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Review of the National Tuberculosis Programme in Belarus

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Executive summary

Belarus is a top-priority country for prevention and control of multidrug-resistant tuberculosis (MDR-TB), recently documented at the highest levels in the world. In recent years, Belarus has revised its national tuberculosis (TB) policies and guidelines according to international recommendations and supported the effective implementation of two TB grants received from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). In consideration of the revised TB policies and guidelines and the need to evaluate their implementation in the light of the high rates of MDR-TB, the Ministry of Health of Belarus decided to undertake an external review of the National TB Programme. In June 2011, it asked the WHO Regional Office for Europe to assist in the organization of the review.

The review took place from 10 to 21 October 2011, with the participation of 11 international and nine national experts visiting Minsk city and the three oblasts (regions) of Minsk, Gomel and Vitebsk.

Main findings

According to the latest surveys, one third of newly diagnosed TB patients and two thirds of those returning for treatment have MDR-TB. Many of them have extensively drug-resistant tuberculosis (XDR-TB). These are the highest rates ever documented in the world. Applying the above rates, the actual number of MDR-TB cases is significantly higher than previously estimated. Similarly, more equipment and consumables will be needed for early detection and treatment (laboratory and anti-TB drugs). The national currency devaluation in 2011 made imported equipment and consumables even more expensive than before.

The review members were impressed by the significant progress made by the National TB Programme in recent years. The leadership and dedication of its staff made it possible to update national policies and guidelines and implement and monitor them. The commitment to the DOTS Strategy that the Government of Belarus made in 2005 has been translated into effective action that can be used as an example for other MDR-TB high-burden countries in our Region. Reference should be made to the Ministry of Health Order on the "Organization of observed outpatient treatment of TB patients" issued in 2008, the establishment of the National MDR-TB Expert Commission and the revision of TB and MDR-TB treatment guidelines, the reorganization of the national laboratory network and its quality assurance, the integration of TB care into primary health care, the availability of anti-TB drugs, the development of infection control guidelines, the strengthening of national surveillance, the regular supervision of facilities delivering TB services and the ongoing training of health workers. The effective coordination with and support from international partners also deserves to be mentioned. The extent of MDR/XDR-TB in the country is due particularly to non-evidence-based policies and practices implemented over the past decades in all countries of the former Soviet Union.

A number of technical aspects in the National TB Programme need to be further improved, of which National TB Programme management is already aware and which it is addressing. For many of them, renewed Ministry of Health support is essential. MDR-TB patients should be diagnosed earlier so that the most appropriate treatment and infection control measures can be

decided. Noninfectious TB patients are treated in hospitals unnecessarily, causing a significant financial burden for the health system, and affecting the quality of life of many patients without medical or public health justification. In addition, the number of TB patients involuntarily isolated and treated is a major concern of the review members. The scaling-up of social support for patients would ensure treatment completion, limit the need for involuntary isolation as a last resort, and reduce the financial burden.

Main recommendations

Ministry of Health and National TB Programme

1. MDR/XDR-TB should be considered a public health emergency in Belarus and preventing and combating it a top-priority intervention for the country and the WHO European Region.

2. The National TB Programme's capacity to address MDR-TB, including treatment, should increase significantly to reflect the additional burden indicated by the findings of the drug resistance survey in Minsk and later confirmed by the drug resistance survey countrywide.

3. Funding at central and oblast level should be guaranteed for priority interventions such as early diagnosis of MDR-TB cases, uninterrupted supply of quality anti-TB drugs and TB infection control.

4. Funding of hospital care should reflect the objectives of the system and consider mechanisms which ensure continuity of care, reduce overhospitalization, improve detection and match care to the needs of patients.

5. TB planning, currently conducted at rayon (district) level, should be centralized at oblast level in order to pool resources and ensure their more effective redistribution. This is especially important for the rational distribution of anti-TB drugs.

6. Ineffective interventions, such as annual mass screening of population not at TB risk and unnecessary hospitalization of nonsevere, noninfectious TB cases, should be abandoned. The new policy on active TB case-finding among children (Ministry of Health Order N 803 of 2011) should be be implemented and its impact evaluated countrywide to determine further possible changes. Cost savings can be reallocated to support priority interventions for MDR-TB control.

7. The current legislation limiting the retail sale of anti-TB drugs in pharmacies should be reinforced. Quinolones must be dispensed on medical prescription only.

8. Infection control and laboratory biosafety should be expanded to reduce transmission of MDR-TB among patients and health-care workers in all facilities. Priority should be given to revising national hospitalization policies (admission and discharge criteria) to avoid unnecessary hospitalization of noninfectious cases and substantially reduce the length of hospital stays.

9. Modern microbiology and molecular laboratory techniques should be introduced urgently to create improved and more rapid TB diagnostic services. The new

technology should be properly organized and evaluated for appropriateness, sensitivity and specificity, and cost-effectiveness.

10. Involuntary isolation and treatment should be considered as measures of last resort, to be used only after other interventions, such as professional counselling and organization of social support during outpatient TB treatment, have been found to be ineffective. Current legislation and its applications should be revised to take into account the most important international commitments, standards and best practices.

11. Support for TB patients should be urgently scaled up and integrated under the Ministry of Labour and Social Protection in order to assist treatment completion in outpatient settings.

12. All cases identified through drug susceptibility testing, including the backlog of MDR-TB patients, should be properly recorded in the laboratory register and also reported and recorded in the oblast MDR-TB register and cross-checked by the National TB Programme.

13. The supply of all drugs required to complete the treatment of each MDR-TB patient should be guaranteed.

14. The basic salary and bonuses of all health workers involved in TB care should be increased to reflect their higher occupational risk. Occupational disease and death insurance should be provided. Financial incentives should be provided for health workers involved in TB care, including primary health care workers, and be linked to their patients' treatment adherence.

15. Noninfectious TB patients employed in jobs in contact with the public (health-care workers, teachers, etc.) should continue receiving their disability benefit after their discharge from hospital and until completion of treatment and cure. The criteria for limiting their return to work should be revised.

16. Hospitalization of children should be restricted to severe forms of TB and not used for those with BCG complications. High-quality BCG vaccine should be procured.

17. The indicators in the health-care system performance tool used by the Ministry of Health to monitor National TB Programme performance should be revised and include MDR-TB outcomes in accordance with WHO recommendations.

18. The two parallel systems for TB recording and reporting should be merged into a single system in accordance with international standards.

19. A separate electronic database should be established as soon as possible for monitoring MDR-TB case detection and treatment. This should become part of the national TB register once it is finalized and introduced countrywide.

20. All patients with a history of previous TB treatment and currently starting Category II treatment, which is ineffective for many of them, should be considered as a priority for rapid drug susceptibility testing, and their treatment adjusted based on the test results.

21. The follow-up of patients after their treatment completion and cure should be abandoned.

22. After discharge from hospital or release from prison, the patient's complete medical documentation (treatment cards, bacteriology, X-rays, etc.) should follow him/her on referral to any other treatment facility.

23. Effective collaboration should be established between different ministries involved in MDR-TB prevention, treatment and care, e.g. the Ministries of Health, Labour and Social Protection, Internal Affairs, Defence, Transport, Education, Economy and Finance. The National Interagency Coordination Council of TB Control should be reactivated, with the National TB Programme acting as its Secretariat.

24. Effective collaboration should be ensured between national TB and HIV/AIDS programmes at all levels by establishing TB/HIV coordinating bodies which should operate on a permanent basis and have a clear mandate with stated objectives and terms of reference. Existing interdisciplinary HIV and TB bodies, from national to rayon levels, should be merged or plan joint TB/HIV meetings and activities.

25. In the penitentiary system, TB diagnosis and treatment, including TB/HIV, and airborne infection control must be improved for detainees. The collaboration between the Ministry of Health and the Ministry of Internal Affairs should be formalized as soon as possible to ensure a continuum of care for those TB patients moving from the penitentiary to the civilian system.

26. A national advocacy, communication and social mobilization (ACSM) strategy should be developed jointly with nongovernmental organizations and patients' representatives, including efforts to involve local governments and policy-makers, patient-centred approaches and involvement of patients and nongovernmental organizations. A national ACSM action plan should be formulated accordingly.

27. An operational research agenda should be developed, outlining priority topics to be studied, identifying key investigators and including adequate financial resources that will lead to improved and effective programme performance.

International partners

28. The United Nations Development Programme (UNDP), together with the National TB Programme and in coordination with the Global Fund, should reprogramme available funds in order to scale up MDR-TB treatment and patient support.

29. Other international partners to continue their assistance and support.

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Swedish Institute for Communicable Diseases, Stockholm, Sweden
Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland
United Nations Development Programme, Minsk, Belarus

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Abbreviations

ACSM	advocacy, communication and social mobilization
AIDS	acquired immunodeficiency syndrome
BCG	bacillus Calmette-Guerin
BelMAPO	Institute for Postgraduate Medical Education, Minsk
BSMU	Belarusian State Medical University
CD4	CD4+ T lymphocyte count to measure immune function
CIS	Commonwealth of Independent States
DOT	directly observed treatment (for TB)

DOTS	the basic package that underpins the WHO Stop TB Strategy
ECDC	European Centre for Disease Prevention and Control
FTE	full-time equivalent
GDP	gross domestic product
GLC	Green Light Committee
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
HIV RNA	HIV nucleic acid
KAP	knowledge, attitudes and practices
MDR-TB	multidrug-resistant tuberculosis (resistant to, at least, isoniazid and rifampicin)
MGIT	mycobacteria growth indicator tube
NTP	National TB Programme
PAL	practical approach to lung health
PAS	*p*-aminosalicylic acid
PLHIV	people living with HIV
RSPCPT	Republican Scientific and Practical Centre for Pulmonology and TB
SES	Sanitary Epidemiological Service
TB	tuberculosis
TB/HIV	HIV-related tuberculosis
TST	tuberculin skin test(ing)
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
UVGI	ultraviolet germicidal irradiation
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

1. Introduction

Belarus is a priority country for tuberculosis (TB) control in Europe and is included among the 27 high-burden multidrug-resistant (MDR) TB countries in the world. In 2010, according to the latest estimates of the World Health Organization (WHO), Belarus had a TB incidence (all forms) of 70 (57–85) cases per 100 000 population, a prevalence of 98 (38–170) per 100 000 and a mortality due to TB of 11 (6.3–17) per 100 000. The drug resistance survey completed in the city of Minsk in December 2010 found MDR-TB in 35% and 76%, respectively, of the newly diagnosed and previously treated TB cases (*1*). These rates were the highest ever documented in the world. HIV coinfection is estimated to be present in 3.6% of TB patients (2010). In 2009 (latest treatment outcomes reported to WHO), 64% of new TB patients were treated successfully, 10% died, 4% failed treatment, 1% defaulted from treatment and 20% were not evaluated.

In 2008–2010, a National Coordinating Working Group worked to update national TB policies and guidelines according to international recommendations and to support the effective implementation of the two TB grants received from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) in Rounds 6 and 9. In consideration of the revised TB policies and guidelines and the need to evaluate their implementation in the light of the recently documented high rates of MDR-TB, the Ministry of Health of Belarus decided to undertake an external review of the National TB Programme. In June 2011, it asked the WHO Regional Office for Europe to assist in the organization of the review.

The review took place from 10 to 21 October 2011, with the participation of 11 international and nine national experts, and limited participation by five other experts (Annex 1). The review team analysed the relevant documents available (publications, mission reports, etc.), conducted site visits (of relevant institutions and facilities) and interviews (with policy-makers, health providers and beneficiaries, general population, main national and international partners) at national level as well as in four areas selected for their epidemiological status and geographical distribution: Minsk city, Minsk oblast (region), Gomel oblast and Vitebsk oblast. An overview of the activities and the programme of the review are contained in Annex 2. During the first week, the review members were organized in four field teams, each of them coordinated by an international expert (Annex 3). The second week was spent by all reviewers in Minsk in meetings and visits at central level and in working on the various sections of this report. The review was also used as an opportunity to conduct the annual monitoring visit on behalf of the Green Light Committee (GLC).

The main findings and recommendations of the review were conveyed to the First Deputy Minister of Health on the last day of the review. As part of the debriefing, the review team invited the Ministry of Health to apply to the Global Fund Round 11 for a TB grant (at that time, the call for applications had not yet been cancelled) and proposed specific action for this process, as already discussed with international partners.

2. General information

Belarus is bordered by Lithuania and Latvia in the north, the Russian Federation in the east, Ukraine in the south and Poland in the west. It is a fertile, flat country crossed by three major rivers (Neman, Pripyat, Dnieper) and with many streams and lakes, some tracts of marshy land and large forests.

The population of Belarus has fallen from 10.2 million in 1990 to 9.48 million in 2009. Seventy-two per cent of the population live in urban areas. There are six administrative regions or oblasts (Brest, Gomel, Grodno, Mogilev, Minsk, Vitebsk) subdivided into 121 districts or rayons. Each oblast has an oblast council elected by the residents and an oblast administration appointed by the President. Each rayon has a rayon council and a rayon administration. The capital city is Minsk, which is divided into nine rayons.

Most of the Belarusian economy is directly controlled by the State, although private business, including foreign-owned business, is expanding progressively. The biggest exports are heavy machinery (especially tractors), fertilizers, timber and wood products, textiles and leather, agricultural products and energy products. Oil is imported from the Russian Federation. After a period of steady growth, the economy in Belarus has been severely affected by the recent global financial crisis, with the result that its national currency was devalued by 180% between March and October 2011 (*2*).

In 2009, the average life expectancy at birth in Belarus was 64.7 years for men and 76.4 years for women. Leading causes of mortality were cardiovascular disease (591 deaths per 100 000 population), external causes such as accidents, poisoning, injuries (139 per 100 000) and cancer (164 per 100 000) (*3*). High levels of alcohol consumption and smoking are key public health challenges in Belarus. More than 70% of the radioactive pollution from the Chernobyl nuclear accident in neighbouring Ukraine in 1986 fell on the southern part of Belarus and contaminated large areas of arable land.

3. TB epidemiology

Belarus is one of the 18 high-priority countries for TB control in the WHO European Region (*4*), with an estimated TB incidence of 70 (range 57–85) new cases, estimated prevalence of 98 (38–170) cases and estimated mortality of 11 (6.3–17) deaths per 100 000 population (2010) (*5*). Translating rates into absolute numbers, it is estimated that 6800 (5500–8200) new TB cases and 1000 (600–1600) deaths due to TB occur every year in Belarus. Over the last five years, the estimated incidence and prevalence of TB have slightly decreased, while mortality has remained the same. In 2010, the total number of TB cases notified by the National TB Programme was 5554 (*6*), of which 5003 (89%) were new cases and relapses. Among the new cases reported by sex, the male:female ratio was 2:3. The peak of TB notification was between 45 and 54 years of age in men and between 35 and 44 years of age in women.

Belarus is also listed among the 27 MDR-TB high-burden countries in the world (*7*). The findings of the latest drug resistance survey (*8*) (performed countrywide in 2010–2011 after the survey in Minsk city and with results finalized only after the review of this report), indicate a MDR-TB rate of 32.3% (29.7–35.0%) and 75.6% (72.1–78.8%), respectively,

among newly detected and previously treated TB cases, which are the highest documented rates in the world. XDR-TB was found in 11.9% (95% CI: 9.7–14.6) of the MDR-TB patients. Translating rates into absolute numbers, it is roughly estimated that 3100 (2300–4000) new MDR-TB cases occur every year in Belarus.[1]

HIV is a concentrated epidemic in Belarus, with an estimated prevalence of 0.3% (0.2–0.3%) among adults and 10.7% ±0.7 among people who inject drugs (*9*). New HIV infections increased from 467 to 559 during the first half of 2010 and 2011, respectively. HIV prevalence among new TB cases is estimated at 3.6% (range 3.1–4.2%), i.e. 250 (200–310) new TB/HIV cases per year, of whom 187 (60–93%) were detected in 2010. HIV counselling and testing have countrywide coverage.

Main recommendation

3.1 MDR/XDR-TB should be considered a public health emergency in Belarus and preventing and combating it a top-priority intervention for the country and the WHO European Region.

4. National TB Programme: achievements, strategies, structure and resources

The National TB Programme reported 5554 TB cases registered in 2010 to the surveillance network run by WHO and the European Centre for Disease Prevention and Control (ECDC) (*6*), of which 5003 (89%) were new cases and relapses. Therefore, the National TB Programme achieved in 2010 a TB case-detection rate (all new TB cases) of 74% (61–91%) compared with the WHO estimates. The latest treatment success rates reported by the National TB Programme (2009) among newly diagnosed and previously treated laboratory-confirmed sputum-positive pulmonary TB cases were 64% and 42%, respectively. MDR-TB treatment cohorts were not evaluated. Low treatment success rates can be explained by the high rates of MDR-TB in the country.

Before the latest drug resistance survey, 1670 (1570–1800) new MDR-TB cases were estimated among the new and retreatment TB cases notified in 2010 to WHO. Of these, 1576 were notified and placed on treatment with second line anti-TB drugs; only 200 (13%) started treatment with anti-TB drugs procured through GLC. Based on the latest countrywide drug resistance survey, the estimated number of new MDR-TB cases among the notified TB cases is 2300 (2150–2450), a much higher figure which challenges the capacity of the National TB Programme to provide universal diagnosis and treatment.

The Ministry of Health has the overall responsibility for TB control in the country. It undertakes this function through the Republican Scientific and Practical Centre for Pulmonology and Tuberculosis (RSPCPT) in Minsk and the health department of the oblast executive committees. The Department of Epidemiology, Prevention and Organization of TB Care of the RSPCPT can be considered the central unit of the National TB Programme, with

[1] These estimates are calculated by applying 32.3% (29.7–35.0%) to 5900 (4800–7100) estimated new TB cases (all forms) and 75.6% (72.1–78.8%) to 1640 (1330–1980) estimated TB cases for retreatment; the numbers are derived by applying the same proportions to the total cases actually notified and the total cases estimated, i.e. the new cases being 87% of the total new and relapse cases and the proportion of retreatment cases being the same among notified cases and estimated cases.

functions of guidance, monitoring and supervision of TB services both directly and through the oblast TB coordinators. The oblast health authorities are responsible for the delivery of TB services in the same way as any other health service. The Ministry of Internal Affairs runs a parallel system of health care, including TB services, in the penitentiary system. The Council of Ministers recognizes TB control as a cross-cutting public health intervention extending through other ministries and government agencies and has set up the National Interagency Coordination Council of TB Control at central level and an oblast executive committee in each oblast, including Minsk city, with similar functions of coordination. As part of the requirements of the Global Fund, the Country Coordinating Mechanism was set up in 2006 to include representatives of the Ministry of Health, the National HIV Programme, National TB Programme, international partners and representatives of civil society (currently active only in relation to HIV). The Country Coordinating Mechanism is led by the Vice Prime Minister.

In 2010, the expenditure for TB control was 2.1% of total expenditure on health, with 95% of funds coming from the Government and 5% from donor funding. Eighty-seven per cent of total TB expenditure is used for hospital treatment, 12.6% for ambulatory treatment and 0.4% for prevention. Donor funding consists mainly of the two Global Fund grants given in Round 6 (US$ 14.8 million for 2008–2012) and Round 9 (US$ 27 million for 2008–2012) (*10*). Government funding is essential for running all TB facilities, paying their staff and ensuring the supply of equipment and commodities, including diagnostics and drugs. Most of these are imported from abroad, and the recent drastic currency devaluation may limit their importation in future, requiring the Ministry of Health to reconsider and possibly increase the budget allocated to the National TB Programme.

Belarus adopted the DOTS Strategy in 2001 and expanded its implementation to cover the whole country by 2005, including the penitentiary system. Since then, the national strategy for TB control has been inspired by the Stop TB Strategy and, more directly, by five-year national strategic plans such as the National TB Programme 2005–2009 (endorsed by the Council of Ministers in Order N° 613 of 9 June 2005) and the National TB Programme 2010–2014 (endorsed by the Council of Ministers in Order N° 11 of 8 January 2010). A National Coordinating Working Group has been working in 2008–2010, with the support of WHO and UNDP, to update national TB policies and guidelines according to international recommendations.

Anti-TB control interventions are delivered through a network of dedicated TB facilities and primary health care services. There are 24 TB hospitals in the civilian system, with a total capacity of 4605 beds, and one TB hospital in the penitentiary system with 1860 beds (including 160 beds for MDR-TB patients). In recent years, 740 beds in eight hospitals have been reassigned to MDR-TB patients. For outpatient care, there are six oblast TB dispensaries, 29 rayon TB dispensaries and 132 TB cabinets with a TB doctor located in general polyclinics which provide primary health care in urban areas. In rural areas, primary health care services are delivered by general practitioners working in ambulatories (small rural outpatient clinics) and by feldshers (medical assistants) in feldsher ambulatory practices. Both of these services have been involved in TB control since 2002 (Ministry of Health Order N° 106 of 4 June 2002 on “Instruction on TB diagnostics in adults”). The total number of staff working in TB facilities is 5441, including 473 TB doctors, 40 laboratory doctors (bacteriologists) and 98 laboratory technicians. Of these, 620 persons (including 52 TB doctors) are assigned to MDR-TB inpatient treatment.

Main recommendation

4.1 Funding at central and oblast level should be guaranteed for priority interventions, such as early diagnosis of MDR-TB cases, uninterrupted supply of quality anti-TB drugs and TB infection control.

