Strengthening TB Diagnostics in Resource-limited Settings

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American Society for Microbiology

- The oldest & largest life science organization in the world - 1899-2008
- Membership >43,000 worldwide (30% reside outside the United States)
- ASM members represent 26 disciplines of microbiological specialization
- Publications and journals (translated books, 11 journals covering spectrum of microbiology, Microbe – the News Magazine of ASM)
- Meetings & conferences (ASM General Meeting, Interscience Conference on Antimicrobial Agents & Chemotherapy)
The International Board includes the following structure:

- **International Membership Committee**
  - Global Outreach Program
  - Ambassadors Network

- **International Education Committee**
  - Fellowships, professorships
  - Mentoring Program
  - Translators Network

- **International Laboratory Capacity Building (Lab Cap) Committee**
“Building international laboratory capacity for all clinical microbiology in resource-poor countries”

- Cooperative agreement with Centers for Disease Control & Prevention (CDC) – signed in Fall 2005

- Technical support to the CDC’s Global AIDS Program (GAP) & U.S. Presidents Emergency Plan for AIDS Relief (PEPFAR) initiatives – activities initiated in Summer 2006

**ASM’s Comparative Advantage:**

- ASM’s main strength is its more than 43,000 members, >5,000 of which are clinical microbiologists

- ASM is rapidly able to engage numerous experts as volunteers to provide clinical microbiological technical assistance
ASM Deliverables

- Mentoring to improve lab diagnosis of TB and other HIV/AIDS-related opportunistic infections (OIs)
- Providing advice on lab renovations, equipment, & supply needs
- Developing & harmonizing international training tools for TB & OIs
- Maintenance of relationships with in-country laboratorians
- Pulling from strong international collaborators to gain information on activities already ongoing in-country & harmonizing our efforts
- Collaborations with international agencies such as CDC, WHO, International TB Union (IUATLD), Foundation for New Innovative Diagnostics (FIND), leading to development of best practices
ASM’s Approach to Lab Capacity Building

Strengthening of the public health laboratory network for all clinical microbiology – including TB

- National Reference Laboratory
- Regional/Intermediate Laboratories
- Peripheral Laboratories

- Equipment & consumables
- Biosafety
- Lab Physical Infrastructure
- Quality Assurance/QA
- Referral Networks & Reporting
- Human Resources
Laboratory Network in Resource-Poor Countries in the Context of TB

**National Reference Laboratory**
- Surveillance of drug resistance
  - TB culture, drug susceptibility testing (DST) & identification
- Training & EQA for AFB smear microscopy for lab network
- AFB smear microscopy

**Regional/Intermediate Laboratories**
- TB culture & DST when decentralized
- Training & EQA for AFB smear microscopy for peripheral labs
- AFB smear microscopy

**Peripheral Laboratories**
- AFB smear microscopy
ASM in Botswana

ASM assistance requested by CDC/BOTUSA for strengthening of AFB smear microscopy training & external quality assessment (EQA) programs

- Population: 1.8 million
- TB prevalence rate (2006): 454/100,000 population/year*
- New TB case rate (2006): 551/100,000 population/year*
December 2007, Kampala, Uganda – CDC conducted sensitization workshop for **Acid-Fast Direct Smear Microscopy Training Package** – a consensus “workshop in a box” developed by WHO, CDC, RIT, IUATLD, & APHL

Representatives from 10 countries in sub-Saharan Africa & the Caribbean - including Botswana, ASM Program Managers & ASM consultants in attendance

Participants learned to customize new training package, plan for roll-out of training on a national scale, & develop plan for strengthening EQA
March 2008- ASM consultant began working with 4 Botswanan laboratorians selected as trainers by Botswana National Health Laboratory (NHL) to develop their AFB microscopy training program

Spent 2 weeks at a remote site customizing the consensus training package to Botswana
- Trainer’s Guide
- Workshop agenda & schedule
- Participant’s Guide & handouts
- Manual for lab sessions

Other activities included:
- Development of a strategic plan & timeline for national roll out
- Stakeholders meeting for input & support from key players
June 2008 - trainers conducted a 5-day workshop for 10 participants to pilot the training materials before national rollout

Consultant returned one week prior to workshop to assess trainer & material preparation, assisted with the pilot, & provided feedback

Training team accomplishments:

- Trainers ensured participation of all invitees
- Trainers well prepared
  - Comfortable presenting material & managed workshop time well
  - Applied adult learning principles & engaged participants
  - Met at the end of each day to review comments
- Trainers filled out self-evaluations and conducted peer reviews
- Participant improvement seen in post-test scores
Challenges to Training Rollout

- **Availability of trainers**
  - All four trainers critical to completing training schedule

- **Availability of lab and classroom space**
  - Classroom space ultimately too small; trainers made arrangements to use meeting space in adjacent facilities

- **Availability of supplies & equipment**
  - Shipment for workshop delayed; trainers found temporary replacements & could conduct all modules

- **Development of training materials and data analysis**
  - Not all trainers are proficient with computers; trained each other

- **Selection of target audience**
  - Designed questionnaires to profile trainees to determine who was trained when evaluating training impact
Conclusions & Next Steps

The Botswanan training team has ownership of this training program as they will be ultimately responsible for carrying it out.

