WHO Europe Regional TB diagnostic testing priorities and progress

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World Health Organization
European Region

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ROLE AND IMPORTANCE OF RAPID AND RELIABLE DST RESULTS

The WHO European Region highest rates of DR-TB globally

Genotypic and phenotypic DST is key to optimize treatment regimens

Novel treatment regimens must be accompanied with high-quality DST results

Resistance to bedaquiline, delamanid, and pretomanid has arisen repeatedly in different genetic backgrounds of the MTBC prior to the clinical use of these novel agents

AVAILABILITY OF P AND G DST FOR MTBC IN THE WHO EUROPEAN REGION

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- Detailed survey on pDST and gDST, including tNGS and WGS availability
- Comprehensive overview of the DST availability in a Region

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DST AVAILABILITY SURVEY RESULTS

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Online survey sent to all national and supranational reference laboratories in the WHO European Region

Responses were received from 52 countries including all 18 WHO Europe HPCs and 29 EU/EEA countries

pDST availability for all drugs recommended by WHO

Availability of gDST assays including all WHO mWRDs and sequencing based technologies

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DST AVAILABILITY SURVEY RESULTS

At the time of the survey pretomanid was not approved in eight countries in the Region and thus excluded when analysing the results for pretomanid as routine DST as this drug would not be needed in those settings (8 countries).

DST AVAILABILITY SURVEY RESULTS

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Only analysing the results using countries as the denominator would provide a distorted picture of the DST availability

Minimising this distortion by using the estimated incidence of all TB or RR-TB as the second denominator.

To account for the uneven burden of TB within the WHO European Region, we stratified countries into 18 HPCs and EU/EEA countries.

