



## Case Study: Impact of the Ethiopian National Laboratory Logistics System on the Harmonization of Laboratory Commodities

### Background

Laboratory commodities are used in the provision of HIV/AIDS prevention, care and treatment services in Ethiopia. These services are provided through a variety of public health facilities offering antiretroviral therapy (ART), care and support services, sexually transmitted infection (STI) diagnosis and treatment, and voluntary counseling and testing (VCT), and include hospitals, health centers and regional laboratories providing ART monitoring and testing. These sites order laboratory commodities using standard inventory control system procedures and receive commodities from the Pharmaceutical Fund and Supply Agency (PFSA), a public sector entity responsible for storing and distributing all health commodities to public facilities. As a public sector partner, the Ethiopian Health, Nutrition and Research Institute (EHNRI) of the Federal Ministry of Health (MOH) is responsible for establishing and maintaining a public health laboratory system, setting policies and standards for the management of laboratory commodities, and providing technical support and monitoring laboratory logistic system performance, as well quantifying laboratory commodities.

EHNRI in collaboration with the Ministry of Health and other key stakeholders developed the National Health Laboratory System Master Plan and accompanying Guidelines with the objective of establishing a standard health laboratory system in the country. EHNRI's operational plan for the National HIV/AIDS laboratory services was developed and elaborated to fit into and implement the laboratory activities envisaged in the Road Map for Accelerated Access to HIV/AIDS Prevention, Care and Treatment in Ethiopia (2007). EHNRI, being the country's National Reference Center, was seen as having the comparative advantage to undertake leadership in the National ART Laboratory Service Program.

The development of the country's National Laboratory System Master Plan and Guidelines on Communication for the National HIV/AIDS Laboratory Program was concurrently launched with the MOH's National Pharmaceutical Logistics Master Plan for all health commodities, including laboratory. The latter builds upon the premise that a systemic response is needed to meet the supply needs of public sector service facilities and their clients, and that efficient mechanisms for reaching these sites are key, including a model of direct delivery to sites from regional hubs.

Prior to the logistics system design, the Ethiopian laboratory logistics system was weak, consistently being hampered by several systemic challenges that caused frequent stockouts of critical items, thus impeding continuous and quality testing for patients. The laboratory logistics system was characterized by an inadequate supply of required reagents and supplies, which in turn was affected by the lack of information on these commodities for procurement and re-supply decisions. In addition, distribution systems for laboratory commodities were not systematically designed, strengthened or supported. Patients were requested to wait 2-3 months or longer to receive results from hospitals for critical commodities such as CD4 reagents.

### SCMS Project Team

Laboratory machine failures, and PFSA’s limited capacity to deliver reagents to facilities, were among the major problems that affected the national laboratory logistic system in the country.

### Standardization Process

Many of the aforementioned logistics problems were traced back to the fact that the system managed multiple commodities while reporting and ordering remained unstandardized. Some testing practices also remained unstandardized, making PFSA’s role in commodity management even more challenging. To address these difficulties, the Supply Chain Management System (SCMS) project was requested to lead the design of a standardized laboratory logistics system as a means of solving the logistics obstacles and supporting EHNRI’s Master Plan and the MOH National Pharmaceutical Logistics Master Plan. Following that exercise in March 2007, a robust laboratory logistics system was designed to support the scale up of the HIV/AIDS care and treatment program, including up to 470 ART sites in the country. Among these, 107 are laboratory monitoring hospitals including regional laboratories providing direct and referral laboratory services. More than 1,500 VCT facilities are providing HIV testing and counseling services.

During the design of the laboratory logistics system, special attention was given to ensuring that the commodities managed in the logistics system would be a standard list of products, in accordance with standard treatment and testing guidelines for ART monitoring. The process harmonized test menus, test techniques, operating procedures, and laboratory equipment for each type of test and ART facility in the system. By doing so, a total of 64 regularly used, stored and distributed laboratory commodities were chosen for the newly designed logistics system. For CD4 testing, 9 reagents were chosen; for chemistry, 14, and for hematology, 12, including controls and calibrators. The consumables list consisted of 23 commodities, with three rapid tests and an additional three diagnostic tests. Restricting the number of commodities in the logistics system was a key first step in ensuring that a standardized list of laboratory commodities are used to support in HIV/AIDS treatment services. The standardized list of equipment chosen by testing area is provided in Table 1 below.

