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Assessment of Integrated Pharmaceutical Logistic System for the Management HIV/AIDS and Tuberculosis Laboratory Diagnostic Commodities in Public Health Facilities in Addis Ababa, Ethiopia

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Abstract

Background: Managing HIV/AIDS and TB laboratory commodities through the Integrated Pharmaceutical Logistics System (IPLS) is a strategy to enhance the smooth flow of commodities and prevent frequent stock outs of critical items that could hinder continuous provision of quality diagnostic services. However, data on IPLS implementation status at the health facility level are scarce. This study assessed the status of IPLS implementation for HIV/AIDS and TB laboratory commodities at health facilities in Addis Ababa, Ethiopia

Methods: A descriptive cross-sectional study was used. Thirty three public health facilities were selected using stratified sampling method. Information on selected indicators for IPLS implementation was collected using semi-structured questionnaire customized from USAID|DELIVER's LIAT and LSAT. Data for selected indicators was collected through document review, physical inventory, and in-depth interview with key informants

Results: Availability of IPLS formats for recording and reporting - bin cards, internal facility report and requests (IFRR), and report and request forms (RRF) - was reported in 25 (92.6%) facilities. Regular update of bin cards was reported in 16 (61.5%) facilities, while IFRR and RRF were completed by 22 (84.6%) and 24 (92.6%) facilities, respectively. Utilization of bin cards was higher at health centers (76.5%) compared to hospitals (33.3%). Furthermore, 25 (92.6%) facilities reported stock out for one or more commodities during the last six months; stock out for SGPT, EDTA test tube, and 1% Carbol Fuchsin on date of visit was reported by 10 (41.6%), 12 (54.5%), and 11 (46.7%) facilities, respectively. Management support for IPLS implementation was significantly associated with improved data quality and utilization of IFRR.

Conclusions: The majority of facilities reported the availability and utilization of IPLS tools to manage HIV/AIDS and TB laboratory commodities. However, most experienced stock out of one or more commodities during the last six months, which could be due to failure to implement IPLS in full scale.

Keywords: Public health facilities; Antiretroviral; Hematology; Pharmaceutical logistics

Abbreviations:

IPLS: Integrated Pharmaceutical Logistics System, LMIS: Logistics management information system, LIAT: Logistics Indicator Assessment Tool, IFRR: Internal Facility and Request and Report, RRF: Report and Request, RTK: Rapid Test Kit, SGOT: Serum Glutamic Oxaloacetic Transaminase, SGPT: Serum Glutamic Pyruvic Transaminase, EDTA: Ethylene diaminetetraacetic acid, AACA HB: Addis Ababa City Administration Health Bureau, EPHI: Ethiopian Public Health Institute, AFB: Acid Fast Bacillus, ART: Antiretroviral, LSAT: Logistic System Assessment Tool, LSAT: Logistic Indicators Assessment Tool, PFSA: Pharmaceutical Fund and Supply Agency, AA: Addis Ababa, SOP: Standard Operating Procedure, FEFO: first-to-expire, first-out

Introduction

Laboratory diagnostic service is a dynamic process for new tests to be introduced with new technology which requires new and variable commodities. The extensive number of commodities used by laboratories and the technological advancement makes logistics management of laboratory commodities more complex. The management of HIV/AIDS and TB requires uninterrupted supply of quality laboratory reagents. The purpose of a laboratory logistics system is to obtain and move commodities in a timely fashion to the places where they are needed at a reasonable cost with acceptable quality [1].

Ethiopia has a number of health programs that require efficient pharmaceuticals supply chain system for their effective and efficient implementation [2]. The national assessment conducted on the public health pharmaceutical supply system in 2004 identified a number of

challenges in the supply chain of health commodities, where set of vertical programmes involving multiple stakeholders were responsible for managing supply chain for ART, TB, Family Health, EPI, etc., and other essential medicines [2,3].

To avert historical problems associated with the pharmaceutical supply chain system, Pharmaceutical Fund and Supply Agency (PFSA), a semi-autonomous agency under Federal Ministry of Health, was nationally established by the House of People's Representatives with a mandate to run and coordinate the whole pharmaceutical supply chain operations for public health system (HoPR, 2007). This national pharmaceutical supply system reform has gave rise to the designing of an Integrated Pharmaceutical Logistics System (IPLS) as primary mechanism to ensure un-interrupted supply and continuous availability of quality-assured essential medicines at all public health facilities at affordable prices [2,4].

IPLS is the term applied to a single pharmaceuticals reporting and distribution system. It integrates the supply chain management of all types of pharmaceuticals (medicines, medical supplies and equipment, and laboratory chemicals and reagents) in the public health sector. The IPLS has three main components including the policies and guidelines for LMIS, inventory control and storage of pharmaceuticals at all levels of the supply chain system throughout the country [4]. Each component (sub-system) has its own set of indicators for measuring progresses and performances [4, 5]. These indicators can also be used to check for: system leakages, to track the availability and utilization of records (e.g. bin card records), and to determine the extent to which facility laboratories complete and submit LMIS reports [5,6].