5. Case-finding and diagnosis

Case-finding

Active case-finding

Active case-finding through annual mass screening of the general population has always been seen as a top priority for TB control in Belarus, as a means for early detection, and hospitalization of cases is intended to interrupt TB transmission in the community. Primary health care providers, such as general practitioners in rural areas and community paediatricians and internists (therapeutists) in cities, are responsible for mass screening using tuberculin skin testing (TST), chest X-rays and other tests.

Tuberculin skin testing is performed annually on all children aged 1–16 years, aiming at detecting positive cases who will receive isoniazid preventive therapy and negative cases who will be revaccinated with BCG at seven and 14 years of age (see section on Childhood TB below). The new Ministry of Health Order N° 803 of 8 August 2011 on "Approval of instructions on tuberculin diagnosis among children", to be implemented from January 2012, limits annual tuberculin skin testing to groups of children at higher risk of TB: children in contact with a new TB case; children without a scar showing past BCG vaccination; children with immunodeficiency, including HIV infection; children of migrant parents from TB high-burden countries; handicapped children under institutional care; and children from socially vulnerable families.

Starting from the age of 17 years, large parts of the population are screened annually by chest X-ray (mostly digital) in polyclinics following referral by the primary health care doctor or self-reporting. In addition, 93 mobile units equipped with digital technology are used to cover rural areas. Ministry of Health Order N° 106, dated 4 June 2002, on "Instruction on TB diagnostics in adults" considers two target groups of population for TB screening – those with a potential risk of transmission within the community because of their occupation and those at higher risk of developing TB.

- *Population with potential risk of TB transmission to community:* workers in medical facilities and elderly people's homes, pharmacies and the pharmaceutical industry, educational institutions and libraries, food factories, toy factories, workers in the municipal sector who deal with the public (shop assistants, hairdressers), dairy farms, the water supply industry, hotels and hostels, transport (taxi drivers, train conductors, etc.); all students from the age of 17 years.

- *Population at special risk of developing TB* (three subgroups):
  - people at social risk of TB: homeless people, migrants, ex-prisoners, persons living in elderly people's homes, alcoholics and drug users, army recruits;

- people at medical risk of TB: people living with HIV, drug addiction, psychiatric disorders, diabetes mellitus, chronic gastrointestinal diseases, silicosis, chronic obstructive pulmonary disease, pleuritis, major post-TB lung residuals, cytostatic or radiological treatment, cachexy, period after delivery, exposure to Chernobyl radiations;
- TB contacts: people in contact with infectious TB cases (at home or professionally), on farms with endemic *Mycobacterium bovis*, with prisoners or former prisoners for two years following their detention.

The first group is estimated to be around 1.1 million people (11.6% of the total population); the second group is estimated at 3.8 million people (40% of the total population). Ministry of Health Order N° 106 was partly superseded by Ministry of Health Order N° 92 on "Organization of outpatient care follow-up of adult population", dated 12 October 2007, and then by Ministry of Health Order N° 51, dated 1 June 2011, on "Amendments to the Order of the Ministry of Health on the organization of outpatient care follow-up of adult population", which states that all adult persons in Belarus should undergo fluorography every year as part of their general medical check-up. Currently, these orders are implemented simultaneously, implying that fluorography in at-risk groups is "more mandatory" than in the rest of the population targeted for general medical check-ups.

In accordance with Ministry of Health Order N° 106, mass fluorography should be supplemented by laboratory investigations such as:

- bacteriological microscopy (three specimens) and culture (two specimens) from nontransportable elderly patients with severe somatic conditions;
- urine culture in people with chronic renal conditions with lumbar pain, dysuria, proteinuria and haematuria; undefined low back pain; patients on haemodialysis or following kidney transplantation; patients with a history of TB; farmers working in areas endemic for *M. bovis*.
- menstrual blood culture in all infertile women before in vitro fertilization and in chronic inflammatory disease of the ovaries.

TB mass screening is extensively practised, reportedly covering 82% of the adult population of the country. In 2010, around 6.5 million fluorography investigations were performed at the cost of about US$ 13 million (estimated cost US$ 2 per fluorography). In Minsk city in the first nine months of 2011, 733 414 fluorography investigations detected 3504 cases of pneumonia, 345 cases of lung cancer, 187 cases of TB, 144 cases of sarcoidosis and 904 cases with unspecified pathology. Therefore, according to these data, one TB case was detected for every 3922 fluorography investigations, at the high cost of US$ 7844 per case. Moreover, international evidence suggests that lung cancer can be prevented far more effectively by a good tobacco control programme than by early detection through mass fluorography. The fact that pneumonia was frequently detected may indicate that many patients were self-reporting, seeking care at primary health care level, rather than asymptomatic people targeted for mass fluorography. The review team is also concerned by national statistics showing overdiagnosis of non-bacteriologically-confirmed TB cases (pulmonary and extrapulmonary). This situation is well known to the National TB Programme, which introduced an Internet-based system of fluorography cross-checking in Minsk city, linking primary health care polyclinics and TB dispensaries. In 2011, it set up a special consilium (expert panel) for diagnosis in non-bacteriologically-confirmed TB suspects at RSPCPT. However, overdiagnosis of TB is still a problem, especially outside the city of Minsk.

Again, the high costs and workload, especially in laboratories, involved in active case-finding are not balanced by increased or earlier detection of TB cases. At the time of this review, the Ministry of Health was also considering revising the existing policies and limiting active case-finding to specific risk groups.

Passive case-finding

Passive case-finding means conducting TB investigations on those patients self-reporting to primary health care facilities or directly to TB facilities. As per Ministry of Health Order N° 106, all respiratory patients with a cough lasting more than two weeks should have a chest X-ray, depending on the available local budget and equipment, and bacteriological examination of three samples of sputum. All TB-related investigations are free of charge. If suspected or diagnosed with TB at primary health care level, the patient still needs to be referred to a TB hospital for a new set of investigations and final diagnosis.

The detection of infectious TB cases through passive case-finding is seen by many professionals as the result of late diagnosis and failure of mass screening.

Diagnosis

Laboratory

The national network of TB laboratories consists of the National TB Reference Laboratory (Level IV laboratory) in Minsk, seven oblast TB reference laboratories (Level III) located in Brest, Gomel, Grodno, Minsk, Mogilev, Orsha (this laboratory serving the penitentiary system) and Vitebsk, 33 TB laboratories at rayon level (Level II) and around 150 laboratories (Level I) below rayon level.

The National TB Reference Laboratory performs smear microscopy (light microscopy and fluorescence microscopy, recently introduced), culture (solid- and liquid-based), identification of *M. tuberculosis* and some other relevant species of mycobacteria, drug susceptibility testing of first and second line anti-TB drugs (Bactec MGIT and Lowenstein-Jensen absolute concentration). Rapid testing is implemented (Bactec MGIT and line probe assay). As the national TB reference laboratory, it is also in charge of the monitoring and supervision of the national laboratory network and the training of staff. It is connected to the Supranational TB Reference Laboratory in Stockholm, Sweden, which provides the external quality panels that can be used in all laboratories performing drug susceptibility testing in the country. Proficiency testing is ensured through the exchange of a 20-strain panel, subsequently distributed to all other laboratories performing drug susceptibility testing in the country. A good correspondence of the results between laboratories has been observed since the start of the external quality assurance in 2009, which confirms the high-quality work of the national laboratory network.

The oblast TB reference laboratories perform smear microscopy (mainly light microscopy), culture (solid and, in some settings, liquid culture), identification of *M. tuberculosis* and drug susceptibility testing of first and second line anti-TB drugs (Lowenstein-Jensen absolute concentration and, in some settings, Bactec MGIT). They are responsible for external quality assurance and supervision for all smear microscopy performed in all laboratories in the oblast. The laboratories at rayon level are usually located in the rayon hospitals and perform smear microscopy and culture. All positive cultures are then transferred to the oblast laboratories for

verification and drug susceptibility testing. These laboratories provide external quality assurance for the smear microscopy performed in the lower laboratories (rechecking of all positives and 10% of negative slides, sending smear panels twice a year) and supervision. The lowest level of laboratories are microscopy centres located in primary health care institutions. These centres often merely collect and transport sputum samples to the closest laboratory at a higher level.

Over the last three years, the national laboratory network has been downsized (reducing the number of Level III laboratories from 84 to 33) to favour appropriate levels of biosafety and quality of work. Many laboratories were also supplied with modern equipment of a high international standard. However, too many laboratories at district level are still housed in outdated facilities without a proper ventilation system. In some laboratories, the equipment is suboptimal. These conditions limit the recruitment of new laboratory staff and cause many positions to remain unfilled. The implementation of existing plans to upgrade several laboratories under the Global Fund grant should be considered a priority.

The introduction of more modern microbiological and molecular methodologies is highly urgent in Belarus. This can drastically shorten the turnaround time for the detection of TB and MDR-TB patients and provide guidance on the most appropriate clinical management and infection control. Moreover, modern laboratory methodologies can improve working conditions and performance and encourage new staff to take up the vacant posts. During the review, international and national laboratory experts developed a diagnostic algorithm that considers the use of the new laboratory tests to be introduced in Belarus soon under the Global Fund grant.[1] A plan is being drawn up to redesign the national TB laboratory network, incorporating the new laboratory techniques and their different distribution of the workload.

Bacteriological confirmation of TB cases in Belarus stands at around 50%, when the 27%–29% of cases positive on direct microscopy are combined with the 23% positive only on bacteriological culture. This figure is unexpectedly low, considering the extensive laboratory investigations conducted in the country. The review team explains the very low bacteriological confirmation of TB cases in some laboratories as being due mainly to their excessive workload, since too many suspected TB patients are investigated and unnecessary investigations are requested (e.g. urine, menstrual blood). Bacteriological investigation of surgical specimens is not performed in many eligible cases. At the time of the review, new guidelines excluding urine and menstrual blood testing had already been developed by the RSPCPT in its "Guidelines on TB diagnosis and treatment for primary health care facilities" and submitted for Ministry of Health approval.

In some primary health care facilities, sputum containers were unavailable, or of inappropriate size, or inappropriately sent to the TB laboratory. In the TB laboratories, the review team noticed that the critical concentration of isoniazid used to test resistance is 0.1 mg/L (as per international recommendations) for liquid culture with Bactec MGIT and 1 mg/L for culture in solid media. Using this very high concentration, mycobacteria with low isoniazid resistance are classified as susceptible and the overall isoniazid resistance level may have been underestimated. The stocks of pure drug substances for preparing drug susceptibility testing media were sometimes found with no indication of their expiry date, making it impossible to know their potency. With the exception of the National TB Reference Laboratory, all isolates

[1] The Global Fund grant is intended to develop the capacity for rapid MDR-TB diagnosis in the laboratories of RSPCPT, all oblast TB dispensaries and the IK-12 prison hospital by supplying 5 BACTEC/MGIT and eight Xpert MTB/RIF machines, to be procured by the beginning of 2012.

are discarded by the laboratories after a few months, a practice which makes it impossible to build up a national collection of mycobacteria strains.

Recording in laboratories is still paper-based. The major weakness in the present system is the recording of samples rather than patients investigated, which makes difficult to assess individual cases as well as overall laboratory performance. In some of the TB laboratories visited by the review team, the request forms for laboratory investigation were not filled in properly, allowing mistakes to occur in the registration of cases. An electronic laboratory register is currently under development.

Radiology

Radiology machines are available in all polyclinics and TB facilities at district level. However, in contrast with the widespread availability of radiological digital equipment in the general health-care sector, equipment in the TB facilities is not always up to date. The review team visited TB facilities where there were patients with poor quality chest X-rays and with no previous X-ray films, which may lead to clinical mismanagement of cases, especially when patients are returning to treatment.

Main recommendations

5.1 Ineffective interventions such as annual mass screening through tuberculin skin testing and fluorography should be discontinued. The cost savings can be reallocated to support priority interventions for MDR-TB control.

5.2 The new policy on active TB case-finding among children (Ministry of Health Order N° 803 of 2011) should be implemented in practice and its impact evaluated countrywide.

5.3 Modern microbiology and molecular laboratory techniques should be introduced urgently to create improved and more rapid TB diagnostic services. The new technology should be properly organized and evaluated for appropriateness, sensitivity and specificity, and cost-effectiveness.

Other recommendations

5.4 Current policies indicating the targets for active TB case-finding should be revised to exclude professional groups harmless to the community, according to the current evidence, and focus on population groups at higher risk of TB (Ministry of Health Order N° 106 of 2002); annual universal fluorography should be also reconsidered (Ministry of Health Order N° 51 of 2011).

5.5 Efforts should be made to identify and discontinue unnecessary routine screening of samples (e.g. urine, menstrual blood) or groups of population very unlikely to contract TB. Cost savings can be reallocated to support priority interventions for MDR-TB control.

5.6 A new laboratory algorithm (proposal provided by the review team during its visit) should be considered in order to incorporate the more rapid TB diagnostics tests

available for rapid testing and guide the most appropriate clinical management of patients and infection control.

5.7 For the introduction of new laboratory techniques, cultures and drug susceptibility testing should be progressively centralized at Level III laboratories. The capacity of these laboratories should be strengthened while the number of Level II and Level I laboratories should be decreased as soon as a proper system for collection and transport of samples has been set up.

5.8 A backup system for the rapid detection of TB and MDR-TB should also be considered, in case the molecular techniques cannot be introduced because of lack of funds or for any other reason. This system can be based on low-cost WHO-recommended technologies such as nitrate reductase assay or microscopic observation drug-susceptibility (MODS) culture.

5.9 Biosafety must be urgently improved in most TB laboratories. A comprehensive assessment should be carried out and followed by an action plan to address the problems identified. If the necessary funds to upgrade Level II laboratories are not available, the Ministry of Health should consider converting these laboratories to Level I, perhaps equipping them with a system for rapid diagnosis of TB and MDR-TB (Xpert MTB/RIF).

5.10 Routine and sustainable service and maintenance should be provided for biosafety cabinets. Daily monitoring of airflow is recommended. Certification of proper functioning of biosafety cabinets should be conducted urgently and repeated at least annually, and whenever a unit is moved within the laboratory. The technical expertise needed should be made available within the national TB laboratory network.

5.11 Standard operating procedures should be developed and implemented. Basic quality criteria should be established for the different levels of the national TB laboratory network. Fulfilling these criteria (after receiving relevant training and support) could form the basis of an accreditation system.

5.12 The capacity of central National TB Programme laboratory expertise should be strengthened by establishing a national expert group for TB bacteriology. Such a group could be made up of the heads of the oblast TB laboratories and chaired by the head of the National TB Reference Laboratory. This expert group should meet at least twice yearly, as has been done successfully in other countries.

5.13 A human resource development plan should be drawn up to meet the future demands of staff and identify and offer relevant training to staff members (e.g. in laboratory management for heads of Level III and IV labs). Also new demands for technical knowledge, e.g. in molecular methods, should be identified and policies developed to meet this demand.

5.14 A checklist for supervision of TB laboratories should be drawn up.

5.15 Isoniazid susceptibility should be tested with the concentration at 0.1 mg/L, irrespective of the media used. Patients showing resistance at this concentration should be considered to have isoniazid-resistant TB.

5.16 The production of culture and drug susceptibility testing media should be centralized, with the National TB Reference Laboratory responsible for purchasing pure substances and supplying them to Level III laboratories for the preparation of drug susceptibility testing media. This system will prevent the use of out-of-date substances and create cost savings.

5.17 Selected clinical isolates from all over the country should be collected and kept in a national strain database that could act as a reference for future examinations and operational research.

5.18 Primary health care facilities should be given incentives to detect more TB cases (and their contacts) and to treat them successfully**.**

5.19 Primary health care facilities should be supplied with the basic diagnostic equipment needed for the collection and transport of sputum samples from TB suspects (sputum containers, preservatives, transport boxes). A system of transportation should be established to send sputum samples from primary health care facilities to TB laboratories.

5.20 Request forms for laboratory examinations should be filled in properly (by doctors) to prevent mistakes in case registration and decrease the unnecessary workload of the laboratories. Previous chest X-ray examinations should be made available and used for proper case management.

5.21 Bacteriological examinations from surgical material should be provided to ensure proper case management (diagnosis, TB activity, treatment duration, drug susceptibility testing, etc).

5.22 High-quality X-ray machines should be provided for TB facilities which need them.

6. Treatment and case management

Ministry of Health Order N° 11 of 12 January 2009, entitled "Clinical manual on treatment of TB and MDR-TB", describes the national treatment guidelines, which are updated according to WHO recommendations. All patients are subjected to drug susceptibility testing. All new patients start the Category I regimen (as defined by WHO), with six months of daily isoniazid and rifampicin and with pyrazinamide and ethambutol in addition during the initial two-month intensive phase of treatment (2HRZE/4HR). Previously treated patients are prescribed the Category II regimen, with seven months of daily isoniazid, rifampicin and ethambutol, plus pyrazinamide during the initial three-month intensive phase of treatment and streptomycin for the first two months (2HRZES/1HRZE/5HRE). When the drug susceptibility testing results are received, the treatment may be changed to an individualized regimen including the required second-line anti-TB drugs (Category IV regimen). All cases without a bacteriologically confirmed diagnosis are considered by an expert commission. The number of patients without a bacteriologically confirmed diagnosis has decreased over the years. TB patients are usually admitted to hospital during the intensive phase of treatment, or for longer, until their bacteriological sputum culture becomes negative. Then patients are referred to TB dispensaries for continuation of their treatment, or to primary health care practices if they live in a rural area. Since the issuance of Ministry of Health Order N° 517 of 11 June 2008 on "Organization of supervised treatment of TB outpatients", directly observed treatment (DOT) has been provided countrywide. Clinical follow-up is supervised by the TB specialist. When not staying in hospital, patients may receive enablers and incentives (mainly under the Global Fund project) – see below.

In the period 2007–2011, thanks to Global Fund grants, a social package was provided for 7508 outpatients in all 24 oblast TB dispensaries in the country. Patients with drug-susceptible TB (Round 6) and drug-susceptible or MDR-TB (Round 9) benefited from a social package after signing an agreement with the oblast TB dispensary which lays down each party's responsibilities in ensuring treatment adherence. Each patient is entered on a "social support card" which is maintained in parallel to the "TB treatment card". The social package consists of: 1) one voucher, equivalent to approximately US$ 8, distributed every two weeks and exchangeable for various food and hygiene items in agreed shops; and 2) one transport ticket valid for return public transport daily from the patient's residence to the facility and back, also valid for two weeks. The transport ticket is returned when it is used up in order to prove that it has not been sold. If a patient misses more than five appointments in a row, the voucher is suspended; in the case of further nonadherence, sputum-smear-positive patients are subjected to involuntary isolation and treatment. Financial incentives are also given to staff providing TB outpatient care, not linked to treatment outcome but to number of patient visits (equivalent to US$ 0.20 for the nurse and US$ 0.10 for the doctor per patient visit).

These incentives and enablers were inspired by practices implemented in the Russian Federation (Tomsk oblast). The system encountered resistance from many shops which refused to join the voucher scheme and have TB patients coming in. Eventually, only a few shops participated, including only two shops for the whole of Minsk city. It was not considered practicable to deliver the social package from the TB dispensaries, because they have no capacity to manage food items.

The review team found many discrepancies between the national guidelines described above and actual clinical practice, mostly because the training programme scheduled under the

Global Fund grant was not completed. Many doctors still prescribe incorrect diagnostic procedures and treatment regimens, especially for suspected extrapulmonary TB patients. For many of these, the diagnosis is based on large-scale urine testing and old-fashioned tests (e.g. Koch test,[1] culturing of menstrual blood) which cause unnecessary work for the laboratories and frequently leads to overdiagnosis. Many patients visited in the Extrapulmonary Department of RSPCPT actually did not have TB. Treatment with one or two anti-TB drugs is sometimes used for diagnostic confirmation.

The levels of MDR-TB documented in Belarus are among the highest ever recorded globally. In the light of these findings, the Category II treatment regimen appears inadequate and should be replaced by empirical treatment with second-line anti-TB drugs, waiting for drug susceptibility testing results and guided by the countrywide drug resistance survey profile, or by prioritizing rapid drug susceptibility testing followed by individualized treatment. The second option seems more appropriate in Belarus for a number of reasons, including the risk that empirical treatment may increase resistance to second-line anti-TB drugs. Translated into action, it is recommended that all patients with a history of previous TB treatment should be considered a priority for rapid drug susceptibility testing and their treatment adjusted according to the results.

Patients are usually hospitalized more often and for longer than necessary, partly because the budget allocated to hospitals is based on the number of beds and their occupancy rate (see section on Health system and TB control). Other reasons claimed are the poor treatment compliance by "difficult" patients outside hospital and the need to offer temporary shelter to "social" patients (see section on Other vulnerable populations and social determinants).

Moreover, TB patients receive a disability benefit that is withdrawn shortly after their hospital discharge, which is very inconvenient for those patients previously working in contact with the public (see section on TB case-finding and diagnosis) who are not allowed to work during the entire period of their treatment (Ministry of Health Order N° 47 issued on 28 April 2010 on "Instructions on mandatory medical examinations of working people and amendments of some resolutions of the Ministry of Health of the Republic of Belarus"). The result is that many of these patients remain in hospital unnecessarily. Some action has already been taken by the National TB Programme, which has submitted a draft order to the Ministry of Health on "Instructions on allowing TB patients to work or study".

