World Health Organization

REGIONAL OFFICE FOR Europe

Review of the national tuberculosis programme in Belarus

8–18 December 2015

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ABSTRACT

Belarus is a top priority country for prevention and control of multidrug-resistant (MDR) tuberculosis (TB). In October 2011, the WHO Regional Office for Europe conducted a comprehensive review of the national TB programme (NTP). In 2015, it was decided that a further review should be carried out to follow up the recommendations of the 2011 review and to consider additional challenges arising from new evidence and policies in recent years. The second review took place from 8 to 18 December 2015 with the participation of nine international and eight national experts who visited four areas of the country (Minsk city, Minsk region, Gomel region, Mogilev region). While acknowledging the important progress made since 2011, the review team also provided some recommendations for improvement to the Ministry of Health and the NTP.

Keywords

TUBERCULOSIS – prevention and control
NATIONAL HEALTH PROGRAMS
PROGRAM EVALUATION
REPUBLIC OF BELARUS

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Acknowledgements

The review team gratefully acknowledges the cooperation and hospitality of all government officials, members of nongovernmental organizations and patients. Their understanding and flexibility allowed us to accomplish effectively all the visits and interviews planned, despite an ambitious schedule that often forced people to work late. We apologize for the inconvenience this caused.

The WHO country office in Minsk and the health administrations of the regions visited provided efficient administrative and logistics support, which made all the meetings possible and travelling easy.

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

Ministry of Health, Minsk, Belarus
Department of Execution of Punishment, Ministry of Internal Affairs, Minsk, Belarus
Regional health administrations, Belarus
WHO Country Office, Minsk, Belarus
United States Agency for International Development, Washington (DC), United States
Public Health Agency of Sweden, Stockholm, Sweden
Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland
United Nations Development Programme, Minsk office, Belarus.

Their support is highly appreciated and underlines their commitment to improving tuberculosis control in Belarus.

A special acknowledgment is due to the United Nations Development Programme office in Minsk, whose support made this review possible.

Abbreviations

ACSM	advocacy, communication and social mobilization
ART	antiretroviral treatment
BCG	bacillus Calmette-Guérin
CPT	co-trimoxazole preventive therapy
DOT	directly observed treatment (for TB)
DST	drug susceptibility testing
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
IPT	isoniazid preventive therapy
MDR-TB	multidrug- resistant tuberculosis (resistant to, at least, isoniazid and rifampicin)
MGIT	mycobacteria growth indicator tube
MTB/RIF	*M. tuberculosis* rifampicin-resistant
NRL	national tuberculosis reference laboratory
NTP	national tuberculosis control programme
PAL	Practical Approach to Lung Health
PLHIV	people living with HIV
RSPCPT	Republican Scientific and Practical Centre for Pulmonology and Tuberculosis
SES	Sanitary Epidemiological Service
TB	tuberculosis
TB/HIV	HIV-associated tuberculosis
USAID	United States Agency for International Development
XDR-TB	extensively drug-resistant tuberculosis

Executive summary

Belarus is a top priority country for the prevention and control of multidrug-resistant (MDR) tuberculosis (TB). In October 2011, the WHO Regional Office for Europe conducted a comprehensive review of the national TB programme (NTP) which provided a number of recommendations for improvement. Since then, Belarus has made important progress.

To follow up the recommendations of the 2011 review and to consider the additional challenges arising from the new evidence and policies of recent years, it was decided that a further NTP review should be carried out. This took place in December 2015 with the participation of nine international and eight national experts who visited four areas in the country: Minsk city, Minsk region, Gomel region and Mogilev region. This document is the report of that review.

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. Over one quarter of these have extensively drug-resistant (XDR) TB. These are still the highest proportions documented in the world. Although TB incidence and mortality rates have been steadily decreasing in recent years, with a mean annual percentage decrease of -2.7% and -3.7%, respectively, between 2005 and 2014, new notifications of people living with HIV with TB as the main cause of morbidity and mortality are increasing, especially among people who inject drugs.

The team acknowledged the tremendous progress made by the NTP since the last review in October 2011. The majority of the recommendations made in 2011 have been implemented and institutionalized through 19 orders issued by the Ministry of Health. State and regional budgets have been increased to improve TB services and compensate for the progressive disengagement of the Global Fund to Fight AIDS, Tuberculosis and Malaria. Rapid diagnosis of drug-resistant (DR) TB has been widely introduced. Belarus is one of the few priority countries in the Region where the reported number of MDR-TB patients placed in treatment exceeds the number of estimated cases among notified cases. TB facilities have been renovated to create appropriate in/outpatient care. Involuntary TB treatment has been reduced from 22% to 11% of the total number of TB patients detected between 2010 and 2014. TB care has been decentralized to primary health care institutions and the government planned to begin funding support for all TB patients in January 2016. Highly innovative initiatives have been taken, such as the introduction of bedaquiline and a demonstration project in Mogilev region where primary health care providers received financial incentives generated from the closure of some hospital beds and the implementation of digital health (electronic TB register, pharmacovigilance, video-observed treatment, Practical Approach to Lung Health).

Nonetheless, the team noted a number of aspects of the NTP that need to be further improved. Although overall hospitalization has been reduced, non-infectious TB patients are still being unnecessarily treated in hospital. The number of TB patients being involuntarily isolated and treated (which has also decreased) is of concern. A lot of public resources are still spent in mass screening of individuals or occupational groups at low risk of TB while case-finding and the tracing and treatment of household contacts (including children) are not well coordinated.

The team made a number of recommendations to the Ministry of Health and the NTP with the aim of further strengthening the prevention and control of TB. The main ones are listed below.

Main recommendations to the Ministry of Health and the NTP

1. Priority should be given to ensuring access to effective treatment regimens for all subgroups of MDR-TB, including XDR-TB and beyond XDR-TB. International support for the procurement of bedaquiline should be explored urgently and the treatment for XDR-TB decentralized as soon as possible to regional level.
2. Bacteriological culture in solid media (number of level II laboratories) should be further reduced and countrywide coverage with rapid molecular testing ensured so as to reduce the delays in diagnosing TB and drug-resistant (DR) TB. Prompt transport of laboratory specimens should be ensured. The application software for proper analysis and reporting of laboratory data should be improved. Government funding should be ensured to avoid shortages of laboratory commodities.
3. The new and repurposed anti-TB drugs (such as bedaquiline, delamanid, linezolid, clofazimine and imipenem/cilastatin) should be included in the national list of essential medicines. The central procurement of all anti-TB drugs (including the aforementioned) should be ensured based on actual and estimated needs (forecasting based on patient resistance patterns and existing and buffer drug stocks). The drug supply should be coordinated with the regions and across the different sources of funding, including national and local budgets and international support (Global Fund, Médecins Sans Frontières, the United States Agency for International Development and others).
4. Infection control should be further expanded to reduce transmission of DR-TB among patients and health care workers in TB facilities. The implementation of airborne infection control measures should be prioritized in facilities with a large number/rate of DR-TB, such as those for M/XDR-TB, and more advanced resistance patterns in patient care, involuntary TB treatment, palliative TB care and laboratories. The implementation of a range of infection control measures should be optimized, including the good design and maintenance of mechanical ventilation
5. Outpatient TB care should be strengthened by: enabling TB doctors at district level to diagnose and treat drug-susceptible TB; ensuring the continuum of TB care for patients released from prison; ensuring that a full package of joint services for vulnerable populations (harm reduction, treatment of alcohol abuse disorders) is available; and increasing TB service coverage through social contracting.
6. The number of TB hospital beds should be further reduced and the cost savings used to strengthen ambulatory TB care through incentives to providers and support for patients. Various options for financing TB hospitals could be considered for a pilot project, such as introducing a global budget, or maintaining the current line-item budget with a lower budgetary ratio of doctors to hospital beds while preserving their actual monthly income and without affecting the quality of services in place. Unnecessary hospitalization (non-severe, non-infectious pulmonary and extrapulmonary TB cases) should be avoided and inpatient stays shortened by revising hospital admission and discharge criteria.
7. Involuntary isolation and treatment should be reduced by increasing outpatient TB treatment and including support for patients.
8. The annual TB screening (fluorography, skin tests) of large parts of the population should be further reduced in favour of a focus on groups with documented cost-effective targeting,

such as TB contacts (currently not screened enough), as per the most recent WHO recommendations. Significant cost savings can be found and allocated to support priority interventions for the prevention and control of TB and DR-TB.

9. Universal coverage by the collaborative HIV-associated TB (TB/HIV) interventions should be ensured, with priority given to access for people living with HIV to intensified TB screening through rapid molecular test and isoniazid preventive therapy and for TB patients to rapid HIV test, antiretroviral treatment and co-trimoxazole preventive therapy.

10. Early detection of TB among children by should be improved by tracing and carefully investigating those in close contact with TB cases. Diagnosis and ambulatory treatment should be strengthened at regional level (rather than obliging all paediatric TB cases to be treated in Minsk) and hospitalization limited to severe forms of TB. Non-infectious children (including bacteriologically-converted) should be allowed to attend school. Consideration should be given to admitting children >15 years of age into adult inpatient services. WHO prequalified bacillus Calmette-Guérin (BCG) vaccine should be used and BCG revaccination at seven years of age should be abandoned.

11. Support for all TB patients, with or without employment, should be further expanded by covering their direct and indirect medical costs (transport for directly observed treatment, ancillary treatment) and compensating them for non-medical costs (absence or loss of income not covered by disability benefit/sick leave during in/outpatient treatment or a ban on return to work).

12. Catastrophic costs of TB should be documented through participation in the global survey organized by WHO. Social protection for TB patients should be synergized with the national schemes of the Ministry of Labour and Social Protection.

13. The specialties of pulmonology and phthisiology should be merged and undergraduate, postgraduate and continuing medical education harmonized to ensure the rational and flexible use of existing resources and to increase career opportunities that will attract more doctors.

14. The electronic databases for TB and laboratory and drug management should be developed to facilitate data aggregation, analysis and reporting at central and regional levels. Other features should be added, such as registration of drug adverse events, TB/HIV interventions and interoperability with the HIV national register. Support for digital health for TB, such as video-observed therapy and eLearning, should continue and adequate measures should be ensured to capture user feedback and to collect evidence on their impact.

15. The new national advocacy, communication and social mobilization strategy for 2016–2020 should be developed jointly with all main TB stakeholders in the country and included in the National TB Plan 2016–2020.

16. A new operational research agenda should be developed outlining priority topics for study, identifying key investigators and including adequate financial resources to lead to a better and more effective performance by the NTP.

Introduction

Belarus is one of the 18 countries in the WHO European Region where the control of tuberculosis (TB) is a high priority *(1)*, and among the 30 high-burden multidrug-resistant (MDR) TB countries globally *(2)*.

In October 2011, the WHO Regional Office for Europe conducted a comprehensive review of the national TB programme (NTP) which provided a number of recommendations for improvement *(3)*. Since then, Belarus has made important progress in addressing the MDR-TB epidemic with the support of international partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the United States Agency for International Development (USAID), the United Nations development Programme and WHO.

A second review of the NTP took place from 8 to 18 December 2015 to follow up the recommendations given in 2011, to assess the impact of the changes in policies implemented since then, to collect evidence on these interventions and to assess any new challenges and developments emerging in the last few years. The review was part of the technical assistance requested by the Ministry of Health from the Regional Office on 14 April 2015, funded under the current Global Fund TB grant.

Nine international and eight national experts participated in the review (Annex 1). The team analysed the relevant documents available (publications, mission reports and programme data), visited relevant institutions and facilities and interviewed policy-makers, health providers and beneficiaries, patients and representatives of the main national and international partners at national level and in four areas (Minsk city and Minsk, Gomel and Mogilev regions) selected according to their epidemiological status and geographical distribution.

The programme of the mission is given in Annex 2. During the first week, the members divided into three field teams, each coordinated by an international expert, to visit the four areas listed above. The second week was spent in meetings and visits in Minsk and work on this report. The main findings and recommendations were provided at the end of the review in a debriefing with Dr Dmitry Pinevich, First Deputy Minister of Health.

The review was also an opportunity for the annual monitoring visit on behalf of the WHO/Stop TB Partnership Green Light Committee, whose report has been produced separately from this report.

General information

The Republic of Belarus in eastern Europe has a total population of 9.5 million people, 75% of whom live in urban areas *(4)*. The country is administratively divided into six regions: Brest, Gomel, Grodno, Minsk, Mogilev and Vitebsk, with the city of Minsk (which contains one fifth of the total population) as a separate administrative entity. The regions are divided into 121 districts with populations varying from 12 000 to 120 000.

Belarus is ranked by the World Bank as an upper-middle income country. The gross national income was US$ 6460 per capita in 2015 (a sharp fall from 2014), with 5.1% of the population living below the national poverty level *(5)*. Most of the economy is directly controlled by the state, although private businesses, including those owned by foreigners, have been progressively

expanding. After a period of steady growth, the economy was severely affected by the recent global financial crisis and slowing of the economy in the neighbouring Russian Federation, causing further devaluations of the national currency totalling -35% in the course of 2015 *(6)*.

In 2011, the average life expectancy at birth was 64.7 years for men and 76.9 years for women. The leading causes of mortality were cardiovascular diseases, external causes such as accidents, poisoning, injuries and cancer (571, 130 and 158 deaths per 100 000 population, respectively) *(7)*. The high levels of alcohol consumption and tobacco smoking are key public health challenges. In 2012, WHO estimated that the total consumption of pure alcohol (recorded and unrecorded) per individual aged >14 years was 17.5 litres per year *(8)*. The incidence of smoking among men and women in 2011 was 50% and 10%, respectively, one of the highest in the European Region *(7)*.

Environmental factors are significant. It is estimated that over 70% of the radioactive fallout from the 1986 nuclear accident in Chernobyl (Ukraine) fell over southern Belarus and contaminated large areas of arable land, posing long-term health hazards to a sizeable part of the population.

TB epidemiology

In 2014, according to the latest WHO estimates, Belarus had a TB incidence (all forms) of 58 (50–67) cases per 100 000 population, a prevalence of 81 (40–136) and a mortality due to TB of 7.7 (7.1–8.3). Translating these rates into absolute numbers, it is estimated that 5500 (4700–6400) new TB cases and 810 (744–888) deaths due to TB (including those associated with HIV infection) occur annually in Belarus. Incidence and mortality rates for TB decreased by a mean annual percentage of -2.7% and -3.7%, respectively, between 2005 and 2014. The peaks of notifications of new and relapsed TB cases by the NTP in 2014 were between 45 and 54 years of age among men and between 35 and 44 years among women, with a female to male ratio of 1:3.5.

MDR-TB is estimated to be present in 34% (32–36%) and 69% (66–72%) of the newly detected and previously treated TB cases, respectively – the highest levels in the world. Extensively drug-resistant (XDR) TB was found in 30.4% of the MDR-TB patients tested for second-line anti-TB drugs. Translating these rates into absolute numbers, it is estimated that 1710 (1610–1850) new MDR-TB cases occur annually in Belarus.

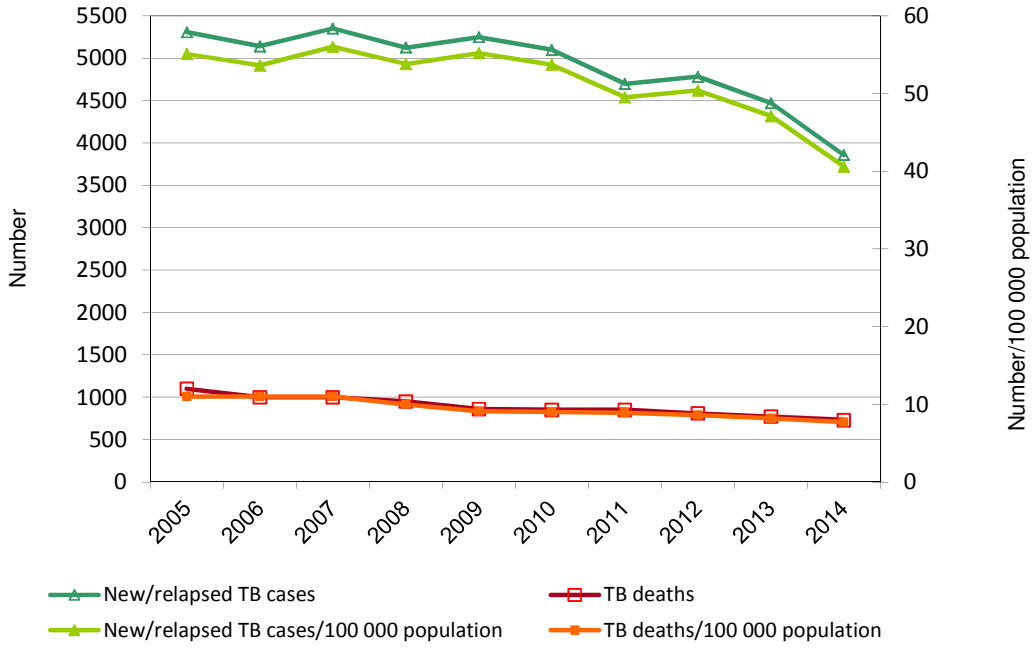
The first HIV-positive person found in Belarus was in 1987. Since then, 19 605 HIV diagnoses have been made. By November 2015, 15 069 people were registered as living with HIV (PLHIV) in the country. The prevalence of HIV was estimated in 2015 to be 0.6% (0.5–0.8%) among adults aged 15–49 years, that is, 35 000 (29 000–43 000) PLHIV *(9)*. Some 1811 new HIV diagnoses were reported in 2014, of whom 1349 (74%) claimed to be after heterosexual contact, 376 (21%) from injecting drug use and only 53 (3%) from men to men sexual intercourse *(10)*. Injecting drug use should, however, be considered the main driver of the HIV epidemic and of the significant increase in new HIV infections in the country in recent years (see section below on HIV-associated TB).

