

## Supply chain management of laboratory supportive services and its potential implications on the quality of HIV diagnostic services in Tanzania

GIBSON B. KAGARUKI<sup>1\*</sup>, MATHIAS L. KAMUGISHA<sup>2</sup>, ANDREW M. KILALE<sup>3</sup>, ERASMUS KAMUGISHA<sup>4</sup>, ACLEUS S.M. RUTTA<sup>2</sup>, VITO BARAKA<sup>2</sup>, CELINE I. MANDARA<sup>2</sup>, STEPHEN M. MAGESA<sup>5</sup>, GODLISTEN MATERU<sup>1</sup>, AMOS M. KAHWA<sup>3</sup>, RASHID MADEBE<sup>2</sup>, JULIUS J. MASSAGA<sup>6</sup>, MARTHA M. LEMNGE<sup>2</sup>, LEONARD E.G. MBOERA<sup>6,7</sup> and DEUS S. ISHENGOMA<sup>2</sup>

<sup>1</sup>National Institute for Medical Research, Tukuyu Research Centre, P.O. Box 538 Tukuyu, Tanzania

<sup>2</sup>National Institute for Medical Research, Tanga Research Centre, P.O. Box 5004, Tanga, Tanzania,

<sup>3</sup>National Institute for Medical Research, Muhimbili Research Centre, P.O. Box 3426, Dar es Salaam, Tanzania

<sup>4</sup>Catholic University of Health and Allied Sciences, P.O. Box 1464, Mwanza, Tanzania

<sup>5</sup> National Institute for Medical Research, Amani Research Centre, P.O. 81, Muheza, Tanzania

<sup>6</sup>National Institute for Medical Research, Headquarters, P.O. Box 9653, Dar es Salaam, Tanzania

<sup>7</sup>Southern African Centre for Infectious Disease Surveillance-Africa Centre of Excellence in Infectious Diseases of Human and Animals, Morogoro, Tanzania

### Abstract

**Background:** Reliable supply of laboratory supportive services contributes significantly to the quality of HIV diagnostic services. This study assessed the status of supply chain management of laboratory supportive services and its potential implications on the quality of HIV diagnostic services in selected districts of Tanzania.

**Methods:** The study was conducted in 39 health facilities (HFs) from eight districts in four regions of Tanzania, namely Iringa, Mtwara, Tabora and Tanga. Facilities with care and treatment centres for HIV/AIDS patients were purposively selected for the study. The study utilized a quantitative method of data collection. A questionnaire was administered to heads of laboratories to obtain information on laboratory supply chain management.

**Results:** A total of 39 health facilities (HF) were included in the study. This included 23 public and 16 private facilities. In 82% of the HFs, ordering of supplies was performed by the laboratory departments. The information commonly used to forecast requirements of the laboratories included the number of tests done (74.4%; n=29), current stock levels (69.2%; n=27), average monthly consumption (64.1%, n=25) and minimum and maximum stock levels (10.2%, n=4). Emergency orders were significantly common in public than private facilities (73.9% vs. 56.3%, p=0.004). Delivery of ordered supplies took 1 to 180 days with a significantly longer mean period for public than private facilities (32.5 vs. 13.1 days, p=0.044). Most of the public HFs ordered supplies from diverse sources compared to private facilities (68.2% vs. 31.8%).

**Conclusion:** There was a weak inventory management system and delays in delivery of supplies in the majority of HFs, which are likely to impede quality of HIV care and treatment. Strengthening capacity for data management and ensure constant supply will potentially improve the quality of HIV diagnostic services.

**Keywords:** laboratory services, supply chain, diagnosis, HIV/AIDS, Tanzania

### Introduction

Efficient and reliable laboratory operations require an uninterrupted availability of reagents, supplies, consumables and other related services. However, poor supply chain management at all levels of health system in developing countries is common and is leading to stock-outs of key reagents, supplies and consumables resulting in interruptions of service delivery (Kagaruki et al., 2013). Effective supply chains help to ensure commodity security and determine the success or failure of any public health programme (Manso et al., 2013). Available evidence shows that the performance of a supply chain system affects the coverage of services as well as clients seeking behaviours (Manso et al., 2013). A strong and well-functioning system of supply chain management

\* Correspondence E-mail: [gkagaruki@gmail.com](mailto:gkagaruki@gmail.com)

which is lacking in most of the low-developing countries provides an assurance for sustainable HIV/AIDS prevention, care and treatment services (Mfinanga et al., 2007). An efficient system also helps to link planning, implementation and controls the flow of information, materials and services from the health care providers to suppliers and ultimately to HIV/AIDS patients (MoHSW, 2018).