Some patients are referred from one facility to another but are not accompanied by their complete medical records, which means that investigations are repeated unnecessarily and sometimes patients are registered wrongly and the wrong treatment is prescribed.

Pursuant to Ministry of Health Order N° 106 of 4 June 2002 on "Improvement of dispensary follow-up and identification of TB patients in the Republic of Belarus", former TB patients are called back for an annual clinical check-up for two years after they have been declared cured. This practice is considered an unnecessary burden.

The review team has two major concerns regarding TB treatment and case management. The first is the unnecessarily long hospitalization that, considering the poor infection control measures in place (see section on Infection control), may be considered a major cause of TB

[1] The Koch test is also performed on women suspected of genital tuberculosis. A standard dose of tuberculin is injected intradermally and then the vaginal mucosa is checked three times (after 24, 48 and 72 hours) for increased infiltration.

superinfection among patients, including superinfection with MDR-TB strains of mycobacteria. The second concern is the widespread use of involuntary isolation and treatment in hospitals (see section on Ethics and human rights). Existing evidence (*11*) shows that scaling up social support for patients can effectively increase treatment completion in outpatient settings and drastically limit the need for involuntary isolation as a last resort. This is also shown by the lower treatment default rate of those patients receiving incentives and enablers (transport vouchers, food parcels) provided under the Global Fund grant. Moreover, patient support by social workers could cost less than hospital care.

Main recommendations

6.1 Inpatient care should be run down and outpatient care encouraged for TB and MDR-TB cases. Nonsevere, noninfectious TB cases should have limited hospitalization.

6.2 All patients with a history of previous TB treatment currently starting Category II treatment, which is ineffective for many of them, should be considered a priority for rapid drug susceptibility testing, and their treatment adjusted based on the test results.

6.3 After discharge from hospital or release from prison, the patient's complete medical documentation (treatment cards, bacteriology, X-rays, etc.) should follow him/her on referral to any other treatment facility. At the end of treatment, all medical documentation should be kept in the oblast TB dispensary of the patient's residence. If the patient is admitted to hospital again, the treating doctor should request the documentation from the previous treatment facility.

6.4 Follow-up of patients after their treatment completion and cure should be abandoned.

6.5 Incentives and enablers (transport vouchers, food parcels, etc.) intended to support treatment adherence in outpatient settings should be scaled up urgently for all TB patients in the country and integrated under the Ministry of Labour and Social Protection.

Other recommendations

6.6 The duration of the intensive phase of treatment in hospital for drug-susceptible cases should be based on smear conversion checked by sputum direct microscopy and should not be unnecessarily prolonged thereafter.

6.7 The diagnosis and treatment of extrapulmonary TB should follow WHO guidelines. Bacteriological investigation from surgical material should be ensured for proper diagnosis and treatment.

6.8 Noninfectious TB patients employed in jobs in contact with the public (health-care workers, teachers, etc.) should continue receiving their disability benefit after their discharge from hospital and until completion of treatment and cure. The criteria for limiting their return to work should be revised.

6.9 A strategy should be developed in order to increase the number of shops where vouchers can be exchanged for food/goods by TB patients. Bottlenecks should be identified and specific interventions undertaken.

6.10 The incentives for medical providers should be linked to treatment outcomes.

7. Childhood TB

New TB cases notified among children (aged <15 years) and among adolescents (10–19 years) stood at 20 and 52, respectively, in 2009, corresponding to a rate of 1.4 and 14.3 per 100 000 population. In 2010, the number of notified cases was 31 and 36, respectively, corresponding to a rate of 2.2 and 10.6 per 100 000 population.

Prevention and control of TB among children have always been given special emphasis in Belarus. Ministry of Health Order N° 143 of 28 July 1992 on "Instructions on tuberculin skin test diagnostics" prescribed annual tuberculin skin testing for all children aged 1-16 years and enrolment on isoniazid preventive therapy for positive cases (see section on Case-finding and diagnosis). Ministry of Health Order N° 76 of 29 September 2006 on "Implementing preventive vaccination" confirmed the BCG vaccination of all newborn babies and revaccination of all children at seven and 14 years of age if they produce a negative result on tuberculin skin testing. More recently, the Ministry of Health issued a new Order N° 83 on 8 August 2011 on "Approval of instructions on tuberculin diagnosis among children", which will be enforced only from January 2012. This stops the second revaccination with BCG at 14 years of age and limits annual tuberculin skin testing and the first BCG revaccination (strongly advised by TB paediatricians) at seven years of age to groups of children at higher risk of TB (TST-negative children under the conditions described above in the section on active case-finding). This Order is expected significantly to decrease the workload of primary health care staff responsible for the above activities, and limit the number of children wrongly prescribed with isoniazid preventive therapy because they are TST-positive following previous BCG vaccination.

TB in children is diagnosed using all tools, including direct microscopy, culture of sputum samples and gastric lavage, if necessary and possible.

In Belarus, all children and adolescents diagnosed with TB are admitted to the Paediatric TB Department of RSPCPT in Minsk, where the review team found all staff to be knowledgeable and following the latest international recommendations. New guidelines for the clinical management of TB in childhood are under development with the assistance of international experts. First- and second line drugs are available, even if not in paediatric drug formulations, and prescribed in the right regimens and doses.

Some areas are still in need of improvement. The low number of children with TB and the high proportion of those confirmed bacteriologically (35%) may indicate late case detection owing to insufficient investigation of contacts. BCG-related complications are reported quite frequently, especially ostitis (76 children had surgical treatment for this in 2010) and may indicate poor vaccine quality. All children have to stay in hospital until completion of treatment: even if they receive some education in hospital, their social life is unnecessarily disrupted when they are no longer infectious, as shown by bacteriological culture, or have

never been infectious because they have an extrapulmonary form of TB. All children with BCG-related complications are also admitted in the Extrapulmonary TB Department and, potentially, exposed to TB infection during their stay. The limited infection control measures and the difficulty of enforcing them in children aged 1–18 years of age increase the risk of cross-infection between children with different TB drug resistance patterns.

Main recommendations

7.1 Hospitalization of children should be restricted to severe forms of TB disease and not used for those with BCG complications.

7.2 High-quality BCG vaccine should be procured in order to prevent the current high rate of adverse reactions.

Other recommendations

7.3 Infection control measures in the Paediatric TB Department of RSPCPT in Minsk should be improved, including the isolation of infectious children and adolescents and limitation of contacts with relatives suffering from infectious TB.

7.4 Outpatient treatment should be preferred for children and organized in such a way that their education and social life are protected as much as possible. Outpatient providers, such as primary health care and TB dispensary staff, should be properly trained.

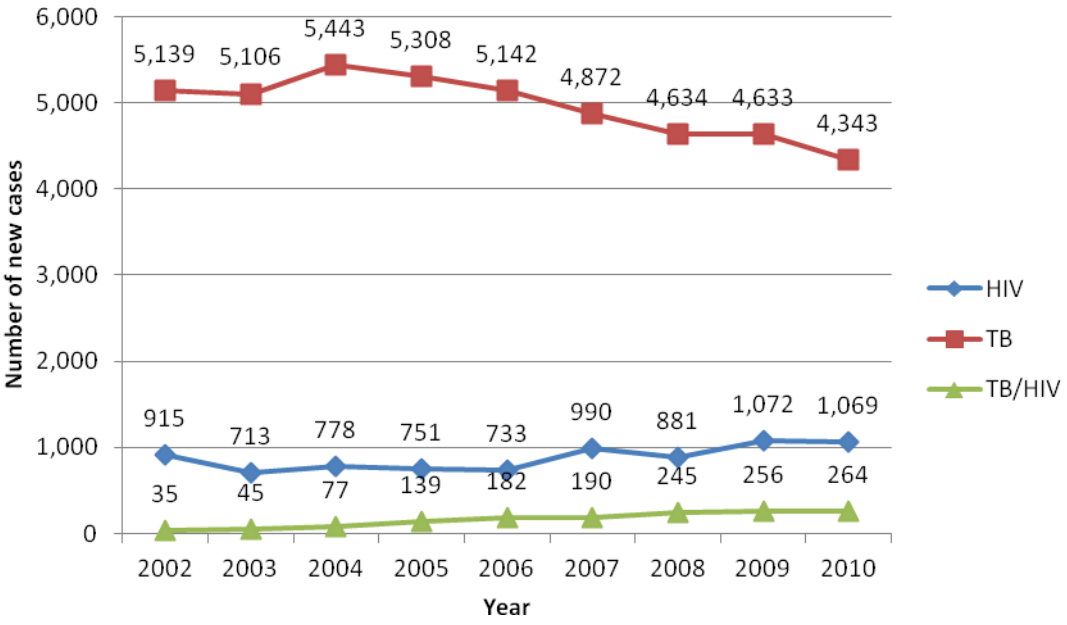
7.5 Children in close contact with TB cases should be carefully investigated to prevent late diagnosis and development of severe TB forms.

7.6 The new national guidelines for TB management in children should reflect the most up-to-date, internationally recommended standards and be finalized soon.

8. HIV-related TB

HIV is a concentrated epidemic in Belarus, with an estimated prevalence of 0.2%–0.3% among adults (2009) (*12*) and 10.7% ±0.7 among people who inject drugs. HIV incidence has increased from 467 to 559 new HIV cases registered during the first half of 2010 and 2011, respectively – an increase of 20%. In 2010, TB was the cause of death of 88 out of 235 people living with HIV (PLHIV) (37.4%). While TB notification was stable or even decreased in recent years, the number of HIV-related TB (TB/HIV) cases increased (Fig. 1).

Fig. 1: New cases of HIV, TB and TB/HIV notified in Belarus, 2002–2010



Until 1 July 2011, a cumulative figure of 1672 TB/HIV cases was reported in Belarus, of which 1274 (76%) were men, 988 (59%) were people who inject drugs and four were children infected with HIV by their mothers. In 2010, the estimated HIV prevalence among TB patients was 4%.

During the period from 2007 to June 2011, 1220 out of 1672 new TB/HIV patients (73%) were already aware of their HIV infection before being diagnosed with TB. A total of 114 out of 293 PLHIV (39%) during January–June 2011 were found to have TB, when their their AIDS status was revealed for the first time. From an ad hoc analysis of the 2010 records, only 264 out of 1069 of the patients enrolled for HIV care (25%) were recorded as having had TB screening during their last visit (*13*). Meanwhile, 5153 out of 5554 TB people (93%) notified in 2010 were already aware of their HIV status, and 25.6% of TB/HIV patients received both antiretroviral therapy and anti-TB treatment (*14*). These data suggest a high frequency of HIV screening among TB patients and limited TB screening and isoniazid preventive therapy among PLHIV, as well as poor collaboration between the national TB and HIV programmes.

The current National TB Programme 2010–2014 and National HIV Programme 2011–2015 do not have a TB/HIV component and run separately with their own management and service delivery mechanisms. This vertical approach could be considered a serious barrier to access to high-quality and timely diagnosis and treatment and the continuum of care.

In 2010, the Ministry of Health established a national working group to draft the national policy for collaborative TB/HIV activities, which was officially endorsed in Ministry of Health Order N° 1217 dated 11 November 2010 “On instruction about organization of treatment and care of patients with HIV/TB”. It states that TB/HIV patients should be treated in TB facilities in consultation with infectious disease specialists responsible for monitoring HIV infection and the prescription of antiretroviral therapy. The Ministry of Health Order also recommends isoniazid preventive therapy in line with eligibility criteria for patients, services

and providers. A new law[1] was issued by the President of the Republic of Belarus after the National TB Programme review documented in this report.

The only nongovernmental organization active in HIV issues in Belarus is the Republican Society of PLHIV. The Society, established in January 2008, has been implementing a project in Gomel oblast, with support from the AIDS Foundation East-West (Netherlands) and the International Treatment Preparedness Coalition (ITPC), where peers gave lectures and hotline telephone counselling on TB treatment. Collaboration with the National TB Programme has been limited so far, but could be expanded, starting with refresher training for the staff of the nongovernmental organization.

Belarus regularly reports on TB/HIV indicators recommended by WHO and included in the annual "Report on Health Sector Response on HIV".[2] This report is produced by the monitoring unit at the Ministry of Health as an attachment to the Declaration of Commitment adopted by the twenty-sixth special session of the United Nations General Assembly on HIV. However, the main indicators on TB/HIV collaborative activities (coverage of antiretroviral therapy and co-trimoxazole and isoniazid preventive therapy for PLHIV) are not reported by the National TB Programme to WHO, indicating a communication gap between the national programmes for HIV/AIDS and TB.

TB screening and diagnosis for PLHIV

Treatment and care for PLHIV in Belarus form part of infectious diseases services. There are HIV outpatient departments in Minsk city and in each of six oblast infectious disease hospitals. There are also HIV outpatient consulting rooms in polyclinics at district level. The infectious disease specialists working in these facilities are responsible for regular check-ups for PLHIV (according to national guidelines and including the monitoring of CD4 and HIV nucleic acid (HIV RNA) levels), provision of antiretroviral therapy, isoniazid preventive therapy and co-trimoxazole preventive therapy and diagnosis and treatment of opportunistic infections.

TB screening is carried out by means of history-taking and clinical examination at every consultation. However, there is no specific routine registration or reporting to monitor this activity. Under national guidelines, PLHIV should also have a chest X-ray at least twice a year at the polyclinic. However, communication between the tertiary level of infectious disease care and the primary level of care (polyclinic) is poor, and PLHIV often do not show up for the check-up. When PLHIV are suspected of having TB during a regular visit to the infectious disease specialist, they are referred to TB services. Communication between these two services is also poor. TB services are the only services legally allowed to diagnose TB, and any investigation carried out elsewhere cannot be accepted and must be repeated by the

[1] A new Law N° 345-3 on "Prevention of diseases posing a threat to the health of the population, HIV" was issued on 20 December 2011 by the President of the Republic of Belarus. This Law explicitly refers to the Ministry of Health Order N° 31 of 13 June 2002 on "Adoption of the list of diseases representing a public health threat". The Law will come into effect when the necessary operational guidelines have been developed. There are initial concerns from the international community about the potential of the Law to increase stigma and discrimination against PLHIV. Moreover, the use of involuntary isolation and treatment is increased for a number of conditions with different types of transmission and public health threat, including TB.

[2] Indicator E2: percentage of estimated HIV-positive incident TB cases that received treatment for TB and HIV; indicator E3: percentage of adults and children newly enrolled in HIV care given treatment for latent TB infection (isoniazid preventive treatment); indicator E4: proportion of adults and children enrolled in HIV care who had their TB status assessed and recorded during their last visit.

TB specialist. These repeated TB investigations in different services lead to diagnostic delays, frequent patient drop-outs and unnecessary costs. The algorithm for TB diagnosis among PLHIV is not well developed, and available technologies for rapid diagnosis of TB and drug-resistant TB are not used, despite their proven effectiveness in decreasing the high mortality among TB and MDR-TB/HIV patients. PLHIV are not informed or educated about their risk of developing TB, its symptoms and the importance of treatment adherence.

The harm reduction programme in Belarus includes a range of interventions, including needle and syringe exchange, condom distribution, opioid substitution therapy, information-education-communication activities, outreach and other components. However, such services have not incorporated any intervention for TB prevention, early diagnosis or treatment adherence. All people who inject drugs who visit drug addiction dispensaries should undergo a chest X-ray annually (being a vulnerable group as defined in national regulations). However, no clinical screening or education are performed by drug addiction specialists on a regular basis. Although most PLHIV in Belarus inject drugs, there is very limited collaboration between drug addiction, infectious disease and TB services.

Isoniazid preventive therapy among PLHIV

Isoniazid preventive therapy was included in the national HIV/AIDS clinical guidelines in 2008, but actually enforced only after the issuance of Ministry of Health Order N° 1217 of 11 November 2010. This Order defines as eligible for isoniazid preventive therapy those PLHIV found to have latent TB infection, those in close contact with an active TB case, and those with a CD4 cell count <200/ml. Tuberculin skin testing or other tests are not mandatory for the initiation of isoniazid preventive therapy in PLHIV. Pregnancy and previous TB treatment are contraindications for isoniazid preventive therapy. In 2010, 257 out of 1069 new PLHIV (24%) started and completed isoniazid preventive therapy. Nongovernmental organizations are not involved in dispensing therapy. At the time of the review, no isoniazid preventive therapy awareness campaigns had been undertaken among PLHIV.

TB infection control in services for PLHIV

Some administrative infection control measures have been introduced specifically to prevent TB transmission among PLHIV, such as inviting TB specialists to HIV facilities for consultations or organizing TB consultations for PLHIV in TB dispensaries only on specific days. However, TB/HIV patients are usually hospitalized together with other TB patients, a situation in which superinfection with MDR-TB strains may occur.

HIV testing and counselling among TB patients

Belarus has a national policy for mandatory HIV testing for all TB patients, which means that almost 100% of patients are tested for HIV. There are special sections in the TB patient's records about HIV testing (date of test and result) and pretest HIV counselling (date and patient's signature). However, very few TB physicians have been trained in HIV precounselling issues, which is not considered so important because the HIV test is mandatory anyway. An HIV screening test (ELISA) is usually offered within 1-3 days in TB institutions of the TB diagnosis. However, the test result may be significantly delayed, affecting the

clinical management of the patient.[1] The delay is mainly due to the inadequate procedure for HIV testing and diagnosis. HIV testing is centralized at each oblast centre of hygiene, epidemiology and public health, where all blood samples taken from any oblast facility should be sent. Blood samples are not transferred daily. As per national guidelines, an initial positive ELISA test should be repeated and confirmed by a western blot test. The final result is then sent to the AIDS prevention department at the centre for registration in the oblast HIV database. Then an epidemiologist from this department goes to the referring clinic to provide HIV postcounselling and record HIV status in the patient's file. Finally, the infectious disease specialist is invited for medical assessment and prescription of further necessary investigations and antiretroviral therapy.

HIV prevention among TB patients

TB patients do not receive any education on HIV different from that provided for the general population.

Co-trimoxazole preventive therapy among TB patients

Co-trimoxazole preventive therapy is recommended in the HIV/TB section of the national HIV/AIDS clinical guidelines, issued in 2008, when the CD4 cell count is less than 200 or HIV is at clinical stage 3 or 4 (WHO classification), and suspended when CD4 cell count is above 200 for 4-6 months. The guidelines also recommend co-trimoxazole preventive therapy during TB treatment. However, they do not describe how it should be delivered, e.g. where to store drugs, who should provide it (infectious disease or TB specialist), whether it should be provided free of charge to the patient, etc. Ministry of Health Order N° 1217 does not clarify these operational aspects either. Consequently, co-trimoxazole preventive therapy is not provided in practice, as observed by the review team, and not shown in the Reports on Health Sector Response on HIV for 2008–2010.

HIV care and support for TB patients, including antiretroviral therapy

TB/HIV care and support are major elements of Ministry of Health Order N° 1217 and described in the National TB/HIV clinical guidelines developed jointly by infectious disease and TB specialists in 2008. However, the actual collaboration between TB and HIV specialists is not ideal. HIV results are not sent back to the TB hospital in time, consultations by infectious disease specialists are sporadic and delayed, the monitoring of HIV infection (CD4 cell count, HIV RNA) and antiretroviral therapy is not regular. Only seldom do TB or infectious disease services proactively approach one another.

After discharge from the TB hospital, the TB/HIV patient is supposed to be taken in charge by both the TB service (to complete TB treatment) and the HIV service (to follow-up HIV infection and antiretroviral therapy). However, no formal links exist between the two services. While the referral between the TB hospital and TB dispensary is standardized, HIV services are not provided with any TB medical records and are left unaware of the TB status of the patient and its treatment. The recently approved Ministry of Health Order improves the TB/HIV continuum of care, but leaves the decision to see an infectious disease specialist after release from a TB hospital to the patient.

[1] A review of patients' charts has found that more than one month can elapse between taking the blood sample and receiving the result of the HIV test, and even more time between receiving the result and obtaining access to HIV care and treatment.

A TB diagnosis can be reached only by a TB doctor, and this is difficult to organize in an infectious disease hospital where PLHIV are admitted. TB consultations are possible, but challenged by the difficulty of diagnosing smear-negative pulmonary or extrapulmonary forms of TB. TB may remain undiagnosed for some time and treated too late, contributing to the high mortality among TB/HIV patients. Infectious disease specialists look forward to the development of better tools for early diagnosis of TB among PLHIV.

Main recommendation

8.1 Effective collaboration should be ensured between TB and HIV/AIDS national programmes at all levels by establishing TB/HIV coordinating bodies which should operate on a permanent basis and have a clear mandate with stated objectives and terms of reference. Existing interdisciplinary HIV and TB bodies, from national to rayon levels, should be merged or plan joint TB/HIV meetings and activities.

Other recommendations

8.2 TB case-finding (TB screening and diagnosis) should be intensified for all PLHIV at every contact with the health service (infectious diseases, TB, primary health care, opioid substitution therapy), whether routine or for treatment. A formal referral mechanism between services should be established, providing feedback.

8.3 TB specialists, infectious disease specialists and primary health care doctors should be properly trained in the national TB/HIV clinical guidelines. Formal education provided by the Institute for Postgraduate Medical Education (BelMAPO) and medical schools should include TB/HIV, as well as in-service training of health-care workers.