NTP: achievements, strategies, structure and resources

In 2014, the NTP registered 4274 TB new cases for treatment *(11)*. Of these, 3858 (90%) were new and relapsed cases, some 70% (60–81%) of those estimated as occurring by WHO. Only 24 (<1%) were aged under 15 years. The NTP also reported 1282 laboratory-confirmed MDR-TB new cases, 75% (62–80%) of those estimated. In the meantime, 1903 MDR-TB cases were placed in treatment, meaning that 621 additional cases were taken from the backlog of patients on the waiting list for treatment with new and repurposed anti-TB drugs. The latest treatment success reported by the NTP (2013 cohort of patients) was 87% among newly diagnosed TB patients, 71% among previously treated pulmonary TB patients, 65% among TB/HIV patients and 54% among MDR-TB patients (2012 cohort).

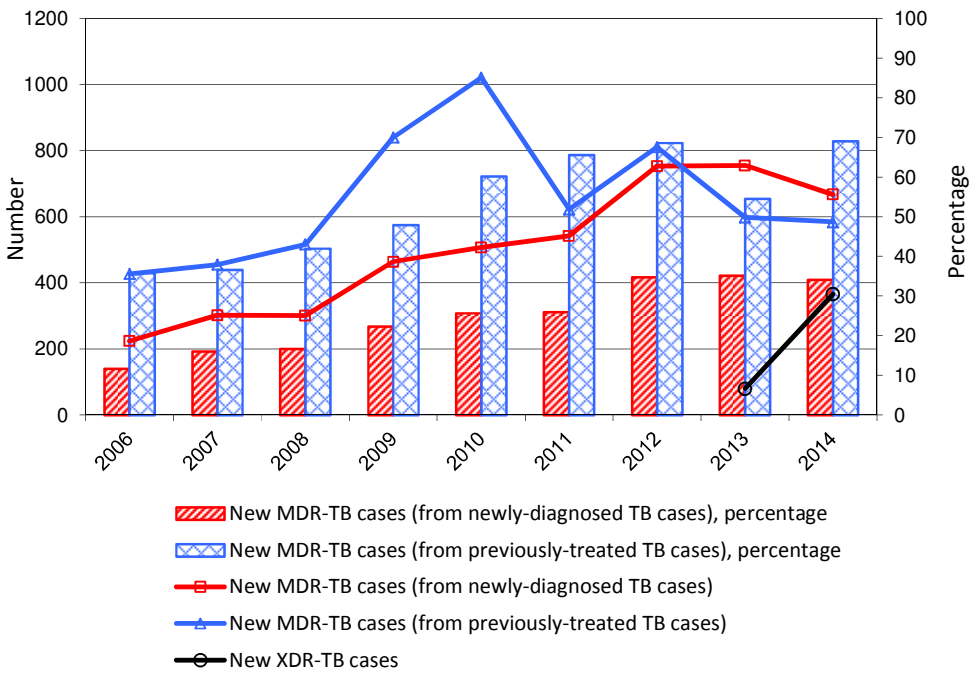
From 2005 to 2014, the NTP reported a decreasing number of new/relapsed TB cases and deaths (Fig. 1) and death rates with a mean annual percentage of -2.7% and -3.7%, respectively. The number of new MDR-TB cases, either among newly diagnosed or previously treated TB cases, fell in 2013–2014 (Fig. 2). The percentage of MDR-TB patients increased among the previously treated TB cases, which could be explained by the increased availability of drug susceptibility testing. This could also explain the increased number of cases identified with XDR-TB.

Fig. 1. Number and rate of new/relapsed TB cases notified by the NTP, Belarus, 2005–2014



Since the 2011 review of the NTP, the Ministry of Health has issued 19 orders related to TB (Annex 3) and implemented the National Programme of Tuberculosis 2010–2015 and the Action Plan for Prevention and Fight against MDR-TB 2012–2015, in line with WHO's Consolidated action plan to prevent and combat multidrug- and extensively drug-resistant tuberculosis in the WHO European Region 2011–2015 *(12)*. These resulted in a 100% detection rate of MDR-TB, 54% treatment success (target: 75%) and stability in the reporting of MDR-TB among previously treated TB patients (target: 20% decrease).

Fig. 2. Number and percentage of new MDR-TB cases notified by the NTP by past TB history, Belarus, 2006–2014



The new National Strategic Plan to Prevent and Control MDR-TB 2016–2020 is part of the state programme Healthy Population and Demographic Security 2016–2020, which is awaiting approval by the Council of Ministers. The objectives of the Plan are by 2020: (i) to decrease the TB notification rate by 2% annually or overall by 12% (compared with 2013); (ii) to decrease the total number of notified MDR-TB patients by 2% annually or overall by 12% (compared with 2013); and (iii) to treat successfully 75% of the MDR-TB patients.

The structure of the NTP has not changed since 2011. The Ministry of Health has overall responsibility for TB control. It undertakes this function through the Republican Scientific and Practical Centre for Pulmonology and Tuberculosis (RSPCPT) in Minsk and the health departments of the regional executive committees. The Department of Epidemiology, Prevention and Organization of Tuberculosis Care of the RSPCPT carries out the NTP's central functions of guidance, monitoring and supervision of TB services directly and through the regional TB coordinators. The regional health authorities are responsible for the delivery of TB (and all other health) services. The Ministry of Interior Affairs runs a parallel system of health care, including for TB, in the penitentiary system. The Council of Ministers, recognizing that TB control is a public health intervention which cuts across other ministries and government agencies, has set up coordination bodies such as the Inter-Agency Coordination Council to Fight TB at central level and executive committees in each region and Minsk city. As part of the Global Fund's requirements, the Country Coordinating Mechanism was established in 2006, chaired by the Vice Prime Minister of Health, with representatives of the Ministry of Health, the NTP, the national HIV/AIDS programme, the main international partners and civil society.

TB services 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 4274 beds (including 1840 beds for MDR-TB patients), and one TB hospital in the penitentiary system with 1860 beds (including 160 beds for MDR-TB patients). Between 2009 and 2014, a total of 406 beds were closed, including 120 beds for involuntary isolation and treatment, and others were reassigned for the treatment of MDR-TB patients. Separate hospital beds have been allocated to palliative care. A total of 5460 staff work in the TB facilities, including 540 pulmonologists and 1200 nurses.

Outpatient care is provided in urban areas through six regional pulmonology dispensaries, 29 district pulmonology dispensaries and 132 pulmonology surgeries (with a doctor) in general polyclinics. In rural areas, TB care is delivered in rural outpatient clinics (with a general practitioner) and in *feldsher* (medical assistant) ambulatory practices. The integration of TB services at primary health care level was further promoted in 2012 by new national guidelines approved by the Ministry of Health *(13)* and in 2014 by the launch of the Practical Approach to Lung Health (PAL) guidelines, eventually adopted in under- and postgraduate medical education (see section on human resource development). A new funding model privileging TB outpatient services was piloted in Mogilev district in 2014–2015 (see the section on the health system and TB control).

In 2014, TB control absorbed 2.1% of the total expenditure on health: of this, 94.7% came from the government, 4.3% from international donors and 1.1% from private spending *(14)*. Of the total expenditure on TB, 80.7% was for hospital treatment, 19% for ambulatory treatment (increased since 2010) and 0.3% for prevention. Private spending has increased in recent years, mainly for ambulatory TB services. Government funds are essential for running all pulmonology facilities, paying salaries and ensuring the presence of equipment and commodities, including diagnostics and drugs. Since most of these are imported, the current rate of currency devaluation poses concerns about the capacity to maintain adequate funding in coming years. Donors' funds come mainly from the two Global Fund grants given in Round 6 (US$ 14.8 million for 2008–2012) and Round 9 (27 million for 2008–2015), both with the United Nations Development Programme as principal recipient *(15)*. Recently, the Global Fund approved a US$ 11.8 million grant to ensure universal coverage with rapid laboratory diagnostics of drug-resistant TB and universal coverage of patients with drug-resistant TB with quality treatment in Belarus for the period January 2016 to January 2018 with the RSPCMT as new principal recipient. This grant has the following objectives: (i) to ensure universal access to high-quality rapid laboratory diagnosis of all forms of TB, including M/XDR-TB; (ii) to enhance the coverage of M/XDR-TB patients with high-quality treatment; (iii) to improve MDR-TB treatment outcomes with appropriate patient-centred support, including for patients from high-risk groups and vulnerable populations; (iv) to improve the management of TB/HIV; and (v) to strengthen the health system by introducing new funding mechanisms for ambulatory TB care.

Case-finding and diagnosis

Case-finding

Active case-finding

Annual TB screening of large parts of the general population with digital fluorography is still widely used, even though the 2011 NTP review recommended targeting only groups at high risk for TB. In 2015 the NTP reported 20% fewer TB screenings than in 2011, although these still exceeded four million.

Annual digital fluorography is still recommended among those considered at higher risk of developing TB disease or transmitting it to the community, which is in practice 80% of the adult population of Belarus.

People at special risk of developing TB disease include:

- those with a social risk of TB: homeless people, migrants, former prisoners, residents of accommodation for the elderly, people addicted to alcohol, drug users, recruits to the armed forces;
- those with a medical risk of TB: people with HIV, narcological and psychiatric disorders, diabetes mellitus, chronic gastrointestinal diseases, silicosis, chronic obstructive pulmonary disease, pleuritic or major post-TB lung residuals; those undergoing cytostatic or radiological treatment or suffering from cachexia; mothers during the period after delivery; people exposed to radiation from Chernobyl;
- contacts (home and professional) of people with infectious TB, people working on farms with endemic *M. bovis* or with prisoners or former prisoners for two years after detention;
- former TB patients, who should be checked every six months for two years following completion of treatment.

The population at risk of transmitting TB to the community includes:

- workers in: medical facilities and accommodation for the elderly, pharmacies and pharmaceutical industries, educational institutions and libraries, businesses serving or delivering items to the public (restaurants, postal delivery), food factories, toy factories, dairy farms, the water supply, hotels and hostels, transport (taxi drivers, train stewards) and other jobs dealing with customers (shop assistants, hairdressers);
- all students from the age of 17 years.

Digital fluorography is often combined with a digital chest X-ray to confirm the diagnosis. Such double investigations create confusion in the process of diagnosis and generate unnecessary additional costs.

Another active TB case-finding practice which is popular among general practitioners, paediatricians and other specialists is the annual tuberculin skin test for all children below 18 years of age using Diaskintest®[1] in preference to the classical Mantoux skin test. Despite such extensive screening, the number of cases of TB detected in children is much lower than those estimated to be occurring (see section on TB in children).

The NTP promotes the investigation of TB contacts as an effective strategy to decrease TB transmission in the community. In 2013, however, the NTP reported that of the 8745 TB contacts screened (mainly household contacts averaging 7.4 contacts per each sputum-positive TB case), only 13 (0.15%) were found with active TB *(16)*. In 2014, the NTP recorded 7046 TB contacts screened, 14 (0.19%) of them found with active TB (and later 10 of these with MDR-TB). Such a low yield raises a serious concern about the quality of such screening and the efficiency of its organization.

[1] A Russian manufactured test which is claimed not to cross-react with past bacillus Calmette-Guérin (BCG) vaccinations and to be able to measure the activity of TB infection, in other words, to monitor the effectiveness of TB treatment. It has not yet been adequately documented in the peer-review scientific literature and is not, therefore, recommended by the international community.

The Ministry of Health issued two relevant orders, in 2013 *(17)* and in 2014 *(18)*, to reorient the Sanitary and Epidemiological Services (SES) from household disinfection to contact-tracing. The 2014 order includes standard definitions for TB epidemiology and infection control and sets out the principles for contact-tracing. The overall responsibility lies with the pulmonology dispensary, working with the medical epidemiologist of the local SES office. Any situation with two or more interrelated new TB cases must be notified within six hours to all institutions (regional/municipal health agencies including SES, RSPCT and the executive committee of the Board of Health in Minsk). The review team observed instances in the field where there was a lack of clarity in the coordination between the SES, pulmonology dispensaries/surgeries and primary health care services.

Passive case-finding

Passive case-finding occurs through self-reporting by respiratory patients to facilities. All patients with respiratory symptoms are asked to undertake a sputum examination and chest X-ray free of charge. General practitioners in Gomel and Minsk had recently been equipped with a telemedicine toll line that enables the sharing of digital chest X-ray images with a pulmonologist. Doctors in non TB-dedicated facilities, on the other hand, are insufficiently aware of TB and often delay requests for specific investigations.

Laboratory diagnosis

The national network of TB laboratories consists of the level IV national TB reference laboratory (NRL) in Minsk, seven level III TB laboratories in the main regional towns (Brest, Gomel, Grodno, Minsk, Mogilev, Orsha and Vitebsk), 21 level II laboratories in district towns and around 150 level I laboratories at a lower level.

The NRL carries out the complete range of TB diagnostic tests that includes sputum-smear microscopy (Ziehl-Neelsen stain and fluorescent light-emitting diode microscopy), bacteriological culture (in Löwenstein-Jensen solid media and mycobacteria growth indicator tube (MGIT) liquid media), identification of *M. tuberculosis* and other mycobacteria, rapid molecular tests (Xpert MTB/RIF assay[2] and GenoType® MTBDR*plus* assay) as well as drug susceptibility testing (DST) for first and second line anti-TB drugs (MGIT and Löwenstein-Jensen absolute concentration). The samples received from the level II laboratories are processed for culture and DST, species identification and molecular testing.

The NRL also ensures the monitoring and quality control of the level III TB laboratories through regular visits and training. The NRL and most of the level III TB laboratories enter their data in a web-based national TB laboratory data management system. The data analysis function of this system needs further development to become fully functional (see Annex 4).

The supranational TB reference laboratory (SRL) for Belarus is in the Public Health Agency of Sweden in Stockholm (Sweden). It provides technical assistance and DST quality control through the annual exchange of a 20-strain panel with the NRL, which shares it with all laboratories performing DST in the country. Since the start of such assistance in 2009, a good correspondence of results has been observed between the SRL and NRL.

[2] A cartridge-based automated diagnostic test that can identify *M. tuberculosis* (MTB) and resistance to rifampicin (RIF) by nucleic acid amplification test.

In 2014, of the total 2917 new pulmonary TB cases notified by the NTP (bacteriologically confirmed or clinically diagnosed), 1990 (68%) were tested for rifampicin resistance (by Xpert MTB/RIF or traditional DST). This is just below the 75% benchmark required to consider the routine DST system able to produce reliable estimates of drug resistance (see section on monitoring and evaluation). The extension of Xpert MTB/RIF to pulmonary sputum smear-negative TB patients is under discussion *(19)*.

The NRL has recently been renovated and looks to be in good general condition. A copy of the standard operating procedures is available although not easily accessible for consultation as it is outside the laboratory working area (as recommended by the SES). The staff are well trained but nobody is specifically assigned to the laboratory quality management system. A few aspects could be improved: (i) the door between the room for DST and the room for culture should be tightened to limit the airflow; (ii) the centrifuges should be relocated from their current position on the floor in the centre of the laboratory, which increases the risk of manipulation of the infectious material; and (iii) a copy of the standard operating procedures should be available in a dedicated place for easy consultation.

The level III TB laboratories perform sputum smear microscopy (mainly direct microscopy), culture (in solid media and some of them in liquid media) and identification of *M. tuberculosis* and DST of first- and second-line anti-TB drugs (by Löwenstein-Jensen absolute concentration and some of them by MGIT). Consideration should be given to strengthening molecular line probe assays for detecting resistance to second-line anti-TB drugs due to the level of resistance in Belarus and recent evidence of the possibility of using standardized shorter treatment regimens (see the section on drug-resistant TB) *(20)*. The level III laboratories are responsible for the external quality assurance of all direct microscopy performed by the level II laboratories and the supervision of these laboratories.

The level II TB laboratories are usually located in district hospitals and perform sputum smear microscopy and bacteriological culture in solid media. The identification of *M. tuberculosis* is performed through the time-demanding classic methods, which delay the results. After identification, all positive cultures are sent to the level III TB laboratory for verification and DST. The level II TB laboratories provide external quality assurance (cross-check of all sputum-smear acid-fast bacillus-positive and 10% of the negative slides, and sharing of smear panels twice a year) of the smear microscopy performed in the level I TB microscopy centres and the supervision of these centres.

The level I TB microscopy centres are located in district primary health care facilities and usually just collect the sputum samples for further investigation at the closest level II laboratory.

Since 2011, major improvements have been made towards ensuring universal access to quality and rapid diagnosis of drug-susceptible and drug-resistant TB. The national laboratory network has been downsized, reducing the number of level II laboratories in the districts from 33 to the current 21. Regional and district laboratories have been supplied with modern equipment, including the Xpert MTB/RIF assay platform that is increasingly being used. New national guidelines for TB laboratories were published in 2013. A national diagnostic algorithm has been made available to guide the prompt detection of TB and M/XDR-TB. Laboratory staff are well trained and laboratory data are entered into a national electronic TB laboratory register. External quality assurance of DST with either first- or second-line anti-TB drugs is running in all level III laboratories with good results.

The review team did, however, notice some weaknesses. Some of the laboratories have very low positivity rates in sputum smear microscopy (0.5%) and bacteriological culture. Fluorescence microscopes, where available, are scarcely used. The transport of sputum samples between laboratories is complicated, with delays and a lack of safety that make it preferable to send patients for investigation to the higher level laboratory at their own cost. The use of Löwenstein-Jensen in solid media is still common, delaying the diagnosis and proper selection of the treatment regimens. The identification of TB and non-TB mycobacteria strains requires one month of intensive work that causes another unnecessary delay to the start of treatment and exposes the laboratory staff to serious occupational hazards. The ventilation in many laboratories is poor. No properly trained and certified technician is available in Belarus to service and maintain the biosafety cabinets. Some of the level II TB laboratories are still located in old facilities with suboptimal equipment and no proper ventilation, which militates against new staff filling the many vacant positions. Further development of the national TB laboratory register is needed for the accurate recording, analysis and reporting of the results (see Annex 4).The external quality assurance of smear microscopy is not widely implemented.

Main recommendations

1. The annual TB screening (fluorography, skin tests) of large parts of the population should be reduced in favour of a focus on groups with documented cost-effective targeting, such as TB contacts (currently not screened enough), as per the most recent WHO recommendations. Significant cost savings can be found and allocated to support priority interventions for the prevention and control of TB and drug-resistant TB.
2. Bacteriological culture in solid media (number of level II laboratories) should be reduced and countrywide coverage with rapid molecular testing ensured so as to reduce the delays in diagnosing TB and drug-resistant TB.
3. Prompt transport of laboratory specimens should be ensured.
4. The application software for proper analysis and reporting of laboratory data should be improved.
5. Government funding should be ensured to avoid shortages of laboratory commodities.

