Assessment of Supply Chain Management of HIV/AIDS Related Commodities in Selected Public Hospitals and Health Centers in Addis Ababa, Ethiopia

---

BY

EyerusalemBerhanemeskel (B.Pharm)

Under the supervision of

Dr.Teferi Gedif

Thesis Submitted to the Department of Pharmaceutics and Social Pharmacy, School of Pharmacy in Partial Fulfillment of the Requirements for the **Degree of Master of Science** in **Pharmacoepidemology And Social Pharmacy.**

Addis Ababa University

Addis Ababa, Ethiopia

June 2014

ADDIS ABABA UNIVERSITY

SCHOOL OF GRADUATE STUDIES

This is to certify that the thesis prepared by EyerusalemBerhanemeskel, entitled: Assessment of Supply Chain Management of HIV/AIDS Related Commodities in Selected Public Hospitals and Health Centers in Addis Ababa, Ethiopiaand submitted in partial fulfillment of the requirements for the Degree of Master of Science inPharmacoepidemiology and Social Pharmacy complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Signed by the Examining Committee

Advisor:_____ Signature_____Date_____

Examiner:_____ Signature_____ Date_____

Examiner:_____ Signature_____ Date_____

_____

Chairman of Department

Abstract

A wide range of medicines and other pharmaceutical products are needed for diagnosis, treatment, care, and prevention of HIV/AIDS. However, interrupted supplies and stock outs are the major challenges in the supply chain of ARV drugs. Therefor the aim of this study was to assess the supply chain management of HIV/AIDS related commodities at hospital and HCs level in Addis Ababa, Ethiopia. A descriptive cross sectional survey complemented by qualitative approach was conducted in 24 government owned health facilities (4 hospitals and 20 health centers) that provide ART, VCT and PMTCT service in Addis Ababa. The sample of health facilities were calculated by using the Logistic Indicators Assessment Tool (LIAT) for ARV drugs and Test kits developed by USAID/DELIVER. The data was collected r using semi-structured questionnaires and observation check lists. The study revealed that 16(80%) of Health Center and 1(25%) of hospital pharmacies properly report and have the record of patients by regimen data. Almost all facilities had Electronic Dispensing Tool and used it for recording patient information on daily bases. Only, 14(70%) of the Health Centers used paper based ARV drugs dispensing register as a backup. Six months prior to the study, 14(70%) of Health Centers and 2(50%) of the hospitals stopped VCT service due to lack of adequate supply. The majority of the hospitals 3(75%) and 18(94.7%) of Health Centers were able to submit the requisition and report of ARV drugs to Pharmaceutical Fund and Supply Agency according to the schedule. More than three- fourth of the Health Centers had one or more emergency order of ARV drugs, while all of hospitals had emergency order more than 3 times within 6 months prior to the study. All of the hospitals and nearly half of the Health Centers had an emergency order of test kits more than 3 times in the past 6 months. The mean percentage difference between quantity ordered and received was high for 3TC300/TDF300 (69.6% in hospitals and 51.7% in HCs). Over all 14(73.7 %) of the Health Centers and 3(75%) of the hospitals faced stock out of one or more ARV drugs on the day of visit. Stock out was high for nvp200 in hospital 2(50%) and it was high for tdf300/3tc300 in HCs 7(36.8%). Regarding the stock status of test kits on the day of visit; only 7(36.8%) of the HCs were fully stocked, while the rest of them were stock out of one or more selected test kits. Whereas, all of the hospitals were stock out one or more test kits on the day of visit. Unlike ARV drugs, only 10(52.6%) of HCs and 2(50%) of hospitals had bin card for the selected test kits on the day of visit. All of the health facilities used both computerized

and paper based LMIS; they used computerized electronic dispensing tool at dispensary and Health Commodities Management Information System in the store. The study concludes that there was not adequate data on patient by regimen and stock status of ARV drugs and Test kits. There were frequent stock outs of ARV drugs and HIV test kits, which are an indicator of weak supply chain. The reporting and receiving system of ARV drugs were more organized compared to HIV test kits. It was also noted that in majority of the cases the professionals were unable to handle the computerized LMIS, as desired. It was recommended for the hospitals and health center handling HIV/AIDS related commodities to have adequate and reliable patient information and drug utilization data on hand and improve their storage conditions and prevent expiry and wastage of expensive ARV drugs and HIV test kits.

Key words: HIV/AIDS, ARV drugs, HIV test kits, supply chain Management, pharmaceutical storage

Acknowledgment

First of all I would like to thank Almighty God for everything I have and everything that happened in my life.

I am very much grateful to my advisor Dr. Teferi Gedif for his valuable advice and comments for developing the proposal and finalizing the thesis. I would like to express my heartfelt gratitude to Mr. G/Medhin B/Mariam for his cooperation and constructive comments in developing and finalizing this research paper. I am also pleased to thank School of Graduate Studies of Addis Ababa University for sponsoring this research. I want to express my deep felt gratitude and respect to my mother, who contribute a lot in my life as well in this research paper. Finally, I would like to acknowledge all who had been cooperative and helpful during my study time.

