Fight With TB In Russia With A Focus On Anti-TB Drugs Management – Situation Review

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Antalya, Turkey
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Population in 2012 - 143,201,721 people
Epidemiology of Tuberculosis in the Russian Federation, 1990 – 2012
Epidemiology of Tuberculosis in the Russian Federation, 1990 – 2012

Number of cases per 100,000 population

- Incidence
- Detection rate
- Mortality

Mortality peak

1990: 7.9
1992: 12.6
1994: 17
1996: 20.2
1998: 21.6
2000: 22.6
2002: 17.9
2004: 14.2
2006: 12.4
2008: 68.1
2010: 157.7
2012: 272.8

Crisis
World bank
GF

2
TB Mortality Rate in the Russian Federation (per 100,000 population)

The HIGHEST rates
As of January-September 2013
(per 100,000 population)

Republic of Tyva (59.5)
Jewish AD (34.1)
Irkutsk Region (34.0)

The LOWEST rates
As of January-September 2013
(per 100,000 population)

Belgorod Region (1.7)
Orel Region (2.4)
Nenets Autonomous District (3.1)
Karachayev-Cherkessian Republic (3.1)
Moscow (3.1)

Significant increase of mortality is registered in:
- Chukotka AD (2 folds)
- Magadan Region (by 52.2%)
- Republic of Altay (by 52.1%)
- Republic of Mordovia (by 48.9%)
- Stavropol Territory (by 31.1%)

TB Mortality is decreasing in 53 regions

Significant reduction of TB mortality is registered in:
- Karachayev-Cherkessian Republic (by 67.7%)
- Amur Region (by 44.8%)
- Novgorod Region (by 44.0%)
- Yamalo-Nenets AD (by 36.1%)

The rates remain unchanged in 6 regions
Socio-Demographic Structure of TB Patients

- **2012 год**: 84.6% (86.0% permanent population), 10.4% (12.5% foreigners), 1.9% (2.2% without a determined place of residence)
- **2011 год**: 83.8% (86.7%), 11.3% (12.1%), 1.9% (0.8%)
- **2010 год**: 84.0% (86.0%), 12.0% (12.5%), 1.9% (0.7%)
- **2009 год**: 84.3% (86.0%), 12.0% (12.1%), 1.9% (0.5%)
- **2008 год**: 84.4% (86.7%), 12.0% (12.1%), 2.1% (0.7%)
- **2007 год**: 85.4% (86.7%), 11.7% (12.1%), 1.9% (0.7%)
- **2006 год**: 86.7% (86.0%), 12.1% (12.5%), 0.7% (0.8%)
- **2005 год**: 86.0% (86.0%), 12.5% (12.5%), 0.7% (0.7%)

**Legend:**
- Yellow: Permanent population
- Red: Foreigners
- Blue: Without a determined place of residence

Years: 2005-2012
Percentage of MDR-TB Among New TB Cases in the Russian Federation

- МЛУ среди больных ТЛ, прошедших ТЛЧ, постоянное население (Форма №7-ТБ)
- МЛУ среди больных ТЛ, прошедших ТЛЧ, все население, включая ФСИН (Форма №7-ТБ)
- МЛУ среди больных ТОД, постоянное население (Форма №33)
Normative-Legal Regulation On TB Patient Care

**Federal Law**
of 21.11.2013 No. 323-ФЗ
“On Fundamental Health Care Principles in the Russian Federation”

**Federal law**
of 18.06.2001 No. 77-ФЗ
“On the Prevention of Tuberculosis Spread in the Russian Federation”

**Order of the Ministry of Health of the RF** of 21.03.2003 No. 109
“On Improvement of TB Control Activities in the Russian Federation”

**Procedure** of TB patient care in the Russian Federation is approved by the Order of the Ministry of Health of the Russian Federation of November 15, 2012 No. 932н

**Standards** for Tuberculosis care approved by the Orders of the Ministry of Health of Russia

**Federal Clinical Recommendations** on TB diagnostics and treatment approved by the professional medical community (Russian Society of TB Specialists)
State TB Control Activities in the Russian Federation

- **1998-2004** – Federal Target Program “Urgent Measures of TB Control in Russia”, with the amount of funding – RUB 17 550.5M

- **2002-2004** - Federal Target Program “On Prevention and Control of Social Diseases” (including 2005-2006 Sub-program “Urgent Measures of TB Control in Russia” with the amount of funding – RUB 33 824.95M

- **2007 - 2012** - Federal Target Program “Prevention and Control of Socially Significant Diseases” (Sub-program “Tuberculosis”), amount of funding – RUR 37 020.1M

- **since 2006** – National Priority Project - Health aimed at improving quality of care, the Project will be conducted till 2015

(provision of medical equipment, diagnostic tools, antibacterial and second line anti-TB drugs)
Planning and Funding of Drug Procurement for TB Treatment

2007-2012

Regional Health Regulating Authorities
(83 Federal Subjects of the Russian Federation)

Ministry of Health of Russia
(Centralized Procurement (Medicines price reduction ))

Order

Medicines

Development of the Monitoring system
Provision of equipment

TB+YIV becoming more acute
Increasing MDR rates

Reporting
Planning and Funding of Drug Procurement for TB Treatment (2)

Regional Health Regulating Authorities
(Procurement with the funds of the consolidated budgets)

OTBD

Statistics

Drugs

Inter-budget transfers
(transfer to targeted drug delivery)

Ministry of Health
(Federal Budget Funds)

