WHO Policy Advances Toward Achieving Universal Access to TB Testing Services

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WHO Recommends Early & Universal Access to TB Testing

End TB Strategy Pillar 1 on Integrated, Patient-Centered Care and Prevention highlights the importance of the early diagnosis of TB, including universal drug susceptibility testing (DST)

WHO recommends that ***all*** people with presumptive TB receive initial WHO-recommended rapid diagnostic (or WRD) testing

WHO recommends that ***all*** people with TB be tested for resistance to at least the first-line anti-TB drug, rifampicin

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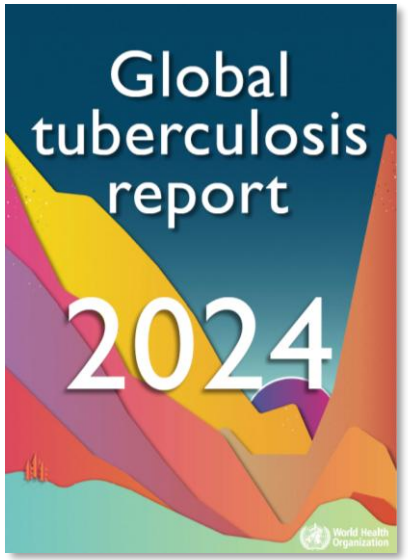
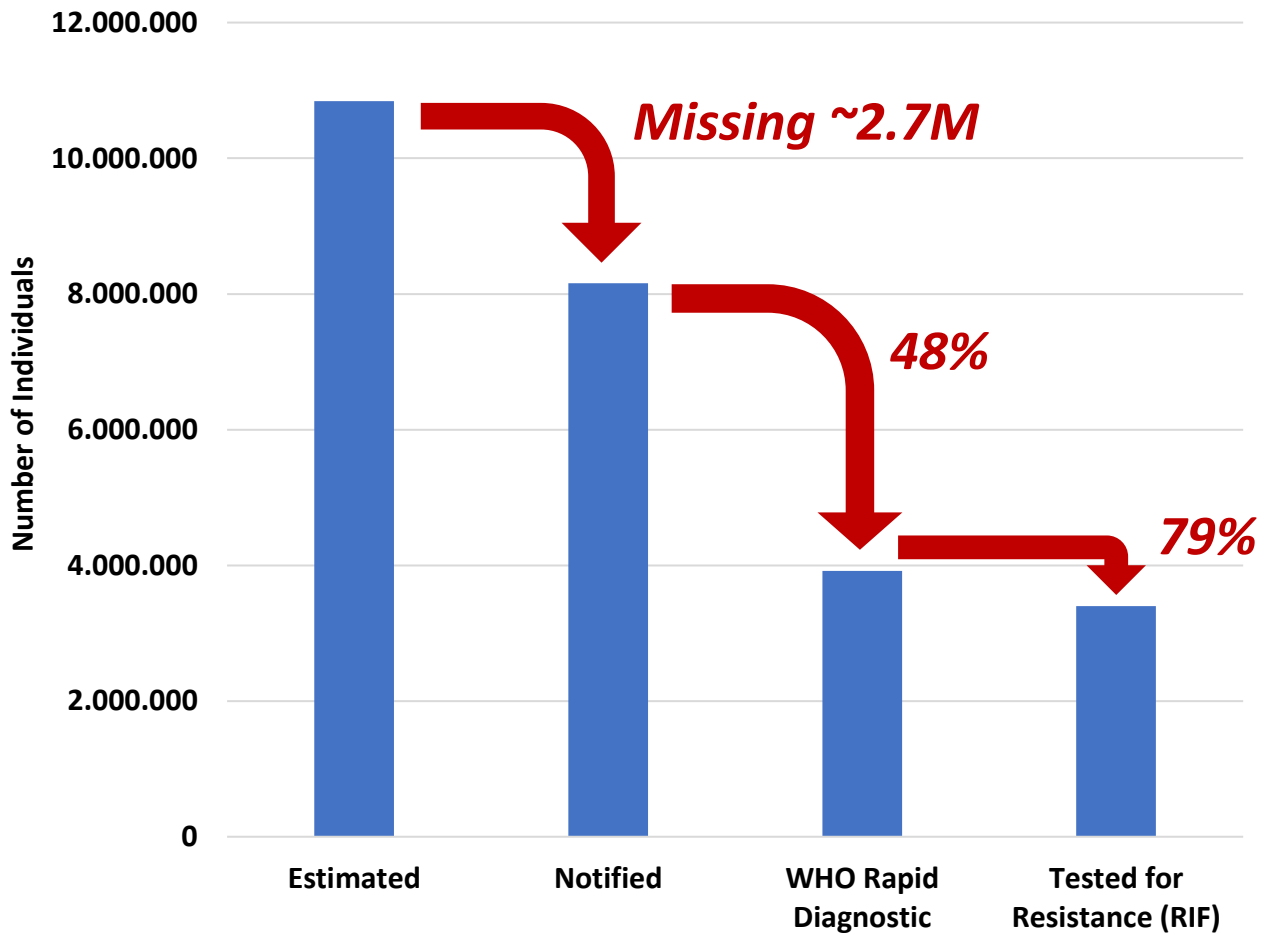
Global Data Highlight Continued Gaps in TB Diagnostics