Table of content

List of figures

Page

List of tables

page

List of Abbreviations

AA: Addis Ababa

AACAHB: Addis Ababa City Administration Health Bureau

ADT: ARV Dispensing Tools

AIDS: Acquired Immune Deficiency Syndrome

ART: Antiretroviral Therapy

ARVs: Antiretroviral

CDR: Central Data Repository

CHAL: Christian Health Association of Lesotho

DACA: Drug Administration and Control Authority

DDI: Didanosine

D4T: Stavudine

DSM: Drug Supply Management

EFV: Efavernez

EDT: Electronic Dispensing Tools

FMOH: Federal Ministry of Health

FEFO: First Expired First Out

HACTS: HIV/AIDS Automated Commodities Tracking System

HAHPCO: HIV/AIDS Health Products Coordinating Office

HAPCO: HIV/AIDS Prevention and Control Office

HC: Health Center

HCMIS: Health commodities Management Information System

HIV: Human Immunodeficiency Virus

IFRR: Internal Facility Reporting and Requisition

INN: International Nonproprietary Name

LMIS: Logistic Management Information System

MOH: Ministry of Health

MOHS: Ministry of Health of Sera Leones

MSH: Management Sciences for Health

NDSO: National Drug Services Organization

NVP: Nevirapine

OIs: Opportunistic Infections

OPD: Out Patient Department

PEP: Post Exposure Prophylaxis

PFSA: Pharmaceutical Fund and Supply Agency

PHU: Primary Health Care Unit

PI: Principal Investigator

PIS: patient information sheet

PMTCT: Prevention of Mother to Child Transmission

PSM: Pharmaceutical supply management

RHB: Regional health Bureau

RPM plus: Rational pharmaceutical Management plus

RRF: Report and Requisition Format

RTK: Rapid Test Kit

SCMS: Supply Chain Management System

SPS: Strengthening Pharmaceutical System

SOH: Stock on Hand

STGs: Standard Treatment Guideline

STIs: Sexually transmitted infections

TDF: Tenofovir

3TC: Lamivudine

USG: United States Government

VCT: Voluntary Counseling and Testing

WHM: Warehouse Manager

WHO: World Health Organization

USD: United States Dollar

USG: United States Government

ZDV: Zidovudine

1. Introduction

The human immune virus (HIV) epidemic remains a major global public health challenge, with more than 34 million people living with HIV worldwide. In 2011 alone, 2.2 million people were newly infected with HIV and 1.7 million people died of acquired immune deficiency syndrome (AIDS) (WHO, 2011). In the early 1980s when the AIDS epidemic began, people living with HIV were not likely to live more than a few years. However, with the development of safe and effective drugs, HIV positive people now have longer and healthier lives (WHO, 2009)

A wide range of pharmaceutical products are needed for diagnosis, treatment, care, and prevention of HIV/AIDS. These include, medicines to treat HIV infections, antiretroviral (ARV); medicines to prevent and treat opportunistic infections (OIs); medicines for palliative and supportive care; medicines to prevent and treat sexually transmitted infections (STIs); medicines to treat HIV-related cancers; diagnostic test kits for HIV, and OIs and laboratory reagents, supplies, and equipment (Helena and Douglas, 2009).

At the beginning of the 21st century, very few people in the developing world had access to HIV treatment. This was in large part because of the very high prices of ARV drugs and the international patents that stopped them from being manufactured at cheaper prices. In 2001 drug manufacturers in developing countries began to produce generic drugs under special terms in international trade law. The vast reduction in price made possible by the manufacturing of generic drugs meant for expansion of treatment on a global scale (AVERT, 2012). Now, through the concerted efforts of governments, the World Health Organization (WHO), and other international agencies, more than a third of the people in low- and middle-income countries who need antiretroviral therapy (ART) and treatment of opportunistic infection are receiving it. However, many without access are still in need of ART (Walensky *et al*., 2010)

Drug management cycle comprises four basic components: selection, procurement, distribution and use. At the center of the pharmaceutical management cycle is the core of related management support systems including the planning and organization of services, financing and financial management, information management and human resource management. These

management support systems hold the management cycle together. The entire cycle rests on a policy and legal framework that establishes and supports the public commitment to supply essential medicines (MSH 2000).

Supply chain management of essential health commodities, including high-value medicines like ARV drugs, involves a series of activities to guarantee the continuous flow of products from the point of manufacture to the point where they are used by consumers (Yasmin *et al*., 2006). The nature of ART and the specific characteristics of ARV drugs and how they are used pose particular challenges for managing the supply chain for ARV drugs (Allers et al., 2006).

This study was conducted to assess the supply chain of ARV drugs and HIV test kits in governmental hospitals and Health Centers in Addis Ababa and to identify the possible gaps that exist in the supply chain of these commodities. This study would help decision makers and other stakeholders to have an insight about the supply chain of HIV/AIDS related commodities in governmental hospitals and health centers in other parts of the country. The result of the study is believed to have significance in reduction of resource wastage and emergency of drug resistance.

