



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

**Edited by: Pierpaolo de Colombani
and Jaap Veen**

Review of the National Tuberculosis Programme in Ukraine

10–22 October 2010



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ABSTRACT

Ukraine has the highest burden of tuberculosis in the WHO European Region after the Russian Federation. In February 2010, the Minister of Health asked WHO to organize a review of the National Tuberculosis Programme, the recommendations of which would help develop the Programme plan for 2012–2016. The review took place from 10 to 22 October 2010 and involved 13 international and 23 national experts who reviewed documents, visited institutions and interviewed people in 8 *oblasts* and in Kyiv. The reviewers found that the Stop TB Strategy was not being implemented consistently, with wide variations between and within *oblasts*. Tuberculosis services are designed around health providers instead of patients. Current efforts to improve are limited by non-supportive legislation and an outdated health system based on hospital care and inflexible financing. There is an urgent need for action to stop the increasing reservoir of infectious and non-treatable multidrug-resistant and extensively drug-resistant tuberculosis (M/XDR-TB) cases, the acceleration of HIV co-infection and the high nosocomial tuberculosis transmission. Fourteen recommendations are made to the government, the Ministry of Health and its partners.

Keywords

TUBERCULOSIS – epidemiology – prevention and control
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The WHO Country Office, Ukraine in Kyiv and the health administrations of the *oblasts* visited provided efficient administrative and logistics support, which made all the meetings possible and travelling easy.

The following institutions and organizations provided their most experienced staff, irrespective of their official duties, to participate in the review and ensure its comprehensiveness:

- Ministry of Health, Kyiv, Ukraine
- State Department for the Enforcement of Sentences, Kyiv, Ukraine
- *oblast* health administrations, Ukraine
- WHO country office, Kyiv, Ukraine
- United States Agency for International Development (USAID), Washington, USA
- Royal Netherlands Tuberculosis Foundation (KNCV), The Hague, Netherlands
- WHO Collaborating Centre for Research and Training in MDR-TB, Riga, Latvia
- Centers for Disease Control and Prevention (CDC), Atlanta, USA
- Management Sciences for Health (MSH), Cambridge, USA
- Program for Appropriate Technology in Health (PATH), Kyiv, Ukraine.

Their support has been highly appreciated and underlined their commitment to improving tuberculosis control in Ukraine.

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Acronyms

BCG	bacille Calmette-Guerin (vaccine)
CDC	Centers for Disease Control and Prevention (United States of America)
DOT	directly observed treatment
DOTS	first component and pillar of the Stop TB Strategy recommended to control tuberculosis
KNCV	Royal Netherlands Tuberculosis Foundation
MDR-TB	multidrug-resistant tuberculosis (resistant to isoniazid and rifampicin)
NTP	National Tuberculosis Programme (Ukraine)
PATH	Program for Appropriate Technology in Health
SES	sanitary–epidemiological services
TB	tuberculosis
TB/HIV	HIV-related tuberculosis
USAID	United States Agency for International Development
XDR-TB	extensively drug-resistant tuberculosis (resistant to isoniazid and rifampicin and to any one of the fluoroquinolone drugs and to at least one of the three injectable second-line drugs (amikacin, capreomycin or kanamycin))

Executive summary

Main findings

After the Russian Federation, Ukraine has the highest burden of tuberculosis (TB) in the WHO European Region. WHO estimates that the incidence, prevalence and mortality rates of TB in 2009 were 102 (83–122), 135 (50–234) and 27 (18–40) cases, respectively, per 100 000 population. Multidrug-resistant TB (MDR-TB) comprised 16% (14–18%) of newly detected TB cases and 44% (40–49%) of previously treated cases, with 8700 (6800–11 000) new MDR-TB patients in need of treatment each year. Although the limited testing capacity of the TB laboratory network could not provide evidence, the members of the review teams are convinced that an epidemic of untreatable extensively drug-resistant TB (XDR-TB) is also present and rapidly increasing. Together with the spreading epidemic of HIV, which risks becoming generalized through heterosexual contact, the proportion of TB patients with HIV infection is also increasing rapidly (11% in 2009). There is already evidence of the deadly coexistence of MDR-TB and HIV infection among vulnerable groups in the population.

The current National Tuberculosis Programme (NTP) was approved in 2007, when DOTS was adopted as the national strategy to control TB after careful piloting of revised TB control interventions supported by international organizations and approved by the Ministry of Health in selected *oblasts* (provinces). The government's commitment to switch to new, internationally recommended standards for TB control was confirmed by the establishment in the same year of the National Council for the Prevention of TB and HIV/AIDS and the Ministry of Health's Committee on HIV/AIDS and Other Socially Dangerous Diseases. Since then, Ukraine has taken bold steps towards improving TB control, including the allocation of significant funds. The firm dedication of all health workers in the Ministry of Health has made it possible to update key national policies and guidelines, challenge *oblast* health administrations constructively, plan consistently for the support of the Global Fund to Fight AIDS, Tuberculosis and Malaria and eventually gain a grant. Lastly, the fact that the government requested WHO to organize an open and comprehensive external review of the NTP (the findings and recommendations of which are reported in this document) is another sign of its commitment and sincere willingness to achieve the TB-related targets of the Millennium Development Goals.

Despite the efforts of the Committee on HIV/AIDS and Other Socially Dangerous Diseases, the review teams noted that the Stop TB Strategy was not being implemented consistently. Wide variations were observed between and within *oblasts*, depending on the level of support received from international partners. TB financing depends mainly on the commitment and capacity of the *oblast* authority. Case-detection efforts are diluted by the screening of non-targeted populations, which is not cost-effective, and limited laboratory capacity. Treatment is mainly hospital-based and dependent on the erratic availability of locally purchased anti-TB drugs. Recording is often not accurate, leading to unreliable figures in reports. The efforts to fight MDR-TB are largely inadequate and sometimes produce additional drug resistance. Collaboration on TB/HIV co-infection is limited and nongovernmental organizations are not being used to their full potential. Overall, TB services are designed around health providers instead of patients. Even though the approval by the Global Fund Round 9 of a five-year TB grant is an important opportunity to strengthen the NTP according to international standards, this may still not be enough.

The Stop TB Strategy

Despite the official adoption of the Stop TB Strategy in Ukraine, there is widespread scepticism about its appropriateness and potential for successful implementation. Most doctors have their own personal approaches, resulting in a mixture of old and new interventions which may harm the clinical management of the individual patient and the overall public health impact of the NTP.

Doctors still rely on diagnosis by X-ray, even though it has been obvious since Robert Koch's discovery in 1882 that an infectious disease such as TB must be diagnosed by isolating the causative agent. Laboratory diagnosis is still underused. New molecular techniques are on the brink of introduction that will change the algorithms of diagnosis and allow rapid tests for identifying drug resistance. This has implications for the infrastructure of laboratories and the competence of the laboratory staff. A good test done badly is worse than no test at all.

Drug-resistant tuberculosis, especially MDR-TB and XDR-TB, poses new challenges for doctors who must learn about new drugs, new regimens and new protocols for case management, as well as about adverse effects and interactions, including with antiretroviral drugs. Drug-resistant TB requires longer hospitalization, meaning a different use of hospital beds, as well as much longer ambulatory treatment involving the primary health care facilities. The health care reform planned by the Ministry of Health must incorporate TB care in order to allow (drug-resistant) patients to adhere to lengthy treatment. Drug-resistant TB also challenges drug management: the selection, quantification, procurement, distribution and storage within a certain temperature and humidity range of second-line drugs with short shelf-lives require trained staff and adequate infrastructure.

In addition, the rising trend in TB/HIV co-infection calls for close cooperation and coordination between the TB and HIV services. Standard operating procedures must be developed to offer patients one-stop services, where the patient is at the centre of the organizational infrastructure. This means integrating HIV interventions into training curricula for TB and vice versa, as well as integrated facility-based and outreach services. This can only be done by rigorous prevention of transmission of either causative agent. Infection control interventions for TB are, therefore, an important part of these integrated services. Shorter hospitalization can contribute significantly to a decrease in nosocomial transmission. Infection control risk assessment is the key to deciding on the interventions needed.

Poverty and vulnerable populations

The world over, poor people and those from disadvantaged social groups suffer more illness and die sooner than the more privileged. In Ukraine, 20% of the population lives below the national poverty level. There are 300 000 injecting drug users and 100 000 female sex workers at risk of HIV infection, a prison population of 147 000 (of whom 39 000 are on remand) and a Roma population of 47 500. TB and MDR-TB incidence among these groups is only partially known but is thought to be much higher than in the general population. There is limited social support during illness. To be effective, interventions must be tailored to each vulnerable group, addressing not only the underlying conditions but also the social determinants. It is clear that the costs of diagnosis and treatment will increase, and it is important that the effectiveness of these interventions should be carefully monitored and evaluated.

Human resources and capacity building

Health workers have suffered greatly during the last two decades. They are, however, critical in the overall health system. DOTS, which has been introduced by government order, has not been

well implemented. In general, the majority of the health labour force is trained according to traditional clinical practice and has little knowledge of new strategies in TB control, and only a few doctors are able to implement it. Basically, health care workers lack proper training in DOTS and the later expanded Stop TB Strategy.

Human resources are regulated by laws which are rather rigid and do not take into account changing epidemiology, including drug-resistant TB and TB/HIV co-infection, nor a changing strategy that includes the involvement of primary health care services for case-finding and a more ambulatory approach towards the delivery of treatment. New diagnostic and treatment procedures are about to be introduced. There is a need to develop a national strategic plan for human resources aimed at competence-oriented training and the redeployment of available staff. This is the main challenge for the Human Resources Working Group established by the Ministry of Health in February 2010 to look specifically at the human resource development problems of the TB services.

Access

Health and access to health care are human rights. For many patients, the essentially hospital-based and specialist-centred approach of TB control is a barrier to seeking health care, as are financial considerations such as transport costs and payments for extra services or medicines. More patient-centred services, such as primary health care, are not properly involved in the early diagnosis of TB suspects and the follow-up of ambulatory patients. Patients often have to undergo a number of investigations at different levels of care, sometimes unnecessary or duplicative. When a patient is diagnosed with TB, the presence of drug resistance is uncertain. Testing for HIV co-infection is sometimes done in facilities outside the TB services. For treatment, patients are often kept for an unnecessarily long time in hospital without proper infection control and with disruption to their social and working lives. There is little knowledge of the Patients' Charter for Tuberculosis Care and it is not actively promoted or followed. Vulnerable populations in particular are affected.

Information

For decision-makers, correct information on case notification, treatment outcomes and process indicators is crucial. The information systems duplicate each other, are not well maintained and are often confusing. One standardized system is needed, either electronic or paper-based. The introduction of the e-TB Manager electronic system is likely to be helpful in the medium term but it cannot replace a national strategy for monitoring and evaluation. Regular feedback to those that provide the information is important, as is the possibility for management decisions to be taken based on the outcomes obtained.

Information for patients is important to help them keep up their treatment. This needs to be more than just a leaflet handed out to them. A complete strategy needs to be developed for health education, which means identifying what should be included and who is responsible for it, as well as the development of a curriculum and materials and training for educators. It also includes teaching health providers how to deal with patients, for which the key word could be "respect". Keeping the general population informed helps in encouraging individuals to seek early care and creating a supportive attitude towards TB patients. Stigma is difficult to eradicate, but it can be diminished by providing the right messages. What these messages should be, how they will be formulated for separate target groups and in what way their dissemination will be most effective must be part of a national communication strategy.

Health system

The efforts of the Committee on HIV/AIDS and Other Socially Dangerous Diseases have been seriously limited by a non-supportive environment represented by complex and contradictory legislation and an outdated health system based on hospital care and inflexible financing. The health system is complex and multi-layered, with responsibilities fragmented between central government (the Ministry of Health and many other ministries and public authorities), the 27 *oblast* administrations and numerous bodies at municipal, *rayon* (district) and village level. This multiplicity of authorities responsible for the financing and management of health care facilities, with vested interests and responding to different stakeholders, creates major challenges for the implementation of government orders and the development of a consistent reform plan. There is a high degree of verticalization in which different parallel structures provide specialized care, for example through AIDS centres, TB dispensaries, clinics for sexually transmitted infections and narcology centres. Collaboration between such structures is generally suboptimal. Equally, links between the various echelons of care are weak, as is collaboration between the health and social services. Preventive and primary health care remain largely neglected.

The health system is fragmented, hospital-centred and highly rigid, leading to inefficient service provision and thus under-spending on quality-enhancing investment. Important bottlenecks in the implementation of the Stop TB Strategy lie at the intersection of the general health system and the TB system, such as for patients (pathways, coordination of care), for staff (attraction and retention of TB specialists), for funding (government spending on health and the proportion allocated to TB) and for governance (responsibilities at national, regional and local levels). Short-term action taken within the NTP would only be sustainable if it was accompanied by substantial reform of the health system. Recently, the President has called for a socioeconomic reform programme, to include a section on health care services reform. If TB is not incorporated into this reform, the current financing of the infrastructure will continue to absorb scarce resources which are necessary for more effective prevention and control of TB and MDR-TB.

Main recommendations

To the government

1. There is an urgent need for action. The increasing reservoir of infectious and non-treatable M/XDR-TB cases, aggravated by the acceleration of HIV co-infection and the high risk of nosocomial TB transmission due to lack of infection control measures, poses a considerable and urgent threat to public health.
2. An uninterrupted supply should be ensured of first- and second-line anti-TB drugs to treat all patients diagnosed in all sectors, but especially for the Ministry of Health and the State Department for the Enforcement of Sentences. The present shortages are leading to chaos in treatment regimens, which aggravates drug resistance. To treat all the estimated 46 000 TB cases, including 8000 MDR-TB cases, the budget required exceeds US\$ 85 million per year. Only a small part of this requirement is being met through the Global TB Drug Facility and the Green Light Committee (under the Global Fund grant). The drugs to be procured should be of proven high quality and based on standardized treatment regimens which take into account the epidemiological situation and public health approaches. Until reliable drug-resistant tests become available, a standardized regimen IV should be used for all cases that fail to be cured with regimen II. The review teams observed extensive use of very expensive injectable anti-TB drugs (for example, fluoroquinolones and isoniazid), which should be discouraged. MDR-TB national guidelines should be revised.

3. Alternative mechanisms need to be developed to finance TB services. At present, these are financed on the basis of a budget allocated per hospital bed. This is an important incentive for the excessive hospitalization of TB patients. Alternative financing mechanisms should be developed to give preference to outpatient care and treatment outcomes.

To the Ministry of Health

4. Current TB legislation needs to be revised. Several laws and regulations affect the organization and delivery of TB services. New laws and regulations with high relevance for TB control are coming as part of the reform of the health sector. An overarching TB law should be developed, that can be further detailed through updated issues of a national TB manual as the main reference for all providers.
5. Only defined risk groups for TB should be targeted for case-finding by fluorography. The money saved should be redirected towards other needs of the NTP. TB screening with fluorography is done extensively and includes groups that are not at special risk for TB. The criteria for TB screening should be revised based on cost-effectiveness and documented by quality-checked data. Financial incentives for TB screening should be carefully reconsidered.
6. Outpatient treatment should be promoted over inpatient treatment. TB patients stay in hospital for an unnecessarily long time. Patients without severe clinical conditions and those that are sputum smear-negative should be treated outside hospital. Ethical principles recognized internationally should be adopted and actively promoted. Standardized regimens should be used and directly observed treatment (DOT) should be ensured throughout all treatment courses. Seasonal treatment should be stopped. Solid forms of TB medicines should be preferred to expensive and unnecessary injectable products (isoniazid, fluoroquinolones). TB infection control measures should be urgently introduced in civilian and penal settings based on risk assessments of the facilities.
7. TB/HIV collaborative interventions should be improved and their implementation monitored. Outreach services provided by nongovernmental organizations should be promoted. Even though several of these organizations ensure outreach interventions for the groups of population most at risk of HIV and TB, medical-oriented thinking and current legislation prevent non-medical workers from dispensing medicines outside health facilities. As a consequence, nongovernmental organizations cannot be used for direct observation of TB treatment, isoniazid preventive therapy or co-trimoxazole prophylaxis.
8. TB control should be included in the initial design and pilot implementation of the health care reform. The Ministry of Health is considering new forms of organization for the health services for introduction in pilot regions. This is an opportunity for the NTP to test new ways of financing and service delivery which can increase the quality of inpatient and outpatient care, while readjusting gaps in the human resources for TB.
9. TB indicators (output, outcome, impact) should be included in monitoring the implementation of the health care reform. TB encompasses several areas, often resulting from socioeconomic determinants and poor access to health care. For this reason, TB can be used as a proxy for monitoring the overall development and performance of the health sector.
10. Understanding of and compliance with the Stop TB Strategy should be improved. Despite official adoption of the Strategy, there is widespread scepticism about its appropriateness and potential for successful implementation. Most doctors have their own personal

approaches, resulting in a mixture of old and new interventions which may harm the clinical management of individual patients and the overall public health impact of the NTP.

11. The role and capacity of the Committee on HIV/AIDS and Other Socially Dangerous Diseases should be strengthened. At present, the Committee is in the Ministry of Health and is responsible for national TB planning and policy formulation. It comes under the National Council for the Prevention of Tuberculosis and HIV/AIDS. Below the Committee, the TB Control Centre is located in the F.G. Yanovsky National Institute of Tuberculosis and Pulmonology of the Academy of Science. There seems to be some overlap in the roles and responsibilities of the Committee and the TB Control Centre with regard to the implementation and monitoring/supervision of the NTP. The Committee has gained in expertise over recent years, but its authority is limited. The governance of the NTP should be streamlined, and the position and terms of reference of the Committee clarified and its functions strengthened.
12. The functions of the NTP need to be strengthened to ensure the quality implementation of the Stop TB Strategy in the general health services at central and regional levels and involve all TB care providers (State Department for the Enforcement of Sentences, National HIV/AIDS Programme, primary health care providers, nongovernmental organizations, etc.). Regular monitoring and supervision should be ensured from the centre to the *oblasts* and from the *oblasts* to the *rayons*. Supervision should be supportive (with opportunities for on-the-job training) and comprehensive of all aspects (laboratory, drug management, infection control, etc.). It is important to strengthen regular training and proper recording and reporting. Operational research should be a guiding tool.

To partners

13. The State Department for the Enforcement of Sentences should increase the financial resources for TB control. Leaving ethical and equivalence issues aside, this underfunding seriously contributes to the increased transmission of TB among detainees, personnel working in penal institutions and the population in general.
14. International partners need to continue and enhance their support to fight TB in order to reach the TB-related targets of the Millennium Development Goals. Ukraine is a dynamic middle-income country with diverse resources and an expanding private sector. It has, however, been seriously hit by the global financial crisis and suffers from the social inequities often produced by an expanding economy. International partners are still very much needed to provide technical and financial assistance.

1. Introduction

Ukraine has the highest burden of tuberculosis (TB) in the WHO European Region after the Russian Federation, with an estimated 46 000 (38 000–56 000) people becoming infected and 12 000 (8000–18 000) dying from it every year. The National Tuberculosis Programme (NTP) is based on the Stop TB Strategy and covers the period 2007–2011. By the end of December 2011, a new five-year national plan should be approved by the government. In a letter dated 16 February 2010 to the WHO country office in Kyiv, the Minister of Health officially requested WHO to organize an external review of the NTP by international and national experts. The recommendations of the review would help the Ministry of Health to develop the next NTP plan for 2012–2016.

The external review of the NTP, organized by the WHO country office and the WHO Regional Office for Europe, took place from 10 to 22 October 2010; 13 international and 23 national experts participated (Annex 1). The objectives of the review were:

- (i) to assess the epidemiological situation for TB and the features of the NTP, with reference to the Millennium Development Goals, the implementation of the Stop TB Strategy and its links with the general health system;
- (ii) to make specific recommendations for the development of the new NTP plan for 2012–2016;
- (iii) to prepare a comprehensive WHO report of the review.

Only two similarly comprehensive external reviews of the NTP have taken place before in Ukraine, one organized by WHO in December 1999 (1) and the second sponsored by the United States Agency for International Development (USAID) in February 2006 (2).

The Ministry of Health selected eight *oblasts* (provinces) using convenient criteria such as geographical distribution, access to international support and absence of information from previous assessments. Dnipropetrovsk and Kyiv *oblasts* receive international support (Dnipropetrovsk from the Program for Appropriate Technology in Health (PATH) and WHO, and Kyiv from PATH only). The other six *oblasts* (Kirovohrad, Volyn, Mykolayiv, Sumy, Luhansk and Chernivtsi) have never been part of a collaboration agreement with international partners.

The reviewers formed eight field teams, each led by an international expert and each visiting one *oblast*. All *oblasts* were visited during the first week, and the second week was spent in Kyiv in meetings and visits at national level and working on the initial draft of the report (see detailed programme in Annexes 2 and 3). The reviewers analysed relevant documents already available (publications, mission reports, etc.), conducted site visits to relevant institutions and facilities and interviewed policy-makers, health providers and beneficiaries, as well as representatives of the general population and of the main national and international partners. A number of tools were developed and used to interview health providers and beneficiaries as well as to guide field observations, interviews with policy-makers and focus group discussions. Questionnaires were distributed to a sample of patients (129 TB and 102 primary health care patients) and physicians and nurses (147 TB staff and 100 primary health care staff) at the facilities visited.

2. General information

Ukraine is bordered by the Black Sea and the Russian Federation in the east, Hungary, Poland and Slovakia in the west, Belarus in the north and Romania and the Republic of Moldova in the south. Most of the country consists of fertile plains (steppes) and plateaus, mountains being found only in the west (the Carpathians) and in the Crimea.

In 2009, the population was 45.7 million, 12% less than in 1991 when the country gained its independence. There are three major subdivisions: *oblasts* (provinces), *rayons* (districts) and municipalities (both urban and rural). Kyiv and Sevastopol municipalities have the same administrative importance as *oblasts*. Major municipalities in urban areas (23 in 2010) are subdivided into several urban *rayons*. Within the *oblasts*, the main cities may have the same administrative importance as a *rayon*.

The economy has been severely affected by the recent global financial crisis, which has led to a fall in demand for its major export items, steel and wheat. Additional setbacks are the recent depreciation of the currency (the hryvnia – Hrv), rising unemployment and the need for the government to cut expenses and undertake more cost-effective interventions, including in health. The national budget for health in 2009 remained the same as in 2008, but with a 20% reduction in expenditure for medicines and no capital investment.

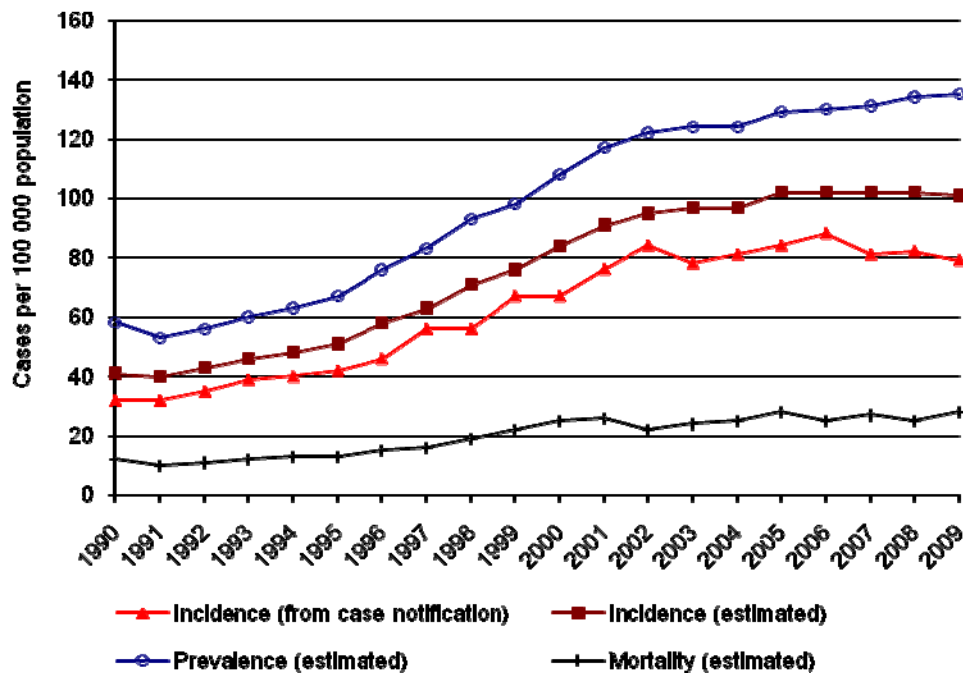
A recent World Bank report shows the divergence in mortality and morbidity trends from central Europe, with excess deaths among males of working age in particular owing to modifiable behavioural risk factors such as hypertension, alcohol and smoking (3). An important role is also played by risk factors such as environmental conditions, poisoning and injuries. One third of Ukrainians die before the age of 65 years, a much higher rate than in other European countries. It is believed that about half of the deaths before the age of 75 years could be avoided through adequate prevention and treatment.