In Tanzania, health laboratories play a key role in HIV testing for screening of infections, diagnosis, patient's management, disease progress and surveillance (Grossman & Kra-Oz, 2013; Manyazewal et al., 2013; Shinnick et al., 2013). Thus, the laboratory systems offer a vital role for effective implementation of anti-retroviral treatment (ART) scaling up, expansion of the programmes for clinical testing, voluntary counselling and testing (VCTs) services, prevention of mother-to-child transmission (PMTCT) and provider initiated testing and counselling (PITC) (MoHSW, 2018).

The Tanzania National Health System is made up of several levels of service delivery including a dispensary, health centre, and the district plus regional and national levels (Mboera et al., 2015a). The national level (i.e. the Ministry of Health is responsible for policy formulation, development of guidelines and implementation of different control programmes. The Ministry through the centralized Medical Store Department (MSD) is responsible for establishment of national laboratory policy framework, supply chain management, provision of guidelines, infrastructure, and resource allocation for maintaining a balanced logistic framework (MoHSW, 2008). The laboratory supplies for regional hospital and faith-based health facilities are most often procured and distributed directly from central or zonal MSD (MoHSW, 2008). Public district and primary health centre/dispensary laboratories receive their supplies on quarterly basis from the District Medical Office. Unlike public health laboratories, private health facilities can choose to procure supplies from various suppliers. This system most likely make private health facilities more capable of managing their supply chain system compared to the lower level public facilities. To avoid frequent stock-out of laboratory supplies, logistics management information systems (LMIS) and inventory management are required to establish the maximum and minimum stock levels as stipulated in the National Laboratory Guidelines and Integrated Logistic Manual (MoHSW, 2009).

Although establishing and maintaining a well-functioning supply chain system for laboratory reagents, supplies and consumables was among of the priority components in strengthening the National Health Laboratory System (NHLS) in Tanzania before launching of the national-wide HIV/AIDS care and treatment plan in 2004 (MoHSW, 2009), there is limited information on the status and operationalization of the system at different levels of the health system. This study was therefore, carried out to assess the supply chain management of laboratory supplies, reagents and consumables and its potential implications on the availability and quality of HIV diagnostic services in selected districts of Tanzania.

## **Materials and Methods**

### **Study design and sampling procedures**

This cross-sectional study was conducted from September to November 2013 in four regions of Iringa, Mtwara, Tabora and Tanga in Tanzania. The four regions were selected according to the HIV prevalence status (low, moderate and high HIV prevalence regions) as previously described (Mboera et al., 2015a; Ishengoma et al., 2017). Of the four selected regions, Iringa was among the regions with high prevalence of HIV (9.1%), while Tabora (5.1%) and Mtwara (4.1%) had moderate and Tanga had lower prevalence of HIV (2.4%) (THMIS, 2013). The four regions were randomly selected from the clusters of regions with low, moderate and high HIV prevalence (THMIS, 2013). From each region, two districts one being rural and another urban were also selected whereby the urban districts were purposely selected while the rural were selected randomly from a list of rural districts. The selected eight districts were Iringa Rural, Iringa Urban (Iringa), Masasi, Mtwara (Mtwara), Igunga, Tabora (Tabora), Muheza and Tanga (Tanga).

In each district, a list of public and private health facilities (HFs) with care and treatment centres for HIV/AIDS patients and offering laboratory diagnostic and supportive services for HIV (including dispensaries, health centres and hospitals) was used to select study HFs. The study targeted six HFs per district with equal numbers of dispensaries, health centres and hospitals (one HF in each category had to be a private facility). However, where hospitals owned either privately or publically did not exist, one or two health centres were sampled to replace them. Although six health facilities (public and private) were expected to be selected from each district; the required number of HFs could not be attained in some of the districts we sampled due to prior set inclusion criteria. The inclusion criteria of the HFs were availability of HIV Care and Treatment Clinics (CTC) and HIV laboratory diagnostic services. Facilities not providing HIV diagnostic services were excluded from the sampling frame of this study.

### **Data collection**

The study utilized a quantitative method of data collection. A questionnaire with both closed and open ended questions was administered to heads of laboratories to obtain information on inventory management, logistics management information system, transport services and storage of reagents and consumables. This questionnaire was piloted and refined to ensure that the required information was captured using this tool.

