Resistance to implementing policy change: the case of Ukraine
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Abstract Tuberculosis (TB) is a major public health problem in eastern Europe. Since 1990, the incidence rates of TB have continued to increase in Belarus, the Russian Federation, the Ukraine and the central Asian republics of Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan. Eastern Europe, and in particular the Russian Federation and the Ukraine, also face the public health challenge of an escalating multidrug-resistant tuberculosis (MDR-TB) epidemic. Of the 17 283 global MDR-TB cases reported in 2004, over 60% (10 595) were from the European region and the vast majority of these from eastern Europe, including the Baltic states of Estonia, Latvia and Lithuania. Of particular concern is the fact that, along with Africa, treatment success for DOTS in eastern Europe is substantially below average when compared with other regions of the world, and DOTS coverage and smear-positive case detection rate remain the lowest in the world. Collectively, along with Africa, these problems in eastern Europe remain the principal obstacle to meeting the Millennium Development Goals for TB in Europe. The Ukraine has worsening epidemics of TB, MDR-TB and HIV, against a background of epidemics of sexually transmitted illness (STI) and injecting drug users (IDUs). The TB and HIV epidemics are converging. In spite of attempts, the Ukraine has failed to implement DOTS policy due to health systems organization, financing and provider payment systems that created disincentives to change while opposition by policy-makers and clinicians to DOTS strategy hindered implementation efforts.

Introduction

From 1990, the tuberculosis (TB) incidence rate in eastern Europe rose to reach a peak in 2001. Although the rates have begun to decline in many of these countries, they are still increasing in Belarus, the Russian Federation, the Ukraine and the central Asian republics of Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan.

Eastern Europe, and in particular the Russian Federation and the Ukraine, also face increasing multidrug-resistant tuberculosis (MDR-TB). Of the 17 283 global MDR-TB cases reported in 2004, over 60% (10 595) were from the European region – especially from eastern Europe and the Baltic states of Estonia, Latvia and Lithuania. Treatment success levels for DOTS are substantially lower in eastern Europe than other regions of the world (except Africa), while DOTS coverage and smear-positive case detection rate are the lowest globally. These problems are key obstacles to meeting Millennium Development Goals for TB in Europe.

Following the end of the Soviet Union in 1991, health systems in post-Soviet countries experienced substantial reductions in financing, decline in population coverage and huge increases in out-of-pocket payments. Along with epidemics of sexually transmitted illness (STI) and injecting drug users (IDUs), eastern Europe now has the world’s fastest rate of growth of HIV incidence.

This paper explores the evolving epidemiology of TB, MDR-TB and HIV in the Ukraine as well as the policy and health systems’ responses to these. The paper identifies shortcomings of these responses and, by drawing on experiences and evidence from neighbouring countries with similar TB control systems, it examines possible reasons for these shortcomings. It concludes by identifying options to strengthen health system responses to improve TB control.

A cause for concern

In the Ukraine, the second-largest country in eastern Europe with a 2005 population of 47.1 million, the incidence of active TB rose from 41.7 per 100 000 population in 1995 to 84.1 per 100 000 in 2005 (Fig. 1). In the same period, the prevalence of active TB increased from 193.1 per 100 000 population in 1995 to 219.1 per 100 000 in 2005 (Fig. 2). Meanwhile, the mortality rate from TB has almost doubled, increasing from 14.3 per 100 000 population in 1995 to 25.3 in 2005 (Fig. 3). But the TB burden is not evenly distributed. The incidence rate in penitentiary institutions is 3 to 4.5 times higher than the civilian sector. South-eastern Ukraine, which has a large number of penitentiary institutions, has incidence rates (e.g. Kherson region, 174 per 100 000; Mykolayev region, 111.1 per 100 000) that are 1.5 to 3 times higher than those in the capital city of Kiev (46.8 per 100 000; Fig. 1). In 2005, the Ukraine reported a case detection rate of 86% for new and relapsed cases of TB and DOTS coverage rate of 29%, one of the lowest rates in Europe. The latter is of particular concern, as the Ukraine has one of the highest MDR-TB levels (10% of new and 29% of previously treated cases) in Europe. In the WHO 2006 Report on Global Tuberculosis Control, the Ukraine...
was the only eastern European country for which no trend data was available for the notification and treatment success rates, collaborative TB-HIV activities and MDR-TB levels for the whole country.1