Global TB Estimates in 2023

- *1/4 World Infected*
- *~10.8M Incident cases*
- *~400,000 MDR/RR TB cases*
- *1.25M Deaths*



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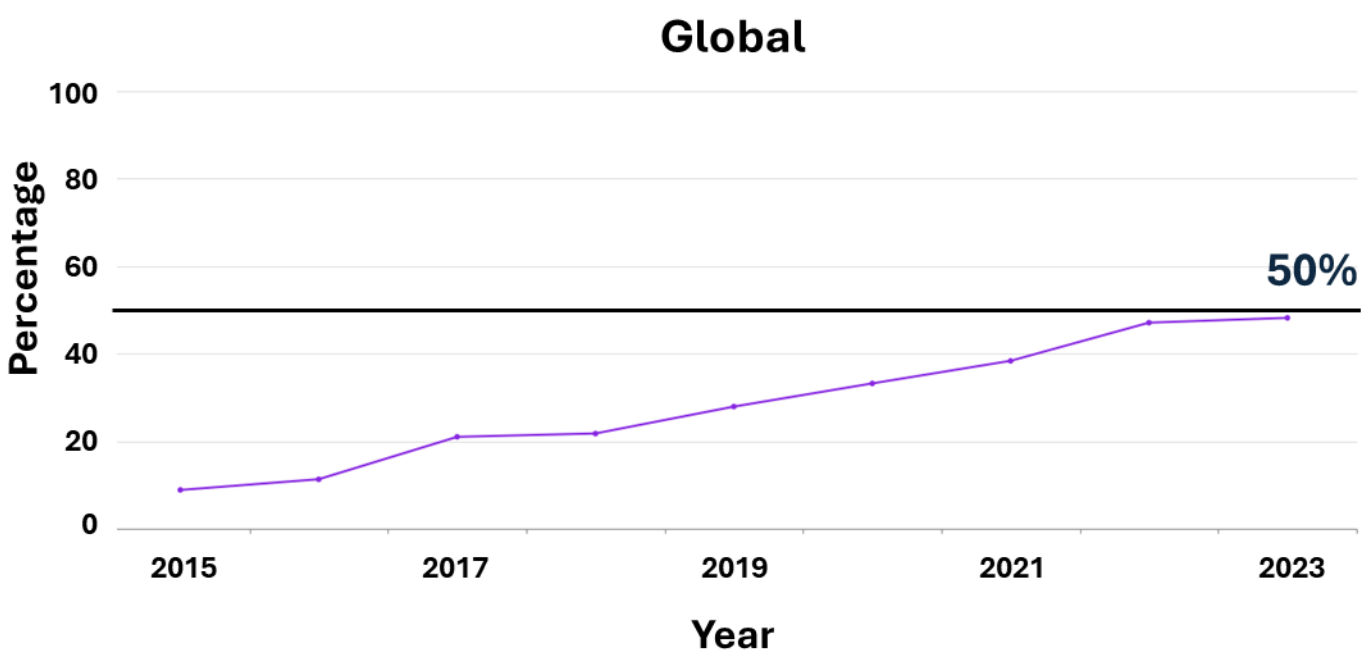
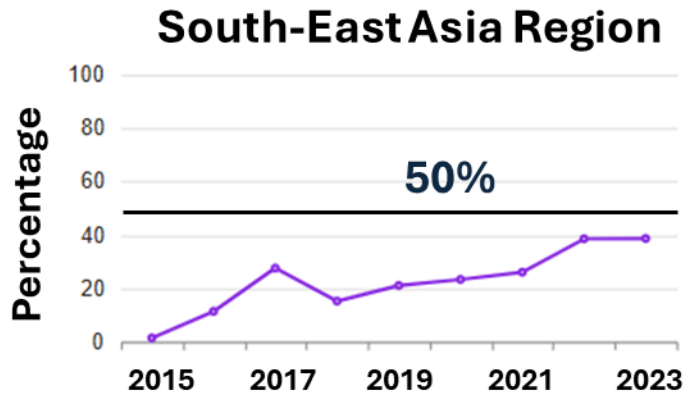
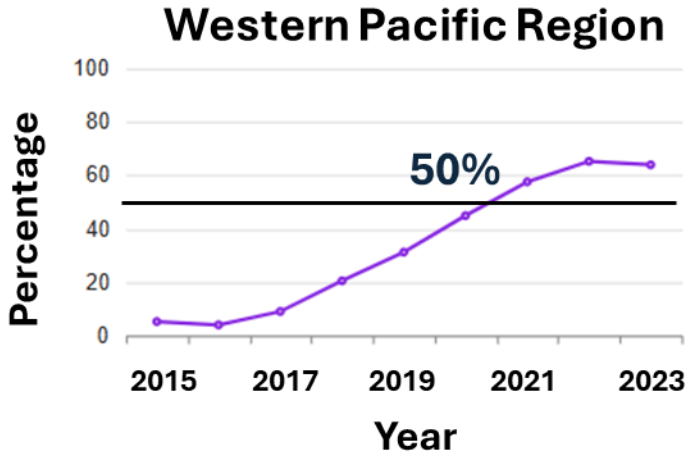
Initial WHO-Recommended Diagnostic Testing by Region







