World Health Organization

REGIONAL OFFICE FOR Europe

Prevention, control and care of tuberculosis in Ukraine

14–22 April 2015

Abstract

The prevention, control and care of prevention of tuberculosis (TB) as determined by the performance and strategies of the Ukrainian national TB control programme was reviewed comprehensively between 14 and 22 April 2015. The objectives were to: assess the progress of the programme between 2012 and 2016, especially in implementing the Stop TB Strategy; summarize experience, lessons learnt and methods used for successful TB prevention, control and care; and prepare recommendations for the Ministry of Health and international technical and financial partners as well as proposals for technical agencies and donors. The team consisted of 20 people from international organizations—the WHO Regional Office for Europe, the WHO Country Office and the Green Light Committee Europe—and also the United States Agency for International Development, PATH, WHO temporary advisers and national experts.

Keywords

NATIONAL HEALTH PROGRAMMES
PUBLIC HEALTH
TUBERCULOSIS
MULTI-DRUG-RESISTANT TUBERCULOSIS
UKRAINE

The mission and publication of the report were made possible by the support of the American people through the United States Agency for International Development in the framework of the Partnership Project for TB Control implemented by WHO. The contents do not necessarily reflect the view of the United States Agency for International Development or the United States Government.

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Acknowledgements

The authors of the report acknowledge the management and staff of the National Centre for Socially Dangerous Disease Control of the Ministry of Health of Ukraine, the chief doctors and nurses and the chief TB doctors, nurses and health care staff in the *oblasts*, *raions* and facilities visited. This extensive review of TB prevention, control and care in Ukraine could not have been conducted without their full collaboration.

The WHO Regional Office for Europe would like to thank national and international partners, particularly the United States Agency for International Development.

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Executive summary

Preamble

In 2014, Ukraine was cited for the first time as one of the five countries with the highest burden of multi-drug-resistant-TB in the world.[1] At the request of the Ministry of Health, the WHO Regional Office for Europe and the WHO Country Office, in coordination with the Ukrainian Centre for Disease Control (UCDC) and the National Tuberculosis Programme (NTP), conducted a review of TB prevention, control and care activities, in two steps: an epidemiological review in January 2014 and a core review between 13 and 22 April 2015. A previous review of the NTP was conducted in 2010.

Process

The WHO Country Office in Ukraine, with support from the WHO Regional Office for Europe, led preparation and coordination of the review. It was made possible by support from the United States Agency for International Development.

The review was conducted in two stages. The first stage, in January 2015, comprised an epidemiological review by two international experts. The second stage, the core review, was performed in April 2015 by a team of five international experts, including one from the regional Green Light Committee for Europe, and a national team of experts. The reports and the epidemiological and surveillance data were reviewed by two teams, each visiting two *oblasts*: one team visited Poltava and Mykolaiv, and another visited Vinnytsya and Chernivtsi. The *oblasts* were chosen by the UCDC and the NTP as being the most representative with regard to regional epidemiology; for security reasons, the regions most affected by the on-going military conflict or flooded by internally displaced people were not considered, and these regions (mainly Donetsk and Lugansk, Government-controlled and uncontrolled areas) will be evaluated separately at a later date.

Before visiting the *oblasts*, the members of the mission agreed on the method for the review. Then, both teams met with regional health authorities, interviewed chief doctors and other health staff in TB and primary health care facilities, AIDS centres, TB laboratories, prison facilities and medical units, nongovernmental organizations and also TB and TB/HIV co-infected patients. Back in Kyiv, the team interviewed authorities at the Academy of Medical Science and visited wards, the National Reference Laboratory, the National Penitentiary Service and the UCDC. Preliminary recommendations were compiled and presented to the Ministry of Health on 21 April 2015 by the team led by Dr Viorel Soltan, representing the Division of Communicable Diseases at the WHO Regional Office for Europe.

Main observations and findings

Since the last NTP review in December 2010, Ukraine has made considerable progress, having increased universal access to the diagnosis and treatment of TB and drug-resistant TB (DR-TB) patients.

In 2013, Ukraine had a total estimated population of 45.49 million and a gross national income of US$ 3960 per capita.[2] From 2012, Ukraine experienced a period of stagnation, with 0 registered economic growth rate in 2013, followed by a sharp decrease of about 8% in 2014. According to official statistics, income inequality remained moderate, with a Gini coefficient of about 0.25 registered in 2012.[3]

[1] "China, India, Pakistan, the Russian Federation and Ukraine have 60% of all MDR-TB cases." From a presentation by Dr Mario Raviglione, Director of the Global TB Programme, The end TB strategy, role of WHO in supporting implementation of the new global strategy.

[2] World Bank. Development indicators. Washington DC (http://data.worldbank.org/country/ukraine, accessed 9 May 2015).

[3] World Bank. Report No. PAD939. Washington DC; 2015.

About 11.2% of the population lives in extreme poverty, with expenditure of < 900 UAH per month in 2012.[4]

In 2013, there were an estimated 44 000 incident cases of TB in Ukraine (uncertainty range, 39 000–50 000), equivalent to a rate of 96 (87–110) per 100 000 population. The estimated prevalence and incidence of TB in Ukraine have been decreasing since 2008 at an annual average rate of 4.4% and 3.3%, respectively. Nevertheless, the current TB prevalence in Ukraine is over three times higher than the Stop TB Partnership target of 36 cases per 100 000 population. The absolute number of new cases notified has remained stable over the past 5 years, but the number of previously treated cases has increased markedly in the past 4 years. The proportion of bacteriologically confirmed new pulmonary TB cases increased, due to an increase in PHC and in the performance of the laboratory network, including use of X-pert MTB-RIF.The prevalence of MDR-TB estimated from routine surveillanceis much lower than that found in a survey of drug resistance, indicating a very large gap in routine surveillance. According to routine surveillance of drug resistance in 2013, the proportion of MDR-TB among newly detected TB cases was 19% and that among previously treated cases was 41%. These estimated prevalence rates of MDR-TB are much lower than those found in a survey of drug resistance (DRS), which were 23.4% and 58.6%, respectively (DRS preliminary data). An impressive increase in the number of patients with MDR-TB who have access to second-line treatment, from about 3200 to 8400, could contribute to better control TB epidemic.

A notable increase of up to 19.6% in HIV/TB co-infections reflects the growing HIV epidemic in the country. ART coverage is 48%, which is far from universal coverage. The rate of successful treatment outcome among new and relapsed TB cases is the second lowest in the Region (70.9%), and the success rate of MDR treatment is also low (34%).

The health system is characterized by inefficient use of resources, overcapacity in some areas and underinvestment in others. During the past 5 years, the number of TB beds has been reduced by 17%, from 25 329 to 21 701. In total, there were 80 TB dispensaries with 15 174 beds, 36 TB hospitals for adults with 5255 beds, 3 children's TB hospitals with 250 beds and 89 sanatoria with 12 128 TB beds.

The average length of hospital stay was 91 days for adult patients and 81 days for children; the average length of stay varied significantly among regions, from 117 days in Zaporizhzhya to 67 in Zhitomir for adults and from 164 days in Zaporizhzhya to 38 days in Ternopol for children.

Inpatient TB facilities have no incentive to de-institutionalize service delivery, because their funding is indirectly linked to the number of patient bed–days. Thus, the health resource roster is calculated on the basis of population size, and the number of beds is calculated subsequently. There is no incentive to reduce excessive hospitalization or to orient resources to the priorities of modern TB control, including patient-centred ambulatory care. Reducing hospitalization time by 1 day could save US$ 2.3 million. There is, however, no viable mechanism to use the potential savings for PHC or TB ambulatory services or to provide incentives and enablers to TB patients.

The main challenge for the Ukrainian health system is to adjust and improve the TB care delivery model by strengthening links at all levels of care and provider, first and foremost by further strengthening the role of PHC in TB case finding and case management in the current situation of a high burden of drug resistance. One of the main lessons learnt during implementation of the NTP is the importance of outpatient treatment, which requires multidisciplinary patient-centred approaches that often extend beyond the traditional boundaries of the health system and require rigorous action by other public services (such as social services) and non-State and community actors.

The current capacity of TB Hospitals is excessive and requires substantial optimization and downsizing.

[4] Extreme relative poverty is the percentage of individuals with a total expenditure per adult < 60% of the median; US$ 5 per day is the comparison used.

Human resources

Existing human resources are aligned with the hospital model of treatment and are not used optimally. Although staff salaries account for 57% of all costs of TB hospital treatment, individual salaries for TB physicians and nurses are insufficient and not competitive enough to attract young doctors and nurses.

Human resources are regulated by laws that do not take into account changing epidemiology, including drug-resistant TB and TB/HIV co-infection. There are no social workers, psychologists or visiting nurses at TB hospitals or outpatient TB dispensaries, although these cadres are necessary to deal professionally with the social issues of TB patients, including psychological, social and legal support to improve their adherence to treatment. The low status of medical staff working with TB patients in Ukraine is well recognized. An important recent achievement is integration of PHC services into TB control, with decentralization of DOT to family medicine centres (polyclinics) close to patients' residences and at PHC settings in rural areas.

Health system

Ukraine's health care system is based on the former Soviet Union Semashko model. It is organized hierarchically through the Ministry of Health, which sets health sector policies, approves health norms and legal acts, plans national budget expenditure and is responsible for health information, recording and reporting. The health system is characterized by inefficient use of resources, overcapacity in some areas and underinvestment in others. Ukraine has an oversized, inefficient hospital sector, both in terms of beds and the number of hospitals: there are 2200 hospitals, 8300 polyclinics and over 400 000 hospital beds in the public sector, about 40% more beds per capita than the average in the WHO European Region. There is a high degree of verticalization, in which different parallel structures provide specialized care, for example through AIDS centres, TB dispensaries, clinics for sexually transmitted infections and drug abuse centres. Collaboration between such structures is generally suboptimal.

The national TB response depends strongly on external funding: Global Fund resources cover about 40% of the national programme. The Global Fund has approved new funds for TB/HIV in Ukraine up to 2018 as part of its new funding model; thereafter, the Ukrainian Government is expected to finance its own TB and HIV response fully from domestic sources. Integration of TB control into PHC is part of the reform, in guidelines updated by Ministry of Health order No. 620 of 4 September 2014 on "Comprehensive clinical protocol for primary, secondary and tertiary level health care providers to adults on tuberculosis".

Vulnerable populations

Ukraine has a high burden of HIV infection, with an estimated 210 000 (180 000–250 000) people living with HIV and a prevalence rate of 0.8% (0.7–1.0%) among adults aged 15–49 years in 2013.[5] The prevalence of HIV infection increased steadily over the past 5 years, and the number of cases of TB/HIV co-infection has increased even more rapidly since 2012. WHO estimated that there were 7100–7200 cases in 2013, corresponding to an incidence rate of 16 per 100 000. TB remains the leading cause of death among people living with HIV, with an estimated 1300 (960–1700) deaths in 2013.

Significant progress has been made in collaboration on TB and HIV since the previous review, as the UCDC is coordinating programmes on both, including monitoring and evaluating performance and keeping a register of both TB and HIV cases. Since 2013, a national e-TB register has been operational, which is the main indicator of collaboration on TB and HIV.

[5] http://www.unaids.org/en/regionscountries/countries/ukraine

Another large group of TB patients consists of prisoners, who represented 6% of the TB burden in Ukraine in 2013. Integrated services for the diagnosis and treatment of TB and HIV exist, but there is no opioid substitution treatment. Funding is lacking for TB prevention and treatment programmes in prisons, and there is little cooperation with the civilian medical system, especially for external quality control of diagnosis and treatment. Investigations on drug resistance should be coordinated with the civil sector to ensure their quality.

Main recommendations

Health system

1. Develop a patient-centred care model oriented to ambulatory care. Include TB hospitals in general health care reform, with new performance-based funding mechanisms. Reinvest the resources saved by cost–efficiency measures in TB control to cover urgent needs for ambulatory care, including prevention, diagnosis, patient support, treatment follow-up and adherence, social contracting and incentives for TB, PHC and other staff.

Case finding

2. Revise Ministry of Health order No. 327 of 15 May 2014 mandating extensive, obligatory fluorography screening for people in professions with little risk for spread of airborne infection, to focus on well-defined risk groups, in line with WHO recommendations. Costs could be reduced as a result of the workload reduction and unified diagnostic procedures; the estimated cost of annual mass screening with more than 19 million fluorography examinations per year at a cost of US$ 2 per test is about US$ 38 million. As recommended above, the saved funds should be reinvested in TB control measures based on patient-centred care.

Laboratory network

3. Rationalize the laboratory network and particularly the number and effectiveness of level-1 and level-2 laboratories, some of which could be merged. Level-2 and level-3 laboratories should be distributed geographically on the basis of population density and numbers of suspected cases of TB and MDR-TB.
4. Strengthen level-3 laboratories to perform all microbiological examinations in the country (sputum smear microscopy, culture of liquid and solid media, first- and second-line drug susceptibility testing, GeneXpert), including quality control for peripheral laboratories. Early diagnosis of TB, particularly MDR-TB, should be the main strategy for halting the spread of MDR-TB in the country.
5. Ensure access to TB diagnosis in remote territories by improving the logistics of sputum transport and access to rapid molecular tests.
6. Revise or define norms for roles, tasks and responsibilities at all laboratory levels, including workload, types of investigation, equipment, qualification and number of staff required and molecular examinations.
7. Institute a training plan for all laboratories in the network, including for new methods and external quality assessment of level-1 laboratories by level-2 laboratories, with continuous capacity-building of laboratory personnel.
8. Further strengthen the national quality assurance programme, and support it financially. Currently, there is no quality control of smear microscopy or line probe assays (LPA) in level-3 laboratories,

including in the penal system. Give the NRL adequate staff and budget to plan regular monitoring and training for level-3 laboratory workers in the penal system.

9. Ensure that laboratory data are entered into a data management system. A laboratory module of "eTB manager" should be available, and data should be entered into the current data management system by laboratory staff. This will lead to more accurate, rapid data communication within and between laboratories and clinicians.

Drug supply and management

10. Adopt the Global Drug Facility method for drug quantification to ensure procurement from the State budget and supply at all levels.
11. Ensure the availability and distribution of drugs for complete treatment regimens for all patients, particularly those with pre- and extremely drug-resistant (XDR)-TB.
12. Strengthen pharmaceutical management at all levels to ensure consistent access to first- and second-line TB drugs of assured quality.
13. Integrate drug management in the civil and prison sectors.
14. Ensure adequate management of side-effects at all levels and reporting of serious adverse reactions. Record side-effects on treatment cards, and send completed pharmacological vigilance forms to the Ministry of Health expert centre.

Infection control

15. Use rapid TB laboratory diagnostics and early isolation of infectious TB patients, and apply administrative control measures.
16. Extend ambulatory treatment for patients with TB and drug-resistant (DR)-TB, particularly when they are not infectious.
17. Strengthen the role of the NTP in monitoring infection control measures in TB facilities, and assess the risk regularly.

Treatment and case management

18. Gradually replace hospital-based models of care by specific ambulatory care for all TB and DR-TB cases, including in children. Reinvest savings made by this reform accordingly. Support all patients in ambulatory care effectively to ensure treatment adherence, thus minimizing the risk for treatment interruption, failure and on-going TB and DR-TB transmission. Ensure sustainable incentives and enablers for all patients.

Childhood tuberculosis

19. Update childhood TB control measures, including increasing coverage with BCG vaccination at birth from 65% to 95%, abolishing BCG revaccination at the age of 7 years, transforming annual mass screening with tuberculin skin testing in every child to focused, active case finding in risk groups, and applying the WHO recommended scheme of preventive treatment in children with latent TB infection.

20. Abandon the outdated strategy of hospitalizing children who are not ill (e.g. contacts of TB cases) and children with non-severe forms of TB, as this is a huge financial burden for the country, increases the risk for nosocomial TB transmission (especially of children without TB), is unethical and increases stigma and psycho-emotional trauma for children and their families.
21. Urgently update TB diagnosis, treatment and prevention protocols, and introduce the latest international standards to ensure access to relevant diagnostic tools, adequate treatment regimens (including dosages) and isoniazid preventive treatment at an evidence-based dose and duration.

Tuberculosis and HIV co-infection

22. Implement the WHO recommendations to start antiretroviral treatment (ART) for patients with HIV infection (without TB) if their CD4 count is < 500.
23. Ensure an uninterrupted supply of anti-TB drugs to all patients with TB/HIV co-infection (including isoniazid preventive treatment), irrespective of whether the drugs are registered in Ukraine.
24. Allocate earmarked resources from local and/or national budgets to support TB detection, contact tracing and treatment adherence in affected populations by social contracting mechanisms.

DR-TB and MDR-TB

25. Ensure access to adequate treatment (including the fifth group of anti-TB drugs and compassionate use of new anti-TB drugs) for all XDR-TB patients to halt further development of resistance and to limit transmission of XDR-TB.
26. Introduce new, shorter treatment regimens and new anti-TB drugs under operational research conditions in line with WHO recommendations (including pharmacovigilance), thus improving treatment outcomes, ensuring patient-oriented care and decreasing treatment costs.
27. Ensure palliative care for patients in whom treatment of DR-TB has failed by preparing and introducing national guidelines for palliative care and establishing treatment facilities with adequate case management and proper infection control.

Human resources

28. Merge the two specialties of pulmonology and TB into one respiratory disease speciality, including in pre- and post-graduate education and specialization. Harmonize the pre- and postgraduate curricula, and revise them in accordance with new approaches to TB care.
29. Review the human resources plan and job profiles of staff in line with the projected changes in childhood TB care, strengthening the ambulatory model of care and introducing new staff to ensure patient adherence to treatment, such as social workers, psychologists and visiting nurses.
30. Increase the salaries (incentive) for TB physicians and nurses and PHC staff involved in TB care by using the savings made by reducing the number of beds for TB patients and cost–efficiency measures.

TB control in prisons

31. Improve coordination of TB control activities between penitentiary and civil health care systems at all levels to ensure equitable health care provision.

32. Define collaboration mechanisms between prison medical and non-medical services (e.g. security staff) to ensure optimal implementation of TB control in the penitentiary sector.
33. Facilitate the provision of standardized TB control measures in all prison facilities, and ensure full integration into the NTP in 2017–2021. Develop a cross-sectoral framework with the Ministry of Justice within the NTP.

Advocacy, communication and social mobilization

34. Prepare a strategy for advocacy, communication and social mobilization in line with the changing approaches of the NTP that will include community participation and social mobilization.

Vulnerable populations and social determinants of tuberculosis

35. Extend access to rapid TB laboratory diagnosis and patient-oriented care in vulnerable groups. Ensure the sustainability of activities in such population groups that are currently implemented by nongovernmental organizations (NGOs) through social contracting with funding from local (regional or district) budgets. Support service provision to vulnerable groups close to their area of residence, extend harm-reduction programmes, and deploy mobile multidisciplinary teams with the required equipment and consumables.

Ethics and human rights

36. Ensure universal access to TB diagnosis and good-quality TB and DR-TB treatment for all patients with TB, irrespective of their social status, comorbid conditions or poor treatment adherence in the past.
37. Provide social support (living place, incentives and enablers) to all TB and DR-TB patients who require it during ambulatory treatment, irrespective of the form of TB or funding source, by using funding from local budgets.
38. Revise existing legislation on coercive treatment (isolation). Find the necessary legal support to use other means, such as social support, incentives and enablers, before considering coercive measures.
39. Revise the definition of "palliative care", align it to international standards, and add it as an amendment to the national TB protocol for immediate implementation.
40. Systematically include socially disadvantaged patients, especially homeless people, in TB registers, even if they have no residential registration (*propiska*).

Operational research

41. Set up a platform for national and regional operational research on the care of TB, DR-TB and DR-TB/HIV co-infection with public health agencies to obtain documented evidence of cost–effectiveness for policy decision-making on further improvement of financing mechanisms and budgetary allocations at national and regional (*oblast*) levels.

1. Introduction

The objective of the review was to determine the baseline situation of TB and TB control activities to be used in drawing up the NTP plan for 2017–2021. The WHO Country Office in Ukraine led preparation and coordination of the review, with support from the United States Agency for International Development.

