. tuberculosis* complex is not performed in four DL, and non-tuberculous mycobacteria (NTM) are not isolated at all in four DL. Only one third of new pulmonary TB cases were bacteriologically confirmed in 2010.

In many DL, first-line DST is performed on the slower solid LJ media instead of rapid commercial liquid culture methods. In five DL, first-line DST is not performed. Second-line DST is currently performed on solid media at the NRL only.

Rapid molecular methods are available at the NRL and in some DL. Those laboratories can perform the rapid identification of the most common NTM and the rapid detection of M/XDR-TB. Owing to financial and logistic issues, these methods are not yet routinely used.

Specimen collection and shipment to the laboratories is not optimal. Some health-care centres send more than 2-3 samples for initial smear and *Mycobacterium tuberculosis* culture, sometimes even up to six or more. Some health-care centres send their specimens to a laboratory located more than 200 km from the centre, instead of sending the samples to the nearest laboratory in the same city. The long delay in arrival at the laboratory (5-7 days or more) and inappropriate storage during transportation lead to high contamination rates (approx. 30% at NRL) when the liquid culture system is used. This means that the advantages of using the liquid culture system are greatly reduced.

The NRL and one DL have unused capacity for molecular typing of TB strains for public health purposes. The TB MIRU-VNTR subtyping for public health services is not performed owing to lack of funding.

The laboratories report laboratory surveillance data routinely to the National TB Surveillance Registry in case-based format (Excel spreadsheet or online).

Some DL lacked or failed EQA. The NRL has no jurisdiction to perform audits or coordinate EQA schemes in DL.

The laboratory-confirmed TB cases are not always HIV-tested, or the result is not known because of the prevailing legal barriers.

There is a high proportion of senior staff working in the laboratories. The recurring need to replace staff reaching retirement may become a serious challenge in the near future.

Some DL are not using the updated national TB laboratory guidelines and diagnostic algorithms.

## **Suggested action**

### *Laboratory*

- Develop a level 1 laboratory network that ensures timely detection of infectious TB patients using smear microscopy with quality control (Annex 3, Proposed restructuring of the laboratory network system in Hungary).
- Proceed with the plan to close down the underperforming level 2 TB laboratories.
- Consider the introduction of LED microscopy for routine smear examination according to the recent WHO policy statement for introduction of LED microscopy into the routine diagnosis of TB (15).
- Ensure that the NRL is legally assigned to perform EQA and audit of other TB laboratories.
- Perform DST according to international standards (16).
- Conduct mycobacteriology culture examination of all pulmonary TB patients.
- Keep the national diagnostic guidelines up to date and implement them in all DL.
- Second-line DST should continue to be performed by the NRL only.
- Promote HIV testing for all TB patients.
- Support the use of rapid molecular diagnostic methods for detection of M/XDR TB cases and identification of common NTM.
- Support the routine use of molecular typing for public health purposes, at least for M/XDR TB strains.
- Optimize the logistics of sample transportation to minimize the delay in samples reaching the laboratory.
- Ensure that senior staff are replaced when they retire.
- Make it possible for DL to report online to the National TB Surveillance Registry.

### *Active case-finding*

- Consider revising the current policy in favour of a more targeted screening approach that takes into account the risk of smear-positive and MDR-TB in different population groups.
- Discontinue X-ray screening of the general population for TB.
- Perform active case-finding in well-defined risk groups (e.g. people living with HIV, prisoners, socially disadvantaged groups, TB contacts, etc.).

## **2.4 Treatment**

### **Observations**

The national guidelines for treatment of TB are outdated. A group of patients are put on a retreatment regimen without solid evidence of relapse or recurrent disease. Models of care for treatment include both inpatients and outpatients. Observed treatment is provided in outpatient facilities, but the drugs are distributed to patients once a month and therefore there is no daily observation of treatment. There is no strategy for improving adherence, particularly among difficult-to-reach and marginalized populations. The latest treatment outcomes are 57.1% among new TB laboratory-confirmed pulmonary TB cases (17).

### **Suggested action**

- Define treatment schedules and the duration following the WHO recommendations and the European Union Standards for Tuberculosis Care (18).
- Restrict prolonged treatment duration to situations with evidence of benefit.
- Define the conditions for hospitalization and release from hospital.
- Improve ambulatory care and DOT, paying particular attention to difficult patients who show poor adherence.
- Reconsider control procedures during and after treatment (reduce the number of sputum and CXR, reduce the duration of routine follow-up after cure).
- Provide fixed-dose combination therapy for patients in the ambulatory phase of treatment to avoid patients taking only some drugs and not others.
- Revise the definitions of cohort analysis of treatment outcome.
- Define the conditions for forced isolation and treatment.
- For treatment of MDR-TB, administer at least four SLD to which the strain is considered to be sensitive. Consider ethionamide/prothionamide and maintain pyrazinamide in the treatment schedule of MDR-TB, whatever the DST results. Consider use of other second-line drugs (linezolid, clofazimine, amoxiclav if needed (19)).

- Discontinue procurement and supply of ciprofloxacin for treatment of TB and MDR-TB.
- Develop criteria for hospitalization and discharge of TB and MDR-TB patients.

## 2.5 Care

### Observations

Hungary has a screening policy that, in areas with a TB incidence over 25 per 100 000, annual X-ray screening is obligatory for everyone over 30 years of age (for specific comments on this intervention, please refer to screening chapter). In District VIII and among the homeless, where TB incidence is high, the screening programme, which in this situation is conducted in a setting of TB-vulnerable groups, is a robust system to detect persons suspected of TB.

Challenges identified during the visit include the steps that should be followed once a person is identified as a TB suspect through screening, i.e. the stages of TB diagnosis, treatment and care. With regard to treatment and care, this gap can be seen in the low rate of treatment success (57% of new laboratory-confirmed pulmonary TB cases notified in 2009 had a successful outcome), as well as the high rate of treatment failure and loss to follow-up (17). In Hungary, DOT is assured during the intensive phase of treatment, typically when the patient is in hospital. However, for outpatient care this was less evident.

The pulmonology centres provide outpatient treatment. As described to mission members at the District VIII pulmonology centres, the resources (human and financial) are not sufficient to provide full patient support during the outpatient, continuation phase of treatment. A further challenge is the lack of collaborative measures between the health services and social services, as the two operate under different government structures. As they have two different remits and are seen as very separate, collaboration between the social and health services is challenging and is the most likely cause of the gap in patient support and patient-centred approaches to TB treatment. This in itself is most likely a major cause of the high treatment losses and failures (and treatment lasting >6 months).

When the team visited the Maltese Charity Health Centre in Budapest, the plans to initiate a collaborative approach between the Korányi Institute and the Maltese Centre for providing TB diagnosis and care at the centre were described. The activity was planned to commence shortly after the mission visit. This initiative is a fine example of patient-centred approaches to TB treatment and care, a model that could be adopted to strengthen collaboration between social services and health-care services.

Support from nongovernmental organizations in Budapest is valuable for reaching homeless people with screening services. The Hungarian Maltese Charity Service offers individual support by bringing persons to screening. However, it is the steps after this that are lacking.

### Suggested action

- Develop and implement a national strategy for patient-centred approaches to treatment and care, including DOT and social support (an example being the

intersectoral cooperation between the Korányi Institute and the Hungarian Maltese Charity Service).

- Revise the existing TB care delivery model by promoting outpatient (ambulatory) management of TB cases (including MDR-TB cases) and decreasing the frequency and length of hospitalization, starting as soon as possible with demonstration projects in selected districts.

## **2.6 Special populations**

### **2.6.1 Prison TB service**

#### *Observations*

No visit to prisons and no contact with prison authorities were organized during the visit. According to unverified oral information, prisoners are submitted to routine screening for TB at entry and have access to the same diagnosis and treatment facilities as the civil population.

#### *Suggested action*

- Ensure access to diagnosis and treatment.