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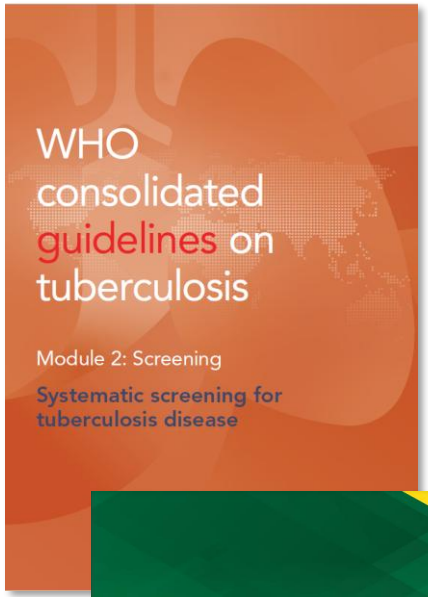
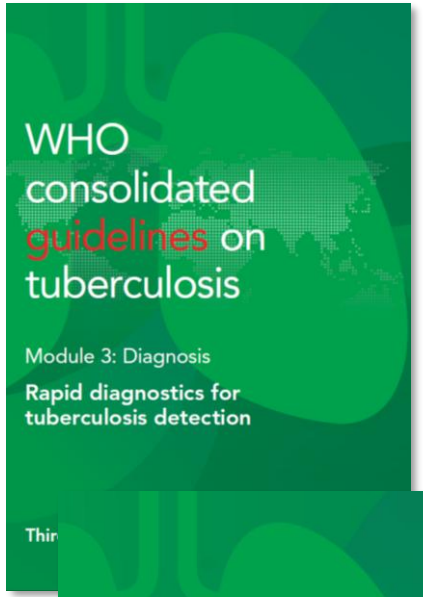
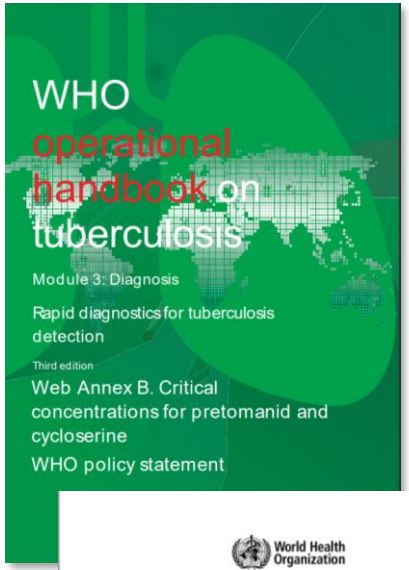
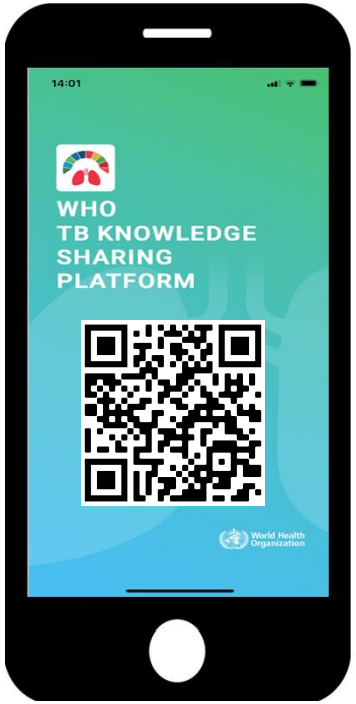
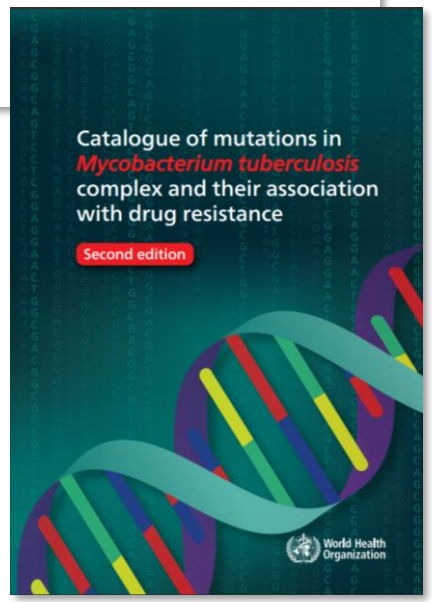
WHO Guidance: Advancing with Technologies and Strategies for Use