Routine monitoring reports show that the implementation of IPLS has improved the performance information system (recording and reporting), storage and distribution systems, as well as the availability of essential commodities at service delivery points. However, no objective measurement so far was made to assess IPLS implementation status and performance of supply chain system in general and for laboratory commodities specifically [7]. Therefore, this study attempts to assess the implementation of IPLS for the management of HIV/AIDS and TB Laboratory Commodities using the availability and utilization of selected IPLS tools at public health facilities in Addis Ababa.

Methods

Settings and study design

Facility based descriptive cross-sectional study was used to assess the status of IPLS implementation for HIV/AIDS monitoring and TB diagnostic commodities management among public health facilities in Addis Ababa from December 2013 to May 2014 spanning 3 bi-monthly reporting periods.

Study participants

The study population were all public health facilities and supply chain units involved in HIV/AIDS and/or TB diagnostic commodities management that are found in the Addis Ababa. These were the 5 federal specialized hospitals, 6 hospitals under AACA HB, 26 health centers under AACA HB, 10 sub-city pharmaceutical and medical supply distribution pharmacy service, 1 AACA HB store, 1 AACA HB regional laboratory and the national referral laboratory in EPHI (FMOH, 2012).

Inclusion and exclusion criteria

Health facilities with laboratory setup that performs CD4 count, hematology and chemistry tests; or facilities that refer samples for CD4 testing but perform rapid HIV test, AFB smear examination, hematology and/or chemistry tests; and institutions that provide technical and management support for the implementation of IPLS system were included in this study. Facilities that don't provide ART laboratory monitoring and TB diagnostic test services were excluded from this study.

Sample size determination

Sample size was calculated according to the guide for conducting supply chain assessments using the LSAT and LIAT [8].

To generate representative sample for LIAT survey, an assumption that 50% of the facilities would poorly function with regard to IPLS implementation was considered as similar studies in Ethiopia were not available. In addition, a confidence level of 95% with a margin of error of 10% was used. The sample size was then calculated using formula for calculating sample sizes in finite population bases. With this formula, sample size of 33 was obtained.

Sampling design

Stratified sampling method was used to select 33 public health facilities comprising of federal and regional hospitals, health centers, sub city pharmacy units, regional store, regional laboratory, and national referral laboratory.

Sampling procedures

A total of 50 public health facilities that are involved in supply chain of HIV/AIDS and TB laboratory diagnostic commodities were used as a study population from which 33 selected facilities were drawn.

For selection of the sample population, first the health facilities were categorized into 7 different strata as per their type. The strata includes 5 federal hospitals, 6 regional hospitals (under AACA HB), one AACA HB store, 10 sub-city health departments, one regional laboratory and one national referral laboratory of EPHI and 26 health centers under AACA HB. The number of facilities to be included into the calculated sample of 33 facilities from each of the stratum was determined by using proportionate sampling respective sizes. Once the sample size per stratum was determined, individual facilities were identified using lottery method.

Data collection tools

Semi-structured questionnaire was customized from tools for logistics system assessment developed by USAID/DELIVER. The qualitative section of the questionnaire was adopted from LSAT while the quantitative section was adopted from LIAT [8].

The questionnaire used to collect the data was pretested in three health facilities rendering the intended laboratory services. The tool was modified based on the feedback obtained during the pretest. Aspects of the tool which were out of the intended facility's scope / mandate (such as product selection, procurement, etc.) or which were of less significance to objectives of the study (organizing, staffing, financing, etc.) were excluded from the tool following the piloting schemes.

The quantitative section of the questionnaire was designed to collect data on selected indicators including: availability of laboratory commodities for HIV/AIDS and TB diagnostics service on day of visit; stock out situation and average duration of stock outs; percentage of facilities with physical counts matching bin card balance; percentage of facilities with personnel trained/oriented on IPLS; percentage of facilities that have expired commodities; percentage of facilities with bin cards and percentage of facilities with accurate bin card records; availability of report and request formats and reporting rates for health facilities; percentage of facilities with acceptable data quality for report and request formats; percentage of facilities with lab/stores resupplied with products as per their requests.

The qualitative section was designed to understand the logistics system for HIV/AIDS and TB laboratory diagnostic commodities, to identify its strength and weaknesses, and the challenges associated with the implementation of IPLS for HIV/AIDS and TB laboratory diagnostic commodities.

Implementation of data collection and quality assurance

Three data collectors with first degree in medical laboratory science having an experience in laboratory commodity management participated in data collection after taking two days training. Data collectors were trained on how to collect the necessary data using the tool and additional written guide was provided to them on interpreting each of the study variables. The data was collected in the same language as recorded.

The principal investigator was closely supervising the data collection process so as to ensure the completeness and consistency of the data gathered. In addition, data was double entered to prevent error during data entry via cross-checking.

