

## INTRODUCTION OF BPAL-L 6-MONTH RR-TB REGIMEN WEBINAR

## REVISED TB DIAGNOSTIC ALGORITHMS

Dr Lindiwe Mvusi
30 August 2023

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## OUTLINE

- Background to the changes
- New diagnostic platforms
- Placement
- Implications
- Diagnostic Algorithm revisions
- Way forward

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## BACKGROUND

- Xpert cartridge shortages experienced in 2021-22
- Diversification of testing platforms
- WHO Update on the use of nucleic acid amplification tests to detect TB and drug-resistant TB

| Technology Class | Products included in evaluation |
| :---: | :---: |
| Moderate complexity automated NAATs for detection of TB and resistance to rifampicin and isoniazid | Abbott RealTime MTB and Abbott RealTime MTB RIF/INH (Abbott) <br> FluoroType MTBDR and FluoroType MTB (Hain Lifescience) BD MAX ${ }^{\text {™ }}$ MDR-TB (Becton Dickinson) cobas MTB and cobas MTB-RIF/INH (Roche) |
| Low complexity automated NAATs for detection of resistance to isoniazid and second-line anti-TB agents | Xpert MTB/XDR (Cepheid) |
| High complexity hybridization-based NAATs for detection of resistance to pyrazinamide | Genoscholar PZA-TB II <br> WHO <br> consolidated |
|  | Rapid diagnostics for tuberculosis detection |

## TB TESTING PLATFORMS



COBAS MTB and COBAS MTB RIF/INH (ROCHE)


BD MAX MDR-TB (BECTON DICKINSON)

## PLACEMENT OF TESTS

| DR-TB reflex testing |
| :---: |
| will be conducted in |
| the 15 culture and |
| LPA laboratories |

Existing Xpert footprint:

- $\mathrm{n}=162$
- High, medium and lowvolume processing sites

Changing landscape with moderate-complexity platforms:

## IMPLICATIONS

- No reference to Xpert as first line test but TB-NAAT which is the class of all these tests
- Cobas and BD Max conducted on sputum only
- Xpert conducted on sputum, gastric washings/aspirates, lymph node biopsies or fine needle aspirates, tissue biopsies, Fluids (joint, pleural, ascitic, peritoneal, pus collection) and cerebro-spinal fluid (CSF) - ? stool, urine
- Results reported as RS, RR, HR, MDR TB
- Major change is HR diagnosis upfront, requiring appropriate management at point of diagnosis
- Patients with RR/MDR-TB will be referred to treatment initiation site
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## MTB NOT DETECTED

## MTB NOT DETECTED



Clinical assess the patient
Symptoms, physical examination findings, Chest x-ray (where available)


HIV NEGATIVE
Continue routine care

HIV POSITIVE

- collect another sample for culture and DST
- defer treatment until culture and DST results are available
- Continue routine care

Clinical presentation consistent with TB Symptom and signs suggestive of TB, and/ Chest x-ray suggestive of TB
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## TEST UNSUCCESSFUL <br> UNSUCCESSFUL



- Start DS-TB treatment.
- Collect sample for culture and DST.
- Follow up and review culture and DST results.


## MTB DETECTED - NO TREATMENT WITHIN THE LAST 2 YEARS



## MTB DETECTED - TREATMENT WITHIN THE LAST 2 YEARS



## TRACE (Xpert ONLY)


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## WAY FORWARD

- Implementation in September dependent on laboratory readiness
- Laboratory reports will be revised
- Training
- Knowledge Hub webinars
- Printing and dissemination of algorithms
- Revision of data elements and NIDS
thank