**TB and HIV**

As with TB, the incidence and prevalence of HIV has also risen. In 2006, there were 16 078 new registered cases of HIV, almost a tenfold increase from the number of registered cases in 1995 (Fig. 4). By 2005, Ukrainian authorities had reported a cumulative total of 88 626 HIV cases, but the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates put this figure nearer to 410 000, with an estimated incidence rate of 1.4% in adults aged 15 to 49 years.7 The Ukraine is now the most HIV-affected country in Europe and has the second-highest number of HIV-positive people after the Russian Federation. The HIV epidemic is predominantly driven by IDUs, but most IDUs do not have access to appropriate services.10 According to sentinel surveillance in IDUs, prevalence rate of HIV infection is 38.6% (59% in Odessa and Simferopol) and among commercial sex workers who also inject drugs, this level rises to 83%.11 According to the UNAIDS definition, the Ukraine is at the edge of a concentrated HIV epidemic among IDUs and other risk groups that account for over 60% of all cases of HIV reported to date, and the share of heterosexual transmission has grown.12

In 2004, the Ukraine had the highest HIV prevalence in adult incident TB cases (8.3%) in Europe,1 but other studies estimate this figure to be nearer 9.4%.13 In Kiev, the prevalence of HIV infection in TB patients has increased from 6.3% in 2004 to 10.1% in 2005.14 High levels of TB cases coinfected with HIV suggest that the TB and HIV epidemics are converging.15

**Policy responses to the epidemic**

**Organization and delivery of TB services**

TB service in the Ukraine is organized as a vertical system comprising a large network of specialized institutes, dispensaries, hospitals, outpatient clinics, sanatoria and rural operations.

A deputy minister of health and the department of socially dangerous diseases have the lead responsibility for TB. There is no national TB programme (NTP) or an NTP manager. The Research Institute for Respiratory Disease and Tuberculosis of the National Academy of Sciences leads development of policies and standards for TB control. Sanitary Epidemiology Services, a separate vertical structure, is responsible for data collection, surveillance and bacille Calmette–Guérin (BCG) vaccination.

In January 2006, the Ukrainian president issued a decree on infectious diseases, signalling that TB was of major concern.16 This followed decrees of the Ukrainian Parliament17 and orders of the health ministry18 to create a five-year strategy to address TB by establishing a National Programme for Tuberculosis Control 2007–2011 and introducing DOTS strategy. The Cabinet of Ministers of the Ukraine has also requested the ministry and other counterparts improve coordination of HIV and TB programmes by changing the National Coordination Council on HIV/AIDS (established in 2005) to a National Coordination Council on HIV and TB chaired by the deputy prime minister. This has yet to be implemented.

**Infrastructure and human resources**

In 2005, there were 120 dispensaries (97 with inpatient facilities) and 33 adult TB hospitals with approximately 23 000 dedicated TB beds, and three TB hospitals for children with 365 beds. In addition, there were 6600 TB beds in general medical facilities. Around 2765 TB specialists worked at these facilities. But, as with the rest of the health system in the Ukraine, much of the infrastructure for TB control needs capital investment for rationalizing and upgrading. Some TB facilities, which lack basic amenities such as heating, create very poor working environments for health workers who have low salaries (about 50% less than the average salaries in other sectors). Although health workers in the TB control system receive a 30% increase in their salaries to compensate for working in a “risky” environment, the absence of any other incentives, such as ongoing training or housing support, means attracting a new generation of workers to the TB system is difficult.

**Diagnosis and treatment**

TB cases are identified by active and passive case-finding. Diagnosis still relies on mass screening of the population by X-ray (which reaches around 50% of the adult population each year), clinical evidence and sputum smear
examination by direct microscopy in suspected cases (including any person with persistent cough of three weeks or more). Widespread use of sputum smear microscopy creates a high volume of work for under-resourced laboratories, leading to poor-quality microscopy and low yield. General practitioners who work in polyclinics are responsible for screening and referring suspected cases to TB specialists at TB dispensaries, then to TB hospitals. This results in delays between detection and treatment, during which some patients drop out of the system.19

Once diagnosed, patients are treated using a variety of TB drugs, WHO regimens and additional drugs to reduce side-effects or boost immunity. As fixed-dose combinations are not used to rationalize the number of drugs taken, adherence is a problem. However, an agreement reached with the Global Drug Facility in 2006 will enable importation and use of fixed-dose combinations in the Ukraine.19

Over 90% of patients are admitted to hospital for the initial phase of treatment. All of sputum smear-positive cases admitted for a period of 60–120 days (mean in 2005: 82.7 days). During inpatient stay drug intake is not directly observed. Up to 5% of the admitted patients have surgical interventions to treat TB. Once discharged from hospital, patients are referred back to the network of TB dispensaries for the continuation phase, during which patients are given drugs in advance for periods of 7–10 days and many are not directly observed.19

The TB patients are deemed cured when they have a negative sputum smear examination, when X-ray cavi ties have closed (or are static) and when general clinical parameters are stable. Most of these patients are monitored for a minimum of three years but some for longer periods of ten years or more, as are patients with inactive TB. These practices vary from internationally adopted practices.