Other recommendations

6. The tracing and management of TB contacts should be strengthened through on-the-job training and supportive supervision of all relevant staff (TB-dedicated, primary health care and SES).
7. The TB laboratory network should be rationalized based on a comprehensive assessment including location, positivity rate and diagnostic delays, biosafety, workload and human resources. TB culture should be limited to fewer and better equipped laboratories, such as the NRL and the regional TB laboratories. Solid culture and biochemical tests should be discontinued and replaced by rapid molecular assay. Such swift changes should be supported by an efficient and safe system for transporting the biological samples.
8. Line probe assays[3] should be introduced to detect pre-XDR-TB[4] and XDR-TB patients among those found with rifampicin resistance by Xpert MTB/RIF assay.

[3] Line-probe assay (HAIN test) for first- or second-line medicines.
[4] Pre-XDR-TB is defined as MDR-TB (resistant to isoniazid and rifampicin) with additional resistance to either a fluoroquinolone or a second-line injectable drug (amikacin, kanamycin or capreomycin) but not both. XDR-TB is resistant to all.

9. Quality criteria should be established for the different levels of the laboratory network according to WHO's recommendations. Fulfilling these criteria after relevant training and support could form the basis of a stepwise approach towards laboratory accreditation.
10. The newly developed laboratory diagnostic algorithm for reliable and prompt laboratory detection of TB and M/XDR-TB should be fully implemented following WHO's recommendations.
11. Further training in the acquisition of line probe assay and interpretation of the results is highly recommended.
12. The use of modern rapid laboratory techniques should be evaluated for their appropriate use and cost-effectiveness.
13. A comprehensive assessment of biosafety (controlled ventilation system) and laboratory infection control should be carried out and followed by an action plan to address any problems identified.
14. An adequate budget allocation for laboratory maintenance, including preventive and regular annual checks and certification of equipment and ventilation system, needs to be in place to ensure that laboratory services function well and are sustainable.
15. Routine maintenance and sustainable servicing should be provided for the biosafety cabinets. Daily monitoring of the airflow is recommended. Certification of the proper functioning of the biosafety cabinets should be conducted urgently and repeated annually and whenever a unit is moved within a laboratory.
16. Experts available in the country should be helped to become officially certified to perform the maintenance and certification of biosafety cabinets.
17. A human resource development plan is needed to meet the present and future needs for numbers and qualifications of laboratory staff. The introduction of molecular tools demands appropriate training and capacity-building.
18. A standardized checklist should be drawn up for monitoring the TB laboratory network at all levels.
19. A national collection of *M. tuberculosis* strains of selected clinical isolates from all over the country is needed, with appropriate equipment (freezers). This should be kept at the NRL and used as an important source for future examinations and operational research.
20. The time-consuming and potentially hazardous biochemical identification of *M. tuberculosis* complex at level II laboratories should be replaced with rapid alternative techniques (immune chromatography or molecular tests).
21. A countrywide external quality control system for smear microscopy should be established.
22. Communication between laboratories and physicians needs to be improved so as to guarantee prompt and accurate patient diagnosis and treatment.
23. Prompt procurement of drugs and reagents for laboratory examinations should be assured.
24. Terms of reference for biosafety managers need to be developed with the assistance of the SRL in Stockholm.
25. The logbooks recommended by WHO need to be provided for recording laboratory data.
26. Patient duplications in the national TB electronic register (MIS Lekar) are found by filtering the name, family name and date of birth in one line. If there is a typing mistake in

any of these elements, the duplication cannot be identified. To avoid this, the birth date should be recorded separately from the name and family name.

27. The date of sample collection is missing in the data entry part of the electronic register. It should be added.

28. Rejection criteria need to be defined, preferably in the form of standard operating procedures, and entered into the data management system with the reasons for rejection described in the standard operating procedures.

29. For the results acquired by Xpert MTB/RIF assay, the option of "data not obtained" should include the error codes of Xpert MTB/RIF assay and other reasons such as "absence of cartridges" or "electricity cut". This would help to understand why Xpert MTB/RIF assay results would not be available for a patient that (following the algorithm) should have such results. The same recommendation is valid for the reasons why line probe assay and culture results (MGIT and Löwenstein-Jensen) could not be obtained, including error codes for MGIT and other reasons such as "absence of reagents" or "contamination". Currently only one option is available for data not obtained: "data not available".

Treatment and case management

The NTP has made substantial progress in the management of TB and drug-resistant TB. All TB patients have access to DST, including rapid diagnostics. Each region has a functioning TB consilium (expert committee) and the capacity to diagnose, treat and monitor TB cases properly, including those with drug resistance *(21)*. Treatments are in accordance with WHO's recommendations, both in composition of the regimens and in duration. Most of the anti-TB drugs are procured with funds from the state budget. TB patients are divided between hospital departments based on their drug resistance pattern. Outpatient treatment has been scaled up and includes the involvement of primary health care services. Patients' records, at both regional and district levels, have substantially improved through the digitalization of the national TB register. Some important problems do, however, remain.

For many patients, TB treatment is prescribed by the regional TB consilium, even in uncomplicated drug-susceptible TB cases, which leads to delays. Such a policy seems unnecessary in view of the professional capacity of the doctors working at district level, as the review team was able to verify. It also underutilizes local knowledge of the specific conditions in the district and the needs of individual patients.

Hospitalization is still preferred to ambulatory TB care from day one. It is requested for all smear-positive TB patients (as per the NTP guidelines)[5] and actually carried out for 80% of smear-negative and extrapulmonary TB patients. This is justified by claiming severe clinical conditions or the need to speed up the start of treatment or to carry out diagnostic services (such as audiometry) that are not available free outside.

In the regions, not all new and repurposed anti-TB drugs are available. This forces the NTP to centralize the treatment of many patients at the RSPCPT in Minsk (see the section on drug-resistant TB).

[5] The NTP guidelines recommend the hospitalization of all smear-positive TB patients, at least until they become bacteriologically negative (at sputum culture).

New ways to reduce the loss to treatment follow-up are being explored, such as video (or virtually) observed treatment which will be offered soon to 10 TB patients in Minsk Dispensary No. 2. The Ministry of Health has already signed a specific order *(22)*, and the review team saw that the software for recording and e-mailing videos and maintaining a database is at an advanced stage of development. This pilot is supported by WHO and the European Respiratory Society, and the Global Fund grant will provide funding for its expansion to cover 500 TB patients countrywide. Five of the initial 10 patients will use their own smartphones and mobile data subscriptions, while the NTP will provide for the others. The patients with either drug-susceptible or drug-resistant TB will be chosen from among those able to use a smartphone and without a history of alcohol abuse and will be specifically trained through two weeks of directly observed treatment (DOT). Each patient will keep the weekly supply of anti-TB drugs in a pill dispenser, record a video showing his/her drug intake and e-mail it to a nurse working in the dispensary who will update a special register daily.

Social protection

A lot more can be done to support TB patients during their ambulatory treatment. Direct medical costs can be reduced by providing free treatment for anti-TB drug adverse reactions (currently free only in hospital), as can indirect medical costs, such as the reimbursement of daily transport expenses for DOT. An important component of a modern interpretation of social protection is preventing the loss of income and unexpected household expenditure that can plunge patients into poverty, especially socially vulnerable patients at higher risk of MDR-TB. Unfortunately, such support is limited at present.

In recent years, the Global Fund has supported MDR-TB patients in some regions with food parcels and transport vouchers to help improve treatment outcomes. This support was the object of operational research which documented how MDR-TB patients receiving it had better treatment outcomes (70% treatment success, 27% failure and 2% mortality) than those without (53% treatment success, 40% failure and 6% mortality*) (23)*. In view of those results and the recommendations of the 2011 NTP review, the government revised its policy. In February 2015, the Ministry of Health and the Ministry of Finance updated the nutritional standards and food supplements (food parcels) for TB patients *(24)*. In June 2015, the Ministry of Finance cut the tax on imported high-calorie food products for TB patients. From 2016, all TB patients will be provided with four different packages by the Ministry of Health every two weeks conditional on their completing 20 or more DOT per month. The vouchers for public transport previously provided under the Global Fund and only to MDR-TB patients in some regions are to be discontinued *(24)*.

Financial support for TB patients varies according to their employment status. Employed patients are entitled to a maximum six months' sick leave, paid monthly while the patient is in hospital (excluding those in involuntary isolation) but suspended when the patient is discharged until the treatment has been completed, when the accumulated amount is paid. The sick leave payment does not, therefore, cover those patients in need of longer treatment, such as the treatment for MDR-TB which lasts at least 20 months. The suspension of the sick leave payment after hospital discharge particularly affects patients employed in the public sector (teachers, doctors) who are not allowed to return to work before their treatment is completed even if they have a negative sputum culture. Such patients risk losing their jobs.[6]

[6] According to the Labour Code (art. 42), employers have the right to terminate a contract when the employee exceeds four months' sick leave, or six months in the case of specific diseases such as TB.

Self-employed workers may receive some financial support from the local authorities (depending on the status of the local budget) or from the state, depending on their income.[7] State support might consist of an invalidity pension or a monthly allowance (for buying food, medicines and clothes or paying utility bills) or a lump sum allowance paid in special circumstances such as total disability caused by an illness the treatment of which requires the use of drugs for a long period of time, or on the death of a spouse or of parents. Patients in involuntary isolation do not qualify for any social support of this kind.

Involuntary isolation

From 2010 to 2015, the NTP reported a significant decrease in the number and proportion of patients placed in involuntary isolation (Table 1).

Table 1. Number of TB patients placed in involuntary isolation by region, Belarus, 2010–2015 (January–September)

Region	2010	2011	2012	2013	2014	2015 (January–September)
Brest	168	151	98	89	52	45
Gomel	172	188	129	137	102	30
Grodno	210	143	86	65	42	24
Minsk region	163	140	113	99	75	33
Minsk city	109	79	66	45	37	24
Mogilev	123	200	101	101	66	42
Vitebsk	284	251	150	96	76	47
Total patients in involuntary isolation	1229	1152	743	632	450	245
Total patients notified	5554	5118	5246	4859	4274	–
Proportion of patients in involuntary isolation (%)	22	23	14	13	11	–

This decrease is attributed by the NTP to the increasing support for patients (food parcels and transport vouchers) under the Global Fund grant.[8] Current legislation could, however, be improved in this regard (see the section on ethics and human rights).

Main recommendations

1. Priority should be given to ensuring access to effective treatment regimens for all subgroups of MDR-TB, including XDR-TB and beyond XDR-TB. International support for the procurement of bedaquiline should be explored urgently and the treatment for XDR-TB decentralized as soon as possible to regional level.
2. Outpatient TB care should be strengthened by: enabling TB doctors at district level to diagnose and treat drug-susceptible TB; ensuring the continuum of TB care for patients released from prison; ensuring that a full package of joint services for vulnerable populations (harm reduction, treatment of alcohol abuse disorders) is available; and increasing TB service coverage through social contracting.[9]

[7] According to Presidential Order No. 550 of 5 December 2013 *(25)*, the level of income is the determining factor to qualify for social support. As for any other disease, the presence of TB is not taken into consideration.
[8] From February 2016, the food parcels will be provided to all TB patients through domestic funding (see the section on treatment and case management), which is expected to further decrease the practice of involuntary isolation.
[9] Social contracting refers to the contract, including funding, that a government may make with an institution/ organization (usually a nongovernmental organization) to provide socially relevant services.

3. Involuntary isolation and treatment should be reduced by increasing outpatient TB treatment and including support for patients.
4. Support for all TB patients, with or without employment, should be expanded by covering their direct and indirect medical costs (transport for DOT, ancillary treatment) and compensating them for non-medical costs (absence or loss of income not covered by disability benefit/sick leave during in/outpatient treatment or a ban on return to work).
5. Catastrophic costs of TB should be documented through participation in the global survey organized by WHO. Social protection for TB patients should be synergized with the national schemes of the Ministry of Labour and Social Protection.

Other recommendations

6. Pulmonology doctors working in districts should be allowed to initiate the treatment of at least drug-susceptible TB patients.
7. The treatment of adverse anti-TB drug reactions should be free and assured at all levels.
8. The rate and duration of hospitalization should be reduced and ambulatory treatment should be scaled up. Doctors working in outpatient TB services and general practitioners should be trained in TB case management.
9. Regulations should be revised to allow the patients from the "obligatory contingent" (teachers, doctors, children) to work or attend school after they have been discharged from hospital if their sputum culture has converted to negative (recommendation from the 2011 NTP review).
10. Cooperation between the Ministry of Health and the Ministry of Labour and Social Protection should be encouraged and developed so as to define common needs and develop common solutions and strategies.

Childhood TB

The national policy is to vaccinate all newborns with BCG. Revaccination at 14 years of age was cancelled in 2012 and the revaccination at seven years of age was to be cancelled in 2016 (as part of the overall revision of the national immunization schedule). In 2014, only 22 children were reported in the whole country with adverse reactions to BCG vaccination (vaccine imported from a foreign manufacturer) (Table 2).

Table 2. Number of adverse reactions after BCG vaccination, Belarus, 2010–2014

Diagnosis	2010	2011	2012	2013	2014
BCG vaccinations (approximate number)	100 000	105 000	97 500	103 000	110 000
Cases of adverse reaction	60	42	39	31	22
- cold abscess	17	8	12	16	12
- lymphadenitis	29	24	12	10	3
- osteitis[a]	14	10	14	5	6
- disseminated infection	0	0	1	0	1

[a] Osteitis can be diagnosed several years after vaccination, so it does not necessarily relate to the number of children vaccinated in the same year.

The number of adverse reactions to BCG seems to be low and does not support the concern that some providers shared with the review team.

From 2010 to 2014, the number of children (aged <15 years) with TB never exceeded 0.6% of the total number of new/relapsed TB cases reported by the NTP (Table 3). Such a low proportion, taken together with the high rate of bacteriological confirmation observed by the review team, indicates possible under- and/or delayed diagnosis.

Table 3. Number (percentage) of TB cases detected among children aged <15 years, Belarus, 2010–2014

TB cases	2010	2011	2012	2013	2014
Total (No.)	5098	4697	4783	4470	3858
Among children (No.)	32	27	21	15	24
Among children (%)	0.6	0.6	0.4	0.3	0.6

Among children and adolescents (aged 15–17 years), the NTP registered 39 TB cases during 2013, 52 during 2014 and 58 during 2015 (January–November). During these years, the bacteriological confirmation of pulmonary TB increased and thus decreased the proportion of extrapulmonary TB (Table 4). Of the 52 new TB cases detected among children and adolescents in 2014, 13 (25%) had MDR-TB, including one with XDR-TB. In 2015 (January–November), there were already 25 (43%) with MDR-TB, including 11 with XDR-TB.

Table 4. Number (percentage) of TB cases detected among children aged 0–17 years, Belarus, 2013–2015 (January–November)

Diagnosis	2013	2014	2015 (January–November)
Total	39 (100%)	52 (100%)	58 (100%)
Pulmonary	–	36 (69%)	46 (79%)
- bacteriologically confirmed	–	21 (40%)	27 (46%)
Extrapulmonary	–	16	12
- lymphadenitis	–	6	4
Disseminated/miliary	–	3	1
MDR-TB bacteriologically confirmed	–	12 (23%)	24 (41%)
MDR-TB non-bacteriologically confirmed	–	0	10
XDR-TB	–	1	11

Children in contact with TB patients are targeted for tuberculin skin tests every six months for two years, or five years if their contact was an MDR-TB patient who died. Children found positive are further tested with Diaskintest® to differentiate between a latent TB infection and an active TB disease condition (see section on case-finding and diagnosis). Preventive TB treatment is provided through six months of isoniazid or three months of isoniazid and rifampicin. Children are still being isolated from their sources of infection in sanatoria or special boarding schools. The team observed that children who had a contact with TB are not adequately screened and the roles of the different services (general practitioners, SES, TB dispensaries) are not clear, despite the recommendations of the 2011 NTP review. The team could not find systematic records on TB contact-tracing among children that allowed the analysis of main performance indicators.

The diagnosis and treatment of TB in children and adolescents is centralized at the Childhood Tuberculosis Department of the RSPCPT in Minsk. Owing to the limited number of beds, some adolescents may also be kept in the Department of Extrapulmonary Tuberculosis (for adults) of the RSPCPT. Many months of hospitalization are common, during which the children and adolescents are isolated from normal social life and often mix with older patients, which may

cause the development of negative behaviour such as smoking, stealing from nearby shops or premature sexual activity.

The Childhood Tuberculosis Department has access to all laboratory investigations (microscopy, bacteriological culture, Xpert MTB/RIF assay, line probe assay) usually conducted on biological samples of sputum or gastric or bronchoalveolar lavage. The TB treatment is consistent with the latest international recommendations and includes pre-XDR and XDR-TB treatment with new and repurposed anti-TB drugs such as bedaquiline. The Childhood Tuberculosis Department should be considered a centre of excellence for childhood MDR-TB in the WHO European Region for its diagnoses and treatment as well as for the active safety monitoring and management of new and repurposed anti-TB drugs in children and adolescents.

The 2012 revision of the NTP guidelines contains a chapter on childhood TB *(26)*, although it has not been updated in accordance with the latest international recommendations *(27)*. Childhood TB has been the topic of dedicated one-hour lectures given periodically in the past to TB paediatricians working in the regions.

Main recommendations

1. Early detection of TB among children by should be improved by tracing and carefully investigating those in close contact with TB cases.
2. Diagnosis and ambulatory treatment should be strengthened at regional level (rather than obliging all paediatric TB cases to be treated in Minsk) and hospitalization limited to severe forms of TB.
3. Non-infectious children (including those bacteriologically converted) should be allowed to attend school. Consideration should be given to admitting children >15 years of age into adult inpatient services.
4. WHO prequalified BCG vaccine should be used and BCG revaccination at seven years of age should be abandoned.