### **2.6.2 Migrants**

#### *Observations*

All migrants (asylum-seekers claiming asylum and accepted refugees) are screened (CXR, TST, HIV and medical examination). The examinations are performed at the local hospital. In Debrecen camp, two cases of TB were detected in 2011 (among 700 migrants) and one in 2012 among 276 migrants (rate 250/100 000).

As migrants stay on average one year in the camp, they have access to medical care (daily visits by a general practitioner). Asthma, hypertension and gastrointestinal disorders are the main medical problems.

Migrants detained for any reason (before retransport to another country or because of criminal activities) are managed by the police and subject to the same screening procedure as other detainees.

#### *Suggested action*

- Continue screening and ensure access to diagnosis and completion of treatment.

### **2.6.3 People living with HIV/AIDS**

#### *Observations*

Available data show a low burden of HIV in the country. However, there is a high prevalence of TB among PLHIV. The high case-fatality rate among TB/HIV coinfecting people may be due to poor collaboration between the TB and HIV services (see more in section 1.2 above, Epidemiology of TB and HIV in Hungary).



HIV is detected using the second-generation HIV surveillance approach (20). HIV is tested for anomalously using an express test at the health-care centre, and later confirmed by the NRL by immunoblot testing.

TB surveillance is not integrated into the communicable disease information system, so HIV and TB data are not managed on a case-based platform, mainly due to the confidentiality of PLHIV. Therefore access to voluntary counselling and testing and active HIV testing among TB patients, as well as TB diagnosis and prevention among PLHIV, was either limited or absent and difficult to document. Instead, clinicians detect HIV in TB patients passively, when the symptoms indicate immunosuppression.

### *Suggested action*

- Provide early diagnosis of TB for PLHIV, monitor progress in detection of TB among people living with HIV.
- Continue screening and ensure access to diagnosis and completion of treatment.
- Initiate isoniazid preventative therapy for PLHIV diagnosed with latent TB and monitor treatment outcomes.
- Implement HIV testing and counselling for all TB patients.
- Establish systematic collaboration between the TB and HIV programmes.
- Initiate antiretroviral therapy for all TB/HIV coinfecting patients as soon as TB treatment is tolerated.

## **2.6.4 Children**

### *Observations*

The number of children notified with TB remains low in Hungary (11 cases under the age of 15 were notified in 2012 – 0.7% of all TB), nevertheless it is essential to maintain a strong system to ensure rapid detection and treatment of all cases. From the current visit, it was our understanding that Hungary does not have national guidelines for childhood TB diagnosis, treatment and care.

The Pulmonology Institute, Törökbálint, in Pész has a specialized ward for paediatric lung disease, with two rooms for children with TB. At the time of our visit, two teenage boys were in hospital, being treated for TB. Both were sputum-smear-negative at the time of the visit. Although national guidelines for management of childhood TB are not available, the children were being treated following the WHO 2010 guidelines on childhood TB treatment (21). One challenge identified was the lack of child-friendly drug-formulations (with a few exceptions). The hospital pharmacist provided a number of the drugs in powder form by crushing them manually.

In the children's ward, the two rooms for children with TB were located at the end of the corridor, an appropriate location ensuring minimal person circulation. However, the corridor was not physically blocked, and was thus fully accessible to adults and children walking and playing in the ward. For example, the children's play corner was located very close to the two rooms. Although children are often non-infectious, this mainly applies to children of very low age, and children with pulmonary TB can be infectious. Incidents of children infecting persons in their surroundings have

been reported. It is therefore essential to ensure appropriate infection control measures in children's wards (22).

### *Suggested action*

- Include recommendations for management of childhood TB in the national TB guidelines, following international recommendations and standards.
- Procure child formulations where possible, even if there are only a few child cases.
- At the Pulmonology Institute, Törökbálint, and any other institute treating children with TB, ensure appropriate infection control measures to protect other children in the ward.

## **2.6.5 Hard-to-reach populations**

### *Observations*

Homeless people are one of the key risk groups for TB in Hungary, accounting for a large proportion of the TB cases detected, especially in Budapest. Thanks to the X-ray screening programme and requirement for a six-monthly certificate of freedom from TB (under a law entitled "Act III of 1993 on Social Services"), homeless people are reached for active case-finding. A robust system is in place to screen this vulnerable group and detect persons suspected of TB.

A well-functioning support system for TB screening for homeless people was observed in Budapest, operating through the Hungarian Maltese Charity Service.

One key challenge identified is the lack of a system for providing patient support, in the form of social support, from the point of diagnosis through to the end of treatment. As described to the mission during the visit and as observed by mission members, this is largely a result of the gap in collaborative approaches between social and health-care services.

### *District VIII*

The District VIII pulmonology centre visited also receives homeless people for screening and treatment; this district is challenged with the highest number of vulnerable groups in Budapest. District VIII had five centres in 2011, in which 44 patients (25%) were lost to follow-up during treatment.

This is an area with a large hard-to-reach population, in which strong collaborative approaches between the health and social services are sorely needed to provide patient-centred approaches to treatment. This will be essential for ensuring increased treatment success rates and thereby decreased transmission in this setting.

### *Hungarian Maltese Charity Service*

This nongovernmental organization provides general health care for the key risk group of homeless people, including TB screening. A well-functioning system was seen to be in operation in Budapest. The charity has its health centre in the city centre, and receives both the homeless and the extremely poor. The charity has itinerant general practitioners providing health care on the street, and also has a mobile X-ray bus. The charity actively goes out on the streets to conduct TB screening for homeless people, and upon suspicion of TB (following X-ray examination) ensures support

through volunteer social workers, who accompany individuals to the health centres/pulmonology centres where they receive full diagnostic services.

Between 2002 (when the mobile bus programme started) and 2011, 75 000 TB screenings were conducted. In 2011 alone, 10 600 screenings were conducted on the mobile X-ray bus. Around 25-30 new TB cases are identified annually. In 2011, 85 suspected cases of TB were identified, of whom 33 were confirmed on later diagnosis to be active TB.

When the mission visited the health centre of the Hungarian Maltese Charity Service in Budapest, plans were described for the initiation of a collaborative approach between the Korányi Institute and the Maltese Centre in providing TB diagnosis and care services at the centre. This initiative is fine example of patient-centred approaches to TB treatment and care, a model that might be adopted in order to strengthen collaboration between social services and health-care services.

### *Suggested action*

- Provide tailored services for hard-to-reach populations in District VIII of Budapest.
- Develop and implement patient-centred approaches to treatment and care, including DOT and social support (e.g. intersectoral cooperation between the Korányi National Institute for TB and Pulmonology and the Maltese Centre) for the hard-to-reach groups. Targeting TB among the hard-to-reach groups of Budapest will have a substantial impact on decreasing TB in Hungary, as this group is the most challenged by TB.
- Develop and provide tailored services, with cross-cutting health and social services, for the hard-to-reach populations of District VIII of Budapest.

## **3. Health workforce**

### **Observations**

Generally, there is an increasing shortage of health-care workers in the Hungarian health-care system, and this group of professionals is growing older. As described during the visit, there is a substantial loss of health-care workers to emigration, as they seek better working conditions in other countries. At the central level, reforms aim to improve working conditions for health-care workers, in an attempt to reduce the number of workers leaving the country after completing their training; this is part of the Semmelweis Plan for the Rescue of Health Care (23).

Specific challenges described in human resources (including in the TB health services) were the following:

- low salaries among health-care workers;
- need to build/increase capacity of health-care workers in all counties (i.e. disproportionate human resources);
- ageing of this group;

- retaining newly trained health-care workers in the country;
- medical training: theoretical knowledge is excellent and recommendable – there is a need to increase practical training at an earlier stage.

At the **District VIII pulmonology centre** visited by the mission, the staffing (for all the provided services, including non-infectious respiratory diseases) was as follows:

- four doctors (three working full-time)
- 16 specialized staff (nurses, assistants, administration, human resources).