### **Ethical considerations**

Ethical approval was sought and provided by the Medical Research Coordinating Committee of the National Institute for Medical Research. Permission to conduct the study at the health facilities was sought from the regional and district medical officers and the in-charges of the respective health facilities. Verbal and written informed consent was obtained from each respondent before taking part in the interviews.

### **Data analysis**

Completed responses in all questions in the study questionnaires were coded by numbers and double entered in a computer software Epi-data version 3.1. The data was then exported to Statistical Package for Social Sciences version 20 for windows (SPSS Inc, Chicago, USA) and Stata version 11 (STATA Corp Inc., TX, USA) for cross-checking, cleaning and analysis. Pearson Chi-square test was used to compare group differences for categorical variables. T-Test was used to compare the mean difference between variables. Bar graphs were used for pictorial presentation of the results. Differences or association between variables were considered statistically significant if the p-values were  $\leq 0.05$ .

## **Results**

### **Types of Facilities**

This study involved 39 HFs including six dispensaries, 20 health centres and 13 hospitals. Fifty-nine percent (23) of the facilities were public owned and most (56%) of the facilities were from rural districts (Table 1). By profession, the respondents included laboratory technologists (38.5%), laboratory assistants (33.3%), laboratory attendants (15.4%), laboratory scientists (7.7%) and clinical officer (5.1%).

### **Inventory and stock management**

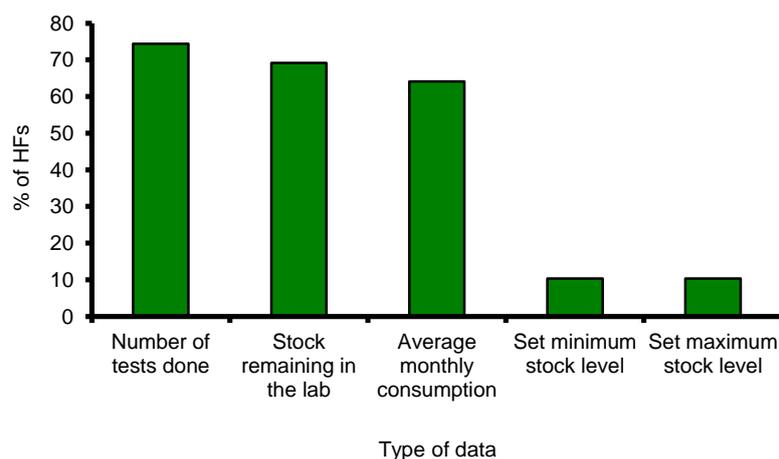
In 25 (64.1%) HFs, the heads of laboratories were responsible for supply chain management. In some facilities, other health workers were also responsible for the supply chain management and these included heads of health facilities (12.8%), store keepers (5.1%) and pharmacists (2.6%). In six (15.4%) HFs, clinical officers and laboratory assistants/attendants were involved. In 32 (82.1%) health

facilities, the laboratory units were responsible for determining quantities of laboratory reagents, supplies and consumables to be ordered.

**Table 1: Type, ownership and location of the health facilities covered in the four regions (n=39)**

Variable		Iringa n (%)	Mtwara n (%)	Tabora n (%)	Tanga n (%)	Total n (%)
<b>Type of facility</b>	Dispensary	2(18.1)	3(30.0)	1(10.0)	0(0.0)	6(15.4)
	Health Centre	5(45.5)	4(40.)	5(50.0)	6(75.0)	20(51.3)
	Hospital	4(36.4)	3(30.0)	4(40.0)	2(25.0)	13(33.3)
<b>Ownership</b>	Public	7(63.6)	6(60.0)	6(60.0)	4(50.0)	23(59.0)
	Private	4(36.4)	4(40.0)	4(40.0)	4(50.0)	16(41.0)
<b>Setting</b>	Rural	4(36.4)	5(50.0)	5(50.0)	3(37.5)	17(43.6)
	Urban	7(63.6)	5(50.0)	5(50.0)	5(62.5)	22(56.4)

Only six (15.4 %) HFs had minimum and maximum inventory stock levels of the laboratory supplies. The most reported data used to forecast the laboratory requirements was the number of tests done was the most frequently (74.4%; n=29) reported data used to forecast laboratory requirements. Other type of information included current stock levels in (69.2%; n=27) and average monthly consumption (64.1%; n=25). The minimum and maximum stock levels were rarely used to determine the requirement of laboratory reagents, supplies and consumables (Figure 1). Ordering of supplies and consumables was either done on monthly or quarterly basis by 31 (79.5%) HFs; six-monthly basis in four (10.2%) and in the other four (10.2%) facilities ordering was done on ad hoc basis. In private facilities, ordering of reagents and consumables was only done on six-monthly basis.



