

USAID PERSPECTIVES FOR ROLLING-OUT XPERT MTB/RIF

Mukadi Ya Diul, MD, MPH
Office of Health, Infectious Diseases and Nutrition
Global Health Bureau

4th Global Laboratory Initiative (GLI)
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U.S. TB Strategy: Goals and Target

Impact – MDGs by 2015

- 50% reduction in TB deaths vs. 1990
- 50% reduction in TB disease burden vs. 1990

Outcome

- Detect at least 70% of all cases (all forms)
- Successfully treat 85% of all TB cases

Output – based on ~2.2B over 6 years

- Successfully treat at least 2.6 million new TB cases
- Diagnose and initiate treatment for at least 57,200 MDR TB cases



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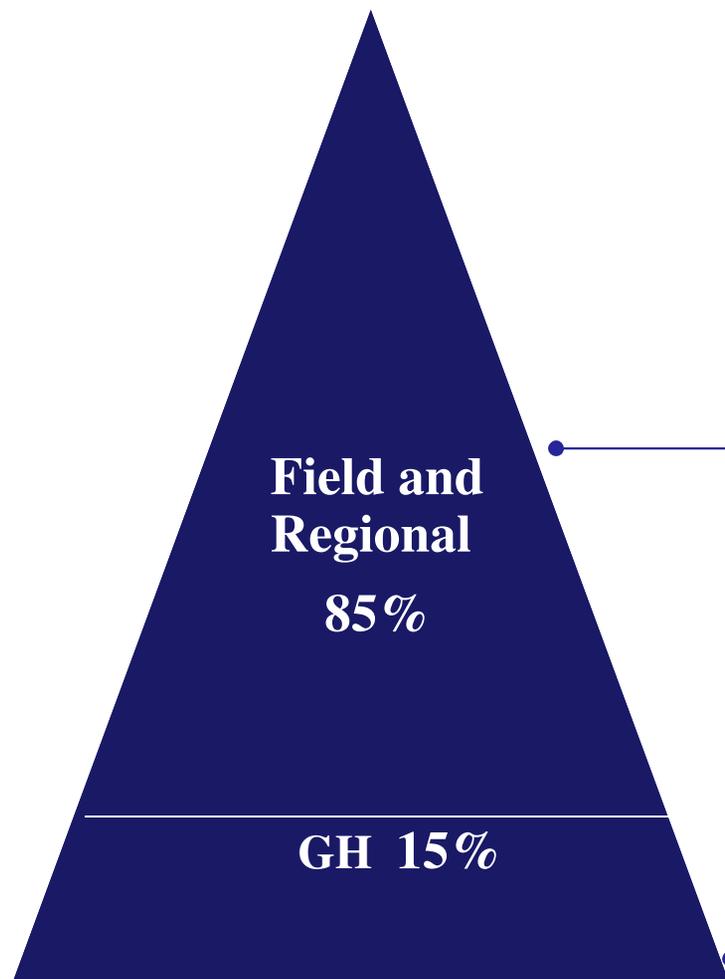
Integrated U.S. Government Response to the Global TB Epidemic

Agency	Leadership Role
National Institute of Health	<ul style="list-style-type: none"> • Lead for biomedical research and research training
Office of the Global AIDS coordinator	<ul style="list-style-type: none"> • Lead for control of TB/HIV co-infection
U.S. Agency for International Development	<ul style="list-style-type: none"> • Lead for international TB control • Technical support in 41 countries including universal access, MDR-TB and laboratory strengthening; implementor for OGAC-funded TB/HIV programs • Support late-stage research, programmatic and operational research and introduction of new tools
U.S. Centers for Disease Control and Prevention	<ul style="list-style-type: none"> • Lead for domestic TB control and international lab support • Implementor for OGAC-funded TB/HIV programs • Lead for operational research/reference laboratories
U.S. Department of Defense	<ul style="list-style-type: none"> • Research laboratories and mobile care units • monitor the quality of diagnostic services and conduct research

TB Programming: Key Approaches

Approach	Examples
Promote country ownership	<ul style="list-style-type: none"> • Develop 5-year NTP Strategic Plans • Support development and implementation of GF grants • Support NTP routine monitoring and supervisory systems • Support participatory MOH led external evaluations • Joint annual work planning with NTP and other partners
Sustainable systems	<ul style="list-style-type: none"> • Strengthen drug/supply chain management • Strengthen facility level routine M&E system • Develop/improve lab network at all levels • Build primary health care capacity
Leverage resources	<ul style="list-style-type: none"> • Develop GF proposals to fill gaps in strategic plans • Coordinate TB/HIV funds through PEPFAR • Expand health platforms (community, lab, drug mgmt.)
Provide global technical leadership	<ul style="list-style-type: none"> • Develop and pilot new tools, policies, guidelines • Provide TA to countries/in targeted technical areas • Participate in WHO core working groups and STAG • Lead USG international TB efforts

Country Level Focus – Supporting the Field



Field level support:

- Response to local needs/gaps based on NTP Strategic Plan, GF grant, and PEPFAR COP
- TA to MOHs, private sector, and NGOs; coordinate with other partners
- Expansion of new approaches/technologies (e.g., PMDT and Xpert)
- Global Drug Facility (GDF)

