Multi-disease testing: current status and future prospects

Advanced TB Diagnostics course

June 2018, McGill SI

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

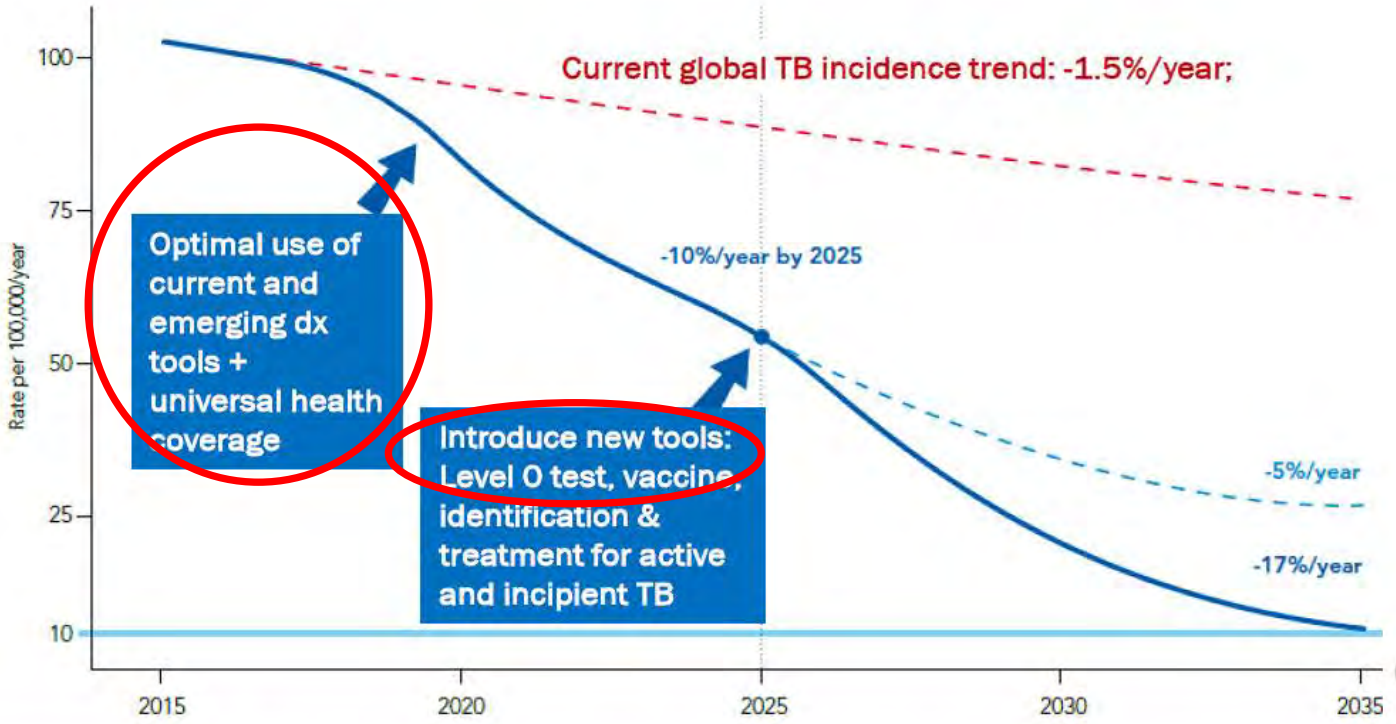
Background

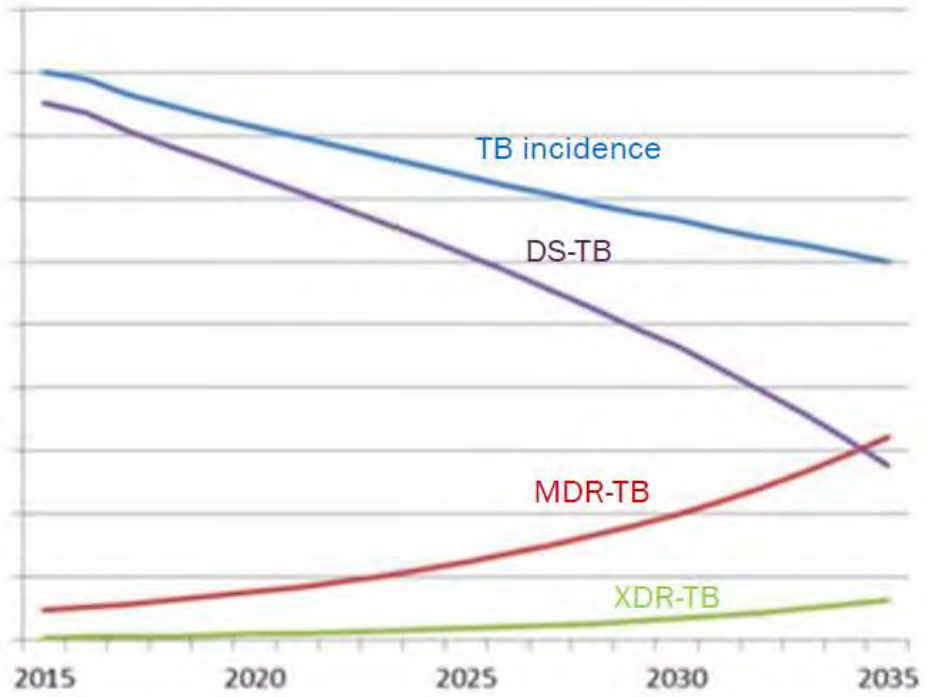
- At the end of 2016:
  - 10.4 million estimated new TB cases and 4.3 million cases were missed
  - ~20million (of estimated 37million) are on ART, and require VL testing.
  - 256 million people were living with chronic hepatitis B infection; and only 9% knew their status
  - 71 million people were living with chronic hepatitis C infection; and only 20% of knew their status.
- Coinfection is common in many populations (HIV, TB, hepatitis etc) and these are all disease of global health importance and we have targets to achieve.
  - In addition to the increasing concern of coinfections, AMR is also emerging as a major challenge to the effective treatment of a growing number of infectious diseases. It is estimated that AMR will lead to 10million deaths annually by 2050.
- Limited **access** to diagnostics remains a bottleneck.

Without finding the missing TB and MDR-TB cases, we will not bend the curve(s) and achieve End TB targets

Only 60% of TB cases detected and notified: 4.3 of 10.4 million TB cases missed

Only 20% MDR cases diagnosed or treated: 448,000 of 580,000 MDR cases missed





Source: WHO, Global TB Strategy 2015. MoxAfrica: World Tb Day 2016 - Disaggregating the pandemic into its drug-susceptible and drug-resistant parts; Sharma Lancet ID 2017

So what do we have?

- Laboratory technologies are available that allow for disease-specific tests using a common platform and this could be an essential next step in the quest to end these pandemics.
- Multi-disease platforms can bring new opportunities for collaboration and integration, which can provide significant system efficiencies and cost savings; increase patient access; and ultimately improve quality of care.
- Leveraging on multi-disease testing devices could help to enhance the impact of investments in diagnostics reducing mortality from comorbidities (*increase coinfection screening*) that would otherwise remain undiagnosed and untreated.
- External funding is slowly reducing and we need optimization of technologies and holistic thinking beyond vertical programs