The terms of reference of the review were as follows:

Main objective: To provide the Ministry of Health with an overview of key challenges in the prevention, control and care of patients with TB, DR-TB or TB/HIV co-infection and recommendations for addressing them

Specific objectives

- to document the status of implementation of the recommendations of the previous programme review (October 2010);
- to assess the epidemiological situation of TB in Ukraine and the links between the NTP and the health system;
- to assess prevention, treatment and follow-up activities for drug-susceptible (DS)- and DR-TB in selected areas of the country; and
- to recommend interventions to be included in the NTP plan 2017–2021 in line with the global post-2015 TB strategy and suggest areas for support by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and other partners.

Expected outputs

- summary findings and recommendations within 2 weeks of completing the review and
- a comprehensive report within 3 months.

2. Epidemiology

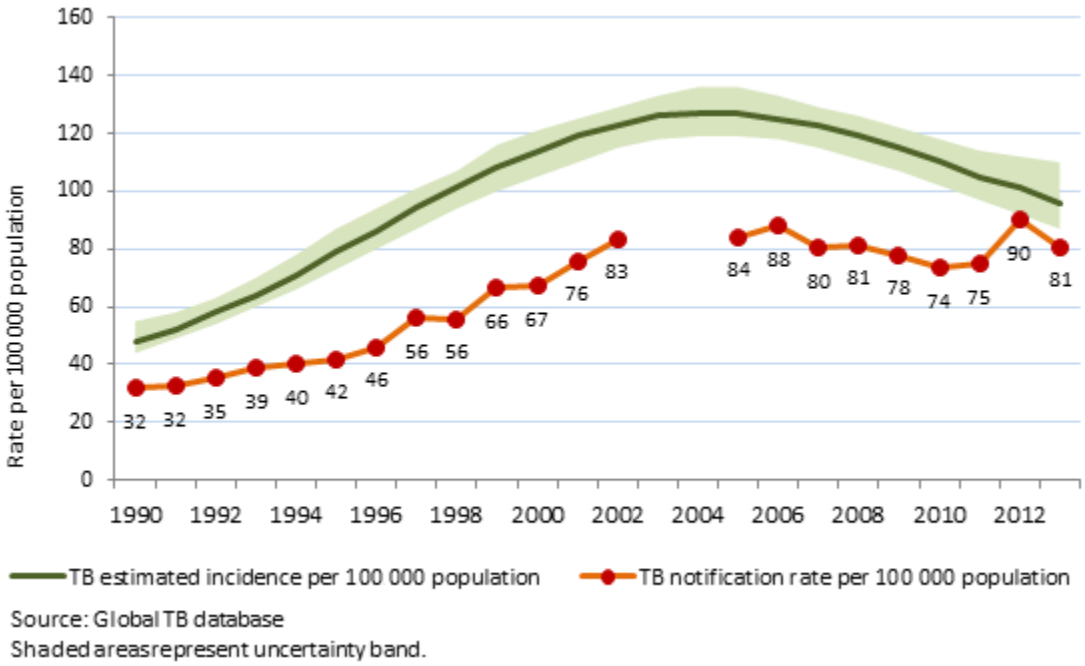
2.1 Main findings

- According to the vital registration system, which has adequate coverage and completeness to be used for TB surveillance, TB mortality in Ukraine has been decreasing since 2006 by an average of 7.6% annually; however, it is far from achieving the Stop TB Partnership targeted reduction to 4.8 per 100 000 population.
- The estimated prevalence and incidence of TB in Ukraine have been decreasing since 2008 at an annual average rate of 4.4% and 3.3%, respectively. Nevertheless, the current TB prevalence in Ukraine is over three times higher than the Stop TB Partnership target of 36 cases per 100 000 population.
- The increasing trend in TB incidence was stopped in 2004 and reversed from 2007. The mean annual rate of decrease between 2007 and 2013 was 3.3%. Currently, the estimated incidence is 96 per 100 000 population.
- The absolute number of new TB cases notified has remained stable over the past 5 years, but the number of previously treated cases has increased notably in the past 4 years.
- The proportion of bacteriologically confirmed new pulmonary TB cases increased, due to an increase in PHC and in the performance of the laboratory network, including use of X-pert MTB-RIF.

- The age-specific notification rates of new TB cases decreased in the past 5 years, especially among people aged 14–24 and 25–34 years, suggesting a decrease in the TB burden in the country.
- The proportion of previously treated cases varies widely by region; however, the variation cannot be explained by known risk factors such as the prevalence of HIV infection or of MDR-TB.
  - The prevalence of MDR-TB estimated from routine surveillanceis much lower than that found in a survey of drug resistance, indicating a very large gap in routine surveillance. According to routine surveillance of drug resistance in 2013, the proportion of MDR-TB among newly detected TB cases was 19% and that among previously treated cases was 41%. These estimated prevalence rates of MDR-TB are much lower than those found in a survey of drug resistance (DRS), which were 23.4% and 58.6%, respectively (DRS preliminary data).
- An impressive increase in the number of patients with MDR-TB who have access to second-line treatment, from about 3200 to 8400, could drive the TB epidemic downwards.
- A notable increase of up to 19.6% in HIV/TB co-infections reflects the growing HIV epidemic in the country. ART coverage is 48%, which is far from universal coverage.
- The rate of successful treatment outcome among new and relapsed TB cases is the second lowest in the Region [to put % here], and the success rate of MDR treatment is one of lowest in the Region (34%).

In 2013, there were an estimated 44 000 incident cases of TB (uncertainty range, 39 000–50 000), equivalent to a rate of 96 (87–110) per 100 000 population. The incidence increased sharply from 48 in 1990 to 127 per 100 000 population in 2004 (Fig. 1).

Fig. 1. Estimated TB incidence rates and notifications of incident TB cases (new and relapsed) in Ukraine per 100 000 population (1990–2013)

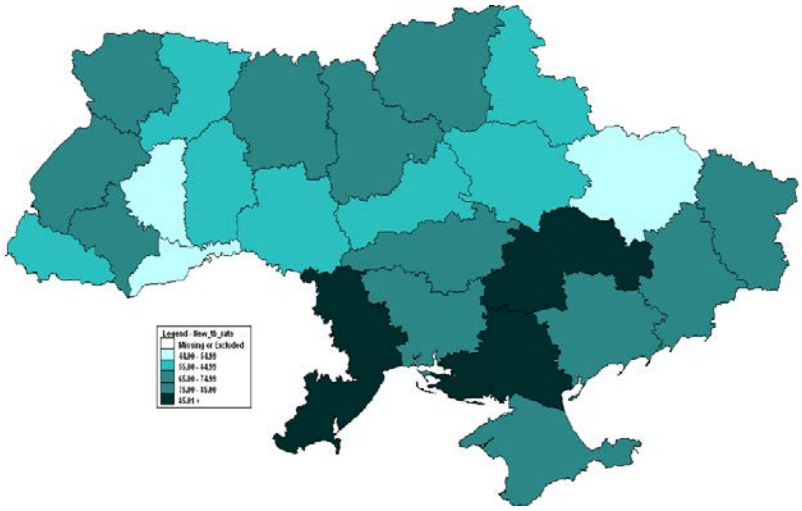


Source: Global TB database
Shaded areas represent uncertainty band.

The TB notification rate varies widely by geographical region and setting. The variation could reflect a true difference in the TB burden or differential access to good-quality health care and the detection of TB.

In 2013, the lowest rate of notification of new TB cases was in Kharkiv *oblast* (44.7/100 000), while the rates in Kherson, Odessa and Dnipropetrovsk *oblasts* were > 90/100 000, more than twice as high as in Kharkiv (Fig. 2).

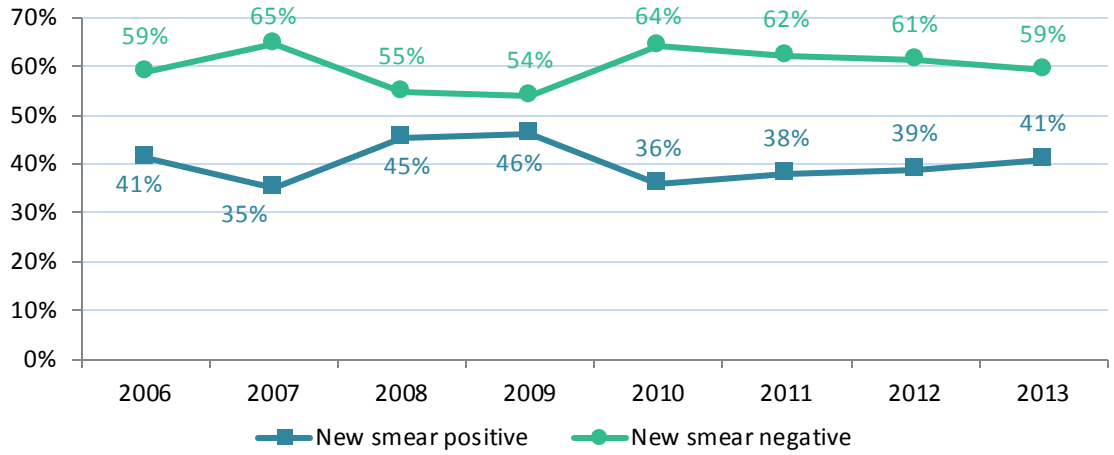
Fig. 2. Rates of notification of new TB cases per 100 000 population by region, Ukraine, 2013



Data source: Ministry of Health official website

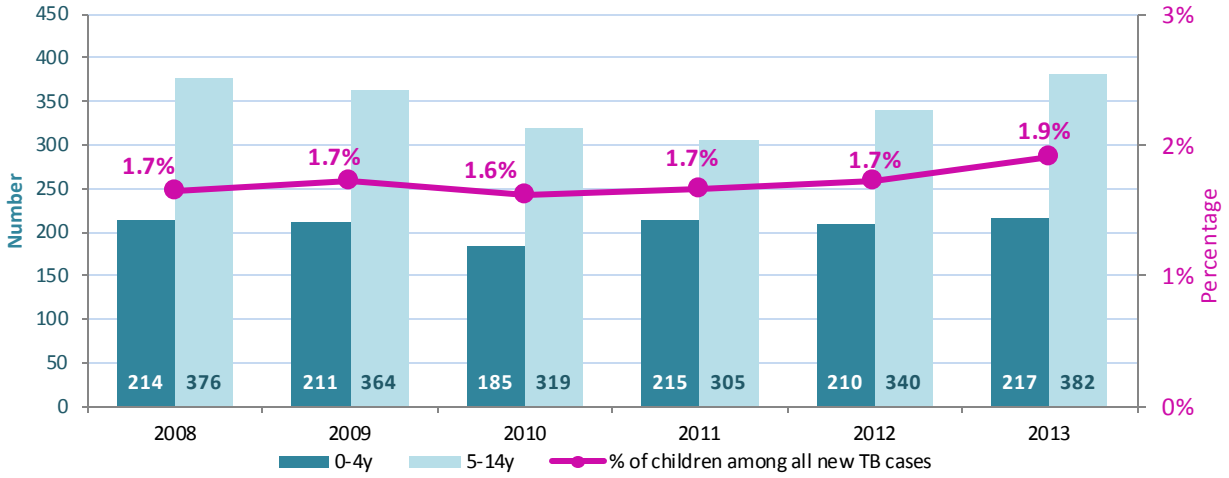
The proportion of smear-positive cases among new pulmonary TB cases between 2006 and 2012 ranged from 36% to 46%, with notable year-to-year fluctuations, indicating inconsistency in recording and reporting (Fig. 3). In 2013, Ukraine reported to a sharp increase in the proportion of TB smear- and culture-confirmed cases, from 39% to 57%, with a corresponding increase in the absolute number of smear-positive cases, from 11 139 to 16 125, and a decrease in smear-negative cases, from 17 398 to 12 218. The large increase in smear-positive cases might be due to the introduction of X-pert MTB-RIF in Ukraine in 2013.

Fig. 3. Trends in the proportion of new smear-positive and smear-negative pulmonary TB cases among new cases, Ukraine, 2006–2013



According to routine notification data in 2013, 217 of 599 children with TB were under 5 years of age (36%), suggesting that TB in this age group is probably undetected or under-reported. The TB notification rate in children decreased from 9.1 in 2008 to 7.8 per 100 000 in 2010 and then gradually increased to 9.0 per 100 000 in 2013 (Fig. 4).

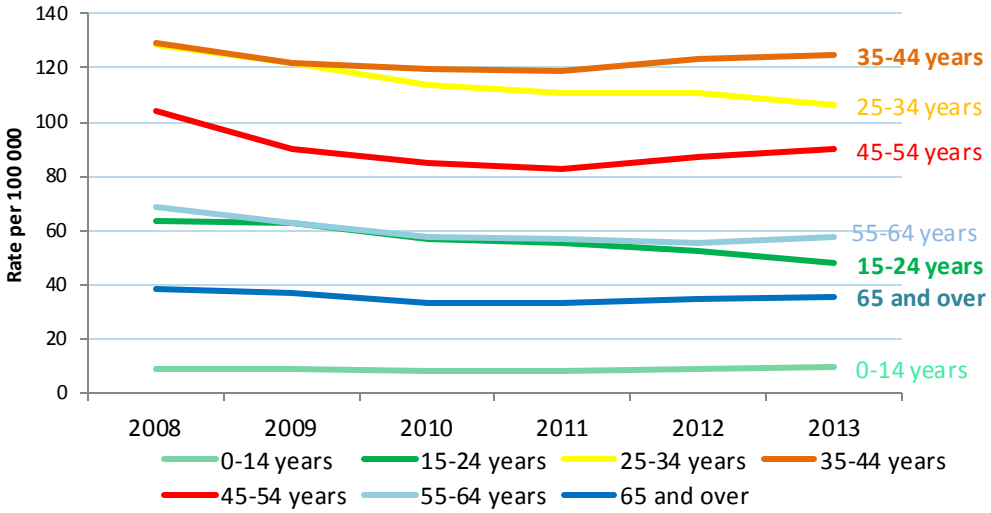
Fig. 4. Trends in numbers of notified TB cases in children disaggregated by age group, and proportion of childhood TB among all new TB case in Ukraine, 2008–2013



Data source: Global TB database

Fig. 5 shows the trends in age-specific rates of notification of new TB cases between 2008 and 2013. The rates decreased mainly in two young age groups (14–24 and 25–34 years); although there was some decrease in the age groups 45–54 and 55–64 years, the trends fluctuated widely over time. The rate remained unchanged for the 35–44 and ≥ 65-year groups. The decrease in the age-specific notification rate among younger people might indicate a decrease in the number of recently infected cases.

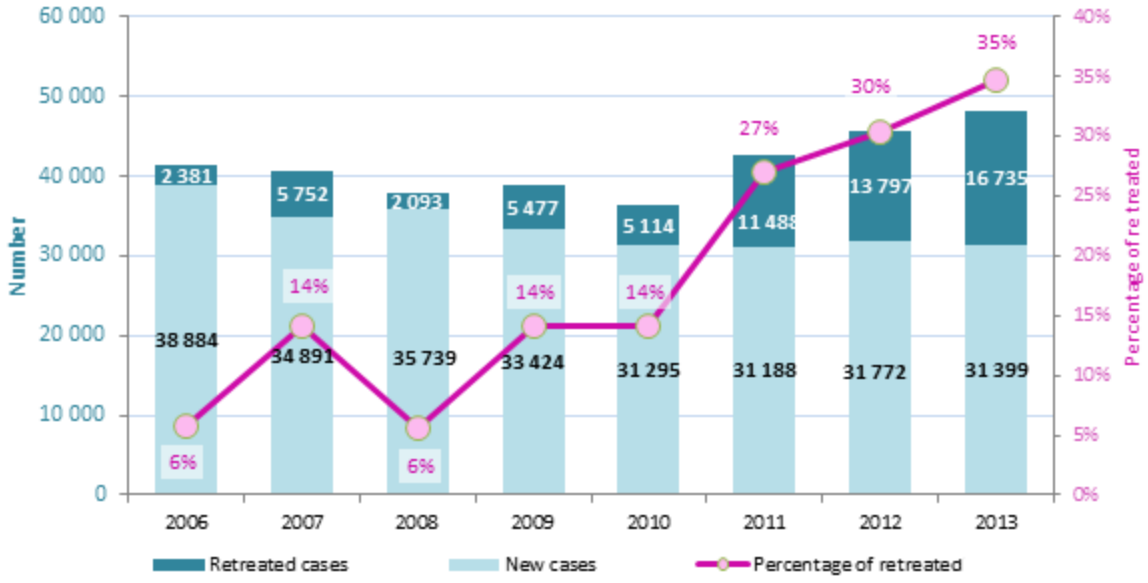
Fig. 5. Age-specific rates of notification of new TB cases, Ukraine, 2008–2013



Source: Global TB database

The proportion of retreated TB cases among all notified cases increased notably in the past 8 years (Fig. 6), varying from 6% to 35% at national level but with sharp year-to-year fluctuations between 2006–2007, 2007–2008 and 2008–2009, indicating gaps in surveillance. From 2010, the notification of retreated cases increased steadily, from 14% in 2010 to 35% in 2013, corresponding to an increase in the absolute number of retreated cases from 5114 to 16 735. It is noteworthy that, with the increase in number of previously treated cases, the absolute number of new cases was almost stable between 2010 and 2013 years at around 31 000. The rapid increase in the absolute number of previously treated cases in Ukraine is probably due to changes in recording and reporting practices rather than a true increase in the burden of TB.

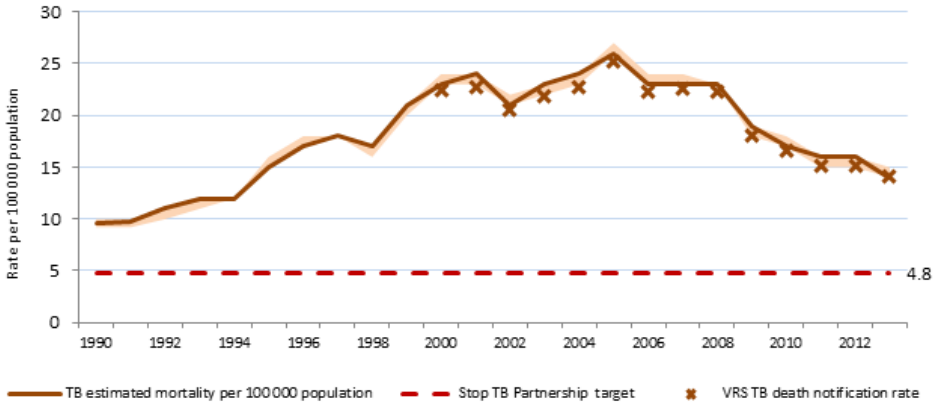
Fig. 6. Numbers of notified new and retreated TB cases and proportion of previously treated TB cases, Ukraine, 2003–2013



Source: Global TB database

From 2006, the trend in mortality from TB began to decrease at an average annual rate of 7.2% (Fig. 7); in 2013, the estimated rate was 14 per 100 000. Despite this impressive decrease, the current mortality rate in Ukraine is about three times higher than the Stop TB partnership target to halve TB mortality by 2015 from that in 1990. In 2013, 6390 deaths from TB were recorded in Ukraine among HIV-negative people. Thus, Ukraine is far from achieving the Stop TB partnership target of a reduction in TB mortality to 4.8 per 100 000 population.

Fig. 7. Estimated TB mortality rates (excluding that from TB/HIV) in Ukraine, per 100 000 population (1990–2013)

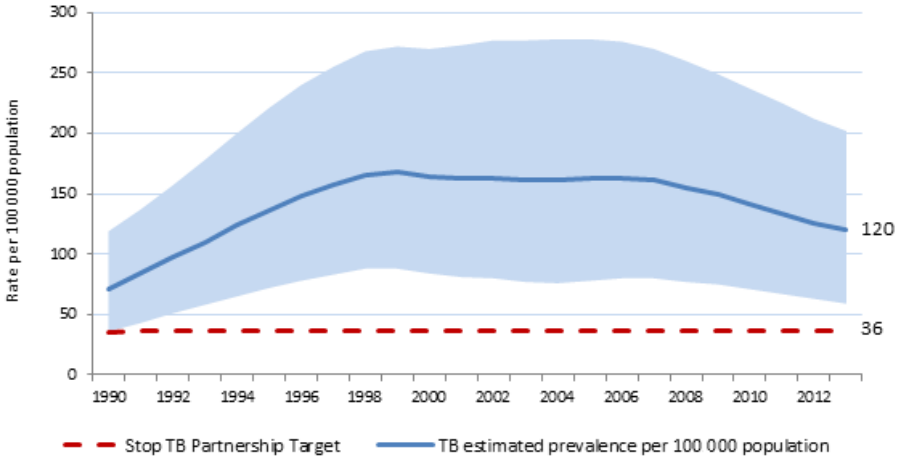


Source: Global TB database
VRS, Vital registration system

Shaded areas represent the uncertainty band of the WHO estimate, while the horizontal dashed line represents the Stop TB Partnership target of a 50% reduction in TB mortality rate.

