

HARMONISATION AND STANDARDIZATION OF TESTS AND EQUIPMENT IN TANZANIA

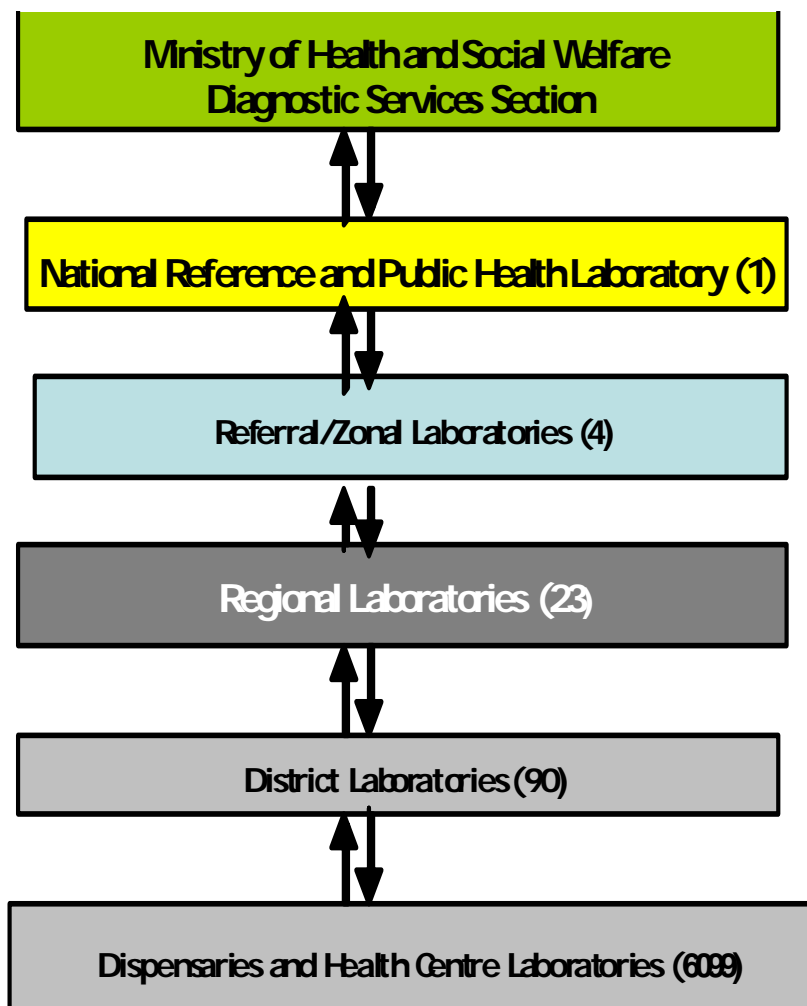
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Introduction

The health laboratory system of Tanzania is multi tiered (Fig 1) with the test menus, complexity of testing and personnel expertise and numbers decreasing from the National level to the health centre and dispensary levels. There is 1 national reference, 4 zonal referral, 23 regional, 90 district and 6099 health centre (577) and dispensary (5522) level laboratories. Some of these facilities are under the management of faith based organisations but fall within classification of public health facilities. The allocation of test menus to the different tiers, equipment placement and expertise requirements are prescribed through the National Health Laboratory Standard Guidelines (NHLSG) ⁽¹⁾. The Health laboratory strengthening activities are guided by The National Laboratory Strategic Plan formulated² in 2009 through the support of a cooperative agreement³ between the Ministry of Health and Social Welfare (MOHSW) and United States Government (USG) under the Presidential Emergency Plan for AIDS Relief (PEPFAR). There are numerous private laboratories some of which are attached to private hospitals. The scope of this document does not include the private sector laboratories.

Fig. 1The organisation of the public sector is as indicated in, Tanzania



The National HIV/AIDS Care and Treatment Plan⁴ was formulated by the National AIDS Control Program (NACP) (MOHSW) in 2001 with an estimated 2.2 million people requiring treatment. This prompted a readiness assessment of the laboratory system to cater for the increased demands on the services. Using 35 representative laboratories from the public and private sector, a three week rapid assessment was undertaken in 2002 under the auspices of the MOHSW assisted by the Centres for Disease Control and Prevention (CDC) and the Clinical Laboratory and Standards Institute (CLSI). The areas assessed included test-specific equipment, ancillary equipment, reagents and consumables, physical facility attributes such as internal finishing, office and storage space, security, electrical and water supply systems, temperature control, general laboratory supplies, laboratory safety, data management, the human resources availability and capacity, quality management systems, training and laboratory management. The results revealed inadequate modern or automated equipment, inadequate human resources both in numbers and skill sets, an irregular reagent and supply chain and poor physical facilities, inadequate data capture and its management and almost no implementation of quality management systems⁵.