8.4 Patient education should be expanded and enhanced on issues related to both TB and HIV (such as infection control, HIV prevention methods, diagnosis and treatment regimens, outreach and patients' rights).

8.5 PLHIV should have access to rapid diagnosis of TB and drug-resistant TB.

8.6 The eligibility criteria for isoniazid preventive therapy, as well as contraindications, should be updated. A past history of TB and current pregnancy should not prevent the start of isoniazid preventive therapy. Isoniazid preventive therapy should be given irrespective of the degree of immunosuppression, and also given to those on antiretroviral therapy. Adults and adolescents living with HIV who successfully complete their TB treatment should be enrolled for isoniazid preventive therapy every two years.

8.7 Home-based care should be preferred for TB/HIV patients in order to limit the length of hospitalization and risk of superinfection by MDR-TB strains.

8.8 All nongovernmental organizations already working with TB patients, PLHIV or people who inject drugs should embrace collaborative TB/HIV activities as part of

their core business. Refresher training for their staff could be considered by the National TB Programme.

8.9 Routine voluntary HIV counselling and testing should be offered to all TB patients. It should be simplified by using rapid HIV testing and allowing infectious disease specialists to make HIV diagnoses and prescribe antiretroviral therapy as early as possible. Staff from TB services should be properly trained in HIV counselling.

8.10 Co-trimoxazole preventive therapy should be introduced and rapidly expanded to include all coinfected individuals. A regulatory framework governing the administrative and organizational details of co-trimoxazole preventive therapy should be developed.

8.11 TB/HIV case management should be improved by:

- updating the national HIV/AIDS treatment protocols including eligibility criteria for antiretroviral therapy in HIV/TB patients in line with new WHO standards;
- drawing up diagnostic and treatment algorithms that provide objective criteria for treatment of smear-negative pulmonary TB and extrapulmonary TB in HIV-infected persons;
- for inpatients (in TB facilities), organizing a system for timely and regular visits by infectious disease specialists (monthly, or more frequently if required), monitoring of antiretroviral therapy (CD4 cell counting and proper measurement of HIV RNA according to national HIV treatment protocols), and an effective flow of information between the two services during and at the end of TB treatment;
- for outpatients, establishing multidisciplinary teams of TB and infectious disease specialists (drug addiction specialists optional).

9. Drug-resistant TB

The National TB Programme has greatly improved its capacity to manage MDR-TB over the years. The first cohort of 200 MDR-TB patients was approved for treatment by GLC in April 2008 under the Global Fund Round 6 grant. A second cohort of 200 patients was approved in November 2009 and a third cohort of 2200 in May 2010, reaching the total of 2600 MDR-TB patients approved by GLC in the country. Disregarding the GLC mechanism, all TB patients are subjected to drug susceptibility testing and all those found with any drug resistance are evaluated by the National MDR-TB Expert Commission, which decides the most appropriate treatment regimen. All patients starting treatment are registered and well managed without distinction between GLC-approved and non-GLC-approved cohorts. Second-line anti-TB drugs are provided from the State budget and Global Fund grants. Reserve drugs for the treatment of XDR-TB patients are available. Adverse drug reactions are managed well and ancillary drugs are available.

However, the National TB Programme is now challenged by the burden of MDR-TB, indicated by the last drug resistance survey, of 2700 (2000–3500) new cases occurring every year in the country, more than the 2300 (1700–2900) previously estimated and far more than those placed under treatment within or outside the GLC mechanism. The Ministry of Health

should significantly increase its capacity in treating MDR-TB. The National TB Programme also needs to improve further, especially its recording and reporting of MDR-TB cases.

The review team observed that only half the MDR-TB patients recorded in the laboratories are then recorded in the oblast MDR-TB registers, usually the ones who have actually started treatment with second-line anti-TB drugs. Besides the possible primary defaulting of some patients, this may happen because patients are preregistered and placed on a waiting list (MDR-TB backlog) until second-line drugs become available. In practice, the lack of correspondence between registers delays the initiation of treatment for a large number of patients and leads to incorrect estimates of the need for second-line anti-TB drugs and the required budget. Successive GLC monitoring missions have recommended that consistency should be maintained between the oblast laboratory register and the MDR-TB register. Additional delays in starting treatment are caused by poor recording of the patient's address in the laboratory register. Furthermore, the practice of testing isoniazid susceptibility with two concentrations of isoniazid (see section on TB case-finding and diagnosis) wrongly classifies a number of true MDR-TB patients as resistant to rifampicin only, and these patients consequently receive inadequate treatment. Audiometry is not available to evaluate adverse drug reactions which may affect the patient's hearing.

The review team also observed a poor recording of the patients registered, e.g. previous treatment history not properly collected, inaccuracy in reporting laboratory information on the patient's treatment card, improper referral between facilities, all of which encourage mistakes in clinical management of cases and possibly explain the higher number of relapses compared with defaulters among the retreatment cases. Inaccurate patient records have further increased the already high workload of the National MDR-TB Expert Commission. Polydrug-resistant TB patients (i.e. patients with resistance to some drugs, but not to both isoniazid and rifampicin) are not properly considered. At the central unit of the National TB Programme, data processing was found to be very weak. making it difficult for the review team to retrieve national data on MDR-TB case-finding and treatment outcomes.

It is also important to report the periodic shortages of various second-line anti-TB drugs (see section on Management of medicines and other commodities), possibly creating further drug resistance in the country. Vitamin B6 is procured only in injectable form.

At present, MDR-TB patients are discharged from hospital only after the sputum culture fails to show mycobacterial growth. They could be discharged sooner if 2-3 consecutive sputum-smear microscopy investigations come out negative and the patient has shown clinical improvement.

Main recommendations

9.1 The National TB Programme's capacity to address MDR-TB, including treatment, should increase significantly to reflect the additional burden indicated by the findings of the drug resistance survey in Minsk and later confirmed by the drug resistance survey countrywide.

9.2 All cases identified through drug susceptibility testing, including the backlog of MDR-TB patients, should be properly recorded in the laboratory register and also reported and recorded in the oblast MDR-TB register. The correspondence between the two should be cross-checked by the National TB Programme.

9.3 All necessary drugs for completing the treatment of each MDR-TB patient should be guaranteed.

Other recommendations

9.4 All patient records should be properly completed. Full information for each patient should be collected and made available to the facility to which the patient is referred.

9.5 MDR-TB expert commissions should be set up gradually at oblast level to decentralize the workload of the central level and prevent delays in starting the treatment of patients. The oblast commissions should be assisted and closely supervised by the National MDR-TB Expert Commission.

9.6 Technical assistance and on-the-job training in MDR-TB programmatic and clinical management should be given to all providers.

9.7 Polydrug-resistant TB patients should be evaluated for their risk of developing MDR-TB. Minor changes in their regimens should not be seen as a reason to put them under Category IV treatment. A plan for managing polydrug-resistant TB cases should be developed and implemented.

9.8 MDR-TB patients showing clinical improvement may be discharged from hospital on the basis of a negative result in 2-3 consecutive sputum-smear microscopy investigations, rather than time-consuming bacteriological conversion in culture.

9.9 Audiometry should be conducted for all MDR-TB patients before starting treatment and every month while the patient is being treated with injectables. Audiometers should be provided for all main MDR-TB treatment facilities.

9.10 Palliative care should be provided for all patients in need.

10. TB control in prisons

In 2010, the TB notification rate in prisons was six times higher then outside, i.e. about 315 new TB cases per 100 000 population.[1]

The Ministry of Internal Affairs is responsible for the penitentiary system, and the Medical Unit of its Department of Execution of Punishment is responsible for health services, including TB services. There are 34 penitentiary institutions with a medical service (physician and nurse), one pretrial detention centre hosted in Pischalauski Castle in Minsk city and the Central Prison Hospital with 1860 TB beds, based in TB Colony N° 12 in Orsha city. Penal Colony N° 4 in Gomel city is for female detainees. Cooperation between the Ministry of Health and Ministry of Internal Affairs in the area of TB control has improved substantially

[1] The prison population in Belarus in 2010 was about 52 000 inmates, as reported by the Department of Health Care of the Penitentiary Service and documented on the Web site of the International Centre for Prison Studies (http://www.prisonstudies.org/, accessed 21 June 2012).

over the years, as reflected in a number of joint normative documents and interventions, such as TB screening in prisons, centralized procurement of first-line anti-TB drugs and laboratory supplies, and follow-up of ex-prisoners on TB treatment after their release.

All detainees are screened using chest X-ray on entrance to pretrial and detention institutions and every six months during their stay. TB-suspect patients are isolated and if diagnosed with TB are transferred to TB Colony N° 12 in Orsha city, Vitebsk oblast (or stay in the TB section of Colony N° 4, if female). All TB patients are tested for HIV and drug susceptibility (first and second-line anti-TB drugs). All MDR-TB cases are considered by the National MDR-TB Expert Commission in Minsk. TB Colony N° 12 has a high-quality laboratory, which provides smear, culture and drug susceptibility testing (including MGIT). All TB patients in the penitentiary system are registered in an electronic database which is connected with the National TB Programme register. MDR-TB cases are registered in a separate journal (resistance patterns, regimen, registration date, etc.).

The review team observed some progress since the last GLC mission (August 2009): all first line anti-TB drugs were available without stock-outs and provided by the National TB Programme; anti-TB drugs were provided in adequate regimens and doses, via DOT provided in cabinets under the control of medical staff and guards; collaboration with the civilian facilities was good and based on the effective exchange of medical records and discussion of MDR-TB cases by the National MDR-TB Expert Commission.

The review team also found further needs for improvement. In Colony N° 4 (for female prisoners and TB patients) the shortage of disposable sputum containers stopped drug susceptibility testing for several months. In the laboratory of TB Colony N° 12, MGIT reagents were out of stock. All female and half the male MDR-TB patients were not receiving treatment with second-line drugs, and stock-outs were frequent (*p*-aminosalicylic acid (PAS) was not available at the time of the visit). Only 50–60% of MDR-TB cases were registered for treatment soon after they were identified, because of delays by the National MDR-TB Expert Commission or because second-line anti-TB drugs were not available. The treatment success rate among newly detected pulmonary laboratory-confirmed TB cases was 51.2%. Mortality is also high among TB/HIV patients, owing to incorrect clinical management. Infection control measures in prisons are inadequate, with different types of patients (with MDR-TB or XDR-TB, under treatment or not, etc.) sharing a room, bringing the risk of cross-infection. Personal protection is not widely used by the staff working in prisons because of their inadequate training and supervision.

Finally, the treatment default rate among the 67 patients released from prison during 2010 was 70%. The rate was so high mainly because of the limited communication and coordination between the penitentiary and civilian systems. Formally, prisoners' medical records can be handed over to the TB dispensary only following a request; in practice, the documentation is not always requested and there is a lack of proper follow-up.

In October 2011, the Ministry of Health approved a resolution jointly prepared by the Ministry of Health and the Ministry of Internal Affairs to establish a formal collaboration for the management of TB patients. This Order is entitled "Measurements for increasing efficiency of detection, registration and medical examination for tuberculosis and provision of medical care for people kept in the penitentiary system of the Ministry of Internal Affairs of the Republic of Belarus, releases from such institutions, people without a specific place of

residence and on the organization of interactions between public health organizations, internal authorities and penitentiary institutions of the Ministry of Health".

Main recommendation

10.1 In the penitentiary system, TB diagnosis and treatment, including TB/HIV, and airborne infection control must be improved for detainees. The collaboration between the Ministry of Health and Ministry of Internal Affairs should be formalized as soon as possible to ensure a continuum of care for those TB patients moving from the penitentiary to the civilian system.

Other recommendations

10.2 All diagnosed MDR-TB patients should be registered and their number cross-checked with the laboratory register. Communication between those requesting and those providing laboratory results should be improved.

10.3 Additional staff are needed to ensure the proper isolation of different groups of TB patients and to ensure DOT.

10.4 An infection control plan should be developed for the pretrial and post-trial detention centres, and specific training designed and provided for administrative staff and guards.

10.5 Collaboration and coordination between the penitentiary system and the civilian system should be improved by ensuring advance warning of a prisoner's release and complete documentation of the case. Nongovernmental organizations could be considered as possible partners for interaction between the two systems. The draft agreement between the Ministry of Internal Affairs and the Ministry of Health should be formalized.

11. Other vulnerable populations and social determinants

As per Ministry of Health orders, a number of population groups are considered at risk of TB and subjected to annual screening (see section on Case-finding and detection). A countrywide survey carried out by UNDP in 2011 found that the groups of population at higher risk of developing MDR-TB are actually people who abuse drugs and alcohol, unemployed people, people living more than 20 km from a TB facility and those with on low incomes (defined as lower than US$ 50 per month). The drug resistance survey conducted countrywide in 2010–2011 (see also section on TB epidemiology), besides confirming very high rates of anti-TB drug resistance, provided a snapshot of people detected as having TB and MDR-TB: 95% had completed secondary/higher education (secondary school, college or university), 86% were living in a household of three people or fewer, 96% owned or rented their apartment or house, 49% were unemployed and 15% had been in prison in the previous 10 years. Further, 21% smoked tobacco daily (or had done so in the previous five years), 57% had consumed alcoholic drinks (at least five units of alcohol in a day) over the previous month, and 5% were HIV-positive. A history of previous treatment for TB was the strongest risk factor for MDR-TB, followed by HIV coinfection, history of imprisonment, smoking tobacco and drinking

alcohol five or more days per month (defined as drinking at least five units of alcohol in a day).

Forms of social protection are in place in Belarus for TB patients in formal employment. Sick leave is paid from social protection funds at the level of 80% of the basic salary during the first week of sickness and 100% from the second week up to a total of six months, which may be adequate for a drug-susceptible TB patient, but not for a MDR-TB patient requiring much longer treatment and care. In these cases, a temporary occupational disability benefit can be requested. TB patients not in formal employment do not have any social protection.

The possibility of including social support under the State budget is considered in the recently endorsed National TB Programme 2010–2014 (item 1.9). However, the mechanisms for this support have not yet been elaborated. Funds cannot be used for social support by the Ministry of Health because the necessary legal framework is lacking, and the patient cannot be accepted by the Ministry of Labour and Social Protection, which can work only with an official list of vulnerable groups, not including TB patients (Order N°458 of the President of the Republic of Belarus dated 14 September 2009 on "State targeted social support"). It should be mentioned that local government funds in Vitebsk oblast have been used to provide support for TB patients since 2000.

The Belarusian Red Cross Society has plans to provide daily hot meals for low-income and homeless TB patients, as well as psychological support and legal counselling.

Main recommendations

11.1 Support for TB patients should be urgently scaled up and integrated under the Ministry of Labour and Social Protection in order to assist treatment completion in outpatient settings.

11.2 Collaboration with nongovernmental organizations providing assistance for TB patients (counselling, psychological support and social support) should be scaled up.

12. Infection control

Updated national guidelines on TB infection control have been developed in line with WHO recommendations and enforced in Ministry of Health Order N° 1151 of 11 December 2009 on "Guidelines on infection control measures in TB facilities". Unfortunately, national and external funds were not sufficient to install and regularly maintain expensive ventilation systems for environment control, and documented TB incidence among staff working in TB hospitals can be very high, e.g. 550 cases per 100 000 people in Gomel TB Hospital, which is 10-12 times higher than in the general population.

Administrative control

The infection control training curricula developed and used by a few medical schools (as seen by the review team in Gomel oblast) include adequate and updated airborne TB infection

control measures. In most of the TB hospitals, patients are separated according to sputum smear, culture, drug susceptibility test results, HIV status and treatment regimen, but the lack of rapid laboratory diagnostic techniques and effective environmental control measures means that this separation of patients is inadequate to prevent nosocomial TB superinfection. Undergraduate and postgraduate medical education still includes obsolete infection control measures based on TB transmission by droplets and direct contact rather than by aerosol of infective droplet nuclei.

Environmental control

The most effective environmental control intervention is reducing patient contacts. Therefore, by reducing the number of TB beds and creating sufficient floor space per bed (at least 7.5-8 m^2), infection control in TB dispensaries and hospitals can be most effectively improved with budget savings that can be used more appropriately for the installation of equipment in the highest-risk settings (mechanical ventilation, upper-room ultraviolet germicidal irradiation (UVGI), laboratory biosafety equipment) and for hospital renovations designed for better isolation and patient comfort.

In a few TB facilities, ventilation systems are currently planned or under installation using Ministry of Health funds and Global Fund resources. UVGI fixtures have been installed and effectively used 24 hours a day in high-risk rooms of the RSPCPT in Minsk and in most of the oblast TB dispensaries. Digital ultraviolet high-sensitivity meters (UVC meters) are also available in the above-mentioned facilities for the monitoring and maintenance of upper-room UVGI fixtures. Natural ventilation and traditional whole-room (unshielded) UVGI fixtures (e.g. OBN-150), the only available environmental control measure in the majority of TB facilities, are not effective in controlling airborne TB transmission in a country with a cold climate like Belarus. In a few cases, room air cleaners are installed, which should be considered an inefficient use of the limited funds available for TB infection control. Despite some efforts to separate the various categories of TB patient in the prison TB hospitals, these settings, including the TB hospital in Orsha, should be considered at very high risk of drug-resistant TB transmission.

Laboratory biosafety

With Global Fund support, it is planned to rehabilitate several Level III and IV laboratories during 2012 to achieve biosafety level 2 or 3. Biosafety laboratory equipment (fume hoods, Class II Type 2A biosafety cabinets, centrifuges) has already been procured and installed in oblast TB laboratories. However, laboratory staff lack updated knowledge of the biosafety requirements (personnel flow, specimen flow, safe laboratory practices, use of biosafety equipment, certified maintenance). Consequently, there are no laboratory biosafety-related standard operating procedures and most laboratories do not have the proper layout, space and equipment. There is no maintenance and no certification of biosafety cabinets anywhere in the country because these services are not budgeted for and the required certified professionals are not available.

Personal respiratory protection

Implementation of personal respiratory protection in TB facilities is currently at an early stage. Policies are being developed, initial supplies of respirators and surgical masks are being procured, and respirator fit test kits are being procured for the oblast TB dispensaries. TB

workers, other high-risk health care professionals (pathologists, infectious disease specialists, anaesthesiologists), as well as staff in the penitentiary system, lack knowledge and skills on respirator donning, utilization and care. There are no training courses on respirator fit testing. Low-quality noncertified respirators (i.e. not meeting the EN149:2001+A1:2009 standard)[1] have been imported from China, which could have been avoided by performing a simple qualitative respirator fit test. A rational and robust administrative infection control programme and the application of engineering measures in selected areas can limit the need for personal respiratory protection, since only limited high-risk staff should use this protection for a limited time in designated areas and for designated procedures.

Main recommendation

12.1 Infection control and laboratory biosafety should be expanded to reduce transmission of MDR-TB among patients and health-care workers in all facilities. Priority should be given to revising national hospitalization policies (admission and discharge criteria) to avoid unnecessary hospitalization of noninfectious cases and substantially reduce the length of hospital stays.

Other recommendations

12.2 Adequate funding should be ensured for TB infection control and laboratory biosafety in line with the principles of international airborne infection control.

12.3 A regular (at least annual) TB transmission risk assessment should be performed by trained authorized personnel in all TB and HIV facilities, in the penitentiary sector and in primary health care institutions with a high TB load in order to develop and update realistic and adequately budgeted TB infection control plans.

12.4 To ensure adequate funding for TB infection control, the National TB Programme budget should include such components as:

- reconstruction of TB facilities, designed to comply with internationally recommended regulations and recommendations;
- design, installation and maintenance of mechanical ventilation systems for limited high-risk facilities (laboratories, wards for contagious patients, MDR-TB departments);
- procurement and installation of upper-room UVGI fixtures in high-risk settings and UVGI lamps for replacement;
- procurement, installation and annual certification of Class I and Class II Type A2 biosafety cabinets and biosafety centrifuges;
- procurement of EN149:2001+A1:2009 certified FFP2 respirators (and a few FFP3 respirators for the highest-risk procedures) based on the fit test results for the respirator concerned.

12.5 National sanitary and construction norms and regulations for health-care, laboratory, penitentiary and other high-risk facilities for TB transmission should be revised and updated in accordance with WHO-recommended airborne infection

[1] EN149:2001+A1:2009 *Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking.* This European Standard specifies minimum requirements and the classification for filtering half masks as respiratory protective devices against aerosol particles.

control and laboratory biosafety principles and the national guidelines on "Infection Control Measures in TB Facilities", approved by the Ministry of Health.

12.6 The incidence of occupational TB among the staff of health-care and penitentiary facilities and the relative risk for selected high-risk professional groups could be used as a feasible tool for monitoring the risk of TB transmission and the effectiveness of infection control programmes.

12.7 The Sanitary Epidemiological Service (SES) should play a constructive and coordinating role in implementation of airborne infection control measures in high-risk settings in civil and penitentiary TB and HIV services, following international approaches.

12.8 The national health-care education system, including postgraduate education, needs to integrate updated airborne TB infection control principles into curricula for medical students, TB specialists and nurses, epidemiologists, primary health care professionals, pathologists, pulmonologists, etc.