No data are available for direct measurement of the prevalence of TB in Ukraine, and WHO has made indirect estimates. In 2013, the estimated number of prevalent cases of TB in Ukraine was 54 500 (27 000–91 000), equivalent to 120 (59–202) per 100 000 population. From 2008, the TB prevalence steadily shrank by a mean of 4.3% per year (Fig. 8). At the current estimate of 120 per 100 000, the prevalence of TB in Ukraine is over three times higher than the Stop TB partnership target of 36 per 100 000 population (half the 1990 level).

Fig. 8. Estimated TB prevalence rate in Ukraine per 100 000 population (1990–2013)

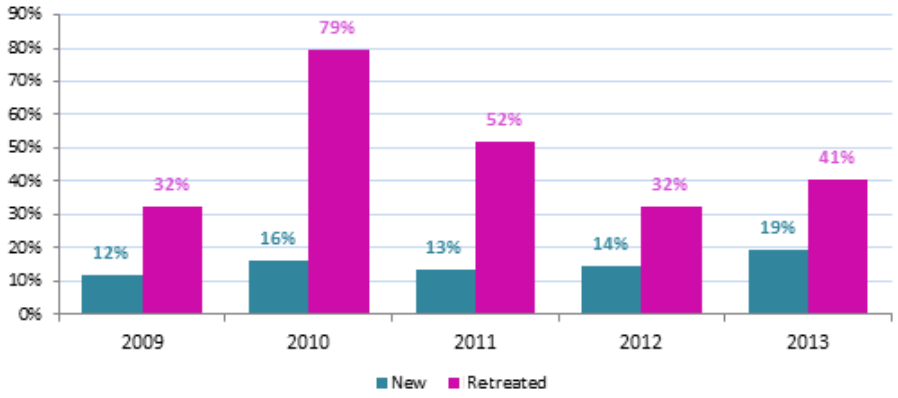


Source: Global TB database

Shaded areas represent the uncertainty band. The horizontal dashed line represents the Stop TB Partnership target of a 50% reduction in prevalence by 2015 from that in 1990.

According to routine surveillance of drug resistance in 2013, the proportion of MDR-TB among newly detected TB cases was 19% and that among previously treated cases was 41% (Fig. 9). These estimated prevalence rates of MDR-TB are much lower than those found in a survey of drug resistance (DRS), which were 23.4% and 58.6%, respectively (DRS preliminary data). The large difference indicates a gap in routine surveillance. In some *oblasts*, patients in social risk groups, such as homeless people and ex-prisoners, are often not registered in DR-TB patient cohorts.

Fig. 9. Proportions of MDR-TB patients among new and previously treated pulmonary TB patients tested for drug susceptibility during routine surveillance, Ukraine, 2007–2013

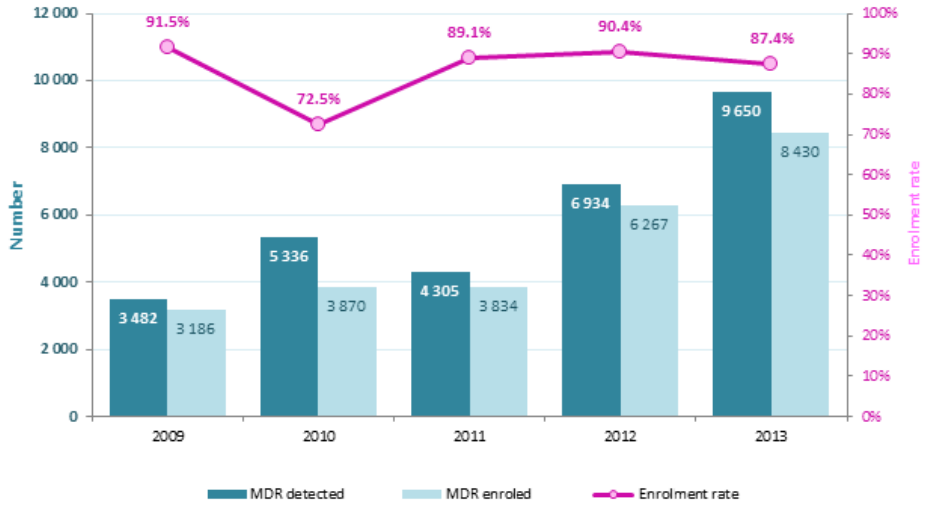


Source: Global TB database

2.2 Patients with MDR-TB (presumptive or confirmed) enrolled in treatment

The proportion of patients with MDR-TB enrolled in second-line treatment during the past 5 years was about 90% (except in 2010), although the absolute number of MDR-TB cases enrolled increased from 3182 in 2009 to 8430 in 2013. This impressive increase in access to second-line treatment might be one of the drivers of the TB epidemic downwards.

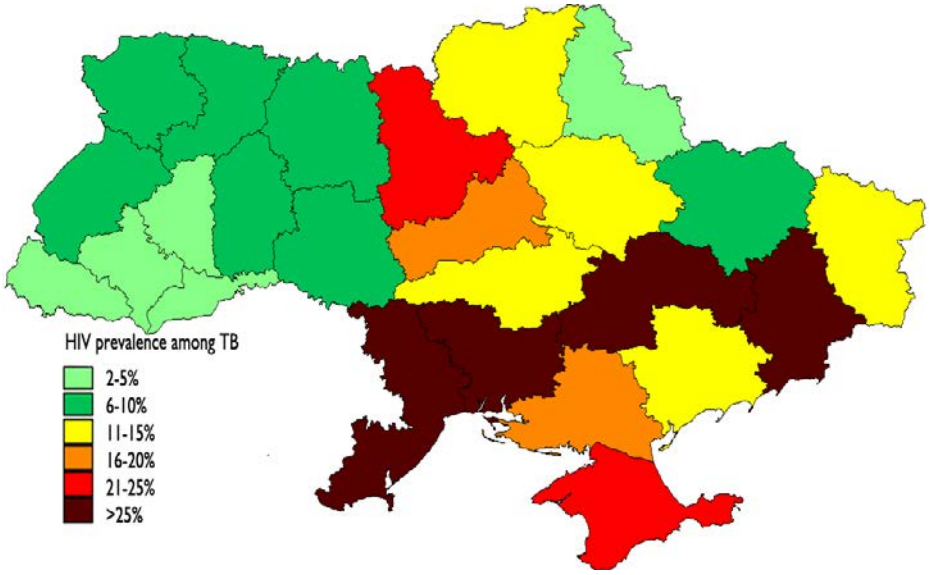
Fig. 10. Numbers of cases of pulmonary MDR-TB detected and numbers of patients with confirmed or presumptive MDR-TB enrolled in treatment, Ukraine, 2005–2013



Source: Global TB database

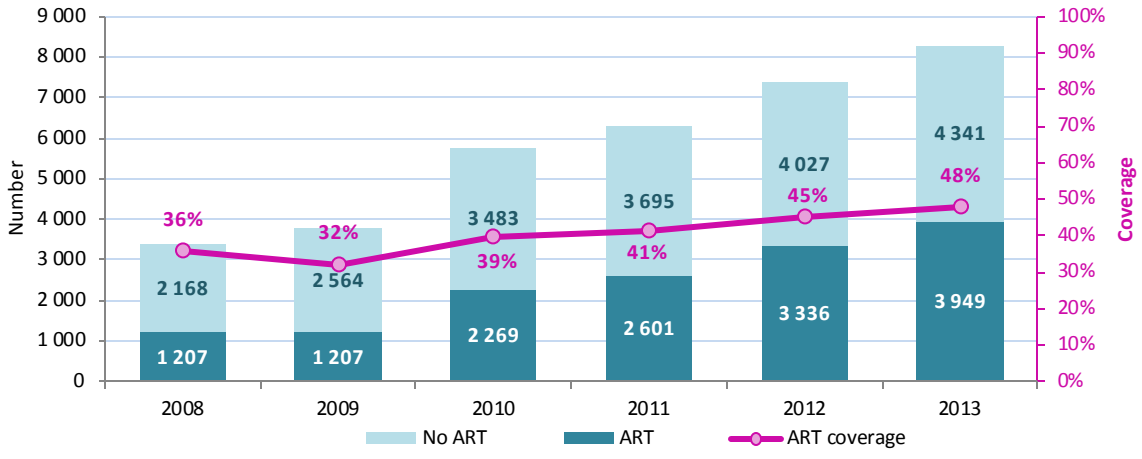
In routine surveillance, the proportion of HIV/TB co-infections in Ukraine between 2007 and 2013 increased by an average of 22% annually. In 2013, 19.6% of TB patients with documented test results were HIV positive. This large increase in HIV/TB co-infection reflects the growing burden of the HIV epidemic in the country, which is expected to drive the TB epidemic upwards. The rates of TB/HIV co-infection in Ukraine ranged from 2.4% in Zakarpattia *oblast* to 31.7% in Donetsk *oblast* in 2013, according to routine surveillance data (Fig. 11).

Fig. 11. HIV/TB co-infection rate per region, Ukraine, 2013



ART and co-trimoxazole preventive treatment are critical for improving the survival of HIV/TB co-infected patients. WHO recommends that all HIV-positive TB patients be eligible for both treatments, regardless of their CD4 count. Between 2008 and 2013, ART coverage in Ukraine increased from 36% to 48% (Fig. 12), which is still far below the WHO target of 100% ART coverage.

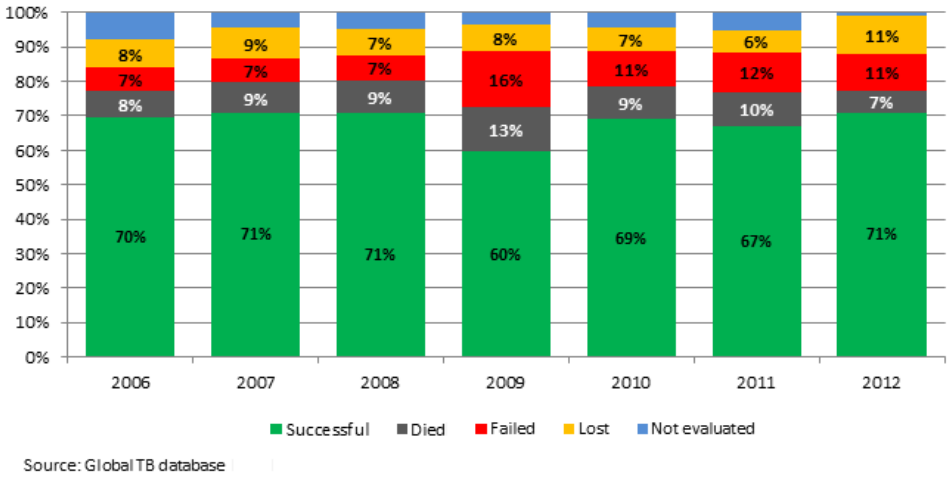
Fig. 12. Numbers and percentages of HIV-positive TB patients enrolled in ART, Ukraine, 2008–2013



Sources: Global TB database and official Ukrainian NTP website

Treatment of TB is effective in reducing the number of prevalent cases and transmission of the infection in the population. Within the past 10 years, about 70% of new TB cases were successfully treated, except in 2009, when the treatment success rate was reported to be only 60% (Fig. 13) owing to a high prevalence of MDR-TB among new TB cases, an inadequate drug supply, poor adherence to the WHO standard TB treatment regimen,[6] common alcohol and drug use (known risk factors for non-adherence to treatment) and frequent HIV/TB co-infection. Failure and loss to follow-up (11% each) were the main reasons for an unfavourable treatment outcome. The treatment success rate of new and relapsed TB cases in Ukraine is the lowest in the Region after the Russian Federation.

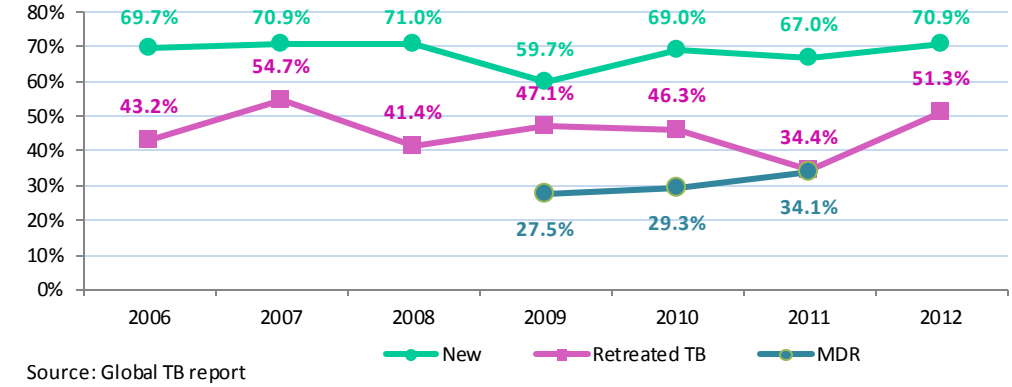
Fig. 13. Treatment outcomes in new TB cases (pulmonary and extra-pulmonary), Ukraine, 2006–2012 (2012 data include all new and relapsed cases)



Source: Global TB database

The treatment success rate (Fig. 14) among retreated TB cases dropped from 43.2% in 2006 to 34.4 in 2011; after transition to a new reporting framework, the treatment success rate in 2012 was 53.1% for retreated cases (excluding relapses). The treatment success rate among MDR-TB cases slightly increased from 27.5% in 2009 to 34.1% in 2011; this rate is, however, also one of lowest in the Region. Thus, the effectiveness of treatment for certain groups of TB patients is low, which might be one of the main reasons for the persistence of TB in Ukraine.

Fig. 14. Trends in treatment success rate of new and retreated TB and MDR-TB cases, Ukraine, 2002–2012



Source: Global TB report

[6] de Colombani P, Veen J, eds. Review of the National Tuberculosis Programme in Ukraine, 10–22 October 2010. Copenhagen: WHO Regional Office for Europe; 2011

3. Health system

3.1 Main recommendations

- Develop a patient-centred care model oriented to ambulatory care. Include TB hospitals in general health care reform, with new performance-based funding mechanisms. Reinvest the resources saved by cost–efficiency measures in TB control to cover urgent needs for ambulatory care, including prevention, diagnosis, patient support, treatment follow-up and adherence, social contracting and incentives for TB, PHC and other staff.

3.2 Specific recommendations

- Change input-based to performance-based funding and contracting for TB control. Ensure the necessary funding for providing incentives and enablers for TB patients in ambulatory care to adhere to treatment.
- Build the necessary mechanisms for social contracting of NGO TB control service providers, especially those working with vulnerable populations, as part of the new TB care model.
- Prioritize patient-centred care models in ambulatory services, and prepare relevant hospitalization criteria in line with WHO recommendations. As a result, abandon unnecessary interventions such as long hospitalization and hospitalization for non-severe, non-infectious TB.
- Increase the capacity of the UCDC for TB management, strategic planning, coordination, supervision, regular information and feedback, training, monitoring and evaluation.

3.3 Main findings (achievements, challenges and examples from field visits)

Ukraine gained independence after the break-up of the former Soviet Union in 1991. The period of transition to a democratic society and a market economy was complicated by severe economic downturn, worsened living conditions, breakdown of the social safety net and profound disintegration of the health system. Economic recovery began in the late 1990s. In 2013, Ukraine had a total estimated population of 45.49 million and a gross national income of US$ 3960 per capita.[7] From 2012, Ukraine experienced a period of stagnation, with 0 registered economic growth rate in 2013, followed by a sharp decrease of about 8% in 2014. According to official statistics, income inequality remained moderate, with a Gini coefficient of about 0.25 registered in 2012.[8] About 11.2% of the population lives in extreme poverty, with expenditure of < 900 UAH per month in 2012.[9] On the UNDP Human Development Index (GDP per capita, educational attainment and health outcomes), Ukraine is rated 78th out of 186 countries (19th out of 29 countries in the eastern Europe and central Asia region). The World Bank defines Ukraine as a lower- to middle-income country. Administratively, the country comprises 24 *oblasts*, one autonomous republic and two cities with special status.

Despite some registered progress, overall health outcomes are poor in Ukraine. The infant mortality rate decreased from 17 to 9 and under-5 mortality from 19 to 10.7 per 1000 live births between 1990 and 2011; over the same period, maternal mortality decreased from 49 to 32 per 100 000 live births. Life expectancy at birth is 71.3 years (66.2 for men and 76.2 for women), about 11 years less than the average in the European Union and 6 years lower than that in the WHO European Region. About 85% of all

[7] World Bank. Development indicators. Washington DC (http://data.worldbank.org/country/ukraine, accessed 9 May 2015).
[8] World Bank. Report No. PAD939. Washington DC; 2015.
[9] Extreme relative poverty is the percentage of individuals with a total expenditure per adult < 60% of the median; US$ 5 per day is the comparison used.

deaths in 2012 were linked to cardiovascular disease, cancer or external causes such as accidents and poisoning.

Ukraine's health care system is based on the former Soviet Union Semashko model. It is organized hierarchically through the Ministry of Health, which sets health sector policies, approves health norms and legal acts, plans national budget expenditure and is responsible for health information, recording and reporting. Health care is administered mainly by the administrations of *oblasts* and *raions*, which operate most hospitals and polyclinics in the country. Responsibilities are fragmented between the central government, *oblast* administrations and numerous bodies at municipal and level, creating major challenges for implementation of national policies and strategies. Polyclinics and hospitals are usually State-owned and -operated. The health service delivery system is hospital-centred, with services focused on individual acute treatment and minimal prevention.

The health system is characterized by inefficient use of resources, overcapacity in some areas and underinvestment in others. Ukraine has an oversized, inefficient hospital sector, both in terms of beds and the number of hospitals: there are 2200 hospitals, 8300 polyclinics, and over 400 000 hospital beds in the public sector, about 40% more beds per capita than the average in the WHO European Region. Small inpatient facilities, such as municipal and district hospitals, and municipal single-disease hospitals (e.g. for TB and sexually transmitted infections) have about 75% of all hospital beds but provide only very basic services. Regional hospitals and specialized clinical and diagnostic centres of national research institutes represent the remaining 25% of hospital beds.

In Ukraine, TB services are vertical and provided only at specialized hospitals. During the past 5 years, the number of TB beds was reduced by 17%, from 25 329 to 21 701 in 2013. In total, there were 80 TB dispensaries with 15 174 beds, 36 TB hospitals for adults with 5255 beds, 3 children's TB hospitals with 250 beds and 89 sanatoria with 12 128 TB beds (Table 1).

Table 1. Numbers of TB facilities and numbers of TB beds, Ukraine, 2013

Administrative territory	TB dispensaries			TB hospitals				TB sanatoria	
	All	With TB beds	No. of beds	For adults	No. of beds	For children	No. of beds	All	No. of beds
Crimea	1	1	630	1	55	0	0	18	3 505
Vinnytsia	2	1	500	4	145	0	0	5	295
Volyn	1	1	380	3	220	0	0	2	300
Dnipropetrovsk	6	6	1 375	1	40	0	0	7	530
Donetsk	13	11	1 625	1	705	0	0	4	600
Zhytomyr	1	1	500	0	0	0	0	2	390
Zakarpattia	1	1	50	1	535	0	0	1	210
Zaporizhzhya	11	3	840	1	95	0	0	2	100
Ivano-Frankivsk	7	7	670	0	0	0	0	4	880
Kyiv *oblast*	2	2	415	1	155	0	0	2	260
Kirovohrad	5	3	140	1	320	0	0	2	190
Luhansk	9	7	915	1	120	1	50	7	410
Lviv	9	8	1 105	2	290	0	0	3	320
Mykolaiv	2	1	590	0	0	0	0	1	201
Odesa	3	2	610	2	565	0	0	7	1 620
Poltava	3	3	504	2	220	0	0	3	230
Rivno	1	1	370	3	190	0	0	2	180
Sumy	2	2	365	0	0	0	0	1	110
Ternopil	4	4	420	2	80	0	0	2	160
Kharkiv	8	5	490	3	450	0	0	6	535
Kherson	1	1	480	2	200	1	60	1	75
Khmelnytsky	2	1	360	2	155	0	0	2	110
Cherkasy	1	1	500	0	0	0	0	1	160
Chernivtsi	2	2	285	0	0	0	0	2	357
Chernigiv	3	2	650	1	50	0	0	1	100
Kyiv city	2	2	170	2	665	1	140	1	300
Sevastopol city	1	1	235	0	0	0	0	0	0
Ukraine	103	80	15 174	36	5 255	3	250	89	12 128

The average length of hospital stay was 91 days for adult patients and 81 days for children; the average length of stay varied significantly among regions, from 117 days in Zaporizhzhya to 67 in Zhitomir for adults and from 164 days in Zaporizhzhya to 38 days in Ternopol for children (Table 2).