BD MAX™

Roche Cobas

Abbott m2000 sp/rt

Bioneer ExiStation

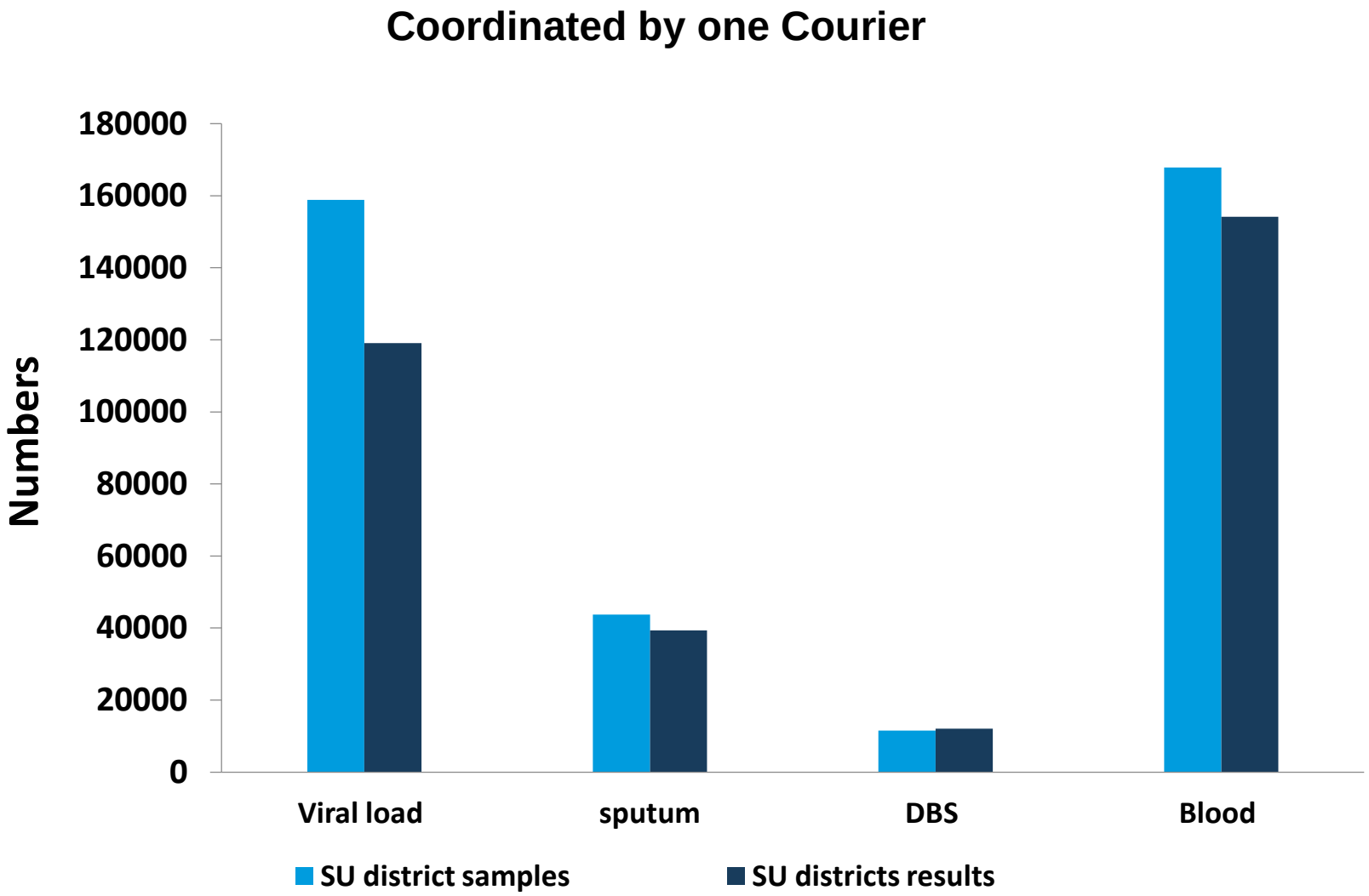
GeneXpert Infinity

- HIV-1 (VL, EID), HCV (VL), HCV (genotyping), HBV, HPV, CMVs, CT and NG assays etc, which are all CE marked and US FDA approved.
- **MTB RIF/INH** in sputum 3-days <35°C
- Simplicity, automation, multi-disease testing capabilities and high throughput capabilities
- Many centralized platforms are under-utilized (*have unfavorable RAP due to volumes*) and also POC Xpert are under-utilized.
- GeneXpert often underused because of high cost, inadequate decentralization, weak implementation policies. Can we leverage the centralized platforms to assist in initial TB dx in adults and children and Xpert for multi-disease testing.
- Optimization of available devices!!!!