GH support:

- Global policy and guideline development
- Global research and operational, technology, regimen development
- Technical support for evaluation, program design, monitoring, mentoring, and project management

Implementers: Stop TB Partnership, WHO, CDC, TB CARE I and II, TO 2015, TREAT TB, SPS, USP, Global Alliance, GDF, GLC, TB TEAM, IFRC, and CSHGP



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USG's Support to Xpert Implementation

Global Technical Leadership	
Support to Global Lab Initiative	Global policy guidance, norms and standards
TB CARE I Global Project	Intensified introduction of Xpert through systematic approach
USG Coordination/Guidance	Translating and developing policy and approaches for country projects; Mission strategies (i.e. CAR)
Country Roll-out	
Procurement of machines, cartridges, other hardware	USAID – procured and planned to procure >100 machines in 24 countries by end of next year (<i>TBCARE I, TBCARE II, TB Task Order, Other mission partners</i>)
Technical assistance	Extensive support in countries through systematic approach
Monitoring & Evaluation	Baseline, data collection, impact evaluation

USG Xpert Roll-out: Coordination and Guidance

- Obtained no **'source-origin waiver'** to allow USAID supported countries to procure Xpert machines and cartridges
- Developed **policy guidance** on Xpert for USAID missions
- Assisted USAID missions with the development of **strategies**
- Developed **technical approaches** to guide implementation
- Compiled **lessons learned/experience** to share regionally and globally (CAR & Africa workshops)

USG's Xpert “Technical Approach”

Components

1. **Coordinate efforts & define priorities and needs**
2. **Develop implementation plan**
 - **Diagnostic algorithms, site selection**
3. **Preparing laboratories and sites for implementation**
 - **Operational issues, ensure infrastructure, procurement, distribution**
 - **Set of materials (training presentations, supervision checklists, software guides, registers/request forms, lab SOPs)**
4. **Training**
5. **Monitoring and Evaluation**

USG's Xpert “Technical Approach”

Key Principles

- * All support should be carried out in collaboration with the Ministry of Health and in line with the NTP Strategic Plan and National TB Lab Strategic Plan
- * Roll-out should be carried out in a phased manner according to WHO policy, USG guidance and global best practices
 - Evidence collected should feed back to country and global knowledge-sharing to better inform policies and practices
- * Roll-out should be coordinated with scale-up in capacity to treat and other diagnostic services

USAID Xpert Roll-out in Countries

Intensified introduction of Xpert through a:

systematic technical approach

- **Started in 3 countries in summer 2011**
 - **Nigeria, Indonesia, Vietnam**
 - **Continuing in Kazakhstan, Ethiopia, Kenya**
- **Purpose is to stimulate the roll-out of Xpert**
 - **Systematic and comprehensive technical approach**
 - **A few initial machines and cartridges**
- **Capture/share evidence and operational lessons for future implementation**
- **Exchange knowledge among stakeholders in different countries to use as an implementation “model”**

USAID Xpert Roll-out in Countries

Intensified introduction of Xpert through a: **systematic technical approach**

- Had procured and planned to procure >100 machines in 24 countries
- Extensive technical assistance to countries throughout the implementation process

USG Xpert Monitoring and Evaluation

- **With CDC and OGAC, developing a USG Xpert M&E framework with defined programmatic and lab outcomes and outputs**
- **Routine data collection (compared to a baseline)**

USG Xpert Monitoring and Evaluation (2)

Example Outcomes

TB Case Notification Rate

- Among HIV-infected TB suspects
- Among MDR-TB suspects

Health Service Delays

- Time to detection
- Time to initiation of appropriate treatment
- Proportion on appropriate treatment
- Proportion who died before treatment
- Proportion lost to follow-up before treatment

Treatment Outcomes

Lab/Xpert operations outcomes (WHO)

Indications for Xpert Testing (WHO)



Lessons Learned

- **The placement of Xpert might result in decreased workload at laboratory but identifies more patients and increases workload for the treatment clinic**
 - **Careful pre-plan and assess sites to examine the ability to test and treat– particularly relevant for MDR - before placing the machines**
 - **Change clinician treatment protocols and/or NTP regulations to ensure rapid treatment**

Lessons Learned

- **Plan in advance for adequate DST & forecast appropriate drug and cartridge supplies**
- **Use a phased approach and select relevant targets for the countries needs**
- **Coordination across donors is useful. Specifically discuss timing of funds, limitations, etc. (particularly Global Fund)**

A Few Final Words...

- **Implementation is more than buying and installing Xpert machines**
- **A comprehensive implementation plan with a systematic technical approach is necessary – and must be coordinated and budgeted**
- **Leadership from the NTP through all steps is critical to the success of the implementation**
- **We are at the beginning stages of Xpert implementation – focus on roll-out, not scale-up**
- **Implementation cannot be done without the appropriate capacity in treatment and other diagnostic tools**

Necessary & Important Issues to Consider

1. **Strengthening the Lab Network**
2. **Strengthening the management of TB**
3. **Strengthening Programmatic Management of Drug-Resistant (PMDT) Services**
4. **Sustainability of Investments**