

## Case Study: Harmonization of Laboratory Items in Zambia

### Background

In 1997, the Zambian Ministry of Health (MOH) developed a National Medical Laboratory Policy. The policy included a 5-year implementation plan, one step of which was to achieve standardization of laboratory procedures and equipment. Around 1999, the MOH developed an Essential Equipment List for Level 1, 2, 3 and Health Centres. This list documented the specifications for various instruments as well as the proposed make of the instrument. Based on this list, the MOH secured funding through the Japan International Cooperation Agency (JICA) to procure standard equipment, including haematology and chemistry analysers.

The Republic of Zambia is now in the midst of rapid expansion of the national HIV and AIDS programme. In particular, it has been recognized that reliable laboratories are critical to the success of a comprehensive HIV and AIDS programme.

To develop a truly effective HIV and AIDS programme, it is recognized that a full array of HIV and AIDS tests, including clinical chemistry, haematology, and CD4, must be available to diagnose and monitor patients.

In December 2005, a Laboratory Technical Working Group (TWG) was formed to develop a coordinated approach to improving laboratory services in Zambia. In May 2006, the TWG created the Operational Plan for the National Laboratory System, 2006-2008. TWG subcommittees were formed in the following areas to plan on a larger scale:

- Program Management
- Procurement and Logistics
- Instrumentation and Infrastructure
- Quality and Data Management
- Human Resources and Training

**Table 1: Laboratories by Level**

| Level              | Level Description       | Number of labs |
|--------------------|-------------------------|----------------|
| Health Centre      | Periphery               | 124            |
| Level 1 Laboratory | Intermediate (district) | 70             |
| Level 2 Laboratory | General (province)      | 18             |
| Level 3 Laboratory | Referral/teaching       | 4              |
| <b>Total:</b>      |                         | <b>216</b>     |

The Instrumentation and Infrastructure TWG subcommittee was tasked with updating the Essential Equipment List by facility level, including identification of new types of equipment needed such as CD4. Zambia currently has 216 active labs in the public sector. Table 1 shows the number and organization of laboratories by level in Zambia.

### Standardization Process

Following the May 2006 Operational Planning meeting, the Instrumentation and Infrastructure TWG subcommittee developed a list of potential standard equipment by facility level to include in the review and update. The subcommittee included members from the Ministry of Health as well as key cooperating partners. The main criteria that the subcommittee agreed to review are listed below.

- Instrument capacity, requirements and appropriateness
- Current technologies
- Instrument reliability
- Maintenance and support
- Costs for instrumentation, maintenance and reagents and consumables
- Supply chain implications

In September 2006, the MOH, with support from the PEPFAR funded USAID SCMS project, both members of the Procurement and Logistics TWG subcommittee, hosted a national laboratory commodity quantification workshop. The quantification brought together a team of representatives from the central-level MOH, different facility levels in the country, and cooperating partners. Although the nature of the new standard equipment was still in discussion, the quantification team agreed on some key elements in order to build assumptions about the quantities of laboratory products needed for the countries testing needs. These elements included agreement on the test menus by level, identification of the standard techniques implemented for each test by level, and agreement on the standard equipment to include by level. The test menus and standard technique definition followed the Zambia Standard Operating Procedures for the National Laboratory System for health centres, level 1, 2 and 3 laboratories. The standard equipment list by level that the quantification team agreed upon at the 2006 quantification workshop can be found in Table 2.

**Table 2: Standard Laboratory Equipment, 2006**

|                      | CD4                       | Chemistry                         | Haematology                 |
|----------------------|---------------------------|-----------------------------------|-----------------------------|
| <b>Health Centre</b> | Dynabeads                 | Humalyzer                         | Sysmex PocH 100i            |
| <b>Level 1</b>       | FACSCCount                | Humalyzer                         | ABX Micros 60               |
| <b>Level 2</b>       | FACSCCount                | Cobas Integra 400<br>Vitros DT 60 | ABX Micros 60               |
| <b>Level 3</b>       | FACSCCount<br>FACSCalibur | Olympus AU 400                    | ABX Micros 60<br>ABX Pentra |

After the 2006 laboratory commodity quantification, the MOH made a commitment to following this standard equipment list. The cooperating partners were encouraged to follow this list as a guide for all new equipment procurement.

