What do we need to have a patient centered approach?

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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

- **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**

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.

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

• 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/μL.

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.

Pipeline

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

<table>
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<th>Star Trek</th>
<th>2014</th>
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<tr>
<td>Hypospray</td>
<td>Jet injectors – vaccinations</td>
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<td>Non-invasive surgery device</td>
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Are you ready for the future?
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

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

- Diagnosed
- Treatment
- Care & support
- Cure
Systems of Care

**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

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

- 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

One patient

Integrated diagnosis, treatment, care & support
- This includes labs!
- Where do you fit into this process?
- Are you an advocate?
Thank you