Table 2. Occupancy rate and average length of hospital stay for TB of adults and children per region, Ukraine, 2013

Administrative territory	Occupancy rate (%)			Average length of stay (days)		
	Subtotal	Adults	Children	Subtotal	Adults	Children
Cherkasy	327	328	314	81.49	83.35	61.66
Chernihiv	323	323	327	101.11	101.74	92.18
Chernivtsi	293	293	0	84.42	84.42	0.00
Crimea	302	300	338	106.58	106.05	114.82
Dnipropetrovs'k	309	311	256	89.61	88.57	131.83
Donets'k	310	308	370	98.39	97.42	143.23
Ivano-Frankivsk	313	311	336	76.62	78.08	55.96
Kharkiv	278	280	246	88.69	86.80	135.43
Kherson	331	329	359	95.29	95.90	89.09
Khmelnytskyi	244	243	276	73.70	76.98	42.80
Kyiv oblast	289	297	196	95.79	95.87	94.44
Kirovograd	307	309	266	90.51	90.49	90.93
Lugansk	323	322	346	103.13	104.81	78.22
Lviv	318	326	144	73.72	73.84	67.75
Mykolaiv	385	391	314	96.09	96.20	94.31
Odessa	306	307	288	98.68	97.67	153.57
Poltava	266	260	350	101.65	115.11	43.90
Rivne	239	242	184	98.44	99.33	78.74
Sumy	265	260	372	80.79	83.74	52.24
Ternopil	295	299	97	67.57	67.88	38.88
Vinnytsa	308	307	329	84.61	83.27	121.98
Volyn	322	330	235	102.47	101.28	125.10
Zakarpattya	315	316	248	96.43	96.86	74.52
Zaporizhzhya	309	309	318	117.07	114.76	164.62
Zhytomyr	314	322	251	67.46	70.96	46.08
Kyiv City	222	220	230	96.67	104.48	68.38
Sevastopol City	330	322	447	62.70	63.49	55.36
Ukraine	302	303	281	90.55	91.11	81.02

Inpatient TB facilities have no incentive to de-institutionalize service delivery, because their funding is indirectly linked to the number of patient bed–days. Thus, the health resource roster is calculated on the basis of population size, and the number of beds is calculated subsequently. The funding of hospital-oriented TB care in Ukraine is provided by global contracting in a rigid mechanism, with little possibility for reallocating funds between budget lines. The main hospital costs are for staff salary payments (about 59%), food for patients (about 14%) and hospital maintenance (about 18%). An average of US$ 32 is spent per hospital bed, about 10% of which is for TB diagnostics and treatment. The breakdown of costs per typical hospital day of treatment is shown in Table 3.

Table 3. Breakdown of costs for 1 day of treatment, TB hospital in Mykolaiv (2015)

Budget item	Code	Cost in UAH	Cost in US$	Percentage of all costs
Staff salaries	2111	111.35	13.9	42%
Taxes on staff salaries	2120	40.42	5.1	15%
Items and materials	2210	1.19	0.1	0%
Diagnostics, drugs and bandages	2220	17.85	2.2	7%
Meals and food products	2230	36.51	4.6	14%
Services (except communal services)	2240	4.75	0.6	2%
Duty travel	2250	0.06	0.0	0%
Water	2272	1.61	0.2	1%
Electricity	2273	8.72	1.1	3%
Gas and heating	2274	35.99	4.5	14%
State programmes	2280	0.00	0.0	0%
Pension contributions and material support	2710	4.61	0.6	2%
Other payments	2730	0.00	0.0	0%
Other operational expenses	2800	0.00	0.0	0%
Total		263.17	32.9	100%
Drugs and bandages procured centrally	None	7.78	1.0	3%
Resources from the Global Fund	None	31.61	4.0	12%

There is no incentive to reduce excessive hospitalization or to orient resources to the priorities of modern TB control, including patient-centred ambulatory care. Reducing hospitalization time by 1 day could save US$ 2.3 million on the assumption of a turnover of 3.3 TB hospital beds, an average cost of US$ 32 per day and 21 701 TB beds. There is, however, no viable mechanism to use the potential savings for PHC or TB ambulatory services or to provide incentives and enablers to TB patients.

The national TB response depends strongly on external funding: Global Fund resources cover about 40% of the national programme. The Global Fund has approved new funds for TB/HIV in Ukraine up to 2018 as part of its new funding model. Thereafter, the Ukrainian Government is expected to finance its own TB and HIV response fully from domestic sources. Given the forecasted decrease in external funding and limited domestic resources, it is crucial to find means of increasing efficiency to ensure continuation of services. The Ministry of Health has therefore begun to reorganize and optimize the structure of health care delivery, with PHC, an efficient referral system, use of modern clinical protocols, licensing of medical practices and accreditation of health facilities. Integration of TB control into PHC is part of the reform, in guidelines updated by Ministry of Health order No. 620 of 4 September 2014 on "Comprehensive clinical protocol for primary, secondary and tertiary level health care providers to adults on tuberculosis". The protocol clearly defines the main aspects and responsibilities of health care staff in both PHC and TB facilities in organizing TB care for patients.

With World Bank support, the Government initiated pilot projects in *oblasts* to change from input-based to performance-based financing and contracting, introduction of modern methods of payment (capitation in PHC and case-based methods in hospital care) as well as other elements (such as pooling of funds at regional level, decreasing informal payments, legalizing co-payments, improving health information systems). It is essential that the TB service system be part of wider health system reform in the country.

3.4 Observations and challenges

3.4.1 Health sector reform

The Government of Ukraine has not made serious health system reforms, although some have been proposed and even legislated over the years, because of political instability and frequent leadership changes in the Ministry of Health. To address the TB challenge in Ukraine, the country's health system should be reoriented from an acute care, input-based model to a comprehensive disease management model. TB care is financed by a rigid method based on the funding indirectly linked to the number of occupied TB beds. The hospitalization of TB patients must be reduced while improving service delivery at PHC level, as well as infection control standards, and restructuring the financing system.

3.4.2 New model of care

The main challenge for the Ukrainian health system is to adjust and improve the TB care delivery model by strengthening links at all levels of care and different providers, first and foremost by further strengthening the role of PHC in TB case finding and case management in the current situation of a high burden of drug resistance. One of the main lessons learnt during implementation of the NTP is the importance of outpatient treatment, which requires multidisciplinary patient-centred approaches that often extend beyond the traditional boundaries of the health system and require rigorous action by other public services (such as social services) and non-State and community actors.

3.4.3 Inefficient TB hospital sector

The funding allocated for TB control as it is currently structured in Ukraine is inefficiently used and is therefore insufficient for making priority interventions; as a result, the country remains dependent on external donor support. The current grant from the Global Fund covers procurement of second-line anti-TB drugs, equipment and consumables for laboratory diagnosis, patient incentives for adherence and other key activities such as monitoring, supervision and training. Inpatient treatment continues to play an important role in TB case management in Ukraine, as the vast majority of TB patients are hospitalized for treatment for periods that depend on infectious status and resistance profile. The current capacity of TB hospitals is excessive and requires substantial optimization and downsizing.

3.4.4 Strong NTP management, monitoring and evaluation

The UCDC was created from the National AIDS Centre and the National TB Centre. It is charged with the control of HIV and other socially dangerous diseases and performs traditional NTP functions in relation to TB control: management, strategic planning, coordination, supervision, regular information and feedback, training, monitoring and evaluation. Additional work is needed to ensure the readiness, institutional capacity and sustainability of the UCDC.

4. Case finding

4.1 Main recommendation

- Revise Ministry of Health order No. 327 of 15 May 2014 mandating extensive, obligatory fluorography screening for people in professions with little risk for spread of airborne infection, to focus on well-defined risk groups, in line with WHO recommendations. Costs could be reduced as a result of the workload reduction and unified diagnostic procedures; the estimated cost of annual mass screening with more than 19 million fluorography examinations per year at a cost of US$ 2 per test is about US$ 38 million. As recommended above, the saved funds should be reinvested in TB control measures based on patient-centred care.

4.2 Specific recommendations

- Implement WHO recommendations on active case finding only in high-risk groups, also described in order No. 620 of the Ministry of Health of 4 September 2014.
- Extend contact investigation beyond household contacts to ensure early TB diagnosis, especially in children. The regulatory basis should be changed to enable more active case finding, taking into account ethical considerations and confidentiality.
- Provide training and technical assistance on use of diagnostic algorithms, with close monitoring of implementation, at all levels (including non-TB services such as general health care and PHC facilities).
- Include a laboratory component in the TB register to ensure timely access to laboratory results at all health care levels and registration of all laboratory-confirmed TB cases (including DR-TB cases).
- Abolish current fluorography testing of the general population every 2 years. Optimize TB screening by analysing the yield for each group screened and identifying at-risk groups for screening.
- Revise the attachment to the order of the Ministry of Health of 15 May 2014, “List of laboratory and other examinations required for obligatory medical check-ups and their periodical implementations”, and reduce the number of fluorography tests by abandoning the requirement for annual fluorography when it has little impact on the spread or outbreaks of airborne infection (workers in food and food processing, textiles, laundries and dry-cleaning facilities, hairdressers, massage, cosmetology, saunas, hotels, sport facilities, theatres, culture houses, pharmaceutical industry, water and sewage facilities, subways, central railways, airports, ports, fishing, people providing private services at home and others).
- Review the order of the Ministry of Health of 15 May 2014 to consider only initial fluorography testing before starting work in or study for such professions as teachers and staff of kindergartens, medical staff in general health care facilities, staff working in the penitentiary sector, students and the military. These are not vulnerable populations and have good access to health system services; they therefore do not require annual fluorography after an initial X-ray examination.
- After careful evaluation of the effectiveness and yield of TB cases by screening the above-mentioned groups in operational research, further revise situations in which fluorography is required, with full-format digital chest X-ray examination for active case finding in at-risk groups.
- Combine the two parallel systems of small-format fluorography digital X-ray machines and full-format digital X-ray machines into digital full-format X-ray at general health care facilities. Use mobile fluorography systems for active TB case finding only among affected populations and high-risk groups. This recommendation can be carried out if the number of annual fluorography tests is limited to high-risk groups.

- To ensure early TB detection, consider improving the logistics of sputum transport to sites of rapid TB diagnosis from general health care and TB facilities by using courier service networks. Ensure funding for this purpose.
- Include bacteriological examination of surgical material and extra-pulmonary specimens to ensure proper case detection and management, including treatment duration and drug susceptibility testing.

4.3 Main findings (achievements, challenges and examples from field visits)

TB cases are found by two approaches, active and passive case finding. Active case finding by annual chest X-ray or miniature chest fluorography has been given high priority since Soviet times, despite the very low yield and high costs associated with maintenance of parallel fluorography infrastructure and conventional X-ray diagnostics at general health care facilities (polyclinics). PHC providers and specialists at TB dispensaries are responsible for organizing the screening of asymptomatic patients by fluorography. In 2013, 19 444 664 fluorography tests were performed on people aged ≥ 15 years, covering up to 56% of the adult population. The estimated cost of annual screening within the general health care sector is more than US$ 38 million on the basis of the estimated cost of one fluorography test of 16 HRV or US$ 2 in 2014. The yield of mass screening fluorography is very low; for example, 717 936 fluorography examinations were performed in 2014 in Poltava out of a total adult population of 1 500 000, with a yield of 536 diagnosed TB cases, or 0.07%. In the current system, therefore, one TB case detected costs US$ 2678. Furthermore, some of the TB cases identified by fluorography had TB-related symptoms and should have been classified as detected by passive case finding. In some polyclinics, the fluorography machines are in better technical condition than the X-ray machines and are therefore also used for differential diagnosis in cases of respiratory complaints. If a decision is taken to reduce the number of fluorography tests to high-risk groups, either by full-format digital X-ray at general health care facilities or by mobile fluorography machines, additional savings will be made. During the field visit, duplication of X-ray equipment was noted in general health sector polyclinics (Fig. 14).

Fig. 14. Two digital X-ray systems (digital fluorography and digital full-format X-ray) functioning in parallel at the same health care facility (a polyclinic in Mikolaiv)

The groups at risk for TB that are eligible for active case finding, including by X-ray examination, are defined by Ministry of Health order No. 620 of 4 September 2014 and are in line with WHO recommendations on systematic active case finding for TB. The groups include migrants from countries with a high TB burden, homeless people, contacts of people with TB or previously treated for TB, people

living with HIV, diabetes mellitus, chronic obstructive pulmonary disease or gastric or duodenal ulcer, alcohol and drug addicts, people receiving immunocompromising treatment, people in mental health clinics, prisoners and ex-prisoners and health care workers. The Ministry of Health order of 15 May 2014 stipulates the scope of medical examinations among professional groups; however, these include several large population groups who are at low risk for TB and low risk for transmission, such as workers in the food and food processing industry, textile industry, laundries and dry-cleaning facilities, hairdressing, massage, cosmetology, saunas, hotels, sport facilities, theatres, culture houses, pharmaceutical industry, water and sewage facilities, subways, central railways, airports, ports, fishermen, people providing home services and others, including all students. The general population must also undergo a fluorography examination once every 2 years. Contact investigation is focused mainly on household contacts.

Ministry of Health order No. 620 of 4 September 2014 sets the policy for passive case finding in PHC settings. All patients with complaints suggesting TB (cough for more than 2 weeks, fever, weight loss, TB contacts) should undergo a clinical examination, give two sputum samples and be examined by X-ray or fluorography.

Access to and proper use of rapid diagnostic tests has improved enormously. In theory, all suspected TB cases have access to a bacteriological examination. Diagnostic algorithms have been updated (including for the rapid diagnostics Xpert MTB Rif and HAIN test) and introduced into the new TB guidelines to be distributed shortly. It has been difficult, however, to establish a reliable, effective system for transporting sputum samples to the site of rapid TB laboratory diagnostics. The current system relies on occasional possibilities for transport between health care facilities or sending TB patients to a TB dispensary at a higher level for sputum examination. In view of the poor condition of roads in some regions and the vast distances between facilities, sputum samples are often of bad quality, delaying a diagnosis of TB. The existing system of courier transport could be considered for this purpose, provided funding is available. Very often, laboratory feedback is delayed because laboratory data are not included in the TB registry or because clinicians are given only selected feedback.

Passive case finding is based on self-reporting by symptomatic patients to PHC and general health care services or directly to TB facilities. Diagnostic algorithms and awareness of TB are insufficient in PHC and general health care facilities. For example, during the visit, a case of “poly-DR” (sputum smear-positive, resistance to izoniazid and ethambutol hydrochloride) was found in a patient in a general hospital, who received levofloxacin for > 10 days. Patients suspected of having TB and referred to a TB facility for diagnosis are often kept in hospital, where they share a ward with TB patients. In view of the currently insufficient infection control, there is a very high risk for nosocomial TB, including DR-TB.

4.4 Challenges

- the inherited system of mass screening of vast population groups (56% of adult population), with the perception among decision-makers and the general public that this is the most effective TB control measure;
- inefficiency associated with duplication of X-ray services in the general health care system (fluorography and full-format digital X-ray);
- existing regulations that require annual fluorography screening for more than 90 professional groups, which is not justified for public health;
- a rigid funding system, which does not allow reallocation of funds that could be released by reducing the population groups to be screened for use in priority TB control interventions;
- narrow case detection (mainly household contacts);
- lack of awareness about TB in the general health care sector, leading to late diagnosis and amplification of drug resistance;

- insufficient sputum examination and access to and use of rapid diagnostics during differential diagnosis outside TB services; and
- limited, delayed laboratory feedback due to the absence of a laboratory component in the TB registry and selective feedback to clinicians, especially at district level

5. Laboratory network

5.1 Main recommendations

- Rationalize the laboratory network and particularly the number and effectiveness of level-1 and level-2 laboratories, some of which could be merged. Level-2 and level-3 laboratories should be distributed geographically on the basis of population density and numbers of suspected cases of TB and MDR-TB.
- Strengthen level-3 laboratories to perform all microbiological examinations in the country (sputum smear microscopy, culture of liquid and solid media, first- and second-line drug susceptibility testing, GeneXpert), including quality control for peripheral laboratories. Early diagnosis of TB, particularly MDR-TB, should be the main strategy for halting the spread of MDR-TB in the country.
- Ensure access to TB diagnosis in remote territories by improving the logistics of sputum transport and access to rapid molecular tests.
- Revise or define norms for roles, tasks and responsibilities at all laboratory levels, including workload, types of investigation, equipment, qualification and number of staff required and molecular examinations.
- Institute a training plan for all laboratories in the network, including for new methods and external quality assessment of level-1 laboratories by level-2 laboratories, with continuous capacity-building of laboratory personnel.
- Further strengthen the national quality assurance programme, and support it financially. Currently, there is no quality control of smear microscopy or line probe assays (LPA) in level-3 laboratories, including in the penal system. Give the NRL adequate staff and budget to plan regular monitoring and training for level-3 laboratory workers in the penal system.
- Ensure that laboratory data are entered into a data management system. A laboratory module of "eTB manager" should be available, and data should be entered into the current data management system by laboratory staff. This will lead to more accurate, rapid data communication within and between laboratories and clinicians.

5.2 Specific recommendations

- Finalize, approve and use a guide for laboratory quality control for microbiological investigation of *M. tuberculosis* at all levels of the laboratory network.
- Regularly revise standard operating procedures for each microbiological laboratory, including molecular methods, and use them in regional and peripheral laboratories. Revise the regulations for microbiological examination.
- Revise, use and regularly monitor the performance indicators for laboratory service (according to WHO recommendations).
- Improve laboratory data management. Data management and collection should start at laboratory level, with direct entry of data into electronic data management systems, to facilitate patient and

sample management. The results of Xpert, Mycobacterium growth indicator tube and Hain tests should be included in the laboratory module of e-TB Manager and similar systems to be shared at national level.

- Prepare a plan for ensuring the maintenance of laboratory equipment, especially biological safety cabinets. The plan should include objectives, responsibilities, tasks, implementation plan and budget. Maintenance should be done systematically and regularly to avoid costs due to late maintenance, and to appropriate bio-safety and security standards.
- Establish regular, uninterrupted, rapid TB services, including laboratory reagents and equipment.
  - Ensure coverage of all patients, early diagnosis and accurate monitoring of treatment.
  - Ensure close collaboration among the structures involved in TB diagnosis (the Global Fund, NTP, NRL).
- Improve the courier system between TB offices, microscopy centres and intermediate laboratories.
- Increase coverage with molecular genetic investigations for most symptomatic TB patients.
- Approve and use the new rational diagnostic algorithms for effective diagnosis with WHO-endorsed tests, treatment with first- and second-line drugs and monitoring of TB treatment. Early detection of MDR-TB should be taken into account.
- Continue laboratory quality control of TB diagnoses, in accordance with the WHO recommendations for microbiological investigation of *M. tuberculosis*, at all levels of the laboratory network.
  - The NRL should ensure regular external quality control of testing for susceptibility to first- and second-line drugs in all laboratories that conduct culture and drug susceptibility testing. (Establish regular expedition of a panel of cultures for proficiency testing, and ensure transport of panel strains in the country.)
  - Prepare a training plan for testing susceptibility to second-line TB drugs with international trainers and external quality assurance (with a certificate from a supranational reference laboratory).
  - Prepare a plan for quality assurance and quality control of the culture method (Mycobacterium growth indicator tube with Löwenstein-Jensen medium) for the NRL and other reference laboratories.
  - Improve quality control of smear microscopy, and consider lot quality assurance sampling. External quality assurance should be conducted at peripheral level by regional (*oblast*) laboratories, and regional laboratories should supervised and assessed by national bodies.
- Supranational reference laboratories at the NRL should regularly assess the quality of molecular tests such as GeneXpert and LPA, and staff should have regular training.
- Improve infection control in regional reference laboratories.
  - Renovate laboratory facilities in small, crowded rooms.
  - Check mechanical ventilation systems and have them accredited by a certificated company.
  - If no ventilation system is installed, guarantee work by regular training and supervision of laboratory workers, regular maintenance of laboratory equipment and strong infection control, with an infection control manager and use of up-to-date standard operating procedures.
- Ensure access to bacteriological testing and the availability of rapid molecular tests, including in remote territories.
  - Establish or improve a sputum transport system, including for PHC and general health care facilities.

