

The first public laboratory in Botswana to receive international accreditation by SANAS

BACKGROUND

An outbreak of infant diarrhea in Botswana in 2006 drew attention to deficiencies in clinical microbiology services in the country. It also led BOTUSA (a partnership of the Government of Botswana & the Centers for Disease Control & Prevention [CDC]) to ask CDC for help in improving the services of the National Health Laboratory (NHL) & the national lab network.¹ With the increased burden on the country due to HIV/AIDS the need for laboratories with qualified personnel, standard procedures & functioning equipment became paramount.

A few years later, WHO stated that efficient & reliable laboratory services & networks were essential & fundamental components of effective, well functioning health systems; however, few developing countries had quality standards which were affordable & easy to implement & monitor.² WHO went on to say it was clear that high-quality laboratory testing was critical for patient care, prevention, disease surveillance & outbreak investigations.

CDC & WHO issued a statement in 2008 regarding laboratory quality systems, calling for countries with limited resources to consider a staged approach toward laboratory accreditation. It was suggested that national laboratory standards establish minimum requirements for all laboratories. National reference laboratories were encouraged to meet international standards.

In 2009, CDC collaborated with WHO and other partners to launch a five-step laboratory accreditation process in the presence of government health officials from 13 African countries. The process was named WHO-AFRO Laboratory Accreditation System.

Internationally-recognized accreditation of the first public laboratory in Botswana heralds a positive change in the standards of laboratories in the country.

Botswana's laboratories have an important role in the fight against infectious and chronic diseases, but the accessibility and quality of testing services have been challenged. The accreditation of the



Bamalete Lutheran Hospital lab, in the small town of Ramotswa near the capital Gaborone, is an important accomplishment as it shows that no matter the size of the lab accreditation is achievable. Two other laboratories also gained accreditation in the past 12 months: the Nyangabgwe Hospital HIV Reference Laboratory in Francistown who received direct support from CDC Botswana and the Botswana–Harvard HIV Reference Laboratory in the capital city Gaborone who gained accreditation as a result of a pathway developed by the Centers for Disease Control and Prevention (CDC).

“Supporting governments’ efforts to strengthen national health care systems, including laboratory quality management, is essential to ensuring

sustainability of country-driven HIV/AIDS interventions,” said Ambassador Eric Goosby, U.S. Global AIDS Coordinator.³ The Ambassador believes lab accreditation processes are essential to equipping countries and communities with the tools necessary for progress on health development.

“Botswana has shown us that with appropriate support, commitment and leadership, laboratory quality management systems can be implemented in Africa in a measurable way” said Dr John Nkengasong, Chief of the International Laboratory Branch - Global AIDS Program.

According to Ebi Celestin Bile, Laboratory Section Chief from CDC Botswana, the Ramotswa laboratory started its accreditation process in 2008. “It is great news for the laboratory services in Botswana especially because the accreditation was done with the technical support of a local structure which speaks to the sustainability of the project,” he said.

There are now eight facilities in Botswana enrolled in the World Health Organization Regional Office for Africa (WHO-AFRO) scheme and it is expected that three more labs will receive a five star rating after completing the Strengthening Laboratory Management Towards Accreditation (SMLTA) process by 2012.

“This clearly shows that the WHO AFRO laboratory quality improvement program, using the step-wise approach, will be scalable, affordable, and practical at all levels of the health system”, Mosetsanagape Modukanele, Lab Technical Advisor, CDC Botswana, said.

“By enhancing laboratory capacity Botswana will be able to monitor the ever increasing number of individuals on anti-retroviral (ARV) treatment better, improve diagnostic testing for TB to decrease turnaround-time and further develop the capacity to perform drug resistance testing and determine HIV incidence more accurately, “ said Dr Andrew Pelletier, Project Officer, CDC Botswana.



“Furthermore, the technicians working in the accredited labs have a huge sense of pride. Having accredited facilities means Botswana is more likely to attract and retain quality staff that is able to deliver accurate and timely test results.

“It is critical that care and treatment programs receive good lab support. An efficient laboratory can dramatically reduce waiting time to get results. This means patients, who sometimes travel far for testing or are reluctant to be tested, receive the laboratory results sooner.”

Studies have shown that when patients need to return for a second visit to a hospital or clinic for test results, significant percentages fail to do so.

The awarding of the accreditation comes after CDC assisted with implementing a Quality Management System (QMS) in all district laboratories. This included teaching technicians how to chart temperatures, document equipment maintenance, develop standard operating procedures, and monitor quality controls. Workshops for lab technicians, facilitated by members of Botswana’s Ministry of Health (MoH) and Bureau of Standards, were held. CDC had provided the training for the trainers.

There were specific advancements in TB laboratory processes (see TB case study) which were critical as culture and drug susceptibility testing remains the main tool to monitor patients undergoing treatment. Liquid cultures were introduced replacing time consuming tests which took more than eight weeks for results to become available. Turnaround times were improved generally and monitoring procedures for patients with resistance patterns (first or second line) were strengthened. A specific program for TB lab procedures which includes external quality assurance was introduced. The program is aimed at improving TB diagnostics in the country. Ten laboratory technicians are trained monthly in matters such as reading and reporting of slides, specimen collection and correct staining techniques. Onsite visits are organized to monitor all laboratories (public and private) performing specialized microscopy, specifically acid fast bacilli.