Data was collected over a two weeks period. The laboratory commodities covered in the assessment were laboratory diagnostic commodities used in ART monitoring, chemistry tests, hematology and CD4 tests, and AFB testing laboratory reagents and supplies of tracer products.

Data collection procedures

Based on results from the sampling exercise, the health facilities that were selected for the assessment were first located. Heads of the facilities were then approached to obtain consent for undertaking the data collection at the establishments. Following this, the logistics system performance data was collected with close collaboration from health facility's pharmaceutical store managers and heads of laboratory units. In addition, pharmaceutical supply and distribution officers at the selected Addis Ababa sub-city health offices, AACA HB, PFSA Central, and PFSA Addis Ababa branch were the focal persons during the data collection process.

Combination of different methods was used to collect data using the questionnaires. In-depth interview with key informants at selected Addis Ababa sub-city health offices, AACA HB, PFSA Central, PFSA Addis Ababa branch was conducted to understand the supply chain management system for HIV/AIDS and TB laboratory diagnostic commodities, to identify the strength and weaknesses pertinent to IPLS implementation, challenges facing the logistics systems, and the level of training and supervision available to facilitate its implementation. The interviewer was conducted by principal investigator.

The level of product availability, accuracy of records and reports associated with HIV/AIDS and TB laboratory commodities logistics was assessed by reviewing records and by conducting physical inventory of those commodities. Results from the physical inventory and record review were then reconciled to evaluate the level of discrepancy between them. Facility's store managers and heads for the laboratory unit were further interviewed to enrich the findings from physical interview and record review process.

Statistical analysis

The quantitative data was entered into excel spread sheet and exported to SPSS version 20 for analysis. Descriptive statistics (mean, median and percentage) were computed and summary results presented using tables and graphs. Chi-square was computed to see the association between selected IPLS implementation indicators with reported management support. The qualitative data obtained from in-depth interview are summarized in narrative form.

Ethical considerations

Ethical approval was obtained from Research and Ethical Review Committee of School of Medical Laboratory Science and Ethical Committee of Addis Ababa Health Bureau. The school has facilitated the issuance of support letter to the AACA HB. Subsequently, the Ethical Review Committee at Health Bureau, after reviewing the proposal and research protocol, issued support letter to all concerned target facilities including the sub-cities and hospitals.

Based on support letter from the health bureau, the pharmaceutical logistics and pharmacy service unit at the sub-city health offices issued support letter to the health facilities. Finally, informed consent from individual facilities and personnel involved in this assessment was obtained. Names of the health facilities assessed and key informants interviewed were kept confidential throughout the process of data collection, analysis, presentation and interpretation of results.

Results

Background characteristics of the health facilities

A total of 33 public health facilities were included in this study. There were 3 (9.1%) federal-specialized hospitals, 3 (9.1%) regional hospitals, 17 (51.5%) health centers, 7 (21.2%) sub-city pharmaceutical and medical supplies pharmacy unit, 1(3.0%) regional laboratory, 1 (3.0%) regional health bureau, and 1 (3.0%) national referral laboratory.

Across these facilities, a total of 59 health professionals 33 (55.2 %) pharmacy and 26 (44.8%) laboratory professionals) were involved in the supply chain management of ART and TB laboratory commodities. As such, these professionals were involved in in-depth interview process (Table 1).

Health facilities	Number(n)	Percent (%)
Federal specialized hospitals	3	9.1
Regional hospitals	3	9.1
Health centers	17	51.5
Addis Ababa sub cities pharmaceutical and medical supplies distribution units	7	21.2

Regional laboratory	1	3.0
Regional health bureau	1	3
EPHI laboratory	1	3
Total	33	100

Table 1: Type and number of health facilities where the study was conducted, December to April, 2014, Addis Ababa.

Flow of information and laboratory commodities in Addis Ababa

Informant interviews were conducted to understand and clearly elucidate the flow of information and laboratory commodities for HIV/AIDS and TB, including the rapid test kits for HIV. Accordingly, the findings are presented in figure 1 and 2.

Figure 1 shows the flow of information and laboratory commodities for HIV/AIDS (except HIV rapid test kits and TB laboratory diagnostic commodities). The assessment shows that PFSA central delivers ART monitoring HIV/AIDS commodities to PFSA Addis Ababa hub, federal specialized hospitals and national laboratory at the EPHI. From PFSA Addis Ababa hub, the commodities are distributed to regional hospitals, health centers and AACA HB medical stores.

The medical store at AACA HB is primarily responsible for supplying the regional laboratory. Whether the commodity delivery is made from PFSA central, PFSA Addis Ababa hub or AACA HB medical stores, the commodities are first delivered to the establishment's pharmaceutical and medical supply stores, where first and instantaneous proof of delivery receipts are also issued. From these stores, the commodities are finally issued to the laboratory units for utilization at a predefined schedule based the reports for consumption and new requests forwarded.