  - Laboratory staff should report test results rapidly and enter them into the TB registry to ensure rapid access to results.
  - All test results should be shared with the district TB doctor or nurse without delay, ensuring that results are not lost.
- The supranational reference laboratory and other partners at NRL level should train laboratory staff in:
  - the use and interpretation of novel molecular methods, biosafety, security and correct waste management, with the support of national and international partners;
  - use of the diagnostic algorithm, with close monitoring, at all levels, including non-TB services, such as general health care and PHC facilities and prisons).
- Use of Xpert MTB/RIF to diagnose pulmonary TB and rifampicin resistance in adults and children should follow WHO's recommendations (see latest Xpert MTB/RIF implementation manual). The recommendations should be checked at laboratory level and, if necessary, revised in consultation with a clinician to avoid errors, late diagnosis or missing patients at risk.
- TB laboratory biosafety should be respected according to national and international (see latest WHO biosafety manual) recommendations at all laboratory levels. In all laboratories, infection control measures and maintenance of major equipment, including biological safety cabinet and autoclaves, should be ensured
- The algorithm for microbiological detection of TB and monitoring of treatment should be revised and monitored, and extension of rapid molecular genetic methods should be considered.

5.3 Achievements

- TB laboratory diagnosis in Ukraine is based on smear microscopy, molecular genetic examination (GeneXpert) and culture examination on solid and liquid media. Drug susceptibility testing on solid and liquid media is performed at the NRL and in level-3 regional TB laboratories. Molecular genetic methods (LPA and GeneXpert) have been used since 2012. LPA is not used systematically for clinical investigation but rather for research purposes at the NRL.
- The laboratory network has been reorganized at various levels:
  - the NRL,
  - regional level-3 TB laboratories,
  - level 0–2 laboratories for culture and sputum smear microscopy and
  - level-1 microscopy centres at peripheral laboratories (not TB-specific).
- The facilities of the laboratory network, including national and level-3 regional laboratories are equipped with sophisticated modern equipment and supplies. Some laboratories have been renovated and infection control measures introduced (NRL and the regional laboratories in Vinnytsia and Mikolaiv).
- A national TB drug resistance survey, covering the entire country, was completed in 2014.
- Staff in level-2 and level-3 laboratories have been trained in culture and sputum smear microscopy.
- Molecular genetic technology has been introduced (LPA, GeneXpert MTB/RIF). For rapid detection of TB and resistance, Xpert machines are present in 24 level-3 laboratories in the network and at the NRL.
- Laboratory guidelines for microbiological investigation have been published.

- TB control activities, including laboratory examinations, are funded by the Ministry of Health and the Global Fund (round 9).
- External quality assurance of drug susceptibility testing is conducted by the NRL.
- Tests for identifying *M. tuberculosis* (BD MGIT™ TBc) are used.

5.4 Challenges

- Rapid molecular methods for early TB diagnosis and drug susceptibility testing are not used in peripheral level laboratories.
- LPAs such as the Hain test are not used systematically for diagnosis but only for research, due to the shortage of consumables.
- The roles and responsibilities of level-1 and -2 laboratories in TB case detection policy are limited; there are still too many laboratories conducting sputum smear microscopy examination, resulting in duplication of some investigations, including culture.
- The distribution of laboratory equipment, including for the NRL, should be revised, as it is often underused or not used. Equipment should be exchanged within the laboratory network at the same time as revision of the network.
- Laboratory data are not managed at laboratory level: all data are sent on paper to the *oblast*, where they are entered into e-TB Manager. (This can result in errors and delays in data registration.)
- Lack of communication between clinicians and laboratory diagnostic staff can cause misunderstandings and thus incorrect diagnosis or treatment. Laboratory feedback should be improved.
- Culture methods do not undergo external quality control in the NRL or other reference laboratories.

6. Drug supply and management

6.1 Main recommendations

- Adopt the Global Drug Facility method for drug quantification to ensure procurement from the State budget and supply at all levels.
- Ensure the availability and distribution of drugs for complete treatment regimens for all patients, particularly those with pre- and extremely drug-resistant (XDR)-TB.
- Strengthen pharmaceutical management at all levels to ensure consistent access to first- and second-line TB drugs of assured quality.
- Integrate drug management in the civil and prison sectors.
- Ensure adequate management of side-effects at all levels and reporting of serious adverse reactions. Record side-effects on treatment cards, and send completed pharmacological vigilance forms to the Ministry of Health expert centre.

6.2 Specific recommendations

- Annul Ministry of Health order No. 374 with changes dated 2 June 2014 (http://zakon4.rada.gov.ua/laws/show/z0889-14).
- The requirements for a full course of treatment with new first- and second-line TB drugs should be calculated as for the Global Fund, and the policy on buffer stocks should meet international recommendations. Calculations should be based on the estimated number of patients, taking into

account the results of the drug resistance survey in 2014. The quantity ordered should ensure an uninterrupted supply of quality-assured drugs at all levels of TB care and coverage of XDR-TB and pre-XDR-TB patients with second-line, fifth-group drugs. As adequate treatment regimens for pre-XDR-TB are not indicated in the protocol, these patients are treated in the same way as MDR-TB patients, which increases resistance and XDR-TB transmission.

- Ensure integrated access to anti-TB drugs and ART in AIDS and TB facilities.
- Ensure reallocation of drugs for patients who move to another *oblast* or area.
- Simplify the distribution and redistribution of drugs from *oblast* to *raion* level to avoid treatment interruption, delays in hospitalization and treatment adherence, in a patient-centred approach.
- Introduce a drug management module in e-TB Manager to improve distribution and redistribution at all levels.
- Improve the efficiency of drug management to ensure consistent access to first- and second-line drugs.
- Improve stock management in each *oblast* TB dispensary.
- Coordinate the strengthening of pharmaceutical management between programmes, donors and partners in the civilian, prison and other sectors.
- Implement law No. 2050 on drug procurement by international organizations.
- Ensure access to ancillary drugs for adequate management of adverse effects.

6.3 Main findings (achievements, challenges and examples from field visits)

- Drug interruptions may occur due to the old-fashioned State budget forecasting, procurement and management of drugs.
- The country currently has a full drug supply through the Global Fund grant.
- The drug management module has not been added to e-TB Manager.
- Lack of drugs leads to the inadequate management of XDR-TB and pre-XDR-TB patients, stigmatization of marginalized groups and a waiting list. Inadequate palliative treatment is due to refusal of treatment, a majority of pre-XDR and XDR-TB patients and incorrect assignment to palliative care of marginalized groups and also patients who could be treated even after a second treatment failure. A palliative care protocol is urgently needed to standardize allocation.
- The distribution and redistribution of drugs is complicated and not standardized, which has led to treatment interruption.
- There are inadequate supplies of certain second-line agents for treatment of MDR-TB, pre-XDR-TB and XDR-TB and very limited access to the fifth-group drug linezolid for treatment of pre-XDR-TB and XDR-TB.
- Prescription of low-dose levofloxacin (500–750 mg/day) has been observed.

In Ukraine, there are two mechanisms for drug procurement: through the Global Fund and through the Ministry of Health. Global Fund procurement is based on treatment regimens and allows the procurement of drugs for the entire length of treatment, including 2 months of buffer stock. Drugs procured through the Ministry of Health are quantified separately as the requirement of each drug for 1 year, which leads to insufficient drug supply; furthermore, there is no clear policy on buffer stocks. Unfortunately, the drug management module in e-TB Manager is used only for drugs procured through the Global Fund.

Currently, there has been no drug interruption, due to the emergency donation of second-line drugs from the Global Fund; without this donation, the supply of second-line drugs would have been interrupted; interruption of first-line drugs occurred in 2012. It is essential to improve the system to allow an uninterrupted supply of anti-TB medications. This will require changes in drug quantification, drug management, including redistribution, and reform of overall drug procurement by the Ministry of Health. Procurement by the Ministry is being revised to allow procurement through international agencies; however, even with better procurement mechanisms, the changes mentioned above are critical in order to stabilize the drug supply.

Drugs procured by the Ministry of Health are usually distributed once a year. Only products for which there was a delay in ordering or production are distributed later, which has resulted in inadequate regimens. At facility and *oblast* level, it is not possible to predict accurately when products will be delivered. As the main supply is annual, readjustment is not possible, and redistribution is the only way to ensure stocks at facilities. The lack of clear delivery dates, quantities and limited storage capacity at *oblast* facilities make reliable planning difficult.

Drug storage is regulated by Ministry of Heath order No. 584 of 16 December 2003. The storage conditions for drugs in health facilities vary from adequate to good. In some facilities, storage practices are aligned with standards, including appropriate organization and first-in–first-out distribution, and the facilities have air-conditioning. In other facilities, the storage area has insufficient space, lacks shelving or lacks air-conditioning to maintain an appropriate temperature.

Drug management at *oblast* level is ensured by pharmacies using the electronic registry. Distribution of drugs from *oblast* to *raion* level is complicated and time-consuming. In some *oblasts*, the health department issues a weekly *prikaz* listing the drugs to be distributed; in others, the *prikaz* is issued quarterly. This system results in insufficient drug supplies to the *raions*. A pharmacist at the *oblast* TB dispensary must sign a form at the *oblast* health administration, which can take several weeks and has led to treatment interruptions. Any remaining drugs can be collected from the *raion* after authorization by the head of the *oblast* TB dispensary. The quantity of drugs to be distributed to *raion* level from the *oblast* TB dispensary for patients in the support phase should be increased from 30 to 60–90 doses (Global Fund programme). A more effective process for quantification and periodic (re)distribution adjusted to current needs should be based on better use of data, which could reduce the time and costs required for redistribution. This could be done through e-TB Manager.

There is no system for managing adverse effects, although a system is required in the national treatment protocol. Drugs for the treatment of side-effects are difficult to obtain in the *oblasts* and are not available in all. Side-effects are not registered, except when a patient is treated with drugs procured through the Global Fund, and are not managed properly. Better monitoring of adverse events would improve their diagnosis and treatment; this will become increasingly important with widespread treatment of DR-TB, given the adverse event profile of many of the second-line agents. Laboratory equipment and tests are needed for early diagnosis and adequate management of adverse effects (electrolyte and biochemical end-points and haematology analysers, glucose strips, urine strips). At *raion* level, these tests are not available or only after long delays.

Palliative treatment is needed for patients with MDR- or XDR-TB when the currently available drugs are inadequate for a curative regime, and the need may increase until adequate treatment of both DS- and DR-TB (and adequate infection control) becomes available. “Palliative treatment” and its aims have, however, been defined differently in different *oblasts*, so that implementation is difficult to assess. No drugs are available for palliative care as defined internationally.

The supplies of some second-line agents are inadequate in the regions: none of the regions visited had an adequate supply of linezolid, with enough for only two or three patients.

The National TB Institute has the whole spectrum of first-line and second-line drugs available for use, as they are procured through the Academy of Medical Sciences. After a patient is discharged for the continuation phase of treatment, however, it is difficult to continue treatment, as no new-generation drugs are available at *oblast* level. The lack of a coordinated response adversely affects individual treatment and partially negates the benefits of introduction of new regimens by the Institute. A mechanism is required to ensure adequate access to new drugs throughout treatment and is the joint responsibility of the National TB Institute and the NTP. Similarly, there is no mechanism for cross-budget redistribution for ART drugs if a patient moves from the Lavra Clinic in Kyiv to live in the *oblasts* or *raions*.

7. Infection control

7.1 Main recommendations

- Use rapid TB laboratory diagnostics and early isolation of infectious TB patients, and apply administrative control measures.
- Extend ambulatory treatment for patients with TB and DR-TB, particularly when they are not infectious.
- Strengthen the role of the NTP in monitoring infection control measures in TB facilities, and assess the risk regularly.

7.2 Specific recommendations

- Improve control of airborne infections in health care facilities and other congregate settings. Use natural ventilation and shielded UV lamps in the most dangerous places (for example in sputum collection rooms) for use throughout the day.
- Some facilities (Chernivtsi and Poltava laboratories) require urgent renovation, reconstruction or completion to ensure proper infection control.
- Procurement and distribution of UV meters should be finalized. The UV radiation from shielded lamps should be checked to ensure the safety of medical staff and patients.
- Biological safety cabinets, the ventilation system and the maintenance of equipment in laboratories should be verified regularly.
- Continue to strengthen administrative, environmental and personal infection control programmes in all TB facilities.
- Infectious cases should be strictly isolated. Patients should be educated about preventing transmission of TB, including cough etiquette.

7.3 Key findings (achievements, challenges and examples from field visits)

7.3.1 Achievements

- The infection control programme has been published (document package available).
- Local training courses have been conducted for nurses.
- The Xpert MTB/RIF rapid diagnostic test is used.
- Patients are placed in different wards according to the resistance pattern: new DS, retreatment, poly-DR, MDR.

In August 2010, a standard for TB infection control in medical establishments and long-stay institutions was adopted, which includes all measures for reducing the risk for transmission recommended by WHO.

Administrative personnel are aware of the importance of effective measures for reducing the risk for TB among professionals and patients and also of the WHO-recommended, internationally recognized approaches to TB control, although most employees require special training.

Positive examples were found of sorting of visitors at the entrance to PHC facilities, examination of patients with respiratory symptomatology evocative of TB and adequate streaming of patients. Adults and children have isolated appointments in TB rooms, and sputum samples are collected at a specially designated site off the premises. Numerous examples were found of immediate microscopy of samples from people with suspected TB for rapid detection of the most contagious forms of the disease and urgent admission to hospital for isolated treatment.

7.3.2 Challenges

- Sputum smear-positive cases are not isolated.
- Infectious zones are not clearly marked or separated. Patients with XDR- and pre-XDR-TB are kept in the same unit.
- Most of the staff (including senior staff) do not use respirators or do not use them properly.
- The palliative care department is used to isolate highly infectious treatment failures (including XDR-TB) as well as socially “inconvenient” patients with DS- and/or poly-DR-TB, even after completion of treatment.
- HIV-positive cases are at high risk for superinfection.
- In the surgical department, sputum smear-positive patients and those with DR-, XDR and extra-pulmonary TB are mixed.

Personnel have a high incidence of TB, with three to four cases among 500–530 employees annually; thus, their risk is 12–16 times higher than that of the general population. This also suggests a high risk for nosocomial transmission of TB among patients.

8. Treatment and case management

8.1 Main recommendation

- Gradually replace hospital-based models of care by specific ambulatory care for all TB and DR-TB cases, including in children. Reinvest savings made by this reform accordingly. Support all patients in ambulatory care effectively to ensure treatment adherence, thus minimizing the risk for treatment interruption, failure and on-going TB and DR-TB transmission. Ensure sustainable incentives and enablers for all patients.

8.2 Specific recommendations

- Update the criteria for hospitalization to decrease the frequency of hospitalization and shorten stays.
- Prepare a national or *oblast*-specific model for ambulatory case management to ensure patient-centred care, including psychosocial support and education for all TB patients (including those with DR-TB and children).
- Prepare specific guidance for ambulatory case management.
- Revise the regulation for forced isolation of non-adherent TB patients. Prepare algorithms for the management of non-adherent cases, including legal aspects.
- Clearly define the responsibilities of all care providers. Improve coordination and collaboration between PHC, general health care and TB specialists.
- The regulations should be revised to allow all patients (including the "special contingent"[10]) to continue to work or study during treatment.
- Ambulatory health care providers should be trained in case management (including childhood TB).
- DOT should be ensured throughout treatment.
- All patients should be able to obtain psychosocial support.

8.3 Main findings (achievements, challenges and examples from field visits)

8.3.1 Achievements

- The health care system has been reorganized to provide family medicine.
- PHC services have begun to use the patient-centred approach for TB.
- Some sites are organizing treatment at home, whereby a family doctor or nurse takes drugs to patients.
- In the Global Fund project, Red Cross nurses provide DOT and social support at home.
- In TB hospitals, a psychologist or addiction expert provides assistance to all at-risk patients.
- Alcoholics receive psychological support, detoxification therapy and isolation during periods of delirium.

[10] The "special contingent" is a grouping carried over from the time of the former Soviet Union, which covers certain population groups, including children, teachers, doctors and prisoners.

- TB patients who are drug addicts receive daily methadone therapy after their TB drugs in hospital and in ambulatory care departments. This has improved treatment adherence to almost 100%.
- TB and MDR-TB treatment protocols for adults have been updated in accordance with the latest international recommendations
- Ambulatory treatment has been scaled up by the involvement of PHC practitioners and gradual introduction of outpatient care for MDR-TB patients.
- The treatment regimens and duration are adequate in most cases.

In 2014, the Ministry of Health approved new national guidelines on clinical management of TB and M/XDR-TB and of HIV/TB (order No. 1039 of 31 December 2014). The guidelines have been disseminated to all services and are widely used. Category I treatment is recommended for new patients with DS-TB, and a standard treatment regimen is recommended for MDR-TB under direct observation. The guidelines include a description of hospital-based case management and criteria for discharge from hospital but no detailed description of ambulatory care.

Hospitalization

Because of the current financing system, which is based on the funding indirectly linked to the number of hospital beds filled, long hospitalization of TB patients is still common. Patients stay in hospital during the intensive phase of treatment for DS-TB and for more than 6 months for MDR-TB. Many patients, however, are on so-called "holiday" during hospitalization, when for 30–60% of the time they self-administer their treatment at home.

Hospitals are not safe from TB transmission. The mission observed situations in which MDR-TB patients stayed in DS-TB departments for up to several months before receiving a correct diagnosis.

Forced isolation

Legislation in Ukraine allows forced isolation of non-adherent patients after a court decision. The mission heard many complaints that the system does not work properly, as patients can leave hospital after they have been admitted by the police. The regulations should be revised to ensure humanitarian, ethical isolation and means to improve adherence.

Ambulatory treatment

The health care system is being reorganized to include PHC in centres for family medicine, covering an average of 3500 people, with several ambulatory units. In ambulatory treatment, patients see a TB doctor and are then sent to the ambulatory unit close to their home for DOT. Nurses at the clinics are responsible for providing treatment and registering drugs and side-effects. Patients can see a doctor at the clinic if necessary, but many TB patients refuse to do so. If a patient does not come to take his or her drugs the next day, the nurse reports this to the doctor. The TB dispensary is responsible for tracing the patient and bringing him or her back for treatment. Some sites organize treatment at home, with the family doctor or nurse taking drugs to the patient.

Ambulatory treatment is becoming more widespread. Pilot regions for new models of ambulatory treatment have been established in Poltava and Mykolaiv *oblasts*. The number of TB patients receiving ambulatory treatment is 40–50 a day, of whom about half are DS cases and half MDR-TB.

With the move to ambulatory treatment and the financing of hospitals from *raion* to *oblast* budgets, many small TB hospitals have already closed.

Regulations for the so-called "special contingent" do not allow them to work or study during treatment.

Treatment outcomes

Treatment failure is not properly defined. Sometimes a doctor classifies a patient with MDR-TB at the time of diagnosis as failure if he or she refuses treatment.

The treatment success rate for new smear-positive non-MDR-TB patients is only 68%, due to a high mortality rate and failures. The reasons may be late diagnosis and late start of treatment, particularly for vulnerable populations and people with HIV infection. Loss to follow-up is about 7%. The situation is worse for bacteriologically confirmed retreatment cases, with a mortality and failure rate of 30% and a positive outcome in about 50%. Loss to follow-up and transfer out represent 8–20% of certain groups of patients. These groups should be observed more closely.