- ASM provided guidance through this process & the team learned to move forward despite their challenges.

Next Steps:

- Make final revisions to training material
- Develop sensitization trainings for lab managers to reinforce staff training
- Conduct monitoring & evaluation of training program via External Quality Assessment (EQA)
Botswana’s EQA program was comprised of supervisory visits & panel testing prior to ASM technical assistance. No blinded rechecking program was in place at that time.

Weaknesses included:

- Insufficient funding, data collection & management
- Insufficient time allocated for supervisory visits
- Lack of participation by some labs in panel testing
- Insufficient communication with TB Control Program

By the beginning of 2008, the NTRL had sufficient trained personnel to expand supervisory visits, panel testing, & add blinded rechecking to its EQA program as well as the funding to do so.
Strengthening of the EQA Program

- February 2008 - ASM consultant began work in Botswana to strengthen & expand their AFB microscopy EQA program

- Deliverables included development of:
  - All technical & system procedures; forms for reporting & feedback procedures; & spreadsheets for all 3 EQA components
  - Comprehensive plan to strengthen & expand the EQA program
  - Detailed timeline for implementation

- New plan focuses on the following objectives:
  - Enhancing partnership between labs and BNTP
  - Resuming annual supervisory visits to all labs
  - Undertaking one round of panel testing in all labs
  - Setting up program of blinded rechecking of AFB slides
Conclusions & Next Steps

Strengthening & expansion of an AFB Microscopy EQA program requires a significant time commitment & mentoring – 3+ months for:

- Pre-implementation assessment & collection of past EQA data
- Development of expansion plan
- Development of necessary documentation including forms, procedures, & electronic databases
- Mentoring for panel preparation, supervisory visits, & blinded rechecking procedures

Next steps:

- Additional mentoring is needed for supervisory visits & blinded rechecking
- Budget must be maintained & may require additional funds from the Ministry of Health (MoH) & partners for supervisory visits & training
- Current staffing levels at the NTRL must be maintained
ASM in Haiti

ASM assistance requested by CDC-Haiti for scale up of national TB diagnostic services – including AFB microscopy training & EQA & technical guidance for implementation of TB liquid culture

- TB prevalence rate (2006): 402/100,000 population/year*
- New TB case rate (2006): 299/100,000 population/year*

*WHO Global Health Atlas
Implementation of TB Liquid Culture in Haiti

- June 2008 - ASM met with key representatives from Haiti’s National TB Reference Lab (NTRL), the National TB Control Program, CDC-Haiti, & partners to begin mapping out a coordinated plan for optimizing in-country capacity to diagnose TB

- Renovating the NTRL into a BSL3 TB culture lab that meets international standards determined to be key priority

- Laboratory planning, design, & construction firm experienced with remodeling projects in Latin America & complexity of BSL3 lab design traveled to Haiti on behalf of ASM in June-July 2008

→ **Lab Architect, Containment Specialist, & Materials Architect**
Firm’s mission was to conduct a review of existing conditions & prepare a design narrative to be used as a basis of design for construction documents

- Conducted field survey of existing facilities
- Reviewed suggested location for BSL3 lab & existing construction documents for the facility
- Met with local engineers & contractors to establish basis of knowledge & capabilities found in the area
- Reviewed limitations & discussed mechanical options for ventilation system
- Prepared a draft architectural layout for discussion with Haiti team
- Presented a final draft architectural layout & preliminary mechanical & electrical ideas to Haiti team
Team’s recommendations complied with WHO policy document released in March 2007 “Use of Liquid TB Culture & Drug Susceptibility Testing (DST) in Low & Medium Income Settings Summary Report”

- Specimen processing for culture purposes has to be performed in Biological Safety Cabinets (BSCs), at least in Biosafety Level 2 (BSL2) facilities
- Culture manipulation (conventional identification, subculturing & DST activities) must be performed in BSL3 facilities

Key recommendations included:
- Design of a BSL2 area & BSL3 suite
- Changes to wall, ceiling, floor, door, & window construction
- Specific electrical upgrades
Haiti Conclusions

- Building a BSL3 lab facility that complies with WHO & CDC biosafety standards & can be maintained in the future is an achievable endeavor.

- Expertise to build a successful BSL3 lab in Haiti is available.