According to the centre, this was considered to meet minimum needs. It was unclear whether there was a plan for recruitment/increase in staff numbers or for replacement of staff who have retired.

At the **Pulmonology Institute, Törökbálint**, visited by the mission, staffing was not a challenge. This is an attractive institute for specialized health-care workers. The director highlighted the importance of involving the staff in their work to create a good working environment, and also to create opportunities for medical students to work at the specialized pulmonology centres in order to increase interest in the specialization.

At the **health centre of the Hungarian Maltese Charity Service**, the number of staff is identified as a limitation on activities at the centre. As regards TB screening (the Centre provides other health services as well), a total of seven persons are dedicated to the mobile TB screening bus:

- one doctor and one associate doctor, working three hours a week each
- one technical manager – organizing activities and driving the bus
- four volunteers (including assistants and social workers).

### **Suggested action**

- Continue to pay attention to the problem of ageing and migrating TB health-care staff.
- Conduct training for TB health-care staff on new guidelines, approaches and techniques.

## **4. Information systems**

### **4.1 Surveillance, monitoring and evaluation and use of data for decision-making**

#### **Observations**

The TB surveillance system was upgraded in 2010 and includes information about notifications, laboratory results, treatment monitoring and outcomes. This allowed better documentation of TB detected cases, and therefore a slight increase in TB notification was identified.

The National TB Register uses the latest technology and is secure, sustainable and well-functioning. However, its full potential is not yet widely exploited.

Data analysis and interpretation of epidemiological trends and assessing programme performance still need to be strengthened. Standard indicators should be automatically generated as lists and shown in tables, graphs and maps.

The smear microscopy recording rate is low: 27% of new pulmonary TB cases have no records for smear microscopy, and therefore laboratory confirmation by culture in new pulmonary TB cases is only 35%, compared with an average of 61% in the western countries of the WHO European Region. The indicator is approximately the same (30%) for new extrapulmonary cases: this is evidence of poor data communication between laboratory and clinician. There is thus great potential for improvement in laboratory diagnosis for appropriate patient management.

Recording and reporting documentation for patient managers in the field was found not to be standardized and did not follow the latest recommendation for recording and reporting of TB patient information.

### **Suggested action**

- Develop standards and benchmarks for systematic and regular appraisal of the quality (i.e. completeness, timeliness, consistency and validity) of TB case data at national level and include regular quality reports and patient lists for action in the national electronic register.
- Upgrade and standardize laboratory data management and build a standardized and common platform for TB health-care facilities to enable easy and real-time access to laboratory results and full integration into the national TB register.
- Make greater use of data at the national level for planning service delivery by field coordinators (chief medical officers) and service delivery workers (pulmonologists/TB physicians).
- Develop a list of indicators following WHO and ECDC recommended monitoring frameworks for assessing programme performance, with defined targets for 2015 (17,19). These indicators are to be automatically generated as lists built into the e-system and shown in tables, graphs and maps.
- Revise the set of TB reporting and reporting forms according to the latest WHO recommendations (19).

## 5. Medical products, vaccines and technologies

### 5.1 Drug management

#### Observations

Forecasting, procurement and supply of anti-TB medicines are decentralized. There has been no interruption in the availability of first-line drugs. At least in some settings, ciprofloxacin is used although, according to the latest recommendations, this drug has a very weak anti-TB effect and should not be used. Since there are only a few M/XDR-TB patients, the procurement of the full treatment regimen and all SLD can be cumbersome and interruption of supply of some SLD, including the latest generation of fluoroquinolones, have been observed.

#### Suggested action

- Initiate central procurement of SLD by NHIFA and special formulations of TB drugs for children.
- Discontinue procurement and supply of ciprofloxacin for treatment of TB and MDR-TB.
- Establish a mechanism for centralized pharmaceutical procurement and management.
- Ensure sufficient buffer stocks for first-line TB drugs.

### 5.2 Vaccines

#### Observations

BCG vaccine stocks up to May 2012: Manufacturer SSI. Product: SSI BCG *Mycobacterium bovis* BCG, "Danish strain 1331". May-December 2012: Manufacturer BB-NCIPD. Product: BCG vaccine live freeze-dried BCG (Russian strain). Reason for change: SSI's Hungarian distributor's application for the procurement tender was not valid.

## 6. Finance

This chapter summarizes the findings on estimates of TB funding and expenditures, describes the financial flow and payment mechanism, discusses briefly the impact of payment mechanisms, and finally deals with the issue of efficiency.

#### Observations

##### Budget estimate for TB care

The mission's findings show that, although there is a comprehensive data collection system managed by NHIFA and the Central Statistical Office through highly developed IT systems, there is no widespread and up-to-date review or follow-up of the budget for TB control. The main deficiencies of the reporting system are the lack of a transparent and clear methodology to ensure the completeness of the budget data, as well as a lack of organizational processes in governance for

regular review and analysis of expenditure data and their composition. While the total budget for TB is reported in the WHO TB profile for Hungary to be US\$ 2 million in 2011 (24), NHIFA informed the mission members in its presentation that X-ray screening for TB alone was reported as costing US\$ 4.8 million in 2011.

The mission members therefore focused on collecting comprehensive budget data on TB control, which also made it possible to analyse the allocative efficiency of the expenditure. This required proper methodology to estimate the expenditure data where the financing report by the providers did not allow direct costs to be identified, as was the case with outpatient care provided by dispensaries and financed partly by a global budget.

The mission members' estimates of the funding available for TB control in Hungary are shown in Table 6.

**Table 6. Estimate of total budget for TB care and its allocation to services in 2011**

Providers	Services	Payment mechanisms	Costs HUF (thousands)	Costs USD (thousands)	%
Dispensaries	X-ray screening (1)	Output-based through dispensary case fee	1 163 623	4 848	64,92%
	Out-patient care (3)	Global budget	43 180	180	2,41%
	Pharmaceuticals (2)	Global budget	120 000	500	6,69%
Out-patient centers	Out-patient services (1)	Output-based through fee for service	13 829	58	0,77%
BCG vaccination	Out-patient services (4)	Global budget	80 000	333	4,46%
In-patient	TB care (1)	Output-based through DRG	371 778	1 549	20,74%
<i>Total budget</i>			<b>1 792 410</b>	<b>7 468</b>	<b>100,00%</b>

*Data sources: (1) NHIFA; (2) Korányi Hospitals, personal interview, (3) Estimate made by the mission, based on the financial data of NHIFA for 2011 and the patient turnover data of CSO for 2010; (4) Personal information from the expert of the NPHMOS*

1 USD = 240 Hungarian forint (HUF) (Source: Budapest Bank, 30 December 2011).

Apart from the funding of outpatient care and pharmaceuticals provided by dispensaries, the data come from NHIFA, which collects financial reports from providers financed through output-based payment mechanisms. This means that the providers report their activity to NHIFA on a per-case basis. However, part of the activities of the dispensaries, which cover not only TB care but a whole range of pulmonary services, is financed by a prospective global budget, and this expenditure on TB care is not reported separately. Therefore there are some uncertainty bands on the estimates of the TB budget.

In the absence of an appropriate methodology, the NHIFA experts could not specify the amount which can be used by the dispensaries to finance TB care from their global budget. The experts from the mission therefore decided to use the methodology of cost-of-illness studies to estimate this amount. This method divides the aggregate health-care costs among diseases by using certain allocation keys (25).