Table 4 shows that recording and analysis of outcomes are not in line with WHO-recommended categories for retreatment, and new definitions of patients after diagnosis by molecular methods have not been adapted; for example, rifampicin-resistant TB that is diagnosed only by molecular methods is registered as bacteriologically negative.

Table 4. Treatment outcomes of TB patients registered in basic management units as sputum smear (SS)- and/or sputum culture (SC)-positive or SS- and SC-negative, Ukraine, 2013

	New SS and/or SC positive		New SS and SC negative		Relapsed SS and SC negative		Relapsed SS and/ or SC positive		Other SS or SC positive		Other SS and SC negative	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total reported	14 588	100	10 495	100	94	100	3784	100	5584	100	4041	100
Transferred MDR-TB	2 673	18.3	146	1.4	14	39.7	1565	41.4	1884	33.7	177	4.4
Total evaluated	11 915	100	10 349	100	80	100	2219	100	3700	100	3864	100
Cured	6 640	55.7	-	-	-	-	959	43.2	1259	34	-	-
Treatment completed	1 454	12.2	8 459	81.7	54	67.5	240	10.8	489	13.2	2598	67.2
Died	1 479	12.4	690	6.7	12	15	437	19.7	740	20	417	10.8
Treatment failed	1 049	8.8	119	1.1	1	1	246	11.1	387	10.5	117	3.0
Lost to follow-up	734	6.2	478	4.6	7	8.8	227	10.2	566	15.3	422	10.9
Transferred out	244	2	248	178	1.7	1	41	1.8	119	3.2	111	2.9
Treatment success rate (cured and treatment completed)		67.9		81.7		67.5		54		47.2		67.2

Data from the national TB registry. No patients were still on treatment.

8.3.2 Main constraints

- Treatment is mainly hospital based. Patients stay in hospital during the intensive phase of treatment for DS-TB and for more than 6 months for MDR-TB.

- Long hospitalization of TB patients is still common. Treatment of children and adolescents is provided only in hospital, with very few exceptions.
- Limited ambulatory treatment is due to lack of preparedness of outpatient care providers and the current financing system.
- Old regulations for the so-called "special contingent" do not allow them to work or study during treatment.
- Old-fashioned treatment methods are used, such as transthoracic ultrasound with isoniazid to "improve cavity closure".
- Each *oblast* has a palliative care department, but clinical care, infection control and ethical aspects are not in accordance with international recommendations. Patients with DR-TB and DS-TB, during and after treatment, are hospitalized in the same wards.

9. Childhood tuberculosis

9.1 Main recommendations

- Update childhood TB control measures, including increasing coverage with BCG vaccination at birth from 65% to 95%, abolishing BCG revaccination at the age of 7 years, transforming annual mass screening with tuberculin skin testing in every child to focused, active case finding in risk groups and applying the WHO recommended scheme of preventive treatment in children with latent TB infection.
- Abandon the outdated strategy of hospitalizing children who are not ill (e.g. contacts of TB cases) and children with non-severe forms of TB, as this is a huge financial burden for the country, increases the risk for nosocomial TB transmission (especially of children without TB), is unethical and increases stigma and psycho-emotional trauma for children and their families.
- Urgently update TB diagnosis, treatment and prevention protocols, and introduce the latest international standards to ensure access to relevant diagnostic tools, adequate treatment regimens (including dosages) and isoniazid preventive treatment at an evidence-based dose and duration.

9.2 Specific recommendations

- Prepare and endorse new protocols for childhood TB in line with WHO recommendations.
- Change ministerial order No. 551 of 11 August 2014 on increasing vaccination in Ukraine, which regulates the national vaccination calendar, to abolish revaccination with BCG at the age of 7. Current BCG vaccination coverage at birth is low (65%) and should be increased to 95%, as in previous years.
- Change annual mass screening with tuberculin skin testing of every child aged 4–14 years to focused active case finding among contacts and well-defined risk groups. If the decision on BCG revaccination is approved, annual tuberculin skin testing of all children will be unnecessary, as it is done mainly to identify children for BCG revaccination. This could result in large savings and a reduced workload for PHC staff.
- Update preventive treatment protocols for children in line with WHO recommendations. Alternative preventive treatment regimens (such as isoniazid with pyrazinamide or streptomycin) should not be used.

- Allow the parents of children with TB (except in situations of reported parental negligence) to give them DOT and isoniazid preventive treatment.
- The existing children's TB sanatoria are used inappropriately and consume resources that could be used for other priorities in TB control. Close them or renovate them for other health care needs, such for social cases of TB.
- Organize training in the management of childhood TB at all levels of care, including ambulatory care, and also for academic personnel with teaching responsibilities, who update medical students and postdoctoral trainees.
- Strengthen contact tracing of emerging index TB cases, with contact investigation and in second and third social circles.
- Organize ambulatory treatment for children, and restrict hospitalization to severe forms of TB.
- Revise existing regulations to allow non-infectious children to go to school during TB treatment.
- Provide free access to WHO-recommended diagnostic tools, including tuberculin skin tests, computed tomography scans and Xpert MTB Rif.

9.3 Main findings (achievements, challenges and examples from field visits)

9.3.1 Achievements

According to the national surveillance system, the absolute number of new TB cases among children aged 0–14 years in 2014 was 473, corresponding to a rate of 7.4 per 100 000 population. In 2013, when all regions of Ukraine reported to the NTP (including Crimea, Donetsk and Luhansk), the number of newly notified cases of TB in children was 599, or 9.0 per 100 000.[11] TB was also notified in 286 adolescents (23.1 per 100 000) in 2014, which is fewer than in 2013, with 338 (24.7 per 100 000) in all regions of Ukraine. In children aged 0–18 years in 2014, 47 cases of TB/HIV, including 8 cases of MDR-TB/HIV, were notified.

In terms of TB prevention, there is a concern about the decrease in BCG vaccination coverage at birth to 65% (281 921 of 434 580 children eligible for BCG vaccination at birth had been vaccinated in 2014). Nevertheless, 21 982 children were revaccinated with BCG at the age of 7 years in accordance with ministerial order No. 551 of 11 August 2014, which is not currently supported by WHO.

Annual mass screening with tuberculin skin testing of all children aged 4–14 years (followed by mass fluorography screening for children aged ≥ 15 years) is closely linked to BCG revaccination at 7 years (a second revaccination at the age of 14 was abolished in 2011). Thus, 2 185 220 (36%) children had a tuberculin skin test in 2013. The estimated cost of mass screening, on the basis of 46 UAH (about US$ 2)[12] per tuberculin test (not including the cost of tuberculin syringes, PHC staff costs and the costs of retesting and investigation of false-positive cases due to a booster effect) is US$ 4 370 440 per year. Owing to a shortage of tuberculin, not all children were covered. During field visits to Mikolaiv region, PHC doctors responsible for conducting tuberculin skin testing agreed that mass annual tuberculin skin testing be reconsidered and that a focused intervention for high-risk groups would be more efficient. For example, 143 000 tuberculin skin tests were conducted in Poltava region in 2014 out of a population of 273 000 children aged 0–14 years. In the same year, TB was notified in 17 children (6 aged 0–14, 11 age 15–17 years); however, 50% of them were identified during contact investigation.

[11] http://ucdc.gov.ua/uk/statystyka/epidemiologiya, accessed 4 May 2015
[12] The estimate is based on the cost of a 10-dose vial of 464.25 UAH and the rate of US$ 1 = 25 UAH in December 2014.

The procedure for contact tracing could be improved substantially by extending investigations to "second-circle contacts", outside the households of index TB cases, with an algorithm for the responsibilities of TB specialists, PHC doctors and epidemiologists in contact investigation. Preventive treatment schemes for children who are in contact with people infected with TB infection differ from WHO recommendations in terms of drugs and duration. The mission found multiple examples of delayed diagnosis of TB, including MDR-TB, among children and adolescents due to insufficient contact investigation and follow-up.

Lack of clear diagnostic criteria and limited access to the necessary diagnostics in the regions (shortage of tuberculin skin tests in 2014, limited access to and cost of computed tomography scans) results in insufficient diagnostic capacity.

The requirement for obligatory hospitalization of all children during the intensive phase of TB treatment prevents those with non-infectious forms of TB from receiving ambulatory treatment when the family situation is favourable. According to national regulations, only nurses can give DOT to children, while WHO accepts parents as DOT providers, except in socially vulnerable families. In Ukraine, prolonged hospitalization is justified by the "social situation" at home, but it is clear that hospitalization is the main model of care mainly because of the current financing system. In one childhood TB department visited, only 11 of the 21 registered children were in hospital, as the others were on so-called "holiday" at home.

The unacceptable hospitalization of healthy children on the basis of contacts and tuberculin skin testing, with prescription of inadequate preventive treatment, continues. In addition to a huge financial burden, this practice causes physical and psycho-emotional trauma and stigma. For example, in Chernivtsi *oblast*, four children were notified with TB in 2014; the TB sanatorium for children has 160 beds, of which 112 were occupied during the visit.

9.3.2 Challenges

- The current rate of BCG vaccination at birth is only 65%, jeopardizing prevention of severe TB infection (meningitis and disseminated forms of TB) in children aged 0–5 years.
- The system of revaccination at the age of 7 years and annual mass screening with tuberculin skin testing to identify children eligible for BCG revaccination is not supported by WHO.
- The preventive treatment regimens for children are not in line with international recommendations.
- The diagnostic and treatment protocols for childhood TB are outdated, and new protocols have not been finalized. The available diagnostic tools, such as rapid laboratory diagnostics, are not properly used for children.
- TB drug dosages are not in line with the latest WHO recommendations. Annual mass screening with fluorography of all children aged 15–18 years (irrespective of history of TB contacts), introduced by order No. 327 of the Ministry of Health on 15 May 2014, is not supported by WHO.
- According to current guidelines, parents cannot give DOT or isoniazid preventive treatment to their children, increasing unjustified hospitalization and treatment in sanatoria.
- Children with non-infectious forms of TB are not allowed to go to school, and there are no other means of continuing their education during treatment.
- Contact tracing and follow-up are insufficient and are conducted mainly among household contacts.

Case study

An 18-year-old girl with fever, cough and other signs of late TB diagnosis was found to have confirmed sputum smear-positive MDR-TB. Her uncle had been diagnosed with MDR-TB 2 years previously; however, she was never examined or followed up as a contact because the uncle did not live in the same household and met her only occasionally.

10. Tuberculosis and HIV co-infection

10.1 Main recommendations

- Implement the WHO recommendations to start ART for patients with HIV infection (without TB) if their CD4 count is < 500.
- Ensure an uninterrupted supply of anti-TB drugs to all TB/HIV patients (including isoniazid preventive treatment), irrespective of whether the drugs are registered in Ukraine.
- Allocate earmarked resources from local and/or national budgets to support TB detection, contact tracing and treatment adherence in affected populations by social contracting mechanisms.

10.2 Specific recommendations

- Support TB/HIV coordination bodies at regional (*oblast*) level with allocated funds from local budgets to implement TB control activities among affected populations by social contracting.
- Enforce countrywide implementation of the approved guidelines for TB/HIV collaboration (Ministry of Health order No. 1039 of 31 December 2014), and extend ART and co-trimoxazole preventive treatment coverage from the reported 49% to ≥ 95%.
- Ensure rapid diagnosis of TB in people living with HIV through the network of laboratories conducting rapid molecular TB testing.
- Remove artificial barriers to the distribution of anti-TB drugs to TB and TB/HIV patients being treated in a region other than that in which they are registered.
- Extend isoniazid prevention therapy to people living with HIV at HIV/AIDS centres.
- Improve infection control measures, especially at TB facilities.
- Strengthen current contract tracing procedures for index TB patients with HIV infection.
- Ensure that ART is initiated rapidly for TB/HIV co-infected patients

10.3 Key findings (achievements, challenges and examples from field visits)

10.3.1 Epidemiology

Ukraine is a high HIV-burden country, with an estimated 210 000 (180 000–250 000) people living with HIV and a prevalence rate of 0.8% (0.7–1.0%) among adults aged 15–49 years in 2013.[13] The prevalence of HIV infection increased steadily over the past 5 years, and the number of cases of TB/HIV co-infection has increased even more rapidly since 2012. WHO estimated that there were 7100–7200 cases in 2013, corresponding to an incidence rate of 16 per 100 000. TB remains the leading cause of death among

[13] http://www.unaids.org/en/regionscountries/countries/ukraine

people living with HIV, with an estimated 1300 (960–1700) deaths in 2013. According to data reported in 2013 to WHO, 42 213 (88%) of all TB patients knew their HIV status, and 8290 (20%) had notified TB/HIV. Of all notified TB/HIV cases, 3949 (48%) were on ART and 4092 (49%) were receiving co-trimoxazole preventive treatment. The number of people living with HIV who received isoniazid preventive treatment in 2013 was 15 816. (For further details see Hovhannesyan et al., 2015.[14])

Significant progress has been made in collaboration on TB and HIV since the previous review, as the UCDC is coordinating programmes on both, including monitoring and evaluating the performance of the programmes and keeping a register of both TB and HIV cases. Since 2013, a national e-TB register has been operational, which is the main indicator of collaboration on TB/HIV. This can be considered a major achievement.

Ministry of Health order No. 1039 of 31 December 2014 on a comprehensive clinical protocol for providing health care for TB/HIV at primary, secondary and tertiary institutions sets the policy for collaboration on TB/HIV and was being implemented in the regions that were visited. The order is in line with WHO recommendations and describes the main areas for collaboration between the programmes.

During the field visits, good collaboration was observed with opioid substitution treatment services. For example, in Poltava, one of the opioid substitution treatment centres is sited in the TB facility, with good adherence of patients to treatment.

10.3.2 Reducing the burden of TB in people living with HIV

Ukraine is considering adopting the new WHO recommendation to initiate ART in all patients with a CD4 count < 500, as this measure might also reduce TB mortality and severe morbidity in people living with HIV. In Ministry of Health order No. 551 of 12 July 2010 on approval of the clinical protocol for administering ART to adults and adolescents, ART treatment will be given to patients with a CD4 count of ≤ 350.

Isoniazid prevention therapy is organized at HIV/AIDS centres, and collaboration with the TB programme was well established at the sites in Poltava, Kremenchuk and Mikolaiv regions that were visited. Isoniazid is provided by the TB service to HIV/AIDS centres and recommended for self-administration by all people living with HIV at a dose of 5 mg/kg body weight for at least 6 months. In Poltava, the NGO "Light of hope" provided TB/HIV services, including isoniazid prevention therapy.

TB screening questionnaires have been introduced in HIV facilities, and rapid molecular tests (Xpert MTB/RIF) have been introduced for people living with HIV and presumptive TB in the regions visited. Sputum specimens from symptomatic people living with HIV were collected at the AIDS centres in Poltava, Kremenchuk, Vinnytsia and Chernivtsi and delivered for diagnosis to TB facilities; however, rapid diagnosis with Xpert MTB/RIF is not evenly distributed in the country, with shortages of cartridges in some regions.

One of the best practices in Poltava, Vinnytsia and Chernivtsi was the presence of an HIV specialist on the staff of the TB dispensaries and a TB specialist as part-time staff of the HIV/AIDS centre. This ensures good collaboration in rapid diagnosis in symptomatic people living with HIV and good access to Xpert MTB/RIF diagnostics (Poltava, Kremenchuk and Mikolaiv). Infection control measures are well observed in HIV/AIDS facilities but pose a major challenge at inpatient TB facilities. The responsibilities of PHC and TB specialists in contact tracing are described in Ministry of Health order No. 620 of 4 September 2014, but a more unified approach is required, especially in investigations in the second circle of contacts.

[14] Hovhannesyan A, Motrich I, Dadu A. Tuberculosis in Ukraine: epidemiological impact analysis. Copenhagen: WHO Regional Office for Europe; 2015

Artificial barriers were observed in access to anti-TB drugs for TB/HIV patients registered in other regions but who were receiving their treatment in Kyiv. Because of the requirements for reporting to the national e-TB register, the procedure for reallocating anti-TB drugs for TB patients who move to another region is cumbersome.

10.3.3 Reducing the burden of HIV in patients with TB/HIV

Almost all TB patients are tested for HIV at TB facilities (88% TB patients knew their HIV status in 2013) by rapid test procedures, ensuring a timely start of ART. No delays in the start of ART were observed in the regions visited.

According to Ministry of Health order No. 1039 of 31 December 2014, ART is administered to all TB patients; in 2013, 48% of all TB/HIV patients were receiving ART. Co-trimoxazole preventive treatment is recommended for all TB/HIV patients in accordance with order No. 1039. In 2013, 49% of patients with TB/HIV were covered.

Infection control measures were observed in HIV/AIDS centres, with a separate flow of patients with cough, and use of personal protection (surgical masks for patients and respirators for staff). TB treatment for TB/HIV patients is, however, given at TB hospitals, which have suboptimal infection control measures and thus a risk for nosocomial transmission of DR-TB strains.

10.3.4 Challenges

- An important measure for preventing TB in people living with HIV is to extend coverage of ART to those with a CD4 count of ≤ 500, which is higher than that recommended by WHO. More funding will be needed.
- Access to rapid molecular laboratory diagnosis of TB in symptomatic people living with HIV should be ensured by improving the logistics for sputum transport, providing sufficient cartridges for Xpert MTB/RIF and installing Xpert MTB/RIF machines in large HIV/AIDS centres.
- Activities are being conducted to reduce the burden of TB in people living with HIV; however, artificial barriers and ineffective logistics for ensuring the supply of anti-TB drugs and isoniazid limit collaboration and increase the costs and the workload.
- Apart from Global Fund support, there is little social contract funding from local budgets for NGOs to support TB control-related activities.
- Passive case detection is conducted only once a year.
- Isoniazid preventive treatment is not widespread.
- HIV-infected TB patients, including cases of extra-pulmonary TB undergo unnecessary, prolonged hospitalization.

11. Drug-resistant and multi-drug-resistant tuberculosis

11.1 Main recommendations

- Ensure access to adequate treatment (including the fifth group of anti-TB drugs and compassionate use of new anti-TB drugs) for all XDR-TB patients to halt further development of resistance and to limit transmission of XDR-TB.
- Introduce new, shorter treatment regimens and new anti-TB drugs under operational research conditions in line with WHO recommendations (including pharmacovigilance), thus improving treatment outcomes, ensuring patient-oriented care and decreasing treatment costs.
- Ensure palliative care for patients in whom treatment of DR-TB has failed by preparing and introducing national guidelines for palliative care and establishing treatment facilities with adequate case management and proper infection control.

11.2 Specific recommendations

- Properly monitor, diagnose and record adverse reactions to TB drugs (pharmacovigilance).
  - Introduce all necessary tests (including for renal function, thyroid hormones, lipase, electrolytes, audiometry).
  - Use an analysis of the number and type of side-effects to forecast and procure ancillary drugs for hospital-based and ambulatory care.
- Establish a legal framework for compassionate use of new TB drugs and for importation of new anti-TB drugs.
- Introduce adequate treatment regimens for XDR-TB. Clearly describe regimens for pre-XDR and XDR-TB in a protocol, and train staff members (starting with members of MDR-TB consiliums[15]) in the management of XDR-TB.
- Prepare national guidelines on palliative care for terminally ill TB patients.
- Extend the responsibilities of consiliums to provide more follow-up and monitoring of MDR-TB programme performance and treatment outcomes and to provide supportive supervision and training for regional staff.
- Provide regular advanced training for consilium experts to ensure that their information is up to date.
- Analyse the situation with regard to patients with poly-DR-TB to assess their risk for developing MDR-TB.
- Plan management of poly-DR-TB cases in close collaboration with laboratory experts.
- Improve communication between clinicians and laboratory experts to ensure the most effective use of laboratory diagnostics in clinical decision-making.
- Analyse the reasons for poor treatment outcomes, and prepare a plan to address the situation.
- Register all MDR-TB patients in a database, including those in the penitentiary system and homeless patients.

[15] Consiliums, consisting of panels of experts, are established in each *oblast* TB dispensary to confirm MDR-TB diagnosis and treatment.

