USING CONNECTED DIAGNOSTICS TO IMPLEMENT THE NEW WHO SHORTER MDR TREATMENT REGIMEN

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ABSTRACT BODY:

BACKGROUND: In May 2016, the WHO announced new recommendations for the use of innovative, rapid diagnostics for multidrug-resistant tuberculosis (MDR-TB) combined with a shorter, cheaper treatment regimen that is easier for patients to complete.

Quick triage using MTBDRsl combined with Xpert results enables fast and appropriate treatment initiation under these guidelines. This Line Probe Assay (LPA) is a DNA-based test that identifies genetic mutations in MDR-TB strains, making them resistant to fluoroquinolones and injectable second-line TB drugs. The test is a critical prerequisite for determining MDR-TB patient eligibility for the newly recommended shorter regimen, while avoiding placing patients resistant to second-line drugs on this regimen. Rapid implementation is expected to improve outcomes, reduce loss to follow-up, and decrease deaths due to better adherence to treatment. **The use of a connected diagnostics platform (e.g. Aspect, GxAlert, etc.) can achieve this by making Xpert and LPA results interoperable, connected, and available immediately to the clinician.**

METHODS: Results must be linked together from multiple TB diagnostic platforms and different levels of the lab network. Current information systems are based on manual data entry and ownership of that data stays with the lab doing tests but is not easily shared. The purpose of this work is to digitally connect the necessary TB diagnostic results into a single record and to make that data remotely available for patient management.

While unique national patient IDs remain elusive in the developing world, it is possible to combine test results within "micro-populations". A Rif-positive GeneXpert result can trigger custom notifications for the technician and assign a unique "Shorter Treatment Regimen ID" (to be renamed) at connected diagnostics promises. The terms of the DUA are codified in the MOH connectivity software (www.GxAlert.com) which allows Ministries to audit the use of its data.

RESULTS: This method is under evaluation for Myanmar, Tanzania, and Mozambique; results are expected in Q2 2017.

CONCLUSION: If successful, this demonstrates the role connected diagnostics can have in executing policy objectives, and also demonstrates a capability in Tuberculosis that can easily be ported to HIV, Zika, Ebola, and other diseases.

CHOOSING THE MDR-TB TREATMENT REGIMEN IN PATIENTS WITH CONFIRMED RIFAMPICIN-RESISTANT OR MDR-TB

CRITERIA: Do any of the following apply ?

- ✓Confirmed resistance or suspected ineffectiveness to a medicine in the shorter MDR-TB regimen (except isoniazid resistance)
- ✓Exposure to >1 second-line medicines in the shorter MDR-TB regimen for >1 month
- ✓ Intolerance to >1 medicines in the shorter MDR-TB regimen or risk of toxicity (e.g. drug-drug interactions)
- ✓Pregnancy
- ✓Extrapulmonary disease
- ✓At least one medicine in the shorter MDR-TB regimen not available in the programme

NO — **Failing Regimen, Drug Intolerance, Return After Interruption >2 Months, Emergence Of Any Exclusion Criterion** — **YES**

Shorter MDR-TB regimen

Intensive phase
Duration: 4-6 months
Composition: 4 second-line drugs

Continuation phase
Duration: 5 months
Composition: 2 second-line drugs

Supported by selected first-line TB drugs

Individualised ("conventional") MDR/RR-TB regimens

Intensive phase
Duration: Up to 8 months
Composition: 4 or more second-line drugs

Continuation phase
Duration: 12 months or more

Composition: 3 or more second-line drugs

Supported by selected first-line TB drugs

Boston + Johannesburg

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