

What do we need to have a patient centered approach?

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Treatment Action Group
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Global Laboratory Initiative Meeting

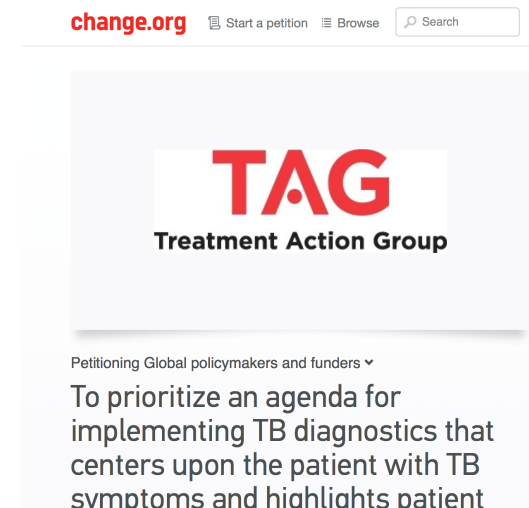
R&D TB Diagnostics

- Funding
 - Grossly insufficient
 - 23.4% decline between 2011 and 2012
 - 2012, USD \$42,429,160 spent globally versus Global Plan \$340,000,000
 - Serious lack of investment - lack of movement of more products in the pipeline
 - BRICS countries must contribute to TB R&D
- Develop linkages between researchers and developers
- Crucial need for point of care

Patient Centered Approach

TAG

- **Focus on cure** accurate diagnosis leading to rapid treatment, active management of co-morbidities and symptoms, follow-up to ensure adherence, and cure.
- **Access to care**
- **Systems of care** Patients are
- diagnosed not by assays but by
- complex systems. All weaknesses in
- those systems must be addressed
- **Empowered patients**
- **Sustainability**



<https://www.change.org/petitions/global-policymakers-and-funders-to-prioritize-an-agenda-for-implementing-tb-diagnostics-that-centers-upon-the-patient-with-tb-symptoms-and-highlights-patient-well-being-and-cure>

Xpert MTB/RIF

- Assay can be effectively administered by nurses in primary health care settings (Theron 2014)
- Same day treatment initiation for more patients
- (Hanrahan 2013) found that those who received an Xpert MTB/RIF positive test had a median time of zero days time to treatment initiation
 - The median time to tuberculosis treatment was 0 days (IQR: 0–0) for Xpert positives, 14 days (IQR: 5–35) for those diagnosed empirically, 14 days (IQR: 7–29) for radiological diagnoses, and 144 days (IQR: 28–180) for culture positives.
 - Xpert at point-of-care resulted in same day treatment initiation in Xpert-positives

In settings with high HIV/TB burdens where TB is still the biggest cause of mortality in HIV-infected people early initiation of TB treatment is key to keeping people alive.

Theron G, Zijenah L, Chadra D et al. Feasibility, accuracy, and clinical effect of point-of-care Xpert MTB/RIF testing for tuberculosis in primary-care settings in Africa: a multicenter, randomized, controlled study. *The Lancet*. Vol 383, 2014 February 1

Hanrahan C, Selibas K, Deery C, Dansey H, Clouse K, Bassett J, Scott L, Stevens W, Sanne I, Van Rie A. Time to Treatment and Patient Outcomes among TB Suspects Screened by a Single Point of Care Xpert MTB/RIF at a Primary Care Clinic in Johannesburg, South Africa. *Plos One*. June 2013. Volume 8. Issue 6.

Alere Determine TB- Ag lipoarabinomannan (LAM) lateral flow test

TAG

- Add-on rather than standalone test
- Lawn CROI 2014: Increase in detection from 26.6% to 80.6%, when the urinary LAM test was added to an Xpert MTB/RIF test.
- When combined Determine TB LAM and Xpert MTB/RIF could detect 69.1% of culture confirmed cases.
- By adding the test they were also able to find 85% of TB cases in persons with CD4 below 100/ μ L.

This test is cheap, produces results in less than 30 minutes and is a point of care assay.

Alere, the test developer and the WHO must work quickly to achieve approval so that this assay can be implemented widely.