Although TB control activities are guided by ministry orders, there is no nationally agreed set of standard procedures or manuals for TB programme activities. Similarly, there are no guidelines for managing TB/HIV, and guidelines on management of TB/HIV coinfection recommended by the WHO European Regional Office (for eastern European countries) have not been accepted by local experts. Consequently, the scope and quality of services for TB, MDR-TB and co-management of TB-HIV vary in each region. This results in late detection and variability of treatment approaches – leading to low treatment adherence, inappropriate use of second-line drugs and high mortality (two per 100 000 population) from HIV-associated TB.19

The National Coordination Council on HIV/TB was established in 2005, but since then has only met on an ad hoc basis with no activities in the intervening periods between meetings; it has failed to provide the necessary leadership to encourage integrated approaches. This lack of coordination coupled with vertical services for TB and HIV hinder coordination with TB-HIV services; the result is a system that manages “two diseases but not as one patient”.

Prevention
Prevention activities include BCG vaccination, mass screening, preventive treatment in contacts and risk groups, hospitalization of TB cases (including infected persons without active TB) and BCG revaccination. BCG revaccination and hospitalization of non-active TB cases persist, along with mass screening by fluorography and obligatory preventive examination of certain population categories in spite of international evidence which demonstrates ineffectiveness and inefficiency of these approaches.

Laboratory services
A key weakness in the Ukrainian TB control system is the absence of an established laboratory network that can provide high-quality and timely diagnostic support. Although there is a national-level laboratory based at the Institute of Respiratory Medicine and Tuberculosis, it does not have a coordinating or quality assurance role for the laboratories in the country. High volumes of work, obsolete equipment, inadequate financing and human resources, absence of external quality assurance and lack of monitoring systems impact adversely on the quality of laboratory services.19

Procurement and supply of drugs
Although the supply of essential drugs to treat TB is adequate, reserve stocks in providers are well below the WHO-recommended level of a one-year reserve for first- and second-line drugs. There is no quality control of essential drugs after they are procured and distributed to providers.19

Management of TB in the penal system
TB system in prisons and pre-trial detention centres are managed by the Ministry of Internal Affairs as separate vertical structures. DOTS strategy has
been introduced in 11 prison-based TB hospitals. However, management of TB in pre-trial detention centres remains problematic: as these centres lack facilities to diagnose and treat TB, inmates with TB are treated in civilian facilities but managed by workers from the Ministry of Internal Affairs. Although a decree has been issued to address this problem, it has yet to be implemented. A further problem relates to coordinating continuity of treatment for inmates discharged before their treatment is completed. This leads to failures in follow-up, poor adherence and increased risk of transmission to general public – as reflected by the higher-than-average incidence levels in regions that have prisons.

Implementing DOTS strategy

Between 2000 and 2004, a pilot project in the Donetsk region (which accounts for 10% of the Ukraine's population) supported by WHO, the United States Agency for International Development (USAID) and the Ukrainian authorities demonstrated it was feasible to implement the DOTS approach in the Ukraine. The project achieved 100% DOTS coverage in both the civil and penitentiary systems and, with improved case detection rates from 52% to 62%, also assisted the ministry of health in developing regulatory frameworks for TB surveillance and modern laboratory practices (yet to be developed into policies and implemented), as well as training for around 4000 specialists and 1000 general practitioners in modern methods of TB control.

Financing, resource allocation and payment

TB services are free for patients at the point of delivery and financed from national, regional and local budget transfers, augmented by funds from external agencies.

TB funding is subsumed in a joint budget with HIV/AIDS and oncology services. The funds received from the treasury for these three areas are internally allocated by the health ministry. Regional health departments and municipality-level governments have separate budgets for TB control. The penitentiary system has its own separate budget from the Ministry of Interior. The Institute of Respiratory Medicine and Tuberculosis and the Sanitary Epidemiology Services system have their own ring-fenced funds. The Ministry of Youth and Sport and the Ministry of Labour and Social Affairs, which have TB-related activities, receive separate and independent funding streams for TB control. Hence, the finances for TB are pooled at different levels and managed by different actors. This leads to fragmentation and inefficiency and hinders “corporate” planning efforts.