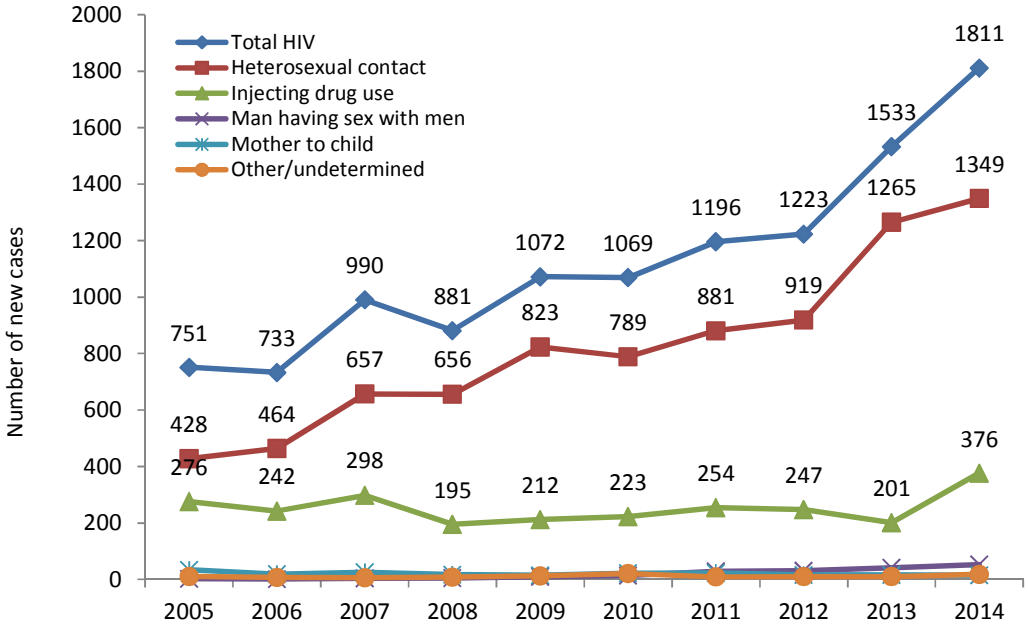
Other recommendations

5. The responsibilities of and coordination between the services involved in contact-tracing (general practitioners, SES, TB dispensaries) should be clarified.
6. The NTP electronic database should be expanded to document and analyse the main childhood indicators (for example, number of children eligible for contact-tracing actually screened, preventive TB treatment started and completed, adverse reactions to anti-TB drugs observed).
7. A national working group of experts should be established to ensure that the national guidelines on childhood TB are routinely updated as and when required by new international evidence becoming available.
8. Childhood TB should be a mandatory topic in the NTP in-service training courses and postgraduate medical education.
9. The Childhood Tuberculosis Department of the RSPCPT in Minsk should be promoted as a centre of excellence for childhood MDR-TB in the Region.

HIV-associated TB

Injecting drug use should be considered the main driver of the significant increase in reports of new HIV infections in the country in recent years (Fig. 3). The social stigma attached to sexual intercourse between men and to injecting drug use as modes of HIV transmission should be acknowledged as well as the likelihood that such transmission is hidden in heterosexual intercourse. People who inject drugs are at increased risk of TB, irrespective of their HIV status, and they are also disproportionately affected by HIV, hepatitis B and hepatitis C *(28)*. The WHO guidelines on collaborative TB and HIV services for people who inject drugs were updated in 2016 *(29)*.

Fig. 3. New HIV diagnoses by notified transmission mode, Belarus, 2005–2014



Since the start of a major HIV epidemic in 1996 in Svetlogorsk,[10] the highest HIV rates have always been in Gomel region, which reported 6264 PLHIV (42% of the country burden) in 2015 (January–November), a rate of 434.8 per 100 000 population (Table 5). Compared with the previous year, Gomel region had a 72% increase of new HIV diagnoses (484 in 2014 and 672 in 2015) and Minsk City had a significant 56% increase (327 in 2014 and 737 in 2015). These increases were explained to the review team as a consequence of the increasing use of home-produced heroin and amphetamine-type substitutes that replaced the much more expensive injecting of opioid substances *(30)*.

While TB notifications have been decreasing in recent years (see the section on epidemiology), the number of new HIV infections and the number and percentage of HIV-associated TB (TB/HIV) have increased (Fig. 4). TB (pulmonary and extrapulmonary) is the most common AIDS-indicative disease and cause of death among PLHIV.

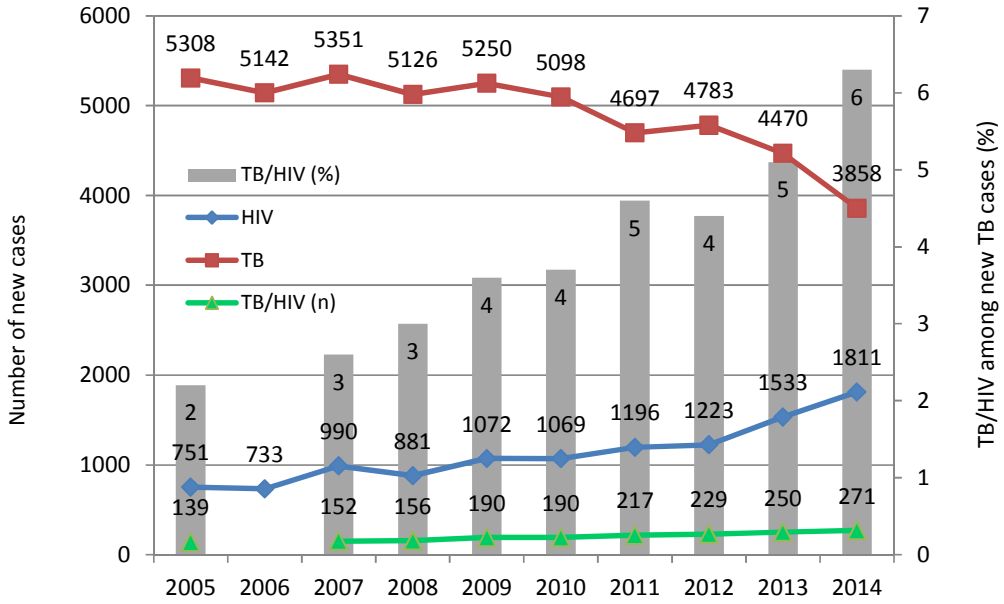
[10] A city in Gomel region and the location of Svetlogorsk Khimvolokno, the biggest petrochemical state company in the country which produces textile and technical products for the domestic market and exports to more than 30 countries.

Table 5. PLHIV by region, Belarus, 2015 (January–November)

Region	Population[a]	PLHIV		
		No.	%	No. per 100 000 population
Brest	1 401 177	1 185	8	84.6
Gomel	1 440 718	6 264	42	434.8
Grodno	1 072 381	646	4	60.2
Minsk	1 422 528	2 254	15	158.5
Minsk city	1 836 808	2 859	19	155.7
Mogilev	1 099 074	1 019	7	92.7
Vitebsk	1 230 821	842	6	68.4
Total	*9 503 507*	*15 069*	*100*	*158.6*

[a] According to the 2009 national census.

Fig. 4. New cases notified of HIV, TB and TB/HIV, Belarus, 2005–2014



Both the NTP and the national HIV programme claim that TB patients are fully covered for HIV counselling and testing and PLHIV are fully covered for TB screening. WHO estimates that there were 310 (260–370) new TB/HIV cases in 2014, of which the NTP reported 271. For the same year, however, the national HIV programme registered 297 new TB/HIV cases (203 among HIV-positive people and 94 among TB patients), an additional 26 new TB/HIV cases.

Among the 2013 cohort of TB/HIV patients, the NTP reported that 65.2% were successful, 23.2% died, 7.2% failed, 2.2% were lost to follow-up and 2.2% were not evaluated. It was not possible to monitor separately the treatment outcome among MDR-TB/HIV patients, but MDR-TB is strongly associated with HIV infection *(31)* and significantly associated with unsuccessful TB treatment outcome (death, failure, loss to follow-up) in the absence of antiretroviral treatment (ART) *(32)*.

Substantial support for prevention and control of HIV/AIDS has been provided for several years by the Global Fund. The most recent grant of US$ 12 million signed with the Republican Scientific and Practical Centre for Medical Technologies, Information, Administration and Management of Health covers the period from January 2015 to December 2018. This grant is expected to fill the gaps in implementing the National HIV Strategic Plan 2016–2020 by the

national HIV programme, including the scaling-up of HIV preventive and treatment services to high-risk groups in the population. The nongovernmental organizations currently supported by the Global Fund grant are expected in 2017 to become part of the government's social contracting system. Legislation to allow this is currently undergoing scrutiny and revision.

TB screening and diagnosis among PLHIV

HIV consultation services are provided through a network of outpatient departments of infectious diseases hospitals in Minsk City and all regional main cities and consulting rooms in polyclinics at district level. Infectious diseases specialists working in these facilities are responsible for regular check-ups of PLHIV, provision of ART, isoniazid preventive therapy and co-trimoxazole preventive therapy, and the diagnosis and treatment of main opportunistic infections.

TB screening is done through history-taking and clinical examination at every HIV consultation. As per the national guidelines, PLHIV should also have a chest X-ray at least twice a year in a polyclinic. When a person is suspected of having TB, the infectious diseases specialist requests a consultation with a TB specialist, which is carried out in either the infectious diseases or the TB facility. The equipment for rapid diagnosis of TB (Xpert MTB/RIF) is available in the HIV laboratories. All TB/HIV patients are treated in a TB hospital.

A harm reduction programme is implemented through a range of interventions including needle and syringe exchange, condom distribution, opioid substitution therapy, information, education and communication, outreach and other components. All people who inject drugs visiting narcological dispensaries should have an annual chest X-ray (as a vulnerable group as defined in the national regulations). Collaboration between the narcological, infectious diseases and TB services has improved since the 2011 NTP review.

Isoniazid preventive therapy among PLHIV

Ministry of Health Order No. 1217 of 11 November 2010 prescribes six-month isoniazid preventive therapy (IPT) to PLHIV found with latent TB infection, those in close contact with an active TB case, and those with a CD4[11] cell count of <200/ml. A tuberculin skin test is not mandatory to initiate IPT. Pregnancy and past TB treatment are contraindications for IPT. The number of PLHIV who receive IPT doubled from 258 in 2012 to 539 in 2014 but it is still low.

TB infection control for PLHIV services

Administrative TB infection control measures have improved since the 2011 NTP review. TB is now rapidly diagnosed in HIV laboratories, TB consultations are arranged in HIV facilities and TB/HIV patients are referred promptly to TB facilities for treatment.

HIV testing and counselling among TB patients

In practice, an HIV test is mandatory for all TB patients within one to three days after the TB diagnosis. The blood samples are sent to the regional centres of hygiene, epidemiology and public health. The final result (confirmed by Western Blot test) is then sent to the AIDS Prevention Department for registration in the regional HIV database and to await the visit of an epidemiologist responsible for HIV post-counselling of the patient. Finally, an infectious

[11] CD4+ T lymphocyte count to measure the immune function.

diseases specialist is invited to give a medical assessment and prescription for further necessary investigations and ART. This procedure often delays the start of ART.

Co-trimoxazole preventive therapy among TB patients

The national HIV/AIDS clinical guidelines indicate that patients should receive co-trimoxazole preventive therapy (CPT) while they are being treated for TB. In 2014, all 271 new TB/HIV patients reported by the NTP were placed on CPT.

HIV care and support among TB patients, including ART

The national HIV/AIDS clinical guidelines indicate that all TB patients should receive ART. In 2014, however, only 191 of the 271 new TB/HIV patients registered by the NTP were placed on ART. The improved collaboration between TB and infectious diseases specialists in recent years has still not fully overcome the cumbersome procedure for HIV testing and treatment (see above) that also seems to be keeping the overall coverage of PLHIV with ART to a low 24%.

After discharge from a TB hospital, TB/HIV patients are the responsibility of both the TB services (to complete their TB treatment) and infectious diseases services (to follow up HIV infection and ART). Although no formal links exist between these two services, communication between them has improved since the 2011 NTP review.

Main recommendation

1. Universal coverage by the collaborative TB/HIV interventions should be ensured, with priority given to access for PLHIV to intensified TB screening through rapid molecular test and IPT and for TB patients to rapid HIV test, ART and CPT.

Other recommendations

2. The national HIV programme should give priority to the prevention, early diagnosis of and treatment for TB among people who inject drugs. The national TB and HIV guidelines should be updated to include the latest WHO recommendations on integrating collaborative TB and HIV services within a comprehensive package of care for these people.
3. Collaboration should be further strengthened between the TB and HIV/AIDS national programmes at all levels for the joint planning, delivery and monitoring of services to TB/HIV patients.
4. Early access to ART should be ensured for all TB/HIV patients by simplifying the procedures for HIV counselling and testing and prescription for ART as currently followed by TB and HIV (epidemiologists and infectious diseases specialists) providers. Staff from the TB services should be properly trained in HIV counselling.
5. IPT should be provided according to international recommendations every two years, including for those PLHIV who complete their TB treatment. Its alternatives should be tested during operational research, as suggested in recent literature.
6. Nongovernmental organizations with access to HIV key populations should increase their support to TB/HIV patients.

Drug-resistant TB

As already mentioned (see the chapter on treatment and case management), access to early diagnosis of and treatment for drug-resistant (DR) TB has much improved since the 2011 NTP review. New and repurposed drugs are being used according to the drug resistance profile and subject to close cohort event monitoring in collaboration with the Department of Pharmacovigilance located at the Centre for Examinations and Tests in Health Care of the Ministry of Health.

MDR-TB patients are, however, predominantly treated in hospital, as are those with drug-susceptible TB, while all pre-XDR and XDR-TB patients are treated in the RSPCPT despite the presence of qualified doctors in the districts and regions. In 2015, the average time between diagnosis and start of treatment for DR-TB, as seen in the national TB register (see section on monitoring and evaluation), was comparable across the regions and rarely exceeded 20 days. This calculation includes those patients identified with drug resistance before registration but it excludes those who had not started treatment and it does not take into account possible delays before diagnosis.

In 2015, with the support of the Global Fund, the RSPCPT started a bedaquiline access programme that, at the time of the NTP review, had already enrolled 100 patients with pre-XDR-TB,[12] all of whom had been reviewed by a national TB consilium against specific eligibility criteria (including accepting to be treated only in the RSPCPT). In the same year, Médecins Sans Frontières launched its delamanid compassionate use project covering three pulmonology dispensaries in Minsk city and the pulmonology hospital in Volkovichi, Minsk region; four XDR-TB patients were enrolled in this project. The plan for 2016, under the Global Fund grant, is to treat at least 290 pre-XDR and XDR-TB patients from a waiting list of 800, with regimens containing repurposed drugs (for example, linezolid and amoxicillin-clavulanate). The NTP is also planning to apply to USAID's bedaquiline donation programme to cover the full treatment of these patients *(33)*.

The limited availability of new and repurposed anti-TB drugs, the increasing detection of patients with different drug-resistance patterns and the inadequate forecasting of drug needs in the regions (see section on management of medicines and other commodities) are concurrent causes of a substantial proportion of pre-XDR-TB cases (25–30% is guessed by the review team) being treated outside the RSPCPT with only one to two effective drugs (amoxicillin-clavulanate, in rare cases linezolid).[13] These patients may be formally considered to be in treatment but they are actually receiving an inadequate treatment which is likely to amplify their resistance to all drugs. These patients develop XDR-TB and beyond-XDR-TB and may transmit it to other patients admitted to hospital. To prevent this, these patients should be moved to a palliative TB care-dedicated facility until all necessary anti-TB drugs are made available. Such facilities are present in every region but they are run with inadequate staff (numbers and training) and infection control measures.

[12] Pre-XDR-TB is defined as MDR-TB (resistant to isoniazid and rifampicin) with additional resistance to either a fluoroquinolone or a second-line injectable drug (amikacin, kanamycin or capreomycin) but not both. XDR-TB is resistant to all.

[13] The international recommendation is to treat TB with at least four drugs to which *M. tuberculosis* is susceptible.

Main recommendation

1. Priority should be given to ensuring access to effective treatment regimens for all subgroups of MDR-TB patients, including those with XDR-TB and beyond XDR-TB. International support for the procurement of bedaquiline should be explored urgently and treatment for XDR-TB patients decentralized to regional level as soon as possible.

Other recommendations

2. Access to new and repurposed anti-TB drugs should be increased and decentralized to the regions.
3. Outpatient care for DR-TB patients should be scaled up, especially for those with MDR-TB only.

TB control in prisons

The Medical Unit of the Department of Execution of Punishment (under the Ministry of Internal Affairs) is responsible for the health services in the penitentiary system, including the TB services. There are 34 penitentiary institutions with medical services (physician and nurse), one pre-trial detention centre in Pischalauski Castle in Minsk city, the TB Colony No. 12 in Orsha city (Vitebsk region) for males and a TB department for females in the central prison hospital in Gomel.

The NTP reported to the European Centre for Disease Prevention and Control and WHO that in 2014, 99 new TB cases were found among the total prison population of 29 000, corresponding to national rates of 341 per 100 000 population and 2.2% of the total TB cases. In 2013, a total of 99 new or relapsed TB cases were registered in the prison population, of whom 81 (82%) were successfully treated, seven failed, two died, eight were lost to follow-up and one was not evaluated. In 2015 (January–November) 71 new TB cases (25 with MDR-TB) and 25 relapsed cases (20 with MDR-TB) were registered in the penitentiary system.

All detainees are screened using chest X-ray on entrance to pre-trial and detention institutions and every six months during their stay in penitentiary institutions. All detainees with presumptive TB are isolated and those who are diagnosed are transferred to the TB colonies where they are housed according to their drug susceptibility pattern. TB Colony No. 12 in Orsha has a renovated X-ray department paid from the state budget. The laboratory is well equipped with all diagnostics equipment, including two Xpert MTB/RIF assays (since 2013) and MGIT, and scored very good results in the external quality controls. The Hain test has not been performed for some time due to the lack of a qualified maintenance service. The samples taken from all presumptive TB cases in the penitentiary system are sent here for Xpert MTB/RIF investigation and MGIT. Drug-susceptible TB patients are then treated with anti-TB drugs procured by the Ministry of Justice. MDR-TB patients are all formally treated with drugs procured either through the state budget (50 patients) or the Global Fund grant (40 patients). The limited availability of new and repurposed anti-TB drugs may result in ineffective treatment regimens for patients with pre-XDR or XDR-TB, further amplifying their drug resistance. ART is prescribed for TB/HIV patients by the TB doctors, an important step forward since the 2011 NTP review. The review team noted that infection control measures were adequate but noticed poor compliance with personal respiratory protection measures by the prison staff. Information on each TB patient in the penitentiary system is entered via internet into the NTP register

maintained by the NTP. This is not done regularly, however, due to the need to use an outside internet point as the internet is forbidden inside the prison. The final treatment outcome, when this occurs in the civilian system, is reported to the prison where the patient was initially registered.