**Figure 1: Types of data used to calculate the quantity of reagents or consumable to be ordered**

#### **Ordering and delivery time of reagents and supplies**

Twenty six (66.7%) health facilities reported to have made at least one emergency order within 12 months before this study. Emergency orders were significantly more often placed by public than private facilities (73.9% vs. 56.3%, respectively;  $p=0.004$ ). The number of emergency orders placed during the period 12 months before the study ranged from one to 20 (mean emergency order was 3.0 (95% CI, 1.4-4.6)). Although the mean number of emergency orders placed by public (3.8; 95% CI, 1.3-6.2) was higher than that of private HFs (1.7; 95% CI, 1.1-2.2,  $p=0.207$ ); the difference was not statistically significant. The minimum duration from placing an order to delivery ranged from one to 60 days with a significantly higher mean waiting time in public than private HFs (13.9; 95% CI,

6.7-19.4 and 5.3; 95% CI, 0-10.9 days;  $p=0.045$ , respectively). The maximum duration from placing an order to delivery ranged from one to 180 days with a higher mean waiting time in public than private HFs; 32.5(95% CI, 13.5-51.4) and 13.1(95% CI, 0-27.8) days respectively ( $p=0.044$ ). Twelve (30.8%) HFs reported to have at least one order that took longer than usual (ranging from one to 270 days) to deliver and 10 of these (83.3%) were public facilities including seven hospitals. Inadequate funds, stock out at MSD and transportation problems were the main reasons for delays of the deliveries to the HFs. Majority of the laboratories (72.2%) obtained their supplies from different sources. Most of the public facilities ordered their supplies from different sources compared to private facilities (68.2% vs. 31.8%).

**Table 2: Types of laboratory reagents and supplies which were frequently stocked out at the study health facilities (n=39)**

Reagents/Supplies	Overall, n (%)	Region				Ownership	
		Iringa	Mtwara	Tabora	Tanga	Public	Private
<b>Type of reagents</b>							
Determine <sup>®</sup>	11(28.2)	3	1	5	2	7	4
Uni-Gold <sup>™</sup>	11(28.2)	5	0	5	1	8	3
SD Bioline	2(5.1)	1	0	1	0	1	1
CD <sub>4</sub> counts	3(8.3)	1	2	0	0	2	1
Biochemistry reagents**	11(28.2)	1	4	2	4	6	5
Haematological reagents	3(7.7)	0	1	0	2	2	1
Opportunistic infection tests*	3(7.7)	0	1	0	2	2	1
<b>Infection control supplies and consumables</b>							
Hand soap	5(12.8)	2	1	1	1	1	4
Unused sharp boxes	4(10.3)	2	2	0	0	2	2
Gloves	3(7.7)	1	0	1	1	2	1
Waste receptacle liners	19(48.7)	6	6	3	4	12	7
Waste receptacles	7(17.9)	2	0	2	3	2	5
Goggles	27(69.2)	10	9	5	3	16	11
Masks	19(48.7)	5	4	7	3	14	5
Aprons	19(48.7)	5	4	6	4	13	6
Laboratory coats	3(7.7)	1	0	2	0	2	1

\*\*ALAT = alanine aminotransferase (ALAT), ASAT = aspartate aminotransferase and urea; \*Included reagents for diagnosis of opportunistic infections

### Logistics Management Information System

Twenty two (56.4%) HFs reported to use ledgers for keeping track of laboratory reagents and supplies. Seven facilities (17.9%) reported use of stock cards while others (25.6%; n=10) utilized physical count, bin cards and other types of forms. Information generated from these tools was mainly used to calculate order quantities in 16(42.1%), and monitoring of consumptions of reagents and supplies in 15 (39.5%) HFs. Order books (29.2%), requisition/issue voucher (19.5 %), and request and reports forms \or delivery notes (9.8%) were commonly used by the laboratories in ordering and receiving supplies.