In the case of HIV test kits and TB laboratory diagnostic commodities, a different pass for commodity flow is observed.

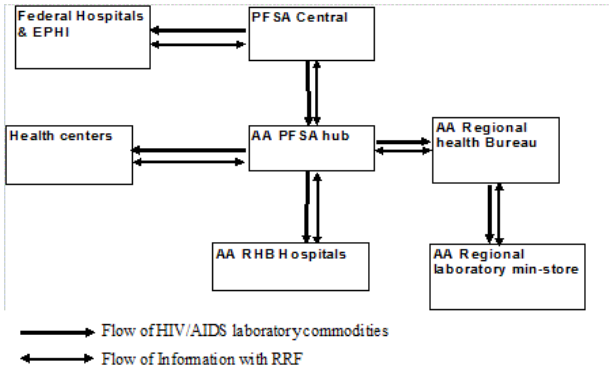

Figure 1: Flow of HIV/AIDS laboratory commodities and Information in IPLS, December to April 2014, Addis Ababa.

Figure 2 shows that PFSA central is responsible to deliver HIV test kits and TB laboratory diagnostic commodities up to AACA HB and federal hospitals based on centrally prepared allocations or distribution plans.

Then, AACA HB distributes to regional laboratory and regional hospitals. For TB diagnostic commodities, AA regional laboratory reconstitutes the reagents conducts distribution to health centers via sub city pharmacy units. In the case of HIV rapid test kits, the commodities are directly distributed from AACA HB to the regional hospitals and health centers via respective sub cities pharmacy units. Finally, distributions from facility stores to the laboratory section for routine consumption are made.

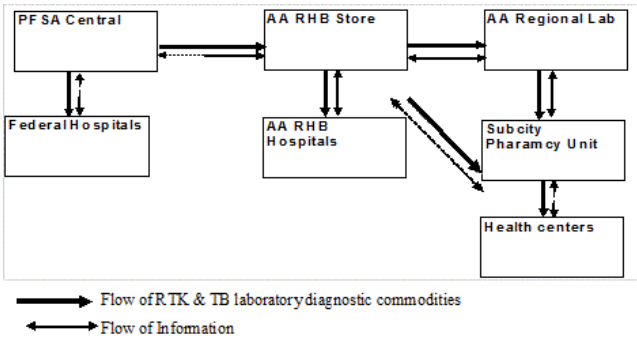

Figure 2: Flow of RTK and TB diagnostic commodities and information in IPLS, December to April 2014, Addis Ababa.

Training of professionals on IPLS and laboratory commodities management

As shown in Table 2 below, 24 (72.7%) and 17(51.5%) of the facilities had up to five IPLS and lab commodity management trained pharmacy staff respectively.

IPLS trained staff per health facility	Number of health facilities	Percent (%)
None	3	9.1
1-5	24	72.7
6-10	2	6.1
11 and above	4	12.1
Lab commodity management trained staff per health facility	Number of health facilities	Percent (%)
None	14	42.4
1-5	17	51.5
6-10	0	0
11 and above	2	6.1

Table 2: Health facilities with pharmacy staff trained on IPLS and lab commodity management Addis Ababa, 2014, (n = 33).

Assessment of stock situation at the health facilities

Assessment of stock situation for HIV/AIDS and TB laboratory commodities was made to review the level of product availability and stock out situation at these facilities.

Accordingly, a total of 24 (92.6%) facilities reported stock out for one or more of these reagents during the last six months.

Twenty two (84.6%) facilities reported that HIV/AIDS and TB laboratory commodities are not refilled as per their request (Table 3).

Variables	Availability	Number	%
Stock refill per requested quantities	Yes	4	15.4
	No	22	84.6
Stocked out during the last six months	Yes	24	96
	No	1	4
Over stocked after resupplied	Yes	14	56
	No	11	44

Table 3: Trend of HIV/AIDS and TB diagnostic reagents stock refill and availability at health facilities, Addis Ababa, 2014, (n = 26).

Stock out situation during the visit and/or during the last 6 months was also reviewed. As indicated in table 4, 10 (41.6%), 12 (54.5%) and 11 (46.7%) facilities were stock out for SGPT, EDTA test tube and 1% Carbol Fuchsin, respectively, on the day of the visit. Seven (43.8%), 9 (64.7%) and 9 (69.8%) facilities were stock out for SGOT, SGPT and Acid alcohol, respectively, during the last six months of the review period. Among the facilities performing CD4 and hematology tests, however, only 1 (33.3%) facility for CD4 reagent and another 1 (25%) for detergent were found to be stocked out. The average duration of stock outs (in days) in the last six months was found to be highest for EDTA test tube, DBS kit and SGPT reagents with 86, 70 and 64 days, respectively.

The lowest average stock out duration was observed for CD4 reagents and detergents, 21 and 12 days respectively. The mean stock out frequency within the last six months was 2.3 times for 1% Carbol Fuchsin and 1.5 times for detergent and EDTA tube (Table 4).