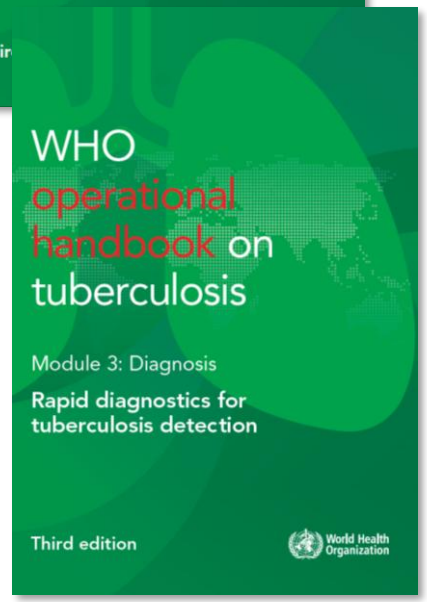


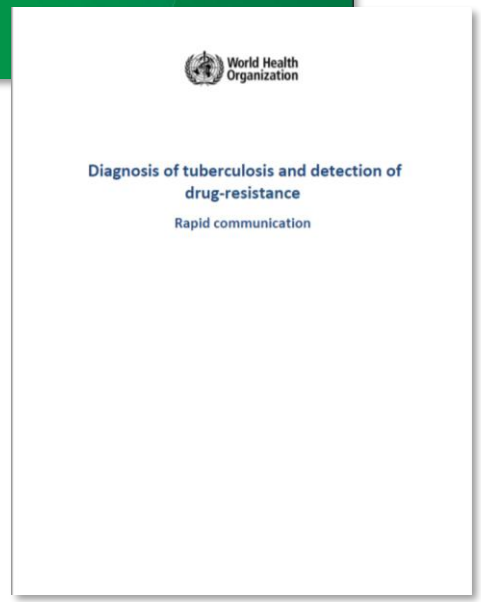












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WHO Classes of TB Diagnostics Grouped by Purpose

Initial tests for detection of TB *with* drug resistance