- Ensure timely initiation of MDR-TB treatment.
  - Improve communication with the laboratory component, which should be part of the registration system.
  - Introduce centralized follow-up of the results of drug susceptibility testing to ensure that they have reached clinicians and to determine whether the case has been reviewed by the consilium, whether treatment has been started and whether the patient is registered on a TB registration form or in e-TB manager.
- Change the system for supply of second-line drugs to hospitalized patients to avoid a delay in treatment after hospitalization. The supply should be based on monthly drug consumption, the number of patients on treatment and the treatment regimens.
- Organize operational research on new drugs and new regimens.
- Train human resources in proper use of the new definitions of palliative care, case management and the algorithms for early diagnosis of MDR-TB and immediate start of treatment, and define responsibilities and functions.
- Prepare protocols for the management of pregnant women with TB, and train staff in their use.

11.3 Main findings (achievements, challenges and examples from field visits)

11.3.1 Achievements

- The MDR-TB treatment regimens used are in accordance with the Ukrainian national treatment protocol, which is in line with international standards.
- Drug prescription is the responsibility of a central consilium based in *oblast* TB dispensaries. Timely initiation of treatment (based on the results of Xpert MTB RIF) is increasing.
- Patients with different types of resistance, including mono- and poly-DR, are separated in different hospital departments.
- Outpatient treatment for DR-TB is begun earlier and is also provided at district level.

11.3.2 Management of M/XDR-TB

Ukraine uses a standard MDR-TB treatment regimen in accordance with the Ukrainian national treatment protocol accepted in 2014, which is in line with international standards. Drug prescription is the responsibility of consiliums based in *oblast* TB dispensaries, which prescribe mainly treatment with second-line drugs. Because of better diagnostics and the fact that not all MDR-TB cases are recorded, the drug supply is sometimes limited, and, at *oblast* level, access to group-5 drugs for XDR-TB is very limited. Most XDR-TB patients receive only standard MDR-TB treatment and fail it; they thus remain infectious for months but are hospitalized with other patients, exacerbating the risk for nosocomial transmission of XDR-TB. All the necessary drugs are available at the central research institute, and XDR-TB and other severe cases are managed properly; however, only a limited number of patients manage to be admitted to this hospital through various channels, resulting in an unethical situation in which only a few "lucky" XDR-TB patients have access to adequate treatment. Timely initiation of treatment is based on the results of Xpert MTB RIF; however, the consilium often sees patients very late. Communication between clinicians and laboratory experts should be improved to ensure early reporting of rapid diagnostic results and detection of MDR-TB, so that resistance to rifampicin can be monitored and

discrepant results can be resolved. To ensure timely access to laboratory results, the TB registry should have a laboratory component, and the system of reporting of results should be streamlined.

Regional consiliums are established and functioning, but their activities are limited to reviewing individual cases. The responsibility (and capacity) of each consilium should be extended to include not only individual patient management but also MDR-TB programme management in each *oblast*. This would include monitoring, supportive supervision, training, case management and prevention of new MDR-TB cases.

A standard treatment regimen is prescribed for pan-DR-TB cases; the risk for MDR-TB is often not evaluated, which can lead to the development of pre- and XDR-TB.

During 2012, 27 extra-pulmonary MDR-TB patients, representing 0.6% of all treated MDR-TB patients, received MDR-TB treatment, and 56% were cured or completed treatment. Treatment outcomes are extremely bad: the average treatment success rate is 33.9% (Table 5). The highest success rate was 53.7% among newly diagnosed cases, but this is much lower than the 80% in international data. The low success rates are due mainly to very high mortality and treatment failures, ranging from 21.7% to 58.2% in different patient groups (average, 42.8%).

Table 5. Treatment outcomes among MDR-TB patients registered for treatment in 2012

	Total registered for MDR-TB treatment		Newly diagnosed MDR-TB		Relapsed diagnosed MDR-TB		Loss to follow-up		Treatment failure on one regimen		Retreatment failure		Other MDR-TB	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total evaluated	3955	100	1110	100	720	100	401	100	369	100	717	100	611	100
Cured	1026	25.9	426	43.7	199	27.6	79	19.7	100	27	117	15.3	85	14
Treatment completed	314	8	108	9.7	61	8.4	23	5.7	38	10	37	5.1	39	6.4
Died	1101	27.8	136	12.2	199	27.6	134	33.4	90	24.3	227	31.7	219	35.8
Treatment failed	601	15	105	9.5	100	13.8	66	16.4	50	13.5	152	21	137	22.4
Lost to follow-up	570	14.4	140	12.6	105	14.6	69	17.2	55	15	115	16	82	13.4
Still in treatment	167	4.2	40	3.6	30	4.1	14	3.5	22	6	37	5.2	28	4.6
Transferred out	176	4.5	55	5	26	3.6	16	4	14	3.8	32	4.4	21	3.4
Treatment success rate (cured and treatment completed)		33.9		53.7		36		25.4		34.3		20.4		20.4

Data from the national TB registry

The risk for amplification of resistance in cases of poly-DR-TB is due to insufficient awareness and "conflict" with laboratories about additional testing. Group-5 drugs are needed to manage XDR-TB, and additional finances are urgently needed from the Global Fund or the Government. A legal framework should be established for compassionate use and for importation of new anti-TB drugs into the country.

After prescription of a treatment regimen with second-line drugs, patients are transferred to an MDR-TB treatment facility. Because of inadequate drug management, treatment initiation is delayed for an additional 6 days. A similar situation arises when patients are discharged from hospital to ambulatory care.

11.3.3 Management of side-effects

The side-effects of drugs are not managed or registered properly. On average, adverse events are registered for < 10% of MDR-TB patients. Access to some of the main tests for detecting side-effects is very limited in the regions, including electrolyte, renal function and thyroid hormone tests and audiometry. Access to ancillary drugs is very limited in all treatment facilities.

11.3.4 Palliative care

Palliative care departments are established in each *oblast*, but they do not function in accordance with international recommendations regarding clinical aspects, infection control and ethics. Generally, patients receive palliative care in separate rooms in hospital MDR-TB departments, or they are treated at home. Patients with all types of TB who are receiving palliative care are hospitalized in the same wards as patients with XDR-TB or DS-TB, after treatment or while on treatment for "social" cases (e.g. homeless people and ex-prisoners).

There are no clear definitions of "palliative care" and "end-of-life care". The term "palliative care" for TB patients is generally used incorrectly, with many different interpretations. Patients who could be cured are placed in palliative care if their treatment was interrupted several times before the start of MDR-TB treatment, they refused treatment or could not be encouraged or motivated to start (or not interrupt) their treatment.

11.3.5 Main constraints

- Not all MDR-TB patients receive treatment; short waiting lists are kept in the regions.
- Not all MDR-TB cases are registered (such as homeless people and ex-prisoners).
- Treatment is mainly in hospital.
- Registration, diagnosis and management of drug side-effects is suboptimal.
- DR-TB treatment failures are hospitalized with people with all types of TB on the basis of the patients' social profile.
- There is no clear protocol for treatment of XDR-TB, and access to group-5 drugs is very limited; these patients are often prescribed the regimen used for MDR-TB. Inadequate treatment of XDR-TB leads to a very high failure rate and creation or transmission of increasing drug resistance.
- New drugs are available only for clinical research in the TB institute and not for wider use.
- The rigid system for drug delivery to treatment sites leads to treatment delays and prolonged hospitalization.
- The risk for amplification of resistance in cases of poly-DR-TB is due to insufficient awareness and "conflict" with laboratories about additional testing.

- Inadequate infection control leads to transmission of XDR-TB, exacerbated by the proximity of DR-TB treatment failures with patients with all types of TB on the basis of the patients' social profile.
- Treatment failures are given palliative care. There are no specific facilities for palliative care and no clear definitions of palliative care or end-of-life care.

12. Human resources

12.1 Main recommendations

- Merge the two specialties of pulmonology and TB into one respiratory disease speciality, including in pre- and post-graduate education and specialization. Harmonize the pre- and postgraduate curricula, and revise them in accordance with new approaches to TB care.
- Review human resources plan and task profiles of staff in line with projected changes (childhood TB, strengthening of ambulatory model of care, introduction of new staff to ensure patients adherence to treatment such as social workers, psychologists, visiting nurses).
- Increase the salaries (incentive) for TB physicians and nurses and PHC staff involved in TB care by using the savings made by reducing the number of beds for TB patients and cost–efficiency measure.

12.2 Specific recommendations

- Improve the status of health care professionals working in TB care by increasing their salaries with the savings made by reducing the number of beds, by supportive supervision and by training in communication for dealing with "challenging" TB patients.
- Develop a mechanism for contracting PHC nurses (or social workers) to administer DOT to vulnerable and difficult-to-reach TB patients during ambulatory treatment, using the example of Red Cross workers in the Global Fund project.
- Introduce the WHO-recommended practical approach to lung health to help PHC staff improve the diagnosis and management of patients with respiratory conditions (including TB).
- Ensure that all PHC and TB staff are insured against occupationally acquired TB or DR-TB.
- Train academic personnel, conduct international training, and train trainers to support reforms in TB control.

12.3 Main findings (achievements, challenges and examples from field visits)

12.3.1 Achievements

During the field visits and consultations with national specialists, improvements were reported in understanding of the key aspects of the TB and MDR-TB control programme; in many cases, however, the level was still insufficient. Existing human resources are aligned with the hospital model of treatment and are not used optimally. Understanding in several areas, such as childhood TB and TB management in special situations such as pregnancy is very limited.

Supportive supervision is insufficient; it should gradually replace the command-and-control style of supervision. In some regions, leading staff members did not have up-to date-knowledge. For example, hospital directors and deputy directors did not use basic infection control measures.

Regular under- and postgraduate medical training should be aligned with international standards and WHO approaches to ensure the sustainability of the human resource development plan for TB control. Academic staff should take part in international courses on TB and MDR-TB control in a train-the-trainers approach.

Although there is a common under- and postgraduate curriculum and common academic chairs of pulmonary TB at the medical universities, in practice two separate specialties (pulmonology and TB) exist in parallel. Currently, there are 514 pulmonologists and 2381 TB specialists in Ukraine. The pulmonologists have insufficient knowledge about TB and refer patients with presumptive TB to specialists for diagnosis and treatment. Post-graduate specialization and qualification approval are different for the two specialties. Pulmonology is perceived as more attractive by young physicians, with much better indicators of staff drain and vacant positions at regional and district levels. Specialization in TB takes 1.5 years, and, after specialization, post-graduate courses must be attended not less than once every 5 years in order to renew qualification as a TB specialist. The numbers of TB specialists on the payroll at regional and district levels are calculated as follows:

- at TB hospitals: one TB specialist salary payroll unit per 30 beds for DS-TB or per 15 beds for MDR-TB; and
- in ambulatory care: one TB specialist salary payroll unit per 20 000 population and one childhood TB specialist per 200 000 population.

In 2014, in Ukraine (with the exception of the uncontrolled territories), 2381 positions out of 2667 planned salary payroll units were occupied, including 1529 staff working in polyclinics and coordinating ambulatory care for TB patients. The overall shortage of TB staff is greater in the eastern parts of Ukraine. Table 6 shows the numbers of salary payroll units and occupied positions in 2014.

Table 6. Numbers of salary payroll units and occupied positions in Ukraine, 2014

Specialty	TB specialist positions (salary staff payroll units)			
	Total in TB programme		Including polyclinics	
	Planned	Occupied	Planned	Occupied
TB specialists	2677	2381	1734	1529
TB laboratory specialists (physicians)	4962	4314	1283	1127

The low status of medical staff working with TB patients in Ukraine is well recognized. Although staff salaries account for 57% of all costs of TB hospital treatment, individual salaries for TB physicians and nurses are insufficient and not competitive enough to attract young doctors and nurses. For example, the starting monthly salary for a young doctor who has just specialized in TB is UAH 2500 (US$ 100), and that of a nurse at a TB facility is UAH 2100 (US$ 84). There is no system of professional insurance or compensation (including priority access to all treatment options) for professionally acquired TB. In addition, there is no training in communication with difficult patients; aggression at the workplace by patients addicted to alcohol or drugs poses a challenge for retaining staff in TB care. For example, creation of a police post at the TB hospital in Mikolaiv improved the security and working conditions of staff.

The current human resources plan is oriented towards a purely hospital-based model. There are no social workers, psychologists or visiting nurses at TB hospitals or outpatient TB dispensaries, although these cadres are necessary to deal professionally with the social issues of TB patients, including psychological, social and legal support to improve their adherence to treatment. In many cases, such activities are conducted by an NGO, where one exists, for example in Poltava.

An important recent achievement is integration of PHC services into TB control, with decentralization of DOT to family medicine centres (polyclinics) close to patients' residences and at PHC settings in rural areas. There is no mechanism, however, for paying a PHC nurse or social worker for conducting DOT for difficult-to-reach TB patients, who require frequent home visits. In the Red Cross (Global Fund) project in Mikolaiv region (Balovnoye family doctor practice), PHC staff were contracted to conduct DOT for 600 UAH (US$ 25) per patient, which was perceived as a good incentive and was effective and acceptable to those involved. Two other TB patients on DOT at the same practice were supervised by a PHC nurse free of charge.

12.3.2 Challenges

- In spite of common pre- and post-graduate curricula in the field of pulmonary TB, in practice there are two separate specialties, pulmonologist and TB specialist, with different specialization categories and career paths and little interaction. Young doctors perceive a career in pulmonology as more attractive than one as a TB specialist. In small districts with a shortage of TB specialists but where the positions of pulmonologists are occupied, the latter do not taking over the functions of a TB specialist.
- The current human resources plan in TB control is hospital-oriented, with insufficient capacity to provide patient-centred care and adherence to treatment in the ambulatory phase. No auxiliary staff (psychologists, social workers, coordinators for ambulatory treatment, visiting nurses conducting TB detection and treatment for vulnerable groups) are present in TB hospitals or at outpatient TB facilities.
- The low status of professionals working in TB care is due to low salaries, insufficient supportive supervision and training and lack of insurance against contracting TB at work.
- Except for the Red Cross initiative in the Global Fund project, there is no mechanism for contracting PHC nurses or social workers to conduct DOT with vulnerable TB patients, who require frequent (or daily) visits by a nurse or social worker during ambulatory treatment.
- The pre- and postgraduate curricula for medical students should be updated to include the most recent approaches of the STOP TB strategy.
- Primary care staff should have clearer guidelines for detecting and dealing with respiratory diseases (WHO *Practical approach to lung health*).

13. Control of tuberculosis in prisons

13.1 Main recommendations

- Improve coordination of TB control activities between the penitentiary and civil health care systems at all levels to ensure equitable health care provision.
- Define mechanisms for collaboration between prison medical and non-medical services (e.g. security staff) to ensure optimal implementation of TB control in the penitentiary sector.
- Facilitate the provision of standardized TB control measures in all prison facilities, and ensure full integration into the NTP in 2017–2021. Develop a cross-sectoral framework with the Ministry of Justice within the NTP.

13.2 Specific recommendations

- Organize an international mission to assess the organizations that provide medical services in the penitentiary system of Ukraine, with the aim of making specific recommendations for optimizing TB activities.
- Prepare a joint inter-ministerial (with the ministries of Health and Internal Affairs) regulation to ensure direct transport of prisoners with suspected TB to TB institutions (with a special escort) in order to diagnose and initiate treatment as well as to reduce the risk for infecting other prisoners and escorting officers.
- Strengthen cooperation with civil and health NGOs to improve the detection of TB, adherence to treatment, further treatment and joint training of medical and non-medical prison personnel.
- Improve TB infection control in the penitentiary services by assessment and improving administrative, environmental and personal protective measures.
- Devise standards for palliative care and the detention conditions of prisoners with MDR- or XDR-TB.
- Ensure that the treatment outcomes of transferred outpatients are registered.

13.3 Main findings (achievements, challenges and examples from field visits)

13.3.1 Achievements

- Healthy prisoners have good understanding of TB, including the steps to be taken when the first signs of TB appear.
- At regional level, NGOs run programmes to prepare prisoners for release; however, some beneficiaries are lost when they move to other regions. No records are kept at central level on released prisoners who had TB or on their treatment outcome.
- Case finding is based on the former Soviet approach of fluorography. All prisoners who enter the system have a chest X-ray ("entry screening"), in addition to a general medical examination. Those who are suspected of having TB are isolated in quarantine for further investigation. Entry screening is complemented by mass fluorography of all prisoners every 12 months.
- Cases of TB among prisoners represented 6% of the TB burden in Ukraine in 2013.
- Integrated services for the diagnosis and treatment of TB and HIV exist, but there is no opioid substitution treatment.
- Since 2014, the penitentiary system has entered data on prisoners with TB into a single national electronic registry.
- Prisons have access to rapid methods of TB diagnosis (Mycobacterium growth indicator tube, GeneXpert).

13.3.2 Challenges

- Funding is lacking for TB prevention and treatment programmes in prisons. Maintenance of equipment is covered by the institution budget (production income) and is not a high priority for the non-medical prison administration.

- There are not enough medical personnel and no strategy for strengthening human resources, which would include staff training, support in case of need and adequate remuneration to ensure the quality of services and retention of staff.
- Little attention is given to infection control in administrative and organizational activities.
- There is little cooperation with the civilian medical system, especially for external quality control of diagnosis and treatment. Investigations on drug resistance should be coordinated with the civil sector to ensure their quality.
- Anti-TB drugs for the penitentiary system are purchased separately from the Ministry of Health.
- There are no internal provisions for the management of prisoners with diagnosed or suspected TB (such as basic infection control); for the distribution of responsibilities of prison staff other than medical personnel, who follow a relatively standardized protocol set by the Ministry of Health; or for defining the responsibilities of medical and non-medical staff in implementing TB control at all levels, such as the role of the supervisor in DOT or in patient distribution to wards, the role of psychologists in adherence to treatment and default prevention and an algorithm for dealing with patients who are coughing on daily rounds.
- Prison staff must be trained in infection control measures and a multidisciplinary approach to TB case management in all prison services.
- People with diagnosed TB when they enter prison are recorded by civilian TB services but not by the prison system. Consequently, access to treatment might be limited if there is weak cooperation between civilian and prison health care services. This is also the case with admission to a detention centre of prisoners from other regions, as administrative services are "unwilling" to register them in the civil list or the prison system.
- Prisoners are often transported for TB treatment out of their region of residence; therefore, when they are released, further treatment and social support are complicated.
- The time from having suspected TB to admission to hospital for treatment ranges from 1 or 5 days to 1 month, with intermediate stops at other institutions because of lack of a direct escorti to TB facilities.
- The treatment success rate in 2013 in Ukraine was 63%, while that in prisons was 46.3%.
- The proportion of patients with new sputum smear-positive pulmonary TB in prisons is 11.3%.
- A high treatment failure rate (12.1% among new sputum smear-positive pulmonary TB patients) and a high mortality rate (12.2%) were seen in 2013 in the prison system.

14. Advocacy, communication and social mobilization

14.1 Main recommendation

- Prepare a strategy for advocacy, communication and social mobilization in line with the changing approaches of the NTP that will include community participation and social mobilization.

14.2 Specific recommendations

- Find a mechanism for continuous monitoring and evaluation of the efficiency and quality of services, activities and events delivered by community organizations, using WHO indicators related to TB and

HIV programmes, including prevention, care, support and funding programmes; consider environmental issues and factors that impede effective control of TB, including violation of human rights, criminal activity and gender inequality.

- Involve NGOs and networks that represent communities of TB patients in monitoring visits and missions by national and international experts in order to build their capacity for advocacy, communication and social mobilization at all levels.
- Give groups, organizations and networks that represent the community of TB patients access to technical, material and financial support. Create groups for reciprocal psychosocial support among both hospitalized and outpatient TB patients.
- Find a system for local budget funding for the detection and treatment of TB in vulnerable groups by NGOs and medical institutions, including funding mobile teams, paying nurses who collect sputum or conduct DOT, the transport of patients, social support for patients and creating centres for integration. Experience in Poltava showed that the local budget could fund social and health programmes for vulnerable groups.
- Involve the medical, social and NGO spheres in joint TB activities for detection, treatment, support, infection control, ethics, human rights, integration of services and multidisciplinary work, as well as a charter for TB patients.

14.3 Main findings (achievements, challenges and examples from field visits)

14.3.1 Achievements

- Two Global Fund recipients are NGOs.
- NGOs are represented on the coordinating council for TB and HIV control at national and regional levels.
- Experience in Poltava showed that social programmes for vulnerable groups can be financed from the local budget.
- Information materials are available for the general population and for vulnerable groups, including the "TB patients' charter".
- NGOs work with HIV-infected people in harm reduction and identifying and treating TB.