P DST AVAILABILITY SURVEY RESULTS

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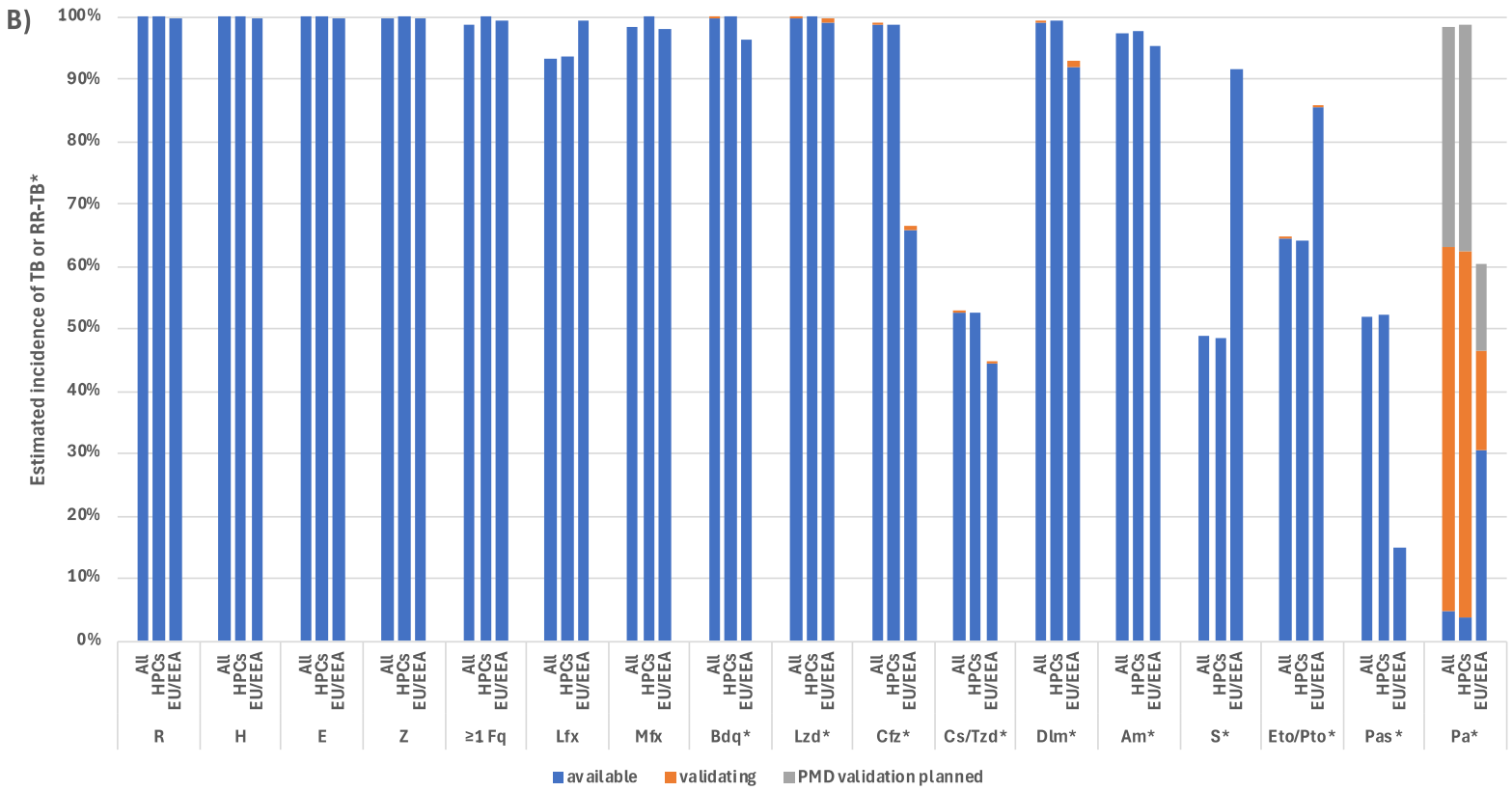
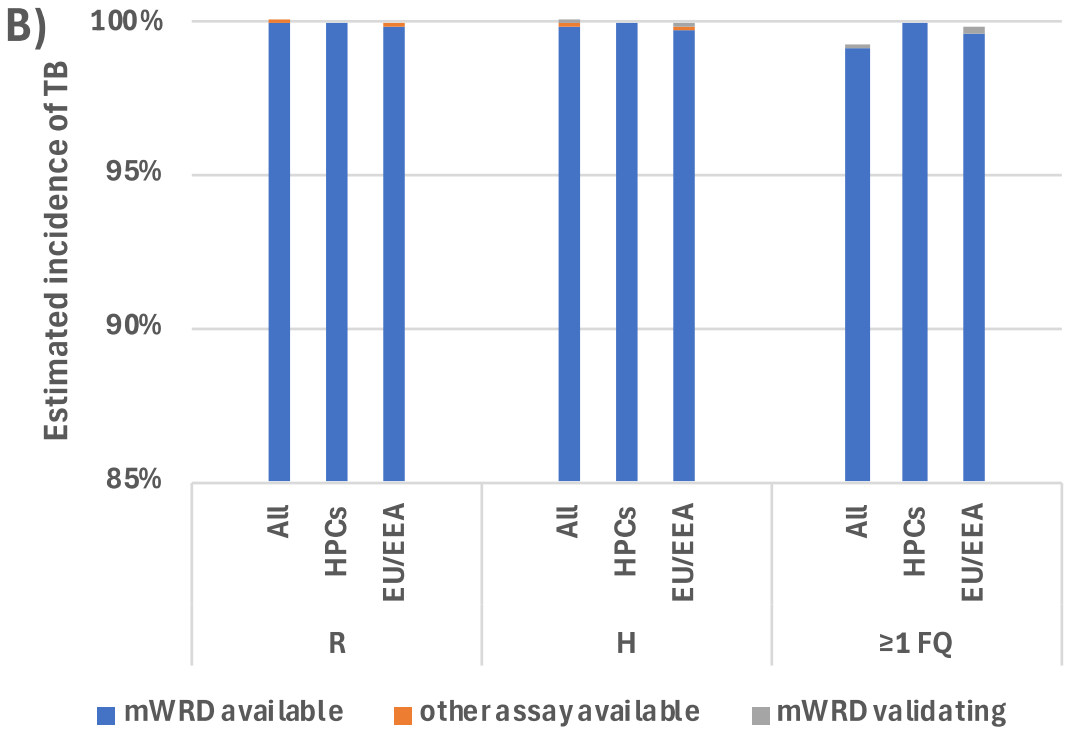


The availability of pDST exceeded 90% of the incidence of TB or RR-TB for all countries for all drugs with only some exceptions due to a combination of epidemiological, technical and/or policy factors.

