TAG's Perspective on Xpert MTB/RIF

Javid Syed

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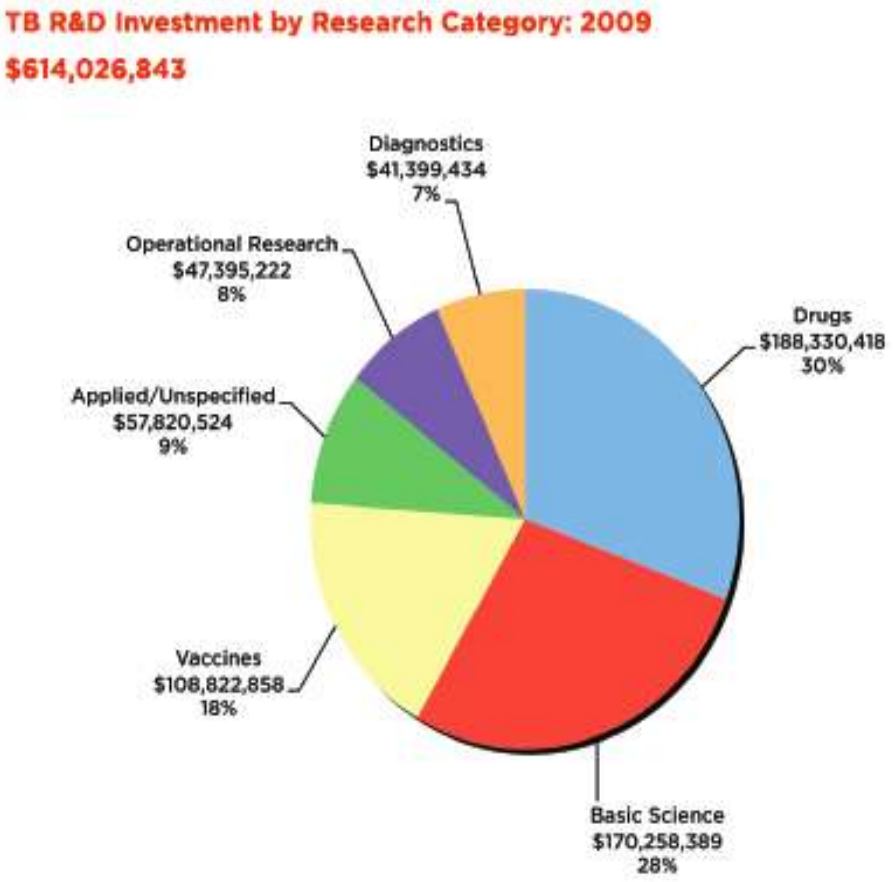
Background (I): Programmatic need

- Rate of case detection still hovers around 63% for all forms of TB
- Smear in routine program settings has been seen to miss nearly 50% of cases.
- Case detection is worse in people with TB/HIV and pediatric TB cases that have higher rates of SS- and EPTB.
- Less than 3% of MDR-TB cases are reported to get treated according to WHO guidelines.
- Less than 1% of people eligible with TB/HIV get access to IPT.

Background (II): Funding



Source: Jimenez, ES. Tuberculosis Research & Development: 2010 Report on Tuberculosis Funding Trends, 2005-2009. www.treatmentactiongroup.org

Background (III): Diagnostic Pipeline

- The pipeline isn't robust, despite unprecedented activity.
- At least 7 products/ strategies were recommended by STAG-TB in the last 4 years, most only offer incremental improvement over current smear and culture tests.
- TAG's 2010 Pipeline Report highlights that only 5 tools are likely to be brought to STAG-TB for recommendation in the next 3 years (including Xpert MTB/RIF, IGRA's, and LAMP).
- Most of the tools are pushing technology to lower rungs of the health system, not appropriate to diagnose TB at peripheral health facilities.
- None of the tools in the pipeline are instrument free, POC.
- Need to make the most of what is currently available and not wait for a magic bullet.

Source: Treatment Action Group. TAG 2010 Pipeline Report
www.treatmentactiongroup.org

Background (IV): Civil Society Engagement in Demand Creation for New Tools and Monitoring of Roll Out

- WHO included ‘Empowering TB Patients and Their Communities’ in the 2006 revision of its Stop TB Strategy, but there has been very little policy guidance on what this entails.
- Sept 2010 WHO global CSO consultation has highlighted the need to invest in TB literacy, funding for CSOs, and engaging CSOs to contribute in policy formulation and program implementation
- Current situation,though improving, is still bleak. There is little investment and leadership from the NTPs to implement the component of the WHO strategy targeted at empowering patients.
- INAT Subgroup (formerly Retooling Task Force) had outlined a process of roll out of new tools that included engaging CSOs, but there are scant examples of this being done.

CSO expectation for Xpert MTB/RIF

- Xpert has advantages of speed, simplicity, and sensitivity over smear and culture, especially for SS- cases, people who have rifampin resistance/are at risk for MDR
- Can reduce morbidity, mortality, and patient costs
- Can provide diagnosis of multiple diseases and increase credibility of health systems, allow for earlier access to treatment.

BUT, to do this we need to…

- Conduct OR to establish utility at different levels of the health system, in different epi contexts, and algorithms and document patient important outcomes (patient satisfaction, clinical outcomes beyond TAT)
- Assess its utility for pediatric TB cases and EPTB using gastric fluids, and other specimens
- Reduce costs and availability of product support
- Need to ensure access to treatment (both curative and preventive) and engage CSOs in supporting treatment completion and support
- Need to ensure that funders, NTP, and CSOs are on board to create demand and support roll out

CSO priorities for Xpert MTB/RIF and beyond

- We have to learn by doing and not let the perfect be the enemy of the good.
- Need to get the best available tools, such as Xpert MTB/RIF as low into the health system as possible while continuing to work on the needed POC test.
- CSOs, especially people at greatest risk for death and disease due to TB are eager to contribute to this effort, we need to take advantage of their untapped potential by engaging them fully in the roll out of this tool.

Thank you!