Collaboration between the penitentiary and civil sectors has improved since 2011 and doctors in the regional pulmonology dispensaries provide regular monitoring and advice in prisons, including in pre-trial detention centres. TB patients released from Orsha and Gomel prisons are taken by the prison ambulance to the regional pulmonology dispensary of their choice to continue their treatment. In 2015, 12 patients refused to continue treatment after their release and were consequently transferred directly to an involuntary isolation facility. The International Committee of the Red Cross planned to launch in 2016 a project for education and support of TB patients while in prison and in the civilian facility with the aim of facilitating collaboration between the two systems and preventing loss of treatment follow-up after release.

Recommendations

1. Prompt and effective treatment for all patients, including those with pre-XDR-TB and XDR-TB should be ensured by:
    - support from NTP experts in analysing existing resistance patterns and designing regimens based on these patterns;
    - adjustment of drug procurement based on analysis of resistance patterns and necessary regimens;
    - adjustment of treatment monitoring tests and a schedule based on adjusted regimens (for example, additional electrocardiograms when bedaquiline is used);
    - active anti-TB drug safety monitoring and management, and training in the management of adverse reactions;
    - analysis of all cases with delayed diagnosis and/or initiation of treatment and discussion with the NTP and regional pulmonological dispensaries the necessary action to address the gaps.
2. Case-holding after release should be improved by:
    - ensuring education and support for TB patients before their release from prison;
    - scaling up outpatient treatment (including social support) for TB patients after their release from prison.

Other vulnerable populations and social determinants

The main TB risk factors were studied in 2011 by the countrywide drug resistance survey, which identified them as a history of previous treatment for TB, the presence of HIV co-infection, a history of imprisonment, tobacco smoking and alcohol abuse *(34)*. The most important population groups to be targeted for TB control were, therefore, considered to be PLHIV, prisoners and people with alcohol use disorders. Such groups experience in various ways the poverty and social marginalization that are well-known determinants for TB.

The *WHO global status report on alcohol and health 2014* documented an average alcohol consumption in 2010 among the population aged over 15 years of 17.5 litres per person per year, the highest in the world *(8)*. Since the launch by the Ministry of Health of the state programme for national action to prevent the harmful use of alcohol 2011–2015, a new law has been issued supporting specific interventions, including a ban on drink-driving, a limit on alcohol marketing in the media and increased taxes on alcohol products, an increase in policy control and fines on home alcohol producers. Since the issue of this law, alcohol consumption and reports of alcohol-related criminal offences have decreased. On the other hand, old practices persist, such as sending people who commit repeated offences while intoxicated to labour camps for treatment of alcohol and drug addiction for long periods of time. It is recommended that the TB and alcohol-related services should collaborate to organize jointly the diagnosis and treatment of both conditions so as to achieve better TB treatment outcomes. Specific experience has been gained in this area in the Region *(35,36)* and a similar approach could be considered in Belarus.

The Belarusian Red Cross Society plans to provide daily hot meals to low-income and homeless TB patients as well as psychological support and legal counselling. This is in addition to its assistance, as a sub-recipient of the Global Fund grant, with supervising the treatment of TB patients (see section on TB treatment and case management).

The literature has documented how international migrants are at higher risk of TB. The NTP did not, however, report any TB cases of foreign origin in 2014 to the European Centre for Disease Prevention and Control and WHO. Free TB diagnosis and treatment (until smear conversion) are ensured for both documented and undocumented migrants *(37)*. Within the Eurasian Economic Union there is free circulation of migrant workers between Belarus and the Russian Federation (the main country of destination) and free access to health services.

Recommendations

1. Innovative interventions should be designed and introduced to support TB patients with alcohol dependence by adapting experience in other countries where other services (such as health services for alcohol-related problems and social services) are included in the NTP.
2. Civil society engagement in TB activities should be scaled up to support different vulnerable groups.

Infection control

TB infection control in health care facilities has markedly improved since the 2011 NTP review. Ministry of Health Order No. 1151 of 11 December 2009 was updated by Order No. 58 of 28 June 2013 aligning the national TB infection control guidelines with international recommendations. Old practices, such the disinfection of patients' homes, are being totally eliminated and replaced by measures for managerial, administrative and environmental control and individual respiratory protection. There is an increased awareness among health care workers of airborne infection control and its main measures, such as the separation of TB cases based on their drug resistance profile and the quality of the environmental conditions and of the respirators to be purchased.

Too many health care workers are still contracting TB. A total of 14 new TB cases were notified among medical staff (physicians and nurses) working in the TB facilities in 2014, an incidence

of 400 per 100 000 staff and a relative risk of 10 compared with the general population. In 2012, TB incidence among health care TB workers was 349 per 100 000 staff, with a relative risk of 8.7 compared with the general population *(38)*.

Further action is needed to address the extensive hospitalization of patients, the lack of maintenance and certified servicing of the equipment, inefficient ventilation in most TB facilities, the inappropriate use of devices and ultraviolet germicidal radiation and the attitude of the staff to individual respiratory protection.

Managerial and administrative infection control

Managerial and administrative infection control measures and practices are implemented unevenly among the facilities. Risk assessment is not done properly and systematically, the "hot" points in each area are not always identified and marked on a map and there is a lack of awareness among the staff despite their good theoretical knowledge of infection control.

Since the availability of rapid diagnostic methods (Xpert MTB/RIF assay), patients can be separated earlier according to their infectiousness and anti-TB drug susceptibility. Even so, the team observed some M/XDR-TB patients mixed with drug-susceptible TB patients. Patients not receiving treatment (mainly due to expanded drug resistance or the presence of comorbidities) are a major concern: they should be moved to more appropriate palliative care facilities with effective infection control. Hospital wards, although not seen by the team to be overcrowded, could be improved by limiting the number of contagious patients with resistant strains to one or a maximum of two per room.

Most of the facilities have a very strict policy that does not allow visitors to enter hospital TB wards. Exceptions are, however, common for various reasons but visitors are not provided with respirators.

Environmental control

Most of the TB inpatient facilities have natural ventilation that could be near to zero when the windows are closed, such as during the winter (as observed during the review conducted in December). Some wards have mechanical ventilation but this does not always meet the parameters needed. Specifically:

- in the RSPCPT, the mechanical ventilation system under construction in the XDR-TB department (a very high-risk area hosting 80 patients) has air inlet and exhaust vents placed close to each other in the same wall;
- in the Mogilev regional pulmonology dispensary, the MDR-TB department has mechanical ventilation that ensures an air flow in the correct direction (from the staff "clean" area to the patients' area) but is inadequate in capacity (1.2 instead of 6–12 air changes per hour).

Ultraviolet germicidal radiation systems are in use in most of the TB-dedicated facilities. The open fixtures have largely been replaced with more efficient upper-room fixtures. Some facilities have been provided with digital ultraviolet high-sensitivity meters (ultraviolet C meters), although staff did not know how to use them to measure the level of radiation. The review team observed several models of ultraviolet germicidal radiation system upper-room fixtures in use and specifically compared the efficacy of two of them: the louvered fixture (Fig. 4a) and the shielded fixture (Fig. 4b).

Fig. 4a. Louvered ultraviolet germicidal irradiation fixture

Fig. 4b. Shielded ultraviolet germicidal irradiation fixture

The louvered fixture ensures a uniform distribution of ultraviolet light over the ceiling, while the shielded fixture provides a relative higher intensity of ultraviolet light in its proximity that decreases significantly two to three metres further away. Both fixtures can be considered safe when positioned 1.80 m above floor level. When repositioned, the safety of the shielded fixture should be checked by measuring the intensity of the ultraviolet light which should be <0.2–0.4 µm/cm^2.

As regards environment control, a worrying aspect is the poor maintenance of the biosafety cabinets and the risk of TB transmission to the laboratory staff in a case of malfunction. None of the laboratories visited by the team in either the civilian or the penitentiary system had a service contract, for two reasons: (i) the lack of dedicated funds; and (ii) the lack of well-trained and certified technicians. The NRL in Minsk has bought the necessary equipment to check the biosafety cabinets (particle counter, aerosol generator) but nobody has been trained to use it.

Respiratory protection

The team observed proper respirators (with EN 149:2001 + A1:2009 standards) available in all visited facilities. The policy regarding respiratory protection is included in the national infection control plan and gives all specifications for the selection, testing, wearing, use, care and disposal of the respirators. Good practices are not, however, always maintained and some staff in both the civilian and the penitentiary systems were observed wearing the respirators incorrectly. Surgical masks were always available and some of the patients were seen using them.

Main recommendation

1. Infection control should be further expanded to reduce transmission of DR-TB among patients and health care workers in TB facilities. The implementation of airborne infection control measures should be prioritized in facilities with a large number/rate of DR-TB, such as those for M/XDR-TB, and more advanced resistance patterns in patient care, involuntary TB treatment, palliative TB care and laboratories. The implementation of a range of infection control measures should be optimized, including the good design and maintenance of mechanical ventilation.

Other recommendations

2. Because of the very high risk of transmission of MDR strains, mechanical ventilation should be used in all wards hosting MDR/XDR-TB patients. If this is not possible for the entire ward, mechanical ventilation (negative pressure) should be implemented in at least several isolation rooms dedicated to contagious patients and positive pressure provided in the rooms for the staff.
3. Ventilation systems should provide:
    - directional airflow (negative pressure in patients' rooms relative to the environment);
    - 6–12 air changes per hour (or 80 m^3 per hour per patient);
    - no air recirculation;
    - safe exhaust of air: decontamination of exhausted air, outdoor exhaust;
    - proper heating or cooling of the air.
4. Staff areas must be separated from patients' areas or provided with positive pressure if they are situated inside the risk area.
5. In the Mogilev MDR/TB department, the heating/cooling of inflow air for the mechanical ventilation system should be improved to make it possible to increase the ventilation rate to at least six air changes per hour in patients' rooms.
6. The installation of the mechanical ventilation system in the MDR/XDR-TB department of the RSPCPT should be completed and it should begin operation after a careful and competent technical evaluation.
7. Upper-room ultraviolet radiation systems should be used in all high- and very high-risk areas. They should function permanently in living areas and be properly maintained.
8. Respiratory protection programmes should be implemented in each TB facility, with information on the selection, testing, use, care and disposal procedures of the respirators.
9. Staff working in TB facilities (including in the penitentiary system) should be trained in respiratory protection in order to increase their adherence. Patients should be educated in cough etiquette and respiratory protection, such as using a surgical mask in the presence of others.
10. Biosafety equipment should be properly maintained and each health unit should be funded for such maintenance.
11. Technical staff should be trained in the proper use and maintenance of the equipment.
12. A company accredited for certifying and maintaining the biosafety cabinets should be identified. Alternatively, at least two engineers should be trained in international biosafety cabinet certification and maintenance.
13. The equipment available in the NRL in Minsk (particle counter, aerosol generator) should be used to evaluate the efficacy and safety of the biosafety cabinets after proper training for the people who may use it.

Management of medicines and other commodities

There are three main parallel TB drug management systems:

- centralized procurement through a national tender financed by the Ministry of Health which ensures the procurement of first-line and some second-line anti-TB drugs such as cycloserine, p-aminosalicylic acid and prothionamide; from 2016, linezolid and moxifloxacin will also be procured through this system;
- procurement from the Global TB Drug Facility financed by the Global Fund, which ensures the procurement of all second-line anti-TB drugs for M/XDR-TB patients such as amoxicillin/clavulanic acid, bedaquiline, capreomycin, cycloserine, levofloxacin, clofazimine, linezolid, pyrazinamide, prothionamide, p-aminosalicylic acid and terizidone;
- local procurement financed by the health facility (local budget), which is used to procure drugs not available from centralized procurement, such as amoxicillin/clavulanic acid, imipenem, levofloxacin, linezolid and moxifloxacin; this form of procurement is an unpredictable buffer supply depending on the level of funds from the local health authority.

Small amounts of medicines (linezolid, amoxicillin-clavulanate) are also received by the NTP as donations from Médecins Sans Frontières (see section on drug resistance).

Drug needs are quantified in two ways:

- through centralized procurement, on the basis of the number of patients and historical consumption in the previous year reported by all TB facilities (one report for each drug);
- centrally through the Global TB Drug Facility (with minimal or no involvement of the facilities), on the basis of the type of treatment regimen and duration of treatment.

All medicines procured through national tender must have a marketing authorization and be included in the national list of essential medicines. The marketing authorization is given by the National Medicines Regulatory Authority, composed of representatives of the Ministry of Health (responsible for drafting policies, legislative proposals, licensing and inspections and supply of centrally procured medicines and supplies) and the Centre for Examinations and Tests in Health Care, which is responsible for technical assessments (drug registration and clinical trials), monitoring (pharmacovigilance, quality control, advertising) and inspection of good clinical practices and good manufacturing practices. Some of the new and repurposed medicines procured from the Global TB Drug Facility are not registered in Belarus but imported through a special order of the Ministry of Health for each batch.

The state unitary enterprise Belpharmacia retrieves the medicines from the manufacturers chosen by national tender and stores them in central and regional warehouses. The company is also responsible for importing and storing the drugs procured from the Global TB Drug Facility. The collection of the drugs from the regional warehouses is the responsibility of the health facilities themselves. They do not collect medicines on a regular basis and their stocks vary a lot, as observed by the review team for some drugs (such as cycloserine or p-aminosalicylic acid) that were found in large quantities in several facilities, some at risk of expiring before consumption. A national electronic database was introduced last year and stocks are now monitored more effectively at facility level.

The team found good storage conditions in most of the facilities visited. The cold chain for p-aminosalicylic acid was found to be assured in all facilities. In some, however, the storage areas were inadequate or lacked proper shelves or air conditioning.

Drugs are collected from the pharmacy of the facility against a standard form to be filled in for the specific drug and period of supply (ranging from three days for inpatients to one month for outpatients) but not including the name of the patient. Neither the pharmacies nor the electronic database, therefore, have a record of the TB patients who collected the drugs.

A pharmacovigilance system exists and each clinician working at any level of care can report electronically any adverse reaction induced by anti-TB drugs. Unfortunately, such reports are not compulsory and the system does not provide either a reward or feedback. As a result, pharmacovigilance is weak, other than for bedaquiline and linezolid which are imported under the Global Fund grant and subject to a specific monitoring mechanism (see section on monitoring and evaluation).

A big improvement in anti-TB drug management was achieved after the drug management module in the national TB database was implemented. This includes all anti-TB medicines, no matter their source of funding (Global Fund, national or local budget). The database provides information regarding deliveries and current stocks, enabling in theory prompt redistribution from facilities with excess quantities of drugs to facilities with shortages. Unfortunately, such redistribution is difficult in practice, especially between facilities in the different regions, due to cumbersome bureaucratic procedures. For the moment, the information on medicines is not linked to the patients. Such a link would ensure that all patients registered for treatment in the national TB register are also on the national drugs register, which helps to ensure that current availability and forecasting of the drugs are correct.

In November 2015, staff from the NTP central unit and the Ministry of Health were trained in Latvia in drug supply management, including drug forecasting. There is a plan for cascade training of the staff working in the regions.

Main recommendations

1. The new and repurposed anti-TB drugs (bedaquiline, delamanid, linezolid, clofazimine and imipenem/cilastatin) should be included in the national list of essential medicines.
2. The central procurement of all anti-TB drugs (including the aforementioned) should be ensured based on actual and estimated needs (forecasting based on patient resistance patterns and existing and buffer drug stocks).
3. The drug supply should be coordinated with the regions and across the different sources of funding, including national and local budgets and international support (Global Fund, Médecins Sans Frontières, USAID and others).

Other recommendations

4. The drug management module developed as part of the national TB database should continue to be improved and linked to the laboratory module for cross-checking. Consideration should be given to the possibility of introducing real time information about drugs (the treatment regimen) for each patient by using electronic prescriptions in health care facilities.

5. Reporting under pharmacovigilance should be improved.
6. Staff in the facilities should be trained in forecasting, quantification, ordering and keeping an inventory of the management of TB products.
7. Facilities should receive feedback regarding forecasting and drug deliveries.
8. The stock of anti-TB medicines should be continuously monitored to prevent shortages or overstocking and losses due to expiry of shelf-life.
9. A system should be organized for the transfer of drugs between units both within and between regions.

Monitoring and evaluation

TB is a notifiable disease in Belarus. The Department of Epidemiology, Prevention and Organization of Tuberculosis Care in the RSPCPT is specifically dedicated to epidemiological surveillance and programme monitoring. The functions of this Department were strengthened by promoting its head to Deputy Director of the RSPCPT and redistributing some of the workload of its staff (five doctors and two technicians) to other RSPCPT departments, such as the pharmacy for monitoring the drug supply and the laboratory for surveillance of drug resistance.

The Global Fund grant tops up salaries of the staff responsible for the generation of reports and field supervision, an important function of the NTP that will have to be expanded to the decentralized primary health care co-management of TB patients and assured by domestic funding to ensure its long-term sustainability. In regional and district facilities, the staff are assigned to TB monitoring and evaluation according to the number of TB hospital beds (usually one physician and two nurses). Surveillance of TB is part of the surveillance of all communicable diseases that is the responsibility of the SES (see the section on case-finding and diagnosis). In the penitentiary system, TB surveillance and monitoring is carried out by the Ministry of Internal Affairs, which eventually reports to the RSPCPT.