3. TB epidemiology

WHO estimates the incidence, prevalence and mortality rates of TB in 2009 to be 102 (best estimate, with a range of 83–122), 135 (50–234) and 27 (18–40) cases per 100 000 population, respectively (4). If the incidence rate is applied to the population, the absolute number of new TB cases is estimated at 46 000 (38 000–56 000), the highest number after the Russian Federation and representing 11% of the TB burden in the European Region. Ukraine is listed among the 18 high-priority countries for stopping TB in the Region (5). In recent years, the incidence of TB has remained around the same while the prevalence and mortality rates have increased (Fig. 1). This may be a reflection of the increasing multidrug-resistant TB (MDR-TB) and HIV-related TB (TB/HIV) epidemics.

In 2009, Ukraine reported to WHO a total of 38 075 new cases of TB (all forms) detected, or 79 per 100 000 population. The TB notification rate was 77 per 100 000 population in rural areas and 71 per 100 000 population in urban areas (6). New smear-positive pulmonary TB cases were notified in a male:female ratio of 2.9:1. The peak of notification in men was between 35 and 44 years of age and in women between 25 and 34 years of age.

Fig. 1. TB notified and estimated incidence (all cases), estimated prevalence and estimated mortality rates per 100 000 population, Ukraine, 1990–2009



The first case of HIV was registered in 1987. Since then, the HIV epidemic has advanced rapidly to an estimated HIV prevalence of 1.1% (1.0–1.3%) among the adult population in 2009. Added to the HIV prevalence among children, this can be translated into 350 000 (300 000–410 000) people estimated to be living with HIV, the second highest burden in the Region after the Russian Federation (7). The HIV epidemic in Ukraine is still concentrated mainly among injecting drug users but is at risk of becoming generalized through heterosexual contact. TB is the main cause of morbidity and mortality among people living with HIV. There is already a worrying overlap between the TB and HIV epidemics, with an 11% HIV prevalence rate among new TB patients in 2009.

MDR-TB comprises 16% (14–18%) of newly detected cases of TB and 44% (40–49%) of treated cases of TB, with an estimated number of 8700 (6800–11 000) new MDR-TB patients in need of treatment with second-line anti-TB drugs every year (8). Matching the growing epidemic of HIV, there is already evidence of the deadly coexistence of MDR-TB and HIV infections (see section 8). According to the Committee on HIV/AIDS and Other Socially Dangerous Diseases, 2870 extensively drug-resistant TB (XDR-TB) cases were registered in 2009.

The high and unchanging rates of TB suggest that the years of TB control have had a very limited impact (Fig. 1). On the contrary, the increasing rates of MDR-TB, and possibly now also XDR-TB, indicate that over-reliance on individual medical expertise and a poor approach to public health have contributed to a worsening of the epidemic.

4. NTP: strategies, structure and resources

In May 2005, the Cabinet of Ministers established the National Coordination Council for the Prevention of HIV/AIDS to offer a high-level platform for dialogue between the government, civil society, people living with HIV and international partners. The Council met the requirement

of the Global Fund to Fight AIDS, Tuberculosis and Malaria for a country coordinating mechanism to provide an effective national response to the HIV epidemic with international support. In July 2007, the Council was converted into the National Council for the Prevention of Tuberculosis and HIV/AIDS with expanded membership and a mandate to apply to the Global Fund for a TB grant. In March 2008, the President established the Coordination Council for AIDS, Tuberculosis and Drug Addiction with high-level national leadership.

In February 2007, the Ministry of Health created the Committee on HIV/AIDS and Other Socially Dangerous Diseases with the role of secretariat to the National Council. Since then, this Committee has been responsible for developing policy for the NTP, its translation into national guidelines (to be endorsed through orders from the Ministry of Health) and the central procurement of anti-TB drugs. Monitoring and evaluation of programme implementation is the task of the TB Control Centre based at the F.G. Yanovsky National Institute of Tuberculosis and Pulmonology in Kyiv (see section 14 and Annex 4). In December 2010 (after this review took place), the Committee was replaced by the State Services on HIV/AIDS and Other Socially Dangerous Diseases.

At *oblast* level, the health departments of the *oblast* state administrations are responsible for the local planning and delivery of TB services through tertiary, secondary and primary health care facilities in *oblast* and *rayon* cities and villages. The heads of the *oblast* state administrations are appointed by the President as the executive authority of the *oblast* councils, which are politically elected. The *oblast* chief TB doctor is usually nominated by the *oblast* health department and has an overview of all *oblast* TB services.

The national bodies established over the years clearly indicate a commitment by subsequent governments to reverse the growing epidemics of HIV and TB and channel specific external support effectively. There is, however, no clear and detailed description of each body's role and responsibility, and overlap and duplication of efforts have been observed.

On 8 February 2007, the government issued Law No. 648-V on the Approval of the National All-State Programme for Counteracting Tuberculosis for 2007–2011, which set up the current NTP. The goal of the NTP is to improve the epidemiological situation by bringing down TB mortality and morbidity among the population, preventing MDR-TB, improving the effectiveness of treatment, institutionalizing the system of training and retraining of health care workers and improving laboratory diagnostics. The NTP is based on the Tuberculosis Prevention and Control Programme, financed by USAID and implemented by WHO during 2001–2004 in Donetsk *oblast*¹ as a demonstration project for DOTS (first component and pillar of the Stop TB Strategy recommended to control TB) (9). In 2005–2009, and with financial support from USAID, WHO introduced DOTS in five additional *oblasts*: Dnipropetrovsk, Kherson, Kharkiv, Zaporizhia and the Autonomous Republic of Crimea. In 2007, Ukraine adopted DOTS as the national strategy to control TB and implemented it through the NTP with adapted national treatment guidelines, a drug procurement system, a recording and reporting system and retraining of chief TB doctors.

The NTP strategy contains 15 objectives, each supported by several indicators. Its targets for 2011 are a 60% detection rate of cases of new sputum smear pulmonary TB, 95% treatment coverage and an 85% treatment success rate.

¹ Ministry of Health Order No. 337 of 16 August 2001, Protocol on the Implementation of an Efficient Strategy for Tuberculosis Control in Donetsk Oblast, ratified by Donetsk *oblast* administration by Order No. 358 of 24 December 2001.

Traditionally, TB control in Ukraine is vertically organized with case-finding, diagnosis and treatment primarily the responsibility of clinically trained TB specialists (physicians, paediatricians and surgeons). Diagnosis and treatment are provided in TB dispensaries, hospitals and sanatoria. Bacille Calmette-Guerin (BCG) vaccination is provided by primary health care services. The sanitary–epidemiological services are responsible for tracing TB contacts or treatment defaulters. TB diagnosis is provided with the support of laboratory and X-ray specialists and technicians, and treatment and care with TB nurses and visiting nurses for outreach activities. The primary health care services organized in polyclinics and health posts with family doctors and feldsher/midwife posts are gradually getting more involved in TB control.

Ministries and other government bodies have separate, parallel health systems for their workers. The ministries of Transport and Communications, Internal Affairs, Defence, and Labour and Social Protection and the Academy of Medical Sciences all have their own health infrastructures. In 2004, this parallel health care network included 265 hospitals (9% of the total number of hospitals in the country) and 1002 outpatient polyclinics (13% of the total). Some 9.4% and 9.3%, respectively, of total inpatient and outpatient contacts occurred in this parallel health care network. The Ministry of Transport has the largest infrastructure, with 80 hospitals and 185 polyclinics.

The parallel health systems take up a lot of resources. Almost half the health expenditure from the national budget and more than 15% of total public health expenditure is spent on parallel medical facilities. NTP finances for 2007–2011 were set at US\$ 240 million, which is not considered sufficient to cover all TB response needs. Ukraine applied successfully to the Global Fund in Round 9 with a five-year TB project exceeding US\$ 103 million (10). The grant agreement for the first two years' implementation was signed in December 2010.

5. Case-finding and diagnosis

Main recommendations

1. Only defined risk groups should be targeted for TB case-finding by fluorography, and the funds saved should be redirected towards other needs of the NTP. TB screening with fluorography is done extensively and includes population groups that are not at special risk of TB disease. The criteria for TB screening should be revised based on their cost–effectiveness and documented by quality-checked data. Financial incentives for TB screening should be carefully reconsidered.

Specific recommendations

2. TB screening should be optimized by: (i) analysing the yield for each group screened, and (ii) identifying the risk groups to screen based on the higher yields.
3. A proper diagnostic algorithm should be followed for sputum smear-negative patients, including the use of a broad-spectrum antibiotic and excluding any fluoroquinolone.
4. In the absence of a rapid molecular test, the diagnosis of TB should always be confirmed with bacteriological investigation.

5. A working group should be set up to develop a strategy for optimizing the national laboratory network, based on a countrywide analysis of the needs of: (i) laboratory services according to population coverage, geographic access and the epidemiological burden of TB; (ii) an upgrading of the laboratories (civil work renovation, purchase of new equipment); (iii) human resources.
6. The National Tuberculosis Reference Laboratory should be officially designated, with clear responsibilities and dedicated human and financial resources and located within the National Institute of Tuberculosis and Pulmonology (under a contract with the Ministry of Health) or in another facility.
7. The quality of laboratory services should be ensured by external quality assurance.
8. New tools should only be introduced, such as the rapid diagnosis of TB, when testing results are proven reliable and all new cases detected can be treated with a full course of second-line TB drugs.
9. The criteria for defining a TB suspect should be improved and promoted widely.
10. Sputum smear microscopy should be improved by: (i) teaching patients how to expectorate better; (ii) organizing the transport of sputum samples in *rayons* and *oblasts*; and (iii) implementing the front-load method (two sputum samples on the spot) to ensure that at least two samples are available for investigation.
11. The National Tuberculosis Reference Laboratory should be officially tasked to: (i) prepare national manuals with standard operating procedures for bacteriology and biosafety; (ii) prepare and coordinate the implementation of a training plan and training materials for laboratory procedures; and (iii) provide consultation and supervision on standard operating procedures.
12. Supportive supervision and quality assurance in the laboratory network should be improved by the establishment of strong level III laboratories in each *oblast* and the provision of transport for regular supervisory visits.
13. Certification of the appropriate functioning of biosafety cabinets should be carried out urgently and repeated annually. Sanitary–epidemiological service units should be included in training in biosafety principles.
14. A collaborative agreement should be established between the Ministry of Health and the State Department for the Enforcement of Sentences, including who will pay for what, and supervision of the prison level III laboratories ensured by the Ministry of Health *oblast* level III laboratory.

In 2009, 13 632 new sputum smear-positive cases (12 007 confirmed by culture) were reported, corresponding to 46% of total pulmonary TB cases reported to WHO. The TB case detection rate (all forms) was 78%, which has not changed much during the last 20 years. Further interventions to increase TB case detection should be targeted towards decreasing the number of patients who have access to health care but do not seek it (currently 10–14%) and those with access and seeking health care but not being properly diagnosed (3–5%).²

In 2009, only 3842 (44%) of the 8700 estimated (best estimate) new MDR-TB cases (among newly diagnosed or previously treated TB patients) were reported. Of these, 3186 (83%) had started treatment with second-line drugs.

² Workshop on Improving TB Estimates: Identifying Gaps and Making the Most of Available Data, Berlin, Germany, 26 April–2 May 2009, attended by Ukrainian experts.

Case-finding

Active case-finding by annual mass miniature radiography or fluorography screening of the adult population is regular practice (see section 7 for case-finding among children). Although the Ministry of Health currently limits fluorography screening to risk groups, most providers refer to previous ministerial orders requesting mandatory TB screening for certain professions (teachers, people working in the food industry, drivers, etc.) and students aged over 15 years. Meanwhile, those most at risk of TB (such as homeless people, migrants and injecting drug users) are not screened since they are not easy to find. Current statistics do not allow calculation of the yield of screening per risk group (effectiveness), or related costs to *oblast* health administrations.³

Passive case-finding is based on the self-reporting of symptomatic patients to general health services or directly to TB facilities. There, they are investigated with chest X-ray and sputum smear microscopy. Many primary health care doctors ignore the definition of TB suspect and ask for sputum microscopy for every respiratory patient (a policy of general sputum analysis), increasing the laboratory workload unnecessarily as shown by the low proportion of cases confirmed with TB. Patients suspected of having TB and referred to a TB facility for diagnosis are often kept in hospital, where they share a ward with TB patients without proper infection control measures.

NTP guidelines include a diagnostic algorithm for smear-negative pulmonary TB that is not always followed, as preference is given to trials with anti-TB drugs instead of a broad-spectrum antibiotic. The latter often includes a fluoroquinolone, a very important second-line anti-TB drug of which the use in these cases may convert underlying TB disease into a fluoroquinolone-resistant form.

Contact investigation of active TB cases (smear-positive and smear-negative/culture-positive) is routinely practised in households and, when necessary, in workplaces. Adults undergo a chest X-ray or a fluorography and children a tuberculin skin test.

Diagnosis

All TB suspects undergo a chest X-ray, a sputum microscopy and bacteriological culture (on solid media). Many doctors rely on the chest X-ray only.

There are three levels of laboratory, whose responsibilities are described in Ministry of Health Order No. 50 of 6 February 2006 (Approval of Standard Provisions on Laboratories and Sites for Diagnosis of Tuberculosis and Sputum Collection Points). Despite the rationalization of the laboratory network in recent years (*11*), there are still 460 level I, 90 level II and 27 level III TB laboratories (one in each *oblast* and two in Kyiv City), too many to be supported effectively (ensuring quality assurance, infection control, an uninterrupted supply of commodities, regular training, etc.). The distribution of these laboratories is historical rather than strategically designed for a functional network.

³ In one *rayon* visited by the team members, 40 931 people had been screened in 2009 and 38 cases of TB and 8 lung cancers had been detected. The total cost for films and reagents was Hrv 135 500 (Hrv 2945 per TB case detected), plus additional expenses such as transport, staff time and other running costs. All eight patients detected with lung cancer during the mass screening were at a very advanced stage of their disease and could not receive surgical treatment.

Most laboratories are inadequately funded and lack modern equipment for an effective and safe working environment. Many still use monocular microscopes. Peripheral laboratories have low workloads, while laboratories in specialized TB services are overloaded with up to 60 sputum smear microscopies per day per laboratory technician. Both situations result in low performance. The World Bank loan supported many level III laboratories with BACTEC MGIT™ 960 equipment for automated liquid culture, biosafety cabinets and infection control interventions. More BACTEC equipment will be installed under the Global Fund Round 9 grant. Unfortunately, this budget does not cover maintenance and service, which is necessarily limited by the shortage of trained hospital engineers.

The number of unnecessary tests contributes to an excessive laboratory workload, creating a relative shortage of staff. Meanwhile, there is a shortage of well-trained laboratory staff due to the high turnover (80% of staff trained over the last few years have left the service). Furthermore, the supervision of TB laboratories by the NTP is minimal and dependent on future additional resources from the Global Fund Round 9 grant.

The State Department for the Enforcement of Sentences has its own laboratory services (see section 10).

The National Tuberculosis Reference Laboratory is recognized by the Ministry of Health. Since 2009, it has been collaborating with the Supranational Tuberculosis Reference Laboratory in Riga, Latvia. It moved recently to the newly constructed clinical laboratory of the F.G. Yanovsky National Institute of Tuberculosis and Pulmonology in Kyiv City. This Institute is part of the Academy of Sciences and independent of the Ministry of Health. The National Tuberculosis Reference Laboratory consists of one room of 17 m², representing 4% of the total 450-m² laboratory area, with an inappropriate layout. It has two Class 2 biosafety cabinets and BACTEC MGIT™ 960 equipment. The Laboratory processes 40–50 samples a day for direct microscopy and bacteriological culture. Drug susceptibility testing on solid media has been limited due to the lack of pure substances, and MGIT is preferred. The salaries of the staff of the National Tuberculosis Reference Laboratory are paid from the Institute's research budget.

Recently, the restrictions for sharing test panels for external quality assurance between the Supranational Tuberculosis Reference Laboratory and the National Tuberculosis Reference Laboratory were lifted. The Laboratory trains level III *oblast* laboratories twice a year, but these laboratories have no clear mandate to supervise lower-level laboratories; thus, no systematic quality assurance system exists. In the pilot *oblasts* assisted by PATH and WHO, there are good level III laboratories implementing external quality assurance for smear microscopy.

The National Tuberculosis Reference Laboratory has neither a budget nor the formal authority to accomplish all the tasks required in addition to routine work such as the development of guidelines, training, quality assurance and supervision. The alternatives for the Ministry of Health are to contract out services to the National Institute or to move the National Tuberculosis Reference Laboratory to another location.

New tools

New tools can help to reduce the TB laboratories' workloads. The newly developed cheap light-emitting diodes microscopes allow fluorescence microscopy, which increases the number of slides that can be read by one laboratory technician.

Laboratories' workloads can also be reduced by use of the line-probe assay for rapid diagnosis of MDR-TB, or the Xpert® MTB/RIF test that simultaneously identifies *Mycobacterium tuberculosis* and resistance to rifampicin, but these should only be introduced in a proper laboratory layout with quality assurance ensured in a well-organized laboratory network. Both these tests are endorsed by WHO.

The Global Fund Round 9 grant includes the introduction of MDR-TB rapid tests in all level III laboratories over the next four years. New diagnostic algorithms must be developed, and assistance from the Supranational Tuberculosis Reference Laboratory is required to select which methodology to adopt and to plan its countrywide introduction. Both internal and external quality assurance are critical, following the principle that a good test done badly may be worse than no test at all.

Furthermore, an increased diagnostic capacity makes sense only if the required treatment with second-line anti-TB drugs is made available for all new cases detected.

6. Treatment and case management

Main recommendations

1. Outpatient treatment should be promoted in place of inpatient treatment. Prolonged and unnecessary hospital care should be avoided. Patients without severe clinical conditions and those that are sputum smear-negative should be treated outside hospitals. Ethical principles recognized internationally should be adopted and promoted actively.
2. Standardized regimens should be consistently used and directly observed treatment (DOT) should be ensured throughout treatment.
3. Seasonal treatment should be stopped.

Specific recommendations

4. The criteria for hospitalization should be reviewed, and it should be limited to severe and advanced forms of TB, MDR-TB in the intensive phase of treatment and sputum smear-positive TB if ambulatory DOT is not possible.
5. Surgery should be limited to MDR-TB and other conditions clearly described in the national guidelines.
6. Patient-centred care should be provided with different options for treatment (in both the intensive and continuation phases), such as ambulatory care (in the closest primary health care facility available), hospital day care, home care ((with DOT provided by visiting nurses) or hospital care.

7. Support should be given to patients in order to enhance their adherence to, and improve the outcomes of, treatment through: (i) transport and food/hygiene packages; (ii) prescription of fixed-dose combination drugs; and (iii) broader involvement of the general health services for DOT.

According to the data sent to WHO for 2008 (4), 62% of the new smear-positive cases were successfully treated, 12% died, in 12% the treatment failed, 9% defaulted on treatment and 5% were not evaluated. The success rate for treatment has remained the same for the last three years. Among the cases retreated, 41% were successful, 16% died, in 21% the treatment failed, 13% defaulted and 8% were not evaluated. Death, failure of treatment and the rate of default increased compared to 2007, reducing the overall success rate of treatment.

Hospitalization is required for bacteriologically confirmed pulmonary cases (sputum smear- and/or culture-positive) until the completion of the intensive phase of treatment and smear conversion. Some doctors also, however, request a culture-negative result before deciding to start the continuation phase of treatment and discharge the patient from hospital. In addition, many patients with smear-negative pulmonary or mild forms of extrapulmonary disease not requiring hospital care are admitted for social reasons that doctors expect to impede the daily treatment in an outpatient facility. The result is widespread hospitalization that, with the poor infection control measures currently in place, contributes further to transmission of TB and MDR-TB among patients and staff.

Ministry of Health Order No. 384 of 9 June 2006 (Protocol on Provision of Health Care for Tuberculosis Patients) standardized the treatment regimens in alignment with WHO's recommendations. The review teams noted that adherence to prescribed regimens differed between the *oblasts* visited. In some facilities, second-line anti-TB drugs were used to treat new patients and the treatment was prolonged beyond six months. This was usually done in patients with cavities showing on the chest X-ray or when drug resistance was suspected before drug susceptibility testing. Directly observed treatment (DOT) was implemented to a limited degree, even in hospitals. Streptomycin was commonly used in the first-line regimen, sometimes with ethambutol. Many patients were prescribed intravenous drugs (isoniazid and ofloxacin) while in hospital. Most of those discharged from hospital for the continuation of their treatment were receiving ambulatory treatment in a TB dispensary; only a few were being treated in general health service facilities (polyclinics in towns and cities and feldsher/midwife posts in rural areas). Usually a nurse in these facilities was in charge of DOT and was also responsible for tracing treatment defaulters. In most of the *oblasts* visited, all first-line drugs were available in locally procured single formulations; fixed-dose combinations from the Global TB Drug Facility have been found in stores but they were only being used for about 20% of the patients. Doctors reported seeing more side-effects with fixed-dose combination drugs, but were unable to provide documented evidence.

Up to 30% of newly diagnosed patients undergo surgical treatment, irrespective of their drug resistance. The decision about surgery is taken without the support of specific national guidelines. After surgery, patients continue chemotherapy for a considerable time and receive an invalidity benefit.

Follow-up sputum smear microscopy and culture are performed on a monthly basis. Doctors are, however, still heavily dependent on radiological confirmation of the closure of the lung cavity, which is considered to indicate a definitive cure. Patients are monitored by TB dispensaries for a few years after completion of their treatment and cure. In some *oblasts*, seasonal treatment (in spring and autumn) with two to three drugs is common to prevent relapses in treatment. There is

no evidence that this intervention is beneficial; indeed, preventive treatment with a combination of isoniazid and rifampicin may favour drug resistance in cases wrongly diagnosed as not having active TB.

There is a high treatment default rate among alcoholics and other risk groups. Inconsistent coordination with the penal services was also observed, resulting in little effort to ensure continuation of treatment for former inmates after discharge. Support for patients is practically non-existent, apart from some involvement by the Ukrainian Red Cross Society in a few *oblasts*.

7. Childhood TB

Main recommendations

1. The national guidelines on management of TB in children should be revised according to the international standards.
2. Inpatient treatment should be limited to complicated and drug-resistant cases of TB.

Specific recommendations

3. BCG should be limited to one vaccination at birth.
4. The national policy on annual skin testing screening should be revised. Such testing should be limited to risk groups of children.
5. Dosage of basic anti-TB drugs should be revised in line with WHO recommendations. Ethambutol should be used rather than streptomycin in the first-line regimen.
6. Isoniazid preventive chemotherapy schemes should be prolonged to six-month regimens and provided under ambulatory conditions.
7. Inpatient treatment should be limited and inpatient preventive chemotherapy in sanatoria should be stopped.

Children can have TB at any age, but the most common age is between one and four years when there is an increased risk of progression from infection to disease. The epidemiology of TB in children depends on the intensity of TB transmission in the area, the age structure of the population, the available diagnostic tools and the extent of routine contact investigation.

In 2009, 571 children were registered with TB (all forms) in Ukraine: 225 with pulmonary TB, 7 with disseminated miliary TB and 339 with an extrapulmonary form. Meningitis was reported among 17 children, 8 of whom died. Altogether, 813 children with TB were being followed up.

BCG vaccination is given at birth and repeated at 6 and 14 years. This is contrary to international recommendations not to re-vaccinate, irrespective of the level of TB transmission in the community, because of the limited evidence of its effectiveness.