The European Commission (EC) has supported implementation of the DOTS strategy in Kiev. Since 2000, USAID has provided US$ 1.5 million annually for TB control, with an additional US$ 3 million in 2005 to implement the DOTS strategy in the Donetsk region and further funds committed until 2008 to expand DOTS coverage in five additional regions and two cities. The World Bank Tuberculosis and HIV/AIDS Control Project for Ukraine, which began in 2003 and is due to be completed in 2007 with a project budget of US$ 60 million, after more than two years of implementation had only disbursed 2% of the loan and was suspended in April 2006. The loan was restructured and implementation resumed in November 2006.

In 2003–2004, the Ukraine was awarded grants totalling around US$ 92–94 million from the Global Fund to Fight AIDS, Tuberculosis and Malaria, followed by US$ 151 million in 2007, earmarked for HIV control but not for TB. This funding goes directly to implementing nongovernmental organizations (NGOs), creating a further parallel system that is not well coordinated by the ministry. However, these NGOs play an important role in educating the general public and people with HIV about TB.

Provider payment systems

Financial resources in the health system are allocated to health-care providers according to the capacity of providers (such as the number of beds), inputs (such as the number of physicians) and activities (such as the number of patients treated, number of bed days used) rather than need.

Monitoring and evaluation

Recording and reporting

Except for in the two regions of Kiev and Donetsk, which are the sites for USAID- and EC-supported projects, there are no TB recording and reporting systems that meet WHO recommendations. There are no national guidelines or systems in place that will allow monitoring and evaluation based on cohort analysis.

Although several indicators (such as numbers of new cases and treatment success) are reported to heads of regional health departments and through them to the ministry, TB-control efforts are not comprehensively monitored.

Figure 3. Mortality rate from tuberculosis by region

- Ukraine
- Kiev (lowest)
- Kherson (highest)
- Donetsk (DOTS pilot 2002–2005)

* Regions with lowest and highest prevalence rates in 2005.

Figure 3: Mortality rate from tuberculosis by region.
Discussion and conclusions

The confluence of the HIV, TB, MDR-TB, IDUs and STI epidemics has significant public health implications. The incidence, prevalence and mortality rates from TB in the Ukraine have more than doubled in the last decade. The increase in HIV prevalence is likely to be closely followed by further increases in TB incidence and deaths in the Ukraine, which already has the highest HIV coinfection in incident cases of TB in Europe. Failure to control MDR-TB during an early HIV epidemic may lead to approximately a third more deaths than if effective treatment were used. In settings of high MDR-TB prevalence, with explosive HIV epidemics among IDUs, effective HIV harm reduction and MDR-TB control programmes must be established concurrently if substantial numbers of deaths are to be averted.

Addressing stakeholder resistance

The Ukraine has failed to effectively respond to the worsening TB and HIV epidemics. Determined leadership and policy responses to move the Ukraine into the era of evidence-based policy and practice are lacking. Instead, most policies and practices reflect outdated approaches inherited from the past that encourage unnecessary hospital admissions and lengthy inpatient stays.

Implementing the DOTS strategy in the Ukraine is challenging. As in the Russian Federation, the regulatory environment, health system structures, fragmented financing and outdated provider payment systems hinder a shift of services from hospitals to community and discourage evidence-based approaches. Lack of leadership, cultural barriers and negative stakeholder attitudes create further policy resistance as many clinicians, policy-makers and patients question the appropriateness and sufficiency of the DOTS approach for their own context.

Development of a locally sensitive and sustainable DOTS strategy in the Ukraine will critically depend on addressing stakeholder concerns. There is a need for stronger health ministry leadership to improve coordination of TB-control efforts by establishing a national TB programme unit and by improving the workings of the National Coordination Council on HIV/TB to encourage a joint approach to management of TB/HIV. But leadership alone will not suffice, as inherent health system weaknesses and barriers must also be overcome.

Barriers to implementing DOTS

A vertically-organized TB treatment system hinders development of multi-sectoral responses to TB management. The system's structure should be modified to improve integration of TB, HIV and IDU services and to enhance linkages with mainstream general health-care systems and social services. In the post-Soviet Union context, verticalized care delivery systems hinder optimal and efficient care for TB and HIV. Empirical evidence supports the delivery of DOTS at primary health care (PHC) settings. Further, health systems with strong PHC and community-based HIV services have been more successful in managing the epidemic. Hence, developing integrated service delivery and strengthening PHC to provide TB and HIV services are critical to improve responsiveness of the Ukrainian health system to the TB and HIV epidemics.