The TB case definitions and reporting framework currently used in Belarus are largely consistent with those recommended by WHO *(39)*. The national guidelines provide standardized definitions of TB cases by site, bacteriological confirmation and previous treatment. Since 2009, the NTP recording and reporting functions have been shifting from the former paper-based system to an online electronic case-based national TB register (MIS Lekar)[14] *(40)* which is aligned with the latest WHO definitions, reporting framework and indicators. Even so, parallel paper and digital recording occurs in the regions even where the internet connection is fairly good. In 2014, the RSPCPT experienced a two-hour shutdown of both internet servers which caused the loss of data for six patients. Some arrangements have already been made (purchase of a more powerful platform and use of optical fibres) to prevent the same problem happening in the future. It is not clear for how long the double TB registration will continue, nor what the overall vision of the Ministry of Health is regarding the future of digital health in Belarus.

TB data are entered into the electronic register for each case. These data replicate the standard demographic, clinical, bacteriological and outcome variables which are inherent in standardized TB recording and reporting systems. The electronic register does not, however, have the automated function of generating reports of main indicators from aggregated data, such as the reported smear positivity rates, average delay between diagnosis and start of treatment or level of

[14] The MIS Lekar electronic register was developed with the support of the Global Fund and WHO and is currently maintained by Informatsionnie Sistemi, a private firm based in Brest, Belarus.

anti-TB drug resistance by region. At present, the electronic register is used in 120 different civilian facilities across the country as well as in one site in the penitentiary system. The team noted that staff at all levels were using it proficiently.

The electronic register has two modules, laboratory and patient management, that could be improved for clinical case management. The laboratory module could include the results of the new diagnostic techniques considered in the revised national diagnostic algorithm and other investigations recommended when new and repurposed anti-TB drugs are prescribed (biochemistry, electrocardiogram). The patient management module could be expanded to include information on: asymptomatic TB contacts placed on preventive treatment; TB patients diagnosed but not yet receiving treatment (by linking the two modules); compliance with directly observed anti-TB treatment; other medications (ART and CPT); aspects of drug supply management (name, formulation, lot number, dose); adverse drug reactions; and risk factors for and social determinants of TB.

An important aspect is the NTP cohort analysis of treatment outcome that currently suffers from mixing drug-susceptible TB patients (with more favourable outcomes) with rifampicin-resistant /MDR/XDR-TB patients (with less favourable outcomes) as eventually determined by DST. The analysis of final treatment outcomes should be done on separate cohorts of patients with similar drug resistance patterns and updated when patients are moved from one cohort to another. In this case, unfavourable treatment outcomes (especially failure and death) will more accurately reflect case management by the NTP.

The electronic register does not interoperate directly with other national databases, such as the mortality register, the register for pharmaceutical management, the register for pharmacovigilance (kept by the Centre for Examinations and Testing in Health Care of the Ministry of Health) and the register for HIV/AIDS care.

Major progress has been achieved in active drug safety monitoring of new and repurposed TB drugs *(41)*. In early 2014, the RSPCPT and the National Pharmacovigilance Centre[15] jointly started cohort event monitoring among the M/XDR-TB patients being treated with linezolid and bedaquiline *(42)*, according to a specific protocol and supported by Ministerial Order No. 690 of 23 June 2014 *(43)*. At the time of the review, the Centre had collected information on 132 patients on linezolid since June 2014 and 65 patients on bedaquiline since June 2015. The electronic close cohort event monitoring database was nearly complete, after some delay due to lack of funds, and was expected to be operative in early 2016. It was expected that entering the backlog of patients' data would require about two months.[16] In addition, there was a plan to add about five variables on adverse drug reactions to the electronic register, to be recorded for all TB patients.

The NTP recording and reporting system was comprehensively reviewed in November 2014 *(16)* against 13 international standards for TB surveillance *(44)*: seven standards were met, four standards were partially met and two standards were not met (Table 6). Such findings indicate that the data reported by the NTP cannot yet be a direct measure of the actual TB incidence and mortality in the country. In other countries, their estimates could be adjusted by using the onion model study and the capture-recapture study. However, the onion model studies the possible underreporting of TB cases and does not look appropriate in Belarus, where all cases are

[15] Located at the Centre for Examinations and Tests in Health Care of the Ministry of Health.
[16] A preliminary data analysis had been done on the first 58 MDR-TB cohort of patients on linezolid-containing treatment regimens. Almost 80% of them had had at least one adverse event but only 5% had to stop linezolid.

diagnosed in NTP or penitentiary facilities and not in the private sector. The capture-recapture study is also unlikely to be informative because only one of the minimum required three independent sources of information (the NTP) is available. Other methodological limitations may also apply, such as no registration of a truly unique patient identifier in lists, the need to do such a study on a nationwide scale because of patient mobility between regions, the likelihood of the different chances of being registered for children and for adults, and a varying degree of ascertainment of TB in different lists. The team nonetheless felt that under-detection of TB is very likely in some groups, such as the contacts of active TB cases who are not adequately screened (see the section on case-finding and diagnosis). Moreover, routine drug resistance surveillance based on diagnostic testing is not on a firm basis. This could be achieved if about 200 more new pulmonary TB cases than in 2014 were to receive DST or Xpert MTB/RIF assay.

Table 6. Standards and benchmarks for TB surveillance achieved, Belarus, 2014

Standard	Met
B1.1 Case definitions consistent with WHO guidelines	Yes
B1.2 TB surveillance system designed to capture a minimum set of variables for reported TB cases	Yes
B1.3 All scheduled periodic data submissions received and processed at national level	Yes
B1.4 Data in quarterly reports are accurate, complete and internally consistent	Yes
B1.5 Data in national database are accurate, complete, internally consistent and free of duplicates	Partially
B1.6 TB surveillance data are externally consistent	No
B1.7 Number of reported TB cases are internally consistent	Yes
B1.8 All diagnosed cases of TB are reported	Partially
B1.9 Population has good access to health care	Yes
B1.10 Vital registration system has high national coverage and quality	Partially
B2.1 Surveillance data provide a direct measure of DR-TB in new cases	Partially
B2.2 Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases	Yes
B2.3 Surveillance data for children reported with TB are reliable and accurate	No

Main recommendation

1. The electronic databases for TB and laboratory and drug management should be developed to facilitate data aggregation, analysis and reporting at central and regional levels. Other features should be added, such as registration of drug adverse events, TB/HIV interventions and interoperability with the HIV national register. Support for digital health for TB, such as video-observed therapy and eLearning, should continue and adequate measures should be ensured to capture user feedback and to collect evidence on their impact.

Other recommendations

2. Electronic data recording and reporting should completely replace paper-based recording and reporting, which should be abandoned. Proper provision should be made for the safe handling of data and backing up the information in secure servers in different geographical locations.
3. Patients eventually found with DR-TB (polyresistant, MDR, XDR) should be removed from the cohort analysis of drug-susceptible TB patients and evaluated separately for treatment outcome.
4. DST coverage should be increased to 200 more new pulmonary TB cases than in 2014 in order to reach the benchmark for routine national drug resistance surveillance that meets international standards.

5. The electronic register should be further enhanced and tested by:
    - creating automated reporting functions able to produce summary reports of activity, quality (for example, smear positivity rates) and epidemiological indicators (such as estimates of drug resistance by region); allowing more flexible use of data reporting, consolidation and analysis at central and regional levels, with the possibility of extracting parts of individual level datasets in real time from the database as a worksheet; and removing all need for the manual computation of data;
    - including the automatic production of simple graphics and dashboards for the main indicators and options to filter data so as to know which patients are eligible for treatment but have not yet started, to see different groups of patients (by region, treatment centre, drug resistance pattern) and the time of culture conversion;
    - producing aggregated quarterly reports on Excel about activities currently recorded on paper, such as active case-finding with the number of TB contacts screened and the yield of TB cases newly detected.
6. Training and supportive supervision should be ensured for all staff for changes in the electronic data recording and reporting.
7. The system of supportive supervision and regular capacity-building at district level should be updated and adequately financed, including the support and monitoring of primary health care services.

Human resources development

The human resources situation had not changed much since the 2011 NTP review. There are 5460 staff working in the TB services, of whom 1200 are nurses and 540 doctors, with some differences across the regions. Salaries are determined by the Ministry of Labour and Social Protection, while the bonuses for occupational risk of TB are decided by the Ministry of Health (since 2012, such bonuses are linked to patients' adherence to treatment). TB doctors and nurses work for a maximum of 35 hours per week (instead of the 38.5 hours worked by all other medical staff) and can retire on pension five years earlier. The Ministry of Health compensates for the shortage of staff by allowing TB doctors and nurses to work 1.5 full-time equivalent, that is, working and being paid for an additional 50% of hours. Unfortunately, despite these incentives (bonus for occupational risk, shorter working week, earlier retirement and overtime) new doctors and nurses are still not attracted to replace those working in TB who have retired or are close to retirement. The recommendation of the 2011 NTP review to raise the salaries of the TB doctors could not be met.

The occupational risk of TB should be considered high in Belarus, as documented in a retrospective study published in 2014 *(38)*. Between 2008 and 2012, a total of 116 health care staff working in TB facilities were diagnosed with the disease. In 2012, the notification rate was 349 per 100 000 workers, 8.7 times higher than in the general population. Seventy-two percent were nurses or nurse assistants commonly working in non-medical hospital wards (29%), general medical wards (22%) and M/XDR-TB wards (20%). Only 38/116 (33%) health care workers were tested for anti-TB drug susceptibility, of whom 28 (74%) were found with M/XDR-TB.

As is the case for other civil servants, TB personnel are entitled to sick leave and disability pensions. Paid sick leave comprises 80% of basic salary during the first week and 100% from the second week up to six months. If a health worker has MDR-TB and the treatment lasts longer than six months, a temporary disability pension can be requested. Alternatively, and only after

sputum conversion, the worker can be offered another job which does not involve contact with the public, if such a job is available. Only when a health worker is cured (treatment completed and sputum smear negative) is he/she allowed to return to work.

Four universities (Gomel, Grodno, Minsk and Vitebsk) provide undergraduate medical education, with elective courses on TB offered during the last year. The Belarusian Medical Academy of Postgraduate Education in Minsk is in charge of postgraduate medical education and professional certification. Phthisiology and pulmonology (much more popular) are separate postgraduate courses with durations of two and three years, respectively. Their curricula are updated every two years by the Academy in collaboration with the RSPCPT.

With support from the Global Fund, the RSPCPT provides quarterly monitoring meetings with the regional TB coordinators and every year holds scientific conferences and on-the-job training for laboratory specialists.

All doctors in Belarus have to renew their professional certification every five years. To do that, they need to accumulate 80 credit hours of continuing medical education, usually through participation in conferences certified by the Ministry of Health or short refresher training courses in the Academy.

Under the Global Fund grant, primary health care staff are trained in TB and PAL separately. The PAL guidelines were launched by the Ministry of Health in 2014 *(45)* and are now included in the curriculum for medical education. With support from WHO and the European Respiratory Society, the NTP has translated the PAL guidelines into an application for mobile phones and tablet devices which helps doctors to navigate easily through the PDF copy of the PAL manual, read how to advise on smoking tobacco cessation, fill in preformatted medical prescriptions and report on adverse drug reactions. The application also supports patients, who can receive e-mails with information on, for example, how to collect their sputum for laboratory examination or how to take nicotine replacement therapy. It will be made available free for downloading from the internet.

Main recommendation

1. The specialties of pulmonology and phthisiology should be merged and undergraduate, postgraduate and continuing medical education harmonized to ensure the rational and flexible use of existing resources and to increase career opportunities that will attract more doctors.

Other recommendations

2. The basic salary and bonuses for all health workers involved in TB care should be increased.
3. A database should be developed centrally of the staff who have been trained so as to prevent duplication and facilitate the future planning of in-service training courses.

Operational research

Since the 2011 NTP review and its recommendation on operational research, increasing numbers of studies have been undertaken and published in international peer-review scientific magazines. The subjects covered have been many and included TB epidemiology with a focus on drug resistance and its determinants, the use of rapid laboratory diagnostic tools, the use of new and

repurposed anti-TB drugs and new regimens, immune therapy, evaluation of treatment outcomes and support for patients, TB/HIV, infection control and ambulatory TB care supported by new payment mechanisms. Local capacity in conducting operational research has been built through the Structured Operational Research and Training Initiative conducted jointly by WHO headquarters Special Programme for Research and Training in Tropical Diseases, the Regional Office and Médecins Sans Frontières. The relevance of Belarus in the global prevention and control of DR-TB has led to strong collaboration between national and international researchers, working together to design, analyse and publish operational research studies.

The team took note of this major undertaking and suggests the following further areas of operational research according to the opportunities and financial resources available:

- TB contact-tracing (coverage/yield by risk groups of the population, compliance with preventive therapy, alternative regimens for treatment of latent TB infection);
- TB in children (reasons for under- and delayed TB diagnosis, high drug resistance, occurrence of severe adverse reactions to BCG vaccination);
- use of new and repurposed anti-TB drugs (drug resistance patterns of bedaquiline and linezolid, cohort event monitoring and active drug safety monitoring and management);
- digital health (PAL uptake and feedback from physicians and patients, effectiveness of video- (virtually-) observed therapy for TB);
- social protection (eligibility criteria, impact on treatment outcomes);
- the relationship between TB and alcohol use disorders and tobacco smoking (epidemiology, programmatic management).

Main recommendation

1. A new operational research agenda should be developed outlining priority topics for study, identifying key investigators and including adequate financial resources to lead to a better and more effective performance by the NTP.

Other recommendations

2. Participation should be arranged in multicentre international studies documenting the necessary evidence for the optimal use of current and new tools to end TB such as new vaccines, new drugs and treatment regimens and point-of-care test.
3. The process of capacity-building in operational research should be continued by promoting collaboration with international partners and the involvement of academic institutions.

Ethics and human rights

In 2010, WHO published its guidance on ethics applied to TB prevention, care and control *(46)*. This was followed by a workshop in 2013, organized by the Regional Office, to discuss the two specific topics of involuntary isolation and treatment[17] and compassionate use of new and

[17] WHO defines "involuntary isolation" as the isolation/hospitalization of a person against his/her will. It should be distinguished from "involuntary treatment" (or "compulsory treatment" or "forced treatment"), which WHO defines as the application of ways to force a person to undergo treatment (forced or induced ingestion or application of medicines) over his/her will.

repurposed anti-TB drugs *(47)*. Six countries (Armenia, Azerbaijan, Belarus, Georgia, Republic of Moldova and Ukraine) participated and asked for follow-up country missions to assess and revise their current legislation. The 2015 NTP review described in this report was used to provide such follow-up in Belarus.

The Constitution of Belarus adopted in 1994 and amended in 1996 and 2004 adheres to international law and human rights standards.

- Section I recognizes the "supremacy of the universally acknowledged principles of international law" (art. 8).
- Section II recognizes "the right to a dignified standard of living, including appropriate food, clothing, housing" (art. 21); equality before the law (art. 22); the right to life (art. 24); the right to personal liberty (art. 25 I); the right to be free from "cruel, inhuman or undignified treatment or punishment" (art. 25 III); the right to private life (art. 28); the right to health care (art. 45 I); and the right to social security in old age in the event of illness, disability, loss of fitness for work and loss of a bread-winner (art. 47).
- Section III states that the Republic of Belarus "shall guarantee the rights and liberties of the citizens of Belarus that are enshrined in the Constitution and the laws and specified in the State's international obligations" (art. 21).

Belarus has ratified a number of international treaties and conventions:

- Convention on the Prevention and Punishment of the Crime of Genocide (1954);
- International Convention on the Elimination of All Forms of Racial Discrimination (1969);
- International Covenant on Civil and Political Rights (1973);
- International Covenant on Economic, Social and Cultural Rights (1973);
- Convention on the Elimination of All Forms of Discrimination against Women (1981);
- Convention on the Rights of the Child (1990);
- Convention on the Rights of Persons with Disabilities (signed in 2015, to be ratified in 2016).

Involuntary isolation and treatment

The legislative reference framework is mainly represented by two laws.

- The Law on Public Health (Law No. 2435-12 of 18 June 1993, revised on 16 June 2014) enounces the principle that persons with diseases presenting a danger to public health may be subjected to "involuntary isolation and treatment" in case of non-adherence to treatment (art. 28). A number of patients' rights are also listed, including the right to refuse medical assistance/intervention (art. 41) and the right to be asked for informed consent (art. 44), which could be oral for simple medical interventions and written for more complex ones.
- The Law on Prevention of Diseases Dangerous to Public Health, HIV (Law No. 345-3 of 7 January 2012)[18] defines the legal and organizational basis for the prevention of those diseases dangerous for human health and of HIV and for protection of the rights of the "persons who have the aforesaid diseases, the persons with good reasons to believe they themselves have got these diseases and the persons providing direct or indirect medical

[18] Ministry of Health Order No. 75 of 15 June 2012 lists "active pulmonary tuberculosis" among the diseases that threaten individual, social and national security *(48)*.

assistance". The law considers the use of involuntary isolation and treatment in cases of socially dangerous diseases (art. 20), including of patients with confirmed TB (infectious or non-infectious) when they refuse treatment. The refusal of treatment is defined as: (i) the refusal to be treated in a public health establishment after the diagnosis has been confirmed; (ii) the refusal to follow the medical prescriptions or to follow the discipline rules within a public health establishment; and (iii) non-attendance at a public health establishment for follow-up examination or treatment, although non-attendance is justified when the disease precludes the travel of the patient or the need for the patient to take care of family members (including their deaths) or *force majeure*. The decision for involuntary isolation and treatment is taken by a court at the documented request of the person(s) responsible for the public health establishment (art. 20). Specially designated health facilities are reserved for involuntary isolation throughout the country. The conditions required of these facilities are stated indirectly in art. 23 in the description of the rights of patients to receive appropriate health care, to be informed about medical procedures (informed consent) and their status, to be treated with respect, to confidentiality and protection of their data, to have visitors and to receive packages or parcels. Some limits on visitors and goods may be imposed if the visitors and goods are potentially dangerous.

Involuntary isolation

From 2010 to 2015, the NTP reported a drastic decrease in the number and proportion of patients placed in involuntary isolation, which is generally reported as an effect of increasing support for patients (see section on treatment and case management). Even so, some areas of the current legislation on involuntary isolation should be improved.