A tuberculin skin test is performed each year in all children aged under 15 years. Children who are in household contact with an adult TB case (all forms) are also screened. In 2009, more than 85% of children had tuberculin skin tests and about 57% of the children with TB were detected in this way. In Ukraine, the tuberculin skin test is considered the best available diagnostic tool to

diagnose TB in children.⁴ However, these tests have low specificity with false positive reactions, especially after BCG vaccination and when repeated skin tests are performed. False negative reactions are common in immune-compromised individuals. The use of tuberculin skin tests should be limited to risk groups of children, such as those in close contact with active TB cases. All children with active TB disease are hospitalized for the entire period of treatment. Only the parents of children aged under three months can stay with them in hospital. Children can continue with their studies in hospital, but recreational arrangements and other support are limited and often depend on support from donors. Regimens are standardized, but streptomycin is preferred over ethambutol in the first-line regimen even if drug resistance to streptomycin is reported to be much higher than to ethambutol. Rifampicin and isoniazid are administered at 10 mg/kg, with a maximum daily dose of 600 mg. Ethambutol is given at 15–20 mg/kg and pyrazinamide at 20 mg/kg, which means that, with the exception of isoniazid, all drugs are given in lower quantities than those recommended by WHO (either in the old guidelines or the new ones issued in 2010) (12).

Children considered to have a latent TB infection are also admitted to hospital for three months to receive isoniazid preventive treatment administered at 10 mg/kg. Children living with HIV receive isoniazid preventive treatment for six months, often with added rifampicin. Hospitalization is not recommended for children with latent TB infection or minimal activity such as primary or glandular TB. Such children can be easily treated in an ambulatory setting without interrupting their normal lives.

8. HIV-related TB

Main recommendations

1. Existing coordination bodies (*oblast* TB/HIV coordination councils) should be revived and focus on improving TB/HIV collaborative interventions and monitoring implementation. At local (*rayon*, city) level, multidisciplinary teams should be established composed of specialists in TB, HIV and support for injecting drug users, to discuss the management of TB/HIV cases and optimize treatment outcomes and support for patients.
2. National TB/HIV guidelines should be updated and completed to include the responsibilities of each service, the frequency and location of screening, infection control procedures, drug management, timing of co-treatment initiation and monitoring of side-effects.
3. Outreach services provided by nongovernmental organizations should be promoted by revising existing laws and regulations and allowing non-medical workers to dispense isoniazid preventive treatment, co-trimoxazole preventive therapy and anti-TB drugs under DOT.

Specific recommendations

4. TB and HIV physicians should be cross-trained on guidelines for diagnosis and treatment of each disease in those who are co-infected, and they should work together to coordinate the

⁴ When physicians were asked by the review team how to distinguish between a positive tuberculin skin test due to a BCG vaccination and one due to latent TB infection, they answered that three years after a BCG vaccination the reaction to the test begins to diminish. When asked about a potential booster effect between annual tests, they explained that this can be avoided by performing the tuberculin skin test on alternate forearms.

continuum of care. In high TB/HIV-prevalence settings, positions should be created for physicians who are responsible for co-infected individuals in both TB and HIV services.

5. There should be a better culture of service to patients among health care workers in order to improve community involvement and enhance adherence with treatment.
6. Patient education should be expanded and enhanced on issues related to both TB and HIV (such as infection control issues, HIV prevention methods, optimal screening, diagnosis, and treatment regimens, outreach and patients' rights).
7. The WHO guide to monitoring and evaluating collaborative TB/HIV activities should be implemented.
8. Counselling about TB should be provided to all HIV-infected individuals and those who present for HIV evaluation at every encounter.
9. All HIV-infected individuals should be screened for TB at regular intervals (quarterly, for example) and as clinically indicated.
10. The potential for transmission of TB to HIV-infected individuals should be reduced by ensuring that TB infection control measures are in place in all sites where TB screening and evaluation is carried out, including AIDS centres.
11. Isoniazid preventive treatment should be provided to HIV-infected individuals (in whom TB has been excluded) at non-TB facilities to reduce their progression to active TB.
12. Recommendations regarding TB infection control and biosafety should be incorporated into the construction of new, and renovation of existing, health facilities for TB, AIDS-related care and general health care.
13. Voluntary HIV counselling and testing should be made available to all TB patients.
14. Co-trimoxazole preventive therapy should be introduced and rapidly expanded to include all co-infected individuals.

The prevalence of HIV, like the prevalence of TB, has been steadily increasing. Ukraine now has the most severe HIV epidemic in eastern Europe and central Asia, with an estimated 350 000 (300 000–410 000) people living with HIV and an adult prevalence rate of 1.1% (1–1.3%). In addition, the overlapping risk factors for TB and HIV have resulted in a steady rise in HIV-related TB (TB/HIV). In fact, TB is the leading cause of morbidity and mortality among people living with HIV, as found by the Ukrainian AIDS Centre that retroactively studied the 2008 records of 10 *oblasts* and identified 1350 deaths (48%) due to TB in a total of 2792 deaths among people living with HIV.⁵

In 2009, WHO estimated HIV prevalence among TB patients to be 11%. Among the total number of 38 901 TB cases notified to WHO, only 33 424 (86%) knew their HIV status, of whom 3771 (11%) were positive, suggesting that the prevalence of HIV among TB patients might be higher than currently estimated.

On a positive note, Ukraine reported that 57% of individuals with both HIV and TB were placed on co-trimoxazole preventive therapy, a major achievement considering that none had been reported in 2006. There is no information on the number of TB/HIV patients who had started antiretroviral treatment or on the rate of TB screening among people living with HIV, making it

⁵ A retrospective assessment of HIV mortality in 2008 in 10 *oblasts* of Ukraine (Dnepropetrovsk, Donetsk, Volynsk-Lutsk, Sumy, Zhytomir, Kharkiv and Kherson *oblasts*, the Autonomous Republic of Crimea, Kyiv City and Odessa City) was carried out in 2009 by the Ukrainian AIDS Centre. The report has not yet been published.

impossible to assess these critical interventions for reducing morbidity and mortality among people living with HIV.

In recent years, there have been a number of efforts to improve TB/HIV collaborative interventions. The Committee on HIV/AIDS and Other Socially Dangerous Diseases has been representing a platform to expand and reinforce collaboration between the TB and HIV sectors, and to explore possible interventions to improve the outcomes of those co-infected. Other positive developments have been the creation of *oblast* TB/HIV coordination councils and a number of TB/HIV pilot projects in *oblasts* and *rayons* (13,14). However, the Committee has yet to fulfil its potential as a collaborative forum and the implementation of the pilot projects has been limited, making it difficult to evaluate the success of interventions (15). So although some inroads have been made in addressing TB/HIV, significant additional work remains to be done.

One of the major challenges in diagnosing, treating and ultimately preventing TB among people living with HIV is the vertical nature of the two national programmes. Despite the literature describing the need for collaboration and for the introduction of steps allowing the programmes to work closely together, implementation varies significantly among the *oblasts*, as do the services available to individuals with HIV, with TB or with co-infection.⁶

The following issues should be raised for immediate attention in addition to those considered in other sections of this report.

TB screening of HIV-infected individuals

- HIV-infected individuals sent to a TB hospital for bi-annual screening often do not present there for evaluation.
- HIV-infected individuals who do present for evaluation cannot always gain access to adequate diagnostic procedures that are capable of detecting pulmonary or extrapulmonary TB or drug-resistant forms of the disease.
- HIV-infected individuals who do present for evaluation at TB hospitals are at high risk of exposure and infection from patients with active TB (and potentially drug-resistant TB).

⁶ In one *oblast* visited by the review team, despite good communication between the TB and HIV programmes there were no defined responsibilities, no framework for service delivery and no shared algorithm for continuum of care. Voluntary counselling and testing was only available at the AIDS centre and important diagnostic procedures (magnetic resonance imaging, computerized tomography and CD4 counts) were not available. Individuals with HIV were scheduled for TB screening twice a year but rarely presented, and those who did come were patients with TB or MDR-TB as a result of inadequate infection control measures. HIV-infected individuals diagnosed with TB were only able to access TB medications at the TB hospital, and often did not start antiretroviral treatment before completing TB treatment (which could last from 6 to 24 months). Co-trimoxazole preventive therapy was only provided in TB hospitals to co-infected patients on special request.

In another *oblast*, the review team found a well-equipped AIDS centre able to perform CD4 counts and viral loads. TB prevalence was reported in 70% of the individuals with AIDS. Even so, not all those detected with HIV were being screened for TB or sent for screening to TB dispensaries lacking infection control measures. Patients in TB dispensaries/hospitals were rarely offered voluntary counselling and testing. Many people living with HIV were diagnosed with TB very late because of their atypical symptoms and the insufficient diagnostic algorithm (biopsy, other). One physician interviewed noted that > 60% of patients successfully treated for TB later relapsed with MDR-TB, suggesting an initial incorrect diagnosis or a suprainfection due to poor infection control measures. A rapid records review of several dually infected individuals found that all had been prescribed isoniazid preventive treatment but none had been prescribed co-trimoxazole preventive therapy.

Diagnosis of TB

- The only service permitted to diagnose TB is the TB service. In the few instances where HIV/AIDS clinics have the capacity (and expertise) to perform sputum microscopy, the results are not accepted by the TB services. As a consequence, patients are referred for repeat testing, leading to unnecessary dropouts and considerable diagnostic delay. Moreover, the final diagnosis is made by a panel of three TB physicians in a secondary-level institution to which the clinical and laboratory data are sent. Since this process can take a significant amount of time, local physicians often start treating those patients they strongly suspect of having active TB disease prior to the panel's decision. The panel may then overturn the initial decision, leading to intermittent or inadequate treatment, particularly in those with HIV, as TB specialists are often unaware of the atypical presentation of TB.
- The diagnostic capability for extrapulmonary TB is poor. Diagnosis of extrapulmonary TB is inherently more difficult, even under optimal conditions, and tends to cost more than diagnosis of pulmonary TB. Since TB physicians are not always aware of the special free services for HIV/AIDS, expensive investigations such as magnetic resonance imaging, computerized tomography, etc. are denied to HIV-infected individuals who are unable to pay for them.

Case management of TB/HIV

- A clinical protocol for the case management of TB/HIV, with clear recommendations for concurrent treatment of TB and HIV, has been developed and disseminated. However, it is often not followed: antiretroviral treatment is interrupted when TB treatment starts, or starts later than recommended after the start of TB treatment, or is inadequately monitored with insufficient resources for CD4 counts or viral loads.
- The distinct vertical nature of the TB and the HIV/AIDS programmes at *oblast* and *rayon* levels often leads to disparate methods of treatment in the different settings and different interpretations of the clinical protocol. In addition, HIV-infected individuals often do not receive complete physical examinations, nor are standard treatment regimens necessarily followed, leading to an individualized approach to both diagnosis and treatment.
- There continues to be a critical gap in surveillance and monitoring of the TB/HIV collaborative services. It is not yet possible to collect accurate data to guide management decisions (WHO's TB/HIV monitoring tool is currently used in several *oblasts* but has yet to be implemented widely).
- A few *oblasts* have developed a network model to support multidisciplinary teams (TB department, HIV department, social workers and DOT nurses where available), while other *oblasts*, with Global Fund support, have incorporated nongovernmental organizations in the provision of social support and incentives and bridging between the TB and HIV/AIDS programmes, but these experiences have not yet been widely integrated into the TB/HIV services.

Infection control

- Infection control is inadequate at all levels, creating a dangerous environment for those who are immunocompromised (see section 12)

- HIV-infected individuals are sent to TB hospitals with little or no infection control measures in place. As a result, they are at high risk of becoming infected with TB or MDR-TB. Those who are admitted to hospital are often put in wards without any infection control measures (separation of patients according to infectiousness, susceptibility patterns, etc.) and are exposed to infectious individuals with susceptible and drug-resistant TB, a particularly devastating and deadly problem for those who are immunocompromised.

TB/HIV in harm reduction settings

- Several nongovernmental organizations ensure outreach interventions for the population groups most at risk of HIV and TB. However, medical-oriented thinking and current legislation prevent non-medical workers from dispensing medicines outside health facilities. As a consequence, these organizations cannot be used for DOT, isoniazid preventive treatment and co-trimoxazole preventive therapy.
- TB, HIV and harm reduction activities are not well integrated. There is no national body or plan to address these three interrelated issues, no inclusive training curriculum and no way to coordinate monitoring and evaluation.
- The Global Fund supports several facility-based sites providing HIV, TB and harm reduction services (for example, opioid substitution therapy). Unfortunately, it appears that these services are coordinated on an ad hoc rather than codified basis, and although the potential for “one-stop shopping” exists, regulations make it difficult for doctors to implement this holistic approach, which often causes them to be harassed by police or local authorities.
- Little effort has been made to mobilize community outreach services to reduce stigma, build trust and gain access to those at highest risk.

9. Drug-resistant TB

Main recommendations

1. A working group of key specialists from the main national and international stakeholders should be established to revise the existing Ministry of Health order on MDR-TB management in accordance with WHO guidelines and recommendations.
2. A standardized regimen IV should be used to treat all cases that fail treatment on regimen II, as long as drug susceptibility testing results are not fully reliable.

Specific recommendations

3. An MDR-TB management expert team should be established at *oblast* level to be responsible for diagnosis, treatment, consultation assistance on case management and outcome evaluation.
4. A systematic approach should be established in every *oblast* for MDR-TB case management according to the availability of quality-assured bacteriological diagnostics, and/or based on the medical history and clinical patterns using an established standard (regimen IV) or empiric treatment regimen.

5. DOT should be carried out for all patients, in hospitals as well ambulatory, to prevent the development of MDR-TB.
6. An uninterrupted second-line TB drug supply should be ensured for all drug-resistant TB patients (including poly- and multidrug-resistant cases). Second-line drug procurement must also include those drugs used during the ambulatory phase for the treatment of adverse reactions. These drugs should all be given free.
7. Infection control should be implemented in MDR-TB departments and all TB health care facilities, including the full separation between infectious and non-infectious patients, drug-resistant and susceptible patients, and patients with chronic MDR-TB who are not eligible for treatment.
8. Facilities should be established for chronic MDR-TB patients (non-eligible for treatment) where palliative care can be provided under proper infection control measures.
9. Training should be ensured for all levels of health personnel in implementation of the Stop TB Strategy, including all aspects of MDR-TB case management. MDR-TB management should be included in under- and postgraduate training curricula.
10. Patients should be supported during the ambulatory phase of daily DOT by the reimbursement of transport expenses on a daily basis.
11. Seasonal preventive treatment of TB patients and contacts of MDR-TB patients should be discontinued.

WHO estimates that 8700 (6800–11 000) MDR-TB patients needed treatment with second-line drugs every year in 2009 (see section 3). The visit by a field team to one TB hospital revealed that among 510 TB patients treated from January to September 2010, 91 (18%) were MDR-TB and 19 (21%) XDR-TB. A survey carried out in Donetsk *oblast* in 2006 documented MDR-TB in 15.5% of newly diagnosed TB patients and 41.5% of those who had previously been treated; among TB patients in the penal system, the figures were 21.8% and 52.8%, respectively (16). The survey also showed a significant association between HIV status and MDR-TB (OR 1.7). According to the Committee on HIV/AIDS and Other Socially Dangerous Diseases, 2870 XDR-TB cases were registered in 2009.

Since 2006, an MDR-TB pilot project has been implemented by WHO in Donetsk *oblast* with financial support from the Foundation for the Development of Ukraine. Policies and guidelines for the programmatic and clinical management of MDR-TB have been developed but have not been fully incorporated into the Ministry of Health orders⁷ that describe how TB and MDR-TB cases should be classified and treated. In many aspects, the Ministry of Health directions do not correspond with international guidelines, causing misunderstandings among doctors and mistakes in treatment and contributing to the further increase of MDR-TB and the creation of XDR-TB. Specifically: (i) case definitions are unclear and need to be updated; (ii) classification allows the inclusion of susceptible cases, cases with irregular treatment at risk of MDR-TB and cases that start MDR-TB treatment without confirmation of MDR-TB diagnosis; (iii) management of adverse reactions to drugs does not encourage specific treatment but promotes cancellation of drugs; (iv) non-TB drugs of group V should not replace second-line drugs when the regimen is strengthened; and (v) information regarding the use of capreomycin, cycloserine and terizidone should be revised.

⁷ Order No. 384 of 9 June 2006 on Provision of Health Care for Tuberculosis Patients, and Order No. 600 of 22 October 2008 on Provision of Health Care for Multidrug Resistant Tuberculosis Patients.

The diagnosis of MDR-TB by laboratories is very poor (see section 5). Even though it has improved in recent years, it has not been matched with an increased treatment capacity, which raises serious concerns about cost–effectiveness and ethical correctness.

When MDR-TB is treated, it is without following defined standards. In the *oblasts* visited, the field teams observed that various types and durations of regimen are being used, often with an insufficient number of anti-TB drugs; DOT is not being implemented, either during inpatient or outpatient care; and the follow-up procedures are not being properly implemented. Second-line drugs are being prescribed by decision of a panel of physicians, based either on drug susceptibility testing or even only on clinical history and status. Moreover, treatment regimens are often decided according to the selected availability of drugs. Drug management, including of second-line drugs, is facility-based and medicines do not follow patients for DOT at primary health care level when they have been discharged from hospital.

There are no outreach activities or patient support in the form of incentives or enablers (such as reimbursement of transport expenses). Sometimes patients are admitted for hospital day care, but food is not provided. There is no special attention for vulnerable groups. A system of temporary disability benefits promotes non-adherence to treatment.⁸

Drugs are not always available, resulting in interrupted treatments. The irregular funding mechanism at *oblast* level, in combination with a lack of training in drug management, contributes to the irregular procurement of drugs. Streptomycin is used routinely, with or without ethambutol. Second-line injectable anti-TB drugs (such as ofloxacin, sparflaxacin, gatifloxacin and para-aminosalicylic acid) are widely used without any specific clinical indication and for a prolonged period of time, increasing the cost of treatment of each MDR-TB case by at least six times. Although there was no documented evidence, the review teams are convinced that an epidemic of untreatable XDR-TB has been created and is rapidly spreading.

There is a high risk of nosocomial infection due to the almost unrestrained transmission of MDR-TB in all health facilities, including in dedicated MDR-TB wards (see section 12).

Although accurate records were not available, it was clear to the review teams that many patients who had on several occasions received uncompleted treatment with second-line drugs had XDR-TB and lung damage. All these patients were kept in TB hospitals with poor infection control measures. These so-called “chronic” MDR-TB patients were no longer eligible for treatment with category IV regimens. Specific palliative care under effective infection control measures must be implemented by the organization of separate health premises.

A set of reporting and recording forms has been developed for drug-resistant TB and is being used by WHO in Donetsk (see section 14). This system has been introduced in other *oblasts* but is not being maintained properly and is thus providing false data on drug-resistant TB, including MDR-TB and XDR-TB.

⁸ A disability benefits scheme exists for all individuals with certified TB disease. The benefit is not, however, linked to any compliance with treatment, and thus becomes a perverse incentive for the patient to continue to be ill (and therefore disabled). The Department of Social Protection and Labour needs to find alternative mechanisms.

10. TB control in prisons

Main recommendations

1. The financial resources for TB control in the State Department for the Enforcement of Sentences should be increased. Apart from ethical and equivalence issues, the current under-funding seriously contributes to the increased transmission of TB among detainees, personnel working in penal institutions and the population at large.

Specific recommendations

2. Case-finding based on symptoms arising during imprisonment should be strengthened. Staff should receive in-service training through cooperation and coordination with the Ministry of Health.
3. TB diagnoses should be strengthened, including the provision of rapid testing equipment and drug susceptibility testing. An increased budget and training of personnel are preconditions, as is the availability of all drugs to treat every case identified.
4. The use of standard regimens for TB should be enforced.
5. An agreement should be made with the Ministry of Health that allows the pooling of anti-TB drugs procurement and savings of scale.
6. Barriers to the continuation of treatment after release from prison should be removed by: (i) providing proper health education in prison; (ii) informing the Ministry of Health well in advance of a release from prison and allowing a Ministry of Health nurse or nongovernmental organization worker to visit the TB patient before release; (iii) allowing TB patients to receive treatment at the nearest health facility to their places of residence after release from prison, independently from their places of registration; (iv) not forcing ex-prisoners to register at police stations.

On 1 December 2009, there were 146 837 prisoners: 319 per 100 000 population. Of these, 100 173 (68%) were in prisons, 1472 (1%) in juvenile centres, 1226 (0.8%) in reformatories, 4502 (3%) in penal settlements and 39 464 (27%) in pre-trial detention centres. The prison population has fallen steadily over the years (17). In 2009, 86 300 persons went to prison, and 530 341 detainees moved in and out of pre-trial detention centres. In one centre visited by the field team, 198 cases of TB had been detected in 2008 and 249 in 2009. Taking into account the 27 931 detainees entering and leaving that centre during 2009, the TB notification rate was 891 per 100 000 population.

On 1 January 2010, a total of 5591 HIV-infected detainees were counted in the penal institutions, of whom 723 had TB/HIV and 390 were receiving antiretroviral treatment. A survey carried out among prisoners in Donetsk *oblast* in 2007 found MDR-TB in 21.8% of newly diagnosed cases of TB and 52.8% among previously treated cases (16). In one TB prison hospital visited by the field team, 408 (80%) of 510 TB patients had been tested for HIV: 107 (26%) were infected with HIV, 72 (14%) with MDR-TB and 19 (4%) with XDR-TB.

The State Department for the Enforcement of Sentences has the status of a ministry although it is not designated as such. Its head is directly answerable to the Cabinet of Ministers. The Department is responsible for incarcerating those suspected and convicted of crimes. It has its own administrative, medical and security staff, laboratory network and 10 TB hospitals in large

TB prisons⁹ with a total capacity of 5000 beds. The Department has a close relationship with the Office of the Prosecutor General, which is under the Ministry of Justice, as are the courts and judges. It also collaborates closely with the Ministry of Internal Affairs, whose police provide temporary cells and transport for detainees.

Detention is in three stages.

- (i) After arrest a suspect is locked in a police cell. The maximum legal length of stay in a police cell is 10 days; in most cases it is thought that it does not exceed 72 hours. During the investigation period a suspect may have to return several times for questioning and spend one to two weeks at a time in the police cell. Police cells are under the jurisdiction of the Ministry of Internal Affairs. It is not known how many there are.
- (ii) Suspects awaiting trial are held in one of the 33 pre-trial detention centres. The average length of stay is not known, but thought to be five to six months. The law states that a person cannot be kept longer than six months in pre-trial detention, but the actual stay can be years if the final sentence is delayed by appeals to the court.
- (iii) Once the final sentence is passed, the person goes to prison. The average length of stay is unknown but thought to be around five to six years.

TB case detection is based on fluorography as part of routine medical examinations in many police cells and all isolation departments in pre-trial detention centres. All convicts transferred to prison are screened on entry by fluorography.

All the pre-trial detention centres and about half of the prisons have level I laboratories, totalling 86. Through a loan from the World Bank, these have been newly equipped. Prisons without laboratories use the services of a pre-trial detention centre or of the Ministry of Health. Each of the 10 TB hospitals has a level III laboratory. When TB is suspected, a sputum smear examination is requested. When an active TB case has been diagnosed in a pre-trial detention centre, the procedures can be different. To limit TB transmission in these centres, the State Department for the Enforcement of Sentences issued Order No. 331/645 on 6 July 2004 instructing that TB patients in them should be admitted to a Ministry of Health TB hospital under police guard and at the cost of the centre. This order was suspended in 2006 and is supposed to be replaced by a new order. In practice, small pre-trial detention centres have managed to maintain good collaboration with the local Ministry of Health TB facilities, while big centres with large numbers of detainees and TB patients have to keep them inside. When an active TB case is identified in a prison, the patient is sent to one of the 10 TB hospitals. Further TB diagnosis here includes bacteriological culture and drug susceptibility testing. Some laboratories have BACTEC™ technology but reagents are not supplied regularly so they have to rely on traditional culture on Lowenstein-Jensen solid media. None of the laboratories under the State Department are included in any external quality assurance system of the Ministry of Health.

In all penal institutions, TB treatment should follow the standard regimens recommended by the NTP. Drug-resistant TB is treated with a selection of second-line anti-TB drugs supplied by the Department in an amount that the review team members estimated as covering no more than 25% of the needs. In the big pre-trial detention centres that cannot refer patients to Ministry of Health facilities and have experienced a serious reduction in resources since 2003, the situation seems to be worse. Dramatic conditions were observed, with no drugs, no treatment, overcrowding and no infection control measures either for the detainees or the staff. Frequent

⁹ TB prisons are in Dnipropetrovsk, Donetsk, Zaporizhyya, Luhansk, Mykolaev, Poltava, Ternopil, Kharkiv and Kherson (1).

temporary transfers of detainees from pre-trial detention centres to police stations occur during their trial hearings, with consequent interruptions in TB treatment, even for two weeks.