In the case of TB care in Hungary, the experts from the mission divided up the total amount of global budgets used for pulmonary care dispensaries, using the patient turnover for TB care in dispensaries as the allocation key. According to NHIFA data, the planned funding through global budgets of dispensaries specializing in pulmonary care accounted for HUF 2.2 billion (US\$ 9.1 million) in 2011. The Central Statistical Office reported patient turnover data from the dispensaries only for 2010,

indicating that the proportion of patients for whom the dispensaries provided TB care was approximately 2%. The data have not shown wide variation since the mid-2000s (Table 7). Based on these data, the global budget of dispensaries for TB care can be estimated at 2% of the total global budget for dispensaries, that is, approximately US\$ 180 000. In addition, the experts from the Korányi National Institute for TB and Pulmonology estimated that the dispensaries finance the pharmaceutical costs of TB patients to the tune of HUF 120 million per year (US\$ 500 000), 50% of which is for MDR-TB. To sum up, the total budget for TB care is approximately HUF 1.8 billion (US\$ 7.5 million), equivalent to 0.13% of public expenditure on health and less than 0.1% of total expenditure on health.

**Table 7. Number of pulmonary dispensaries and patient turnover**

Year	Pulmonary dispensaries			Of which:		
	number	patients turnover	registered TB-patients as % of the total patient turnover	registered TB-patients	non-TB-patients	prevention
1980	171	2 476 118		..	..	..
1990	164	2 077 232		..	..	..
2000	162	2 035 400	3,88%	78 887	1 281 782	674 731
2001	160	2 013 231	3,74%	75 210	1 281 655	656 366
2002	162	2 000 120	4,06%	81 254	1 276 419	642 447
2003	162	1 984 642	3,74%	74 203	1 294 873	615 566
2004	162	2 010 922	3,31%	66 484	1 310 707	633 731
2005	162	2 045 556	2,42%	49 527	1 341 920	654 109
2006	162	1 947 969	2,26%	44 104	1 264 047	639 818
2007	162	1 509 098	2,35%	35 467	1 057 569	416 062
2008	162	1 401 349	2,30%	32 278	1 019 435	349 636
2009	155	1 728 679	1,65%	28 462	1 630 061	70 156
2010	153	1 476 465	2,05%	30 308	1 416 842	29 315

Source: (26). Note: Registered TB patients as % of total patient turnover was calculated by the mission.

Within the estimated TB budget, screening dominates the expenditure, accounting for up to 65% of the total budget. In 2011, only 35% was spent on other treatments and services. Although it is very difficult to define an appropriate division between screening and other treatments and services, the current allocation of resources indicates that the allocative efficiency of the expenditures should be carefully analysed. The Central Statistical Office reported that, in 2010, 10 000 screenings were performed by the dispensaries to find 2.3 TB patients (Table 8). This slightly overestimates the necessary number of screenings, as this number was calculated by dividing the identified pulmonary TB patients by the total number of pulmonary screenings (2 172 685), whereas NHIFA reported that screenings with a TB indication were fewer (1 550 590) in 2011. However, by calculating each screening at US\$ 3.2 (€2.5) per screening (source: NHIFA), and at a treatment cost in hospital of US\$ 1000 (€771) per patient (source: NHIFA), it can be seen that finding one pulmonary TB patient using pulmonary screening can cost more than US\$ 10 000, which is more than 10 times higher than the treatment cost in hospital. In 2012, NHIFA experts expect the cost of screening to be higher, because the fee for screening has been increased significantly this year, so the proportion of the total budget spent on screening may be even higher in the near future.



**Table 8. Number of pulmonary screenings by category of screening**

Year	Number of pulmonary TB-patients found by screenings	Number of verified pulmonary neoplasms found by screenings	Pulmonary TB-patients per ten thousand screenings	Verified pulmonary neoplasms per ten thousand screenings	Patients found by screening per hundred new pulmonary TB-patients	Patients found by screening per hundred new verified pulmonary neoplasms
1980	2 464	1 779	3,8	2,7	54,4	44,9
1990	1 541	2 041	3,2	4,2	46,3	38,7
2000	1 357	1 996	3,4	5,0	40,5	31,9
2001	1 267	2 073	3,1	5,1	41,0	33,2
2002	1 071	2 107	2,7	5,3	35,6	33,1
2003	1 016	2 007	2,8	5,5	39,8	30,5
2004	879	2 123	2,4	5,8	37,8	32,6
2005	643	2 057	1,8	5,9	33,9	31,4
2006	676	1 971	1,8	5,4	37,6	30,1
2007	591	1 906	2,0	6,5	35,7	31,4
2008	488	1 475	2,1	6,4	32,1	25,4
2009	447	1 464	2,0	6,4	32,5	23,5
2010	508	1 424	2,3	6,6	29,3	25,0

Source: (26).

It is noticeable from the data from the Central Statistical Office that the mobile screening capacity, which might be a more efficient solution than fixed screening facilities, has been greatly downsized since the beginning of the 1990s (Tables 9 and 10).

**Table 9. Pulmonary screening stations and pulmonary screenings**

Year	Stabile	Moving	Screening stations together	Pulmonary screenings	Screenings per hundred population aged 14 years and over
	X-ray screening stations				
1980	96	61	157	6 480 073	77
1990	116	62	178	4 828 518	59
2000	128	56	184	3 977 846	47
2001	134	50	184	4 095 134	48
2002	134	48	182	3 913 798	46
2003	134	48	182	3 717 518	43
2004	134	48	182	3 681 879	43
2005	142	37	179	3 508 498	41
2006	135	48	183	3 670 144	43
2007	135	48	183	2 935 269	34
2008	135	48	183	2 308 748	27
2009	136	17	153	2 272 693	27
2010	131	16	147	2 172 685	25

Source: (26).