12.9 A limited number of isolated mechanically ventilated airborne isolation departments (rooms) should be available at regional and country level for TB suspects and contagious TB patients on adequate treatment based on drug susceptibility testing. Such patient rooms should have negative pressure relative to the environment, rational air flow distribution without stagnant zones providing 6-12 air changes per hour (or 80 m^3/hour per patient) and safe exhaust or exhaust air decontamination (preferably through in-duct UVGI).

12.10 To reduce future long-term maintenance costs and the risk of ventilation system failure in the winter season, automation systems should be designed and installed for all major ventilation systems.

12.11 The reconstruction of Orsha penitentiary TB hospital in order to provide adequate isolation and environmental controls for contagious TB patients is highly recommended to reduce drug-resistant TB transmission in the prison system among TB patients and penitentiary staff.

12.12 Engineers at country and regional level TB facilities should be trained in environmental controls (mechanical ventilation, upper-room and exhaust in-duct UVGI fixtures, biosafety cabinets, centrifuge installation, commissioning, use and maintenance).

12.13 Air should not be recirculated in high-risk settings; it is therefore not recommended that room air cleaners are procured for air decontamination, because of their low efficacy and cost-effectiveness.

12.14 To ensure the required annual maintenance and certification of biosafety cabinets, these activities should be included in the National TB Programme budget, a maintenance programme should be developed, certification equipment should be procured for the National TB Programme and two country-level engineers should be trained on international biosafety cabinet certification courses.

12.15 It is recommended that Belarus should adopt European biosafety cabinet certification standard EN 12469:2000 (*15*) (or Russian GOST R EN 12469-2010, which is compliant with the above-mentioned European standard).

12.16 Restructuring of laboratory services, with centralization of culture and drug susceptibility testing at the regional level, and the introduction of new rapid diagnostic techniques in high-load rayon settings, could help to redirect resources to fill the current gaps in laboratory biosafety funding (laboratory supplies, procurement of biosafety equipment, maintenance and certification, environmental controls in high-risk laboratory zones, etc.).

12.17 Since qualified biosafety equipment maintenance is currently unavailable in Belarus, Class I and II biosafety cabinets should be thimble-connected to the exhaust system.

12.18 Personal respiratory protection should be part of the regular educational programme for staff of TB and HIV facilities, including the penitentiary system, as well as for other staff at high risk of TB transmission (pathologists, personnel of homeless people's shelters, etc.).

12.19 Procurement of respirators certified to FFP2 EN149:2001+A1:2009 could be centralized at country or regional level and should be based on respirator fit test results as well as on a realistic evaluation of high-risk staff needs. The use of surgical masks should be mandatory for coughers (TB suspects and patients) and contagious TB patients when indoors.

12.20 Other recommendations important for TB infection control, relating to such areas as TB diagnosis, case management, MDR-TB, TB in prisons and TB/HIV, are provided in the relevant sections of this report.

13. Management of medicines and other commodities

The legal framework for medicinal products in Belarus provides for all regulatory functions and is subjected to a continuous process of improvement towards European Union standards. The National Medicines Regulatory Authority is composed of two institutions:

- Ministry of Health, responsible for shaping policies, making legislative proposals, licensing and inspections and supply of centrally procured medicines and commodities.
- Centre for Examinations and Tests in Health Care, responsible for technical assessments (for drug registration and clinical trials), monitoring functions (pharmacovigilance, quality control, advertisement) and several inspection functions (good clinical practices (GCP) and good manufacturing practices (GMP)).

A total of 124 anti-TB medicines are registered in Belarus (as per 13 January 2012, see Annex 5). There have been only a few occasions in the past when manufacturers did not manage, for various reasons, to supply these items on time – a problem that may be overcome in future by establishing fast-track registration with reduced or waived registration fees for

WHO-prequalified products imported through the Global Fund and the Global TB Drug Facility.

All batches of anti-TB medicines are subjected to quality control by the State control laboratories before entering the distribution system. However, there is concern about the process of reregistration, which is sometimes done without enough clinical and bioequivalence/bioavailability data, and authorizations renewed on the basis of historical data. While it is legally within its powers to do so, the Ministry of Health rarely asks manufacturers to produce these bioequivalence/bioavailability data. Pharmacovigilance is conducted through a system of reporting by clinicians at all levels. Unfortunately, the reporting of adverse drug reactions is weak and consequently this opportunity to trigger additional checks on the quality of medicines is missed.

The review team was able to purchase isoniazid and rifampicin from a retail pharmacy without prescription, as well as quinolones. Meantime, rifampicin is still commonly prescribed for the treatment of aspecific infections (urinary and biliary infections, meningitis, osteomyelitis, etc.). This practice continues despite Ministry of Health Order N° 517 of 11 June 2008 on "Organization of supervised treatment of TB outpatients", which bans over-the-counter sales of first-line anti-TB drugs. Evidence from other countries shows that this uncontrolled use of anti-TB medicines contributes to the development of antimicrobial resistance and should be prevented.

Anti-TB drug procurement and supply management are compliant with existing legislation and National TB Programme guidelines. All items are featured on the national essential medicines list. Procurement is by the Ministry of Health (central procurement of all first-line and some second-line anti-TB drugs) and by the oblast and rayon health authorities (local procurement of quinolones and macrolides), with the responsibility for estimating needs assigned to dedicated personnel. Central procurement is financed from the Ministry of Health budget with Global Fund and Global TB Drug Facility support. Local procurement is financed from the local budget allocated to oblasts and rayons, which may be difficult to access, causing dangerous delays in procurement. In fact, stock-outs, lasting from one day to several weeks, were reported during 2011 and observed by the review team, such as the stock-out of PAS affecting 157 patients, which was rectified within a few days by the Ministry of Health at the central level.

The State unitary enterprise Belpharmacia is responsible for the distribution of all commodities in the country. Storage and distribution fees were fixed five years ago and correspond, as today, to 3% of the product costs. However, similar services under the Global Fund are meant to be charged on the basis of the volume of products distributed, i.e. with costs less than 3%. Hospitals are misinformed and prefer to minimize Belpharmacia services and keep their stores overstocked with medicines. An additional reason is to prevent the drug shortages experienced in the past. The review team observed in a few facilities that drug storage conditions were inappropriate, including the cold chain for second-line drugs, and risked compromising the quality of the products.

In the past, WHO has described major gaps in anti-TB drug monitoring and evaluation, forecasting and quantification (*16*). Stocks are monitored and evaluated monthly, but there is no formal system for assessing the gaps and considering ways of avoiding them in the future. Forecasting depends on the number of patients registered for treatment. However, the number of patients with MDR-TB found by laboratories is estimated to be much higher (1.2–2 times

higher). Scaling up MDR-TB treatment requires improved communication between laboratories and treatment centres (see section on Drug-resistant TB) and forecasting should be based on actual needs rather than historical records.

Main recommendations

13.1 TB planning, currently carried out at rayon level, should be centralized at oblast level in order to pool resources and ensure their more effective redistribution. This is especially important for the rational distribution of anti-TB drugs.

13.2 The current legislation limiting the retail sale of anti-TB drugs in pharmacies should be reinforced. Quinolones must be dispensed on medical prescription only.

Other recommendations

13.3 Incentives (e.g. transparent standard operating procedures, reduced costs for the assessment of drug dossiers) should be introduced to encourage WHO-prequalified manufacturers to register their products in Belarus.

13.4 Currently registered medicinal products should be reviewed to determine their actual standards of quality, efficacy and safety. Those not of an adequate standard should be taken off the market. Bioequivalence should be proved for all generic products. A medium-term update of the bioequivalence of previously registered products should be considered.

13.5 Belpharmacia's storage and distribution fees should be included in budgets at all levels, fixed for the calendar year and index-linked to currency inflation.

13.6 Staff training should include monitoring and evaluation and forecasting and quantification of TB products. Early-warning indicators should be introduced for close monitoring of drug stocks as a daily practice at all levels of the health system.

13.7 Pharmacovigilance reporting should be strengthened.

14. Monitoring and evaluation

The National TB Programme inherited its recording and reporting system from the former Soviet Union. It was maintained intact until the Ministry of Health introduced new forms, as recommended by WHO, in Order N° 759 of 9 October 2006 on "Approval of primary medical documentation for tuberculosis patient management" and following Order N° 1226 of 9 November 2010 on "Reporting on epidemiological situation and treatment outcomes". Later, the Ministry of Health introduced specific forms for recording and reporting of MDR-TB cases in Order N° 11 of 12 January 2009 on "Clinical guidelines for TB treatment", which now form the basis of an effective MDR-TB surveillance system[1] which should, in future, be

[1] In 2010, Belarus succeeded in setting up a continuous drug resistance surveillance system producing "Class A" data with the following characteristics, showing a high degree of representativeness and accuracy: 1) nationwide

able to monitor the MDR-TB epidemic documented by the countrywide drug resistance survey. However, the core elements of the system inherited from the Soviet era have been maintained by the State Statistical Department, which still requires the "State reporting of tuberculosis by Form N° 1-Tuberculosis" (Order N° 317 issued on 21 November 2008 by the State Statistical Committee) from the National TB Programme. The result is two parallel recording and reporting systems for TB monitoring and evaluation in Belarus, one based on WHO-recommended standards focusing on outcome indicators (case detection and treatment outcomes) and the other from the former Soviet Union, focusing on process and output indicators (services delivered) and evaluation of cases based on old clinical case definitions.

The Department of Epidemiology, Prevention and Organization of TB Care of the RSPCPT has a department head and a staff of seven: two people responsible for electronic data management and five medical statisticians (including one dedicated to treatment cohort analysis and interpretation). This department is responsible for collecting data from all reporting TB facilities countrywide, data processing, preparation of reports (including annual reporting to WHO/ECDC) and documents for conferences and meetings, drafting of regulatory documents, National TB Programme planning, management and coordination, and interface with people requests. It collaborates closely with the RSPCPT Deputy Director of Clinical Management to monitor National TB Programme performance, with the Deputy Director of Science in operational research and with the Head of the National TB Reference Laboratory in processing of laboratory data. The department maintains the links with other databases run by the penitentiary system, the National HIV Programme and the implementation unit of the Global Fund TB grants.

At oblast level, TB data collection, analysis and reporting are carried out by one or two specialists at the oblast TB dispensary. At rayon level, these tasks are the responsibility of the TB coordinator working in the rayon TB dispensary. TB data are aggregated annually at oblast level and then reported to the National TB Programme Monitoring and Evaluation Unit by 5 January each year. In its turn, the Monitoring and Evaluation Unit reports to the Ministry of Health by end March each year.

Besides this recording and reporting by the National TB Programme, there is a parallel national early-warning system for surveillance of communicable diseases (including TB) operated by SES that is responsible for rapid response (contact investigation and education, environmental disinfection) when a new TB case is suspected or diagnosed. National TB Programme and SES data do not match, because the latter also includes presumed TB cases which are not yet confirmed by laboratory tests or clinically.

The National TB Programme started to conduct cohort analyses of TB patients routinely in 2007. Since than, the percentage of TB cases not evaluated annually has remained at 8%-9%, reaching a peak of 20% in 2009. The review team considers this to be due to the unnecessary burden of recording and reporting for the two parallel systems described above, limited training of staff in oblasts and rayons (especially in respect of MDR-TB), limited data quality control,[1] and limited supervision and feedback to the reporting units. More guidance from the

coverage and culture results available for 90% of all cases; 2) 50% of all cases culture-positive; 3) drug susceptibility testing results available for 75% of positive cultures; 4) external quality assurance with 95% concordant results.

[1] Data quality at oblast level can be monitored in two ways: 1) by detecting unexpected variations in annual reporting of cases by previous treatment history, disease localization, laboratory confirmation and treatment outcome; and 2) by cross-checking records during supervisory visits.

central-level Monitoring and Evaluation Unit is required on ways to analyse National TB Programme performance indicators, such as case-detection rates and treatment outcomes, and apply specific tools, such as the supervision checklist and the "onion model" for assessing under-reporting (*17*). In addition, the review team observed a shortage of cards, forms and registers in the facilities visited, resulting in incomplete recording and reporting. As a general consideration, it seems that attention and resources are focused more on costly and inappropriate SES outbreak investigations and environmental disinfection (surfaces, dishes, etc.) rather than on National TB Programme surveillance.

There is no centralized laboratory data management. Laboratories keep their data in registers from which information is later reported on the patients' cards and forms used for case management. The review team found frequent disparities between the laboratory and TB registers in the facilities visited. This is explained by the fact that the laboratory registers are designed to count the specimens rather than the patients investigated, and investigations do not distinguish between diagnosis and treatment follow-up. Furthermore, laboratory staff receive limited training. The review team expects the processing of laboratory data to improve through the adoption of a user-friendly software application.

The National TB Programme plans to replace the existing system of processing consolidated TB data with a national TB register, based on an electronic database and accepting single-case data entry by the end of 2011. This register is already under development by a private company based in Brest, Brest oblast, with funds from the Global Fund and technical assistance from WHO. The module for TB case-finding, based on the special form "Urgent notification 89-1/u" approved by the Ministry of Health, has already been developed, while the modules for treatment outcome monitoring, laboratory management, drug management and MDR-TB are not yet ready. The new software application will accept entries via the Internet and will have a Web log (blog) where users may obtain online IT support and share experiences with colleagues. A first draft manual for TB database users has already been developed and is now ready to incorporate the specific instructions for each module. Unsolved problems remaining include the supply of appropriate hardware and the provision of computer services at oblast and central level, establishing reliable Internet communications, developing standard operating procedures to respond to a sudden breakdown of the system and covering future running costs from the State budget.

Under the National TB Programme system of supervision, the central level monitors all TB dispensaries quarterly, and the latter are responsible for supervising the polyclinics and other peripheral units which see TB patients. Supervision includes supporting and mentoring staff but does not include any on-the-job training.

The Ministry of Health monitors the delivery of health services using a list of 50 indicators inherited from the former Soviet Union.[1] Three of these indicators are TB-related, measuring primary health care performance by the number of people screened for TB and the number of unnecessary medical follow-ups. Following the same concept, RSPCPT developed a list of 30 indicators to monitor the performance of TB facilities, which are grouped into health indicators and programmatic management indicators.

[1] Initially endorsed in Ministry of Health Order N° 242 of 2 September 1998 on "Transition to primary health care services based on general practitioners" and later described in more detail in Ministry of Health Order N° 02/2/02/732/107 of 2 June 2006 on "Method for assessing the models of health care organizations in the administrative territories of the Republic of Belarus".

Main recommendations

14.1 The two parallel systems for TB recording and reporting should be merged into a single system in accordance with international standards.

14.2 A separate electronic database should be established as soon as possible for monitoring MDR-TB case detection and treatment. This should become part of the national TB register once it is finalized and introduced countrywide.

Other recommendations

14.3 National TB programme monitoring and evaluation at all levels should be strengthened by increasing funding, redistributing tasks among the staff of the Monitoring and Evaluation Unit and retaining dedicated staff at oblast level and rayon level.

14.4 The recording and reporting system for TB laboratories should be revised to provide better support for clinical management, allow monitoring of laboratory performance and document the use of the new diagnostic techniques considered in the revised diagnostic algorithm. The patient's drug resistance profile should be made accessible to all concerned levels of care. The revised laboratory recording and reporting system should become an integral part of the national TB register once it is finalized and introduced countrywide.

14.5 Patients' treatment outcomes should be fully analysed in line with international standards; consequently, patients "still on treatment" should be defined as "failures". Patients should no longer be followed up after treatment completion.

14.6 The development and implementation of the electronic, case-based and Web-based national TB register should be speeded up.

14.7 The collaboration with SES should be strengthened and reoriented from ineffective house disinfection to contact-tracing (including contacts outside the patient's household).

14.8 Extensive training should be conducted at oblast and rayon levels on data analysis and interpretation for programmatic management. Supervision should become more supporting and less controlling, focusing less on possible administrative errors.

14.9 Current guidelines for monitoring National TB Programme performance should be updated by including targets, MDR-TB-related indicators, analysis of the indicators (e.g. MDR-TB case-finding and treatment outcomes) and a checklist for supervision.

14.10 Current estimates should be confirmed by assessing TB case-finding using the onion model, TB mortality through a capture-recapture study and MDR-TB under notification.

14.11 TB indicators (output, outcome, impact) should be included when monitoring the implementation of health-care reforms. TB is often the result of socioeconomic determinants and poor access to health care. For this reason, TB can be used as a proxy for monitoring the overall performance of health system service delivery.

15. Human resources development

In 2011, there were 2083 nurses and 534 doctors working in the TB services, i.e. 78% of the total 684 established positions, with some differences across oblasts (e.g. 97% in Grodno oblast and 59% in Minsk oblast). To compensate for the shortage of staff and create a financial incentive, the Ministry of Health allows TB doctors and nurses to work 1.5 full-time equivalent (FTE). This is an arrangement that allows a fixed budget to be redistributed among fewer staff. National statistics show that, on average, TB doctors work 1.39 FTE and nurses 1.13 FTE. It also shows that this measure has not reversed the negative trend in the recruitment of new TB doctors and nurses. Many of the staff currently employed are close to retirement (up to 33% in one of the facilities visited). The lack of young doctors and nurses in the TB service was explained to the review mission as a consequence of perceived low salaries which did not compensate for the high risk of TB infection.

In 2010, TB disease was notified at the rate of 726 per 100 000 TB doctors and nurses (higher in nurses) and 54 per 100 000 for other medical staff, i.e. a TB incidence among TB staff almost 14 times higher than in the general population. Similarly to other civil servants, TB personnel are entitled to sick leave and disability pension. Paid sick leave comprises 80% of the basic salary during the first week and 100% from the second week up to a total of six months. However, if a TB health-care worker has MDR-TB, the period of treatment and care is much longer than six months. In this case, a temporary disability pension can be requested. Alternatively the TB health-care worker, after sputum conversion, can be offered another job not involving contact with the public, if such a job is available. Only when the sputum-smear investigations are found to be negative for six months following the completion of treatment is the health-care worker declared cured and allowed to return to regular work. This means that a TB doctor or nurse who has MDR-TB cannot return to regular work for at least two years.

Job descriptions are prepared on the basis of a generic template, adjusted for each facility and revised every three years. Job descriptions are detailed, and describe the line of reporting, functions, responsibilities, rights, evaluation and accountability. The annual turnover of staff observed by the review team in the TB facilities visited was 9% on average. The workload appeared high, and could potentially be decreased by decentralizing some services to primary health care level and community level using social workers, public health nurses and counsellors.

Each of the four medical schools in Belarus covers TB in the graduate training curricula (with the exception of dentistry), through lectures (16–28 hours) and practical exercises at TB dispensaries (55 hours for primary care doctors and 40 hours for paediatricians). Elective courses on diagnosis of TB and extrapulmonary TB are also offered during the last year of medical school for therapists and primary health care doctors. All doctors, including TB doctors, need to renew their licence to practise every five years by accumulating 80 credit hours of continuing medical education organized by BelMAPO in Minsk. Conferences

approved by the Ministry of Health or regional health authorities may also qualify as continuing medical education. Training curricula are revised in collaboration with the National TB Institute every year at universities and every two years at BelMAPO and could potentially include necessary updates, for example on rapid TB diagnostic tools (e.g. Hain test and interferon-gamma release assay (IGRA)).

The RSPCPT provides postgraduate training for TB specialization; it offers PhD positions and on-the-job training for 8–12 laboratory specialists per year, it organizes quarterly monitoring meetings with the heads of oblast TB services and holds annual scientific conferences. In-service training is provided by UNDP in order to achieve the Global Fund grant implementation targets. UNDP has two dedicated staff members, one to organize the courses (outsourcing and monitoring) and another one to develop their content (working with TB specialists, getting Ministry of Health endorsement). All training curricula have been updated in accordance with the new national guidelines and information obtained from international training. By October 2011, UNDP had conducted 23 training courses involving 1081 health-care workers, including 12 specialists who participated in international courses abroad. The training covered TB laboratory, MDR-TB, TB/HIV, infection control and DOT. Only 50% of national specialists providing training had participated in training-of-trainers courses. More training courses are planned for 2012, covering programmatic management of MDR-TB and TB laboratory skills; however, the review team was not able to obtain more details, including the percentage of staff already trained and the remaining needs for national and international training. The training programme is monitored by cumulating the number of individuals trained without distinguishing whether the same individual was trained twice or more. Besides MDR-TB and TB laboratory skills, the National TB Programme needs to develop and strengthen many more skills through training, e.g. infection control, counselling and communication skills.

Extensive on-the-job training of primary care staff on modern approaches to TB control and the practical approach to lung health (PAL) component has been provided under the Global Fund grant in Belarus. In total, since 2009, 1527 primary care physicians have been trained in TB and differential diagnostics of TB compared with other respiratory diseases. With WHO assistance, discussion on a national PAL policy started in 2010 and the Ministry of Health issued Order N° 292a “On creating the working group on development of PAL guidelines for primary care workers” on 10 December 2010. At present, there are PAL national guidelines for primary care physicians developed with the assistance of the Finnish Lung Health Association (FILHA) and WHO. It is planned to pilot them in 2012 in one district of Grodno region, pending a Ministry of Health order.

A bottom-up approach may be preferable in planning intermediate training targets, identifying the actual tasks required for TB and primary health care staff and organizing training courses to bridge skill gaps. In order to ensure that training and other human resource development interventions have the desired impact, they should be carefully and strategically planned, and form part of the overall strategic plan for TB control. It is beneficial to include more elements of supportive supervision, especially as a possibility for on-the-job training as opposed to monitoring or providing services. Results from supervision are also an important way to reinforce the impact of training and identify shortcomings in knowledge, skills and attitudes. This knowledge can then be centrally analysed and used for preparing competency-based training curricula for effective and efficient staff training.