With unreliable drug susceptibility testing and treatment, MDR-TB in penal institutions is on the rise and poses an urgent problem that needs to be addressed before a major XDR-TB outbreak occurs. The effective implementation of the Global Fund Round 9 grant is of paramount importance.

The State Department has an agreement with the Ministry of Health for HIV-testing of detainees. All detained people with TB should be offered voluntary counselling and testing, but only 20% are actually tested. The main reasons reported are the shortage of laboratory consumables and the extra work created in the Ministry of Health laboratories. Antiretroviral treatment is only available to cover 80% of those needing it. Isoniazid preventive treatment is given, but not co-trimoxazole preventive therapy.

The State Department procures its own drugs through a centralized tender procedure. Quantification is based on historic data of the amount of a specific drug needed and not on the number of patients. Drugs are kept in a central warehouse. Once or twice a year, they are collected by the penal facility. Usually, the transport is provided by the *oblast* TB hospital. The review teams noticed that fixed-dose-combination anti-TB drugs (provided in limited amounts by the Ministry of Health) were available but only in limited used. Some stock-outs were observed of pyrazinamide, although enough drugs were found in the central warehouse.

TB infection control measures are limited or non-existent. Once they have been diagnosed, the segregation of TB patients in hospitals helps to prevent transmission to other inmates in general. There, existing guidelines stipulate the need for separation of smear-positive and smear-negative cases. However, confidentiality prevents special arrangements for the HIV co-infected TB cases, thus exposing them to TB overinfections. Staff in the TB facilities are somewhat protected by the provision of surgical masks to both patients and staff. More recently, personal respirators, ultraviolet lamps and disinfectants have been purchased. All staff undergo an annual screening for TB.

According to an agreement with the Ministry of Health, the State Department has to inform the local Ministry of Health facility about the release from prison of a TB patient (3 days before for those in pre-trial detention centres, 25 days before for those in prisons). If a prisoner still has active TB disease, he or she can be kept for one week following release in the TB prison hospital to ensure a proper alert to the civilian authorities. The Ministry of Health may ask the sanitary–epidemiological services to provide transport if the patient is still infectious. In reality, the ex-prisoner is left to find his or her own way, first to the police station of his or her official place of residence (as stated in the documents) and then to the health facility for the continuation of TB treatment. It is estimated that 30% of the former prisoners discontinue treatment because they are living somewhere other than their official place of residence or are not willing to register at the police station. Under the Global Fund Round 9, special attention is given to develop pilot interventions to assure the continuation of treatment for individuals released from prison through cooperation with local nongovernmental organizations.

Senior officers of the State Department visit facilities, but their visits are limited to checking compliance with existing regulations. The TB hospitals may also be visited by *oblast* TB supervisors, who act as consultants and may provide some on-the-job training.

The State Department complains of shortages of staff in general. There are 1238 positions for doctors, of which 1137 (92%) are filled although the actual number of staff working is 1103

(89%). The total number of positions for TB doctors is 209, of which 163 (78%) are filled and 151 (72%) doctors are actually working. Career opportunities are even lower within the penal system. In-service training of prison doctors is irregular and mainly based on a few courses organized by the Ministry of Health. Like all other medical professionals, they have to undertake refresher postgraduate training every five years.

The budget of the State Department is low and sometimes inadequate to reimburse the Ministry of Health for its services. Fortunately, there are examples of good personal relations between colleagues in the civilian and penal facilities that minimize the problem of pending bills. The World Bank invested in strengthening 4 of the 10 level III laboratories in the bigger TB prison hospitals and equipped 68 (50%) level I laboratories. The annual budget for TB drugs and laboratory reagents is Hrv 9.5 million (US\$ 1.2 million). In 2010, the State Department provided a one-off additional budget of Hrv 12 million (US\$ 1.5 million) for the purchase of second-line anti-TB drugs, covering about 65% of the needs. Despite several requests to the Cabinet of Ministers, the State Department received only 25% of the planned budget. The Department is one of the sub-recipients of the Global Fund Round 9 grant.

There is no systematic health education for TB patients, nor are prisoners in general made aware of TB or HIV. In 2008, an All-Ukrainian charitable foundation, the Network of Organizations Working in the Penal System, which is financially supported by PATH, started a pilot project in two *oblasts* aiming to raise awareness and social support for compliance by ex-prisoners with their treatment after their release.

11. Other vulnerable populations and social determinants

Main recommendations

1. Vulnerable populations should be defined by level of TB risk and type of vulnerability. Based on this analysis, adequate interventions should be designed and implemented.

Specific recommendations

2. Each intervention adopted to improve TB case detection and treatment outcome should be analysed for effectiveness and cost-effectiveness.
3. Treatment procedures and access to disability benefits schemes should be coordinated so as to avoid perverse incentives to interruption of treatment and overall prolongation of the duration of treatment.
4. Nongovernmental organizations should be supported, including with advocacy, to work with TB vulnerable groups.

As in many countries, TB does not affect all populations groups in similar ways. Those most at risk of developing the disease include: those who abuse alcohol or drugs; those who are on low incomes, unemployed or retired; people living with HIV; current and newly released prisoners and pre-trial detainees; legal and illegal migrants; refugees and ethnic minorities such as the Roma; and people in professions that put them at higher risk (health care workers, miners, etc.). Street children and orphans may also be included. Considerable evidence shows that stigma and discrimination are major barriers to early detection, diagnosis and completion of treatment for TB. Because many people who develop TB face other challenges and deprivations in their lives, they are prone to

interruptions in their treatment and development of drug-resistant TB. Thus, a major challenge has always been to bring down the treatment default rate. This requires a broad range of interventions that address social, economic, behavioural, programmatic and systemic issues.

The poorest people are most affected by TB. Not only are they more vulnerable to the disease because of their living and working conditions, they are also plunged deeper into poverty as a consequence of it. TB can lead to unemployment, which may lead to homelessness (see also section 9). In the statistics such individuals are often registered as in the homeless risk group, while in reality they are victims of incomplete social support during their illness. There is an association between high unemployment, alcohol abuse, domestic violence, increased migration, increased numbers of sexual partners, intravenous drug use, and the decision by some women to do regular or occasional commercial sex work as a survival strategy. All these make them vulnerable to TB and HIV.

While official statistics indicate that alcohol consumption is lower in Ukraine than in other countries, findings from sociological and expert estimates indicate a high level of alcohol dependence. Alcohol causes 12.3% of all disability-adjusted life years, higher than in all the countries with which Ukraine is compared except Hungary (3). In 2004, more than 13% of deaths were alcohol-related, and a rising trend is observed. Regular alcohol consumption is frequent, especially among younger people. A sociological study in two *oblasts* found that almost half the TB patients drank alcohol regularly; in a similar study, 12% of the respondents confirmed that they used intravenous drugs.

Prisoners are at risk of contracting TB (and HIV) owing to their living conditions and more limited access to adequate diagnosis and treatment. Thus they suffer from the double stigma of being a criminal and having TB, which is one of the reasons they do not report for continuation of treatment after their release from prison (see section 10).

Gender issues may also play a role in vulnerability to TB, since the incidence of TB is twice as high in men as it is in women (see also section 16).

During the last five years, the involvement of civil society in matters relating to TB has significantly increased, especially among the historically HIV-focused nongovernmental organizations. The number of these organizations working with groups vulnerable to TB is, however, still limited. Although financial support from the Global Fund (Rounds 1 and 6) has enabled them to build capacity and gain extensive experience in working with populations vulnerable to, or living with HIV, other marginalized populations receive very little, if any, support in gaining access to TB prevention, treatment and care. The high default rate for TB treatment can be largely explained by this lack of support.

The great challenge is the issue of equity: how to improve health among socially deprived and vulnerable groups by ensuring easy access for them to affordable interventions.

12. Infection control

Main recommendations

1. TB infection control measures should be urgently implemented in the civilian and penal TB, HIV/AIDS and general health care services. The high level of nosocomial TB

transmission and the growing epidemic of drug-resistant TB in high-HIV-prevalence settings (such as in Ukraine) make it imperative to prioritize the introduction of administrative, environmental and individual control measures based on risk assessments of the facilities.

Specific recommendations

2. Annual training courses on TB infection control should be organized at national, *oblast*, *rayon* and facility levels for hospital administrators, doctors, chief nurses, epidemiologists, laboratory managers and technicians. It is vital to include epidemiologists from the sanitary–epidemiological services in national and international training. There is a good training centre for infection control in Donetsk.
3. An educational programme should be established on the prevention of TB transmission and cough etiquette for TB patients, their relatives and other close contacts, as well as for the general population. Infection control policies, a high-risk standard of operations and infection control educational programmes should be developed and implemented for health care workers, patients and the general population.
4. Risk assessments should be organized and TB infection control plans developed for each health care facility, integrated with general infection control measures and taking the available resources into account. These plans need to be updated annually to take account of new evidence-based procedures.
5. TB suspects, outpatients and hospitalized patients should be separated according to their symptoms, the results of sputum smear microscopy and drug susceptibility testing (or the risk of drug-resistant TB) and their HIV status, in both the outpatient and inpatient departments. Shortening the overall length of stay in hospitals and adhering to the national requirement for floor area per patient bed (to reduce overcrowding) are contributory factors in the reduction of transmission. This recommendation also applies to penal facilities.
6. There should be appropriate triage of respiratory symptomatic patients, separation of patients and specimen flows with signage and reallocation of facilities (if needed), and isolation of smear-positive and M/XDR-TB patients.
7. Sputum should be collected in the open air in a well-designated area that is also usable in the winter. If this not feasible, a special room should be assigned to the collection of sputum with proper ventilation, either natural (open window) or mechanical (negative pressure room with at least 12 air changes per hour).
8. Local mechanical ventilation and/or upper room ultraviolet germinal irradiation fixtures should be installed and regularly maintained, and arranged so that they are present in high-load sputum smear preparation rooms, waiting areas, medical examination offices, bronchoscopy rooms, autopsy rooms, common rooms and other high-risk settings where natural ventilation cannot be used effectively.
9. Appropriate funding (5–10% of capital cost per year) should be allocated for the maintenance of sustainable and professionally designed, commissioned and maintained mechanical ventilation and laboratory biosafety equipment. Certification of the biosafety cabinets according to EN 12469 standard by appropriately trained and certified specialists should be sought.
10. One or more engineers should be hired for the NTP who have appropriate education in ventilation, ultraviolet germinal irradiation and biosafety equipment issues, essential for the use, sustainability and cost–effectiveness of equipment.

11. A personal respiratory protection programme should be established for staff at high risk in settings where the use of administrative and environmental controls is not sufficient to reduce the risk of TB transmission. This should include education and the procurement and distribution of certified FFP2 or N95 respirators and annual testing for their fit.
12. Surgical masks should be provided, together with education in how and when to use them, to all potentially contagious patients (sputum smear-positive TB patients, TB suspects, people coughing and those with other respiratory symptoms).

TB infection control standards are laid down in Ministry of Health Order No. 684 of 18 August 2010 on the National Tuberculosis Infection Control Standard for Health Care Institutions and Other High Risk Settings, which lists the interventions to reduce TB transmission in inpatient and outpatient settings, penal institutions and home settings. These standards are in accordance with WHO guidelines, but the review teams found that they had not so far been disseminated among health care providers and other users and some critical parts need to be improved.¹⁰ New national guidelines based on the standards are expected to be developed by the F.G. Yanovsky National Institute of Tuberculosis and Pulmonology and the sanitary–epidemiological services and approved in 2011.

The review teams observed a substantial level of knowledge about infection control among key staff in many TB hospitals and dispensaries following participation in international training courses. Most of the head doctors and medical directors are well-informed about the hierarchic concept of control measures, but only a few attempted to implement it in practice (exceptions were in Donetsk and Luhansk *oblasts*). Most of the TB health care workers (doctors, nurses, cleaners) lack updated knowledge and skills. Virtually all staff members are concerned about the high risk of transmission in TB hospitals and penal settings.

Representatives of the sanitary–epidemiological services are aware of the threatening level of nosocomial transmission of MDR-TB in hospitals and penal institutions and the urgent need to improve this situation in accordance with WHO’s recommendations. Interventions by the sanitary–epidemiological services traditionally rely mostly on disinfection of surfaces and objects, and waste and sewage disposal. These are part of general infection control measures but are not a priority for preventing the transmission of TB.

The general population has little information on how to reduce the risk of transmission. Neither the patients nor their relatives or other contacts practise cough etiquette. Staff do not know how to teach patients about cough etiquette as they are often ignorant of it as well.

The national infection control standard has not yet been translated into facility-level plans based on local risk assessments. Such assessments are essential in all health facilities, both civilian and penal (primary health care, TB, HIV/AIDS), to determine the risk of exposure to TB of staff and visitors in each department and which infection control interventions are most appropriate. The requested infection control plan normally integrates specific measures to prevent the transmission of TB and more traditional general infection control interventions. Good examples of structured and detailed infection control plans are present in TB dispensaries in Donetsk (*18*) and Luhansk *oblasts*.

An important infection control measure is the separation of patients based on the degree of their infection. In most of the civilian and penal TB facilities visited by the field teams, the conditions

¹⁰ Improvements are needed in the sections related to TB risk assessment, ventilation requirements, installation and maintenance of upper room ultraviolet germinal irradiation, and particulate respirator standards and characteristics.

for both patients and personnel were suboptimal. There was no separation of admitted TB suspects and patients based on the results of sputum smear microscopy, culture, drug susceptibility testing and HIV status. Staff rooms were located in high-risk environments. Patients were in rooms with four or more beds and the space per patient was often less than the 7.5-m² minimum national requirement. TB departments were not mechanically ventilated, so that the overall risk of airborne infection was high.

The lack of separation between patients was of even more concern in the HIV facilities where TB/HIV patients share the same departments with AIDS patients without any effective environmental control measures. The usually long hospitalization of patients in such high-risk environments increases the risk of (super-) infection. In most of the outpatient settings (waiting areas in TB and primary health care facilities, polyclinics and outpatient departments), patients with cough or other respiratory symptoms were mixing with other visitors without any separation, environmental controls or masks. Hospital administrators interviewed by the review teams said that inadequate funds had been allocated in recent years for the renovation of buildings and routine maintenance.

The collection of sputum samples for bacteriology is a high-risk procedure. In many cases, it was observed being organized outdoors. When done indoors during the winter, in naturally ventilated rooms without predictable airflows, it poses a substantial risk of TB exposure to nearby staff as well as to other patients and visitors.

With regard to the engineering aspects of infection control, a weakness observed by the review teams is that infection control is usually not taken into account in the design, construction and renovation of TB, HIV and primary health care facilities. There are no staff with the specific expertise that could improve the design, implementation and supervision process. It is important that only evidence-based effective equipment should be used. For example, room recirculation air-cleaners have a low efficacy and are not cost-effective investments. Open ultraviolet germinal irradiation fixtures are used in many of the facilities visited and are appropriately and regularly cleaned with alcohol. They are, however, ineffective when aerosols are generated continuously. Following former practice, records are diligently kept of the patients and personnel moving in and out the rooms. However, UV-C radiometers are usually not available to monitor the effectiveness and safety of ultraviolet germinal irradiation. In general, all equipment needs renewal of specific parts (ultraviolet lamps, high-efficiency particulate air filters) and regular maintenance. Ukraine has no qualified engineers for this purpose, and no regular budget is allocated for the purchase of spare parts.

Most of the TB laboratories visited had been renovated and were quite well equipped during 2004–2006 through international support (from the European Union, USAID/PATH and the World Bank). The teams found that laboratory managers have a basic knowledge of laboratory biosafety principles and, in most cases, carried out administrative measures to reduce the occupational risk. Biological specimens and personnel flows were organized safely, ensuring limited access to the laboratory, the separation of clean and dirty areas, development of standard operational procedures and training for personnel in safe laboratory practices. There was a sufficient number of biosafety cabinets (mostly unducted Class 2, Type A2), but they lacked certification of installation and maintenance. By using smoke-testing and measuring the air intake velocity, the teams found that in many cases the airflow pattern was appropriate, but most of the high-efficiency particulate air filters were approaching the critical loading period. In some laboratories, the biosafety cabinets were not functional because of ventilators that had failed, or not been assembled because of lack of space, or with mechanical ventilation either not installed or not working. Documentation on the ventilation design was not available and the staff were not

trained in maintenance and/or monitoring. No funds were allocated for maintenance, meaning that engineering environmental controls were absent in all the TB facilities visited.

Personal respiratory protection is not commonly practised in settings at high risk for TB transmission. Most institutions do not have personal respirators, even for staff at high risk. Where respirators are available, the staff are not trained in how to correctly do a fit check and to use and dispose of the respirator. Only some TB facilities in Donetsk and Luhansk *oblasts* organized training courses for personnel working in settings with a high risk of TB transmission, including testing of the respirators fit. Following a strict scheme, in every *oblast* visited health care staff were screened free once or twice a year with chest X-ray or fluorography. This should be considered an important administrative measure for a population at such a high occupational risk.

13. Management of medicines and other commodities

Main recommendations

1. The harmonization of drug regulatory procedures should be continued, including drug quality control, with European Union standards. Transparency and accountability in the regulation of medicines should be enhanced.
2. Pharmaceutical management should be strengthened at all levels to ensure consistent access to TB first- and second-line medicines of assured quality and their appropriate use.

Specific recommendations

3. Major funding gaps in drug procurement should be overcome by giving preference to solid forms of anti-TB medicines over expensive and often unnecessary injectable products (isoniazid, fluoroquinolones).
4. The registration of first- and second-line TB medicines according to current national standards should be facilitated, to enable their procurement and distribution through the Green Light Committee, national budget or other sources.
5. A risk–benefit analysis approach should be used to the quality, safety and efficacy of medicinal products at all stages of the regulation of medicines, including post-marketing quality control, and unnecessary duplication of regulatory activities avoided.
6. The necessary human resources and public funds should be made available to support the regulatory activities that protect public health and ensure drug safety.
7. The efficiency of pharmaceutical management should be strengthened and improved to ensure consistent access to TB first- and second-line medicines of assured quality. This should be done through: (i) updating the instructions for calculating the drug needs for TB drugs and clarifying the policy on buffer stocks; (ii) implementing integrated access to TB and antiretroviral medicines in AIDS and TB facilities; (iii) facilitating the introduction of the appropriate use of fixed-dose combinations; and (iv) clarifying the roles and responsibilities of personnel responsible for managing medicines, and developing standard operating procedures and job descriptions where necessary.
8. Manual and electronic reporting and recording systems for TB should be strengthened to facilitate the appropriate diagnosis and management of TB cases, evaluate treatment outcomes and improve the management and use of TB medicines.

9. Efforts to strengthen pharmaceutical management should be coordinated between programmes, donors and partners across the civil, penal and other sectors.
10. The prescribing and dispensing of first- and second-line medicines should be evaluated to identify patterns of inappropriate drug use and develop interventions to address them.
11. Legal, regulatory, policy or other barriers to effective management of first- and second-line TB medicines and other commodities should be identified and addressed. An intersectoral approach should be used to address those areas governed by laws and regulations outside the Ministry of Health.

In 2008, WHO conducted a comprehensive review of the regulatory system for HIV/AIDS and TB drugs in Ukraine (19,20). One of its key findings was the lack of coordination among the agencies constituting the National Drug Regulatory Authority, which is an issue that remains unsolved today. The current review found that key regulatory functions (marketing authorization; licensing of manufacturers, wholesalers and pharmacies; pharmacovigilance; import and market control; control of advertising and promotion, and clinical trials) are carried out by a number of separate agencies. There is no manufacturer's inspection to ensure that good manufacturing practice is in place before a manufacturing licence or marketing authorization for a medicinal product is granted, although this is a very important step in the quality assurance of medicines.

A system of pharmacovigilance was established in 1996 (updated in 2006) to include the reporting of adverse drug reactions and post-marketing surveillance. The State Expert Centre is responsible for pharmacovigilance, which relies on a network of *oblast* affiliates collecting reports of adverse events. Recently, the Centre became supportive of a more comprehensive and active approach to pharmacovigilance and to further development of information systems.

Progress has been made in moving towards integration with international standards for drug regulation. As part of a survey that WHO conducted during 2009 in selected countries of the former Soviet Union (21), anti-TB medicines available in Ukraine were tested: out of 53 samples taken from 13 treatment facilities, only one product failed quality specifications (assessed as minor failure). Moreover, in January 2011 Ukraine became a member of the Pharmaceutical Inspection Cooperation Scheme that promotes good manufacturing practice and other quality assurance practices.

Recent events have underlined the need for applying risk–benefit analysis in the drug regulatory system. In August 2010, the State Inspection prohibited countrywide the use of capreomycin imported from India for three months after allegations of poor drug quality were raised by one of its *oblast* branches. However, the subsequent investigation failed to find any problem. In future, prompt investigation and application of risk–benefit analysis could prevent unnecessary withdrawals of medicines, which lead to interruptions in treatment for many patients. Further enhancement of post-marketing control activities (including pharmacovigilance and risk–benefit analysis for quality control of medicines) will require additional human and financial resources.

In principle, the selection and procurement of medicines should be based on the NTP guidelines according to Ministry of Health Orders Nos. 384 of 2006 and 600 of 2008. In practice, different prescribing practices can be observed: individualized regimens are the norm rather than the exception, and the selection of medicines for procurement reflects ingrained treatment patterns. The field teams found two-, three- and four-component fixed-dose combination products (supplied by the Global TB Drug Facility) available in four *oblasts* and in penal facilities, but they were not on the whole being used. Many providers were reluctant to prescribe them because they believed they were less effective.

Ministry of Health Order No. 361 of 2006 (Instructions for calculation of anti-TB medicines) contains instructions for calculating the supply needs of first- and second-line anti-TB medicines. However, the availability of fixed-dose combinations and the increased needs for MDR-TB and TB/HIV patients means that these orders should be revised. There is little discipline in selecting MDR-TB patients for treatment based on availability of a full course of therapy (see section 9). The quantification of first-line drugs is a complex process: forecasts have to be made well in advance for many months' supply, buffer stocks maintained and some regulatory impediments overcome. The quantification of second-line drugs is even more challenging and needs more complex guidelines.

None of the Ministry of Health facilities visited by the teams experienced drug stockouts in 2009. However, some peripheral facilities reported stockouts of ethambutol and rifampicin and low stock levels of ethambutol and streptomycin. Some of the patients interviewed reported interruptions in treatment lasting three or more days. Very limited stocks of second-line medicines were found, and a few patients reported having had to buy these medicines themselves.

In the penal sector, the availability of anti-TB medicines was variable. Some prisons had all first-line medicines, including fixed-dose combinations, while some pre-trial detention centres had no TB medicines at all. Past offers by the Ministry of Health to provide the State Department for the Enforcement of Sentences with fixed-dose combination anti-TB drugs had been turned down.

For TB/HIV patients, TB and antiretroviral medicines are not equally available: both TB and HIV national programmes are still largely vertical and have only limited collaboration. Some pilot projects are currently considering the integration of the delivery of TB and antiretroviral medicines and methadone substitution therapy.

In 2010, the Ministry of Health budget for TB medicines was approximately Hrv 157 million (US\$ 19.6 million) with roughly Hrv 18.5 million (US\$ 2.3 million) for TB tests, reagents and other commodities. It is estimated that the actual need for treatment of all estimated susceptible and drug-resistant TB is approximately US\$ 85 million annually. Although the Global Fund Round 9 grant will provide some second-line TB drugs (approximately US \$5 million annually from 2013 onward) through the Green Light Committee, there will be a substantial funding gap every year. Medicines procured centrally are distributed to the *oblasts* by UkrVaccina, a public distribution agency. The current quantification and funding cycles result in irregular procurement and distribution time schedules. In nearly all cases, *oblast* TB dispensaries have little or no notice of the delivery of their annual supply of one or more products. A number of facilities do not have sufficient space to store such large quantities of medicines, leading to ad hoc storage arrangements. The low payment rates to UkrVaccina for its services discourage partial shipments and storage of buffer stocks. The storage conditions in health facilities visited by the teams varied from excellent to questionable. Storage practices in some facilities adhere to internationally accepted standards, including security and restricted access, appropriate organization, cold storage (when needed), first in first out dispensing, and tracking of temperature and humidity. Air conditioning to maintain appropriate storage temperatures is rare, which gave problems in 2010 when temperatures exceeded 35 °C for extended periods.

