

Global Health Partnerships

SWOT – Implementing Quality Management in Major Laboratories in Resource Limited Countries

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Outline

- PEPFAR
- CLSI
 - Overview
 - Laboratory Strengthening Program
- Tanzania
 - Where Are We - Laboratory Strengthening Program
- SWOT
- Sightseeing ☺
- Questions




President's Emergency Plan for AIDS Relief (PEPFAR)

Funding*

- 2003 – PEPFAR launched to combat global HIV/AIDS
 - **\$ 15 billion over 5 years**
- 2008 – Tom Lantos & Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, & Malaria Reauthorization Act
 - **\$ 48 billion over 5 years**

* www.pepfar.gov




PEPFAR

Goals*

Through FY2013 – PEPFAR plans to work in partnership with host nations to support:

- Treatment for **3 million** people
- Prevention of **12 million** new infections
- Care for **12 million** people including **5 million** orphans and vulnerable children

* www.pepfar.gov



CLSI – Building on the Past... Focused on the Future

2005


In support of PEPFAR, CLSI enters into a cooperative agreement with the Centers for Disease Control (CDC) to help develop and sustain clinical laboratory capacity in resource constrained countries.

2005 – 2008

CLSI, in partnership with health officials and laboratory professionals, customizes its Laboratory Strengthening Program.

2009 – Future


CLSI continues to customize its Laboratory Strengthening Program and to expand its library of training resources and services to meet international, national and regional accreditation requirements.



CLSI – Laboratory Strengthening Program

A structured, streamlined approach that takes laboratories through six essential phases from initial assessment to accreditation readiness.

- **Phase 1: Gap Analysis I** – Initial on-site assessment to evaluate laboratory operations against accreditation standards.
- **Phase 2: Training and Education** – Customized training modules developed based on needs identified in Gap Analysis I.
- **Phase 3: Mentor Twinning Program** – CLSI professional mentors working side-by-side with laboratory personnel to incorporate new strategies and practices into an on-going quality management system.



CLSI – Laboratory Strengthening Program

- **Phase 4: Self Assessment** – With the use of customized self assessment tools, laboratory management conducts self assessments to identify remaining gaps and focus for improvement.
- **Phase 5: Continuous Quality Improvement** – Based on the results of the self assessment, CLSI develops plans for Continuous Quality Improvement (CQI).
- **Phase 6: Gap Analysis II** – A second on-site assessment conducted jointly by CLSI and laboratory management to determine preparedness for accreditation.



CLSI – Laboratory Strengthening Program

Conceptual Timeline



- Typically 3 months are allowed for each of the six phases
- Laboratories may cycle through the program 2 or 3 times before reaching accreditation readiness



CLSI in Africa

Cote d'Ivoire
Ethiopia
Mali
Namibia
Nigeria
Tanzania



CLSI in Tanzania

Dar es Salaam

- Muhimbili National Hospital

Moshi

- Kilimanjaro Christian Medical Center

Mwanza

- Bugundo Medical Center

Mbeya

- Mbeya Referral Hospital

Zanzibar

- Mnazi Mmoja Hospital



Tanzania – Laboratory Strengthening Program

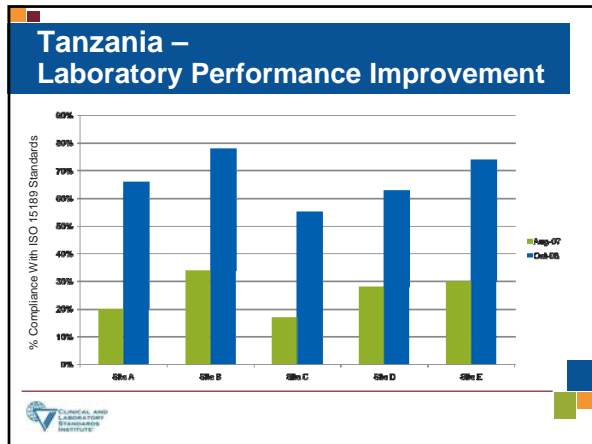
- Phase 1 – Gap Analysis I - August 2007
- Phase 2 – Training & Education
- Phase 3 – Mentoring & Twinning – March – June 2008
- Phase 4 – Self Assessment - July – September 2008
- Phase 5 – Continuous Quality Improvement - July – September 2008
- Phase 6 – Gap Analysis II – October 2008
- Phase 2 – Training & Education – April 2009
- Phase 3 – Mentoring & Twinning – May – July 2009
- Phase 4 – Self Assessment – August+ 2009
- Phase 5 – Continuous Quality Assessment - August+ 2009
- Phase 6 – Gap Analysis - ? October 2009