**Table 10. X-ray screening stations**

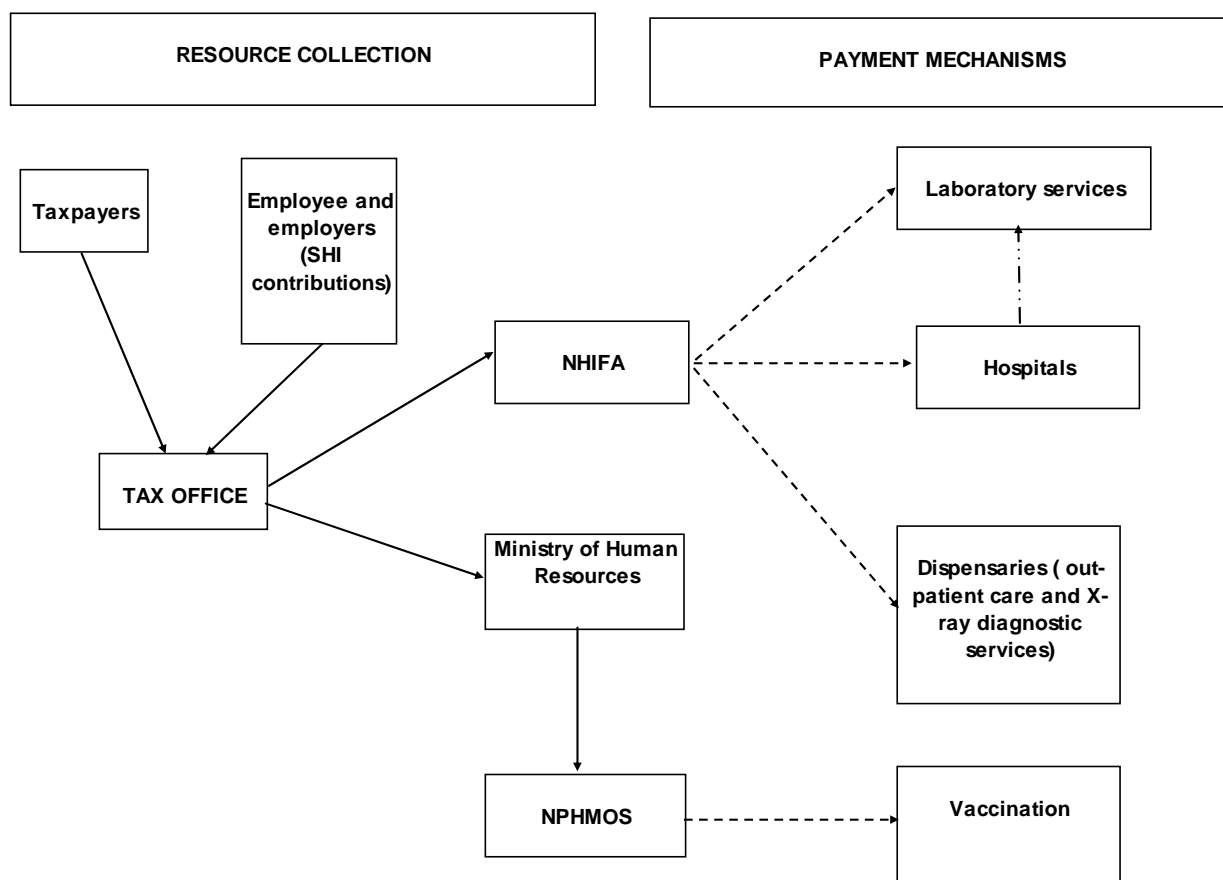
Year	Number of radioscopic screenings	Mechanical screenings			Total	Of which:	
		in stable	in moving	together		number of patients sent to a further examination	number of patients sent to a further examination per hundred screenings
		X-ray screening stations					
1980	22 676	2 995 136	3 462 261	6 457 397	6 480 073	237 791	3,7
1990	8 370	2 574 370	2 245 778	4 820 148	4 828 518	168 552	3,5
2000	18 299	2 038 987	1 920 560	3 959 547	3 977 846	224 990	5,7
2001	1 384	2 114 752	1 978 998	4 093 750	4 095 134	232 840	5,7
2002	2 618	2 084 025	1 827 155	3 911 180	3 913 798	215 300	5,4
2003	4 890	1 933 263	1 779 365	3 712 628	3 717 518	209 720	5,7
2004	1 042	2 067 218	1 613 619	3 680 837	3 681 879	216 761	5,9
2005	4 941	1 863 843	1 639 714	3 503 557	3 508 498	227 122	6,5
2006	..	1 900 816	1 769 328	3 670 144	3 670 144	212 456	5,8
2007	..	1 537 427	1 397 842	2 935 269	2 935 269	212 092	7,2
2008	..	1 389 159	919 589	2 308 748	2 308 748	160 538	7,0
2009	..	1 355 828	916 865	2 272 693	2 272 693	115 908	5,1
2010	..	1 374 408	798 277	2 172 685	2 172 685	120 993	5,6

Source: (26).

### Payment mechanisms for TB care in Hungary

There is a highly complex financing scheme for TB care in Hungary with several different approaches. The financial flow of resource collection and payment mechanisms is shown in Fig. 1.

**Fig. 1. Financial flow of financing of TB care in Hungary**



Firstly, the Ministry of Human Resources allocates the necessary funds for BCG vaccination to the National Public Health and Medical Officer Service (NPHMOS) through a global budget. The vaccine is procured by NPHMOS as a fee-based service and then the vaccination is administered by general practitioners funded by NHIFA through a prospective capitation payment, which also covers the administration of the BCG vaccination.

Secondly, NHIFA finances TB care mainly through output-based financing, particularly through the DRG payment system to hospitals on a per-case basis and through fees-for-service for dispensaries and laboratory services. The main advantage of DRG is that this payment mechanism sets the cost of services on a prospective basis in order to contain costs. Furthermore, the current output-based financing has been effective in improving productivity and availability of services. However, the performance limit system on the volume of health services, which was introduced in 2004 with the aim of strengthening cost containment efforts, puts constraints on the provision of care beyond a certain ceiling. This means that, if a hospital or outpatient centre provides services beyond its performance ceiling, it does not get additional reimbursement. Each provider has an individual institutional performance limit set every month, and is responsible for setting priorities between its services in order to stay below the overall institutional ceiling. The major concern with this approach is how to prioritize between communicable and noncommunicable diseases. In the case of communicable diseases, it is a clearly unfair and unrealistic demand that, if providers are already above their ceiling, they should deliver care without any financial compensation or refuse to provide

care. Obviously, the latter case cannot happen at all in theory, but service patterns should be carefully analysed in this respect, and consideration should be given to cancelling the volume limitation in the case of TB care and perhaps communicable diseases in general. The low cost of treatment and also the current well-established surveillance system seems to provide an adequate guarantee that expenditure would not increase.

Thirdly, in 2011 the outpatient services of dispensaries were financed not only by fees-for-service, but also partly by global budgets. The reason for this mixed financing mechanism was that health policy-makers wanted to shift the dispensaries' overall financing mechanisms towards output-based financing and remove the global budget in order to increase transparency and performance. Therefore, the new output-based payment method was introduced in mid-2011 for the dispensaries on a prospective case-fee basis. Since January 2012, the dispensaries have been financed solely through this new payment method.

### **Suggested action**

- Calculate the total and public expenditure on TB control with standard and transparent methodology to improve efficient use of resources.
- Consider cancellation of the "volume limit" on providers with regard to TB case management.
- Ensure that TB diagnosis and treatment are completely free of charge to the patient.

## **7. Leadership and governance in TB care in Hungary**

### **Observations**

This section will pay special attention to the governance framework of TB care in Hungary, and look at policy questions such as the following.

- Is there a well-functioning, comprehensive monitoring system that includes all functional aspects of the health system, e.g. surveillance, detection, prevention, provision of care and health financing?
- Is there a well established coordination mechanism that would involve all stakeholders in policy assessment and planning?
- Are there established links between the major elements of the governance policy cycle, e.g. monitoring, assessment, planning and implementation?

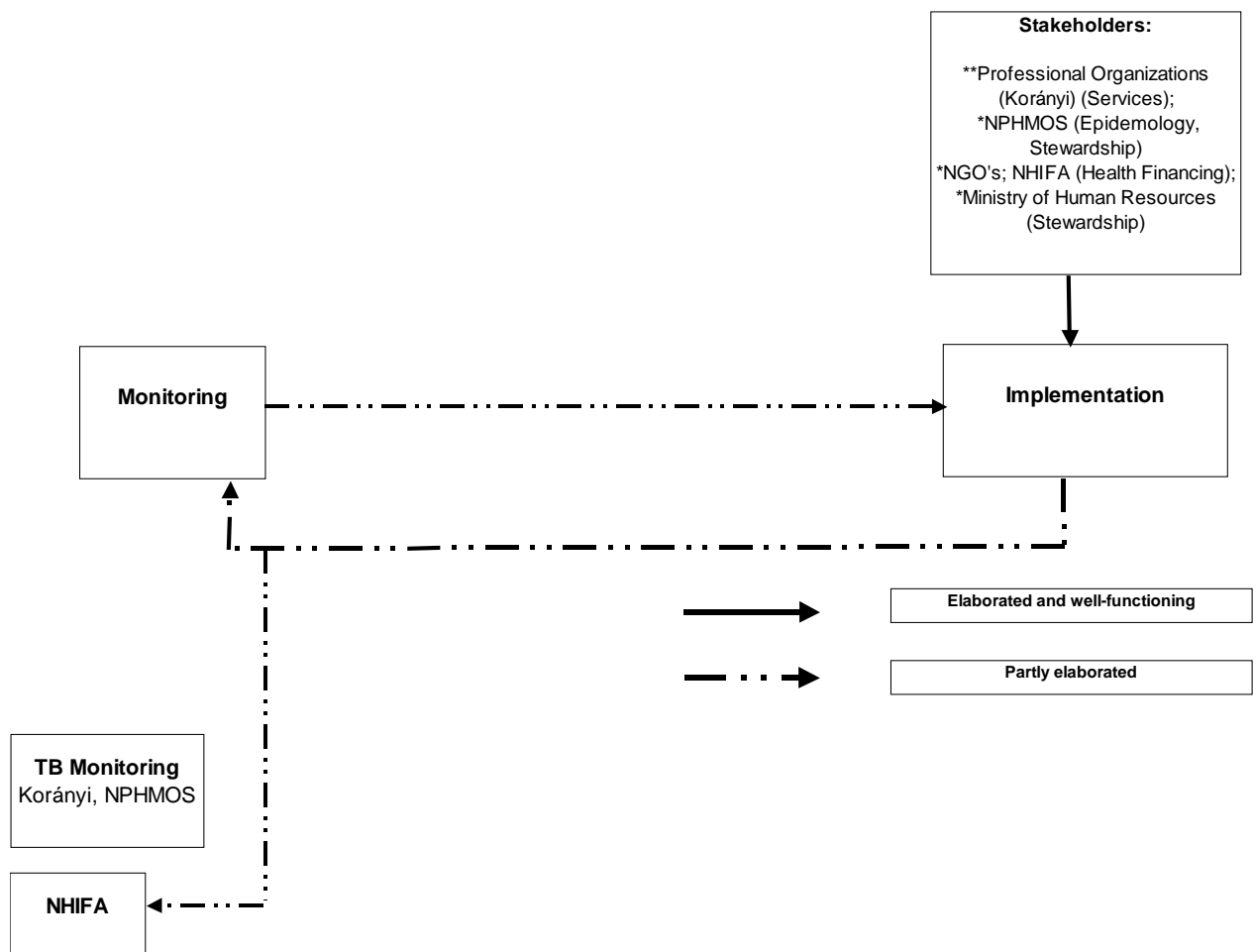
Besides the high-level policy documents of the European Union and WHO (1,2,12,27), the mission also used the United Nations good governance approach, which states that good governance promotes equity, participation, pluralism, transparency, accountability and the rule of law, in a manner that is effective, efficient and enduring (28). In addition to these documents, it should be emphasized that the essence of good governance is a well-functioning policy cycle, without which it is not possible to translate the principles of good governance into practice.