Tracer Commodities	Number of Facilities with bin card updated	Number of Facilities stock out on the day of visit (%)	Number of Facilities with stock out any time in the past 6 months (%)	Mean # of days (range) of stock outs in the past 6 months	Mean # of times stock outs in the past 6 months
KHB	5	7(29.2%)	6(33.3%)	64(8-180)	1
SGOT	6	9(37.5)	7(43.8%)	54(2-90)	1
SGPT	8	10(41.7%)	9(64.3)	64(30-90)	1
CD4 reagent	5	4(33.3%)	3(9.1%)	21(0-60)	1
CD4 control	2	1(11.1%)	1(33.3%)	40(0-80)	1
Detergent	3	4(40%)	1(25%)	12(0-33)	1.5
Diluent	0	3(30%)	0(0%)	30(0-60)	1.3
DBS kit	3	9(56.3%)	3(60%)	70(0-120)	1
EDTA test tube	6	12(54.5%)	6(60%)	86(1-180)	1.5
1% Carbol Fuchsin	9	11(47.8%)	5(38.5%)	36(0-120)	2.3
Acid Alcohol	11	9(69.2%)	9(69.2%)	46(0-180)	1.4

Table 4: Percentage of facilities stock out for selected laboratory commodities Dec 2013-May 2014, Addis Ababa (n = 26).

Availability and utilization recording and reporting formats for IPLS

Various records (such as bin card) and reports (RRF and IFRR) are used in IPLS for recording and reporting of various logistics data sets. Assessment of the availability and level of utilization of such formats by product and facility types was conducted. In addition, evaluation of the level of completeness and accuracy of such records and reports was also made.

Findings of the assessment suggest that bin cards, IFRRs and RRFs were available among 25 (96.2%) of the health facilities. Among these facilities, 16 (61.5%) health facilities update bin cards regularly, and 22 (84.6%) of them complete and send IFRR to their respective facility stores, while 24 (92.6%) of the facilities were completing and sending RRF to supplying PFSA every two months (Table 5).

Variables	Number	%
Bin card availability	25	96.2
IFRR availability	25	96.2
RRF availability	25	96.2
Bin card used and updated	16	61.5
IFRR competed and reported	22	84.6
RRF report sending to PFSA in every two months	24	92.3

Table 5: Availability and utilization of IPLS recording and reporting format for selected HIV and TB laboratory diagnostic commodities at facilities, responded yes, Addis Ababa, 2014, (n = 26).

Difference in the level of utilization of the records and reports was observed among the hospitals and health centers. Among the hospitals, utilization of bin cards, IFRRs and RRFs was found to be 33.3%, 76.5%, and 100%, respectively. In the health centers, however, utilization rate of 76.5%, 94.1% and 94.1% for bin cards, IFRRs and RRFs, respectively, was observed (Figure 3).

Better utilization of the records and reports in general and bin cards and IFRRs (internal records and reporting formats) was observed among the health centers compared to the hospitals.

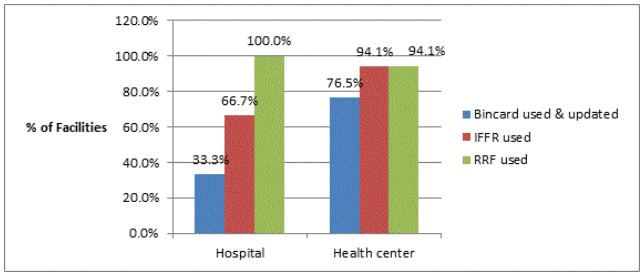

Figure 3: Utilization of bin card, IFRR and RRF by health facility type, December 2013 to April 2014, Addis Ababa (n = 26).

Utilization of bin cards for selected HIV and TB laboratory diagnostic commodities was also assessed and the main findings are presented in table 6. In general, the use of bin cards for these commodities. Out of the facilities assessed, bin card utilization for KHB and CD4 reagents was reported in 15 (57.7%) and 5 (35.7%), respectively.

Comparatively, bin card use for TB reagents (1% Carbol Fuchsin and Acid Alcohol) was reported among 13 (39.4%) health facilities, suggesting no pronounced gap by product type (Table 6).

Tracer reagents	Number of facilities using Bin cards (%)
KHB	15(57.7%)
CD4 reagent	5(35.7%)
CD4 control	4(28.6%)
FACS flow	3(23.1)
Detergent	4(33.3%)
Diluent	4(20%)
DBS Kit	4(12.1%)
BD Vacationer 4ml tube	8(32%)
1% Carbol Fuchsin	13(39.4%)
Acid Alcohol	13(39.4%)

Table 6: Utilization of bin card for tracer HIV and TB laboratory diagnostic commodities at selected facilities, 2014, (n = 26).