The standard list was reviewed slightly in 2007 when the Dynabeads and Vitros DT60 were removed from the health centre level CD4. A number of health centres now have the FACSCounts.

## **Challenges**

As can be expected, this process has had many challenges. In 2008, there remained a large amount of non-standard equipment in the country. As agreed upon with the MOH, the cooperating partners supporting the sites with these non-standard equipment will procure and distribute reagents for all non-standard equipment. This approach is not sustainable and efforts are being made to either equip these facilities with standard instrumentation or review the standard equipment list to include some of the equipment currently omitted from the original standardized list.

Before new equipment can be reviewed for possibly inclusion in the standard equipment list, the University Teaching Hospital (UTH) must validate the equipment. The supplier of the equipment is required to pay the fees for this validation process.

## **Benefits**

Development of the standard equipment list in Zambia allowed for a number of improvements to the national laboratory system.

### **1. Maintenance Contracts**

The Ministry of Health and cooperating partners worked together to negotiate maintenance contracts with the suppliers and link this with the purchase of reagents to ensure sustainability of the maintenance contracts. Since there are a significant number of each equipment in the country with more expected, the group was able to negotiate a fair contract with the local suppliers.

### **2. Cost Savings**

Although it is not possible to estimate the exact amount of cost savings, standardization has led to decreased overall procurement costs through economies of scale. With a reduction in the total number of laboratory commodities by approximately 80%, the procurement partners are procuring more of each individual reagent rather than smaller quantities of many different reagents.

Zambia has experienced additional indirect costs savings from having a standard equipment list by transferring stocks between facilities. In one such instance, reagents were procured for the ABX Pentra which is at level 3 teaching/referral hospitals. One of the main ABX Pentras was not functioning and therefore some of the reagents procured for this equipment were going to expire. Another facility using the ABX Pentra, which was not part of the national system, offered a stock transfer so they could use the shorter expiry products before they were wasted. This stock transfer saved approximately \$30,000 worth of reagents from expiring.

### **3. National Laboratory Commodity Logistics System**

Consistent availability of laboratory reagents has been a known problem with the Zambian Laboratory System. The Procurement and Logistics TWG subcommittee identified the need for development of a national laboratory commodity logistics system. A logistics system design workshop was held in Oct. 2007. The design team, consisting of MOH representatives from all levels and key cooperating partners, recognized that it is not possible to design a rational logistics system for more than 200 commodities. To agree on the priority commodities to include in the logistics system, the design team reviewed the list of standard tests/equipment and the resulting

reagents and consumables. In the end, a list of 185 priority laboratory commodities was identified for the new National ART Laboratory Logistics System.

The design of the National ART Laboratory Commodity Logistics System is being rolled out in 2008-2009. The system is expected to significantly improve the laboratory commodity management at the facility and central level, thus improving laboratory services.

#### 4. Stock Availability

With the rollout of the national logistics system for laboratory commodities and standardization of laboratory equipment, the management of these commodities is streamlined and simplified and facilities are able to transfer stocks from a facility with too much stock risking expiry to a facility with low or no stocks.

In 2007, it was estimated that 70% of the 185 priority laboratory commodities were out of stock at the central level warehouse, Medical Stores Limited. Standardization has increased the focus on these supplies and the stockout rate has dropped to 2% at the end of 2008.

### **Conclusions and Lessons**

Standardization in Zambia has been an iterative process. At the annual forecast and quantification, the standard list of tests, techniques and equipment is reviewed. Additionally, the Instrumentation and Infrastructure TWG subcommittee reviews the list as needed. Currently, the Instrumentation and Infrastructure TWG subcommittee is reviewing new chemistry equipment for lower level laboratories as well as other potential equipment.

With this in mind, the Zambian experience has a few key lessons learned and recommendations:

1. Standardization is an iterative process. Commitment of human resources and time are key factors to make the process successful.
2. The process must be collaborative and should include representation from key partners and staff from different level laboratories. The laboratory staff working at the health facilities may be able to identify very practical reasons why certain equipment are not appropriate for their facility. Ensuring that there is commitment to the agreed standard equipment list from NGO and government partners will avoid disputes about equipment procurement.

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