Twenty nine (74.4%) health facilities had standard printed forms for requesting and recording laboratory test results. The use of printed laboratory forms was not significantly different among public and private health facilities (78.3% vs. 68.8%,  $p=0.076$ ). Patients' prescription note books and papers were used by the health facilities which reported to have no standard printed forms for requesting and recording laboratory test results. The laboratory reports prepared and submitted to higher levels included laboratory tests performed (74.4 %, n=29),

surveillance (30.8 %; n=12) and stock status (23.1%; n=9). About two-thirds of HFs (61.5%) submitted their reports to the higher level (district) on monthly basis. Only 17 (41.5 %) laboratories reported that the laboratory management information system was integrated within the logistics management information system of their HFs. Integration of the logistics management information system was more common among private than public facilities (50.0% vs. 39.1 %).

### **Stock status and storage facilities of reagents and consumables**

Stock-out of HIV diagnostic test kits and biochemistry reagents were frequently reported during the period of 12 months before the study. Other important laboratory supplies and consumables such as masks, apron and waste receptacle liners were in short supply in most of the HF (Table 2).

In three quarters (75%) of the facilities, laboratory supplies were mostly stored in the laboratory storeroom. Guidelines for storing laboratory supplies according to their specifications and flammable and hazardous status in specialized area were available in less than 50% of the facilities (Tables 3). About four-fifth of the facilities were storing cold chain items at appropriate temperature. A significantly large number of private facilities had stored cold items at proper temperature than public facilities (100% vs. 63.6%; p=0.011).

**Table 3: Availability of storage condition in the public (n=23) and private (n=16) health facilities**

Storage condition	Overall	Public Facilities n (%)*	Private facilities n (%)
Guidelines for storage of lab supplies available	18(46.2)	9(39.1)	9(56.3)
Appropriate storage of hazardous chemicals	22(56.4)	13(56.5)	9(56.3)
Reagents are stored according to the first-to-expire, first-out practice	34(87.2)	19(82.6)	15(93.8)
The laboratory makes it a practice to separate damaged and/or expired supplies from good products	35(89.7)	20(87.0)	15(93.8)
The laboratory makes it a practice to remove damaged and/or expired supplies from inventory	34(87.2)	19(82.6)	15(93.8)
The laboratory makes it a practice to follow guidelines for disposal and/or destruction of damaged and/or expired supplies	27(69.2)	17(73.9)	10(62.5)
No reported problem with storing laboratory supplies	21(53.8)	15(65.2)	6(37.5)

\*There were no significant differences between private and public health facilities (p>0.05)

### **Discussion**

This study revealed that the management of laboratory inventory was done by various cadres of health workers; some without adequate laboratory qualifications. Using various cadres in management of laboratory inventory is against the recommended Tanzania National Guidelines (MoHSW, 2009). The guidelines require that at the dispensary and health centre levels, the laboratory assistant should be responsible for the management of laboratory services. At the district and regional levels, the laboratory technologists are responsible for laboratory service management. Hence using different carders apart from the recommended personnel has implications on the quality of services and availability of appropriate laboratory supplies (NCCLS, 1994). Similar findings have been reported in Malawi where a pharmacist was responsible for managing a hospital laboratory (Butao *et al.*, 2009). The use of non-laboratory staff in the laboratory service management in Tanzania is likely to be due to inadequate number of trained laboratory staff (Mboera *et al.*, 2015b). Although the inventory was managed by different cadres; the majority of the facilities involved the laboratory units in determining the types and quantity of reagents and consumables to be ordered.

An adequate stock level is a level between the maximum and minimum levels which helps to minimize frequent stock out (Layer *et al.*, 2014). Absence of minimum and maximum stock level is an

indicator of inadequate stock management resulting into irregular and/or emergency ordering and unforeseen increase in uses of supplies. In this study, few facilities reported availability of minimum and maximum stock levels and a small proportional utilized both minimum and maximum stock levels in stock management. This has implications on stock out, overstocking and expiries of reagents and supplies. The finding that HIV test kits were reported to be frequently out of stock for long periods of time in our study is consistent with reports from previous studies in Tanzania and elsewhere in Africa (Medley & Kennedy, 2010; Desale *et al.*, 2013; Layer *et al.*, 2014). It has been previously shown that frequent stock-out of laboratory reagents, supplies and consumables causes frustration and de-motivates to the service providers and clients (Kagaruki *et al.*, 2013; Layer *et al.*, 2014). Similar results have been reported in Kenya, whereby clients who were seeking HIV services were turned back because of stock out of test kits (Desale *et al.*, 2013). The frequently reported trends of stock out of HIV test kits in Tanzania is likely to compromise patients' access to HIV testing services hence causing a barrier in implementation of HIV/AIDS care and treatment programme in the country. In addition, this study found inadequate availability of other commodities including masks, apron, waste receptacle liners and goggles. Such a situation has also been reported elsewhere in developing countries (Pasquet *et al.*, 2010) and further shows that laboratories cannot offer reliable and high quality services for diagnosis of HIV and other pathogens.