The records and reports used in the IPLS system should be complete and accurate enough so as to allow the generation of informed decisions by appropriate bodies. While the records (e.g., bin card) usually remain at the place where they were first generated, the IPLS reports move from one unit to the other in the same facility (e.g., IFRR) or from one facility to the other in the supply chain (e.g., RRF) for further actions.

The reports used in IPLS (IFRR and RRF) have multiple portions arranged as columns requiring various data sets (such as the beginning balance, quantity received, loss and adjustments, and ending balances) and involving additional computations (consumption, quantity needed to reach maximum stock level, etc). Review of the completeness of the report formats involving two review periods between (Dec 2013 to Mar 2014) show that 24 (92.6%) and 21 (87.5%) of facilities had completed data items on RRF and IFRR, respectively.

Accuracy of information reported on the report formats (RRF) was evaluated by comparing the reports generated between Dec 2013 to Mar 2014 with stock keeping (bin card) and transaction records (stock transfer vouchers and proof of deliveries (Model 19)). Accordingly, discrepancy in the calculated consumption compared to total quantity issued from the facility stores recorded on the bin card during the review period was observed in 17 (68%) facilities.

Similarly, discrepancy in the ending balance record between RRF data and bin card records was seen in 15(60%) of the health facilities. The quantity received portion of the RRF was also compared to records available in transaction documents issued from supply chain units issuing the commodities to facilities and records of quantity received available on proofs of delivery (Model 19) during the same time period. As such, discrepancy in quantity received was seen among 13 (52%) facilities.

Review of accuracy of four internal reports (IFRR) during the two supply periods/intervals assessed showed a discrepancy on the loss/adjustment section of the report among only 4 (16%) health facilities (Table 7).

Variables	Yes		No	
Accuracy/validity of RRF and IFRR	Number	%	Number	%
Verified calculated consumption indicated on the RRF (CC = beg. Bal*. +QR*-SOH*+/- Loss/Adj.*)	17	68.0	8	32.0
Verified maximum stock quantity indicated on the RRF(CC*x2)	19	76.0	6	24.0
Verified quantity ordered indicated on the RRF (Max stock quantity EB*.	16	64.0	9	36.0
Valid Beginning balance. of this reporting period RRF Vs ending balance of the previous RRF report	16	64.0	9	36.0
Valid quantity received of RRF Vs quantity received of STV* or model 19 valid	12	48.	13	52.0
EB* of RRF Vs EB of bin card valid	10	40.0	15	60.0
Loss/adjustment of RRF Vs loss/adjustment of bin card valid	13	52.0	12	48.0
CC* of RRF Vs Quantity issues of bin card valid	8	32.0	17	68.0

DOS* of RRF Vs DOS of bin card valid	8	32.0	17	68.0
IFRR of SOH of start of the period and SOH at the end of the period	20	80.0	5	20.0
Loss/adj. of IFRR Vs Loss/adj. of bin card	21	84.0	4	16.0
IFRR of CC verified by (Beg. Bal. +QR+-loss/adj. –SOH)	21	84.0	4	16.0
Completeness of RRF				
RRF includes beginning Balance	24	92.3	2	7.7
RRF includes Stock on Hand data	24	92.3	2	7.7
RRF includes quantity loss/adjustment data	24	92.3	2	7.7
RRF includes quantity received data	24	92.3	2	7.7
Completeness of IFRR				
IFRR includes beginning balance	21	87.5	3	12.5
IFRR includes stock on hand data	21	87.5	3	12.5
IFRR includes loss/adjustment data	21	87.5	3	12.5
IFRR includes quantity received data	21	87.5	3	12.5

Table 7: Accuracy and completeness of data on RRF and IFRR at health facilities Addis Ababa, 2014 (n = 26), * CC-calculated consumption, QR-Quantity Received, SOH – Stock On Hand, , EB- Ending Balance, DOS- Days Of Stock out, STV- Stock Transfer Voucher.

Assessment of storage condition for HIV/TB laboratory diagnostic commodities

The storage condition for pharmaceutical products should comply with the recommended Good Storage Practices so as to preserve the integrity of the products stored. Accordingly, the storage condition for the HIV/AIDS and TB laboratory diagnostic commodities was evaluated against predefined set of indicators and the major findings are presented in table 8. Majority of the health centers and hospitals reported use of standard guideline for storage of laboratory commodities. Among the hospitals, proper arrangement of the products, clear labeling of the manufacturing and expiry dates, as well as segregation of damaged and expired medicines was seen in 5 (83.3%) of them (Table 8).