The rationale for implementing the DOTS strategy in the Ukraine, as in other countries of the former Soviet Union, is to establish cost-effective TB control by reducing unnecessary care costs due to lengthy hospitalizations while improving cure rates and reducing the development of drug-resistant TB. The DOTS strategy produces the highest cure rates for drug-sensitive TB, including in the post-Soviet context.

Studies from the neighbouring Russian Federation, whose TB control system is similar to the Ukraine's, suggest that on clinical grounds alone the majority of these admissions are not necessary as many are due to social reasons. Bacteriologically unconfirmed cases consume almost half of the expenditure on TB and up to 40% of expenditure is incurred after 12 months of treatment. The Russian Federation, which has the highest costs per TB patient treated in the world, has poor outcomes for TB control. There is potential for generating substantial savings by downsizing the number of TB beds or reallocating these beds for other uses. But this will need to be accompanied by strengthening of primary care and outpatient services for TB and expanding social support for vulnerable patients.

A further health system barrier that needs addressing relates to financing. Fragmented financing and verticalized funding flows are barriers to structural integration. Resources for TB should be pooled and programmed to improve allocative and technical efficiency. Further, the prevailing provider payment systems create perverse incentives for providers to maintain large number of beds and to hospitalize patients with TB. Structural optimization and service shifts can only be achieved with changes to provider payment systems and incentive structures to remove barriers to integrated care delivery.

However, the changes in organization and financing of services must be
underpinned by appropriate infrastructure and systems to enhance service quality. This can be done by adopting evidence-based practices to improve TB and TB/HIV diagnosis and treatment (for example, by adopting WHO’s TB/HIV management guidelines), by establishing high-quality laboratory networks and by creating appropriate recording and reporting systems. These interventions, aimed at improving quality, are key priorities that must be implemented at the earliest opportunity, while the organizational and financing reforms, which will likely take longer, are introduced. If the Ukraine is to avoid the disastrous consequences of TB and HIV epidemics, national and international agencies must focus their efforts on developing and executing national evidence-based policies aimed at medium- to long-term improvements in the health system.

Competing interests: None declared.

Résumé

Resumen
La tuberculosis constituye un importante problema de salud pública en Europa oriental. Desde 1990, la incidencia de la enfermedad ha seguido aumentando en Belarús, la Federación de Rusia y Ucrania, así como en las repúblicas asiáticas centrales de Kazajistán, Kirguistán, Taykistán y Uzbekistán. Europa oriental, y en particular la Federación de Rusia y Ucrania, afrontan además el reto de salud pública que supone la rápida expansión de la epidemia de tuberculosis multirresistente (MDR-TB). De los 17 283 casos mundiales de tuberculosis multirresistente notificados en 2004, más de 60 % (10 595) se dieron en la Región de Europa, la gran mayoría de ellos en Europa oriental, incluidos los estados bálticos de Estonia, Letonia y Lituania. Un dato especialmente preocupante es que, al igual que en África, el éxito del tratamiento DOTS en Europa oriental es sustancialmente inferior a la media en comparación con otras regiones del mundo, y la cobertura y la tasa de detección de casos bacilíferos siguen siendo los menores del mundo. Globalmente, estos problemas que, como África, sufre Europa oriental siguen siendo el principal obstáculo para alcanzar los Objetivos de Desarrollo del Milenio relacionados con la tuberculosis en Europa. Ucrania presenta unas epidemias cada vez más graves de tuberculosis, tuberculosis multirresistente y VIH, con el telón de fondo de las epidemias de enfermedades de transmisión sexual y de consumidores de drogas inyectables. Pese a los intentos realizados, Ucrania no ha logrado implementar su política de tratamiento DOTS, debido a los problemas de organización de los sistemas de salud y a unos mecanismos de financiación y pago a los proveedores que han creado desincentivos para aplicar los cambios, y por añadidura la oposición que la estrategia DOTS ha encontrado entre los altos funcionarios y los médicos ha dificultado las actividades de implementación.

Malhíz
مقاومة تنفيذ التغيير في السياسات: حالة أوكرانيا
بعد السل وحداً من مشاكل الصحة العمومية الرئيسية في أوروبا. منذ عام 1990، وواصل معدلات وقوع السل ارتفاعها في كل من روسيا البيضاء، والاتحاد الروسي، وأوكرانيا، وجمهوريات وسط آسيا: كازاخستان، وقيرغيزستان، طاجيكستان، وأوزبكستان. كما تواجه أوروبا الشرقية، ولا سيما الاتحاد الروسي، أفكارية التحديات التي تلف أمام الصحة العمومية، المتمثلة في

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