Medical staff salaries are determined by the Ministry of Labour and Social Protection, while the Ministry of Health can propose a system of bonuses, including those for occupational hazards. Under the current system, TB doctors and nurses have a maximum of 35 working hours per week (instead of 38.5 hours for all other medical staff). Moreover, they can retire from work five years earlier than other staff. In 2012 the Government plans to introduce a new system of bonuses for all health personnel, based on the quality of the services provided. Bonuses for TB doctors may increase their basic salary by 20% or 300 000–500 000 Belarusian roubles (BYR),[1] i.e. almost reaching the salary of other tertiary care specialists (e.g. cardiologists). Additional bonuses of US$ 0.20 and US$ 0.10 per patient visit are currently paid to nurses and doctors, respectively, working in TB outpatient facilities under a project run in 24 dispensaries by UNDP using the Global Fund grant. Moreover, in 2011 the Global Fund grant had a budget of US$ 64 000 for staff wages, based on extra hours worked. If the results of the above experience are positive, it may be scaled up countrywide in future as an effective measure to increase treatment adherence. The conditions are, however, that the financial incentives for TB staff are linked to treatment adherence and funds are derived from the State budget.

Main recommendation

15.1 The basic salary and bonuses of all health workers involved in TB care should be increased to reflect their higher occupational risk. Occupational disease and death insurance should be provided. Financial incentives should be provided for health workers involved in TB care, including primary health care workers, and be linked to their patients' treatment adherence.

Other recommendations

15.2 A national TB human resources development plan should be an integral part of the National TB Programme strategic plan. The human resources development part of the plan should support the overall goals of the National TB Programme and include objectives, activities, monitoring indicators and a budget.

15.3 Current incentives provided under the Global Fund grant should be adopted permanently, expanded to all primary care doctors and nurses and linked to their patients' treatment adherence.

15.4 The postgraduate specialisms of tuberculosis and pulmonology should be merged into a single discipline, pthisiopulmonology, making it more attractive for newly graduated medical doctors and creating the basis for a more comprehensive approach to detection and management of respiratory diseases.

15.5 Existing curricula for in-service training should be revised and based on the competencies required to perform the tasks concerned. The preparation of additional curricula should be considered, to cover areas such as infection control, HIV counselling, communication, etc., according to the level of service provider.

15.6 The training of primary care doctors and nurses can follow the example of the training for PAL.

[1] BYR 8000 = US$ 1 (20 October 2011).

15.7 A database should be developed centrally, in which trained staff are recorded in order to prevent duplication and facilitate future planning of in-service training courses.

15.8 Training of trainers should be provided for all specialists involved in providing training supported by the Global Fund grant. Such training should preferably be conducted in collaboration with international experts to develop standards applicable beyond the Global Fund project.

16. Operational research

Operational research is one component of the Stop TB Strategy and aimed at 1) improving programme performance; 2) assessing the feasibility, effectiveness and impact of new strategies or interventions in TB control; and 3) collecting evidence to guide policy recommendations on specific interventions (*18*). Consistently, national TB control programmes have to prioritize their topics for research and set an operational research agenda which takes into account the researchers who, or the institutions which, can perform the particular study, the time involved and the amount it will cost. An operational research agenda can be developed in Belarus based on the findings of recent studies and this programme review.

The review team found that the potential for conducting focused studies on ways to improve programme performance is underappreciated in Belarus, despite the genuine commitment of providers to improve National TB Programme performance. Part of this may be due to inadequate training in designing operational research and inadequate funding of the Department of Epidemiology, Prevention and Organization of TB Care of the RSPCPT. The implementation of an electronic national TB register in Belarus creates opportunities for conducting certain types of operational research which should be capitalized upon.

The routine surveillance data shows that overall annual TB rates have been declining. However, the increasing proportion of MDR-TB among reported cases and the extremely high rates of MDR-TB pose a major challenge to programme implementation. The recent countrywide drug resistance survey (*8*) provides important information on MDR-TB risk factors that requires further operational research on issues such as previous TB treatment, HIV infection, young age, history of imprisonment, alcohol abuse and smoking. Focused studies on issues such as drug resistance and transmission patterns in selected groups, such as PLHIV and prisoners, and nosocomial transmission should be considered. Moreover, more operational research should be carried out on the characteristics of the regimens and on possible iatrogenic exposures associated with new MDR-TB cases.

There is a general need to examine the best use of available resources in TB laboratories. Currently, bacteriological examinations are repeated at each referral step. A cost-effectiveness evaluation of the benefit obtained from the additional bacteriological studies could inform guidelines. Access to rapid diagnostic testing for MDR-TB is expanding in Belarus, and operational research on the impact of more rapid diagnosis on infection control and treatment success would help guide optimal implementation of this new laboratory capacity. The

clinical usefulness of the introduction of rapid detection of resistance to rifampicin should be evaluated.

Screening of the general population leads to a very high workload, although the case-detection rate is low. Studies of the efficacy and cost-efficiency of current interventions would help to refocus TB screening. Similarly, the large number of cases diagnosed with negative smear/culture pulmonary TB creates another need for operational research on the appropriateness of the revised diagnostic algorithms proposed by the review team.

The implementation in practice of the recently revised policies of the National TB Programme requires routine monitoring and evaluation, and operational research is needed on prolonged hospitalization and the effectiveness of alternative models of delivering MDR-TB treatment.

In TB/HIV, priority areas for research include the optimization of screening of patients identified with one disease for the other disease, and improved links between TB and HIV services to facilitate prompt diagnosis and the continuum of care. Operational research on the success and cost-effectiveness of TB treatment and antiretroviral therapy in people who inject drugs, with access to medication-assisted-treatment, will help inform policy debates in the Region. The number of TB/HIV cases has been increasing, and PLHIV in care are appropriate candidates for treatment of latent TB infection. The effectiveness of isoniazid preventive therapy should be evaluated, especially given the high levels of isoniazid resistance in Belarus. Co-trimoxazole preventive therapy is not widely provided for PLHIV, and case-control studies can indicate the efficacy of this intervention.

Main recommendation

16.1 An operational research agenda should be developed, outlining priority topics to be studied, identifying key investigators and including adequate financial resources that will lead to improved and effective programme performance.

Other recommendations

16.2 Operational research should be conducted on:

- ways of improving the monitoring of trends in the number of MDR-TB cases;
- factors associated with the development or acquisition of MDR-TB;
- benefit of case-finding among different groups actively screened for TB;
- factors involved in delays in case detection of MDR-TB (delays by patients or by doctors, laboratory performance);
- impact of new technologies (e.g. rapid MDR-TB diagnosis) in laboratory practice;
- treatment default rate among vulnerable groups and patients who started the continuation phase in the rayons (follow-up and DOT in the ambulatory phase, cohort analysis);
- all aspects of service delivery in both TB and HIV services, including different ways of integrating services;
- role of earlier initiation of antiretroviral therapy and its effect on mortality;
- isoniazid preventive therapy and co-trimoxazole preventive therapy;
- quality of drugs, especially rifampicin.

17. Ethics and human rights

The Government of Belarus considers TB a public health priority and works for universal access to free-of-charge preventive, diagnostic and treatment services. Services are provided by the Ministry of Health in every oblast, and when patients leave hospital they can choose the most convenient place for continuation of their treatment. Access to TB services by migrants, both regular and irregular, is governed by the "Agreement on medical care for the citizens of the New Independent States" dated 27 March 1997. The law ensures the access of such migrants to free-of-charge TB diagnosis and treatment until smear conversion. Thereafter, migrants should pay for continuation of their treatment or must be deported to their country of origin.

The review team verified that most of the patients interviewed have received adequate information on their condition and treatment and the importance of laboratory investigations to document their noninfectious status. However, the review team also identified National TB Programme practices aiming to decrease the number of patients defaulting from treatment (and therefore at risk of developing drug resistance) which do not correspond to the most generally accepted international standards and should be converted into more patient-centred approaches.

The Law "On health care", issued by the Council of the Republic of Belarus on 18 June 1993 and revised on 4 January 2010, considers the possibility of involuntary isolation and treatment in State medical facilities for patients with diseases threatening public health who refuse treatment. Ministry of Health Order N° 31 on "Adoption of the list of diseases representing a public health threat" dated 13 June 2002 (see Annex 4) includes "all forms of active pulmonary TB with positive smear/culture sputum". In practice, a court can accept the request of the hospital medical council for the involuntary isolation and treatment of patients with poor treatment adherence (i.e. missing 20 or more days of treatment over two months) until their sputum culture is converted to negative. Involuntary isolation and treatment has been based at one hospital in each oblast and the National TB Programme has progressively increased its resort to this practice over the years, as shown in Table 1 below.

Table 1. TB patients placed in involuntary isolation and treatment, 2004–2010

TB patients	2004	2005	2006	2007	2008	2009	2010
Total patients starting treatment	5443	5307	5142	4872	4634	4633	4345
Involuntarily isolated and treated (n)	293	339	725	816	935	1145	1229
Involuntarily isolated and treated (%)	5.4	6.4	14.1	16.7	20.2	24.7	28.3

The review team also observed that the patients in involuntary isolation and treatment may be kept in hospital even after their conversion to noninfectious status if the treating physician considers the patient at high risk of defaulting treatment after release from hospital.[1] The new Law N° 345-3 on "Prevention of diseases posing a threat to the health of the population, HIV" approved by the Council of the Republic of Belarus on 20 December 2011 (i.e. two months

[1] The review team visited Volkovichy Hospital where the medical council decided that 10 patients held in involuntary isolation and treatment for one year and converted to culture negative sputum should not be released as outpatients because they were at high risk of treatment default. One of the patients interviewed complained in writing to a member of the review team about his situation and asked for assistance in obtaining his release, promising to continue treatment after his discharge from hospital. He also asked for social support and winter clothes.

after the review) refers to the 2002 list of diseases posing a public health threat (see Annex 4), therefore including TB, and is even more restrictive and distant from the most accepted international standards (*19*,*20*) because it extends involuntary isolation and treatment even after sputum conversion. The same law also has components likely to promote further stigma and discrimination against PLHIV.

Main recommendation

17.1 Involuntary isolation and treatment should be considered as measures of last resort, to be used only after other interventions, such as professional counselling and organization of social support during outpatient TB treatment, have been found to be ineffective. Current legislation and its applications should be revised to take into account the most important international commitments, standards and best practices.

18. Advocacy, communication and social mobilization

A number of activities related to advocacy,[1] communication[2] and social mobilization[3] (ACSM) are included in the approved National TB Programme 2010–2014. However, they were not based on a clear national strategy and are mainly dependent on external resources such as the Global Fund grants.

Advocacy has been pursued by holding a number of workshops and conferences to increase the national consensus among academia and local administrators on the revised National TB Programme strategies and policies, including the shifting of focus from hospital care to primary health care. Ministry of Health Order N° 517 of 11 June 2008 on "Organization of supervised treatment of TB outpatients", which prohibits over-the-counter sales of first-line anti-TB drugs, can be considered one important success. Every year, World TB Day has been celebrated with special TV and radio broadcasts. However, advocacy efforts at central level have not been matched by similar efforts addressing oblast and rayon authorities, which actually make the decisions about a large part of the resources allocated to TB control by local governments. Advocacy at this level seems essential to guarantee necessary funds and prevent local drug stock-outs.

In the National TB Programme 2010–2014, communication responsibilities are assigned to RSPCPT, the oblast health authorities and the Ministry of Information, but funding is not specified. However, funds for TB-related communication are available from Global Fund

[1] At the country level, advocacy seeks to ensure that national governments remain strongly committed to implementing TB control policies. Advocacy often focuses on influencing policy-makers, funders and international decision-making bodies through a variety of channels (conferences, celebrity spokespersons, news coverage, meetings, etc.)

[2] Behaviour-change communication aims to change knowledge, attitudes and practices among various groups of people. Behaviour-change communication creates an environment through which affected communities can discuss, debate, organize and communicate their own perspective on TB.

[3] Social mobilization brings together community members and other stakeholders (decision-makers, policy-makers, media, nongovernmental organizations, opinion leaders, private sector, professional associations, TB patient networks, religious groups, etc.) to strengthen community participation for sustainability and self reliance. Implementing the Patients' Charter for Tuberculosis Care is an important component of social mobilization, as is the celebration of World TB Day.

Round 9 and actually implemented under the leadership of UNDP, the principal recipient of the grant. A National TB Programme Web site was created, where people can read about TB (currently containing only information about TB in children); RSPCPT has also set up a telephone hotline for questions and answers on TB. Information and education for TB patients and their families are organized in all TB facilities and primary health care practices. Various printed materials were developed for TB patients, the general public and health-care workers, which the review team found to be consistent with the revised National TB Programme policies, with the exception of old-fashioned directions on disinfection (disinfecting surfaces, using separate tableware and performing extra ironing on TB patients' clothes) practised by the sanitary and epidemiological services during the Soviet era.

Knowledge, attitude and practice (KAP) surveys were conducted in 2008 and 2011, showing that most respondents consider TB an important issue and know its main symptoms. Comparing the two surveys, the number of respondents receiving TB-related information from relatives and friends increased from 15% to 33% and those receiving information from health-care workers decreased from 41% to 27%. Television is confirmed as the leading medium, while radio, newspapers and brochures are becoming less popular; information obtained via the Internet increased from 6% to 14%. The new brochures prepared under the Global Fund grant were not yet in use at the time of the 2011 survey.

Besides the above KAP surveys, communication campaign(s) should be routinely evaluated beyond the materials printed and distributed. Specific indicators can be considered, such as patient satisfaction, providers' attitude towards TB patients, number of TB-related articles and media events per oblast, etc. Assessing patient satisfaction is recognized as an important way of improving quality of services and all outpatient facilities have to conduct quarterly patient satisfaction surveys (*21*). This is a good practice that should be imitated by the National TB Programme or, even better, through an independent external person or organization. Other existing tools can be used (*22*).

The review team met a representative of a local group of former TB patients. Improving information on TB through mass media, acting to combat stigmatization of TB patients and assisting TB patients were underlined as potential activities for the future. This group of volunteers, at the time of the review, was very new and was not yet registered as a nongovernmental organization. It may represent an early example of participation by civil society in TB and MDR-TB prevention and control, in the same way as has happened with HIV/AIDS. In Belarus, laypersons, including social workers, are not allowed to deliver medicines or contribute to DOT. Nonetheless, the involvement of the Belarusian Red Cross Society in providing patient support under the Global Fund grant can be considered a positive development (see section on Treatment and case management). The Patients' Charter for Tuberculosis Care, outlining the rights and responsibilities of TB patients, is not used in Belarus. It could be an important tool for balancing the interests of patients and health-care providers, as well as serving the interests of the larger community.

Main recommendation

18.1 A national ACSM strategy should be developed jointly with nongovernmental organizations and patients' representatives, including efforts to involve local governments and policy-makers, patient-centred approaches and involvement of patients and nongovernmental organizations. A national ACSM action plan should be formulated accordingly.

Other recommendations

18.2 Patients' initiative groups should be supported in their establishment and activities. The National TB Programme should establish formal relationships of cooperation and collaboration with such organizations as the Republican Society of PLHIV, and increase collaboration and coordination with the Belarusian Red Cross Society, from joint strategic and operational planning to implementation, monitoring and evaluation.

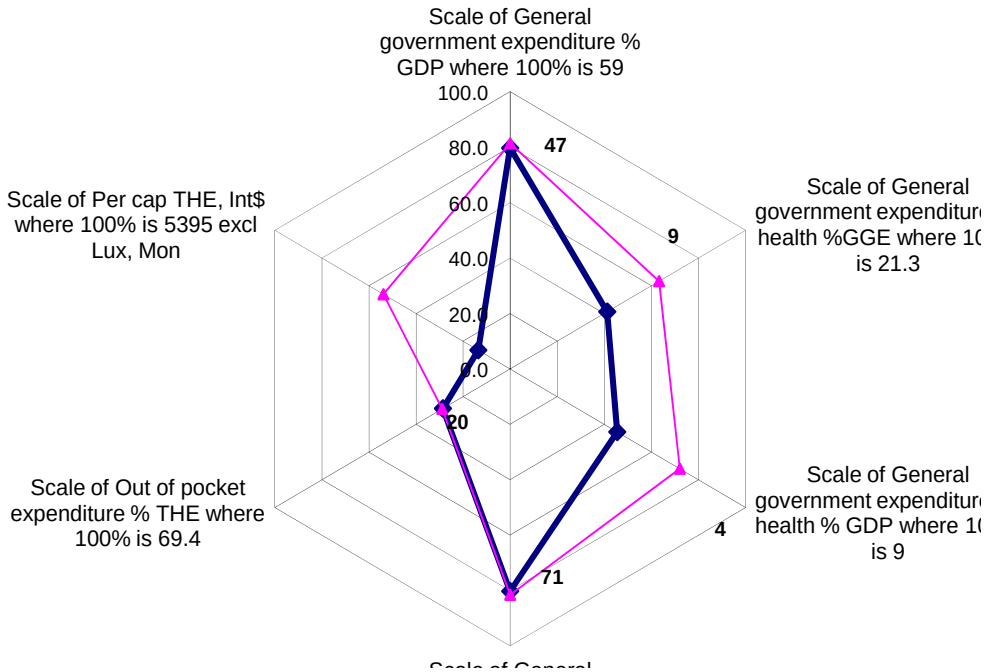
18.3 The Patients' Charter for Tuberculosis Care should be translated and disseminated in order to increase cooperation between care providers and patients and make sure that patients are aware of their rights and their responsibilities to adhere to treatment and contribute to community health.

19. Health system and TB control

Belarus has retained the public provision of health-care services. The overall responsibility for the health-care policy of the country is defined by the Ministry of Health, but governance of the health-care system is heavily decentralized, with about 77% of the funding channelled through the six oblast budgets and the separate budget of Minsk city.

Fig. 2 provides a comparison between health financing in Belarus and the average for the European Union, in proportion to the highest values achieved by a country in the WHO European Region. The proportion of Government expenditure in the public sector in Belarus is relatively large and consistent with the EU average (47% of gross domestic product (GDP)). The priority which the country gives to health is relatively small, however, with only 9% of Government expenditure and 4% of GDP devoted to health, compared with 21.3% in Andorra and 9% in France, respectively, which are the highest in the Region (*23*). Nevertheless, with only 515 per capita Government expenditure on health (PPP international $) in 2009, the country has managed to contain out-of-pocket expenditure at 20%, the lowest value in the Commonwealth of Independent States (CIS). The level of out-of-pocket expenditure is comparable with the European Union average. Thus, the country has managed to support the health system objective of financial protection and minimize the financial barriers to health care.

Fig. 2. Health financing parameters in Belarus and European Union as a proportion of the highest values in the WHO European Region, 2009



THE = total health expenditure; GGE = general Government expenditure.
Source: WHO Global Health Expenditure Database.

The health system is funded primarily by general taxation. Household expenditure is mostly for pharmaceuticals; a very small voluntary insurance sector also exists, which is funded by households or employers. The latter can also provide separate services for their employees. Finally, there is some external funding.

Health care is delivered at three levels: 1) primary health care (feldsher ambulatory practices) and outpatient clinics (ambulatories) in rural areas, polyclinics in urban areas; 2) secondary care (hospitals and secondary-level polyclinics in oblast and rayon cities); 3) tertiary care (specialized hospitals). Most health-care facilities are public property and funded by the Government. Some ministries and employers run a parallel system of health-care services. Government funding is allocated per capita and per calendar year and defined in the Republican Budget, which is then distributed among the oblasts according to their population. Hospital funding is estimated on the basis of utilization of planned budgets and services. Hospitals have no incentive to make savings, because their prospective budgets would be reduced, i.e. they would be penalized financially. Staff shortages are resolved by allowing doctors to work in more than one post and dividing the allocated personnel budget into a smaller number of posts, creating additional bonuses. This creates a small incentive to maximize quality and efficiency. Primary and secondary services are also provided from the oblast and rayon budgets. Tertiary care is cross-subsidized between oblasts when patients from one oblast receive care in another. Primary health care in Belarus is provided by feldshers, general practitioners, district internists and district paediatricians, who do not have a gatekeeping function in allowing access to health services. The only performance-related

indicators at this level are linked to outputs (mass screening, vaccinations, etc.) but not to outcomes.

Most CIS countries were left with large overcapacities in the public sector after the demise of the Soviet Union. With growing financial challenges in the health sector, most countries are aiming to restructure in order to increase efficiency. Belarus has managed to reduce some of this overcapacity, moving from 8.3 to 6.8 hospitals and from 1200 to 1100 hospital beds per 100 000 population in the period 2000–2009; still, hospitals and hospital beds in Belarus are about 50% more numerous than in other CIS countries and three times more numerous than in the European Union (4.8 hospitals and 83 hospital beds in the CIS and 2.7 hospitals and 52 hospital beds in the European Union in 2009). Similar overcapacities exist in personnel (see Table 2) and, accordingly, hospital admissions drastically exceed the European Union average (*3*).