There are numerous partners operating in Tanzania willing to provide laboratory support for the care and treatment program to mitigate the observations documented in the assessment. These include but are not limited to The Global Fund, Columbia University (ICAP-CU), the Elizabeth Glazier Paediatric Foundation (EGPAF), Harvard University (MDH), Family Health International (FHI), the Walter Reed Project, Catholic Relief Services Consortium including AIDS Relief (CRS), PharmAcces, African Medical and Research Foundation (AMREF) and Non-USG Partners such as the Clinton Foundation HIV/AIDS Initiative (CHAI), Abbott Fund, AXIOS, World Health Organisation (WHO), Japanese International Cooperation Agency (JICA), German Technical Assistance (GTZ), Danish International Development Agency (DANIDA), Swedish International Development Agency (SIDA), the Government of Norway, The Italian Cooperation Agency and South Korea

The poor status of laboratory services, the multitude of partners and the demand for a functional, reliable responsive service by the HIV / AIDS care and treatment program necessitated a review of the national health laboratory standard guidelines to harmonise tests, provide guidance on equipment placement to avoid a multitude of different platforms and to ensure equitable distribution of personnel and services and conformity to the National Guidelines for the Care and Treatment of HIV/AIDS in Tanzania⁶ which defined the tests and frequency of ordering for diagnosis, staging and monitoring of patients on care and treatment. Table 1 shows the types of tests and the anticipated frequency of testing

Table 1. Type of Test and Frequency required to support Care and Treatment Program⁶

Type of Test	Test	Frequency
HIV Diagnosis	Rapid test, EIA DNA PCR	As needed
Drug Safety	Haematology	T0 WK 2** WK4** W8** Every six months
	Chemistry	T0, WK2** WK4** WK8** Every six months
Diagnosis of STDs	Syphilis	On clinical indication
Diagnosis of Opportunistic Infections	TB Screening	T0 or clinical indication

Key

T0 = At baseline WK = Week, M = Month

* For patients on AZT ** For patients on NVP

The increased demand for testing versus inadequate personnel and the lack of modern equipment necessitated automation. The NHLSGs were reviewed in 2003 providing guidance on management, the organisational structure for laboratory services, minimum standards of physical infrastructure, equipping and setting range of essential tests at each level of laboratory services, minimum personnel requirements at all health laboratory levels, methodology standardisation and performance assessment systems. The reviewed NHLSGs prescribed manual, low throughput equipment at health centres, medium throughput semi automated equipments at regional and district laboratories and fully automated high throughput equipment at Zonal and National levels. The laboratory personnel were distributed according to their training and skills; certificate level of training personnel at health centres and dispensaries, technicians, technologist with at least a diploma in medical laboratory sciences at regional and district levels, technologists and scientists with at least an advanced diploma at zonal and national referral facilities. The harmonisation of tests and standardization of equipment was intended to provide a sustainable, cost effective equipment, reagent, commodities and supplies procurement and equipment maintenance. The equipment standardization under the guidance of MOHSW involving all stakeholders was based on finding equipment that had a local and or international track record for manufacturer reliability, designated distributor, previous and current experience with the instrument in Tanzania or within the East African Region (robust and reliable performance of selected instruments, ease of use, frequency of breakdowns), reasonable cost of instrument and reagents, availability and reliability of maintenance and service, in-country and/or regional and reliability and flexibility of reagent supply⁸

Under MOHSW leadership, through a series of consultative meetings with stakeholders, an Operational Plan for the National Laboratory System to Support HIV/AIDS Care and Treatment⁸ was formulated in 2005.

The implementation of the NHLSG was effected through this plan with the stakeholders committing themselves to undertake different roles. MOHSW coordinated partner efforts, procured equipment and reagents utilising Global funds, the USG provided technical assistance, training and limited procurement where necessary at the request of MOHSW while CHAI negotiated competitive pricing for equipment, commodities and reagents. All the partners participated in the exercise according to the set plan.

The status in Tanzania as of the end of 2008 shows a good level of harmonisation of tests and standardization of equipment as depicted in table 2

Table 2. Distribution of Tests and Major Equipment at the different levels⁸

Type of Equipment		Public	FBO	Research	Private
HIV ELISA		30	0	0	0
Viral Detection	Cobas Taqman	5	0	0	0
	Cobas Ampliprep	2	0	0	0
	Cobas Magnapure	4	0	0	0
Flow Cytometry	FACS Calibur	7			0
	FACS Count	74			
Chemistry Equipment	Cobas Integra	6	0	0	0
	Fully	30	0	2	1
	Screen Master	65	14	0	3
	Axym	1	0	0	0
	Other				
Haematology Equipment	ACT5 DIFF	5	0	0	0
	Pentra 80	24	0	1	0
	Micro Lab 60	70	15	1	8
	Other	9	10	0	1
TOTAL		305	55	9	18

From the table 94.3% of the equipment in the public health laboratory facilities are standardized according to the Operational Plan⁷.

The rest of the equipment used in laboratories such as refrigerators, centrifuges, incubators, are also procured according to standardised specifications.