Another achievement in CDC’s efforts to strengthen laboratory systems was the standardization of test techniques and equipment. This exercise was conducted through a workshop with 25 participants who included key decision makers in laboratory services from MoH, the National

Health Laboratory, Central Medical Supply, Ministry of Local Government, CDC Botswana and service delivery points. Standardization has helped reduce the number of essential items required to meet testing needs from 850 to 250.

In conjunction with CDC efforts, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) supported the drafting of a five-year National Laboratory Strategic Plan, developing and piloting the Laboratory Information Management System and developed a National Logistics Management Information System (LMIS) which will strengthen laboratory commodity management systems. Twenty-eight participants from a range of different organizations involved in the laboratory supply chain were trained using LMIS and in core concepts of commodity logistics and system design.

CHALLENGES

There were a number of challenges faced during the accreditation process. These included:

- Consistent interruption of testing services resulting from reagents stock outs and expiries because of poor quantification and inadequate logistics systems to support the flow of these commodities.
- Prolonged equipment down time as a result of poor service and maintenance.
- Excessive emergency order situations which interrupted the supply plan.
- Poorly documented procedures and ill-kept logistic records which tended to be frequently unavailable.
- Lack of adequate coordination and inconsistent communication between testing facilities and key entities at the central level.
- Gaps between government and donors on information sharing regarding donated equipment, products and consumables.
- Weaknesses in stakeholder coordination which lead to conflicts and delays in some projects.
- Inconsistent water and power supplies.

MAIN DRIVERS:

A number of key developments drove the implementation of the processes that eventually led to accreditation. The most significant among these were:

1. Thirty-three countries together with CDC and other stakeholders gathered in 2008 in Mozambique to discuss laboratory testing standardization and harmonization in three major areas. The objectives of the meeting were to: a) review and agree on a list of supplies and tests needed at each level of an integrated tiered laboratory network; b) develop a consensus to guide standardization of laboratory equipment; c) develop a consensus on key considerations to guide maintenance and service contracts at various levels of the laboratory network.
2. CDC and WHO issued a statement in 2008 regarding laboratory quality systems, calling for countries with limited resources to consider a staged approach toward laboratory accreditation.
3. In 2007, the Government of Botswana took its first steps towards laboratory accreditation by implementing QMS across the nation. It also launched a range of other measures (e.g., the Bachelor of Medical Laboratory Sciences (BSc) upgrade degree program introduced at the University of Botswana aimed at ensuring sustainability of a better laboratory workforce).
4. During a 2009 meeting in Rwanda, CDC, in collaboration with WHO and others, launched a stepwise laboratory accreditation process in the presence of government health officials from 13 African countries.⁴ The WHO-AFRO laboratory quality improvement process recognizes and encourages year-over-year progress toward fulfilment of the requirements of international standard number ISO 15189.
5. Lab technicians in Botswana were keen participants of the process and key drivers. The first cohort of 17 medical laboratory technicians were admitted into a 12-month university course aimed to upgrade skills in 2010. The course will allow that students to transition into roles as laboratory scientists.
6. The overriding driver was the HIV/AIDS epidemic which placed a huge burden on the nation's laboratories and created a need for efficient and timely services as well as standardization of procedures. HIV/AIDS remains the most significant social and public health problem in Botswana. The country is experiencing one of the most severe HIV/AIDS



epidemics in the world. UNAIDS estimates that in Botswana's population of about 1.8 million; close to one out of four adults aged 15-49 is HIV positive.

LESSONS LEARNED:

There were a number of key lessons learned during the process of accreditation and more generally while trying to improve laboratory systems. These included an understanding that:

1. Laboratory staff and management need to own the project for it to be successful
2. Political will is vital in order for the people and institutions to accept the importance of the project.
3. All stakeholders need to be involved to avoid conflict with existing or future projects.
4. Accreditation of one lab creates desire for accreditation in other labs.

MEASURABLE RESULTS:

- During 2009, 292 laboratories had the capacity to perform HIV tests.
- A total of 1,029,900 HIV- or TB-related tests were performed at CDC - supported laboratories.
- 1,699 individuals were trained in HIV-related laboratory activities.
- During 2010, 3 laboratories received SANAS accreditation.
- 12 labs implemented QMS.

Background Endnotes

Black, B. (2008). Members' experiences in international laboratory capacity building. *American Society for Microbiology*. Retried June 21, 2011, from: <http://forms.asm.org/microbe/index.asp?bid=59978>

World Health Organization Regional Office for Africa. (2008). The Maputo Declaration. Retrieved June 21, 2011, from: http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf

Main Text Endnotes

³ Mensah, K. (2009). New accreditation process for Africa labs. *Africa News*. Retrieved June 21, 2011, from: http://www.africanews.com/site/New_accreditation_process_for_Africa_labs/list_messages/26157

⁴ Gershy-Damet, G. M., Rotz, P., Cross, D.,... Nkengasong, J. N. . (2010). The World Health Organization African regional laboratory accreditation process – improving the quality of laboratory systems in the African region. *Am J Clin Path*, 134, 393-400. doi: 10.1309/AJCPTUUC2V1WJQBM. Retrieved July 3, 2011, from: http://www.finddiagnostics.org/export/sites/default/programs/scaling_up/lab_preparedness/docs/Gershy-Damet_etal_WHO_African_Region_Lab_Accreditation_AJCP_2010.pdf