Early development

Late development

On pathway to WHO evaluation

High complexity assays

Molecular DST

TruArray MDR-TB (Akkoni)*
INFINITIMTB (AutoGenomics)

Culture-based technologies

BNP Middlebrook (NanoLogix)
Rapid colorimetric DST*

Molecular detection and DST

Xpert MTB/RIF (↑Sensitivity), XDR
(Cepheid)
Alere Q (Alere)*
Enigma ML (Enigmadiagnostics)
Q-POC (QuantuMDx)*
DiagCORE (Stat-Diagnostics)
EOSCAPE (Wave80)
RT-PCR Testing Platform (NWGHF)
iCubate 2.0 (iCubate)

Volatile organic compounds

BreathLink (Menssana)
Prototype breathalyzer (Next
Dimensions)
TB Breathalyzer (Rapid Biosensor
Systems)
Aeonose (The eNose Company)
Breath analysis instrument

Microscopy

TBDx (Applied Visual Sciences)
Fluorescent microscopy (ID-FISH Tech.)
Automatic TB Screener (Fluorobot)

Antigen detection

LAM in sputum (Standard Diagnostics)

Antibody detection

Multiplex antibody array (mBio)

Enzymatic detection and DST

β-lactamase reporter (Global
BioDiagnostics)*

Molecular DST

TRC Rapid MTB (Tosoh)
TB Drug Resistance Array (Capital Bio)
VereMTB (Veredus Laboratories)
LPA Pyrazinamide (Nipro)
LATE-PCR PrimeSafe (Hain)

Culture-based technologies

IREK Sensitive MYCOTB (Trek)

Molecular detection and DST

Genedrive MTB/RIF (Epistem)
Truelab/Truenat MTB (Molbio)

Volatile organic compounds

Giant African Pouch Rats (Apopo)

Microscopy

Microimager (BD)

Imaging

CAD4TB (Delft Imaging Systems)

Molecular DST

GenoTYPE MTBDRsl (Hain)*
LiPA MDR-TB (Nipro)
REBA MTB-Rifa (YD Diagnostics)

Molecular detection

TB LAMP (Eiken)

Antigen detection

Alere Determine TB-LAM in urine
(Alere)

Moderate complexity assays

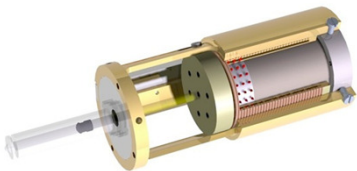
Low complexity assays

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Pipeline

- Pipeline moving albeit slowly
- The future?
 - Whole genome sequencing – the final frontier in addressing health?

Star Trek	2014
Hypospray	Jet injectors – vaccinations
Non-invasive surgery device	Focused ultrasound surgery
Communicator	Cellphone



Are you ready for the future?

Systems of Care

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Know your epidemic

- Accurate estimates of TB in country
- Know your ‘hot spots’ – this will inform placement of new tools

Develop national strategy for **ANY** new tool

- Including appropriate, understandable diagnostic algorithm

Develop policy guidance on use of tool (timing)

- Ensure policy fully disseminated and understood (smear still being used for HIV+ **WHY?**)

Systems of Care

Financial sustainability

- Develop accurate budgets i.e. staff training, consumables, transport, treatment, care and support