Initial tests for detection of TB *without* drug resistance

Follow-on tests for detection of drug resistance

Tests for detection of TB infection

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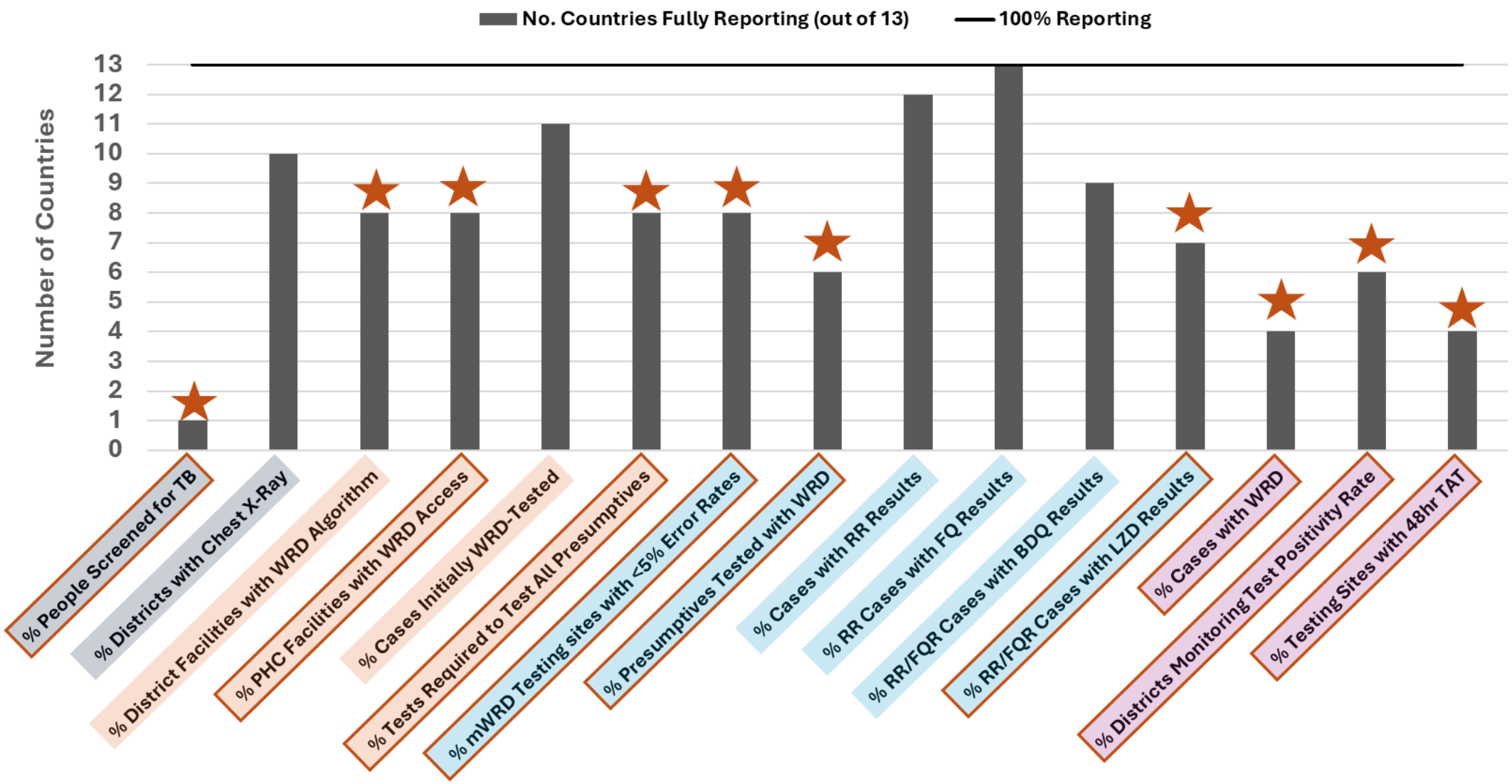
A WHO Standard for Universal Access to TB Testing