The teams found that manual ledgers were regularly kept for recording movements in and out of the medical stores. Additional ledgers were used in each ward or TB cabinet. Computerized records were available in some facilities. Information about medicine stock levels and consumption were reported monthly to the *oblast* level and quarterly to the national level. The current system is burdensome and duplicative. Records allow for the review of stock levels and anticipation of

potential shortages of medicines, although these were unevenly practised. In cases of potential shortages or drug expiry, stock was redistributed quickly within the *oblast*. Medicines are also redistributed between *oblasts*, but this process can require several months. In 2010, there were at least 18 such instances of redistribution. A more effective system of quantification and periodic distribution adjusted to actual needs would make better use of the data reported and reduce the time and costs required for redistribution. Current programme reports focus on financial information rather than measuring and improving programme performance, including pharmaceutical management. This problem is being addressed partly by the e-TB Manager program, a web-based system that provides comprehensive information about patient case management from diagnosis to completion of treatment, including pharmaceutical management information (see Annex 4). The e-TB Manager program was adapted for Ukraine by Management Sciences for Health. It is planned to adopt it countrywide in 2011, pending additional international assistance.

The choice of treatment regimens, selection of products (fluoroquinolones) and changes in therapy appear to be driven by the availability of products and the approach of expiry dates rather than by standard treatment guidelines. Prescription and use of first- and second-line TB medicines were found to be inconsistent. Preventive treatments do not comply with international recommendations. There is an over-reliance on injectable products (notably isoniazid and fluoroquinolones), draining funds that could be used more effectively to procure significantly larger quantities of products in solid form (tablets).¹¹ The question of patients' adherence to treatment is not being adequately addressed (see section 6). Current policies and regulations should be changed to overcome barriers to multiple choice and effective services. Overall, there is a need to document prescribing patterns and guide efforts to improve the selection and use of medicines, as well as to enhance adherence to guidelines and best practices, including the use of fixed-dose combinations.

14. Monitoring and evaluation

Main recommendations

1. The capacity of the Monitoring and Evaluation Unit of the Centre for TB Control should be expanded by increasing the number of technical staff and funding for field supervision.
2. The former TB recording and reporting system should be discontinued, and the two systems compliant with WHO recommendations and in use by the sanitary–epidemiological services should be maintained.

Specific recommendations

3. The development of recording and reporting of MDR-TB should be completed, endorsed by the Ministry of Health and adopted by all other ministries and departments. National guidelines should be updated accordingly.
4. The e-TB Manager program should be introduced countrywide by the end of the first phase of implementation of the Global Fund Round 9 grant, but only after the development of

¹¹ The defined daily dose of ofloxacin costs Hrv 34 in solution and only Hrv 6 in tablets. In one *oblast* visited by the review team, more than 700 infusion bottles were already in stock at the beginning of 2010 against an estimated annual need for 2500 infusion bottles. In that *oblast*, and for the treatment of a much lower number of the estimated MDR-TB patients, the Ministry of Health could have saved Hrv 70 000 in 2010 by procuring ofloxacin in tablets.

automatic outputs for case detection and treatment outcome and the importation of existing databases from the pilot *oblasts*.

5. Extensive training should be conducted at *oblast* and *rayon* levels for recording and reporting TB, with priority given to those *oblasts* without previous international support.
6. A system of field supervision should be created at all administrative levels.

Both the Committee on HIV/AIDS and Other Socially Dangerous Diseases and the Centre for Tuberculosis Control at the F.G. Yanovsky National Institute of Tuberculosis and Pulmonology have responsibilities for NTP monitoring and evaluation. For the Committee, the technical officer in charge provides overall policy guidance and coordination with other components of the programme, maintains official communications with international partners and acts as official country contact point within the European TB surveillance network established jointly by the WHO Regional Office for Europe and the European Center for Disease Prevention and Control, including coordination with the WHO-based Computerized Information System for Infectious Diseases (CISID). In the Centre for TB Control, the Monitoring and Evaluation Unit (Annex 4) is responsible for: (i) data management (data collection based on paper forms or electronic quality control, consolidation, analysis, interpretation and reporting); (ii) monitoring of NTP indicators; (iii) training and supervision at *oblast* and *rayon* levels; (iv) coordination with other services (HIV, sanitary–epidemiological services) for joint data management; and (v) reporting to the Ministry of Health Department of Medical Statistics. In future, this Unit would be supported financially and in its capacity building under the Global Fund Round 9 grant.

At *oblast* level, the same responsibilities are usually carried out by two or three specialists for the Centre for TB Control. However, many *oblasts* lack trained staff and do not receive enough guidance from national level on how to perform quarterly cohort analysis (22) and how to use surveillance tools recommended by WHO, such as the checklist for field supervision and the “Onion model” framework for assessing TB under-reporting (23).

At *rayon* level, NTP monitoring and evaluation is usually the responsibility of the *rayon* TB dispensary or TB coordinator. Most of them are also poorly trained and face a chronic shortage of NTP reporting and recording forms and records (the DOTS forms and records). The result is that *rayon* TB records are not updated and the reports do not reflect the actual situation in the *rayons*.

Three parallel TB data reporting and recording systems are in use:

- the system inherited from the former Soviet Union
- the system compliant with WHO recommendations
- the sanitary–epidemiological services system.

The system inherited from the former Soviet Union focuses on registration and case notification of TB patients, and reporting of patients’ entries, the services delivered and the treatment outcomes based on clinical criteria (Annex 4). The data are aggregated at *oblast* level and published in the annual TB statistical report, which is widely distributed and made available online (24). Despite the countrywide adoption of the Stop TB Strategy since 2007, this system of recording and reporting has been maintained. It provides little information for decision-making and may even wrongly direct resources towards inefficient interventions.

As to the system compliant with WHO recommendations, a set of forms and records was developed by the Ministry of Health and international partners (WHO, PATH) and tested in several *oblasts* before being introduced in all Ministry of Health facilities in 2009 and the facilities of other ministries and departments (Ukrainian Railways, Ministry of Interior Affairs,

State Department for Enforcement of Sentences and the Intelligence Services) in 2010. The first national cohort analysis of TB patients was carried out in 2009 in Ministry of Health facilities. From 2010, the national figures include all TB facilities in the country. Unfortunately, this system still has some drawbacks that are undermining the quality of the information produced (25): (i) the system is not yet officially endorsed by a Ministry of Health Order; (ii) in only 10 of the 23 *oblasts* (where DOTS was introduced) has the necessary training been provided and quality control and supervision properly organized;¹² and (iii) printing of the necessary cards, forms and registers is erratic and depends on the local TB authorities. With financial support from the Foundation for Development of Ukraine, WHO has developed a specific set for recording and reporting drug-resistant TB to be used in the MDR-TB pilot project in Donetsk *oblast*. This system is currently being used as the main reference by the NTP in developing a national system (26). Additional resources, including technical assistance, are needed to complete this task.

The sanitary–epidemiological services (SES) system is part of the routine national epidemiological surveillance of communicable diseases. The SES provide a rapid response to epidemics through isolation of cases, referral for clinical management, outbreak investigation, and infection control and prevention of transmission. SES and NTP data are cross-checked monthly at *rayon* level. Differences are frequently observed, mainly because the services' data are based on presumptive diagnoses of TB without laboratory confirmation.

In Order No. 197 of 31 May 2002 (Rating Assessment of the Health Care Status of the Population and Performance of the Health System), the Ministry of Health adopted a list of TB definitions and indicators for monitoring the health status of the population and the performance of the health system which guide local administrators and financial inspectors. Of the 46 indicators, 7 are related to TB (Annex 4). These indicators refer to old and wrong criteria and compliance with them is resulting in the allocation of resources to interventions which are not cost-effective (mass screening, prolonged follow-ups) and which focus on outputs instead of outcomes. The NTP has also developed a monitoring and evaluation performance framework which includes a number of misleading and outdated indicators¹³ and ignores the diagnosis and management of drug-resistant TB and TB/HIV (27).

There is no centralized laboratory surveillance. Laboratories keep their data in a register from which information is later included on the cards and forms used for managing each TB patient. The teams found frequent disparities in the statistics from the laboratory and the TB registers, especially in those *oblasts* where DOTS was not yet implemented. This can be explained by the fact that the laboratory staff count the number of sputum samples instead of patients investigated and the history of previous TB treatments is not properly taken from TB suspects. Another reason could be the lack of good guidance in using TB cards, forms and registers, as well as the absence of user-friendly computer application software for laboratory data management.

There have been a few attempts to introduce a monitoring and evaluation system based on electronic data management. At present, the NTP promotes the special application software e-TB

¹² Quality control of data in the *oblasts* implementing DOTS with the support of WHO and PATH is of two types: (i) evaluation of trends in case management determinants such as previous treatment history, disease localization, laboratory confirmation and treatment outcome; and (ii) cross-checking of records during supervisory visits. The latter was being poorly carried out because of limited funds and manpower.

¹³ The framework includes 15 areas for monitoring, some of them considered inappropriate: section 3 (Detection and diagnosis) includes “Percentage of children with cavities in the lungs”; and section 4 (Treatment) includes “Coverage of MDR-TB by surgery” (target 60% from those that require it) and “Treatment success rate among MDR-TB cases with surgery” (target 80%).

Manager to integrate the information for case management, medicine management and programme management in a single platform. Since 2009, a number of *oblasts* supported by Management Sciences for Health and PATH have been using this comprehensive web-based tool. The entry module for each case allows real-time entries (through the web) and comprehensive and updated information-sharing. However, e-TB Manager needs to be improved before it is introduced nationwide. Automatic outputs (summary tables, graphs, etc.) need to be developed, the Security Service needs to approve it as a legal tool for processing individual data, and access to the internet at *rayon* level should be made more reliable and confidential.

15. Human resources development

Main recommendations

1. Understanding of and compliance with the Stop TB Strategy should be improved. Despite official adoption of the Strategy, there is widespread scepticism about its appropriateness and potential for successful implementation. Most doctors have their own personal approaches, resulting in a mixture of old and new interventions which may harm the clinical management of the individual patient and the overall public health impact of the NTP. The Ministry of Health should provide ample information on the do's and don'ts in TB control – more than can be contained in a letter or a ministerial order. Doctors need an explanation of why the Ministry of Health is promoting a certain approach. A manual with guidelines and training are also necessary.

Specific recommendations

2. A strategic plan for the development of human resources should be drawn up, based on an assessment by the TB Human Resource Working Group and including a task analysis, the consequent development of job descriptions, changes in the legal and normative bases and the development of an annual implementation plan.
3. Pre- and postgraduate curricula should be reviewed and modernized by moving from knowledge- to competence-oriented training and including teaching on the Stop TB Strategy and the Practical Approach to Lung Health.
4. The capacity for human resources development under the NTP should be enhanced by: (i) establishing a training resource centre; (ii) revising existing training curricula; and (iii) moving from ad hoc to institutionalized in-service training courses according to standardized and accredited curricula.

The deployment of TB staff is based on Ministry of Health Order No. 197 of 31 May 2002 (Rating Assessment of the Health Care Status of the Population and Performance of the Health System), which sets specific health services per populations (Annex 5) but does not take into account changes in epidemiology (the appearance of drug-resistant TB and TB/HIV co-infection) and delivery strategies (the decentralization of TB services to primary health care).

Two institutions under the Ministry of Health are responsible for human resources:

- the Ukrainian Institute of Strategic Research, which is in charge of related research, strategic policy and financial planning of the health system, including human resources;
- the Department of Human Resources, Science and Education, which is responsible for the organization and implementation of policy regarding medical education, staff distribution,

promotion of medical science and implementation of research results, and prevention and eradication of corruption in health care (it receives technical advice from the Ukrainian Institute of Strategic Research).

Other ministries and departments (Ukrainian Railways, Ministry of Interior Affairs, State Department for Enforcement of Sentences and the Intelligence Services) have their own budgets for TB, TB staff and regulatory bodies.

On 1 March 2010, the Ministry of Health issued Order No. 178 (Introduction of Changes and Recommendations to the Standards and Model for the Personnel Working in Health Care Facilities), revising the previous Order and asked the Ukrainian Institute of Strategic Research to develop specific recommendations, taking into account the need to increase human resources and calculating the financial implications.

In February 2010, the Human Resources Working Group was established to look specifically at human resource development problems in the TB services. This was in response to TB specialists' concern about the low salaries and status of their profession, which (as in other countries of the former Soviet Union) deter newly qualified doctors from filling the high number of vacancies.

In 2009, WHO conducted an assessment of the human resources for TB (28). The main findings of this study were as follows.

- In primary health care (all ministries and departments), there were 11 151 established positions for general practitioners, 7244 for paediatricians and 9578 for family doctors. Only 10 613 general practitioners, 5870 paediatricians and 7150 family doctors were, however, on the payroll, leaving staffing gaps of 5%, 19% and 25%, respectively. Wide regional differences were also observed, with vacancy rates varying from 0% in Zakarpatska to 45% in Mykolaiv. Of the 10 613 general practitioners on the payroll, only 8552 (76%) were actually working.
- In inpatient services, there were 3827 positions, 3406 staff on the payroll (11% staffing gap) and only 2695 staff actually working. The vacancy rates varied from 0% in the Ministry of Internal Affairs to the highest number in the penal system.
- In outpatient services, of 2329 positions only 2055 staff were on payroll. The staffing gap of 12% was increased to 30% for the TB specialists employed by the Ministry of Health.
- There were 466 positions of paediatric TB specialists (mainly in paediatric TB hospitals and sanatoria), with 461 staff on the payroll.
- There were 8678 positions of TB medical nurse under the Ministry of Health in inpatient facilities, 1928 in outpatient facilities and 116 in paediatric sanatoria. The staffing gaps were 5%, 6% and 10%, respectively.
- There was also a shortage of pharmacists and pharmacy technicians, who were often replaced by nurses with no formal training.

The overall number of staff working in the TB services has been falling in recent years. At the same time, staff may welcome the widening gaps between established positions and people actually working as the untouched payrolls allow for the redistribution of salaries among a smaller number of workers (sometimes increasing their salaries by half). Two major factors must be considered in trying to improve this situation: (i) the extent of the health reform and the integration of TB services with the general services; and (ii) the need to increase staff with adequate competence and motivation to attack the MDR-TB and TB/HIV epidemics effectively.

Doctors are trained in medical school for six years and then specialize in a certain area. The duration of postgraduate specializations varies, and is generally one and a half years. As part of continuing medical education, doctors should attend postgraduate training every five years. Nurses and technicians receive a basic training and then develop further skills on the job. The majority of the health labour force is trained according to traditional teaching of clinical practices, with very little exposure to public health approaches such as the Stop TB Strategy. A new training programme for primary health care physicians, which includes the Practical Approach to Lung Health (recommended by WHO to improve the diagnosis and management of respiratory patients visiting a primary health care facility) is currently being piloted in a number of *oblasts*, but primary health care providers see their involvement in TB control as an additional burden with no financial incentives. Competence-oriented training is needed. Nongovernmental organizations have developed and provided training in DOTS pilot *oblasts* but have not been able to get it incorporated into the national curricula. SES personnel have never been involved in TB training, which the review teams consider a missed opportunity.

The future reform of the health system will redistribute responsibilities between different levels of care and staff. It is expected that there will be a shift from hospital care to outpatient care as a consequence of a change in financing health care. A number of hospital staff will have to be redirected to other responsibilities, which requires an analysis of their new tasks and the development of revised job descriptions and training.

Members of the review teams feel that there is a lack of coordination and the necessary attention is not being given to TB human resource development, which is so important for supporting effective and efficient implementation of the Stop TB Strategy. The growing MDR-TB and TB/HIV epidemics and the crisis in the NTP workforce need to be addressed urgently. There is a shortage of TB staff and they are not well distributed. An updating of the national TB guidelines with revised criteria for hospitalization (unnecessary for non-infectious TB patients, children with primary tuberculosis, etc.) could also contribute to a redeployment of human resources towards patient-centred outpatient services. For example, the review teams observed the spontaneous piloting of hospital day care by some bright TB administrators, an innovative approach that ensures that there are staff for outpatient services within the current financing mechanisms. Other challenges are the urgent need to improve TB infection control and programme monitoring, to establish TB pharmacosurveillance and to make use of the new diagnostics (and possibly new medicines in the next few years).

A national strategy for the development of all human resources in the health system is needed. For this, a multisectoral working group could be instrumental. A practical approach would be to start with TB control.

16. Operational research

Main recommendations

1. An operational research agenda should be developed, outlining the priority topics to be studied, identifying key investigators and providing an adequate study budget.

Specific recommendations

2. Operational research should be conducted on:

- (i) factors involved in delays in case detection and barriers to access for vulnerable and other groups at risk (delays by patients or by doctors, laboratory performance);
 - (ii) the yield from case-finding among different groups actively screened for TB;
 - (iii) performance of institutions (length of stay, occupation rate, availability of drugs for treatment, rate of patient hospitalization, outcome);
 - (iv) case management – the default rate among vulnerable groups and patients who started the continuation phase in *rayons* (follow-up and DOT in the ambulatory phase, cohort analysis);
 - (v) all aspects of delivery of services in both TB services and AIDS centres, including different ways of integrating services;
 - (vi) isoniazid preventive therapy and co-trimoxazole preventive therapy;
 - (vii) infection control, including successful ways of implementing individual and administrative measures.
3. A process should be developed to facilitate and encourage operational research in the NTP.

The organization of health services and their accessibility, patterns of service delivery, availability of equipment and trained personnel and other service determinants influence the efficacy of TB control interventions. Each country and each NTP should, therefore, study the efficacy and cost-efficiency of the interventions implemented or proposed. Operational research helps in determining what interventions are more effective and cost-effective. The NTP still has to prioritize the topics for research. Setting an operational research agenda also needs to take into account who (or which institutions) can perform the particular study, how much time will be involved and how much it will cost. Although operational research often uses routinely collected data, the analysis and dissemination of findings cost time and money. The outcomes of these studies are, however, important for improved policy-making and better service delivery.

The late stage of the disease at which detection and treatment of patients occurs was frequently cited as a major cause for the failure of treatment and death, especially for TB/HIV patients. No evaluation of the contributory factors (delays by patients, doctors and laboratories) has, however, been made. Identifying the main contributors to the late start of treatment could help to guide improvements to the programme.

Active case-finding by annual mass miniature radiography or fluorography screening of the adult population is regular practice. Screening is stipulated variously in different Ministry of Health orders but it does not effectively target those population groups at higher risk of TB. Studies of the efficacy and cost-efficiency of active case-finding interventions are required to update current policies.

Inconsistent implementation of the Stop TB Strategy has been noted, including prolonged hospitalizations despite sputum conversion and the inconsistent use of first-line medications. Evaluation of the implementation of the NTP (and improved routine monitoring) as well as the outcome of case management will help to improve the programme.

Because of the extremely high burden of morbidity and mortality from TB among people living with HIV, improving the delivery of services to TB/HIV co-infected patients should be given very high priority. Priority areas for research include the screening of patients identified with one disease for the other and improved links between services to facilitate prompt diagnosis and the continuum of care. HIV-testing of TB patients is inconsistent. Screening of HIV patients for TB is formally carried out by radiographic screening. Other issues contributing to suboptimal outcomes for TB/HIV patients include: (i) difficulties with the prompt diagnosis of atypical

pulmonary and extra-pulmonary manifestations of TB, (ii) limited use of antiretroviral drugs because of the fear of side-effects in patients with active TB, and (iii) limited integration of the TB and HIV services. Delivery of diagnostic and treatment services for TB/HIV patients, including aspects of time, accessibility and accuracy, need to be studied in order to improve treatment outcomes.

The effectiveness of isoniazid preventive treatment, especially given the high levels of isoniazid resistance in Ukraine, is uncertain and must be evaluated. The teams found that co-trimoxazole preventive therapy is not given widely to people living with HIV, despite its known impact in reducing mortality among this group. Case-control studies can indicate the efficacy of this intervention.

The teams noticed that many TB hospitals have ventilation systems that are not functioning properly because there is no adequate budget for installation and maintenance. Implementation of administrative measures and personal protection (see section 12) are weak to non-existent. Studies of the implementation of the guidelines (process) or nosocomial infection (outcome) can help in demonstrating the importance of rigorous infection control interventions.

The potential for conducting focused studies on how to improve programme performance is under-appreciated. The teams found *oblast* TB care providers who were genuinely committed to improving the performance of the NTP, but they had limited appreciation of the utility of focused studies beyond routine monitoring. Part of this may be due to inadequate training in designing operational research. The teams are aware of only one training course in operational research, which was organized by WHO in Kyiv in May 2007 and focused on TB/HIV. More training and mentoring in operational research would be useful. The NTP should set up a process to support them. The Stop TB Partnership has been developing a global agenda and guidelines for operational research in TB. It could be used to guide the NTP and its partners in the development of the national research priorities and agenda.

17. Ethics and human rights

Main recommendations

1. Internationally recognized ethical principles should be adopted and promoted actively to ensure universal access to TB prevention, treatment and care.

Specific recommendations

2. Ethical and human rights values should be carefully evaluated and reflected in the new national law on TB.
3. The public health dimension of TB interventions should be strengthened by involving civil society more actively and effectively in redesigning TB services.

Ethical values refer to the way people ought to live their lives, including actions, intentions and habitual behaviour. These values can be the source of disagreements and conflicts between individuals and/or groups. Ethical considerations are required to decide when some rights and obligations are held to be more important than others. Human rights can be seen as a concrete legal expression of ethical values, including for instance non-discrimination, participation and

accountability (29). Ethics and human rights are intimately and dynamically interlinked and refer to such values as social justice/equity, solidarity, the common good, autonomy, reciprocity, effectiveness, subsidiarity, participation, transparency and accountability (see Annex 6).

Taking the above into account, a number of ethical and human rights issues can also be raised in how the Stop TB Strategy is being implemented in Ukraine.

In the eight *oblasts* visited by the field teams, it was observed that TB services are not designed around patients but around providers. Most patients have to undergo a number of investigations by a number of physicians at different levels of care, sometimes unnecessary and duplicative, before being diagnosed with TB. Once TB is diagnosed, the possibility of resistance to TB drugs is uncertain. Patients then stay for an unnecessarily long time in a TB hospital, without infection control measures and with disruption to their social and working lives. Too often, surgical treatment is decided when medical treatment could be more effective and cause less permanent disability. After many months in hospital, patients are discharged with a medical prescription, often with long distances to the nearest daily treatment facility and without the necessary support. There is little knowledge of the Patients' Charter for Tuberculosis Care (30), which outlines the rights and responsibilities of people with TB, and it is not actively promoted or followed.

Poor efficiency and effectiveness of services create barriers to universal access to TB diagnosis and treatment, leading to patients' autonomy and their right to participate in decision-making being ignored. Lay workers in nongovernmental organizations are prevented under current laws from dispensing DOT in outreach settings, which is both contrary to the subsidiarity principle of delivering care as closely as possible to individuals and communities at local level and has a negative impact on compliance with treatment outside hospitals. Screening the adult population with fluorography is not effective, and it both exposes the population to unnecessary medical interventions and is an added burden on health provision. The principle of reciprocity is a challenge to the Ministry of Health because the widespread lack of infection control measures puts health care workers at high risk of TB infection (including M/XDR-TB) and inadequate protection or compensation when harm occurs.

Based on the observations by the review teams, ethical and human rights issues can also be raised with regard to special groups such as children, homeless people, those living with HIV, pre-trial detainees and migrants. Sick children are kept in hospital for their entire treatment, and children with latent TB infection stay for at least three months. However, only the parents of infants aged under three months can stay with them in hospital. Moreover, recreational and educational arrangements in hospitals are limited and often depend on support from donors.

Many TB patients are homeless; for them a hospital is the only place to sleep and get some food. This is not only a subsidiary cause of widespread and prolonged hospitalization (the main cause is the allocation of funds based on hospital beds and bed occupancy), it also represents a medical solution to a social problem that calls for alternative arrangements (such as care/nursing homes) in the spirit of social justice and equity. In the same spirit but based on outreach services, the prevention, treatment and care of TB in people living with HIV should be organized through nongovernmental organizations. Prolonged stays in detention centres awaiting trial, with subsequent exposure to TB infection and limited access to TB diagnosis and treatment, observed by the teams contravene individuals' human rights. Evidence from other countries shows that shortening the pre-trial time reduces the density of the prison population and the incidence of TB. Refugees and asylum-seekers are also reported to have limited access to health care.