Table 2. Health staff per 100 000 population in the WHO European Region, 2009

Area	Physicians	Nurses	Midwives	Pharmacists
Belarus	511	1243	50	32
CIS (12 countries)	378	798	53	20
Central Asian republics (5 countries)	280	788	68	---
European Union (27 countries)	330	823	32	77
WHO European Region (53 countries)	330	812	40	49
Lowest	115 Albania	355 Andorra	4 Slovenia	6 Kyrgyzstan
Highest	612 Greece	1555 Switzerland	105 Azerbaijan	115 Belgium

The TB policy in the country is the responsibility of the Ministry of Health. There is a five-year National TB Programme 2010–2014, which is implemented by RSPCPT. RSPCPT compiles the patient database and is responsible for overall oversight of the project. The responsibility for service provision lies with the regional authorities, just as with any other health-care services. The Ministry of Internal Affairs runs parallel TB services in prisons. The same is true for the Ministry of Defence. Other ministries can also play important roles in the success of the National TB Programme (Ministries of Economy and Finance, Transport, Education, Internal Affairs, Labour and Social Protection, etc.). The Government recognizes that treatment of TB is cross-cutting through other ministries and government agencies and has set up an intergovernmental National Interagency Coordination Council of TB Control, although this is not very active.

Total expenditure on TB as a proportion of total expenditure on health is 2.1%. Of this, 95% comes from the public budget and 4.5% from donor funding. A total of 87% is allocated for hospital treatment, 12.6% for outpatient treatment and 0.4% for prevention.

According to the Ministry of Health, estimated inflation was almost 200% in 2011, and the planned increase in the budget was 200%. Seventy-five per cent of the drugs budget is spent on imported drugs. Global Fund additional funding for first-line anti-TB drugs comes to an end in 2012. Even if the country is successful in Round 11 (not yet cancelled at the time of the review) the funding is not likely to cover even the first half of 2013. If properly managed, the detection of MDR-TB cases should increase substantially over the next few years, with new, faster and more precise laboratory technologies expected to be in use from 2012. The burden on the health system may be substantial financially, but also in terms of human and capital resources. It is essential to increase efficiency by restructuring the system and optimizing the use of resources. Inefficient interventions such as mass fluorography screening and enforced treatment are areas where resources could be freed up.

Hospitals are paid on the basis of fixed, volume-related budgets. There are no incentives for quality improvement or treatment of patients surplus to the defined volume. This method of payment does not create incentives, at any level of care, to increase the number of detected and successfully treated patients, which are the objectives of the National TB Programme. The doctors optimize their income when they treat exactly the planned number of patients. Moreover, the registration of patients is linked to impact indicators (such as TB incidence), which creates incentives to register and treat fewer patients every year. To fulfil the bed occupancy criteria, patients are hospitalized for unnecessarily long periods. This practice is costly and increases the risk of cross-infection because of the poor infection control. The payment mechanisms in the institutions for involuntary isolation and treatment are an even stronger incentive to increase the length of stay, because the hospital is paid per patient, per day. Involuntary isolation and treatment are very resource-consuming and should be applied only in exceptional circumstances, from both an economic and other points of view.

Main recommendations

19.1 Funding of hospital care should reflect the objectives of the system and consider mechanisms which ensure continuity of care, reduce overhospitalization, improve detection and match care to the needs of patients. This is especially important in TB care, which is challenged by the need to interrupt infectious status, provide a complicated diagnosis and lengthy treatment and serve the most vulnerable groups in the population.

19.2 Effective collaboration should be established between the different ministries involved in MDR-TB prevention, treatment and care, such as the Ministries of Health, Labour and Social Protection, Internal Affairs, Defence, Transport, Education, Economy and Finance. The National Interagency Coordination Council of TB Control should be reactivated, with the National TB Programme acting as its Secretariat.

19.3 The indicators in the health-care system performance tool used by the Ministry of Health to monitor National TB Programme performance should be revised and include MDR-TB outcomes, in accordance with WHO recommendations. This will avoid using incidence and mortality indicators for the assessment of National TB Programme performance, which prompts doctors to under-report and refrain from registering TB and MDR-TB patients.

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Annex 1. Members of the review team

Review team members (international)

Pierpaolo de Colombani	Medical Officer, TB and MDR/XDR-TB Programme, WHO Regional Office for Europe, Copenhagen, Denmark **(Team Leader)**
Andrei Dadu	Technical Officer, TB and MDR/XDR-TB Programme, WHO Regional Office for Europe, Copenhagen, Denmark
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Sven Hoffner	Director of the WHO Supranational TB Reference Laboratory, Swedish Institute for Communicable Diseases, Stockholm, Sweden
Zlatko Kovac	Senior Advisor, International Federation of Red Cross and Red Crescent Societies, Minsk, Belarus
Nora Markova	Health Policy Analyst, Health System Financing, WHO Regional Office for Europe, Barcelona, Spain
Oleksandr Polishchuk	Technical Officer, Health Technologies and Pharmaceuticals Programme, WHO Regional Office for Europe, Copenhagen, Denmark
Ģirts Šķenders	Head, Department of Mycobacteriology, Infectology Centre of Latvia, Riga, Latvia
Nonna Turusbekova	Senior TB Consultant, KNCV Tuberculosis Foundation, The Hague, Netherlands
Erika Vitek	Senior TB Technical Advisor, USAID, Kiev, Ukraine
Grigory Volchenkov	Head Doctor, Vladimir Region TB Dispensary, Vladimir, Russian Federation

Review team members (national)

Andrei Astrauko	Manager, Monitoring and Evaluation Department, Republican Scientific and Practical Centre for Pulmonology and TB, Minsk, Belarus
Eduard Drankov	Department of Execution of Punishment, Ministry of Internal Affairs, Minsk, Belarus
Vera Ilyenkova	Programme Coordinator, HIV/AIDS-STI-VH Programme, WHO Country Office, Minsk, Belarus
Viktoria Kralko	Deputy Director, National Pulmonology and TB Centre, Minsk, Belarus
Inna Nekrasova	Senior TB Adviser, Global Fund TB Grant Project Management Group, UNDP, Minsk, Belarus
Valentin Rusovich	National Professional Officer, TB and MDR/XDR-TB Programme, WHO Country Office, Minsk, Belarus
Elena Skryagina	Deputy Director, Republican Scientific and Practical Centre for Pulmonology and TB, Minsk, Belarus
Oksana Zalutskaya	Head of the National TB Reference Laboratory, Republican Scientific and Practical Centre for Pulmonology and TB, Minsk, Belarus
Liudmila Zhilevich	Head of the Department of Primary Health Care, Ministry of

	Health, Minsk, Belarus
Other team members	
Anna Grigoryan	Expert, The Global Fund, Geneva, Switzerland
Malgorzata Grzemska	Coordinator, Technical Support Coordination, Stop TB Department, WHO headquarters, Geneva, Switzerland
Valentina Molochko	Senior TB Adviser, Global Fund TB Grant Project Management Group, UNDP, Minsk
Cheri Vincent	Senior Public Health Advisor, USAID, Washington DC, USA
Elena Zaytseva	Portfolio Manager, The Global Fund, Geneva, Switzerland
Interpreter	
Petr Dobrusov	

Annex 2. Programme overview

9 October 2011, Sunday			
12:30–19:00	Checking-in, Victoria Hotel, Minsk		
21:00	Meeting of the international reviewers, Meeting Hall Victoria Hotel (organizational issues)		
10 October 2011, Monday			
8:30–10:30	Meeting of all review teams, Meeting Hall Victoria Hotel (organizational issues)		
11:00–12:00	Ministry of Health (introducing the expert groups, agenda and expected assessment results)		
12:00	Departure to the field (four review teams visiting Minsk city, Minsk oblast, Vitebsk oblast and Gomel oblast)		
10-14 October, Monday-Friday **Field work (return to Minsk on 14 October)**			
15 October 2011, Saturday			
10:00–17:00	Working meeting (Victoria Hotel). Discussing the results of visits to the regions.		
16 October 2011, Sunday			
14:00	Free time, tour of the city of Minsk		
17 October 2011, Monday			
9:00–12:00	<u>TB Programme</u> Meeting with the Director of the Republican Scientific and Practical Centre for Pulmonology and TB <u>Participants:</u> G.L. Gurevich, A. Astrovko (NTP), I. Nekrasova (UNDP), P. de Colombani, A. Dadu (WHO), G. Dravniece, S. Hoffner, G. Skenders, G. Volchenkov, E. Vitek (USAID)	<u>Human resources</u> Meeting with representatives of Human Resources Department, educational institutions of the Ministry of Health, representatives of the medical educational institutions (Belarusian Medical Academy of Post-Graduate Education, Belarusian State Medical University (BSMU)) <u>Participants:</u> L. Zhilevich, S. Sychik, E. Tkacheva (Ministry of Health),	<u>Advocacy and working with communities</u> Meeting with nongovernmental organizations: Belarusian Red Cross PLHIV Patients cured from TB TB services <u>Participants:</u> D. Klimuk (NTP), Z. Kovac (Red Cross), A. Grigoryan, N. Turusbekova (WHO), I.

	Venue: Republican Scientific and Practical Centre for Pulmonology and TB	P. Krivonos (BSMU), I. Lapteva, L. Mrochek (Belarusian Medical Academy of Post-Graduate Education), O. Kalechits (NTP) N. Markova (WHO) Venue: Victoria Hotel	Kugach (UNDP), representatives of the Ministry of Labour and Social Protection, patients/medical professionals cured from TB Venue: Victoria Hotel
13:00–14:00	Lunch		
14:00–16:40	TB/HIV Roundtable Participants: E. Skryagina, A.Astrovko (RSPCPT), A. Aleksandrov (Ministry of Health), I. Karpov, D. Paduto (Ministry of Health), A. Rusanovich (Republican HIV/AIDS Prevention Centre); E. Drankov (Ministry of Internal Affairs, Department of Execution of Punishment (DEP)); G. Dravniece, E. Vitek (USAID), V. Ilyenkova (WHO); United Nations agencies Venue: Victoria Hotel	Health systems Meetings with: Department of Primary Health Care Representatives of the Ministry of Labour and Social Protection Representatives of the Office of Health Planning and Economy, Ministry of Health Participants: L. Zhilevich, E. Tkacheva (Ministry of Health), G. Gurevich (NTP); G. Volchenkov, N. Markova, V. Rusovich, N. Turusbekova, P. de Colombani (WHO) Venue: Victoria Hotel	
16:40–17:00	Coffee break		
17:00–18:00	Plenary session. Conclusions and recommendations		
18 October 2011, Tuesday			
9:00–13:00	Monitoring and evaluation Participants: E. Skryagina, A. Astrovko (NTP), P. de Colombani, A. Dadu, Girts Skenders, A. Grigoryan, E. Vitek, S. Hoffner (WHO), V. Molochko Venue: RSPCPT	Penitentiary system Participants: E. Drankov, A. Grinevich (Ministry of Interior DEP), D. Vetushko (NTP), G. Volchenkov, N. Turusbekova, G. Dravniece, V. Rusovich (WHO) Venue: Ministry of Internal Affairs, Department of Execution of Punishment (to	Anti-TB drugs Participants: L. Reutskaya, N. Malashko (Ministry of Health), G.L. Gurevich, V. Ovchinko (NTP), A. Shiryakov (Republican Health Expertise Centre), representative of Belmedpreparaty enterprise, O. Polishchuk (WHO)

		be determined)	Venue: Victoria Hotel
13:00–14:00	Lunch		
14:00–16:40	Working in groups		
16:40–17:00	Coffee break		
17:00–18:00	Wrap up (in plenary)		
19 October 2011, Wednesday			
9:00–11:00	Infection control Participants: E. Skryagina (NTP), I. Karaban (Ministry of Health), A. Astrovko (NTP), P.G. Volchenkov, G. Dravniece, A. Dadu, G. Skenders, S. Hoffner (WHO) Venue: Victoria Hotel	Meeting with the Global Fund project management group Participants: L. Zhilevich (Ministry of Health), G.L. Gurevich (NTP); P. de Colombani, V. Ilyenkova (WHO), E. Vitek, C. Vincent (USAID), E. Zaytseva, A. Grigoryan (Global Fund) Venue: Global Fund Office	
12:00–13:00	Roundtable on enhancing health system capacity to fight TB Participants: L. Zhilevich, L. Reutskaya, E. Tkacheva (Ministry of Health), G.L. Gurevich, E. Skryagina, A. Astrovko (NTP), E. Drankov (Ministry of Interior DEP, Ministry of Labour and Social Protection), Z. Kovach (Red Cross), E. Vitek, C. Vincent, J. Novikov (USAID), E. Zaytseva, A. Grigoryan (Global Fund), I. Nekrasova, V. Molochko (UNDP), P. de Colombani, M. Grzemska, G. Volchenkov, O. Polishchuk, G. Dravniece, A. Dadu, G. Skenders, S. Hoffner, N. Markova, N. Turusbekova, V. Ilyenkova, V. Rusovich (WHO) Venue: Victoria Hotel		
13:00–14:00	Lunch		
14:00–16:40	Working in groups (round table continued)		
16:40–17:00	Coffee break		
17:00–18:00	Wrap up (in plenary)		
20 October 2011, Thursday			
9:00–13:00	Working in groups (Victoria Hotel)		
13:00–14:00	Lunch		
14:00–18:00	Discussion of main findings and recommendations (in plenary)		

21 October 2011, Friday	
10:00–12:00	Meeting with the First Deputy Minister of Health: presenting the main findings and recommendations. Participants: D. Pinevich (First Deputy Minister of Health), L. Zhilevich, G.L. Gurevich, P. de Colombani, M. Grzemska, E. Zaytseva
12:30–13:00	Break
13:00–14:00	Organizational meeting of experts (Victoria Hotel)
14:00–18:00	Departure of experts

Annex 3. Programme of the field teams

Team 1: Minsk oblast	Pierpaolo de Colombani (field team coordinator) Andrei Astrauko Erika Vitek Liudmila Zhilevich Petr Dobrusov (interpreter)
10 October 2011, Monday	
10:00–11:00	Meeting at the Ministry of Health (introducing the experts and the agenda)
12:00–13:00	Meeting with the Minsk Regional Health Care Authorities
13:00–14:00	Lunch
14:00–17:00	Visiting the Minsk Regional TB dispensary (day-care unit, laboratory, outpatient treatment)
11 October 2011, Tuesday	
9:00–13:00	Visiting Soligorsk district TB dispensary
13:00–14:00	Lunch
14:00–16:00	Visiting substitution therapy cabinet, Soligorsk drug addiction dispensary
16:00–18:00	Visiting infectious disease cabinet, Soligorsk Central District Hospital
12 October 2011, Wednesday	
09:00–11:00	Visiting Dzerzhinsk Central District Hospital (TB office of the hospital, laboratory, supervised treatment office)
11:00–13:00	Visiting rural outpatient centre, Dzerzhinsk District, supervised TB treatment
13:00–14:00	Lunch
14:00–16:00	Visiting feldsher post, Dzerzhinsk District, supervised TB treatment
17:00–19:00	Discussing the visit; developing recommendations
13 October 2011, Thursday	
9:00–12:00	Visiting TB dispensary in Borisov (laboratory, supervised treatment office)
12:00–14:00	Visiting city polyclinic in Borisov (general health care services)
14:00–15:00	Lunch
15:00–17:00	Visiting opioid substitution treatment office, Minsk Regional drug addiction dispensary

17:30–19:00	Discussing the visit; developing recommendations
14 October 2011, Friday	
9:00–12:00	Visiting Minsk Regional TB dispensary
13:00–14:00	Lunch
15:00–16:00	Visiting the Minsk Regional Health Care Authorities
16:00–17:00	Discussing the visit; developing recommendations
15 October 2011, Saturday	
11:00–17:00	Working meeting (Victoria Hotel). Discussing regional visit results in the groups

Team 2: **Gomel oblast**	Valentin Rusovich (field team coordinator) Anna Grigoryan Sven Hoffner Inna Nekrasova Georgy Volchenkov Oksana Zalutskaya
10 October 2011, Monday	
10:00–11:00	Meeting at the Ministry of Health (introducing the experts and the agenda)
12:00–13:00	Departure from Victoria Hotel to Gomel (302 km, 4 hours)
17:00–18:00	Meeting with the Gomel Regional Health Care Authorities
11 October 2011, Tuesday	
9:00–13:00	Visiting Gomel Regional TB dispensary (laboratory, hospital, anti-TB drugs)
13:00–14:00	Lunch
14:00–16:00	Visiting antiretroviral therapy cabinet, Gomel Regional Infectious Disease Hospital
16:00–18:00	Visiting substitution treatment office, Gomel drug addiction dispensary
12 October 2011, Wednesday	
09:00–11:00	Visiting Svetlogorsk Central District Hospital (TB cabinet, laboratory, DOT office)
11:00–13:00	Visiting HIV counselling cabinet, Svetlogorsk Central District Hospital
13:00–14:00	Lunch
14:00–16:00	Visiting outpatient treatment centre (ambulatory), feldsher post of the Svetlogorsk Central District Hospital
17:00–19:00	Meeting with people living with HIV, nongovernmental organization “Alternativa”
13 October 2011, Thursday	
9:00–13:00	Visiting TB treatment office, Gomel City Polyclinic (laboratory, supervised treatment office)
14:00–15:00	Lunch
15:00–17:00	Visiting TB treatment cabinet at Gomel City Polyclinic (laboratory, cabinet for supervised treatment)
17:30–19:00	Discussing the visit; developing recommendations
14 October 2011, Friday	
9:00–10:00	Visiting Gomel Regional TB Dispensary
11:00–12:00	Meeting with the Gomel Regional Health Care Authorities
13:00–18:00	Return to Minsk
15 October 2011, Saturday	
11:00–17:00	Working meeting (Victoria Hotel). Discussing regional visit results in the groups

Team 3: Vitebsk oblast	Aleksandr Polishchuk (field team coordinator) Eduard Drankov Gunta Dravniece Nora Markova Valentina Molochko Elena Skryagina
10 October 2011, Monday	
10:00–11:00	Meeting at the Ministry of Health (introducing the experts and the agenda)
12:00–13:00	Departure from Victoria Hotel to Gomel (269 km, 4 hours)
17:00–18:00	Meeting with the Vitebsk Regional Health Care Authorities
11 October 2011, Tuesday	
9:00–11:00	Visiting Vitebsk Regional TB dispensary (laboratory, hospital, anti-TB drugs)
12:00–14:00	Visiting TB hospital "Sosnovka", MDR-TB treatment
15:00–17:00	Visiting antiretroviral therapy cabinet at the Vitebsk Regional Infection Hospital
12 October 2011, Wednesday	
09:00–11:00	Visiting Polotsk Central District Hospital (TB treatment office, laboratory, supervised TB treatment office)
11:00–13:00	Visiting rural outpatient centre (ambulatorium), Polotsk feldsher post (site of the outpatient TB treatment)
13:00–14:00	Lunch
14:00–16:00	Visiting Novopolotsk Central District Hospital (TB treatment office, laboratory, supervised TB treatment office)
17:00–19:00	Discussing the visit; developing recommendations
13 October 2011, Thursday	
9:00–17:00	Visiting Orsha Prison TB Hospital, Correctional Institution 17, Orsha
17:30–19:00	Discussing the visit; developing recommendations
14 October 2011, Friday	
9:00–10:00	Visiting Vitebsk TB regional dispensary
11:00–12:00	Meeting with the Vitebsk Regional Health Care Authorities
13:00–18:00	Return to Minsk (transport)
15 October 2011, Saturday	
11:00–17:00	Working meeting (Victoria Hotel). Discussing regional visit results in the groups
17:00–18:00	Additional visit, GLC/Global Fund project
17 October 2011, Monday	
9:00–13:00	Visiting Molodechno Regional MDR-TB Treatment Hospital
15:00–18:00	Visiting MDR-TB Department, Republican Scientific and Practical Centre for Pulmonology and TB

Team 4: Minsk city	Andrei Dadu (field team coordinator) Vera Ilyenkova Zlatko Kovac Viktoria Kralko Girts Skenders Nonna Turusbekova
10 October 2011, Monday	
10:00–11:00	Meeting at the Ministry of Health (introducing the experts and the agenda)
12:00–13:00	Meeting with the Minsk City Health Care Authorities
14:00–18:00	Visiting Minsk city TB dispensary N°2 (outpatient treatment, laboratory)
11 October 2011, Tuesday	
9:00–13:00	Visiting the Republican Scientific and Practical Centre for Pulmonology and TB (laboratory, inpatient department)
13:00–14:00	Lunch
14:00–16:00	Visiting antiretroviral therapy cabinet, Minsk City Infection Hospital
16:00–17:00	Discussing the visit; developing recommendations
12 October 2011, Wednesday	
09:00–13:00	Visiting Minsk City TB Dispensary N° 1(laboratory, supervised treatment office)
13:00–14:00	Lunch
14:00–16:00	Visiting substitution treatment site in Minsk City
17:00–19:00	Discussing the visit; developing recommendations
13 October 2011, Thursday	
9:00–13:00	Visiting City Polyclinic Nos. 25, 34, Minsk (microscopy room, TB detection room)
14:00–15:00	Lunch
15:00–17:00	Visiting TB treatment hospital for compulsory isolation “Volkovichy”
17:30–19:00	Discussing the visit; developing recommendations
14 October 2011, Friday	
9:00–10:00	Visiting Republican Scientific and Practical Centre for Pulmonology and TB
11:00–12:00	Meeting with the Minsk City Health Care Authorities
14:00–16:00	Discussing the visit; developing recommendations
15 October 2011, Saturday	
11:00–17:00	Working meeting (Victoria Hotel). Discussing regional visit results in the groups

Annex 4. Decree of the Ministry of Health of Belarus N° 31 of 13 June 2002: "Adoption of the list of diseases representing a public health threat"

In response to Part II, Article N° 28 of the Law of the Republic of Belarus of 18 June 1993 "On public health", as amended with effect from 20 July 2008, the Ministry of Health of the Republic of Belarus decides:

1. The list of diseases representing public health threat is described in following appendix.
2. This Decree should be disseminated among the parties concerned.
3. The Deputy Ministers, consistently with their terms of reference, are supervising the execution of the present Decree.