Only two countries did not carry out any pDST but referred the samples abroad for pDST. Both are in the EU/EEA account for 0.2% of the estimated TB incidence.

- Pretomanid pDST was only available for 5% of the estimated RR-TB incidence in countries where pretomanid is approved or used programmatically.
- Ongoing validation efforts may rise this number to 58% and planned validations would cover a further 35%, bringing the total incidence to rise to 98% .

G DST AVAILABILITY SURVEY RESULTS

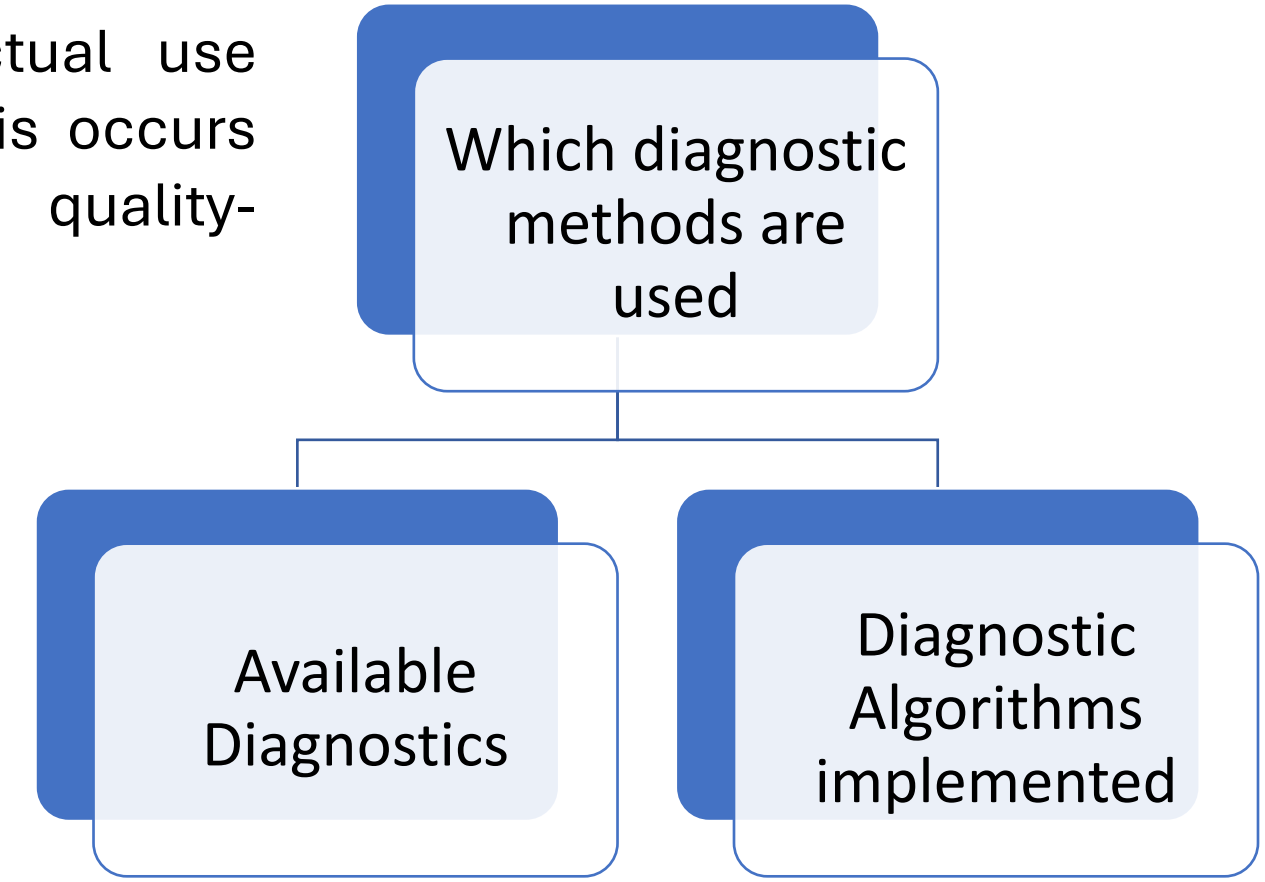


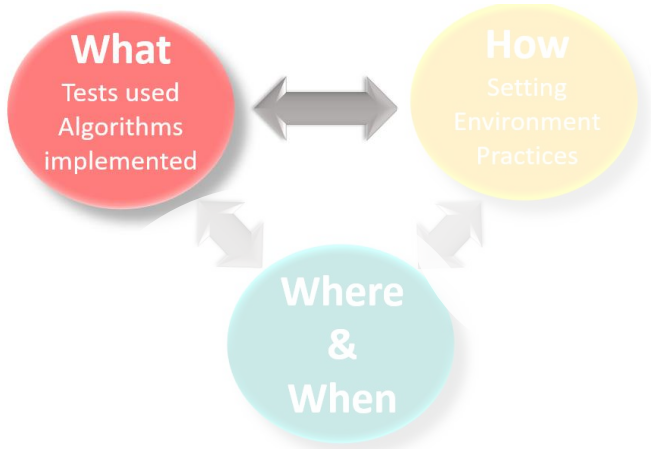
mWRD available to detect resistance to rifampicin, isoniazid and fluoroquinolones for more than 99% of estimated incidence in all countries

Of the 26 countries where WGS is available or is being validated, only five are harnessing the full potential of WGS by interpreting all drugs included in the survey.