- Final design documents must be developed before construction begins.

- Periodic biocontainment inspections & final commissioning must be carried out to assure the lab has been built to comply with regulations & ensure its certification.
ASM in Côte d’Ivoire

ASM assistance requested by CDC-Côte d’Ivoire for strengthening of national TB diagnostic services – including AFB microscopy training & EQA, TB liquid culture & DST, referral networks & reporting, expansion of services to molecular techniques, & procurement of equipment & supplies

- TB prevalence rate (2006): 747/100,000 population/year*
- New TB case rate (2006): 420/100,000 population/year*

* WHO Global Health Atlas
2007 Union World Conference on Lung Health in Cape Town, South Africa - Global Laboratory Initiative (GLI) introduced as an instrument guided by the GLI-Core Group & WHO

Rationale behind GLI creation:

- Need to dramatically expand TB diagnostic services in resource-poor countries (drug resistant TB & TB/HIV co-infection)

- Emphasis on partnerships & coordination to optimize lab strengthening efforts & enable an integrated approach with an end goal of improving lab diagnosis for all infectious diseases

ASM, FIND, CDC, & WHO discussed partnering in a country in the context of the GLI & address lab strengthening vertically, for TB, while improving cross-cutting lab areas that will horizontally impact other disease areas

- Partnership would be used as model for other GLI projects
Côte d’Ivoire selected as first country

- Strong MoH support for TB diagnostic capacity strengthening nationwide
- Motivated National TB Control Program (NTP) & good relationship between NTP & TB National Reference Lab (NRL)
- PEPFAR focus country
- Existence of highly qualified in-country laboratorians & scientists
- French-speaking & regionally isolated country that can serve as regional reference site for West Africa & other French-speaking countries
- Post 4-year socio-political crisis rebuilding needs
- Current non-existence of implementing partners
Côte d’Ivoire Plan

Renovating the NRL
PEPFAR, Global Fund, ASM/CDC

Establish formal referral system
ASM/CDC, PEPFAR

Mentoring & knowledge sharing
FIND/WHO, ASM/CDC

Developing standard recording & reporting
ASM/CDC, FIND/WHO

Optimizing EQA
ASM/CDC, FIND/WHO

Guidance for TB/HIV laboratory integration
Introduction of LED Microscopy (cross-platform tool)
ASM/CDC, FIND/WHO

PEPFAR, Global Fund, ASM/CDC

Linked Referral Services & Timely Reporting

Training & Retention – Human Resources

Logistics & Commodity Management

Quality Assurance

Integrated Laboratory Network

TB
HIV
Malaria
Other disease areas

UNITAID, Others?
Held joint in-country meetings with the MoH of Côte d’Ivoire, NTP, CDC-Côte d’Ivoire, & key stakeholders in April 2008; formalizing partnerships with MoH

New GLI/FIND initiative unveiled June 2008 will secure access for 16 countries to diagnostic instruments, reagents, & supplies at lowest possible price through UNITAID support – includes Côte d’Ivoire

Goal is to improve control of MDR-TB through expanding & accelerating access to new diagnostic technologies & ensure that these tools are properly integrated within TB control programs

Countries can now leverage UNITAID support with additional resources to improve NRLs, ensure training in GLP & new diagnostic methods, & provide sustained technical assistance
ASM & FIND signed a Memorandum of Understanding (MOU) in July 2008

The resulting partnership will:

- Reinforce the expansion & further development of quality-assured lab services as part of a larger framework of health system strengthening within resource-poor settings; and

- Provide novel & lab expertise for tuberculosis and other infectious diseases where they are most needed.
ASM’s Approach to Capacity Building

- Strengthen the **national public health network** for clinical microbiology

- Ensure **countries have ownership** of the lab infrastructure & programs they develop, as they are ultimately responsible for carrying them out

- Understand that the strengthening & expansion of in-country TB programs requires a significant time commitment via **mentoring**

- Implement liquid culture systems only in the context of a comprehensive country plan for TB lab capacity strengthening & expansion; ensure the local infrastructure can establish & maintain **BSL3 lab conditions**

- Establish partnerships & coordination in-country to optimize lab strengthening efforts & enable an integrated approach with an end goal of improving lab diagnosis for **all infectious diseases**
Lab Cap Leadership & Staff

- Steven Specter, Chair Lab Cap Committee
- Lily Schuermann, Director
- Lynee Galley, Manager
- Mah-Sere Keita Sow, Manager
- Juliano Timm, Manager
- Alexis Greenan, Coordinator
The greatest strength of ASM is in its members---their knowledge, expertise, vision, and energy. The breadth of their affiliations---academic, clinical, industrial, and governmental---fosters effective deliberation and action.

Thank you to all of our colleagues who have served as consultants on behalf of ASM.

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