Storage conditions	**Number (%) of facilities**		
	Hospital (n = 6) n (%)	Health Center (n = 17) n (%)	Total n (%)
Products arranged and labeled with expiry date and manufacturing date	5(83.3%)	15(88.3%)	20 (85.8%)
products stored in FEFO manner	4(66.6%)	15(88.3%)	19 (77.4%)
Damaged and expiry products are separate	5(83.3%)	16(93.7%)	21 (88.5)
Products are protected from direct sun light	5(83.3%)	16(93.7 %)	21 (88.5)
Cartons are protected from water and humidity	4(66.6%)	16(93.7%)	20(80.2)
Storage area is free from harmful insects and rodents	4(66.6%)	16(93.7%)	20(80.2)
products are stored at appropriate temperature	3(50%)	16(93.7%)	19(71.5)
Store room in a good conditions(clean, trash removed, shelf organized)	3(50%)	15(88.3%)	19(69.2)
Store room space sufficient for existing products	3(50%)	10(58.8%)	13(54.4)
Fire Safety equipment is available and accessible	3(50%)	12(70.8%)	15(60.4)
Products are stored separately from insecticides and chemicals	4(66.6%)	17(100)	21(83.3)

Table 8: Storage practices of hospitals and health centers for HIV/AIDS and TB diagnostic laboratory commodities, Addis Ababa, 2014 (n = 23).

Factors affecting the implementation and performance of IPLS

Management support, follow-up of IPLS tools implementation and enforcement were found to be associated with properly completed RRF ($X2 = 22.2$, $p = 0.00$), verified beginning balance ($X2 = 4.167$, $p = 0.041$) and verified lose/adjustment ($X2 = 6.83$, $p = 0.013$) of the RRF data. In addition, management support and enforcement was found to have association with of completed and submitted IFRR to facility store manager ($X2 = 5.71$, $p = 0.042$).

Qualitative analysis

Six key informant interviews were conducted with focal persons at PFSA Central, PFSA Addis Ababa Hub, AACA HB Pharmacy units, and 3 Addis Ababa sub-cities in pharmaceutical logistics and pharmacy service units that were not selected for the quantitative analysis.

Response from the key informants shows that the implementation of IPLS has integrated the fragmented distribution channels of the products and has eventually minimized the cost for transportation, level of expiry, recurrent over stock and stock outs. In addition, better availability of tools for recording and reporting logistics data was reported for the health facilities.

Successive intervention through training on IPLS, supportive supervision and on-the-job training has created an improved health facility capacity and ownership at operations and management level in the implementation of IPLS. The level of institutional ownership and supportive supervision however is weaker than what is ought to exist. The level of trained/skilled professional turnover is concerning. Even if improvement in the trend is emerging, the level of coordination among the different stakeholders involved in the system is not strong enough. Less developed accountability and system for monitoring and evaluation of performances and gaps in the system remains a concern. Weak level of motivation and commitment to properly and timely conduct operations in IPLS, combined to the existing level of understanding and commitment by the health facility managers towards enforcing the system is a staff that seems to require urgent interventions.

As some of the HIV/AIDs and TB laboratory diagnostics commodities require cold storage facility, the limited cold storage capacity especially at PFSA Addis Ababa hub could hamper performance with this regard and calls for the need to improve cold chain infrastructure.

Even if commendable commitment is manifested by PFSA Addis Ababa to improve the quality of the LMIS, through timely collection of reports and setting feedback system, many gaps on reporting system and the reports was indicated. Particular to this, failure of some high volume health facilities to make timely report of complete and accurate RRFs, weak stock keeping practices, and inflated refill requests made for laboratory reagents in the others would be problematic. Lack of standard inventory control practice for reagent has remained the source of recurrent stock outs even when such inflated health facility requests were filled by PFSA Addis Ababa hub.

Furthermore, erratic distribution practices for HIV ART lab reagents, multi-tier distribution system and long distribution channel for TB and RTK laboratory reagent, and the resulting frequent stock out remains the main cause of poor product availability.

Discussion

In this study, IPLS implementation for HIV/AIDS and TB diagnostic laboratory commodities were assessed using indicators that measures the availability and utilization of IPLS implementation tools. Availabilities of IPLS recording and reporting formats (bin cards, and IFRR and RRF) were reported in 92.6% of facilities. These findings are comparable with national IPLS survey conducted by PFSA in 2014, in which availability of commonly IPLS implementation tools were above 90% [7].

Our findings showed that 83% of hospitals and 88% health centers reported the availability of IPLS SOPs manual which is higher than study conducted in Lesotho [9] where only 17% had SOPs for managing medical supply. This may be because SOPs were provided during IPLS training to each trainee as a reference material for the health facility. The utilization of bin cards were 33.5% in hospital and 76.5% in health centers, which is lower than finding of a study conducted in Addis Ababa, where 50% hospitals and 54% of health centers [10] reported utilization of bin cards. The lower utilization of bin card in hospitals in this study may indicate poor implementation of IPLS. This might be due to large amount of line items/products integrated in one system through IPLS and managed in hospital pharmacy store, where updating of bin card becoming a tedious and time consuming exercise. On the other hand, higher utilization rate of bin cards at health center might be due to the implementation of quality management system that demands standard inventory control system and storage practices. These findings are consistent with a report from Kenya where more than 70 % of districts/health centers use bin/stock cards to manage health commodities [11].