Coordinate donors so that there is one national program

- Seamless program for delivery
- Choose appropriate sites based on burden

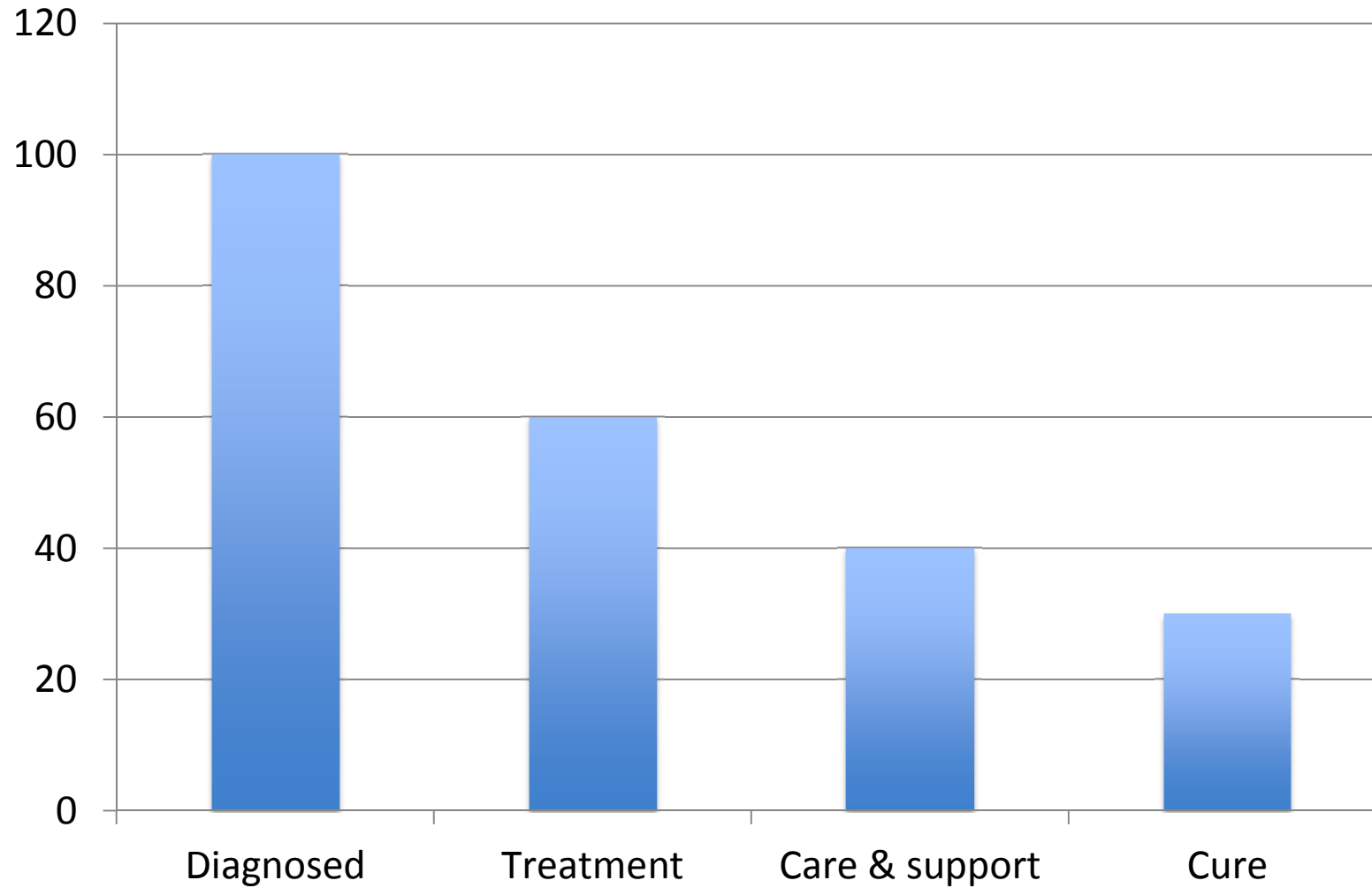
Systems of Care

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Implement M&E indicators for new tool

- Add to current M&E framework
 - # cartridges used
 - linked to treatment
- Adapt recording and reporting forms
- **Use cascades of care**

Cascades of Care



TAG

Systems of Care

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Procurement

- Ensure accurate forecasting for all parts of tool – modules, cartridges, consumables
- Implement procurement measures that happen throughout the year
- **Negotiate** price reductions for your country
 - Lease options for modules
 - Pooled procurement
 - Lower price extended warranties

Where is volume increase and price reduction?

Systems of Care

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Regulatory Issues

- National regulatory authorities must be ready to assess any new tool – sensitize them to TB so roll out can happen quickly
- Standardized processes for tool endorsement

Civil Society/Communities

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- Where are civil society, patients in this process?
- **Successful advocacy**
 - Rifapentine price reduction
 - In 2012, Sanofi reduced from \$73 to \$51 per box, and starting in January 2014, the 340B price will be further reduced to \$32 per box—a 56.2% reduction
- **Empowered patients:** Patients will achieve successful diagnosis and cure
 - Trust and collaborate with their providers and healthcare systems as full partners in their care

Zero TB Deaths

The logo consists of the letters 'TAG' in white, bold, sans-serif font, set against a red rectangular background. This red rectangle is positioned on the right side of the slide, overlapping a light blue textured area at the top and a green textured area below it.

TAG

One patient

Integrated diagnosis, treatment, care & support

- This includes labs!
- Where do you fit into this process?
- Are you an advocate?



Thank you

