WHO guidance on TB and DR-TB care: past, present and future

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Outline

Past, present and future in healthcare and development
 WHO END TB strategy
 WHO guidance on TB diagnostics
 WHO guidance on TB treatment
 Conclusions



MDG6 TB target achieved 43 million lives saved between 2000 and 2014



Rifampicin-resistant TB cases detected and TB cases placed on MDR-TB treatment, global trend, 2009-2014

But huge burden of deaths and suffering remains.

9.6 million people fell ill with TB in 2014, and there were 1.5 million deaths



Health and HTM in SDG agenda 2015-30





World Health

The End TB Strategy: Vision, Targets and Pillars

Vision: A world free of TB Zero TB deaths, Zero TB disease, and Zero TB Suffering Goal: End the Global TB enidemic						
					TARGETS	
					SDG*	END TB
		2	2020	2025	2030	2035
PILLAR 1 PILLAR 2 Integrated, patient- centered Bold policies and supportive systems TB care and prevention Supportive	PILLAR 3 Intensified research and innovation	Reduction in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Government stewardship and accountability, with monitoring and evaluation			20%	50%	80%	90%
Building a strong coalition with civil society and com Protecting and promoting human rights, ethics and	TB-affected families facing catastrophic costs due to TB (%)	0%	0%	0%	0%	
Adaptation of the strategy and targets at country level, with g	lobal collaboration					



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This pillar puts patients at the heart of service delivery.

INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

- Focuses on early detection, treatment and prevention for all TB patients including children.
- Aims to ensure that all TB patients not only have equal, unhindered access to affordable services, but also engage in their care.

1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

- A. Early diagnosis of tuberculosis including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
- B. Treatment of all people with tuberculosis including drug-resistant tuberculosis, and patient support
- C. Collaborative tuberculosis/HIV activities, and management of co-morbidities
- D. Preventive treatment of persons at high risk, and vaccination against tuberculosis





Guidance on TB Diagnostics: Policy and Implementation





Progress in the development and evaluation of TB diagnostics

Molecular technologies

- Xpert MTB/RIF (pulmonary, extrapulmonary and paediatric samples)
- Line probe assays for the detection of MTB and rifampicin resistance conferring mutations in AFB smear positive sputum or MTB cultures

Microscopy

- Light and LED Microscopy
- Same-day diagnosis

Culture-based technologies

- Commercial liquid culture systems and rapid speciation
- Non-commercial culture and DST (MODS, NRA, CRI)

Non-molecular technologies Alere Determine TB-LAM, Alere, USA

Technologies endorsed by **WHO Evaluated by** WHO and not recommended Commercial serodiagnostics (all manufacturers)

Interferon-gamma release assays for the detection of active TB (all settings)



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Xpert MTB/RIF policy and implementation



Provides Technical and operational 'how-to': practical considerations including

- Evidence base
- Positioning the test
- Testing and managing patients
 - Selection of individuals to be tested
 - Interpreting results of Xpert
- Case definitions and patient registration

http://www.who.int/tb/publications/xpert_implem_manual/en/





Use of LF-LAM for TB diagnosis in PLWH

- Conditionally recommends use of lateral flow urine lipoarabinomannan assay (LF-LAM) to assist in diagnosing TB in PLWH and low CD4 counts or who are seriously ill.
- Does not recommend LF-LAM for TB diagnosis in other groups of patients and for screening of TB



http://www.who.int/tb/publications/use-of-lf-lam-tb-hiv/en/



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Implementing TB diagnostics

- Provides a structured framework for introducing WHO's recommended diagnostic techniques for TB.
- Presents algorithms for the optimal use of different diagnostics at different levels of the laboratory network to enable both early diagnosis and rapid DST



http://www.who.int/tb/publications/implementing_TB_diagnostics/en/



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Evaluations for new or updated policies

- Evaluation of TB-LAMP to be released mid- 2016
- Policy on SL LPA tests to be released mid-2016
- Evaluation of utility of phenotypic and genotypic methods (including LPA and DNA sequencing) for DST – started 1st quarter 2016
- Evaluation/non-inferiority studies: Xpert Ultra and Xpert Omni – 2016, ongoing
- Xpert Ultra vs culture methods to start end-2016-17



Guidance on TB Treatment: Policy and Implementation



Guidelines on treatment: TB and DR-TB



Companion handbook to the PMDT guidelines

- Describes ways to implement established WHO policies relevant for the management of MDR-TB.
- Includes laboratory and case-finding chapters
- To be updated in 2016

Companion handbook

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

2014-16





http://www.who.int/tb/publications/pmdt_companionhandbook/en/





WHO guidance on the management of DR-TB, 1996-2015









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Scope of expected new DR-TB guidance

- The optimal combination of TB drugs and regimen design to treat patients with drug-resistant TB:
 - medicines recommended and grouping of drugs (core SLDs and add-on agents); conventional treatment regimens
- The effectiveness and safety of shorter regimens for the treatment for patients with drug-resistant TB in comparison with longer conventional treatment
- Whether time to start of treatment and surgical interventions improve outcomes for patients with drugresistant TB



Conclusions

- Updated (expected mid-2016) WHO guidelines on diagnosis and treatment of DR-TB (in adults and children) are likely to introduce recommendations that may lead to important improvements in the diagnostic pathway, the choice of SLDs and design of the regimens.
- Updated guidelines on TB treatment (expected early 2017) may introduce recommendations on use of fluoroquinolones, retreatment regimens, frequency of dosing, etc.
- Updated guidelines on TB diagnostics may update/introduce recommendations on TB diagnostics with improved performance and the gold standards for DST.
- WHO strives to develop implementation guidance to complement policy recommendations.



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