This study showed that 24 (96%) of facilities reported one or more reagents stocked out during the last six months which is higher than findings of a study in Ghana laboratory logistic system [12] where about 60% of facilities experienced stock out of at least one laboratory commodity within six months prior to the study. This may be due to the increased scaling up of ART services at health facilities leading to demand and supply mismatch.

This study showed 10 (41.6%), 12 (54.5%) and 11(46.7%) of facilities were reported stock out of SGPT, BD vacationer tube and 1% Carbol Fuchsin respectively on the day of the visit. Similar finding was also reported from Malawi in 2009 [13] where 60%, 20% and 8% of the facilities were stock out of chemistry, hematology and HIV test reagents, respectively. This is serious issue because stock out of one or more HIV/AIDS and TB laboratory commodities could significantly affect the service provision of the ART and TB program.

Our assessment of IPLS showed 7 (43.8%), 9 (64.7%) and 9 (69.8%) of facilities reported stock out of SGOT, SGPT and Acid alcohol, respectively, during the last six months. There was different rate of stock out for different HIV/TB lab commodities as compared to a similar study conducted by Desalegn et al. [10] in Addis Ababa, where evaluation of vertical logistic system reveled 75%, 50% and 52% facilities stock out for similar laboratory commodities during the last six months. We might speculate that integrated system by itself couldn't avoid stock out. These were supported by Oslon et al. [14], who reported availability of commodities, may not be automatically improved as a result of the integrated system which is exponentially more complex than managing various supply chains vertically.

Our findings showed only 8 (32%) of facilities had valid and verified RRF, calculated consumption of RRF vs. quantity issued of bin cards and days of stocked out of RRF vs. days of stocked out of bin cards

which is lower than findings of the 2014 national IPLS survey in which 46% facilities had valid and verified RRF [15]. This difference might be because the inclusion of all types of pharmaceuticals in the national survey where the recording practice for the other categories of pharmaceuticals could be better and it can also be due to the large sample size used in the national survey. Alternative explanation for low proportion of valid RRF in the facilities might be the wrong assumption to be resupplied by reporting inflated consumption. Findings of the qualitative study point out that "Most facilities do not calculate their consumption accurately and tend to request huge amount of laboratory reagents above their requirements".

Accurate and complete stock data are critical for logistics system performance. The key informant responded that "high volume facilities are not sending RRF with complete, valid and accurate report and bin cards are not recorded and updated regularly and most of the facilities do not know their consumption and request huge amount of laboratory reagents". These may causes artificial stock out within the system where some facilities will be out of stock and others overstock.

Majority of the health centers meet the standard storage criteria, 100% products are stored separately from insecticides and chemicals and nearly 88.3% of health centers stores practiced FEFO principle. This finding is different from findings of studies done in Addis Ababa [10] and Lesotho [16] in which only 70% and 33% of the facilities failed to adhere to the standard guidelines for storage of laboratory commodities, respectively. The higher proportion of health center that adhered to standard storage guideline for storage of laboratory commodities might be ascribed to the current initiative by Addis Ababa RHB to improve the status of health center drug stores by renovating and constructing new stores that meet the requirement of storage guidelines.

This study was used a combination of both qualitative and quantitative methods that helps to supplement and triangulated the findings to each other. In addition to this most of the data collectors were logistic oriented and performed onsite observation of storage guideline, physical count of tracer items to rechecked with bin cards balance. However, sample size was not large enough to evaluate for most data quality indicators. Also quantitative assessment did not included PFSA central and AA PFSA hub.

Conclusion and Recommendations

Majority of the facilities reported the availability and utilization of IPLS implementation tools for managing HIV/AIDS and TB laboratory commodities, though 24 (96%) of facilities experienced stock out for one or more reagents used in HIV/AIDs and TB laboratory tests during the last six months, which partly is an indication of partial implementation of IPLS.

Based on findings from this study, the following recommendations are made. First, the distribution of all TB and HIV rapid test kits should be integrated with other pharmaceuticals, with improved recording system in place using such tools as bin cards for all facilities. Gaps observed on the quality and timeliness of LMIS reports requires attention. In addition, regular technical and supportive supervision, monitoring and evaluation mechanisms; and enhanced ownership of IPLS at health facilities is required for improved supply chain system for health commodities. RHBs and health facility management unit should collaborate towards enforcement of IPLS, especially at hospitals.

Limitation of the study

As supply chain performance for chemicals and reagents, and their availability is often overlooked, findings of this study are believed to shade light on existing situation and gaps for improving the system. Despite these facts, however, the following limitations should also be noted. First, the study only focused on HIV/AIDs and TB diagnostics commodities among public health facilities in Addis Ababa, capital city for Ethiopia. As such, it lacked diversity in product categories studied for comparison. It also, fails to look into potential regional variations of IPLS performance and product availability. The investigators thus call for assessment on larger number of health facilities and broader product categories (e.g. medicines, supplies, reagents, etc).

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Conflict of interest

The authors declare that they have no conflict of interest to disclose.

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