Near POC GeneXpert

Many pipeline multi-disease testing diagnostics

Enabling environment already: AN INTEGRATED SAMPLE/REPORT TRANSPORT



RESEARCH ARTICLE

Multidisease testing for HIV and TB using the GeneXpert platform: A feasibility study in rural Zimbabwe

PLOS ONE

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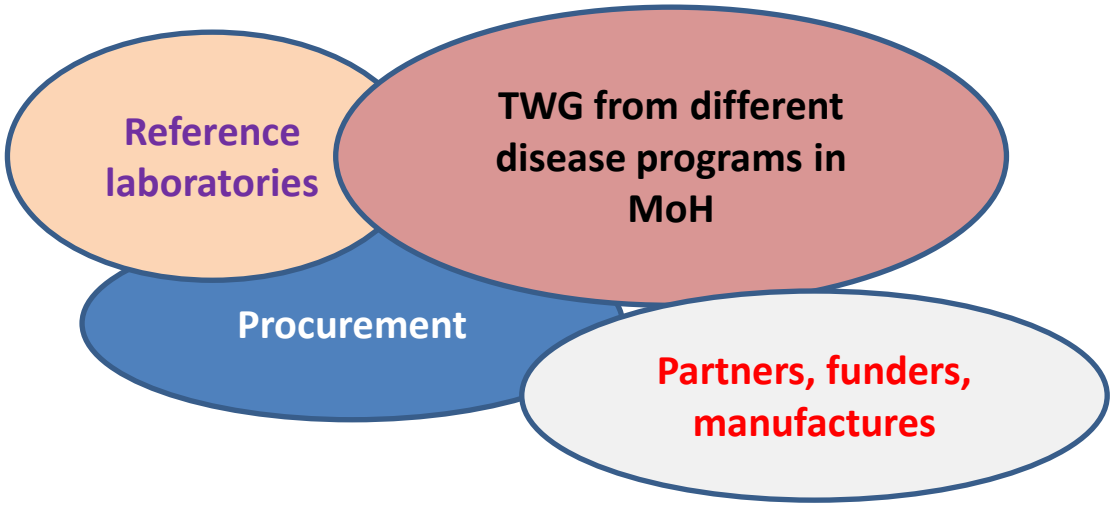
- High TAT of centralized testing results for high risk patients: VL, EID, yet our Xpert MTB/Rif utilization rates were <50%.
- Evaluate the operational feasibility of the polyvalent Xpert systems (HIV VL, HIV EID, MTB/Rif assays) in 3 decentralized settings (districts and sub-districts).
- A total of 1302 HIV VL tests, 277 EID and 1581 MTB/Rif tests were conducted on GeneXpert platforms in the three study sites.
- Reduced TAT : 1day vs +/-28days; VL>1000= 10%; EID +ve=+/-4%.
- All TB suspect samples were tested together with All HIV EID and ONLY priority VL samples (*pregnant women, adolescents, and suspected ART failure patients,* as per clinician's request). HIV VL for patients who are stable on ART, were sent for centralized testing as DBS samples.
- Xpert utilization rates improved up-to +/-63%.