Quality Management - Training Elements

- | | |
|--|--|
| <ul style="list-style-type: none"> ▪ Documents and Records ▪ Organization ▪ Personnel ▪ Equipment ▪ Purchasing and Inventory ▪ Process Control ▪ Information Management | <ul style="list-style-type: none"> ▪ Occurrence Management ▪ Assessments— External and Internal ▪ Process Improvement ▪ Customer Service and Satisfaction ▪ Facilities and Safety |
|--|--|





- ## SWOT – Strengths
- **National Infrastructure Plan** - To strengthen laboratory services at all levels - >700 laboratories
 - Referral/Zonal laboratories
 - Regional Laboratories
 - District Laboratories
 - Dispensary & Healthcare Laboratories
 - **Physical Facility** – renovations that consider workload, workflow and safety
 - **Equipment procurement and training**
 - **Electronic LIS Implementation** to facilitate data capture and transfer – pilot phase in 4 sites
 - **In-country mentoring program**
 - **Specimen Referral system**

- ## SWOT – Strengths
- **National Health Laboratory & Quality Assurance Training Center (NHLQATC)**
 - Provide leadership and serve as a focal point for training on HIV/AIDS, TB, Malaria.
 - Provide technical assistance and leadership to laboratories in implementing quality systems.
 - Serve as the primary resource for receiving information on international standards and guidelines for quality systems and subsequently transferring knowledge to sites.
 - Provide technical assistance to the national laboratory network for management and implementation of laboratory information management systems.
 - Provide technical assistance to national HIV-related surveillance activities, and provide laboratory testing for national HIV surveillance activities.
 - Provide a national quality assurance program.

- ## SWOT – Strengths
- **National Blood Transfusion Service (NBTS)**
 - Coordinate the management and standardization of blood transfusion services
 - Recruit adequately trained personnel
 - Launch awareness programs and promote recruitment and retention of blood donors to ensure adequate availability of safe blood and blood components
 - Create a sustainable mechanism that will ensure availability of adequate financial resources for the BTS
 - Establish a legal framework for blood transfusion safety

- ## SWOT – Weaknesses
- **Leadership**
 - Inadequate training/skill sets
 - **Donor Assistance**
 - Lack of coordination with partners – creates duplication of efforts/waste
 - **Infrastructure**
 - Inadequate/unsafe physical facilities
 - Inadequate/obsolete equipment
 - Rudimentary/inflexible LI systems

SWOT – Weaknesses

- Equipment Maintenance
 - Lack of locally trained engineers and technical representatives to maintain equipment
 - Lack of preventive maintenance programs
- Supplies
 - Inconsistent supply chain - reagents, controls and other consumables
- Technology/Communication Systems
 - Limited internet access
 - Limited intranet access



SWOT – Weaknesses

- Workforce
 - Inadequate numbers
 - Inadequate training/skill sets
 - Extensive absenteeism – illness, training seminars, vacation/statutory holidays
- Language
 - Not all staff are fluent in English - Quality management documents are English
- Specimen Referrals
 - Inadequate transportation system
 - Unreliable reporting system



SWOT – Opportunities

- Leverage the existing organizational structure to develop the necessary infrastructure that will ultimately strengthen laboratories by creating long-term, self-perpetuating programs
- Develop a National External Quality Assessment Program through the National Health Laboratory & Quality Assurance Training Center (NHLQATC)
- Provide training and education through the NHLQATC
- Develop an integrated hospital and laboratory information system with networked instrumentation



SWOT – Threats

- A growing population that will continue to overwhelm already inadequate resources
- Corruption and 'red tape' in granting of contracts and purchasing processes that interfere with the supply chain
- Dependency on outside assistance and donations



"We will meet in the developing world a level of will, skill, and constancy that may put ours to shame. We may find ourselves not the teachers we thought we were, but students of those who work under circumstances that would have stopped us long ago."

...Dr. Berwick - Institute For Healthcare Improvement - Boston, MA



Questions?

“Even if you are on the right track, you’ll get run over if you just sit there”

...Will Rogers

For opportunities to participate in the CLSI Laboratory Strengthening Program, contact Patti Rizzo-Price, Vice President Global Health Partnerships, pprice@clsi.org