Some important findings on governance are illustrated in Fig. 2, which summarizes the most important elements and linkages of the current governance process.

One positive feature of the current system is the well-designed and comprehensive monitoring and data collection in respect of service delivery, which is managed by the Korányi National Institute for TB and Pulmonology and could serve as a basis for strengthening the governance function. Additionally, the Ministry for Human Resources organizes occasional meetings involving the most important stakeholders in order to solve emerging problems concerning service delivery and payment mechanisms. Lastly, although there is no separate law on TB care, the regulation on the prevention and control of infectious diseases and epidemics is widely and transparently incorporated into several acts on the health system and in Ministry decrees on communicable diseases.

However, the monitoring system for TB policies and strategies seems to be fragmented, tends to ignore linkages with other important aspects of the policy cycle, and does not provide a comprehensive picture of the performance of TB care. In this respect, special attention should be paid to the health financing part of the monitoring system (see more details in the health financing section). The most important problem lies in the fact that there is not a regular organizational process to synthesize and review the outputs and outcomes of the monitoring element of the system in an up-to-date manner at the decision-making level. Nevertheless, the sophisticated IT background and data collection in the Hungarian health system would technically make it possible to produce a comprehensive and detailed overview of all important aspects. Summarizing the above facts, it may be said that a sound base for a systematic and regular evaluation process at policy level is lacking. This may cause gaps and result in missed opportunities in systematic planning, which can be partly seen in the lack of national policy targets supported by action plans or strategies. Lastly, up to now there has been no specific platform or partnership established in order to involve stakeholders in a transparent and participatory way.

**Fig. 2. The current governance process in TB care**



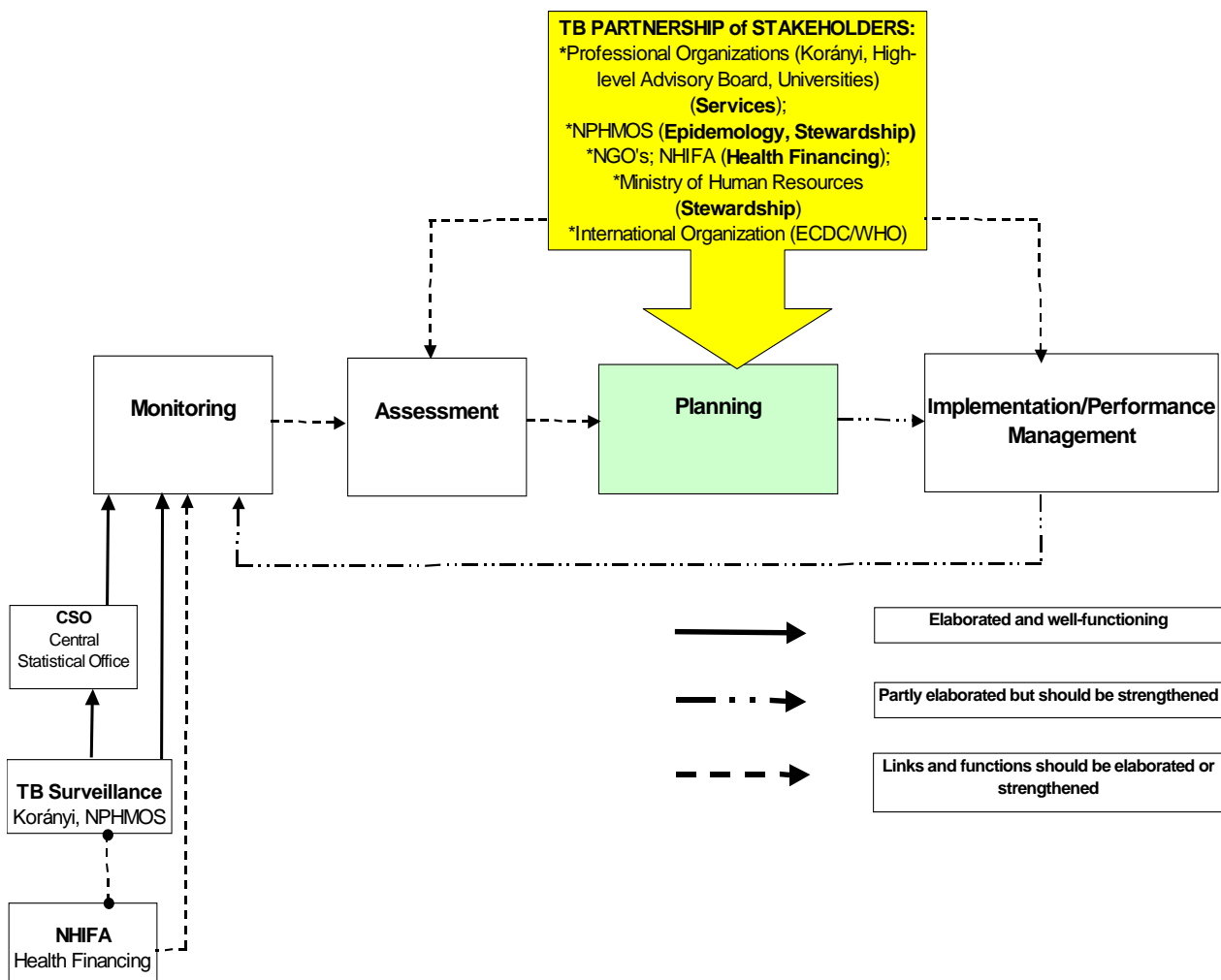
### Suggested action

- Establish a single coordination platform for TB prevention and control, including civil society organizations, private sector and other stakeholders.
- Develop a national TB action plan, including clear goals and following international guidelines such as the ECDC Framework Action Plan (2), the report *Progressing towards TB elimination (20)* and the Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant Tuberculosis in the WHO European Region 2011–2015 (1).
- Develop a monitoring framework with national targets for TB control and document progress towards the targets at national/regional level.
- Develop a systematic process for implementation of new tools.
- Set operational research priorities based on the results of a programme review.
- Increase use of routinely collected data for operational research.