14.3.2 Challenges

- There is no national strategy for advocacy, communication and social mobilization.
- Activities are financed mainly by external donors through grants to NGOs.
- The health system shows little interest in using the good practices of NGOs, including health care for vulnerable groups such as former prisoners, injecting drug users and homeless people.
- Training of medical staff and NGO representatives is usually organized separately.
- Because of reduced external financing, NGOs no longer identify TB cases in vulnerable groups by collecting sputum samples at places where people exchange syringes. With the involvement of personnel of the TB services, a fee is now charged to bringing clients to the clinic for collection of sputum. This is not a patient-oriented approach, as it creates an organizational barrier and reluctance on the part of the patient.

- Social support for patients who are not in the Global Fund cohort is fragmentary, and there is no system for reporting on this component. For example, the travel expenses of patients to hospital should be covered by the regional budget, but in practice they are not.
- NGOs and communities participate only marginally in monitoring visits by national and international experts.
- There are few organizations of TB patients and former patients, and they are weakly involved.
- There is not enough training in helping patients adhere to treatment.

15. Vulnerable populations and social determinants of tuberculosis

15.1 Main recommendation

- Extend the access of vulnerable groups to rapid TB laboratory diagnosis and patient-oriented care. Ensure the sustainability of activities in these population groups that are currently implemented by NGOs through social contracting, with funding from local (regional or district) budgets. Support service provision to vulnerable groups close to their area of residence, extend harm-reduction programmes, and deploy mobile multidisciplinary teams with the required equipment and consumables.

15.2 Specific recommendations

- Establish a social centre for disadvantaged people ((intravenous drug users, homeless people, ex-prisoners, HIV-positive TB patients), including
  - social contracting, with funding for NGOs from the State budget;
  - provision of methadone substitution therapy, ART and TB treatment in one place;
  - provision of shelter, passports, education, encouragement for re-employment and co-financing for accommodation.
- Support the involvement of NGOs in their work with vulnerable groups.
- Use the State budget to support NGOs by reallocating existing funds.
- Conduct operational research in vulnerable populations on the social determinants of TB at national and regional level, such as:
  - risk factors of vulnerability to TB in alcohol, drug and tobacco users;
  - causes of death among patients with TB/HIV co-infection; and
  - the preferences of vulnerable groups for social support to adhere to treatment.
- Disseminate the good practices of NGOs for detecting and treating TB in vulnerable populations at national level, and encourage funding from local budgets.
- Develop a mechanism or algorithm to ensure priority access of vulnerable groups to rapid TB diagnosis.
- Find a mechanism for addressing the combination of TB and alcohol abuse, which is a common reason for discharge from hospital or non-adherence to outpatient treatment.

15.3 Main findings (achievements, challenges and examples from field visits)

- Activities for vulnerable groups are financed mainly by donors. Good practices such as collection of sputum by a dispensary nurse at places where drug users exchange syringes instead of after preliminary screening at the hospital have been changed, because of limited resources, to support in a medical facility. Active intravenous drug users are unwilling to visit health facilities and refuse to be examined; this is therefore an organizational barrier to the diagnosis of TB.
- The required examination procedures for groups at risk for TB (microscopy, GeneXpert, X-ray) are available, but these groups do not have priority for access to rapid diagnostic methods if there is a large volume of biological material.
- Social support is provided only to patients in the Global Fund cohort. Most TB patients in the country who are treated with TB drugs procured by the State or local governments do not have social support.
- Homeless people with TB are usually not registered, as they do not have residential registration (*propiska*) (see below).

16. Ethics and human rights

16.1 Main recommendations

- Ensure universal access to TB diagnosis and good-quality TB and DR-TB treatment for all patients with TB, irrespective of their social status, comorbid conditions or poor treatment adherence in the past.
- Provide social support (living place, incentives and enablers) to all TB and DR-TB patients who require it during ambulatory treatment, irrespective of the form of TB or funding source, by using funding from local budgets.
- Revise existing legislation on coercive treatment (isolation). Find the necessary legal support to use other means, such as social support, incentives and enablers, before considering coercive measures.
- Revise the definition of "palliative care", align it to international standards, and add it as an amendment to the national TB protocol for immediate implementation.
- Systematically include socially disadvantaged patients, especially homeless people, in TB registers, even if they have no residential registration (*propiska*).

16.2 Specific recommendations

- Prepare specific guidelines or a protocol for NGOs conducting activities with vulnerable population groups for early detection of TB and ensuring adherence to treatment.
- Organize specific training for NGO staff and medical staff in communicating with patients in vulnerable groups and in reducing stigma.
- Protect patients and staff from TB by improving infection control.
- Establish a legal basis for ensuring that infectious TB patients do not put others at risk for infection because they do not respect the principles of infection control.
- Ensure equitable approaches for TB detection, treatment and medical, social and psychological follow-up until completion of treatment for both civil and prison populations. Social follow-up

should be continued at places of residence, as many patients in the regions have little chance of survival.

- Strengthen the education of patients, medical personnel and NGO representatives on human rights and the principles of the charter for TB patients in the context of national and international legislation.
- Study the impact of social support on the results of treatment, and conduct a survey of the level of satisfaction of TB patients with medical and social services.
- Provide DOT at all stages, and ensure that each patient signs a contract with the nurse responsible for DOT defining his or her responsibilities.
- Offer legal training for people who live with or are affected by TB, and ensure their access to community workers for advice on legal issues or legal aid programs.
- Organize training in human rights for Government officials, health workers and prison staff.
- Prepare reports for the civil sector on the identification of TB cases in prisons and the results of treatment for TB patients released from prison. Then, make the necessary changes in the national TB registry. Also, include data on TB patients released from prison in national, regional and district statistical reports.
- Ensure equitable care for TB and DR-TB in all the *oblasts* of Ukraine.

16.3 Stigma and access to good-quality care

TB is mainly a disease of socially disadvantaged people and is often associated with other diseases, social status or behaviour. There is no institutionalized programme for socially disadvantaged patients with suspected TB, such as homeless people and ex-prisoners. Although Médecins Sans Frontières programmes in Donetsk and Dnepropetrovsk regions are showing the benefits of social follow-up of ex-prisoners with TB, this is not common practice in other regions. NGOs that are sub-recipients of the Global Fund grant conduct harm-reduction activities for intravenous drug users with HIV/TB co-infection, including opioid substitution treatment; however, these activities lack coverage, and will have no sustainable financing after the end of the Global Fund grant in 2016. Many homeless people with TB are not included in the TB register if they cannot prove their residential status (*propiska*). No special effort is made by medical personnel to maintain patients with "problematic" behaviour (substance abusers) on treatment, and there are no psychologists or social workers on the roster.

Legislation in Ukraine permits forced isolation of non-adherent patients after a court decision. During the field visits, there were many complaints that the system does not work properly, as patients can leave hospital after they were admitted by the police. The regulations under this law should be revised to ensure humanitarian, ethical isolation and techniques to improve adherence.

Many children are hospitalized without evidence of active TB but because they gave a positive response in a tuberculin skin test or were in contact with a TB patient. These children are not only at increased risk for nosocomial diseases but also suffer psychological trauma and often stigma.

16.4 Palliative care

Each *oblast* has a palliative care department, but the clinical, infection control and ethical aspects are not in accordance with international recommendations. Most patients receiving palliative care are hospitalized in MDR-TB wards in separate rooms or stay at home. The wards also have patients with XDR-TB or DS-TB and patients after treatment or on treatment, including homeless people and ex-prisoners. There are no

clear definitions of "palliative care" and "end-of-life care", and the term "palliative care" for TB patients is generally used incorrectly, with many different interpretations. Patients who could be cured are placed in this category, such as those with several interruptions before the start of MDR-TB retreatment, patients who refuse treatment and those who could not be encouraged or motivated to start (or not to interrupt) their treatment.

16.5 Main findings (achievements, challenges and examples from field visits)

- Lack of resources restricts the quality of medical care, including maintenance of premises, equipment, vehicles and staff and the purchase of diagnostic equipment and products. A plan is required to address the problem of staffing at local level, where there are too few, overworked TB specialists, radiologists and laboratory staff, which limits access to diagnosis and treatment.
- Not all data on TB in prisons are included in national reports, such as the numbers of TB patients released from prison and their treatment outcomes and the numbers of identified TB patients admitted to prison. It is therefore impossible to determine the outcome of treatment (default percentage, treatment success) or to assess the quality of programmes to support prisoners with TB and their impact on the main epidemiological parameters.
- The ethical problems in ensuring universal access to TB care include discharging TB patients from hospital when they breach the conditions, transferring patients to palliative care when there are no or insufficient anti-TB drugs and refusing treatment of MDR\XDR because of severe co-morbid conditions or a history of poor adherence.
- A new risk group consists of migrants and settlers from the conflict zone. A referral mechanism must be set up between the immigration and the health services to ensure that measures are taken to detect and treat TB.
- Patients have little support from regional or district budgets for expenses such as for travel to a TB specialist or food packages for outpatient treatment.
- There is no mechanism for sending food parcels from the Red Cross to DOT sites for patients who meet the criteria but refuse to sign a contract for the provision of home care.
- Information materials contain little information about the rights and responsibilities of patients and medical personnel for TB detection and treatment.
- Drugs are sometimes delivered directly to patients.
- TB services have weak links with Government social services.
- The confidentiality of data on medical conditions is poorly maintained, including in prisons.
- Little psychosocial support or education is given to hospitalized patients to establish adherence and prevent default. Evaluation of the socio-economic characteristics of patients is poor.
- Some TB services have refused to treat pregnant women with MDR-TB because of non-adherence. Obstetricians and gynaecologists have refused to follow a pregnancy and often recommend that it be terminated.

17. Operational research

17.1 Main recommendation

- Set up a platform for national and regional operational research on the care of TB, DR-TB and DR-TB/HIV co-infection with public health agencies to obtain documented evidence of cost–effectiveness for policy decision-making on further improvement of financing mechanisms and budgetary allocations at national and regional (*oblast*) levels.

17.2 Specific recommendations

- Set up a sustainable platform for operational research in collaboration with WHO and other stakeholders for the provision of technical and methodological assistance, with representation from national and international implementing agencies, scientists, the donor community and decision-makers.
- Set up a platform to provide assistance at all stages of operational research: planning, monitoring and dissemination to policy-makers of outcomes and lessons learnt.
- Establish a critical mass of operational research.
- Make an inventory of operational research that has been completed, is under way and is planned in Ukraine in the domains of (DR)-TB and TB/HIV co-infection.
- Prioritize prospective and retrospective operational research for Ukraine, including:
  - the cost–effectiveness of ambulatory care for TB and DR-TB;
  - the cost–effectiveness of screening population groups at risk for TB (abolish mass TB screening);
  - the cost–effectiveness of contact tracing among children;
  - use of new short treatment regimens and new drugs;
  - the contribution of a combination of social, medical and psychological support to case finding, treatment outcomes and adherence among affected populations (retrospectively or prospectively) at *oblast* level;
  - the contribution of service delivery and outreach activities to epidemiology, case finding, diagnosis and outcomes among populations at risk;
  - optimal management of pre-XDR-TB and XDR-TB;
  - management with an optimal diagnostic and curative algorithm of comorbid and chronic diseases in intravenous drug users with DR-TB, HIV and hepatitis;
  - timely detection and adverse effects of DR-TB management;
  - development, standard operating procedures and validation of tools for rapid detection of drug resistance, particularly in cases of XDR-TB; and
  - the cost–effectiveness of various treatment approaches, including treatment of patients who fail the category-4 regimen and the efficacy of candidate drugs (including for compassionate use).

Annex 1. Case-finding rates and treatment outcomes of new cases in Ukraine and in the penitentiary system

Table A1. Case-finding rates

Cases		2012				2013			
		Countrywide		Penitentiary system		Countrywide		Penitentiary system	
		No.	%	No.	%	No.	%	No.	%
New cases	Sputum smear-positive pulmonary TB	11 030	28.9	442	14.9	10 882	30.6	272	11.3
	Sputum smear-negative pulmonary TB	17 398	45.7	1221	41.4	15 559	43.7	973	45.6
Previously treated sputum smear-positive pulmonary TB	Relapse	2 798	7.3	377	12.8	3 250	9.1	279	13.1
	Treatment after interruption (default) or after failure	3 691	9.7	256	8.7	4 579	12.8	183	8.6
Other	Relapsed sputum smear-negative	3 178	8.3	654	22.2	1 337	3.7	428	20.1
Total	Total	38 095	100	2950	100	35 607	100	2135	100
				7.7%				6%	

Table A2. Treatment outcomes of new cases

	2011				2012				2013			
	Countrywide		Penitentiary system		Countrywide		Penitentiary system		Countrywide		Penitentiary system	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
No. of cases evaluated	10 502		296		11 030		442		10 882		272	
Transferred to category 4	1 029	9.7	39	13.4	1 505	13.6	58	13.1	1 901	17.5	34	12.5
Cured	4 840	46.9	65	22.3	5 205	47.2	162	36.7	4 821	53.7	90	37.8
Completed treatment	931	8.8	38	13.1	756	6.9	19	4.3	837	9.3	20	8.4
Died	1 481	14.2	44	11.7	1 443	13.1	28	6.3	1 285	14.3	29	12.2
Failure	1 030	9.8	34	11.7	1 013	9.2	55	12.4	1 221	13.6	29	12.2
Default	788	7.7	2	0.7	721	6.5	1	0.2	555	6.2	0	
Transferred out	367	2.8	79	27.1	367	3.3	118	26.7	243	2.7	70	29.4
Treatment success	5 771	55.7	103	35.4	5 961	54	181	41	5 658	63	110	46.2

Annex 2. Status of recommendations from the review of the National Tuberculosis Programme in Ukraine, 10–22 October 2010

Previous recommendation	Status of implementation
Case finding and diagnosis	
14. A collaborative agreement should be established between the Ministry of Health and the State Department for the Enforcement of Sentences, including who will pay for what, and supervision of the prison level III laboratories ensured by the Ministry of Health oblast level III laboratory.	NTP conducts monitoring visits to prisons, but there is no agreement for regular visits on a contract basis. **Partially implemented**
TB control in prisons	
Main recommendations	
1. The financial resources for TB control in the State Department for the Enforcement of Sentences should be increased. Apart from ethical and equivalence issues, the current underfunding seriously contributes to the increased transmission of TB among detainees, personnel working in penal institutions and the population at large.	The incidence of TB among prisoners is falling, but the proportion of MDR/XDR-TB is high. Medications for MDR-TB are purchased with Government funds. New anti-TB drugs to treat XDR-TB have not been procured. **Partially implemented**
Specific recommendations	
2. Case finding based on symptoms arising during imprisonment should be strengthened. Staff should receive in-service training through cooperation and coordination with the Ministry of Health.	Prison and civilian medical personnel are trained together. Training is required at all levels, with the involvement of NGOs. **Partially implemented**
3. TB diagnoses should be strengthened, including the provision of rapid testing equipment and drug susceptibility testing. An increased budget and training of personnel are preconditions, as is the availability of all drugs to treat every case identified.	Prison laboratories are partially equipped (Bactek, GenExpert). A system should be established for the collection and delivery of sputum samples from prison colonies, and prison staff and inmates should be informed about this service. **Partially implemented**
4. The use of standard regimens for TB should be enforced.	Under way. **Partially implemented**
5. An agreement should be made with the Ministry of Health that allows the pooling of anti-TB drugs procurement and savings of scale.	**Not fulfilled**
6. Barriers to the continuation of treatment after release from prison should be removed by: (i) providing proper health education in prison; (ii) informing the Ministry of Health well in advance of a release from prison and allowing a Ministry of Health nurse or nongovernmental organization worker to visit the TB patient before release; (iii) allowing TB patients to receive treatment at the nearest health facility to their places of residence after release from prison, independently from their places of registration; (iv) not forcing ex-prisoners to register at police stations.	Prisoners are prepared for release only by NGOs. Transport of prisoners elsewhere is problematic. There is no mechanism for reporting the treatment results of released prisoners with TB. **Partially implemented**
Advocacy, communication and social mobilization	
Main recommendations	
1. A comprehensive written national strategy and implementation plan for advocacy, communication and social mobilization should be developed and approved. Based on this, consistent oblast/*raion* strategies and implementation plans should be developed and linked	**Not fulfilled**

to the goals and objectives of the NTP.	
2. Financial and human resources should be allocated to implement country and oblast-specific advocacy, communication and social mobilization activities and support the efforts of local organizations to reach out to marginalized populations for TB-intensive case-finding and Management in order to prevent defaulting on treatment.	**Not fulfilled**
Specific recommendations 3. Coordination councils should be designated at all levels to coordinate the implementation of the advocacy, communication and social mobilization strategy and a dedicated focal person and unit appointed within the NTP to oversee its implementation.	Coordinating councils were established at regional level in 2015, which include local NGOs and prison medical services. The presence of NGOs is often only formal, but there are some good practices (e.g. in Poltava). A strategy for advocacy, communication and social mobilization has not been drawn up, and a responsible person has not been appointed. **Not fulfilled**
4. Advocacy, communication and social mobilization interventions should be incorporated into wider strategies to control TB, MDR-TB and TB/HIV, ensuring a community-based, client-centred outpatient approach that also reaches the most vulnerable population groups.	No strategy and no results. **Not fulfilled**
5. There should be a significant increase in the involvement and number of civil society organizations and affected communities in TB care and support, building on the experience of HIV organizations. These should include such organizations as those working with prisoners and former prisoners and social groups that support homeless people.	There is strong involvement of the HIV network, with a harm-reduction programme, but little involvement of the TB patient community. Training by the "equal to equal" method is needed for both hospitalized and outpatient TB patients. **Partially implemented**
6. Training for health care and social service providers (including for staff in nongovernmental organizations) should be supported, built on successful advocacy, communication and social mobilization pilot projects, in the following specific areas: (i) assessing needs through quantitative and qualitative research; (ii) strengthening interpersonal communication and counselling among providers to improve client-provider interactions, reduce stigma and discrimination and increase adherence to TB treatment; (iii) increasing access to voluntary diagnostic counselling and testing for HIV among TB clients; (iv) developing information, education and communications materials based on research; and (v) working with the mass and print media.	There is little involvement of State social services or public anti-TB institutions with TB patients or in identifying and addressing their social problems. Pilot projects for psychosocial support and integration of TB patients are implemented by NGOs, including for vulnerable groups. Information material on TB has been prepared for the general population, including vulnerable groups. **Partially implemented**

Annex 3. Oksana's story

Oksana is a 21-year-old pregnant woman who is undergoing treatment at the Central TB Research Institute in Kyiv on an individual scheme, as she has XDR-TB.

Her medical records showed that TB was first diagnosed in 2014, and she started early treatment with first-line drugs in Ivano Frankivsk region. For personal reasons, she moved to another area, without requesting continuation of her anti-TB treatment; she treated herself by buying ofloxacin and capreomycin from a pharmacy. She did not consult a doctor for approximately 3 months. She did not take the drugs regularly but felt relatively well. When she visited a gynaecologist for her pregnancy, the doctor diagnosed active MDR-TB. A TB specialist and the gynaecologist advised Oksana to terminate the pregnancy, but she refused for religious reasons. Therefore, her health has deteriorated, with a heavy cough and shortness of breath. Her family did not have enough money to purchase a full course of second-line drugs, and Oksana's TB specialist refused to give her second-line drugs because of her history of poor adherence to TB treatment. He advised her to contact the Central TB Research Institute in Kyiv. Oksana has been on second-line drug treatment for 5 months now, and her health has been improving. As she does not have a residence permit to live in Kyiv and she has MDR-TB, gynaecologists refused to follow her pregnancy. Oksana is afraid that, after she is discharged from hospital, she will not find the necessary medication at her next place of treatment, in her place of residence. She does not know how or where she will give birth or what will happen to her and her child. Her husband is healthy and goes to the doctor regularly for check-ups.

Oksana's advice to other TB patients is to ask to medical personnel and other TB patients more questions about TB, so that they understand what a terrible disease it is and are sure to complete the entire course of treatment. When she was asked who supports her the most, she answered, "My family and other patients with TB, who share from their good and bad experiences. It is very important to know that there are people who have successfully coped with this illness. Also, that there are the medical staff who are willing to help."

Annex 4. Participants in the National TB Programme review, 14–22 April 2015

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