**Table 1: Standardized List of Laboratory Equipment, March 2007**

CD4 Equipment	Chemistry Equipment	Haematology Equipment
FACSCalibur FACSCount	Humastar 80	Cell Dyne 1800 Cell Dyne 3700

The Autolab was recently added to the list of approved chemistry equipment, as were the Sysmex KX-21N and Sysmex 1800i for hematology.

To ensure that the standardized system would work well, SOPs were developed and rolled out. Training of trainers (TOT) was provided to 25 professionals from the Ministry of Health and national partners. These trainees in turn conducted regional trainings at 107 ART monitoring sites, successfully reaching 296 additional professionals. On the job training was also provided to 568 professionals to fill the gap in the implementation of the logistics system. In addition to that, sensitization workshops were also organized in the five major regions of the country to discuss the implementation of the laboratory logistics system, in which 769 public health leaders participated. Throughout this process, emphasis was placed on using and ordering a standardized set of commodities.

### **Ongoing Standardization Processes**

In January 2008, the international laboratory community converged for a meeting in Maputo, Mozambique to develop recommendations for clinical laboratory testing harmonization and standardization. Central to the theme of this workshop was the call to promote the standardization of laboratory supplies at each tiered level of the laboratory network. Standardization is the process of harmonizing test menus, test techniques, operating procedures, and laboratory equipment for each type of test and for each level in the system. In response to the Maputo conference, EHNRI has begun the process of adapting the Maputo guidelines to Ethiopia's context and working with key stakeholders towards maintaining a standardized system across Ethiopia.

### **Benefits and Challenges**

The standardized logistics system was set up as a means of eliminating the logistics challenges that existed prior to its design. Since May 2007, no stockouts have occurred for ART laboratory monitoring tests and emergency orders have dropped dramatically. Commodity wastage is also decreased. Laboratory reagents and related supplies are arriving on time in the quantities needed. Patient wait time for tests has been reduced significantly, from two to three months to within hours. Today, the logistics system is positively impacting more than 132,835 ART patients (per the January 2009 MOH report). The laboratory commodities distribution system is now integrated with other HIV/AIDS commodities such as ARVs; ensuring that patients receive a comprehensive package of services. Reporting and requisitioning through the laboratory logistic information system (LMIS) has been standardized in the country by developing reporting formats which can easily be completed at all levels of the system.

From the supply chain perspective, standardization has helped enhance laboratory commodity management by streamlining the number and range of laboratory products. PFSA's central and regional hubs were previously overburdened by the sheer number of commodities they had to manage. Through standardization, the lists of commodities were drastically reduced by retaining only commonly used products per ART program testing guidelines. Reducing the number of commodities that PFSA has to manage has eased the burden on distribution and the inventory control system that now exists at site level. Last but not least, standardization has further enabled rational decision making throughout the supply chain, particularly in product selection, forecasting, quantification and procurement. It also facilitated easier service and maintenance by reducing the number of types of equipment that the EHNRI's biomedical engineers and clinical staff have to service. Notwithstanding, maintaining the current set of standardized equipment has proved challenging, especially in an age where technologies are rapidly changing.

### **Conclusions and Lessons**

Laboratory logistics system has been shown to be viable solutions to addressing many different supply chain challenges in resource limited settings, especially when it comes to the issue of ensuring consistent commodity availability for testing services. Standardization has also been shown to be an integral part in the success of any logistics systems. Standardization efforts will continue to strengthen laboratory capacity by building sustainable laboratory capabilities that will provide access to high quality, rapid, and affordable diagnostic tests for the care, treatment, prevention and surveillance of HIV/AIDS, among other diseases.

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