With regard to improving the governance processes in TB care, the main recommendations are summarized in Fig. 3. Most importantly, more attention should be paid to creating linkages among the important elements of the policy process, especially between monitoring and planning. In addition, a systematic move towards linking the monitoring outputs of service delivery and health financing would be needed in order to get a comprehensive view of the performance of TB care.

In the context of improving participation in governance, it seems that there is strong involvement of the social sector in TB care through the Hungarian Maltese Charity Service. A well-elaborated partnership platform involving stakeholders from the social sector would likely contribute not only to a more appropriate and practical planning exercise, but also to greater intersectoral collaboration between the health and social sectors at policy level. Such partnerships can play an essential role in improving the quality of the assessment process in a comprehensive and timely manner.

**Fig. 3. Recommendation for improving governance process in TB care**



## Annex 1. Programme of the visit

Tuesday 22 May 2012

Venue: Ministry of Human Resources  
1051 Budapest, Akadémia utca 3.  
Mirror room 1<sup>st</sup> floor

12:00 – 12:15	Opening	Dr Hanna Páva Deputy Secretary of State
12:15 – 12:30	Introduction of WHO-ECDC team members, Scope and purpose of TB programme review	Dr Masoud Dara Dr Marieke van der Werf
12:30 – 13:00	Hungarian health care system	Dr Hanna Páva Deputy Secretary of State
13:00 – 13:45	Lunch	Restaurant of the Ministry Arany János utca 6-8. 8th floor
13:45 – 14:20	Regulation of infectious diseases focusing on TB	Dr Emese Szilágyi Deputy Head of Department Chief Medical Officer's Office
14:20 – 14:40	Role of the Municipality of Budapest in TB control	Dr Tamás Szentes Deputy Mayor
14:40 – 15:20	National guidelines for tuberculosis prevention and control	Prof. Dr György Losonczy Director, University Professor Semmelweis University, Department of Pulmonology
15:20 – 15:30	Coffee break	
15:30 – 16:15	Organization and surveillance system for tuberculosis prevention and control in Hungary	Dr Gábor Kovács Director-General, Korányi National Institute for Tuberculosis and Pulmonology
16:15 – 16:35	Laboratory network in Hungary	Dr Nóra Szabó Head of the National Reference Laboratory for Mycobacteria Korányi National Institute for Tuberculosis and Pulmonology
16:35 – 16:50	BCG vaccination in Hungary	Dr Emese Szilágyi Deputy Head of Department Chief Medical Officer's Office
16:50 – 17:10	Summary of current activities in relation to the modification of the Act on the Protection of Non-Smokers and Tobacco Control with a special focus on smoking prevention in kindergartens and schools in Hungary	Dr Tibor Demjén Head of Hungarian Focal Point for Tobacco Control National Institute for Health Development
17:10	Discussion	
18:30	Dinner Restaurant Pomodoro Arany János utca 9.	



**Wednesday 23 May 2012**

**TEAM 1a**

07:00 – 10:15	Travel to Nyíregyháza	Dr Veronika Obbágy
10:30 – 12:30	Pulmonary Clinic in Nyíregyháza	Chief Physician
13:00 – 14:30	TB Laboratory in Miskolc	TBC

**TEAM 1b – Gábor Csehi**

07:00 – 10:15	Travel to Nyíregyháza	Dr Veronika Obbágy
10:30 – 12:30	Pulmonary Clinic in Nyíregyháza	Chief Physician
12:30 - 13:30 13:30 – 14:20	Travel to Debrecen University of Debrecen – Faculty of Public Health	Dr Karolina Kósa Head of Department, Associate Professor University of Debrecen, Faculty of Public Health
14:30 – 16:30	Refugee camp in Debrecen	TBC
17:00 – 17:30	Roma camp	Dr Karolina Kósa
approx. 20:00	Arriving in Budapest	

**TEAM 2a – Gabriella Kiss Erdélyi, Krisztina Tálás**

09:00 – 09:50	Hungarian Maltese Charity Service for homeless health and TB care	Lajos Győri-Dani Vice-President
10:00 – 10:50	TB programme of the Hungarian Maltese Charity Service	Lajos Győri-Dani Vice-President
11:30 – 13:30	Pulmonary Clinic in Budapest, District VIII	Dr Magdolna Szilágyi Head Physician
14:00	Pulmonology Institute Törökbálint	Dr Rudolf Fülöp Hospital Director

**TEAM 2b**

09:00 – 09:50	Hungarian Maltese Charity Service for homeless health and TB care	Lajos Győri-Dani Vice-President
10:00 – 10:50	TB programme of the Hungarian Maltese Charity Service	Lajos Győri-Dani Vice-President
11:30 – 13:30	Pulmonary Clinic in Budapest, District VIII	Dr Magdolna Szilágyi T. Head Physician
14:00	National Health Insurance Fund	Dr Péter Ötvös Head of International Department

**Thursday 24 May 2012 – Dr Krisztina Biró, Gábor Csehi**

09:00 – 09:30	Korányi National Institute for Tuberculosis and Pulmonology (OKTPI)	Dr Gábor Kovács Director-General, Korányi National Institute for Tuberculosis and Pulmonology
	Lead specialists' conference	
10:00	Visit to microbiology laboratory with international accreditation at OKTPI	
15:00 – 17:00	National Centre for Epidemiology	
	HIV/AIDS and TB	Dr Ágnes Csohán Chief Physician, Epidemiologist
17:00 – 19:00	WHO/Europe and ECDC team work on finalization of key findings and recommendations	

**Friday 25 May 2012**

**Venue: Ministry of Human Resources  
1051 Budapest, Arany János utca 6-8.  
Secretary of State's meeting room, 7<sup>th</sup> floor**

09:00 – 10:30	Debrief	Dr Miklós Szócska Secretary of State
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## **Annex 2. Moments from the mission**