The Law on Prevention of Diseases Caused by HIV and Legal and Social Security of People Living with HIV, approved on 21 December 2010, is recognized as an example of national legislation with extensive and commendable provisions for the protection of human rights of people living with HIV. The process of its approval included a public hearing with broad involvement of all stakeholders, including civil society. A draft national law on TB was being approved at the time this report was being compiled, but it does not appear to have benefited from the same countrywide consultation with all key stakeholders, including civil society. While it is a clear sign of the government's strong commitment to fight TB and M/XDR-TB, this law (in the draft given to the review teams) raises serious ethical and human rights concerns. Ineffective TB screening procedures are reinforced, as well as the prolonged treatment of patients in dedicated health facilities (hospitals and sanatoria). The confidential bond between medical provider and patient is infringed by the involvement of employers, who are entitled to suspend working contracts when their employees get TB. Involuntary isolation and detention are introduced not as measures of last resort but to overcome the inability of the system to provide patient-centred treatment and community-based care.

18. Advocacy, communication, social mobilization

Main recommendations

1. A comprehensive written national strategy and implementation plan for advocacy, communication and social mobilization should be developed and approved. Based on this, consistent *oblast/rayon* strategies and implementation plans should be developed and linked to the goals and objectives of the NTP.
2. Financial and human resources should be allocated to implement country and *oblast*-specific advocacy, communication and social mobilization activities and support the efforts of local organizations to reach out to marginalized populations for TB-intensive case-finding and management in order to prevent defaulting on treatment.

Specific recommendations

3. Coordination councils should be designated at all levels to coordinate the implementation of the advocacy, communication and social mobilization strategy and a dedicated focal person and unit appointed within the NTP to oversee its implementation.
4. Advocacy, communication and social mobilization interventions should be incorporated into wider strategies to control TB, MDR-TB and TB/HIV, ensuring a community-based, client-centred outpatient approach which also reaches the most vulnerable population groups.
5. There should be a significant increase in the involvement and number of civil society organizations and affected communities in TB care and support, building from the experience of the HIV organizations. These should include such organizations as those working with prisoners and former prisoners and social groups that support homeless people.
6. Training for health care and social service providers (including for staff in nongovernmental organizations) should be supported, built on successful advocacy, communication and social mobilization pilot projects, in the following specific areas: (i) assessing needs through quantitative and qualitative research; (ii) strengthening interpersonal communication and counselling among providers to improve client-provider interactions, reduce stigma and discrimination and increase adherence to TB treatment; (iii) increasing access to voluntary

diagnostic counselling and testing for HIV among TB clients; (iv) developing information, education and communications materials based on research; and (v) working with the mass and print media.

7. Work with the mass and print media, including the training of journalists, should be properly planned and overseen.
8. The International Standards for Tuberculosis Care (31) and the Patients' Charter for Tuberculosis Care (30) should be promoted. The Patients' Charter should be used to increase the involvement of people affected by TB.

When the teams interviewed a number of patients attending TB facilities, they found that only 15% said that they were very well informed about the symptoms of TB at the time of their diagnosis, while a quarter said that they were very poorly informed or not informed at all (Fig. 2a and 2b).

A number of organizations are involved in advocacy, communication and social mobilization.¹⁴

- A coalition of organizations working in the penal system mainly focuses on HIV/AIDS-related advocacy and social mobilization issues. The penal system and its networks currently collaborate with PATH/USAID in addressing the needs of prisoners and released prisoners to ensure the continuum of care for TB and prevention of treatment default.
- Rinat Akhmetov's Foundation for the Development of Ukraine is the principal recipient of the Global Fund Round 9 TB grant, which includes advocacy, communication and social mobilization as one of its four objectives.
- PATH is an international organization, funded by USAID, which provides technical assistance with TB control and has broad experience with advocacy, communication and social mobilization, including the organization of the mass media and social mobilization campaigns, training of providers, advocacy and legislative consultation round-tables, and assistance with strategic planning to the *oblast* TB/HIV coordination councils.
- WHO plays a significant role in advocating the national adoption of international TB control strategies, guidelines and best practices.
- The International HIV/AIDS and Tuberculosis Institute (a nongovernmental organization) focuses on HIV/AIDS and TB advocacy at national, *oblast* and *rayon* levels and has collaborated with PATH.

Advocacy, communication and social mobilization form one component of the Stop TB Strategy. They remain weak in Ukraine, both at national and peripheral levels. No formal national strategy for these activities has been developed. Although a number of civil society and state organizations engaged in TB and TB/HIV control are increasingly undertaking them, they are unfortunately rarely linked to or guided by the objectives of the current NTP. The Committee on HIV/AIDS and Other Socially Dangerous Diseases does not have a clear understanding of how

¹⁴ *Advocacy* focuses on influencing policy-makers and other key stakeholders to ensure that adequate resources, policies and political commitment are brought to bear on TB control efforts. *Communication* interventions seek to improve TB-related knowledge and attitudes among specific populations and to encourage positive behavioural changes that increase the likelihood of early detection and treatment success. Effective communication initiatives can lead to changes in social norms, thus creating more favourable environments in which affected communities can have a role in guiding TB control interventions. *Social mobilization* is characterized by community engagement and action to ensure sustainability, self-reliance and integration of TB control into overall community priorities. Social mobilization efforts are most successful when people affected by TB, including caregivers, are involved in initiatives to improve knowledge and awareness of TB, strengthen early detection and adherence to treatment, reduce stigma and link TB with larger issues of community health and care.

advocacy, communication and social mobilization are essential for achieving its objectives, and it has no designated staff for conducting or coordinating and monitoring such activities among stakeholders.

Fig. 2a. Answers by 90 TB patients interviewed by the teams to the question: "Before being diagnosed, how well did you consider you were informed about tuberculosis?"

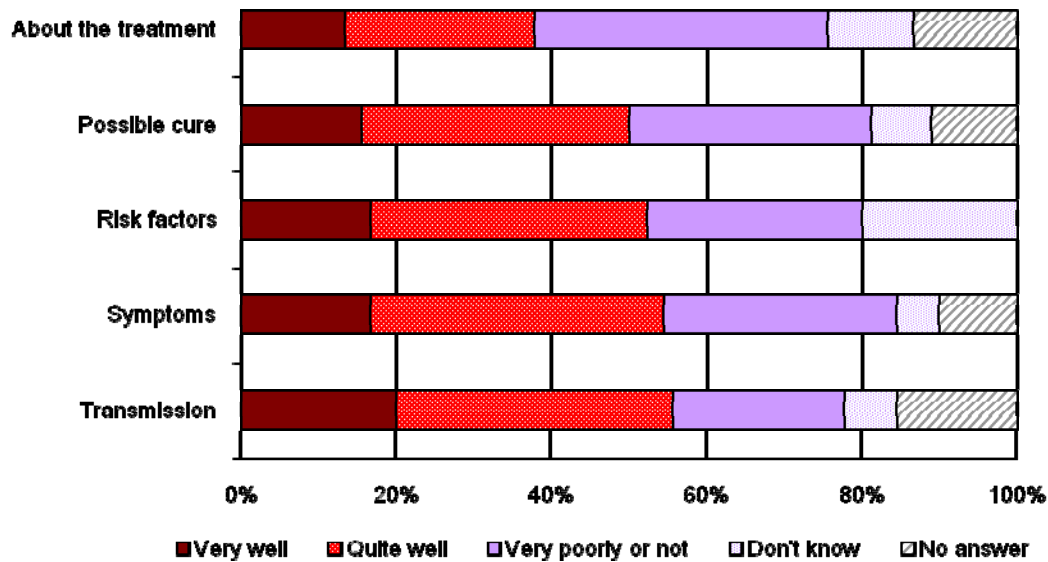
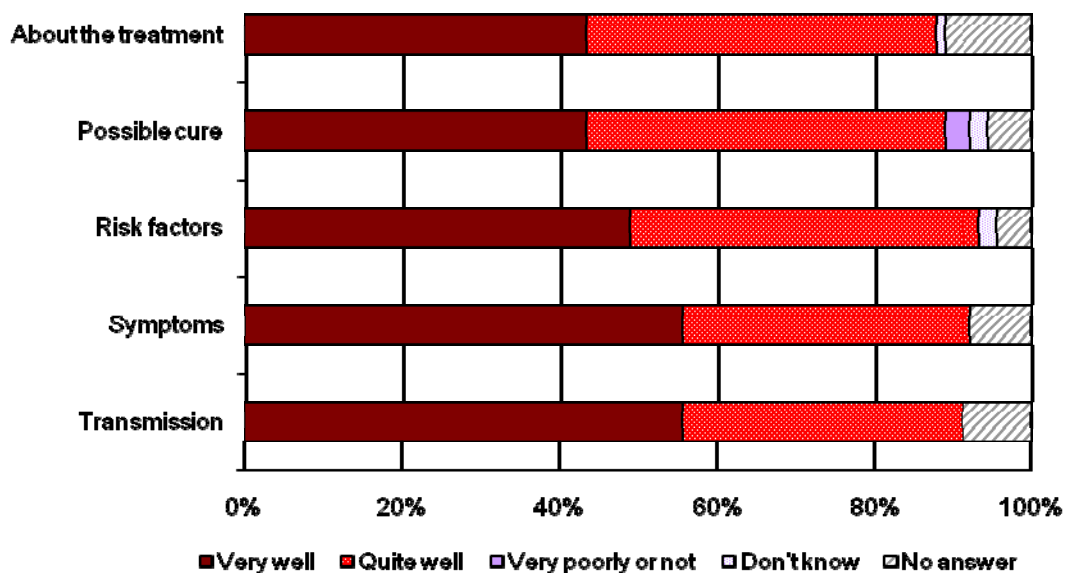


Fig. 2b. Answers by 90 TB patients interviewed by the teams to the question: "How educated would you consider yourself now about tuberculosis?"



Most funding for local nongovernmental organizations comes from external sources and thus depends on the availability and strategic focus of external donors. Externally funded, small, *oblast*-focused projects have made it difficult for funding recipients to measure the impact of

advocacy, communication and social mobilization interventions and to show their results, particularly within short timeframes.

Local organizations working exclusively on TB control do not plan advocacy, communication and social mobilization activities in advance, but act in response to crises or challenges. When situations suddenly arise that pose an immediate threat to the TB programme, such as delays in drug supplies, closures of clinics or lack of access to treatment for other reasons, they turn to crisis advocacy. They will also mobilize when there is a need to lobby for new legislation or regulations. There are, however, no sustained long-term advocacy, communication and social mobilization strategies, neither is there a coordination mechanism within or outside the NTP to lead or coordinate these activities at all levels.

Currently, the NTP's strategy on advocacy, communication and social mobilization includes only one communication component, which is being implemented by the Ukrainian Red Cross Society. The NTP has not allocated any funds to this and the Society conducts communication activities through funds from PATH/USAID.

Communication and social mobilization interventions, including the engagement of civil society, are needed to improve outcomes among socially marginalized groups such as homeless people, those who abuse alcohol or drugs, current and former prisoners, and people living with HIV, many of whom also experience stigmatizing attitudes and discriminatory behaviour in health facilities and communities. Expected outcomes related to communications efforts would include changes in knowledge among specific population groups and clients' satisfaction with care. Such changes are not well documented. Furthermore, the impact of existing advocacy, communication and social mobilization efforts on, for example, improving the identification of TB suspects or reducing defaulting from treatment has rarely been evaluated. Existing examples at the moment are largely drawn from PATH's USAID-supported projects. Its collaboration with the Ukrainian Red Cross Society clearly suggests that treatment default rates can be decreased through a client-oriented approach to health care.¹⁵ In addition, advocacy efforts to increase awareness among key politicians and health authorities by strengthening *oblast* TB/HIV coordination councils has led to the development of regional strategic plans and monitoring systems, increased collaboration between national TB and HIV programmes at *oblast* level, and greater involvement of nongovernmental organizations in work related to TB, and especially TB/HIV.

19. Health system and TB control

Main recommendations

1. TB control should be included in the initial design and pilot implementation of the health care reform. This is an opportunity for the NTP to test new methods of financing and service delivery which can increase the quality of inpatient and outpatient care while readjusting gaps in TB human resources. It also offers an opportunity for re-profiling TB facilities (converting beds without closing facilities). In particular, the role of TB hospitals to offer "roof and food" to patients calls for a wider discussion of this role – especially in TB hospitals – in the social support system.

¹⁵ In Donetsk *oblast*, the treatment default rate fell from from 20% to almost 0% after the Ukrainian Red Cross Society visiting nurses were trained by PATH to provide treatment and other support to TB patients.

2. TB indicators (output, outcome, impact) should be included in monitoring the implementation of the health care reform (see Annex 4). TB is a condition which encompasses several areas as it is often the result of socioeconomic determinants and poor access to health care. For this reason, it can be used as a proxy for monitoring the overall development and performance of the health sector.
3. Current TB legislation should be revised. Several laws and regulations have had an impact on the organization and delivery of TB services. New laws and regulations, with high relevance for TB control, are coming within the framework of the health sector reform. An overarching TB law should be developed, that can be further detailed through updated issues of a national main reference TB manual for all providers.
4. To improve the technical and allocative efficiency of the NTP, health interventions should be assessed for their cost–effectiveness before being translated into orders. Cost–effectiveness analysis is a sub-set of health technology assessments. To support and monitor the wider health system reform programmes, consideration should be given to setting up a semi-independent health technology analysis unit or a health policy analysis centre with the cost–effectiveness analysis of TB interventions and a master plan for TB facilities (as part of the re-profiling exercise) included in its terms of reference.

The NTP has made some major achievements in recent years. The implementation of the Stop TB Strategy, however, still poses a major challenge, in large part because of systemic factors that lie outside, but have a direct impact on, the NTP. The efforts of the Committee on HIV/AIDS and Other Socially Dangerous Diseases have been seriously limited by a non-supportive environment, represented by the existing complex and contradictory legislation and the outdated health system based on hospital care and inflexible financing.

Overview of the performance of the health system

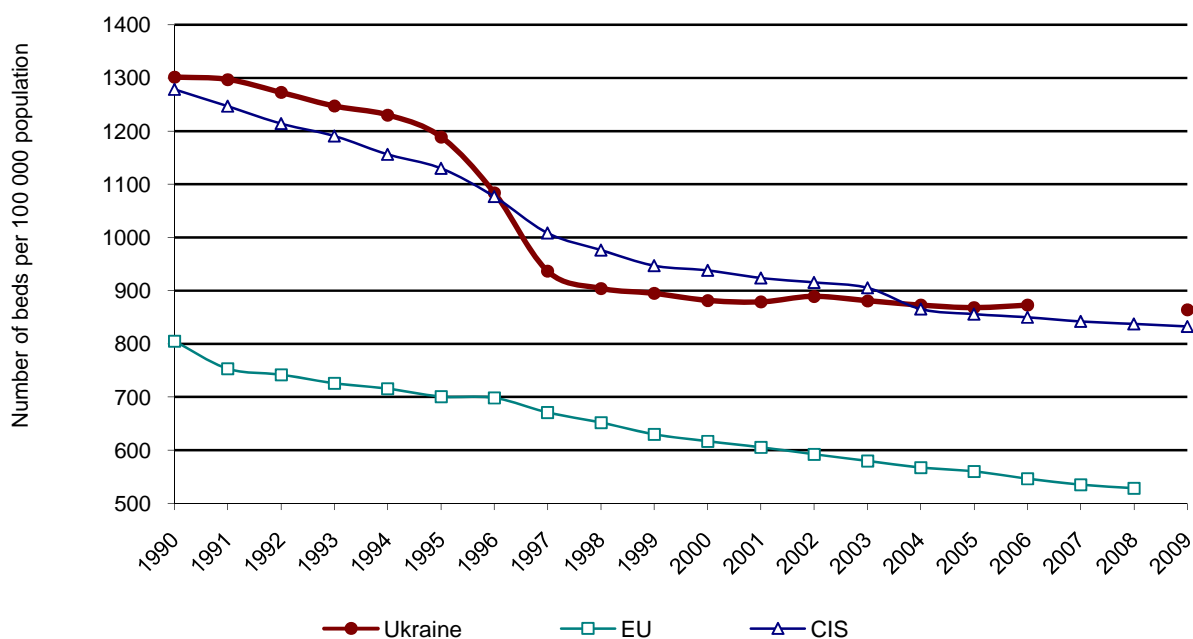
The former highly centralized model of decision-making in the health system has been gradually replaced by a system in which authority has been delegated to the local administration and self-governing bodies. Today, the health system is complex and multilayered (32). Responsibilities are fragmented among central government (the Ministry of Health and many other ministries and public authorities), the 27 *oblast* administrations and numerous bodies at municipal, *rayon* and village level (32). Primary, secondary and tertiary care facilities are owned by the various tiers of local government. This multiplicity of authorities responsible for the financing and management of health care facilities, with vested interests and responding to different stakeholders, creates major challenges for the development of a consistent reform plan and the implementation of government orders.

Health care is administered through Ministry of Health and other orders in a complex and rigid system. As a result, a passive attitude has developed with local authorities waiting for orders and implementing them at their convenience. It is often considered most convenient not to change. The implementation of orders remains chaotic due to their multiplicity, the lack of correct information throughout the multilayered structure, resistance to modern management techniques or new clinical practices, poor capacity and lack of resources. These factors are aggravated by a lack of monitoring and evaluation and a weak accountability structure. Nevertheless, many recent innovative activities that were initiated at *oblast* or *rayon* level should be acknowledged and commended, such as the public-private partnerships for contracting primary health care that the team observed in one city. Such examples of individual initiative highlight administrative autonomy at local level and show that changes are possible within the existing legal frameworks.

At 3.7% of gross domestic product in 2006, government spending on health care is low by regional and European standards and slightly above the international average (33). Due to the inconsistencies between statistical data from different sources and the scarcity of data on health care expenditure in the informal sector, it is difficult to determine the exact level of such expenditure. However, it is estimated that when out-of-pocket payments are added, total spending on health care reaches 6–7% of gross domestic product (34).

There is a constitutional provision against closing health care facilities, even though the diversity of owners of primary and secondary care facilities at local level has created a duplication of services. Local governments face severe constraints on firing personnel, which add rigidities to the system. In addition, inflexible norms drive budgeting and allocation of resources at the local level. Hence, local governments are bound to maintain financially an oversized network of health facilities, lengths of stay are artificially inflated and staffing levels are often higher than necessary. As a result, Ukraine has one of the highest numbers of health system inputs (hospitals, beds, doctors, nurses and non-medical staff) per 100 000 inhabitants in the European Region (35) (Fig. 3 and Annex 7).

Fig. 3. Hospital beds per 100 000 population, Ukraine, Commonwealth of Independent States (CIS) and European Union (EU), 1990–2009

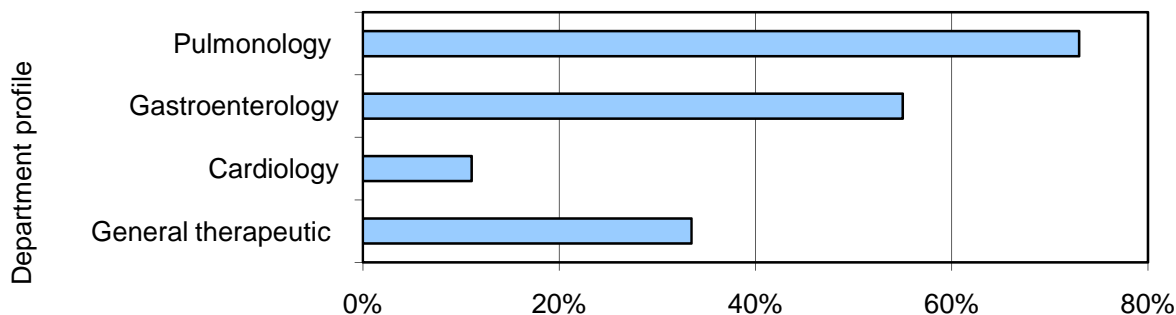


A substantial share of the health budget (86%) is allocated to hospitals and specialized facilities (80–90% for salaries and utilities), although a large proportion of hospitalizations is considered unnecessary (35) (Fig. 4). The average length of stay in hospital is one of the longest in the Region (36).

The maintenance of such an inefficient network and distribution of staffing leaves few resources for training and retraining of medical personnel, provision of adequate medicines, renovation of equipment and laboratories and other infrastructural needs (34). Key areas such as supplies, equipment, and maintenance and repairs to deteriorating infrastructure are generally neglected. The recent global financial crisis has made the situation even worse, forcing Ukraine to approve a health budget for 2009 that did not allow for any spending on equipment or maintenance of

infrastructure. Significant efficiency gains could be achieved by the adoption of modern ambulatory-based treatment methods.

Fig. 4. Rate of unnecessary hospitalizations in different departments



The health system is characterized by a high degree of verticalization, in which different parallel structures provide specialized care, for example, through AIDS centres, TB dispensaries, sexually transmitted infections clinics and narcology centres. Collaboration between such structures is generally sub-optimal. Equally, the links between the various echelons of care are weak, as is the collaboration between the health and social services.

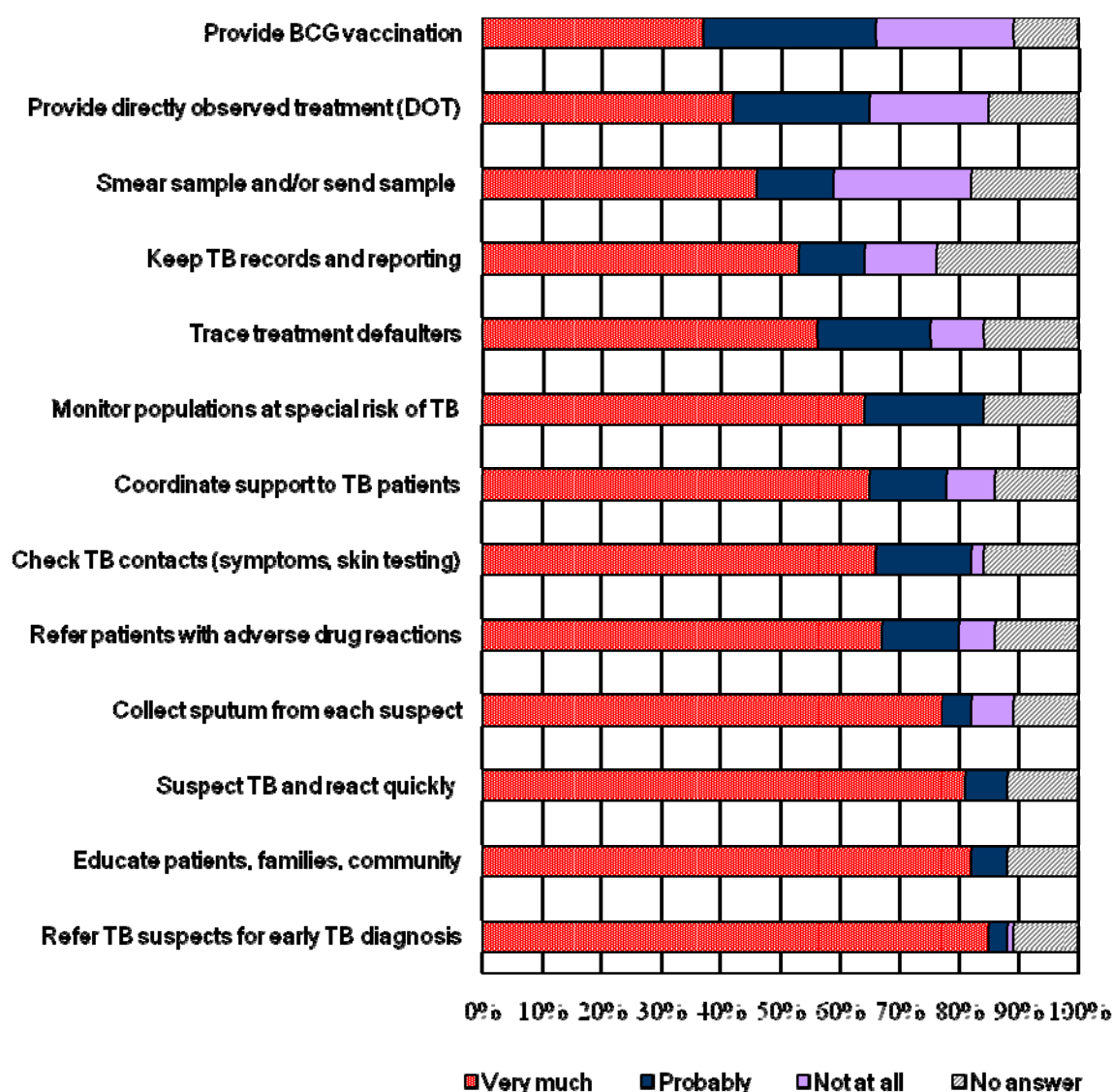
A slow shift towards the involvement of primary health care has recently been taking place (10), but preventive and primary health care is still largely neglected. The official job description of general practitioners or family doctors covers a broad area, including TB. However, of 100 general practitioners and nurses surveyed during the review, 60 did not have a single TB consultation per day, while 33 had one or two consultations and 7 had three or more. This apparent contradiction might be due to the fact that instead of treating TB patients in primary health care facilities, as considered in the job description, there is still a preference for treating them in specialized TB hospitals, either because the patients choose it, because the TB specialists retain patients, or because the primary health care doctors are reluctant to take over the treatment of these cases.