STEP 1	STEP 2	STEP 3	STEP 4
IDENTIFYING PRESUMPTIVE TB	**ACCESSING TESTING**	**BEING TESTED**	**RECEIVING A DIAGNOSIS**
Increase the number of people with presumptive TB in care	Increase access to WRDs	Increase WRD and drug resistance testing	Increase WRD-based diagnosis

2024 WHO Standard Reporting in SEAR and WPR



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TB Diagnostic Benchmarks *WHO standard: universal access to rapid tuberculosis diagnostics*

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A WHO Standard for Universal Access to TB Testing

BARRIERS

Patient level barriers
- Direct costs (price patient pays for test)
- Indirect costs (transport, food and job insecurity)
- Education and community awareness of tuberculosis
- Mistrust in health systems
- Stigma and fear of disclosure

Health facility level barriers
- Technical issues (e.g. module failures and miscalibration)
- Logistical barriers (supply chains, specimen transport, results delivery)
- Issues with mWRD centralisation (e.g. hub-and-spoke model)
- Infrastructure for installation and maintenance
- Staffing shortages and turnover

Care seeking → Access to mWRDs → Use of mWRDs → Diagnosis using mWRD and results delivery

Provider level barriers
- Training on mWRDs & long-term engagement
- Non-adherence to diagnostic algorithms and laboratory SOPs
- Interpretation and perceptions re: mWRD results and value
- Reliance on smear or chest x-ray
- Use of empiric treatment as dual diagnostic and treatment strategy
- Overwhelm, workload

Data management and health systems level barriers
- Lack of electronic medical record and IT systems
- Test and platform costs and inflation
- Non-comprehensive TB care budgets, cover for critical network functions
- Vertical care models

ENABLERS

Patient level enablers
- Provision of comprehensive person-centred care
- Near-patient mWRD-testing, including mobile screening
- Support for direct & indirect patient costs (e.g. transportation and food vouchers)
- Interventions to reduce TB stigma

Health facility level enablers
- Near-patient and same-day mWRD use through process redesign and decentralisation of diagnostic services
- Innovation in sample transportation, incorporation of results into records, and prompt feedback to diagnostic labs
- Incorporation of quality-improvement approach and root-cause analyses into routine practice

Care seeking → Access to mWRDs → Use of mWRDs → Diagnosis using mWRD and results delivery