### **1. Evaluation team, WHO/Europe, ECDC and Ministry of State for Health**



### **2. Debriefing the Secretary of State for Health**



### 3. Sharing the main outcomes of the review



### 4. Fine-tuning the review programme



**5. Discussing the diagnostic algorithm at the pulmonary clinic in Nyíregyháza**



**6. Discussing the diagnostic algorithm at the pulmonary clinic in Nyíregyháza**

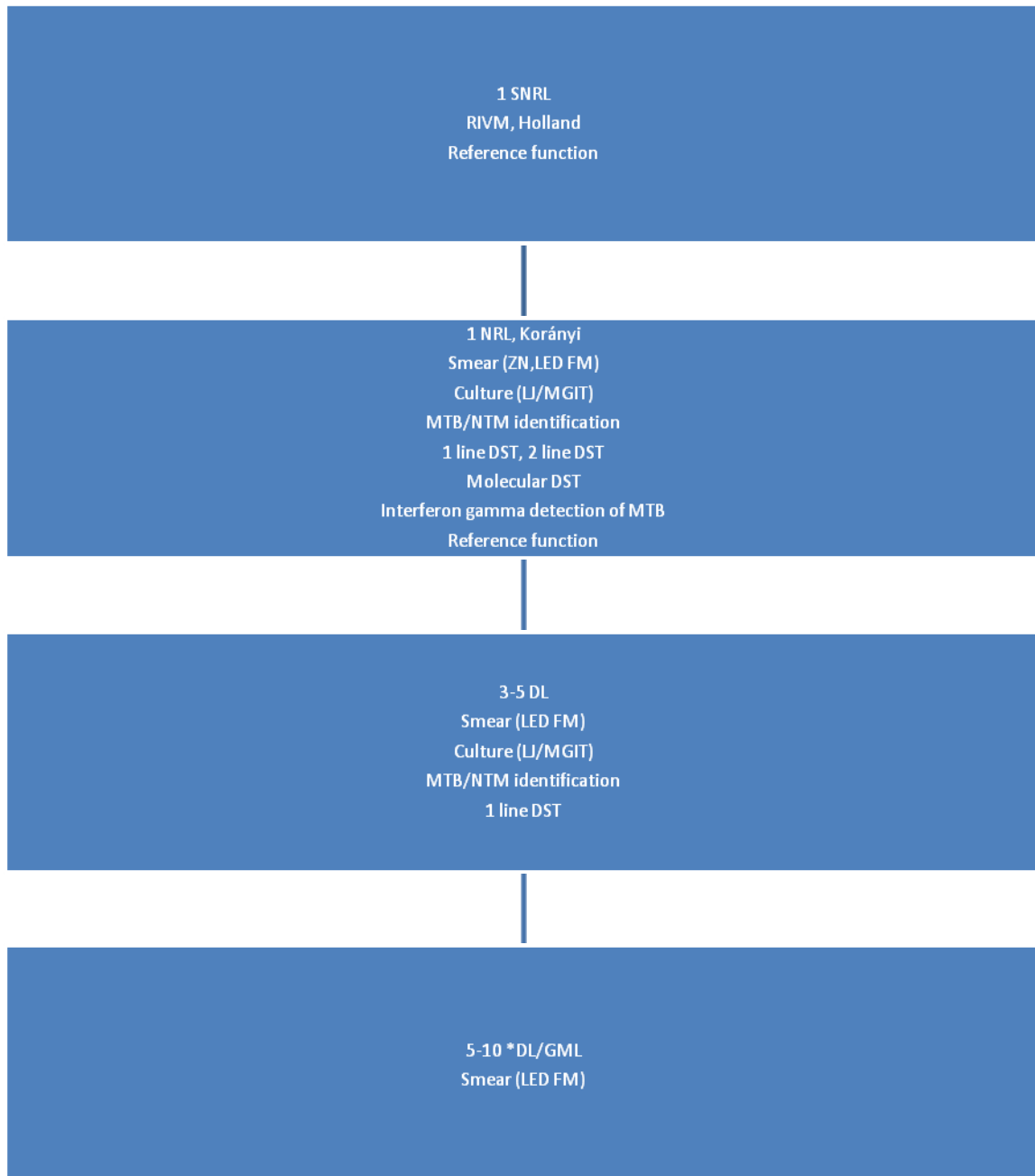


## 7. Discussing health financing consequences at the debriefing session



## Annex 3. Proposed restructuring of the laboratory network system in Hungary

Includes number of laboratories and basic mycobacterial functions required to cover the whole country.



# Annex 4. TB epidemiological country profile

## Hungary

Total population at 1 January 2010 by EUROSTAT: 10 014 704

### Tuberculosis case notifications, 2010

Total number of cases	1740
Notification rate per 100 000	17.4
New & relapses (nbr) number	1543 (88.6%)
New & relapses (nbr) notification rate per 100 000	15.4
Pulmonary	1667 (95.7%)
of which smear-positive	130 (7.9%)
Culture positive of all TB cases	673 (38.6%)
Mean age of new TB cases, nationals	53.7 years
Mean age of new TB cases, non-nationals	37.7 years
Foreign citizens of all TB cases	21 (1.2%)
New (not previously treated)	1487 (85.4%)

### Drug resistance surveillance & TB-HIV co-infection, 2010

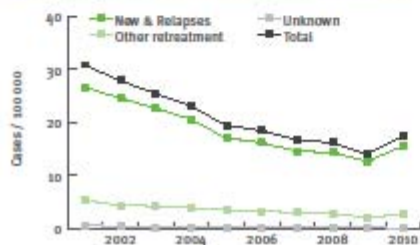
Completeness of ERS data*	No
Completeness of TB-HIV data**	-
Case-linked data reporting	Yes
Cases with DST results	570 (91.9%)
Cases resistant to isoniazid	54 (9.5%)
Cases resistant to rifampicin	23 (4.0%)
MDR cases	19 (3.3%)
of which XDR cases	2 (0.3%)
Cases resistant to ethambutol	16 (2.8%)
Cases resistant to streptomycin	19 (3.3%)
TB cases tested for HIV	-
HIV-positive TB cases	-

\* National coverage 100% on culture only, 100% TB cases 90%, DST done for 75%, ERS 95%  
\*\* More than 90% of TB cases tested for HIV

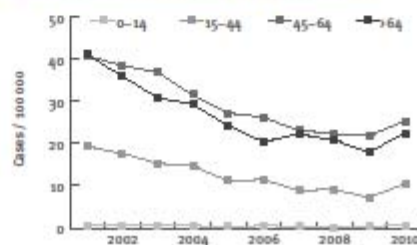
### Treatment outcome monitoring, 2009

Geographical coverage	National
Outcome cohort	New pulmonary culture positive
Case-linked data reporting	Yes
Notified in 2009	507
Success	341 (67.2%)
Dead	50 (9.9%)
Failed	111 (21.9%)
Defaulted	44 (8.7%)
Still on treatment	23 (4.5%)
Lost to follow up	20 (4.0%)

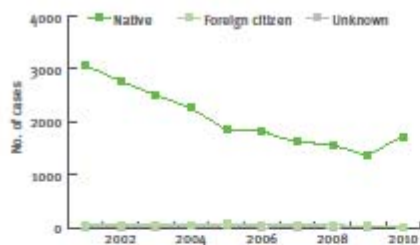
### Tuberculosis notification rates by treatment history, 2001-2010



### New TB cases - notification rates by age group, 2001-2010



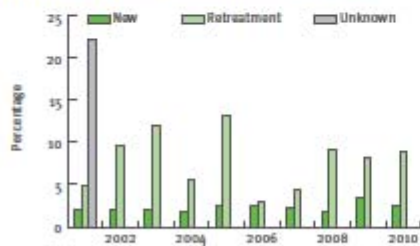
### Tuberculosis cases by geographical origin, 2001-2010



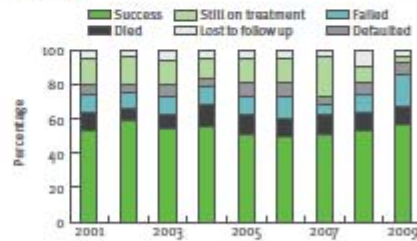
### TB-HIV co-infection, 2006-2010

Data not available

### MDR TB cases by previous treatment history, 2001-2010



### Treatment outcome, new pulmonary culture-positive cases, 2001-2009





TB notification rate per 100 000 population in Hungary by districts, 2011



(Source: Korányi National Institute for Tuberculosis and Pulmonology and National Public Health and Medical Officer Service, unpublished data, 2013).

Notification rate of TB cases confirmed by culture per 100 000 population in Hungary by districts, 2011.



(Source: Korányi National Institute for Tuberculosis and Pulmonology and National Public Health and Medical Officer Service, unpublished data, 2013).

## Annex 5. The Hungarian Childhood Vaccination Schedule

	BCG	DTPa	IPV	Hib	PCV	MMR	HepB
At birth							(1)
2 months		(2)	(2)	(2)	(4)		
3 months		(2)	(2)	(2)			
4 months		(2)	(2)	(2)	(4)		
15 months					(4)		
18 months		(2)	(2)	(2)			
6 years		(3)	(3)				
11 years		(5)					
13 years							

Source: (29). DTPa: diphtheria/tetanus/pertussis. IPV: inactivated poliovirus vaccine. Hib: *Haemophilus influenzae* type b. PCV: pneumococcal conjugate vaccine. MMR: measles/mumps/rubella. HepB: hepatitis B. 1 – Infants of mothers who are hepatitis B surface antigen (HbsAg) positive or with unknown HbsAg status, within 12 hours post-partum. 2 – Pentavalent combined vaccine. 3 – Combined vaccine. 4 – Voluntary. 5 – DTPa.

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