At least an emergency order was made by each facility within a period of 12 months before the study and this was most common in public facilities. This is probably a result of poor planning, untimely delayed responses from the suppliers or delays in availability of adequate funds for procurement of laboratory reagents, supplies and consumables. Contrary to the findings of our study, in Ghana emergency ordering was minimal because procurement was decentralized (Addo *et al.*, 2006). In this study, majority of facilities were obtaining their supplies from the Medical Store Department (MSD) which is a central government procurement and distribution agent with a monopoly of the national medical supply chain for over 60% of the public facilities' demands (<http://www.msd.or.tz>). Similar to findings of this study, centralized system is reported to be associated with delays of essential supplies such as HIV test kits and other reagents (Mfinanga *et al.*, 2007). There was also a reported persistent delay of orders made by public facilities possibly due to the system utilized by these health facilities which mainly obtain their supplies from the office of DMO. Lack of effective laboratory stock management and separate funds to run the laboratories was also found to be a fundamental weakness in the overall management of laboratory services for malaria diagnosis (Nkengason, 2009).

In keeping track of laboratory reagents and supplies; ledgers books were mostly used in the majority of the facilities (>56%) while stock cards were rarely used since only 18% of the HFs were using them. In our study, we found that order books, requisition/issue vouchers, and request and reports forms were also used in laboratory ordering and receiving supplies. The tools which were used are the standard ones stipulated in the integrated logistics system (ILS) manual (MoHSW, 2008). However, there was no consistency in the type of forms used by the facilities. This may be due stock out of the tools which sometimes lead to improvisation resulting into use of other types of forms which are not approved and recommended for this purpose (Kagaruki *et al.*, 2013). This is likely to cause poor tracking systems and source of data might not be known by all the facility workers. Furthermore, in some HFs the forms used for ordering of laboratory tests were not available and this made the attending clinicians to use patients' prescription notebook or printing papers. Utilizing non-standardized tools could compromise patients' confidentiality and lead to poor data management at the point of care. It was also shown that in only few HFs, the laboratory management information system was integrated within the logistics management information system of the respective facilities. Since majority of HFs' laboratory information system was not integrated within the ILS, the laboratories missed important information to support decisions in determining orders or procurement quantity, forecasting, or monitoring system performance (Nkengason, 2009; Gummadi *et al.*, 2014).

Guidelines for storage of laboratory supplies according to their specifications and storing flammable and hazardous chemicals in specialized area were available in few facilities. Although proper temperature conditions were maintained in the majority of private facilities, it was observed only in a few public facilities. Most of HIV diagnostic tests kit do not require refrigeration and are therefore particularly suitable for remote and rural areas and other sites without a constant electricity supply. However, extreme low or high temperatures may affect the quality and shelf-life of these diagnostic tests. Consequently, it is advisable to monitor temperature fluctuations in storage rooms. In practice, a refrigerator or an air-conditioned room may be required in tropical climate (WHO 2004). Exposure to extreme temperatures is a major contributor to poor performance of rapid diagnosis tests, particularly during transfer from the manufacturer, and transport within a country as well as storage (Parekh et al., 2010).

This study revealed low adherence to the standards and regulations governing supply chain management. It was shown that there were significant emergency orders, delays of supplies delivery, and absence of common tools for keeping track of laboratory reagents and ordering and receiving laboratories supplies. Low adherence to standards and regulations and procurement under emergency orders were also other factors reported in this study which could potentially affected availability and the quality of HIV diagnostic services in selected districts of Tanzania. To improve quality of HIV diagnostic and supportive services, there is a need to strengthen the capacity for data management and ensure constant supply of all necessary HIV diagnostic reagents and consumables at all levels of the health system.

### Competing interest

The authors declare that they have no financial and non-financial competing interests

### Author contributions

DSI, GBK, AMK, AMK SMM, JJM and LEGM were involved in the conception, design and implementation of the study. GBK, MLK were involved in data analysis while GBK, DSI and LEGM wrote the manuscript. All authors reviewed and approved the final draft of the manuscript.

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