State task

Federal State Budgetary Institutions

Reporting
<table>
<thead>
<tr>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>Amikacin</td>
</tr>
<tr>
<td>Gatifloxacin</td>
<td>Levofloxacin</td>
</tr>
<tr>
<td>Ofloxacin</td>
<td>Kanamycin</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>Capreomycin</td>
</tr>
<tr>
<td>Kanamycin</td>
<td>Aminosalicylic acid</td>
</tr>
<tr>
<td>Capreomycin</td>
<td>Moxifloxacin</td>
</tr>
<tr>
<td>Aminosalicylic acid</td>
<td>Prothionamide</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>Cycloserine</td>
</tr>
<tr>
<td>Lomefloxacin</td>
<td></td>
</tr>
<tr>
<td>Sparfloxacin</td>
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</tbody>
</table>
WHO Recommended MDR-TB Treatment Strategies (2011)

**Standardized treatment**

Representative data on drug resistance patterns in particular population groups are used to design chemotherapy regimens. All the patients in the given group (category) are treated with the same regimen (scheme).

**Standardized treatment with consecutive switch to the individualized chemotherapy regimen**

Initially, all the patients in a certain group are treated with the regimen based on the representative drug resistance surveys. Chemotherapy regimen is adjusted once patient’s DST results are available (quite often susceptibility testing is conducted for a limited number of drugs).

**Empiric treatment with consecutive switch to the individually tailored chemotherapy regimen**

Each chemotherapy regimen is individually tailored based on the patient’s history and adjusted once DST results of the patient are available (quite often drug susceptibility testing is performed for the first and second line drugs).
## Groups of Drugs to Treat MDR-TB

<table>
<thead>
<tr>
<th>Groups</th>
<th>Drugs (abbreviations)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1</strong></td>
<td>First-line oral agents</td>
</tr>
<tr>
<td></td>
<td>• pyrazinamide (Z)</td>
</tr>
<tr>
<td></td>
<td>• ethambutol (e)</td>
</tr>
<tr>
<td></td>
<td>• rifabutin (rfb)</td>
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<tr>
<td><strong>Group 2</strong></td>
<td>Injectable agents</td>
</tr>
<tr>
<td></td>
<td>• kanamycin (Km)</td>
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<tr>
<td></td>
<td>• amikacin (Am)</td>
</tr>
<tr>
<td></td>
<td>• capreomycin (cm)</td>
</tr>
<tr>
<td></td>
<td>• streptomycin (S)</td>
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<tr>
<td><strong>Group 3</strong></td>
<td>Fluoroquinolones</td>
</tr>
<tr>
<td></td>
<td>• levofloxacin (lfx)</td>
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<tr>
<td></td>
<td>• moxifloxacin (mfx)</td>
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<tr>
<td></td>
<td>• ofloxacin (ofx)</td>
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<tr>
<td><strong>Group 4</strong></td>
<td>Oral bacteriostatic second-line agents</td>
</tr>
<tr>
<td></td>
<td>• para-aminosalicylic acid (pAS)</td>
</tr>
<tr>
<td></td>
<td>• cycloserine (cs)</td>
</tr>
<tr>
<td></td>
<td>• terizidone (Trd)</td>
</tr>
<tr>
<td></td>
<td>• ethionamide (eto)</td>
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<tr>
<td></td>
<td>• protonamide (pto)</td>
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<tr>
<td><strong>Group 5</strong></td>
<td>Agents with unclear role in treatment of drug resistant-TB</td>
</tr>
<tr>
<td></td>
<td>• linezolid (lzd)</td>
</tr>
<tr>
<td></td>
<td>• amoxicillin/clavulanate (Amx/clv)</td>
</tr>
<tr>
<td></td>
<td>• thioacetazone (Thz)</td>
</tr>
<tr>
<td></td>
<td>• imipenem/cilastatin (ipm/cln)</td>
</tr>
<tr>
<td></td>
<td>• clarithromycin (clr)</td>
</tr>
<tr>
<td><strong>Reserve group</strong></td>
<td>Bedaquiline</td>
</tr>
</tbody>
</table>

*MDR-TB* illustrates resistance to multiple anti-tuberculosis agents.
Activities of the Ministry of Health in Priority Areas of TB Control Improvement Including MDR-TB

- Updating regulatory legal acts on TB;
- Improvement of diagnostics, early TB detection, out-patient TB care and follow up, engaging non-TB public health care facilities and healthcare facilities of other types of ownership;
- Improvement of TB surveillance and monitoring, TB mortality including MDR (XDR) and TB/HIV on the bases of the single federal register;
- Introduction of rapid TB diagnostic tools, optimization and standardization of laboratory diagnostics of TB including drug resistance patterns, organization of external quality control, monitoring of drug resistant forms of M. tuberculosis.
Activities of the Ministry of Health in Priority Areas of TB Control Improvement Including MDR-TB

- **Introduction of novel drug management technologies** aimed at improvement of access and cost reduction of quality assured anti-TB drugs;

- **Improvement of patients’ adherence to TB treatment.** Engaging social workers and volunteers with TB care for socially vulnerable population groups;

- **Optimization of TB treatment approaches** in compliance with the international recommendations on TB chemotherapy;

- **Strengthening cooperation between the penitentiary and civil healthcare sectors** for the purpose of effective TB control.
Main Directions of Activities of the Ministry of Health of the Russian Federation

The above-mentioned main directions of activities are envisioned in the National Plan on Prevention of Spread of MDR-TB in the Russian Federation (2014-2015), which is planned to be adopted in December 2013, at the meeting of the heads of executive bodies of the Federal Subjects of the Russian Federation and representatives of regional TB services.