From the list of tasks investigated, the general practitioners said they felt less competent in providing BCG vaccinations, smearing sputum samples or sending them out for testing, providing DOT, keeping TB records and tracing TB treatment defaulters (Fig. 5). This highlights once more how TB remains a marginal activity in primary health care facilities and a possible cause of delayed TB diagnosis.

There are several reasons for the gap between the official job description and the actual services provided by general practitioners and family doctors, including poor description of the tasks, a flat salary without incentives and low expectations from patients who do not demand those services and prefer to go to specialists (37). Moreover, there are no gateways that guide patients to different levels of medical care, and insufficient guidelines for primary health care as well. Patient medical pathways can be characterized as chaotic and uncontrolled and often do not correspond with the gravity and course of the disease (35). The majority of patients circumvent

their primary care physician and refer themselves to hospitals directly to seek specialized care. In one study, it was estimated that 60% of patients go directly to specialists and over half of those visits are to inappropriate providers (3). However, 74% of TB patients surveyed said that they had consulted a general practitioner first when wondering whether they had TB. The main reason (53%) for this choice was the general practitioner’s accessibility. The different care-seeking behaviour between the TB patients interviewed by the teams and the other patients interviewed in the World Bank study quoted above (3) might be attributable to the different study populations: TB patients often have lower socioeconomic conditions and are consequently more keen to consult the primary health care services first.

Fig. 5. Answers by 100 primary health care staff interviewed by the review teams to the question: “If asked to perform the following TB activities, how competent would you feel?”

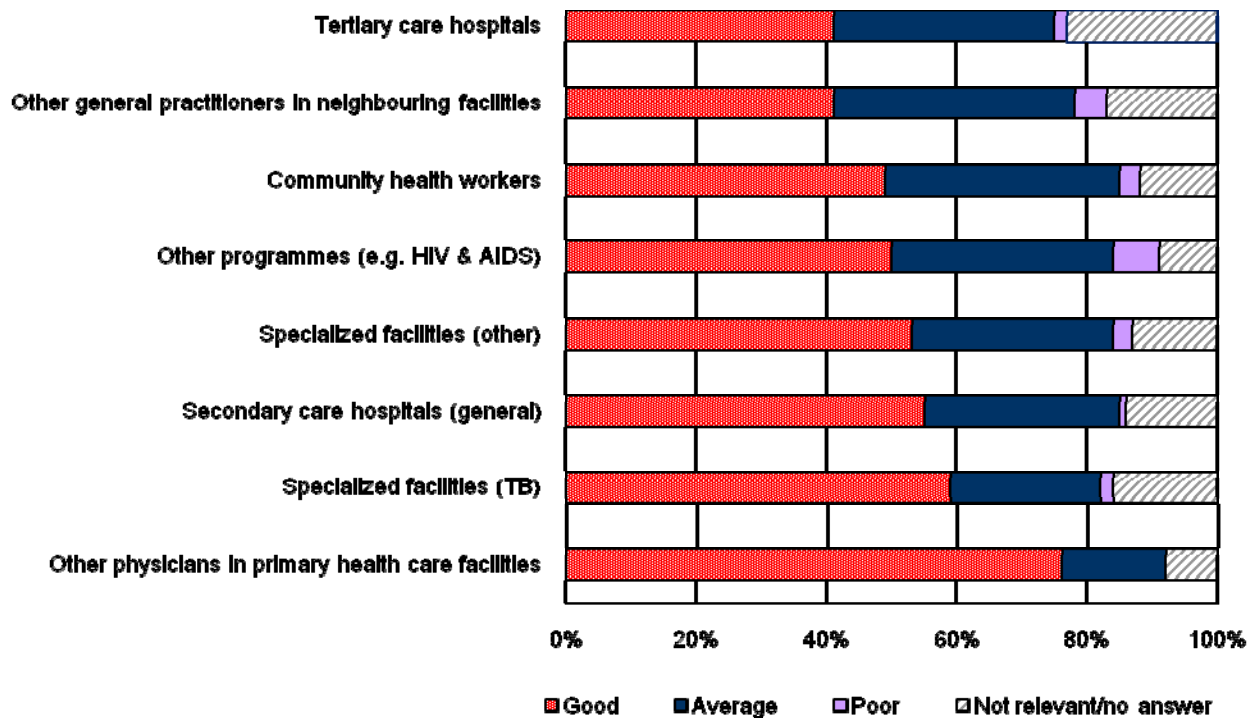


Only 65% of primary health care staff surveyed during the review said that they had good collaboration with the TB specialist hospitals (Fig. 6).

Officially, there is a comprehensive guaranteed package of health care services provided free at the point of use as a constitutional right. In practice, however, providers extract high out-of-

pocket payments to compensate for their low salaries (34). The discrepancy between, on the one hand, the proclaimed practically unlimited guarantees regarding the provision of free health care and, on the other, scarce state financing, has given rise to a public debate on the necessity for the introduction of a more realistic government obligation to provide medical aid.

Fig. 6. Answers by 100 primary health care staff interviewed by the review teams to the question: "How would you describe your collaboration with other colleagues or institutes?"



Although feldsher/midwife aid posts also provide primary health care services, the shortage of doctors in rural areas causes a number of problems with accessibility to, and the quality of, medical care (34). The teams' survey of primary health care patients suggests that there are major barriers in organizational and geographical access: 38% of the patients said they postponed seeking care because they could not afford to take time off work, 31% because they did not feel ill enough, and 7% because of difficulties in getting to the facility due to distance, travel time or cost (Fig. 7). Only 12% said they considered that the health care (providers, drugs or equipment) was inadequate.

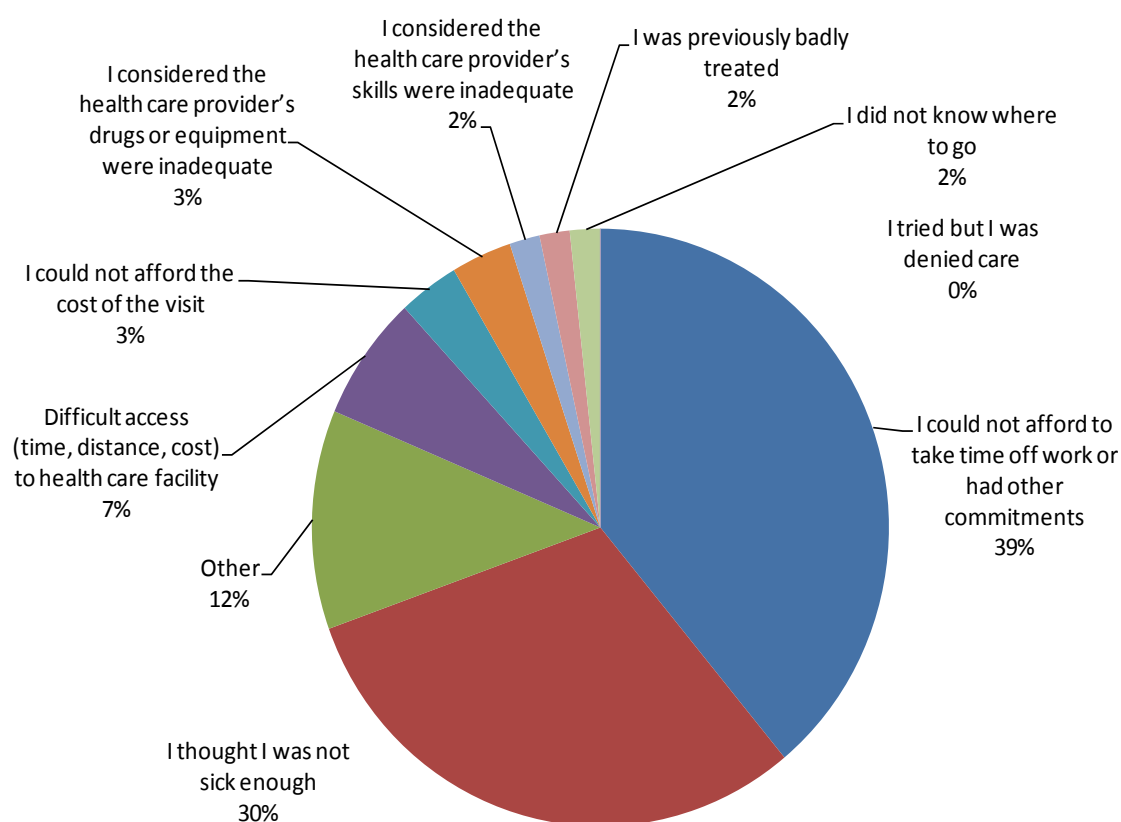
This lack of confidence might explain why so many patients postponed seeking care if they were not acutely ill. It should be noted that the questionnaires were handed out in the facilities visited and not among the general population, which may overrepresent actual accessibility to health care. Moreover, the teams' survey of TB patients found similar reasons for postponing medical care: although these patients presented several TB symptoms, they said that they thought they were not ill enough.

This inadequate care-seeking behaviour facilitates the spread of TB. Indeed, when patients postpone seeking care in primary health care facilities, only to have to visit a TB facility that might be far away from their homes when they are suspected of having TB, a double delay is caused which is even more relevant in rural areas.

Bottlenecks in the health system for the implementation of the Stop TB Strategy

Important systematic bottlenecks can be identified in the effective implementation of the Stop TB Strategy (Fig. 8 and Annex 8). Fig. 8 shows that many of the root causes of the improper implementation of the Strategy lie outside the NTP. Some bottlenecks lie at the intersection of the general health system and the TB system, for patients (pathways, coordination of care), for staff (attraction and retention of TB specialists), for funding (government spending on health and the proportion allocated to TB) and for governance (responsibilities at national, regional and local levels). These bottlenecks need to be recognized and tackled if the full benefits of the Stop TB Strategy are to be reaped. Short-term action taken within the NTP would be sustainable only if accompanied by substantial reform of the health system. More critical reforms to the health system, such as strengthening primary care and social support for vulnerable people, are a prerequisite for full implementation of the Strategy (for example, DOT in ambulatory settings).

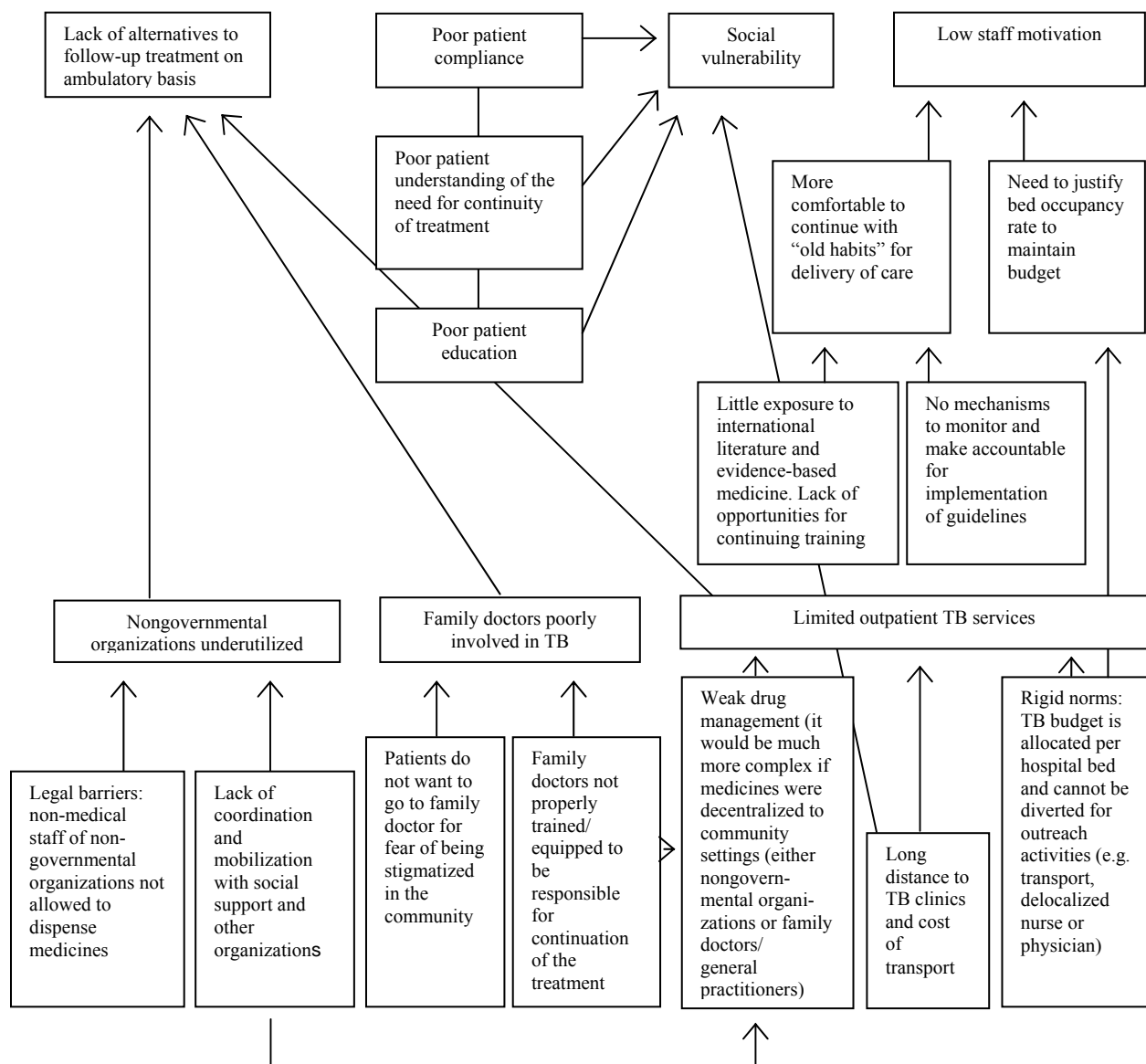
Fig. 7. Answers by 59 primary health care patients who had postponed care at least once during the previous year and who were interviewed by the review teams to the question: "Which reasons best explain why you did not get care or postponed seeking care?"



Stop TB Strategy in the framework of the proposed health system reform

The transition has been relatively slow in Ukraine since the country regained its independence. Health care delivery has changed very little, even if: (i) the government has repeatedly declared the necessity for reform, (ii) recent studies have adequately described the need and options for reforms, and (iii) a number of legal prerequisites have been created in order to change approaches to planning and regulation in public health (3). Many features of the former Semashko model of the public health care system can still be observed. This has been attributed to a lack of institutional capacity for policy-making, difficult and lengthy decision-making processes and subsequent serious delays before approval of policies and programmes (37). The lengthy decision-making process combined with frequent changes of government and, in the Ministry of Health, a lack of political will together with misalignment of incentives at the different levels of authority has seriously hampered the implementation of ambitious and coherent reform programmes. In addition, the legal framework for health care is complex and fragmented and characterized by overlapping and ambiguous lines of accountability (37).

Fig. 8. Root cause analysis of the main bottlenecks for implementing the Stop TB Strategy



The worsening of the population's health and the difficult demographic situation since independence, combined with the great financial and social strains on the health system following the financial crisis and economic downturn, have heightened the need for reforms. Ukraine is, unfortunately, one of the countries that was most affected by the aftermath of the global financial crisis. While the budget for health remained identical for 2009 compared to 2008, expenditure on drugs was reduced by 20% and the budget did not allow for any expenditure on capital investments in 2009. The country is likely to face a constrained fiscal environment for many years.

As an immediate reaction to the financial crisis, several options for reform of the health system have been proposed by a variety of stakeholders but have not materialized. Recently, the President called for a socioeconomic reform programme to include a section on reform of the health care services. This programme proposes a consistent package of reforms directly oriented towards the main causes of inefficiency throughout the health care system, with a revision of the financing principles and the introduction of new models of care based on primary health care.

Three *oblasts* (Dnipropetrovsk, Vinnytsia and Donetsk) were selected to participate as pilot areas and additional piloting sites might be included. The pilot was expected to take place in 2011 and guide the scaling-up of the health reform countrywide in 2012. This reform is supported by international organizations such as the World Bank. It will receive high visibility and direct support from the President. Hence, several key informants met by the review team were positive about the chances of success. A high degree of resistance is, however, expected especially from *rayon* and municipal health authorities who might be afraid of losing some power (34). The managers of health facilities might also be reluctant to change. Finally, there are fears that some medical staff and patients would resist because of incorrect information given by local health authorities.

The main goals of the reform are: (i) to increase the accessibility of medical services for the general population, (ii) to provide quality medical services, and (iii) to ensure the effective use of resources. This will be achieved by reorganizing the network of medical facilities. The focus is on differentiating the systems by level of care, the designation of hospital districts, the development of a network of family doctors and an increase in health promotion and prevention, especially at general practitioner level.

The reform presents a fundamental shift in models of care from an essentially hospital-based and specialist-centred approach to an ambulatory-based and general practitioner-centred approach. The same shift is advocated for the implementation of the Stop TB Strategy (see section 6). Strengthening the primary health care services is a prerequisite for success when implementing ambulatory treatment using DOT. A revision of the job description for general practitioners gives an opportunity to strengthen their responsibilities for health education and the detection and continuation of treatment of TB. But a new job description is not sufficient. Its effective implementation also requires the scaling-up of the infrastructure and equipment (for example, for storage and transport of sputum samples or drugs), the availability of staff (especially in remote areas), the development of financial incentives (such as to motivate coordination of care across care settings), advocacy and mobilization (for stigma-related issues, etc.) and support in the community (social workers). This is well illustrated by the root-cause tree in Fig. 8.

The reform must be complemented with a change in the financing mechanisms for staff and medical institutions. Funds will be pooled at the *rayon* level for primary care, at the *oblast* level

for secondary and emergency care and at the national level for tertiary care and highly specialized services. The defragmentation of funding mechanisms will create opportunities for a more comprehensive approach to planning and financing by health care institutions. This gives rise to the prospect of seeing TB facilities as suppliers of health care, which can be transformed by reducing the number of TB hospital beds, shifting to ambulatory-based TB care and – most effectively – tackling the increased needs arising from MDR-TB. If TB is not incorporated into this reform, the opportunity to reprofile TB hospitals will be lost and the TB infrastructure will be set in stone, as the constitution does not allow for the closing of hospitals, including TB hospitals. Thus, financing the infrastructure will continue to absorb scarce resources which are necessary to strengthen ambulatory care for TB control.

The reorganization of the network of facilities will be instrumental for the shift in models of care. This will be made possible with the change of the financing mechanisms and the definition of health districts. Within health districts, hospitals will be re-profiled to adapt the supply of beds to actual needs. This is a major step for a health system to become more responsive to the needs of the population. It also offers an opportunity for the TB services to address the needs of the population (new diagnostic and treatment protocols, effective assessment of vulnerable groups and access to high risk areas). Currently, the teams estimate that the number of TB hospital beds greatly exceeds the actual needs if the Stop TB Strategy were to be fully implemented (see section 6).

The proposed reforms give more responsibility to *oblast* health administrations. This is a positive step as it enables a much needed rationalization of health care facilities. It is, however, critical that the *oblast* level has the capacity and is accountable for the proper accomplishment of this mission. Stepwise and cautious implementation plans are needed to move from rigid historic norms to the development and implementation of hospital master plans via health care needs assessments. For instance, reform of the hospitals must acknowledge their social dimension, their role as an economic activity and their human resources capital. The current structure of the workforce creates inertia, but this could gradually be changed through retraining, retirement, new quotas for specialization, etc. Hospital master plans need to be built on sound health care needs assessments, which require good information systems. This can be achieved by, for instance, establishing an entity at the national level to support *oblast* health authorities when they develop master plans. In many countries, this role is taken by a health policy unit or similar agency. More specifically, where TB is concerned, agreement must be reached on the clinical protocols and the terms of reference for all care providers and social support agencies intervening in TB patients' care pathways before a master plan deciding the number of TB hospitals and beds is developed.

Quality management and external control of health care services are being introduced as part of the reform agenda and will be further strengthened and scaled up in the context of the reform. The NTP includes some external quality control features (in particular for laboratories) and the development of clinical protocols. Clinical protocols are not, however, being consistently applied for a number of reasons, including poor knowledge (information flows only through orders and there is no proper training about the protocols), reluctance to change and incongruence with the curriculum ("old-style practice"), lack of resources (such as second-line drugs, alternatives for treatment on an ambulatory basis) or disincentives (financing based on inputs creates an incentive for higher occupancy rates). If the development and monitoring of clinical protocols are included in the reform, factors related to the motivation and training of doctors would be tackled.

