

Overcoming challenges in TB care: from policy to practice

Step by step to fully oral regimens for pulmonary RR/MDR-TB: Georgian Experience

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МІНІСТЕРСТВО
ОХОРОНИ
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Country Context – MDR-TB

- Georgia was a high MDR/XDR-TB burden country pre 2016
- In 2016:

MDR among new cases	MDR - Previously treated cases	XDR-TB cases among MDR
10.3%	38.4%	17% XDR TB <ul style="list-style-type: none">➤ 33% any FQ resistance➤ 41% any 2nd LI
(range 2005-16: 6.8%-11.6%)	(range 2005-16: 26.4%-40.3%)	(range XDR 2009-16: 9%-20%) (range FQ 2009-16: 12%-36%)

- In 2014 cohort:
 - RR-TB treatment success rate **49%** (range 2008-14: 56%-44%)
 - XDR-TB treatment success **32%** (range 2008-14: 39%-21%)

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Chronology of access to New TB Drugs

2013

- **Start** BDQ Compassionate Use (CU) Program

From
2014

- MSF supported **scale up** of CU & programmatic use of BDQ and CU of Delamanid

Aug
2015

- Programmatic use of BDQ through **USAID Donation Program**

Nov
2015

- **Universal access** to diagnosis/treatment for TB including 'pre-XDR'/ XDR-TB
- **National TB guidelines:** up to date, endorsed by MoH, include M/XDR treatment regimens and new drug safety monitoring schedule (WHO guidance)

Exposure to New Drugs - Georgia

- Total of **516 Patients** enrolled on new treatments (as of **January 31, 2018**):
 - **Bdq: 677 patients** (**11** of 0-18 years old)
 - 20 through CU
 - 650 through programmatic use
 - **Dlm: 283 patients** (**23** of 0-18 years old)
 - 12 through CU
 - 271 through programmatic use
 - **Bdq/Dlm** combination or consecutive off-label use: **93 patient** (**8** of 0-18 years old)

Country Context – MDR-TB

- In 2019:

MDR among new cases	MDR - Previously treated cases	XDR-TB cases among MDR
11.7%	31,0%	17% XDR TB <ul style="list-style-type: none">➤ 33% any FQ resistance➤ 41% any 2nd LI
(range 2005-16: 6.8%-12.4%)	(range 2005-16: 26.4%-40.3%)	(range XDR 2009-16: 9%-20%) (range FQ 2009-16: 12%-36%)

- In 2017 cohort:

- RR-TB treatment success rate **67%** (range 2014-16: 49%-67%)
- XDR-TB treatment success **57%** (range 2014-16: 32%-57%)

Revolution in RR/MDR-TB treatment



Consolidated DR-TB treatment Guidelines



Companion handbook

to the WHO guidelines for the
programmatic management of
drug-resistant tuberculosis

THE
END TB
STRATEGY



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Research Experience to develop oral regimens

- ❑ endTB “endTB Clinical Trial: Evaluating Newly Approved Drugs for Multidrug- Resistant TB (26/12/2016);
- ❑ STREAM, Stage 2 “The evaluation of a standard treatment regimen of anti-tuberculosis drugs for patients with MDR-TB” (1/06/2017);
- ❑ NC 007-ZENIX” “A Phase 3 partially-blinded, randomized trial assessing the safety and efficacy of various doses and treatment durations of linezolid plus bedaquiline and pretomanid in participants with pulmonary infection of either extensively drug-resistant tuberculosis (XDR-TB), pre-XDR-TB or treatment intolerant or non-responsive multi-drug resistant tuberculosis (MDR-TB)” (5/10/2017)
- ❑ NC 008-SIMPLICI-TB “An open-Label, partially Randomized Trial to Evaluate the Efficacy, Safety and Tolerability of a 4-month Treatment of Bedaquiline plus Pretomanide plus Moxifloxacin plus Pyrazinamide (BPamZ) Compared to a 6-moth Treatment of HRZE/HR (control) in Adult Participants with Drug-Sensitive Smear-positive Pulmonary Tuberculosis (DS-TB) and 6-month Treatment of BPamZ in Adult Participants with drug Resistant, Smear-positive Pulmonary Tuberculosis (DR-TB)” (15/05/2018)

Clinical Trials

- Totally 131 patients were enrolled in clinical trials, DR-TB-88 among them, 66 – on fully oral regimen.

Steps taken for the implementation

- National Tuberculosis Treatment Guideline was updated and approved by the MoH in June 2019.
- By August 2019 cascade training of countrywide TB staff (>250 doctors and programmatic staff) was accomplished.
- The major revisions that targets adults and children include the following:
 - **Modified fully oral shorter regimen for pulmonary RR-/MDR-TB - 9 months BDQ/Lzd/Lfx/Cfz/Cs**, with DLM first drug to substitute in case of toxicity
 - **Longer 18-20 month regimens for all other patients**, e.g. quinolone resistance, extensive TB disease with a **backbone of BDQ/Lzd/Lfx/Cfz**, with additional drugs based on treatment history and drug resistance patterns
- Additional/updated guidance on:
 - Post-treatment pulmonary/respiratory **rehabilitation**;
 - Expansion of the active **TB screening** groups
 - Expansion and revision **LTBI treatment** strategies (3 months of Rifapentine and INH, **3HP**)
 - Surgical management, TB Meningitis, laboratory monitoring, DST to DR-TB drugs

Implementation of all-oral regimens

- In 2019, 281 patients with **R/MDR/XDR/TB** started treatment, 74.4% were included into all-oral regimen
- From 209 enrolled patients 149 had all-oral longer and 60 had all-oral shorter regimen.
- 10 patients already completed all-oral shorter regimen treatment with successful outcome.

Thank you for Attention!