IMPACT

Maintenance contract

As of March 2009 MOHSW was in a position to negotiate preventive and corrective equipment maintenance contracts⁹ for the major automated chemistry, haematology and CD4 equipment supporting the HIV/ AIDS care and treatment programs, There are clauses that allow for additional equipment to be covered in the contract. MOHSW with the assistance of CHAI was able to apply the economies of scale concept to negotiate these contracts. The contract specifies the intervals for preventive maintenance, the expectations of the service provider, the acceptable downtime limits, the payment conditions upon satisfactory fulfilment of maintenance activities, such as the provision of spare parts, consumables and reagents, insurance liabilities and workers compensation. The role of users and health care technical officers is also specified as it relates to distance or online technical assistance.⁹.

Training

The harmonization of tests and standardization of equipment enabled the development of standardised training packages for CD4, Chemistry and Haematology¹⁰ which was rapidly rolled out to laboratory personnel in Tanzania mainland and Zanzibar using a training of trainers (TOT) model This was accomplished with the technical assistance of the American Society for Clinical Pathology (ASCP) and AMREF through PEPFAR funding in 2006 2007 and 2008. Thirty five TOTs were trained who have since trained more than 200 laboratory technicians and technologists. The availability of these training packages and trainers in country has also facilitated training of laboratory personnel as new care and treatment centres open as well as the training of new technicians and re training of existing personnel based on performance evaluations. Becton and Dickinson (BD supplier of Facs count and Facs Calibur CD4 testing equipment has trained MOHSW health care technical personnel on first line maintenance and troubleshooting which has made a great difference on the continuity of laboratory services for CD4 testing.

Quality Management Systems Implementation

With harmonised tests it has been much easier to implement quality management systems. MOHSW with the assistance of CLSI wrote standard operational procedures for all equipment and laboratory procedures supporting diagnosis care and treatment of HIV in 2007. Thereafter MOHSW has written SOPs for other equipment and laboratory procedures including parasitology and histopathology. This was handled at a national level and then disseminated to the facilities. Having only two major testing platforms for CD4 testing has

facilitated the implementation of CD4 External Quality assessment, the feedback and management of non conformities

Patient care

The equipment placed in these health facilities are used for all patients Prior to 2004, there were manual systems with long turn around times; currently the turn around times are within 24 hours resulting in better patient flow management and a more timely laboratory result delivery to the clinical team facilitating timely diagnosis, staging and monitoring of patients

Health Care Technical Services

The health care technical services workforce consists of 5 Biomedical Engineers, 11 Technician and 3 Artisans distributed in the zonal workshops as detailed in Table 3. There are 5 zonal HCTS workshops, Eastern (MNH), Northern (KCMC), Lake (BMC), Southern Highlands (MRH) and Southern (Ligula) Zones and one being established in the Western zone to operate out of Tabora’s Kitete hospital. Due to the high level of standardization of equipment, it is now possible to plan for spare parts procurement, Equipment replacement system and prioritise training on first line maintenance for equipment users and biomedical health care technical officers. An in service module has been developed for first line maintenance and trouble shooting An intensive hands on training has been instituted for those artisans and a few technicians in the fields of mechanical, electrical, and electronics who have not received any orientation training in biomedical engineering. The focus of the training is on the importance, and use of maintenance management tools, such as requisition forms, job registers, job cards, basic circuit diagrams and how to prepare Annual Planned Preventive Maintenance (PPM). Hands on training include dismantling and reassembly of selected electro-mechanic equipment.

The level of standardization has enabled MOHSW to advocate for formal training at the Dar es Salaam Institute of Technology for diploma level biomedical engineering training as well as an in-service course for medical equipment maintenance

Table 3 Distribution of Laboratory Equipment Health Care Technical Officers in Tanzania¹¹

Zones	Engineers	Technicians	Artisans
MOHSW HQ	2	1	2
Lake	1	2	0
Eastern	2	2	1
Northern	0	2	0
S. Highlands	0	1	0
Southern	0	1	0
**Western	0	2	0
Total	5	11	3

Challenges

The procurement act²¹ does not allow use of branded names which places the procurement of appropriate reagents for already procured equipment and any other intended procurement in jeopardy. Vendor monopoly for standardised equipment has created bottlenecks in reagent supply and equipment maintenance due to stretched vendor capacity to deliver the services in a country as large as Tanzania. Donated equipments tend to differ from the standardised lists thereby falling out of the contract negotiations for reagent and maintenance and require different operational procedures. In some cases the facilities receiving the donated equipment have not had the fiscal wherewithal to procure reagents or maintain the equipment.

Conclusion

MOHSW leadership and coordination is essential for the success of harmonisation of testing and standardisation of laboratory equipment in the country. Benefits accrued from standardization of equipment and harmonisation of tests include reduced costs of equipment procurement, maintenance, training for maintenance and end user, easier knowledge transfer, quality management systems implementation, standard operational procedure writing, and comparability of results between laboratories.

Recommendations

Manufacturers reducing the monopoly of vendors in country would increase competition thereby making pricing and service options more competitive. Open system platforms would simplify reagent specification and competitive bidding in accordance with the procurement act. The option for equipment placement rather than equipment procurement should also be explored as this would reduce the initial capital outlay, transfer maintenance to vendor and allow for responsiveness to changes in technology³. Equipment manufacturers should undertake the training of biomedical health care technical officers to enable them perform beyond first line maintenance and trouble shooting.

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