Modified 9-month all-oral regimens for MDR/RR-TB

Recommendation: 2.2 (new)

WHO suggests using the 9-month all-oral regimens (BLMZ, BLLfxCZ and BDLLfxZ) over currently recommended longer (>18 months) regimens in patients with MDR/RR-TB and in whom resistance to fluoroquinolones has been excluded. Amongst these regimens, using BLMZ is suggested over using BLLfxCZ, and BLLfxCZ is suggested over BDLLfxZ.

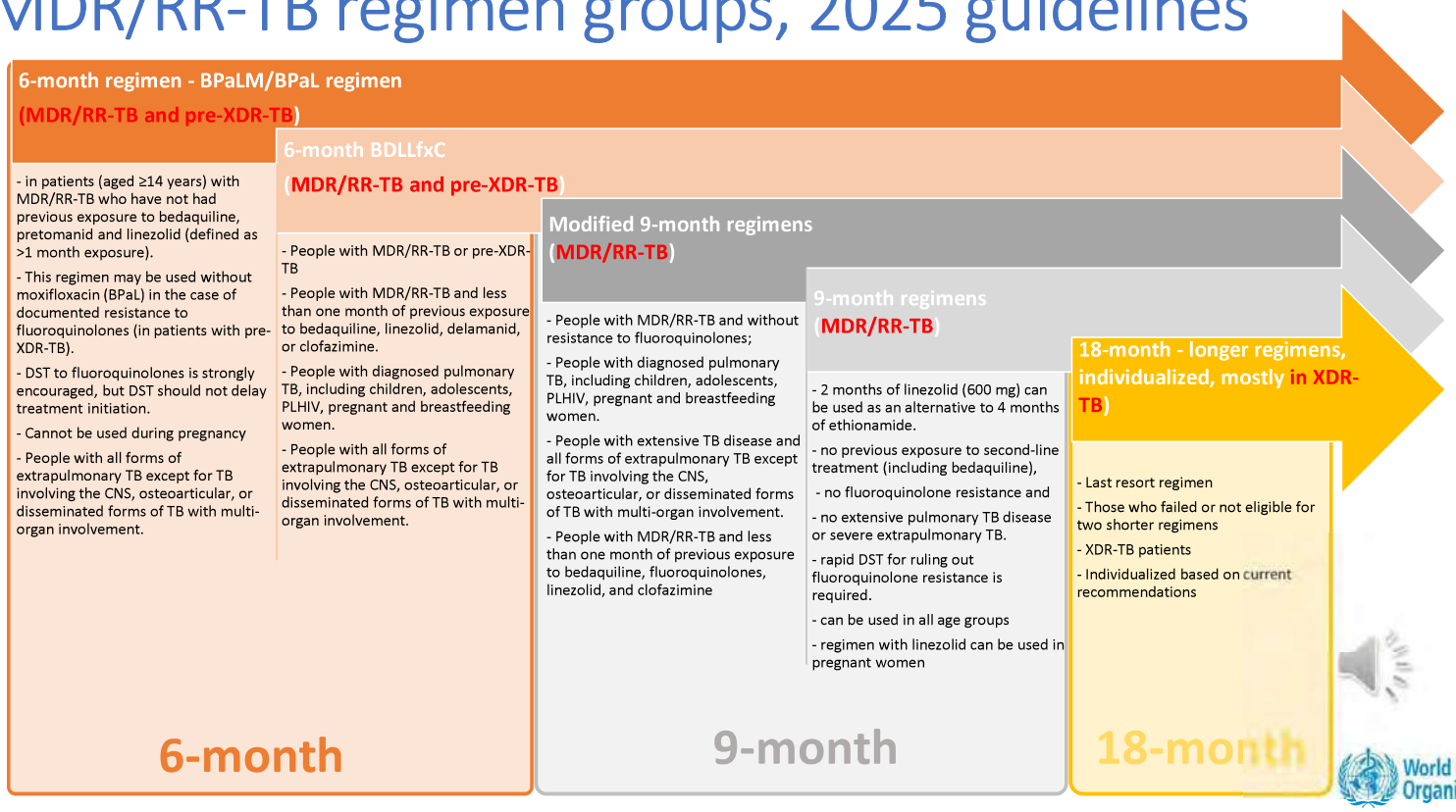
(Conditional recommendation, very low certainty of evidence)

Recommendations: 2.3 (new)

WHO suggests against using 9-month DCLLfxZ and DCMZ regimens compared with currently recommended longer (>18 months) regimens in patients with fluoroquinolone-susceptible MDR/RR-TB.

(Conditional recommendation, very low certainty of evidence)

MDR/RR-TB regimen groups, 2025 guidelines



Implementation challenges with the new regimens

- ✓ Diagnostic barriers
- ✓ High price of some medicines
- ✓ Medicines availability and procurement
- ✓ Programmatic implementation barriers:
  - previous regimens in use,
  - innovation doubts,
  - regulatory barriers,
  - policy updates or local research

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Expected new evidence from treatment trials*

End-stage trials on DR-TB treatment

Next-TB, MDR-End, Stream 1 and 2	Nix, ZeNix	TB PRACTECAL, endTB, BEAT-Tuberculosis	endTB Q
Trials that used de-recommended SoC as comparator or already recommended intervention – important contribution to the knowledge on TB but cannot be used for new policy	no comparator, contributing to the knowledge and supporting regulatory approval but challenge to match the policy development process	Contributed to the policy development	only phase 3 trial that may contribute to the policy in the next couple of years, depending on the results

A wave of phase 2 trials is ongoing and may contribute new products for further research under phase 3 trials in the next 5 years

SMART4TB Consortium

UNITE 4TB IMI AMR Accelerator

PAN-TB PROJECT TO ACCELERATE NEW TREATMENTS FOR TUBERCULOSIS

~ $600 million research investment

World Health Organization

*not including host-directed therapies or stratified medicine

END TB

Main messages

- **Shorter, 6-month BPaLM/BPaL** is the preferred choice for patients with MDR/RR-TB or pre-XDR-TB above 14 years of age
- **6-month BDLLfxC** is a 6-month alternative for those not eligible for BPaLM, and it can be used in all patients (including children and pregnant women)
- **Modified 9-month regimens** can also be used for patients with MDR-RR-TB (but no FQ resistance), adding a choice of regimens with fewer component medicines to the group of **9-month regimens** (including currently recommended)
- **Longer, 18-20 months regimens remain** the “last resort” individualized regimens
- The duration of MDR/RR-TB treatment can be the same as DS-TB treatment for most patients, including children and during pregnancy.

In summary:

- In 2025 - consolidation of several guidelines and handbooks in Module 4: Treatment
- DS-TB: 3 regimens, two shorter, 4-month regimens for and 6-month regimen remains recommended
- DR-TB: 7 shorter treatment regimens – 6-month BPaLM/BPaL and BDLLfxC, 3 new modified 9-month regimens and 2 previously recommended 9-month regimens
- Longer, 18-20 months regimens – the “last resort” individualized regimens

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