Provider level enablers
- Delivery of longitudinal mWRD education addressing local barriers to use
- Technical training for laboratory workers involved in mWRD use
- Strategies to motivate and increase mWRD use, & reduce empiric treatment
- Use of community and logistical workers to strengthen care delivery processes

Data management and health systems enablers
- Software to aid result notification and linkage to care (e.g. GxAlert & GxNet)
- Diagnostic network optimization
- Service integration e.g. HIV/STI/COVID, horizontal programs
- Promoting equitable access to health innovations

Example Benchmarks for Technology Impact

Benchmark	SEAR		WPR	
	No. Countries Reported (n=7)	% Achievement	No. Countries Reported (n=6)	% Achievement
(4) % Primary Health Care Facilities with Access to WRDs	5	82%	3	67%
(5) % Cases Initially Tested with a WRD	6	49%	6	76%
(8) % People with Presumptive TB Tested with WRD	3	22%	3	79%
(9a) % Cases with RR Results	7	83%	6	92%
(10) % Cases with WRD Testing	2	51%	3	82%
(12) % Testing Sites with 48-hour Turnaround Time	3	85%	1	100%

New Target Product Profiles for TB Testing

Target product profile for peripheral initial diagnostic tests for TB

- *Prioritizes classes of diagnostics accessible at peripheral settings*
- *Includes potential for a variety of accessible sample types and testing technologies that can yield results in a single clinical visit*
- *Provides performance targets that consider trade-offs between test accuracy and access*

Target product profile for next-generation TB drug susceptibility tests

- *Includes fluoroquinolones and Group A drugs (BDQ)*
- *Expands target population to include all ages*
- *Expands sample types to include specimens other than sputum*
- *Provides considerations for result time impact on treatment*

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WHO Target product profiles for TB diagnosis and detection of drug resistance

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Target Product Profile Peripheral Testing Settings

Complexity	POC	Near POC	Low complexity
Equipment	None ⊗	Maybe, preferably battery-operated	Yes ✓
Infrastructure	None ⊗	None ⊗	Basic laboratory requirements (i.e. required power supply), but non-specialized laboratory infrastructure
HR skill level	None or minimal skills	Basic technical skills (basic pipetting, precision not critical)	Basic technical skills (basic pipetting, precision not critical)

HR: human resource; POC: point of care.

[a] None or minimal skills refers to the minimal steps required for testing. Ideally, any person who has not done any test before can perform these tests and interpret the results. Examples of such tests include a urine pregnancy test and a self-test for COVID-19.

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Scope of Peripheral TB Diagnostics

Characteristic	Minimal requirements	Optimal requirements	Explanatory notes	Reference
Scope				

Performance Based on Modeling of Accuracy and Access

Characteristic	Minimal requirements	Optimal requirements
Performance		
Diagnostic sensitivity for TB detection		
Sputum, low-complexity assay	90%	≥95%
Sputum, near-POC	85%	
Sputum, POC	75%	

Lancet Preprint: Trade-Offs between Clinical Performance and Test Accessibility in Tuberculosis Diagnosis: A Multi-Country Modelling Approach for Target Product Profile Development

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Next Steps Toward Universal Access to TB Testing

- Continue collecting, monitoring, and supporting member states to review annual WHO Standard benchmark data
- Coordinate sharing of early experiences and successes with WHO Standard benchmark data collection and progress toward achievement
- Publish 2025 Consolidated Guidelines and Operational Handbook on TB Diagnosis
  - Consolidate TB infection, diagnosis, and drug resistance testing
  - Present newly-established classes of low complexity nucleic acid amplification tests
  - Include further details and evidence underlying recent concurrent testing recommendations for children and persons living with HIV
- Continue to survey the landscape of peripheral and/ or non-sputum tests and readiness of evidence for global policy development processes
- Prepare for Guideline Development Group assessment of systematic evidence on new, non-sputum sample types, Near-Point-of-Care technologies, and strategies

Acknowledgements

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Thank You!