The current legislation does not provide a definition of "medical prescription" or "discipline rules", neither does it distinguish between infectiousness and non-infectiousness or the temporary nature of the refusal to receive treatment (occasional or permanent). All this information is necessary to ensure that involuntary isolation is applied as a measure of last resort (which is also not mentioned in the law), as recommended by international standards *(46)*. As it is now, involuntary isolation can be applied to patients who are non-infectious (and thus not dangerous to the community) or unnecessarily prolonged after sputum turns to negativity (non-infectiousness), just because these patients do not respect the rules for discipline or for not reporting for medical examination when both these situations can be variously interpreted by different health providers. The list of reasons given for justifying non-reporting to a medical examination is very limited and does not include causes related to the patient's employment.

The Law on Prevention of Diseases Dangerous to Public Health, HIV does not clearly describe the process for a court to decide on involuntary isolation as expected by international standards. There is no explicit provision in the law to the effect that prior to the initiation of proceedings seeking a court order to detain, the person concerned must be warned by the responsible public health establishment that he or she may be subjected to detention for the purpose of treatment. The team was told that warnings are given by the treating physicians but vary in number (one to three) and are mainly verbal. Moreover, the court decision should lay down the reasons for applying involuntary isolation (new or extended) and why less severe measures are not being applied. Appeals against the courts' decisions are rare, most likely because patients are unaware of their rights because of limited legal counselling. Law No. 334-3 of 30 December 2011on Advocacy and Legal Practice in the Republic of Belarus, art. 6, offers free legal counselling by the state, but it is not enforced and legal representatives are not assigned automatically to patients *(49)*.

Ministry of Interior Order No. 145-50 of 21 May 2012 rules that, as soon as the court decision is issued, the patient must be transferred to a suitable public health establishment with the assistance of the local police and health workers. The involuntary isolation should be of six months and can be prolonged by the court (Law No. 345-3, art. 21) if the medical commission in charge of the patient so requests.

During the first six months, the medical commission must evaluate the patient every month and can decide to terminate the involuntary isolation at any time. Law No. 345-3 does not explicitly define the conditions under which a patient can be considered no longer a threat to public health. The right to appeal against the decision is not explicitly mentioned in the law. After six months, if the involuntary isolation is prolonged, the medical commission suspends its evaluation until the end of 12 months of treatment and when the patient's status has to be documented for a further decision by the court.

Involuntary treatment

Involuntary treatment is considered unethical according to international standards *(46)*.

Law No. 345-3 on Prevention of Diseases Dangerous to Public Health, HIV considers that "physical constraint can be used when no other measures are capable of preventing immediate danger to the patient and to others" but only under strict supervision by medical workers (art. 22). This part of the law, while not necessarily authorizing involuntary treatment, is difficult to interpret. The team did not collect any evidence of involuntary TB treatment. On the contrary, its understanding is that those patients who refuse TB treatment are referred to dedicated health facilities where only palliative care is provided. This practice is consistent with the constitution and the law on public health.

Ministry of Health Order No. 939 of 8 August 2012 on the clinical guidelines to treat TB and resistant forms of TB requires a form to be signed by the patient before the treatment is initiated (one form for sensitive TB patients and a different form for MDR-TB patients). This form confirms that the patient has been informed about his/her disease, its severity (including drug resistance), the possibility of being treated and the consequences of the treatment (long duration, adverse reactions) and of refusing it (drug resistance, chronicity, death). By signing this form, the patient provides his/her consent to treatment and, more specifically, to take the prescribed medicines during the entire treatment period, to undergo the required medical examinations and to follow all sanitary and epidemiological rules. Some supplementary details have been introduced recently, including the obligation on the patient to avoid taking alcohol or smoking cigarettes, to notify the medical staff about his or her status and to remain in the hospital. MDR-TB patients are also informed that long-term drug therapy is necessary for the treatment to have a chance of success and that there are potential side-effects.

Compassionate use of new and repurposed anti-TB drugs

The Law on Medical Products (No. 161-3 of 20 July 2006) only allows their use after they have been registered in the country (art. 8). However, the law also includes a number of exceptions for the import of unregistered drugs (art. 23), such as when they are for pre-clinical or clinical trials, for treatment of individual cases (if brought from abroad by a citizen in a small quantity and if registered in other countries), for use in exhibitions and at conferences, in transit, for registration, for use in major emergencies (disasters, catastrophes, epidemics or treatment of orphan diseases) and for use by military units. It is not allowed to import drugs under development for

compassionate treatment that are limited to a few patients without therapeutic alternatives and outside a clinical trial protocol.

Resolution No. 156 of the Council of Ministers of 17 February 2012 laid down that the decision to import unregistered drugs is taken on a case by case basis by the Ministry of Health on the recommendation of the Centre for Examinations and Tests in Health Care affiliated to the Ministry of Health and of the Humanitarian Commission of Presidential Affairs. The Centre has 15 days to issue a decision on a specific medicine, which must be confirmed by the Commission on Humanitarian Aid. New shipments of the same drugs for the same use have to be decided according to the same procedure.

In 2015, the NTP managed to import bedaquiline and delamanid for a period of six months after three months from the application to the Ministry of Health on the basis of art. 23 of Law No. 61-3.[19] To treat all XDR-TB patients, however, the NTP needs an uninterrupted supply of these new and repurposed drugs and simpler import procedures. The procedure for importing new shipments of previously imported products should be simplified.

Recommendations

1. The Law on Prevention of Diseases Dangerous to Public Health, HIV should be revised as follows:
    - the expression “involuntary isolation and treatment” should be replaced by “involuntary isolation” and clearly defined as a measure of last resort to be used in exceptional cases only, and designed to offer a medical treatment to patients;
    - a general statement that all fundamental rights are guaranteed to persons under involuntary isolation should be included;
    - a clear statement that anti-TB treatment cannot be administered through physical constraint should be included;
    - it should be clearly stated that the patient must give informed consent as a condition for medical treatment;
    - all the most important terms should be defined, as well as all the means used for implementing involuntary isolation.
2. Courts should review cases monthly throughout all periods of involuntary isolation and all decisions relating to these cases suggested by the medical commission, which must provide complete documentation of the patient and the reasons why less restrictive measures are not sufficient.
3. Free legal representation should be provided to all patients.
4. The existing law should be revised to include the controlled use of unregistered drugs for compassionate treatment. Eligibility criteria should be clearly formulated, as well as the procedures to be followed.
5. The procedure for importing drugs that have been approved previously for compassionate treatment should be simplified.

[19] According to art. 23 of Law 161-3, non-registered medicinal products can be imported if they have documentation of their registration in other countries.

Advocacy, communication, social mobilization

The NTP plan for 2010–2014 included some advocacy, communication and social mobilization (ACSM) activities.

In 2012, a knowledge, attitude and practice survey was conducted among health professionals and patients. The majority of health professionals considered TB a hazardous disease. TB patients reported that they had learnt about TB from (in order of importance) health professionals, television, printed materials, the internet, information boards, the radio, family/ friends/neighbours/colleagues/teachers. Majorities of both groups of respondents reported that they had been interested in media announcements and information related to TB, confirming that ACSM can play an important role in supporting the NTP.

In 2012, the NTP also developed a specific ACSM strategic plan for 2013–2015 that included the following:

- completion of the legal registration of the nongovernmental organization People Affected with TB and HIV;
- involvement of TB patients in civil society organizations, as well as enhancement of the rights and capacities of civil society organizations;
- operational research to identify the causes of loss to follow-up with MDR-TB treatment;
- advocacy with policy-makers to increase the salaries and motivation of medical staff;
- training of TB-dedicated medical staff to improve their communication skills with TB patients and families;
- advocacy for inclusion of social support for TB patients in the state budget;
- coordination for ACSM planning among all stakeholders;
- a social mobilization campaign to reduce the stigma of TB involving national and international experts.

In addition, the NTP has been conducting various ACSM activities. Information materials have been printed for TB patients, the general public and health care workers. An important initiative is the TB commitment groups, which provide education for TB patients admitted to pulmonology hospitals and organized with support from the Global Fund. These groups are composed of a team of TB doctors, nurses and psychologists or social workers who assess patients for their knowledge of TB and their attitudes to adherence to treatment. They provide education sessions, with the possibility of individual consultations with a psychologist. Each patient usually attends five or six such sessions, and sessions are also organized for the patients' contacts *(50)*.

The NTP plan for 2015–2020 includes the dissemination of information on the prevention and prompt detection and treatment of TB as well as the promotion of healthy lifestyles through the mass media. A small ACSM component is covered under the third objective of the Global Fund grant for 2016–2020, namely to improve MDR-TB treatment outcomes with appropriate patient-centred support, including for patients from high-risk groups and vulnerable populations.

Despite all these activities and initiatives, the team found insufficient knowledge of TB-related issues among the patients interviewed. More can be done to give patients psychological support,

especially those at higher risk (those with alcohol use disorders, drug users, prisoners and ex-prisoners) to prevent loss to treatment follow-up and reduce the recourse to involuntary isolation. TB contacts have also been somewhat neglected: the team found many of them with limited knowledge of the transmission and symptoms of TB. The general public similarly seems to lack awareness.

The establishment and strengthening of civil society organizations is essential to raise awareness of TB in the community effectively and to provide psychological and social support to TB patients and their families. The legal registration of the nongovernmental organization People Affected with TB and HIV, an association of former TB patients and their supporters, was an important step for future low-threshold interventions aiming to exercise effective advocacy, improve knowledge and reduce social stigma. Another organization working with TB patients is the Positive Movement group of the Red Cross. The Global Fund grant also enables other nongovernmental organizations to work actively with PLHIV. The team appreciated the high motivation of the members of these nongovernmental organizations but also noted that their experience was insufficient or needed to be strengthened on TB-specific issues. Under the Global Fund grant for 2016–2020, the Red Cross will be the only subrecipient organization and it is still not clear if other nongovernmental organizations will receive new funds to continue their work with populations at high risk of TB, such as PLHIV.

Main recommendation

1. The new national ACSM strategy for 2016–2020 should be developed jointly with all main TB stakeholders in the country and included in the National TB Plan 2016–2020.

Other recommendations

2. A knowledge, attitude and practice survey needs to be conducted so as to evaluate progress since the 2012 survey and to develop new recommendations on ACSM.
3. Education of TB patients by health care professionals and nongovernmental organizations should continue. The good practice of hospital TB commitment groups should be expanded to outpatient TB facilities and among communities of prisoners and ex-prisoners and alcohol and drug users.
4. Counselling and education on TB should be provided more actively and continuously to TB patients' households and other close contacts.
5. Information meetings/seminars on TB should be conducted with school teachers and children's parents and in workplaces.
6. The engagement of civil society organizations should be further promoted so as to reach all population groups at high risk of TB effectively, including those with alcohol use disorders, drug users, PLHIV, prisoners and ex-prisoners.

Health system and TB control

The health care system is based on the former *Semashko* model, financed through general taxation and managed directly by the Ministry of Health *(51)*.

Compared with other countries of the former Soviet Union, total government expenditure and general expenditure on health make up relatively low proportions of the gross domestic product

in Belarus at 29% and 4%, respectively, but government spending on health is a reasonable 13% share of gross domestic product *(52)*. Nonetheless, the health system is characterized by high out-of-pocket payments, most of which are direct payments for pharmaceuticals and private services, usually dental care services.

Health care provision consists of a network of state-owned facilities hierarchically organized on a geographical basis. District and regional health care departments are responsible for the organization and funding of primary and secondary health care services in their respective areas. The Ministry of Health at central level has the overall responsibility for the health system and funds the specialized national hospitals directly.

The primary health care level does not have a gatekeeping function. Services are provided through polyclinics in the urban areas (with separate facilities for children and adults) and rural outpatient clinics and *feldsher*-midwife points in the rural areas. In some remote rural areas the outpatient clinics may have 15–30 beds and are more often called rural community hospitals, many of them reorganized in recent years into long-term nursing homes. The *feldsher*-midwife points have only one medical professional (the *feldsher*-midwife) and one auxiliary staff member (cleaner).

The secondary health care level is based on district hospitals, which provide general secondary care services, and regional hospitals, which deal with more complex cases and offer a wider range of services. All hospitals also offer outpatient services.

The tertiary health care level is provided by specialized hospitals located in the main cities.

The allocation of resources in the health system is based on normative legal acts and volume activity indicators that take into account medical and demographic processes in the country. The minimum national health standards and programmes (see Annex 5) are set at central level, but local authorities can add their own priorities. There are seven national minimum standards for the provision of health services:

- minimum budgetary expenditure on health per capita;
- minimum number of primary health care doctors per capita;
- minimum number of hospital beds per capita;
- minimum number of state-owned pharmacies per capita;
- minimum number of emergency care teams per capita;
- minimum number of ambulances per capita;
- minimum sanitary-technical standards for health care facilities.

Accordingly, the health care providers have limited autonomy over capital, staffing, salaries or types of service that could be offered. Capital and staffing levels are decided at regional and district level. The salary scale is decided centrally, as are the types of service to be delivered as per the norms and standards decided by the specialist branches concerned in the Ministry of Health. The health facilities have no flexibility to transfer allocations between their detailed budget line items, nor can they retain and carry forward any budget saving. Adjustments to the budget during the year have to follow a cumbersome centralized procedure that prevents the

management of the health facilities from generating efficiency gains or paying financial incentives to staff.

Since 2001, the allocation of resources has depended on the number of residents adjusted by gender and age group. The national minimum standards for hospital beds are nine per 1000 population in the regions and eight per 1000 residents of Minsk city. In 2014, there were 1086 hospital beds per 100 000 population (the highest number in the Region, 1.9-fold more than the regional average) and 6.8 hospitals per 100 000 population (the third highest level in the Region and 2.1-fold more than the regional average *(53)*). Similar levels were observed during the last 10 years. Many of these hospitals are small and cannot achieve the necessary cost–efficiency ratio through economy of scale. Belarus remains the first or second country in the Region for the highest number of short-stay hospital beds per population (Table 7).

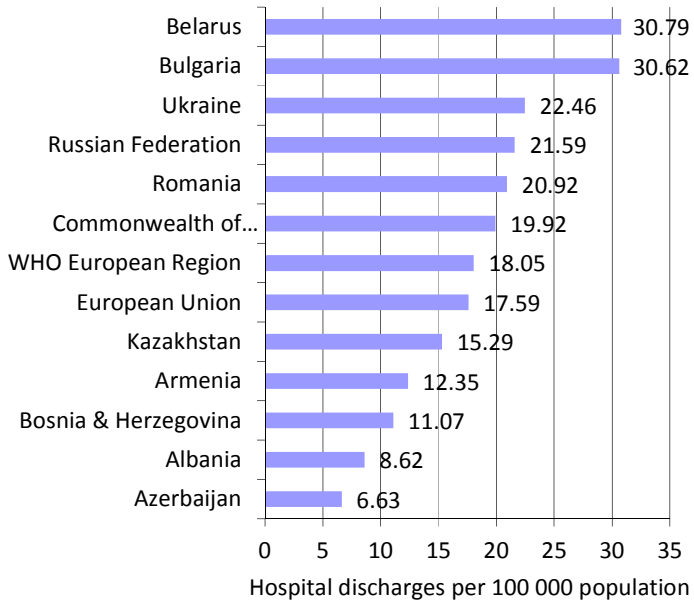
Table 7. Hospital beds by region and type of patient and rate by population, Belarus, 2014

Administrative area	Absolute number				Per 100 000 population			
	Total	Acute patients	Chronic patients	Other	Total	Acute patients	Chronic patients	Other
Brest	14 428	11 647	2 005	776	1 039	839	144	56
Gomel	15 898	12 882	2 166	850	1 117	905	152	60
Grodno	12 394	9 537	2 250	607	1 178	906	214	58
Minsk	14 566	12 649	1 085	832	1 034	898	77	59
Minsk City	20 125	16 349	3 735	68	1 040	843	193	4
Mogilev	11 412	9 213	1 604	595	1 066	860	150	56
Vitebsk	14 067	10 037	2 759	1 271	1 174	837	230	106
Belarus	102 917	82 314	15 604	4 999	1 086	868	165	53

Source: data from the Ministry of Health.

Belarus is also the country with the highest number of hospital discharges in the Region (Fig. 6).

Fig. 6. Number of hospital discharges per 100 000 population by country, WHO European Region, 2013



Source: WHO *(7)*.

Several factors seem to explain the overprovision of hospital beds.

- Historical-based budgeting along unchangeable line items plays a major role, preventing the adaptation of budgets to changing needs and limiting innovative approaches by hospital managements.
- Budgetary guidelines determine the minimum ratio between staff (physicians and nurses) and hospital beds. The high number of beds justifies a high number of staff positions, many of them vacant and justifying the overtime of the present staff who can thus significantly increase their low regular salaries. Belarus has some of the highest numbers of physicians and nurses in the Region *(53)*.
- Besides staffing, budgets for all other needs for running a hospital are set according to the numbers of beds.

Decisions about the organization of TB services are taken centrally by the Ministry of Health. The percentage of TB patients hospitalized is one of the highest in the Region (Table 8). As mentioned by the 2011 NTP review, patients are too readily hospitalized and for unnecessarily long periods of time.

Table 8. Hospitalization rate and length of stay by type of TB patient (not confirmed TB and readmitted cases excluded), Belarus, 2013

Country	Cases hospitalized (%)			Length of stay in hospital (average days)		
	New PTB+	New PTB-/ETB	MDR-TB	New PTB+	New PTB-/ETB	MDR-TB
Belarus[a]	100	80	100	60	30	180
Ukraine	100	30	100	90	50	180
Kazakhstan	95	84	35	80	60	120
Republic of Moldova	95	50	96	56	40	140
Armenia	94	78	75	60	50	90
Uzbekistan	70	60	40	56	56	90
Georgia	70	30	90	25	10	60
Kyrgyzstan	60	34	100	84	84	146
Tajikistan	50	30	30	56	70	80

Note: PTB+= pulmonary TB sputum-positive; PTB-= pulmonary TB sputum-negative; ETB=extrapulmonary TB.
[a] Data from Belarus were not reported to WHO but were estimated by applying the current national guidelines.
Source: WHO data collection form, 2013.

The health system factors incentivizing hospitalization have even more impact on the delivery of TB services.