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Annex 1. Members of the review teams

International

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Annex 2. Programme overview

- 10 October** 19:00–20:00 Arrival in Kyiv. Check-in at the hotel
Meeting of the experts on organizational and logistical issues
- 11 October**
09:00–11:00 Meeting of the experts, discussion of a plan of evaluation and allocation of responsibilities
12:00–13:00 Meeting at the Ministry of Health. Presentation of evaluation plan and expected results
13:00 Departure to the regions
- 12–15 October** Work of expert groups in the regions
- 16 October**
11:00–17:00 Meeting of the experts, discussion of the results of the missions to the regions.
Division into groups, preparation of the reports of site visits
- 17 October** Continuation of work on the reports. Leisure
- 18 October**
09:00–18:00 Division of the experts into groups by sections of the report, discussion of sub-sections, work on the report
- 19–21 October** Meetings of the international experts with central-level experts for clarification and further details. List of organizations to meet:
- Ministry of Health
 - deputy ministers
 - Department of International Affairs and European Integration
 - Department of Sanitary and Epidemiological Surveillance
 - Department of Regulatory Policy in the Area of Drugs and Medical Products Circulation
 - Committee on HIV/AIDS and Other Socially Dangerous Diseases
 - All-Ukrainian Centre for Tuberculosis Control
 - F.G.Yanovsky National Institute of Tuberculosis and Pulmonology
 - Central Reference Laboratory with bacteriological diagnosis of TB
 - State Department for the Enforcement of Sentences
 - Ukrainian Centre for Prevention of AIDS
 - P.L. Shupik Kyiv Medical Academy of Postgraduate Education
 - State Enterprise “Ukrvaktsina” for drug procurement
 - State Inspection for Quality Control of Medicines, Ministry of Health
 - Pharmacological Committee, Ministry of Health
 - Principal recipient of the Global Fund grants (Rounds 1, 6 and 9)
 - International organizations (PATH, USAID, Deutsche Gesellschaft für Internationale Zusammenarbeit (GTZ), CDC, Clinton Foundation)
 - Ukrainian nongovernmental organizations involved in TB and HIV/AIDS control
- 22 October**
10:00–11:00 Briefing at Ministry of Health on the results of the experts’ work
12:00–13:00 Discussion of organizational matters and deadlines for the detailed report
14:00 Departure of the experts

Annex 3. Organization of the field work

Date (October)	Field team 1 (Dnipropetrovsk <i>oblast</i> : Pierpaolo de Colombani Svitlana Cherenko Anna Barbova Eugen Polyakov)	Field team 2 (Mykolayiv <i>oblast</i> : Jaap Veen Olena Pavlenko Larysa Artushkina Katerina Gamazina)	Field team 3 (Sumy <i>oblast</i> : Malgosia Grzemska Olga Stelmakh Alexandr Jurilo Irina Dubrovina)	Field team 4 (Kyiv City and Kyiv <i>oblast</i> : Connie Erkens Ann-Lise Guisset Grigory V. Volchenkov Olena Tarasenko Anna Bobrova)
11	17:00 or 21:00 fly to Dnipropetrovsk	17:15 fly to Odessa 19:00 drive to Mykolayiv Odessa– Mykolayiv, 150 km, 2 h	Drive to Sumy 350 km, 4.5 hours	Departure to Kyiv city and Kyiv <i>oblast</i> Visit to the city clinic providing TB services for patients (14:00–16:00)
12	Visit to <i>oblast</i> state administration (08:00–08:30) Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse (09:00– 13:00) Visit to AIDS centre (14:30–16:00)	Visit to <i>oblast</i> state administration (0800–0830) Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse (09:00–13:00) Visit to AIDS centre (14:30–16:00)	Visit to <i>oblast</i> state administration (0800–0830) Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse (09:00– 13:00) Site of substitution therapy? (15:00–16:00)	Visit to central city TB dispensary, including laboratory, drug warehouse (09:00–12:00) Visit to MDR-TB Department of the National Institute of Tuberculosis and Pulmonology (15:00– 17:00)
13	Visit to central <i>rayon</i> hospital (<i>rayon</i> TB physician) (10:00–12:00) Visit to first-level medical institution (rural clinic, feldsher/midwife station) (13:00–14:00) Visit to the city outpatient hospital, providing TB services to patients (16:00–17:00)	Visit to central <i>rayon</i> hospital (<i>rayon</i> TB physician) (10:00–12:00) Visit to first-level medical institution (rural clinic, feldsher/midwife station) (13:00–14:00) Visit to the city outpatient hospital, providing TB services to the patients (16:00–17:00)	Visit to central <i>rayon</i> hospital (<i>rayon</i> TB physician) (10:00–12:00) Visit to first- level medical institution (rural clinic, feldsher/midwife station) (13:00–14:00)	Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse, etc.) (09:00– 13:00) Visit to first-level medical institution (rural clinic, feldsher/midwife station) (14:00 – 15:00)
14	Visit to TB hospital of State Department for Enforcement of Sentences (09:00–12:00) Visit to remand prison (14:00–16:00) Meeting with nongovernmental organizations	Visit to TB hospital of State Department for Enforcement of Sentences (0900–1200) Visit to remand prison (14:00–16:00) Meeting with nongovernmental organizations	Visit to AIDS Centre (09:00–11:00) Visit to the city hospital providing TB services to patients (12:00–14:00) Meeting with nongovernmental organizations (16:00–17:00)	Visit to City Centre of AIDS or AIDS clinics of Gromashevskiy Institute (09:00–13:00) Visit to remand prison (15:00–16:00)

15	Visit to the city/ <i>rayon</i> TB dispensary (09:00–11:00) Site of substitution therapy? (12:00–13:00) Visit to <i>oblast</i> state administration (15:00–16:00)	Visit to the city/ <i>rayon</i> TB dispensary (09:00–11:00) Site of substitution therapy? (12:00–13:00) Visit to <i>oblast</i> state administration (15:00–16:00)	Visit to the city/ <i>rayon</i> TB dispensary (09:00–11:00) Visit to <i>oblast</i> state administration (12:00–13:00)	Visit to city TB hospital in Mostyshcha (09:00–15:00)
	19:00 Fly to Kyiv	Drive to Odessa. 19:15 fly to Kyiv	Drive to Kyiv	

Date (October)	Field team 5 (Volyn <i>oblast</i> : Amy Bloom Erika Vitek Ludmila Storozhuk Aleksey Bogdanov Olga Nikolayeva)	Field team 6 (Luhansk <i>oblast</i> : Olya Duzey Girts Skenders Igor Raykhert Olena Radzievska)	Field team 7 (Kirovohrad <i>oblast</i> : Olexandr Polishchuk Vaira Leimane Mikhail Kuzhko Tamara Ivanenko)	Field team 8 (Chernivtsi <i>oblast</i> : Andrei Dadu Tamara Tonkil Olga Bilogortseva Igor Pereginets)
11	Drive to Lutsk Kyiv-Lutsk 400 km, 5h	20:40 Fly to Luhansk	Drive to Kirovograd Kyiv-Kirovograd 300km, 4h	19:25 Fly to Chernivtsi
12	Visit to <i>oblast</i> state administration (08:00–08:30) Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse (09:00–13:00) Site of substitution therapy? (15:00–16:00)	Visit to <i>oblast</i> state administration (08:00–08:30) Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse (09:00–13:00) Visit to AIDS centre (14:30–16:00)	Visit to <i>oblast</i> state administration (08:00–08:30) Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse (09:00–13:00) Site of substitution therapy? (15:00–16:00)	Visit to <i>oblast</i> state administration (08:00–08:30) Visit to <i>oblast</i> TB dispensary, including laboratory, paediatric service and drug warehouse (09:00–13:00) Visit to AIDS centre (14:30–16:00)
13	Visit to central <i>rayon</i> hospital (<i>rayon</i> TB physician) (10:00–12:00) Visit to first-level medical institution (rural clinic, feldsher/midwife station) (14:00–17:00)	Visit to central <i>rayon</i> hospital (<i>rayon</i> TB physician) (10:00–12:00) Visit to first-level medical institution (rural clinic, feldsher/midwife station) (13:00–14:00) Visit to th city outpatient clinic providing TB services for patients (16:00–17:00)	Visit to central <i>rayon</i> hospital (<i>rayon</i> TB physician) (10:00–12:00) Visit to first-level medical institution (rural clinic, feldsher/midwife station) (14:00–17:00)	Visit to central <i>rayon</i> hospital (<i>rayon</i> TB physician) (10:00–12:00) Visit to first-level medical institution (rural clinic, feldsher/midwife station) (13:00–14:00) Visit to city outpatient clinic providing TB services for patients (16:00–17:00)
14	Visit to AIDS centre (09:00–11:00) Visit to city outpatient clinic providing TB services for patients	Visit to the TB hospital of the State Department for the Enforcement of Sentences (09:00–12:00) Visit to remand prison	Visit to AIDS centre (09:00–11:00) Visit to city outpatient clinic providing TB services for patients	Visit to the institutions of the State Department for the Enforcement of Sentences

	(12:00–14:00) Meeting with nongovernmental organizations (16:00–17:00)	(14:00–16:00) Meeting with nongovernmental organizations	(12:00–14:00) Meeting with nongovernmental organizations (16:00–17:00)	(09:00–13:00) Meeting with nongovernmental organizations (15:00–17:00)
15 (Friday)	Visit to city outpatient clinic providing TB services for patients (09:00–11:00) Visit to <i>oblast</i> state administration (12:00–13:00)	Visit to the city/ <i>rayon</i> TB dispensary (09:00–11:00) Site of substitution therapy? (12:00–13:00) Visit to <i>oblast</i> state administration (15:00–16:00)	Visit to the city / <i>rayon</i> TB dispensary (09:00–11:00) Visit to <i>oblast</i> state administration (12:00–13:00)	Visit to the city/ <i>rayon</i> TB dispensary (09:00–11:00) Site of substitution therapy? (12:00– 13:00) Visit to <i>oblast</i> state administration (15:00–16:00)
16 (Saturday)	Drive to Kyiv	07:40 Fly to Kyiv	Drive to Kyiv	Fly to Kyiv

Annex 4. Monitoring and evaluation

Centre for Tuberculosis Control

The Centre for Tuberculosis Control at the F.G. Yanovsky National Institute of Tuberculosis and Pulmonology in Kyiv is structured as shown below.

No.	Position	Status
<i>Administration Unit</i>		
1	Director	Acting
2	Deputy Director	Vacant
3	Press Secretary	Occupied
<i>DOTS Implementation Unit</i>		
4	Expert on DOTS implementation	Occupied
5	Expert on DOTS implementation	Occupied
6	Expert on infection control	Vacant, under recruitment
7	Expert on MDR-TB	Vacant, under recruitment
8	Expert on TB/HIV co-infection	Vacant, under recruitment
<i>Laboratory Diagnosis Unit</i>		
9	Expert on laboratory network coordination	Occupied
10	Expert on laboratory diagnosis	Vacant, under recruitment
<i>Human Resources Unit</i>		
11	Expert on training	Vacant, under recruitment
12	Expert on training	Occupied
13	Expert on training	Vacant, under recruitment
<i>Monitoring and Evaluation Unit</i>		
14	Expert on TB registration and reporting	Occupied
15	IT specialist	Occupied
16	Expert on monitoring and evaluation	Occupied
17	Expert on monitoring and evaluation	Occupied
<i>Finance Unit</i>		
18	Financial Manager	Vacant
19	Accountant	Occupied
20	Accountant	Occupied
21	IT specialist	Vacant, under recruitment
22	Expert on procurement	Vacant, under recruitment

TB recording and reporting systems

There are three recording and reporting systems for TB.

1. Inherited from the former Soviet Union

Line 1. Patient notification and registration.

- a. TB cases reported by form 089u (*Notice of a new or relapsed TB patient*¹⁶), which includes a number of variables that allow for monitoring of patient notification by nominal and demographic information, date of diagnosis and detailed clinical diagnosis according to the International Classification of Diseases (ICD10). This information can be aggregated.
- b. Quarterly reports by forms 8 (*Report of active TB*¹⁷) and 33 (*Short report on TB patients*¹⁸). These forms provide notification data of diagnostic groups according to ICD10, age groups, urban versus rural comparison, and confirmation by smear, culture and histology. They also include information on the total number of HIV co-infected TB patients.

Line 2. Patient registration and monitoring of treatment.

- a. Notification of TB patients and monitoring of treatment by form 30–4/o (*Form for TB individual treatment*¹⁹). The information is aggregated and reported to the next level by form 33-health (*Form for reporting TB patients*²⁰), which allows for the monitoring of smear, culture, drug susceptibility testing and X-ray outcomes, co-morbidity, invalidity, treatment regimens and outcome, surgical treatment, relapse, preventive treatment, tuberculin skin test, BCG, social determinants and living conditions of TB patients.

Line 3. Monitoring the TB health facility performance by form 20 (an annual form for all health facilities to monitor all health care activities and human resources of the facility).

The data are aggregated by *oblast* and published in the yearly TB statistical report that is distributed in the field and is also available online.²¹

2. Compliant with WHO recommendations

The system is based on a set of 14 cards, forms and registers:

- TB–05: Referral and results of laboratory diagnosis by smear microscopy;
- TB–05/a: List of TB suspects with results of laboratory diagnosis by smear microscopy;
- TB–04/1: TB laboratory register for smear microscopy;
- TB–06/a: Referral and results of laboratory diagnosis by culture;
- TB–06: Referral and results of laboratory diagnosis by culture and drug susceptibility testing;
- TB–04/2: TB laboratory register for culture and drug susceptibility testing;
- TB–01: Individual TB case management form;
- TB–01/1: Attachment for individual TB case management form for risk factors;
- TB–09: Form for referral of TB case to another health facility;
- TB–03: Rayon TB register for all TB cases;

¹⁶ Ministry of Health Order No. 112/139 of 25 March 2002, Notification of Newly Detected Active TB or Relapse.

¹⁷ Ministry of Health Order No. 261 of 9 June 2005, Reporting Active TB Form.

¹⁸ Ministry of Health Order No. 621 of 27 December 2006, Reporting of TB Patients Form.

¹⁹ Ministry of Health Order No. 302 of 27 December 1999, TB Observation Form.

²⁰ Ministry of Health Order No. 346 of 8 July 2004, Reporting TB Patients Form

²¹ *Tuberculosis in Ukraine: analytic-statistical report 1999–2009*. Kyiv, Ukrainian Centre for Tuberculosis Control, 2010 (<http://tbc.gov.ua/download/tubanaliz/Tubanaliz%20.doc>, accessed 24 March 2011) (in Ukrainian).

- TB–07: Quarterly report of TB case notification (categories 1 and 2) and case detection by primary health care and TB services;
- TB–10: Quarterly report of monitoring of TB case treatment, for smear conversion (categories 1 and 2);
- TB–08: Quarterly report of notification of TB case treatment outcomes (categories 1 and 2);
- TB–11: Quarterly report of TB cases by culture and drug susceptibility testing.

3. Sanitary–epidemiological surveillance

The system allows for:

- **notification** of a case of communicable disease by any doctor in the health care network by recording form 058/o (*Urgent notice of a case of a communicable disease*²²);
- **recording** in the communicable disease register only newly detected active pulmonary and laboratory confirmed cases of TB;
- **reporting** monthly aggregated data to the next administrative level by form 1 (*Report of a communicable disease*).

Current TB indicators for monitoring health system performance

Seven related TB indicators are officially used and approved by law to assess the health status of the population and performance of the health care system:²³

1. coverage of children with tuberculin skin test, every six months (higher is better);
2. coverage of children with tuberculin skin test in rural areas, every six months (higher is better);
3. percentage of pulmonary TB with lung destructions among newly detected patients, quarterly (lower is better);
4. percentage of pulmonary TB with lung destructions among newly detected patients in rural areas, quarterly (lower is better);
5. percentage of closure of cavities, annually (higher is better);
6. percentage of bacteria excretion cessation among newly diagnosed TB patients, annually (higher is better);
7. coverage of population by annual fluorography screening (higher is better).

Proposed new TB indicators for monitoring health system performance

1. Process:
 - a. percentage of sputum smear-positive among TB suspects at the primary health care level.

²² Ministry of Health Order No. 1 of 10 January 2006, Primary Documentation of Notification of Infection, STI and Ontological Morbidity.

²³ Ministry of Health Order No. 197 of 31 May 2002, Rating Assessment of the Health Care Status of the Population and Performance of the Health Care System.

2. Outcome:
 - a. treatment success rate of new sputum smear-positive pulmonary TB cases notified a year previously;
 - b. treatment success rate among MDR-TB cases notified two years previously.
3. Impact:
 - a. TB notification (absolute number of new and relapsed cases and rate per 100 000 population);
 - b. TB notification among health care workers (absolute number and rate per 100 000 population) of new and relapsed cases;
 - c. TB mortality (absolute number of TB deaths and rate per 100 000 population);
 - d. MDR prevalence among all TB cases (absolute number and percentage of population);
 - e. HIV prevalence among all TB cases (absolute number and percentage of population).

Electronic data management

The following pilot projects on electronic data management are in progress.

- The electronic TB register in Kyiv city is based on the standard DOTS forms and adapted to the needs of the Kyiv TB service. It is built in MS Access with data entry management done on local hard drives. The register was developed in the Royal Netherlands Tuberculosis Foundation (KNCV)/Technical Assistance for the Commonwealth of Independent States (TACIS) project supported by the European Union, 2002–2005, and is still functioning. It was designed for Kyiv City only; it was not possible to introduce it countrywide. It allows for the recording of categories 1, 2 and 3 TB cases.
- The electronic TB Management Information System (TBeMIS) is based on the DOTS forms and adopted as part of DOTS implementation in seven areas (Donetsk, Kharkiv, Dnipropetrovsk, Zaporizhia and Kherson *oblasts*, the Autonomous Republic of Crimea and Sevastopol city) which cover 40% of the population of the country. Built in EpiInfo, with data entry done on local drives, the system was developed by the PATH/USAID project, 2003–2007 and designed for countrywide implementation. It is working well in Dnipropetrovsk *oblast*. It allows for the recording of categories 1, 2 and 3 TB cases and for the monitoring of notification and treatment outcomes. It also allows for encryption of data before sending and merging of databases, and has GIS and fully functional operative analysis modules.
- The electronic TB register for MDR-TB cases is based on DOTS plus forms. It has been implemented in the WHO project in Donetsk *oblast* and is supported by the Foundation for the Development of Ukraine. It is still functioning, with built-in MS Access and data managed on local drives.
- The E-TB Manager is a comprehensive web-based tool conceived for strengthening TB programmes by integrating case management (all treatment categories), medicine control and surveillance information into a single platform. Implementation was started in 2009 by Management Sciences for Health in cooperation with PATH, supported by USAID. It is meant for countrywide implementation. The case module allows for real-time, comprehensive and reliable case management and information-sharing. Data entry goes via a web-based interface, based on WHO-recommended TB data recording forms. Output modules are still under development. The NTP is facing the problem of how to get the tool legally recognized and approved by the government as an official tool for TB information management.

Annex 5. Human resources

The deployment of TB staff is based on Ministry of Health Order No. 197 of 31 May 2002 (Rating Assessment of the Health Care Status of the Population and Performance of the Health System), which sets specific health services per population.

Personnel	Setting	1.0 full-time equivalent per unit ^a
<i>Physicians (excluding laboratory)</i>		
TB specialist	TB hospital	30 beds
TB specialist for children	TB hospital	25 beds
Bone TB specialist (surgeon, orthopaediatrician)	TB hospital	35 beds
Urologist, obstetrician, gynaecologist	TB hospital	25 beds
Thoracic surgeon	TB hospital	12 beds
TB specialist for meningitis	TB hospital	15 beds
Ear, nose and throat specialist	TB hospital	200 beds
General practitioner	TB hospital	250 beds
Neuropathologist	TB hospital (cases of meningitis)	40 beds
Narcologist, psychiatrist	TB hospital	60 beds
Psychotherapist	TB hospital	400 beds
Oncologist	TB hospital	800 beds
Physiotherapist	TB hospital	400 beds
Endoscopist	TB hospital	200 beds
X-ray specialist	TB hospital	150 beds
<i>Laboratory staff</i>		
Microbiologist	TB hospital	150 beds
Bacteriologist	TB hospital	300 beds
Microbiologist	TB dispensary (outpatient)	6 TB specialists
Bacteriologist	TB dispensary (inpatient)	6 TB specialists
Microbiologist	TB sanatorium for adults	100–250 beds
Microbiologist	TB sanatorium for children (active cases)	100 beds
Microbiologist	TB sanatorium for children (non-active)	150 beds
<i>Nurses</i>		
	TB hospital (individual examinations)	100 beds
	TB hospital (medical procedures)	50 beds
	TB dispensary (outpatient)	10 TB specialists
	TB sanatorium for adults	25 beds
	TB sanatorium for children (active cases)	80 beds
	TB sanatorium for children (non-active)	50–75 beds

^a 1.0 full-time equivalent is the expression of one full-time staff position.

Annex 6. Links between ethics and human rights

Social justice/equity focuses on the underlying root causes and existence of inequalities in society and the need to address them explicitly. Given the role of socioeconomic factors in increasing the risk of TB infection and progress of the disease, the pursuit of social justice needs to become a key component of TB control.

Solidarity is primarily about standing together as a group, community or nation. Infectious diseases such as TB increase the risks of harm for whole populations. Such risks can be reduced where strong community ties result in cooperative action to enforce the conditions for flourishing, disease-free lives.

Common good relates to the threat that an infectious disease represents not only for the health of an infected individual, but also for the whole population. Moreover, individual health is shaped by the social environment and everybody can gain from a society with strong public health facilities to address TB control and treatment.

Autonomy is generally seen as guaranteeing individuals the right to make decisions about their own lives, including health care. For example, respecting autonomy means that TB patients generally should have the right to choose between treatment options.

Reciprocity seeks to express the idea that health-care workers or members of the community seeking to treat TB might be at greater risk of harm and deserve benefits in exchange for running such risks. It might include an obligation to minimize the risks to individual care-givers (by providing protective equipment) as well as positive interventions to treat and compensate individuals when harm occurs as a result of providing care.

Effectiveness includes the duty to avoid doing things that are clearly not working, as well as the positive obligation to implement proven measures that are likely to succeed. Evidence of effectiveness (or lack of it) in TB programmes requires ongoing monitoring, surveillance and research.

Subsidiarity promotes the idea that decisions should be made as close to the individual and communities at local level as possible.

Participation requires that the public be encouraged to participate in the decision-making process, and that reasons be provided for decisions.

Transparency and accountability require that decisions be made openly and that the decision-making process be fair, responsive and evidence-based.

Annex 7. Health system: general services and TB facilities

Services and facilities	2008	2009
<i>General services</i>		
All hospitals (n)	2 622	2 800
Hospitals per 100 000 population (n)	5.5	5.4
Hospital beds per 100 000 population (n)	873	942
Hospital admissions per 100 000 population (n)	22.6	22.4
Acute care hospitals per 100 000 population (n)	4.9	4.8
Acute care hospital beds per 100 000 population (n)	714.7	708.6
Acute care hospital admissions per 100 000 population (n)	21.4	21.3
Average length of stay in acute care hospitals (days)	10.9	10.8
Bed occupancy rate in acute care hospitals (%)	90	89
Primary health care facilities per 100 000 population (n)	15.0	15.0
<i>TB facilities</i>		
TB hospitals (n)		
TB dispensaries (n)		
Population per TB hospital (n)	396 200	398 100
Population per TB dispensary (n)	294 600	295 400
TB hospitalization rate (%)	94	84
Average length of stay in TB hospitals (days)	86.2	89.8
Bed occupation rate in TB hospitals (%)	68.6	68.9

Annex 8. Comparison of the key findings of the NTP and relevant findings in the general health care system

NTP	Health system
<p>Stop TB Strategy not implemented consistently. Wide variations observed between and within <i>oblasts</i>, depending on local capacity and support received from international partners.</p>	<p>Authority delegated to <i>oblast</i> and local level. Management by orders. Complex and contradictory legislation. Multiple lines of accountability. Rigid monitoring and evaluation system. Multiplicity of sometimes contradictory orders makes it difficult or impossible to monitor and make different levels of authority accountable for their implementation.</p>
<p>Overall TB services designed around health providers instead of patients. TB control is organized under a vertical programme.</p>	<p>Overall the health system is not oriented towards the real health needs of patients. Hospital-centred health care system, with weak primary health care. Fragmented system, no coordination between levels of care, vertical programmes.</p>
<p>Excessive hospitalization common. With poor infection control practices, hospitalization may contribute to continued nosocomial transmission of TB and MDR-TB among patients and staff.</p>	<p>Input-based financing and rigid norms. Over-capacity in network maintained to justify budget allocation. Weak primary health care. No gate-keeping function; patients tend to go directly to specialists.</p>
<p>Many patients with smear-negative pulmonary or mild forms of extrapulmonary disease are admitted to hospital for so-called social reasons as the doctor expects problems with daily treatment compliance.</p>	<p>Poor differentiation in practice between different levels of care. Lack of alternative to hospitalization (e.g. hospices, palliative care) and social support services in the community.</p>
<p>Insufficient TB human resources capacity. TB doctors complain about low esteem for their job and low motivation because of low salaries. High number of vacancies aggravated by ageing workforce and thus an overload with work.</p>	<p>High number of vacant positions and ageing human resources especially in public health, low-paid jobs (in particular for primary health care and TB doctors). More critical situation for TB because of lack of attractiveness of profession (occupational risk, socially difficult patients).</p>
<p>Human resources are regulated by rigid norms which do not take into account changes in epidemiology or a changing strategy that includes involvement of primary health care for case-finding and a more ambulatory approach for treatment delivery.</p>	<p>Rigid norms have not evolved and hence do not represent the actual needs in human resources. Rigidity in budget allocation allows redistribution of salaries among those actually working. Important to distinguish between vacant positions and unfilled needs, especially in rural areas.</p>
<p>Active case-finding by mass miniature radiography or fluography for adult population on an annual basis is regular practice, without clear evidence of its efficacy.</p>	<p>Expensive model of compulsory mass health screenings by a group of professionals without any proof that these screenings are effective.</p>
<p>Generally, the majority of the health labour force is trained according to traditional clinical practice. Little knowledge of new strategies in TB control.</p>	<p><i>Medical education:</i> evidence-based-medicine not yet diffused in university curricula. <i>Continuous education:</i> extremely few opportunities to access national and international literature. Lack of on-the-job training.</p>
<p>Patients are followed up by TB dispensaries for a few years post-treatment completion</p>	<p><i>Development, diffusion and monitoring of guidelines:</i> recent initiatives to build capacity and</p>

NTP	Health system
<p>and cure. No evidence that this is beneficial, while it could be potentially harmful.</p> <p>Significant proportion of newly diagnosed patients (up to 30%) undergo surgical treatment. Indications for surgery are decided at the individual facility level, as national guidelines for surgical intervention in TB do not exist.</p> <p>Many aspects of Ministry of Health orders on how TB and MDR-TB cases should be identified and treated do not correspond to international guidelines.</p> <p>The Patients' Charter for Tuberculosis Care outlines the rights and responsibilities of people with TB. It is poorly known and not actively promoted and followed. In the eight <i>oblasts</i> visited by the teams, it was observed that TB services are not designed around patients but around providers.</p>	<p>strengthen mechanisms for the development of guidelines and to consolidate. Although implementation is critical, there are: (i) no mechanisms to adapt the pre-service curriculum (education books) to new national guidelines, which often results in discrepancies between the norms and what is actually being taught to students; (ii) no strategy for their wide dissemination (this is dependent on the willingness of different levels of authority to pass them down to lower levels, from national to <i>oblast</i> to <i>rayon</i> to facility); and (iii) no monitoring of the implementation of new guidelines.</p> <p><i>Organizational culture and change management:</i> resistance to change noted. Many respondents highlighted a predominant "old Soviet practice".</p> <p>By law, all citizens have the right to information about their health and health services, but the mechanisms for accessing such information are not transparent. No specific legal mechanism for patients' complaints procedures in the health system. Although there are a number of legal provisions for public participation in the health sector and various patient groups, they have not played an active role in policy-making as yet.</p>

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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