INDISPENSABLE ELEMENTS FOR IMPLEMENTATION

Only availability of DST shown not its actual use neither whether this occurs in a timely and quality-assured manner.





WHAT ELSE IS IMPORTANT BEYOND THE AVAILABILITY OF THE RIGHT DIAGNOSTICS

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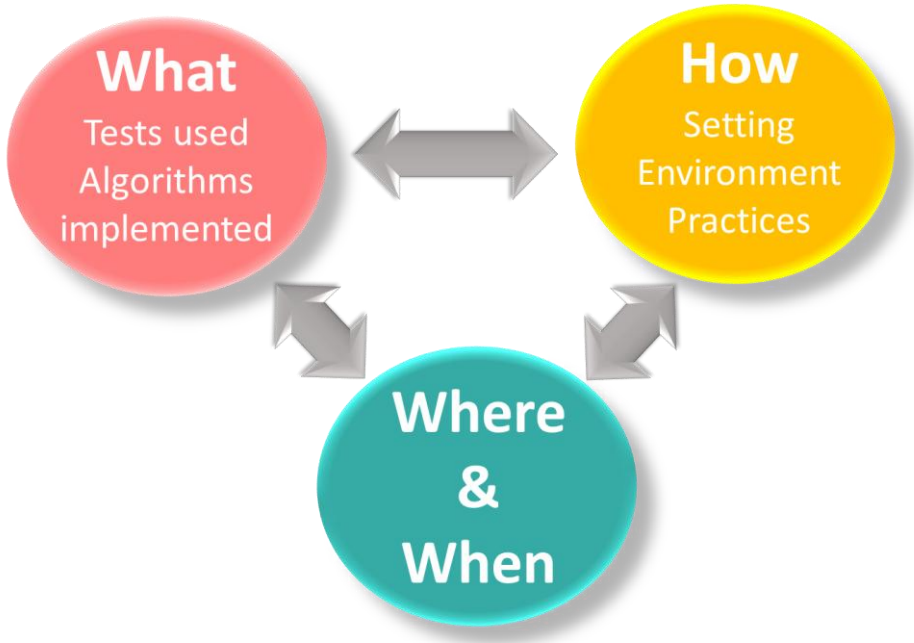
Where are tests performed and with which TAT – algorithm and diagnostic network

Impact of reagent stockouts and interruptions – supply chain and maintenance



- Quality of DST depending on the performance of individual laboratories – QMS
- Laboratories and clinicians result interpretation abilities
- Translation of DST results into treatment regimens

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Thank you for your attention

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