- The minimum ratios applied are one physician for 20 TB hospital beds and one physician for 12 MDR-TB hospital beds. There is less interest in this specialty after graduation, thus more vacancies for TB medical staff than in other specialties. TB physicians would lose more overtime (now increased up to 50% of the regular salary) were the number of hospital beds to be reduced.
- Since TB is a narrow specialty, TB physicians see their redeployment outside TB-dedicated services as challenging and requiring costly retraining.
- If there is a switch to more ambulatory TB care, the workload in outpatient services will increase while salaries are expected to remain at the same level.
- Current legislation lays down that employees with formal contracts who have TB lose their sick leave (an important form of social protection) when they are discharged from hospital.

M/XDR-TB patients represent a significant burden on the health system, needing a coordinated and integrated approach between the different levels of care and health providers. People-centred TB care requires effective outpatient services (TB-dedicated outpatient services, primary health care and community care).

In view of this problem, the health authorities decided to pilot a new model of care with revised payment mechanisms in Mogilev region, starting on 1 April 2014 *(54)*. The pilot project was supported by an order of the Ministry of Health *(55)* and the decision of the Mogilev Regional Council of Deputies. In consultation with the Regional Office, a working group was established to develop the criteria for hospital discharge, standard operating procedures for treatment follow-up (including daily DOT), contracts with ambulatory care providers and administrative documentation. The budget of the regional TB dispensary for five beds was reassigned to generate savings and to financial incentives for primary health care nurses and *feldshers* caring for TB patients (Box 1).

Box 1. Pilot project on TB ambulatory TB care in Mogilev region

The pilot project resulted in the following financial arrangements:

- closure of five hospital beds (1.2%), corresponding to a decrease in annual hospital costs of 169.9 million rubles incurred by hotel services (meals, laundry) and staff salaries (0.25 of a doctor position, 1.25 nurse position, 2 assistant nurse positions);
- generation of financial incentives for providing ambulatory services fixed at US$ 1 per patient visit to the TB dispensary and US$ 4 to the patient's home, much less than the US$ 27 cost of a one-day stay in hospital.

The following patients were enrolled for ambulatory treatment after hospital treatment:

- three drug-susceptible TB patients;
- one polydrug-resistant TB patient;
- nine MDR-TB patients (seven with alcohol use disorders, seven unemployed, one disabled).

As at 1 December 2015, the pilot project had made the following achievements:

- three drug-susceptible and one polydrug-resistant TB patient were cured;
- six MDR-TB patients were cured (67%), two failed treatment, one was still in treatment;
- there was no loss to treatment follow-up among the patients with alcohol use disorders and those living in remote rural areas;
- financial incentives were produced for outpatient care providers, rounding up their salaries by an additional US$ 40–120 monthly;
- Mogilev local budget saved an amount equivalent to US$ 11 000 (1 April–1 December).

As well as the achievements listed above, the pilot project demonstrated that it is feasible to change the model of TB care and engage different levels of administrative authority and health care professional. The good results sustained the recommendation given to the Ministry of Health to expand such interventions. Eventually it was decided that the reduction of the hospital budget (equivalent to five beds) should be maintained in 2016 and incentives should be paid to the primary health care nurses through the Global Fund grant for 2016–2018.

Main recommendations

1. Outpatient TB care should be strengthened by: enabling TB doctors at district level to diagnose and treat drug-susceptible TB, ensuring the continuum of TB care for patients released from prison, ensuring the full package of joint services for vulnerable populations (for example, harm reduction, treatment of alcohol abuse disorders) and increasing TB service coverage through social contracting.
2. The number of TB hospital beds should be reduced and the cost savings used to strengthen ambulatory TB care through incentives to providers and support for patients. Various options for financing TB hospitals could be considered for a pilot project, such as introducing a global budget, or maintaining the current line-item budget with a lower budgetary ratio of doctors to hospital beds while preserving their actual monthly income and without affecting the quality of services in place.
3. Unnecessary hospitalization (for non-severe, non-infectious pulmonary and extrapulmonary TB cases) should be avoided and inpatient stays shortened by revising hospital admission and discharge criteria.

Other recommendation

4. A roadmap should be designed to guide the implementation of a new delivery model of TB care and its financing through a pilot project with the target of reducing the current number of TB beds by 50% by 2018.

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Annex 1

MEMBERS OF THE REVIEW TEAMS

International

Pierpaolo de Colombani	Medical Officer, Joint TB, HIV/AIDS and Hepatitis Programme, WHO Regional Office for Europe, Copenhagen, Denmark *(Leader)*
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Interpreters

Peter Dobrusau
Konstantin Korzh
Igor Gorlatov
Eugeny Tribulev

Annex 2

PROGRAMME

Overall programme

Monday 7 December

18.30 – 19.30 Meeting of the international reviewers

Tuesday 8 December

08.00 – 10.30 Briefing for all reviewers

11.00 – 12.00 Briefing by L. Zhilevich, Head, Primary Health Care Department

Tuesday-Saturday 8–12 December

Visits in Minsk, Mogilev and Gomel regions

Saturday 12 December

13.00 – 17.00 Plenary presentations of the field visits, discussion of the results

Monday 14 December

09.30 – 12.30 Briefing by G.L. Hurevich, Director of the Republican Scientific and Practical Centre for Pulmonology and TB

14.00 – 15.30 Round table on drug supply management with: L. Reutskaya, N. Malashko (Ministry of Health); A. Shiryakov (Republican Centre for Examinations and Tests in Health Care); S. Setkina (Belpharmacia Enterprise); V. Ovchinko (NTP); G. Dravniece, E. Vitek, V. Rusovich

Visits to various parts of the Republican Scientific and Practical Centre for Pulmonology and TB: A. Zalutskaya, E. Nikolenka, D. Klimuk, A. Astrauko (NTP); T. Chakhaia, S. Ehsani, D. Falzon, S. Hoffner, A. Lourenco, C. Popa

Work with translator on legislation: S. Dagron

18.00 – 18.30 Wrap up: day's progress, preliminary results

Tuesday 15 December

Meeting with the Office of Health Planning and Economy, Ministry of Health. Participants: E. Tkacheva (Ministry of Health); D. Falzon, A. Lourenco, V. Rusovich

09.00 – 10.30 Round table on TB in prison. Participants: A. Tryasucheva, A. Grinevich (Department for the Execution of Punishment, Ministry of the Interior); D. Vetushko (NTP); T. Chakhaia, S. Dagron, G. Dravniece, S. Ehsani, C. Popa, E. Vitek

10.00 – 11.30 Meeting with H. Rusanovich, Director of the Republican Centre for HIV/AIDS Prevention. Participants: P. de Colombani, S. Hoffner

11.00 – 13.00 Round table on ethics, human rights, social protection, ACSM, community involvement. Participants: a representative of the nongovernmental organization People Affected with TB and HIV; I. Konorazov, A. Karpov, D. Paduto (Ministry of Health); A. Skrahina, A. Astrovko (NTP); T. Chakhaia, S. Dagron, V. Rusovich

Round table on human resources and research. Participants: E. Bogdan, L. Zhylevich, O. Marshalko, E. Tkacheva (Ministry of Health); A. Lapteva (Belarusian Academy of Postgraduate Education); P. Krivonos (Belarusian State Medical University); O. Kalechits (NTP); P. de Colombani, D. Falzon, A. Lourenco, E. Vitek

	Visit to NRL. Participants: A. Zalutskaya (NTP); G. Dravniece, S. Ehsani, S. Hoffner, C. Popa
14.00 – 15.30	Demonstration of PAL and video- (virtually-) observed therapy for TB by the software developers. Participants: A. Astrauko, A. Skrahina, T. Chakhaia, P. de Colombani, S. Ehsani, D. Falzon, V. Rusovich
16.00 – 17.00	Work on the review report
17.00 – 17.30	Wrap up: day's progress, preliminary results

Wednesday 16 December

09.00 – 13.00	Work on the review report
	Meeting with local lawyer: S. Dagron
14.00 – 17.00	Work on the main findings and recommendations
17.00 – 17.30	Wrap up: day's progress, preliminary results

Thursday 17 December

09.00 – 13.00	Work on the main findings and recommendations
	Debriefing with D. Pinevich, First Deputy Minister of Health. Participants: E. Bogdan, L. Zhilevich (Ministry of Health); D.L. Hurevich (NTP); E. Zaitsev (WHO Country Office, Minsk); P. de Colombani, V. Rusovich
14.00 – 17.00	Work on the main findings and recommendations

Friday 18 December

10.00 – 12.00	Work on the main findings and recommendations

Field teams

Team 1. Minsk region and Minsk city
D. Falzon *(coordinator)*, S. Hoffner, S. Dagron, A. Astrauko, A. Zalutskaya, K. Korzh *(interpreter)*

Tuesday 8 December

13.30 – 17.00	Minsk City TB Dispensary No. 1 (treatment for extrapulmonary TB)

Wednesday 9 December

10.00 – 13.00	Minsk City TB Dispensary No. 2
14.00 – 17.00	Volkovichi Hospital (involuntary TB isolation hospital)

Thursday 10 December

11.30 – 13.00	Minsk Region TB Dispensary (day care unit, laboratory, outpatient treatment)
14.00 – 17.00	Molodechno Region MDR-TB Hospital

Friday 11 December

10.00 – 12.00	Soligorsk District TB Dispensary
14.00 – 16.00	*Feldsher* post in Soligorsk district (supervised TB treatment)

Team 2. Gomel region
P. de Colombani *(coordinator)*, T. Chakhaia, E. Vitek, I. Nekrasova, E. Nikolenka, D. Klimuk, I. Gorlatov *(interpreter)*

Tuesday 8 December

13.30 – 18.30	Travel to Gomel (302 km, 4 hours)

Wednesday 9 December

09.00 – 10.00	Meeting with the Gomel regional health care authorities
10.30 – 16.00	Gomel Region TB Hospital (laboratory, in/outpatient treatment, anti-TB drugs, involuntary isolation)
16.30 – 18.00	Gomel Region Infectious Disease Hospital (ART clinic, opioid substitution treatment)

Thursday 10 December

09.30 – 11.30	Svetlogorsk Central District Hospital (laboratory, DOT, HIV counselling)
12.00 – 13.00	Svetlogorsk *feldsher* post (outpatient treatment)
13.15 – 16.00	Svetlogorsk TB Dispensary
16.30 – 18.00	Meeting with Alternativa nongovernmental organization for people living with HIV

Friday 11 December

09.00 – 13.00	Gomel City TB Dispensary (laboratory, DOT)
15.00 – 17.00	Gomel Prison Hospital IK-4 (women's TB department)

Saturday 12 December

08.00 – 12.00	Return to Minsk

Team 3. Mogilev region
G. Dravniece *(coordinator)*, A. Lourenco, C. Popa, A. Skrahina, V. Rusovich, P. Dobrusau *(interpreter)*

8 December

13.30 – 17.30	Departure to Mogilev (269 km, 4 hours)
17.30 – 18.00	Meeting with the Mogilev regional health care authorities

9 December

09.00 – 16.00	Mogilev Regional TB Dispensary (laboratory, inpatient treatment, anti-TB drugs, involuntary isolation)
16.00 – 17.00	Mogilev Regional Infection Hospital (ART)

10 December

09.00 – 12.00	Mogilev District Outpatient Centre (rural outpatient)
14.00 – 15.00	Central District Hospital (TB treatment, laboratory, DOT)
15.00 – 16.00	TB facility

11 December

09.00 – 17.00	Orsha Prison TB Hospital IK-12, Correctional Institution 17
17.00	Return to Minsk

Annex 3

LIST OF TB-RELATED ORDERS OF THE MINISTRY OF HEALTH, 2012–OCTOBER 2015

1. On prevention of transmission of diseases threatening the health of the population, virus of human immune-deficit (Order No. 345-3 of 7 January 2012).
2. Clinical guide on organization and implementation of anti-tuberculosis interventions in outpatient and polyclinic institutions (Order No. 622 of 23 May 2012).
3. Instructions on flow of patients in tuberculosis facilities eligible for outpatient registration and dynamic follow-up (Order No. 621 of 23 May 2012).
4. Clinical guide on treatment of tuberculosis and its drug-resistant forms (Order No. 939 of 22 August 2012).
5. Guide on monitoring and evaluation (Order No. 1323 of 08 November 2012).
6. Guide on laboratory diagnostics of tuberculosis (Order No. 377 of 22 March 2013).
7. Sanitary norms and rules for tuberculosis facilities (Order No. 58 of 28 June 2013).
8. The organization of interaction of the correctional system of Ministry of Internal Affairs of Belarus and health care organizations providing medical services for diagnosis, treatment and prophylaxis of TB (Order No. 174/558 of 30 April 2013 jointly issued with the Ministry of Interior).
9. Organization of interaction of medical-labour dispensaries and state health care organizations providing medical services for diagnosis, treatment and prophylaxis of TB (Order No. 440/101 of 26 September 2013, jointly issued with the Ministry of Interior).
10. On approval of instructions on provision of tuberculosis services to patients with HIV (Order No. 1034 of 8 October 2013).
11. Instructions on organization of work in tuberculosis infectious cases and detection of contacts (Order No. 15 of 13 January 2014).
12. Instructions on BCG (Order No. 27 of 20 January 2014).
13. On the project for piloting directly-observed treatment mechanisms during outpatient stage (Mogilev pilot project) (Order No. 236 of 12 March 2014).
14. Guide on management of common respiratory diseases among adults for primary care medical staff (Order No. 497 of 7 May 2014).
15. On cohort pharmacovigilance monitoring of XDR-TB patients (Order No. 690 of 23 June 2014).
16. On additional high-calorie food packages per respiratory tuberculosis patient receiving observed treatment in governmental outpatient institutions (Order No. 21 of 18 February 2015).
17. On the pilot project on the organization of video-observed treatment of tuberculosis at the outpatient stage (Order No. 943 of 23 September 2015).
18. On instructions on immunodiagnostics and chemoprophylaxis of tuberculosis among children (Order No. 977 of 2 October 2015).
19. Observed treatment of patients with pulmonary tuberculosis in outpatient conditions in government health institutions (Order No. 995 of 7 October 2015).

Annex 4

OBSERVATIONS AND RECOMMENDATIONS REGARDING THE NTL REGISTER

Observation	Recommendation
All laboratory staff can enter data through an individual login. Errors in data entry are common.	Only one or two well-trained persons should be assigned to data entry in each laboratory.
First name, family name and birthday of the patient are entered in three entry fields on one line, making it difficult to cross-check typing mistakes that cause one patient to be registered several times.	The entry field for birthday should be moved to a separate line, so that patients with the same birthday can be sorted and compared for slight differences in name probably produced by wrong entries.
It was not possible to see why an investigation was requested for TB diagnosis (from which to calculate a positivity rate) or for treatment follow up.	All software should be carefully reviewed for its capacity to calculate the most important laboratory performance indicators.
There is no date for when samples are collected, which prevents the study of the time lost between the collection and analysis of the sample and thus the risk of bacteriological contamination, which would require the sample to be rejected.	A new entry field should be added in the software for “Date of sample collection”.
There is no indication of the reason why a laboratory result is missing.	A new entry field should be added in the software for “Reasons for missing results”.
No distinction can be made between negative and not-obtained Xpert MTB/RIF assay results. It is not possible to know the reason for not obtaining the results.	New entry fields for Xpert MTB/RIF should be added to include “Negative result” and to replace “Result not obtained” with more information on the causes, such as “Error code 123”, “Missing cartridges” or “Power cut”.
It is not possible to understand the reason why Löwenstein-Jensen results and MGIT results were not obtained.	The entry field “Result not obtained” should be replaced with more information on the causes, such as “Error code 123”, “Absence of reagent” or “Contamination”.

Annex 5

MINIMUM HEALTH STANDARDS IN BELARUS

	Norm	Health standard	Note
36	*Ordinance of Council of Ministers No. 227 dated 23.02.2011*		
	Norm of budgetary expenditure per capita in the health sector: average national/regional/city of Minsk	Established by the Law on the Budget of the Republic of Belarus for the next fiscal year	The norm for budgetary expenditure per capita in the health sector (excluding capital construction) is the minimum and reflects the per capita budgetary expenditure used to compensate the cost of health institutions related to free medical services, as established by the Law on the Budget of the Republic of Belarus for the next fiscal year.
37	*Ordinance of Council of Ministers No. 811 dated 20.06.2007, No. 227 dated 23.02.2011*		
	Norm on the number of general practitioners/local therapists + paediatricians, including:	1 doctor per 1300 residents	The norm on the number of local therapists + paediatricians and general practitioners is defined by the number of people using the services per local therapist, paediatrician and general practitioner rated by the number of positions they fill.
	local therapists for adults	1 doctor per 1700 adults	
	local therapists for children	1 doctor per 800 children	
	general practitioners	1 doctor per 1300 residents	
38	*Ordinance of Council of Ministers No. 811 dated 20.06.2007*		
38.1	on beds nationally	9 beds per 1000 residents	The norm on the number of beds is defined by the minimum number of beds in hospitals with 24-hour stay of patients, taking into account the provision of inpatient care at the national level, excluding nursing homes.
	on beds in the city of Minsk	8 beds per 1000 residents	
38.2	*Ordinance of Council of Ministers No. 227 dated 23.02.2011*		
38.2	on pharmacies nationally	1 pharmacy per 8000 residents	The norm on the number of pharmacies of any form of ownership is defined by the minimum number of pharmacies making retail sales of medicines and medical products per number of residents who receive these services.
	on pharmacies in the city of Minsk	1 pharmacy per 11 500 residents	
38.3	on ambulances in the regions	1 ambulance team per 12 000 residents	The norm on the number of ambulance teams is defined by the number of doctors, doctors' assistants and special ambulance teams (total number) per number of residents who receive these services.
	on ambulances in the city of Minsk	1 ambulance team per 12 500 residents	
38.4	*Ordinance of Council of Ministers No. 575 dated 04.05.2009*		
38.4	on special vehicles from:		The norm on the number of special ambulances for outpatient centres, nursing homes and local hospitals is defined by the availability in each outpatient centre and nursing home of a special ambulance and, in local hospitals with 20 beds or less, one special ambulance, >20 beds, two special ambulances.
	outpatient centres, nursing homes	1 special ambulance	
	local hospitals with beds:		
	20 beds or less	1 special ambulance	
	> 20 beds	2 special ambulances	