The Keys to Success

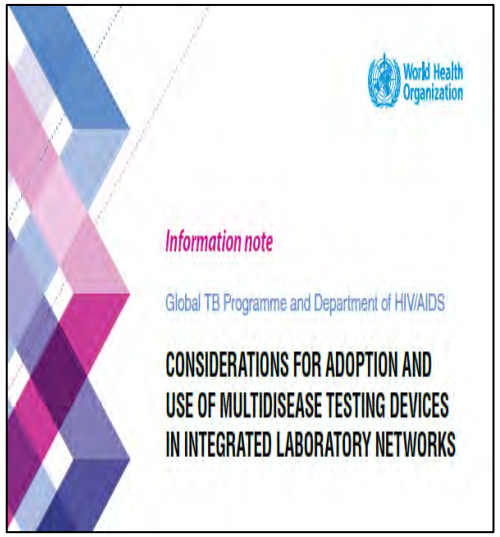
How can we assess possibilities of multi-disease testing?

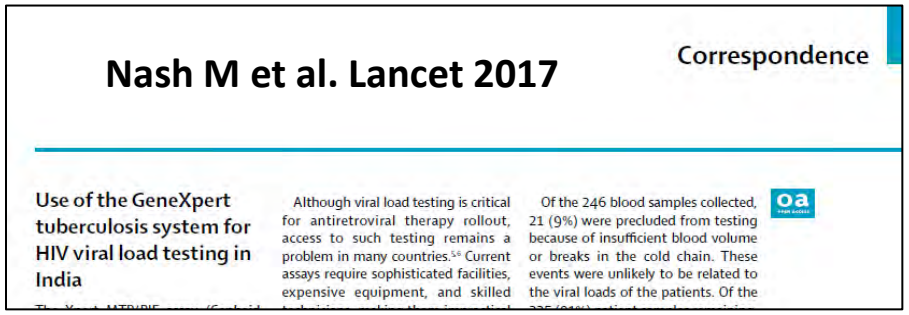
- Country-led and country-coordinated process to develop a strategic country plan for multi-disease testing: mapping of laboratory sites, estimate volumes & specimen referral networks and a results reporting system

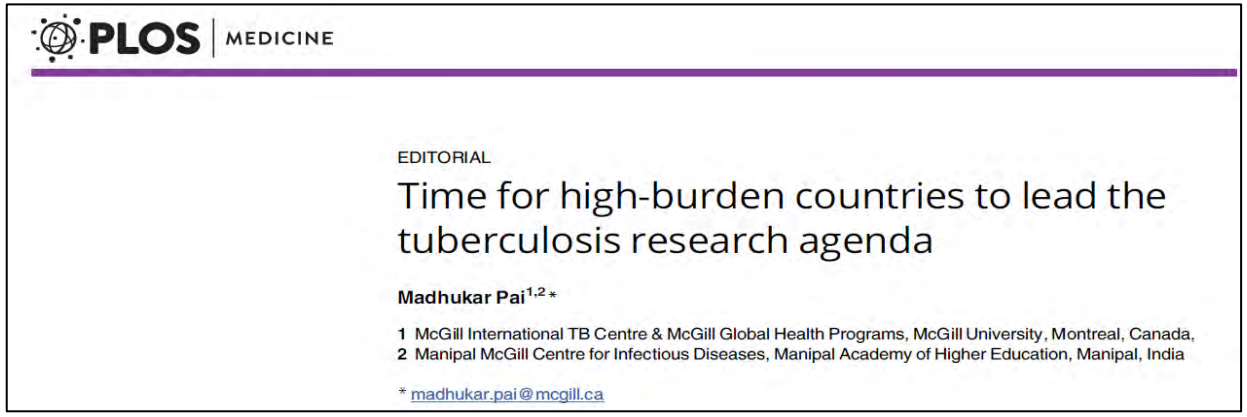


- Potential areas for integration: staff in PHC already providing HIV and TB services, joint planning & budgeting, specimen referral etc
- Unused capacity of existing devices should be assessed before additional devices are procured.
- However, ongoing efforts to increase testing using existing devices for their original purposes should also be considered where necessary.

Guidance and experience available







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EDITORIAL

Time for high-burden countries to lead the tuberculosis research agenda

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Will multi-disease testing be feasible and how do we do it?

If you fail to plan, then you plan to fail.

THE END

Thank You!

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