Appendix to the Ministry of Health Decree N° 31 of 13 June 2002

List of diseases representing a public health threat:

1. Venereal diseases
   - 1.1. Syphilis
   - 1.2. Gonorrhea
2. Active pulmonary TB with positive smear/culture sputum (all forms)
3. Plague
4. Cholera
5. Anthrax
6. Hemorrhagic fevers: Lassa, Marburg, and Ebola
7. Mental disorders (diseases) representing threat for people around
8. Acute psychotic disorders caused by abuse of alcohol or drugs

Annex 5. List of TB drugs and other commodities registered in Belarus (as at 13 January 2012)

Trade name, dosage form and strength	Manufacturer
Isoniazid	
Isoniazid, tablets 300 mg 10% injection solution 5 ml vial	RUE "Borisov Plant of Medical Preparations", Republic of Belarus
Isoniazid, tablets 100 and 300 mg	Lugansk Chemical and Pharmaceutical Plant, Ukraine
Isoniazid-Darnitsa, 10% injection solution, 5 ml vial	CJSC Pharmaceutical Firm "Darnitsa", Ukraine
Rifampicin	
Glurifor, granules for preparation of an oral suspension 0.1 g in 1 g packs – 0.062 $ pack	RUE "Belmedpreparaty", Republic of Belarus
Rifampicin, capsules 150 mg	Holden Medical B.V., Netherlands/Holden Medical Laboratories Pvt. Ltd., India Packed by the Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Rifampicin, capsules 150 mg – 0.027 $ caps	RUE "Belmedpreparaty", Republic of Belarus
Rifampicin, lyophilized powder for preparation of intravenous solution 0.15 g ampoules – 0.526 $ amp	RUE "Belmedpreparaty", Republic of Belarus
Pyrazinamide	
Pizina, tablets 500 mg – 0.02 $ tabl.	Lupin Ltd., India
Pyrazinamide, tablets 500 mg	Holden Medical B.V., Netherlands / Holden Medical Laboratories Pvt. Ltd., India Packed by the Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Pyrazinamide, tablets 500 mg	CJSC Makiz-Pharma, Russian Federation
Pyrazinamide, tablets 500 mg	OJSC "Lugansk Chemical and Pharmaceutical Plant", Ukraine
Ethambutol	
Ethambutol, coated tablets 400 mg – 0.29 $ tabl	Holden Medical B.V., Netherlands. Packed by the Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Ethambutol, tablets 400 mg	Lugansk Chemical and Pharmaceutical Plant, Ukraine
Combutol, tablets 400 mg	Lupin Ltd., India
Tubertham, 500 mg/3 ml 3 ml vials	Vecchi & C.PIAM s.a.p.a., Italy
Ethambutol, tablets 400 mg	CJSC Makiz-Pharma, Russian Federation
Capreomycin	
Capocin, powder for preparation of intravenous and intramuscular solution 1 g, vials	Macleods Pharmaceuticals Ltd., India
Capremax, powder for preparation of intravenous solution 1 g, vials	Plethico Pharmaceuticals Ltd., India
Capreomycin powder for preparation of intravenous and intramuscular solution 1 g, vials	ABODmed, Russian Federation
Capreomycin powder for preparation of intravenous and intramuscular solution 1 g, vials	Belmedpreparaty RUE, Republic of Belarus
Capreomycin powder for preparation of intravenous and intramuscular solution 1 g, vials	Kraspharma OJSC, Russian Federation
Capreomycin powder for preparation of intravenous and intramuscular solution 0.5 or 0.75 or 1 g, vials –	Triplepharm Ltd, Republic of Belarus

Trade name, dosage form and strength	Manufacturer
3.38 $ for 1g	
Capreomycin powder for preparation of intravenous and intramuscular solution 0.5 or 1 g, vials	Swiss Parenterals Pvt. Ltd., India. Packed and labelled by Ferein Ltd, Republic of Belarus
Capreostat, powder for preparation of intravenous and intramuscular solution 0.5 or 0.75 or 1 g, vials	Simpex Pharma Pvt., Ltd., India on the premises at Swiss Parenterals Pvt., Ltd. India
Protionamide	
Protionamide, film-coated tablets, 250 mg – 0.123$ tabl.	Lupin Ltd., India
Cycloserine	
Coxerin, capsules 250 mg	Macleods Pharmaceuticals Ltd., India
Cycloserine, capsules 250 mg	Plethico Pharmaceuticals Ltd., India
Cycloserine, capsules 250 mg – 0.67$ caps	RUE "Belmedpreparaty", Republic of Belarus
Cycloserine, capsules 250 mg	OJSC Valenta Farmacevtika, Russian Federation
Terizidone	
Terizidone, capsules 250 mg – 2.06$ caps	FATOL Arzneimittel - subsidiary of RIEMSER Arzneimittel AG, Germany
PAS	
PAS, lyophilized powder for preparation of infusion solution 3 g in bottles for blood – 12.5$ per vial	RUE "Belmedpreparaty", Republic of Belarus
PAS sodium salt, powder for preparation of oral solution 4 g in packs – 0.405 $ per pack	RUE "Belmedpreparaty", Republic of Belarus
PAS sodium salt, powder for preparation of oral solution 4 g in packs	RUPE Izotron, Republic of Belarus
PAS sodium, dosed powder for preparation of oral solution 5.52 g in packs	JSC Olainfarm, Latvia
PAS- Farmland, powder for preparation of oral solution 3, 4, 6, 9 g	Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Rifabutin	
Rifabutin, capsules 150 mg – 1 $ caps	Lupin Ltd., India
Phtivaside, tablets 0.5 g	Stoma AO, Ukraine
Streptomycin	
Streptomycin sulphate, powder for preparation of intravenous solution 0.5 g and 1 g, vials – 0.179 $ per 1.0g	Kyivmedpreparate, Ukraine
Streptomycin sulphate, powder for preparation of intramuscular solution 0.5 g and 1 g, vials	Ferein SpA, Belarus
Amikacin	
Amikacin, powder for preparation of intravenous solution 500 mg, vials	OJSC "Krasfarma", Russian Federation
Amikacin sulphate, powder for preparation of intravenous solution 500 mg, vials	CJSC "Bryntsalov A", Russian Federation
Amikacin solution for injections 500 mg/2 ml ampoules 2 ml – 0.38 $ per vial	Darou Pakhsh Pharmaceutical MFG Company, Islamic Republic of Iran
Amikacin sulphate, powder for preparation of intravenous solution 0.5 g vials	OJSC “Syntez” Kurgan, Russian Federation
Amikacin-C.K., powder for preparation of intravenous solution 500 mg vials	NCPC International Corp. North China Pharmaceutical Corporation Co., Ltd., China
Amicil, lyophilized powder for preparation of intravenous solution 0.25 g, 0.5 g, and 1 g, vials	OJSC Kievmedpreparat, Ukraine
Kanamycin	

Trade name, dosage form and strength	Manufacturer
Kanamycin, powder for preparation of intravenous solution 0.5 g and 1 g, vials	Kurgan JSC “Sintez” Medical Preparation and Products, Russian Federation
Kanamycin, powder for preparation of intravenous solution 1 g, vials – 0.218 $ per vial	OJSC Kievmedpreparat, Ukraine
Ofloxacin	
Vitoflon, Solution for infusion 200 mg/100 mg, vials 100 mg	Ahlcon Parenterals Limited, India for Vita Pharma, Slovakia
Zanocin OD, coated tablets retard 400 mg and 800 mg	Ranbaxy Laboratories Limited, India
Oflo, solution for infusion 2 mg/ml, vials 100 mg – 0.42$ per vial	Unique Pharmaceutical Laboratories (a division of J.B. Chemicals & Pharmaceuticals Ltd.), India
Ofloxacin, solution for infusion 2 mg/ml (in 0.9% sodium chloride), vials 100 mg	Kurgan JSC "Sintez" Medical Preparation and Products, Russian Federation
Ofloxacin, capsules 200 mg	Holden Medical BV, Netherlands/Holden Medical Laboratories Pvt. Ltd., India Packed by the Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Belarus
Ofloxacin, coated tablets 200 mg	OJSC Farmstandart-Leksredstva, Russian Federation
Ofloxacin-Borimed, coated tablets 200 mg – 0.08$ per tab.	RUE Borisov Plant of Medical Preparations, Belarus
Ofloxacin-Promed, coated tablets 200 mg	Promed Exports Pvt. Ltd., India
Ofloxacin, coated tablets 200 mg, coated tablets 400 mg	ZENTIVA a.s., Czech Republic
Ofloxacin, solution for infusion 2 mg/ml, vials 100 mg	ZENTIVA a.s., Czech Republic, manufactured by Fresenius Kabi Austria GmbH, Austria
Oflomax, tablets 200 mg	MaxPharma (UK) Limited, UK, manufactured by Intas Pharmaceuticals Ltd., India
Ultracin, film-coated tablets 200 mg	Pharmacare Int. Co./ BPC, Palestine
Levofloxacin	
Vitalecin, solution for infusion 500 mg/100 ml, vials 100 mg	Ahlcon Parenterals Limited, India for Vita Pharma, Slovakia
Giracin, film-coated tablets, 500 mg	Aarya Lifesciences Pvt. Ltd., India
Lebel film-coated tablets, 500 mg and 750 mg	Nobel Ilac Sanayii ve Ticaret A.S., Turkey/Nobelfarma Ilac Sanayii ve Ticaret A.S., Turkey
Levolet, coated tablets 250 mg and 500 mg	Dr. Reddy s Laboratories Ltd., India
Levoprim, coated tablets 250 mg and 500 mg	Med-Interplast (India) Pvt. Ltd., India /Akums Drugs & Pharmaceuticals Ltd., India
Levofloxacin, coated tablets 250 mg and 500 mg	Holden Medical B.V., Netherlands / Holden Medical Laboratories Pvt. Ltd., India
Levofloxacin, solution for infusion 0.5%, bottles 100 mg – 1.78 $ per vial.; capsules 250 mg – 0.34 $ per cap.	RUE "Belmedpreparaty", Republic of Belarus
Levofloxacin infusion solution 5 mg/ml, bottles 100 ml	Safarma, Russian Federation
Leflox, solution for infusion 0.5% in polymer containers 100 ml	Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Leflox-250, coated tablets, 250 mg	Holden Medical B.V., Netherlands /Holden Medical Laboratories Pvt. Ltd., India Packed by the Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Leflox-500, coated tablets, 500 mg	Holden Medical B.V., Netherlands /Holden Medical

Trade name, dosage form and strength	Manufacturer
	Laboratories Pvt. Ltd., India Packed by the Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Loxof, solution for infusion 500 mg/100 mg, vials 100 mg; film-coated tablets, 500 mg	Ranbaxy Laboratories Limited, India
Lotor, coated tablets 500 mg and 750 mg	Emcure Pharmaceuticals Ltd., India for Actavis Group hf, Iceland
Remedia, coated tablets, 250 mg, 500 mg, 750 mg	Simpex Pharma Pvt. Ltd., India on the premises of Sai Mirra Innopharm (Pvt) Ltd, India
Tavanik, film-coated tablets 250 mg and 500 mg; solution for infusion 500 mg/100 ml, vials	Sanofi Winthrop Industrie, France
Moxifloxacin	
Avelox, coated tablets, 400 mg – 4.5 € per tablet, solution for infusion 400 mg/250 ml – 49.4 € per vial.	Bayer HealthCare AG, Germany
Linezolid	
Zivox Solution for infusion 2 mg/ml, infusion packs 100 ml and 300 ml – 63.57$ per vial	Fresenius Kabi Norge AS, Norway/Pfizer AS, Norway
Zivox, coated tablets, 600 mg – 61.1 $ per tabl.	Pharmacia & Upjohn Company, USA, manufactured by Pfizer Pharmaceuticals LLC, USA
Amoxicillin and clavulanic acid	
Amoclav-375, film-coated tablets, 375 mg, (250mg/125 mg)	Holden Medical B.V., Netherlands /Holden Medical Laboratories Pvt. Ltd., India
Amoclav-625, film-coated tablets, 200 mg, 625 mg (500 mg/125 mg)	Holden Medical B.V., Netherlands /Holden Medical Laboratories Pvt. Ltd., India
Amoclav-1000, film-coated tablets, 200 mg, 1000 mg (875 mg/125 mg)	Holden Medical B.V., Netherlands /Holden Medical Laboratories Pvt. Ltd., India
Amoxicar PLUS, film-coated tablets, 200 mg, 500 mg/125 mg and 875 mg/125 mg; powder for preparation of suspension 100 ml (125 mg+31.25 mg)/5 ml and (250 mg+62.5 mg)/5 ml in vials; powder for preparation of suspension 70 ml 40 mg+57 mg)/5 ml in vials	Pharmacare Int.Co./Jepharm, Palestine
Amoxiclav, film-coated tablets, 375 mg, (250 mg/ 125 mg) and 625 mg (500 mg/ 125 mg) 1000 mg (875 mg +125 mg); powder for preparation of oral suspension 312.5 mg (250 mg+62.5 mg)/5 ml and 156.25 mg (125 mg+31.25 mg)/ 5 ml in vials 100 ml	Lek d.d., Slovenia
Amoxicomb, powder for preparation of oral suspension 100 ml (125 mg+31.25 mg)/5 ml – 1.95 $ per vial and 250 mg+62.50 mg)/5 ml in polymer vials – 4.05 $ per vial, coated tablets, 250 mg/125 mg, 500 mg/125 mg – 0.2 $ tabl. and 875 mg/125 mg	Aringa UAB, Lithuania, manufactured by Aurobindo Pharma Ltd., India
APO-Amoxiclav, film-coated tablets, 250 mg/125 mg, 500 mg/125 mg and 875 mg/125 mg	Apotex Inc., Canada
Augmentin, coated tablets, 875 mg/125 mg, 625 mg (500 mg/125 mg; powder for preparation of oral	SmithKline Beecham Pharmaceuticals, UC

Trade name, dosage form and strength	Manufacturer
suspension 100 ml (400 mg/57 mg)/5 ml (200 mg/28.5 mg)/5 in vials	
Medoclav, coated tablets 375 mg (250 mg+125 mg), 625 mg (500 mg+125 mg) and 1g (875 mg+125 mg)	Medochemie Ltd, Cyprus
Rapiclav, coated tablets, 250mg/125 mg and 500 mg/125 mg, 875 mg/125 mg	IPCA Laboratories Ltd., India
Taromentin, powder for preparation of solution for intravenous solutions and infusions 500 mg/100 mg and 1g/0.2 g in vials	Tarchomin Pharmaceutical Works Polfa S.A., Poland
Amoxiclav, powder for the solution for injections 1000 mg/200 mg, 500 mg/100 mg	Lek d.d., Slovenia, manufactured by Sandoz GmbH, Austria
Farmentin BD 228 powder for oral suspension (200 mg+28.5 mg)/5 ml	Farabi Pharmaceutical Company, Iran
Farmentin BD 457 powder for oral suspension (400 mg+57 mg)/5 ml	Farabi Pharmaceutical Company, Iran
Flemoklav Solutab solvable tablets 125 mg+31.25 mg – 0.29 € per tabl., 250 mg+62.5 mg, 500 mg+125 mg, 875 mg+125 mg	Astellas Pharma Europe B.V., Netherlands
Amclav, powder for i/v infusion solution 500 mg/100 mg, 1000 mg/200 mg; film-coated tablets 250 mg/125 mg – 0.17 $ tabl.	Belmedpreparate, Republic of Belarus
Augmenta, 1000 film-coated tablets 875 mg/125 mg Augmenta, powder for injection solution 500 mg/100 mg, 1000 mg/200 mg	Asia Pharmaceutical Industries, Syrian Arab Republic
Clavomed, film-coated tablets 500 mg/125 mg 875 mg/125 mg	World Medicine, UK manufactured by Bilim Ilac Sanayi ve Ticaret A.S., Turkey
Flemoclav solutab, dispersible tablets 125 mg/31.25 mg, 250 mg/62.5 mg and 500 mg/125 mg 875 mg+125 mg	Yamanouchi Europe B.V., Netherlands
Clarithromycin	
Clabax OD, retard coated tablets, 500 mg	Ranbaxy Laboratories Limited, India
Clabax, coated tablets, 500 mg	Ranbaxy Laboratories Limited, India
Clarbact, coated tablets, 250 mg, and 500 mg	IPCA Laboratories Ltd., India
Claricar, powder for preparation of suspension 60 ml, 125 mg/5 ml in vials, powder for preparation of suspension 100 ml, 125 mg/5 ml in vials, film-coated tablets, 250 mg and 500 mg	Pharmacare Int. Co./ Pharmacare PLC, Occupied Palestinian Territories
Clarimycin, coated tablets 250 mg and 500 mg	Synmedic Laboratories, India
Eracid, film-coated tablets, 250 mg and 500 mg	The Jordanian Pharmaceutical Manufacturing Company, Jordan
LEVOCLAR, granules for oral suspension 125 mg/5 ml 250 mg/5 ml in vials 60 ml	S.C. Sandoz S.R.L., Romania
Clarithromycin, coated tablets 250 mg	Protech Biosystems Pvt.Ltd., India
Clarithromycin, coated tablets 250 mg	Holden Medical B.V., Netherlands /Holden Medical Laboratories Pvt. Ltd., India Packed by the Belarusian-Dutch joint venture Farmland Ltd. (JV Farmland Ltd.), Republic of Belarus
Clerimed, film-coated tablets 250 mg and 500 mg	Medochemie Ltd, Cyprus
Clacid film-coated tablets, 250 mg, granules for oral suspension 125 mg/5 ml 250 mg/5 ml in vials 100 ml	Abbott S.r.l., Italy

Trade name, dosage form and strength	Manufacturer
Cleromycin 250, coated tablets 250 mg Cleromycin powder for oral suspension 125 mg/5 ml in vials 100 ml	Aegis Ltd., Cyprus
Clacid CP film-coated tablets, suspended release 500 mg	Aesica Queenborough Ltd., UK
Clacid B.B. lyophilized powder for solution for infusions 500 mg	Famar L Aigle, France
FROMULID UNO modified release film-coated tablets, 500 mg – 1.134 $ tabl., granules for the suspension preparation 60 ml, 125 mg/5 ml, film-coated tablets 250 mg, 500 mg	KRKA, d.d., Slovenia
Lecoclar XL extended release film-coated tablets 500 mg	Lek d.d., Slovenia
CLERON MAXPHARMA powder for oral suspension vials 100 ml 125 mg/5 ml; film-coated tablets 250 mg – 0.17 $ tabl., 500 mg – 0.27 $ tabl.	MaxPharma (UK) Limited, UK manufactured by Aegis Ltd., Nicosia, Cyprus
Cleromycin, powder for preparation of oral suspension 100 ml, 125 mg/5 ml in vials	Aegis Ltd., Cyprus
Powder for preparation of oral suspension 100 ml, 125 mg/5 ml in vials; coated tablets, 250 mg and 500 mg	Cleron-MaxPharma, MaxPharma (UK) Limited, manufactured by Aegis Ltd., Nicosia, Cyprus
Fromilid UNO, retard coated tablets, 500 mg	KRKA, d.d., Slovenia
Fromilid, granulate for oral suspension 60 ml, 125 mg/5 ml in vials with a dosing syringe; film-coated tablets 250 mg and 500 mg	KRKA, d.d., Slovenia
J07AN01 Tuberculosis, live attenuated prophylactic vaccine	
BCG 0.5 mg or 1 mg lyophilized powder for intracutaneous injection solutions – 6.72 $ per dose	SRIEM Gamaleya AMSRF (Branch Medgamal SRIEM Gamaleya AMSRF), Russian Federation
BCG 0.5 mg or 1 mg lyophilized powder for suspension for intracutaneous injection	Microgen, Stavropol, Russian Federation
BCG-M 0.5 mg	SRIEM Gamaleya AMSRF (Branch Medgamal SRIEM Gamaleya AMSRF), Russian Federation
BCG-M 0.5 mg	Microgen, Stavropol, Russian Federation
V04CF01 Tuberculin	
Purified tuberculosis allergen in a standard dilution, solution for intracutaneous injection, ampoules 1 ml (10 doses), 2 ml (20 doses), 3 ml (30 doses)	St. Petersburg NII, Russian Federation
Purified tuberculosis allergen in a standard dilution, solution for intracutaneous injection 2 TU/dose – 0.017 $ per dose	Biolek, Ukraine
DIASKINTEST Tuberculosis recombinant allergen in a standard dilution for intracutaneous use vials 3 ml (30 doses)	Pharmaceutical company CJSC LEKKO, Russian Federation

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