2. Statement of the problem

As the HIV epidemic matures, there was an increase in number of people reaching advanced stages of HIV infection. ARV drugs and other pharmaceutical used in diagnosis, treatment, prevention and care of HIV/AIDS have been shown to reduce mortality among those infected patients (WHO, 2012). Initially, resource-limited countries could not afford to provide ART for their populations, and the life expectancy of HIV-positive people remained low (Walensky et al., 2010). However, efforts have been made to make it more affordable within low- and middle-income countries (WHO, 2012).

Effective drug supply management and inventory control avoid stock out, loss due to unnecessary expiry, theft and ensure that the desired pharmaceutical products are available at all times in adequate quantity (RPM Plus, 2006). But in many low and middle income countries, the capacity of the pharmaceutical supply management (PSM) system has always been challenging and weak. The ARV supply chain management has become increasingly difficult due to increasing number of people on ART, increasing number of sites providing ART and a greater diversity of different ARV regimen (Erik et al., 2011).

Moreover, there are certain common challenges associated with the quantification of ARV drugs and supplies mainly in low and middle income countries. Data on ART services and ARV drug supply are limited and when available, are often unreliable or insufficient to be used for quantifying ARV drug requirements (Allers et al., 2006). An accurate quantification is essential for all health commodities but of very importance for HIV/AIDS related commodities because uninterrupted access for patients must be ensured (Erik et al., 2011). Interruption of supplies and stock outs ARV drugs put individual patient at risk of disease progression and death, in drug resistance development, hampers progress towards universal access, and diminishes the credibility of ART programmes in the eyes of patients, community and healthcare providers and generally put the public health in danger (Pasquet et al., 2010).

One of the major reasons that medicines are wasted is that they may have expired without anyone noticing that the shelf life date was approaching. Failure to notice approaching expiry

does might lead to the loss of a significant amount of resources, especially in resources limited countries. This type of lose is not acceptable to pharmaceuticals such as ARV drugs, which are very expensive (RPM Plus, 2006). Besides, due to poor handling of the available drugs and other pharmaceutical products by the patients and professionals, there is also a great loss of resources.

In addition to this, the 2010 WHO guideline and the new 2010 Ethiopian standard treatment guideline (STG) recommend that ART should be initiated when the CD4 count falls below 350/µl for WHO stage 3 disease and should be initiated irrespective of CD4 count for stage 4 disease. If CD4 count is not available it should be initiated irrespective of total lymphocyte count (Walensky et al., 2010; DACA, 2010). So it may lead to a drastic increase of the number of patients who are eligible for ART. Thus it forces to increase ARVs and other HIV commodities, creating an enormous burden to national health care system and health facilities (Elke et al., 2012; USAID/ The Global Health Technical Assistant Project, 2009).

3. Literature review

ART programs in developing countries follow a public-health approach rather than an individualized approach, which is characterized by a limited number of regimens and the standardization of clinical and laboratory monitoring. In resource rich countries, clinician provide individually tailored care for HIV infected people by prescribing combination of ARV drugs chosen from more than 20 approved medicines. It also includes frequent monitoring of viral load, viral resistance testing and regular CD4 cell count. (Keiser *et al.,* 2008 and Walensky *et al.,* 2010). Developing countries followed mainly the recommendations in the 2006 WHO ART guidelines. These guidelines were revised in 2010. The guidelines outlined: earlier ART initiation when the CD4 count falls below 350/µl, instead of below 200/µl of blood as in the 2006 guidelines; the provision of sequential ART regimens instead of a single regimen (switch first line drugs to second line when the viral load is greater than 5000 copies/ml instead of the previous 10,000 copies/ml); and the replacement of the antiretroviral drug stavudine (d4T) with tenofovir (TDF), a less toxic but more expensive drug, in first-line ART regimens. However, many resource-limited countries are still struggling to implement the 2006 guidelines (Walensky *et al.,* 2010).

Supply chain management of essential health commodities, including high-value medicines like ARV drugs, involves a series of activities to guarantee the continuous flow of products from the point of manufacture to the point where they are used by consumers (Yasmin *et al*., 2006). Ensuring there are no interruptions in treatment requires a guaranteed supply of ARV drugs from the factories where they are produced, to the treatment centers in perhaps remote areas of a country. Laboratory supplies, testing kits and information also need to pass along the supply chain (AVERT, 2012).

The nature of ART and the specific characteristics of ARV drugs and how they are used pose particular challenges for managing the supply chain for ARV drugs (Allers *et al*., 2006). They have short shelf lives that can range from 12 to 36 months. Some drugs required cool storage condition. STGs sometimes require three to four different drugs from multiple sources to be available simultaneously to provide and dispense a complete regimen (John Snow,

Inc./DELIVER, 2005; USAID | DELIVER Project, task order 1, 2009). They have high price and limited possibility of substitution in the case of stock outs. Because of these special characteristics, HIV tests and ARV drugs are often managed through vertical or separate supply chains. Solutions appropriate for other commodity groups, such as contraceptives or TB drugs, may not apply for HIV tests and ARV drugs because holding large quantities of stock in inventory at the various levels requires significantly more money and increased storage space and increases the risk of pilferage, damage, and expiration (John Snow, Inc./DELIVER, 2005).

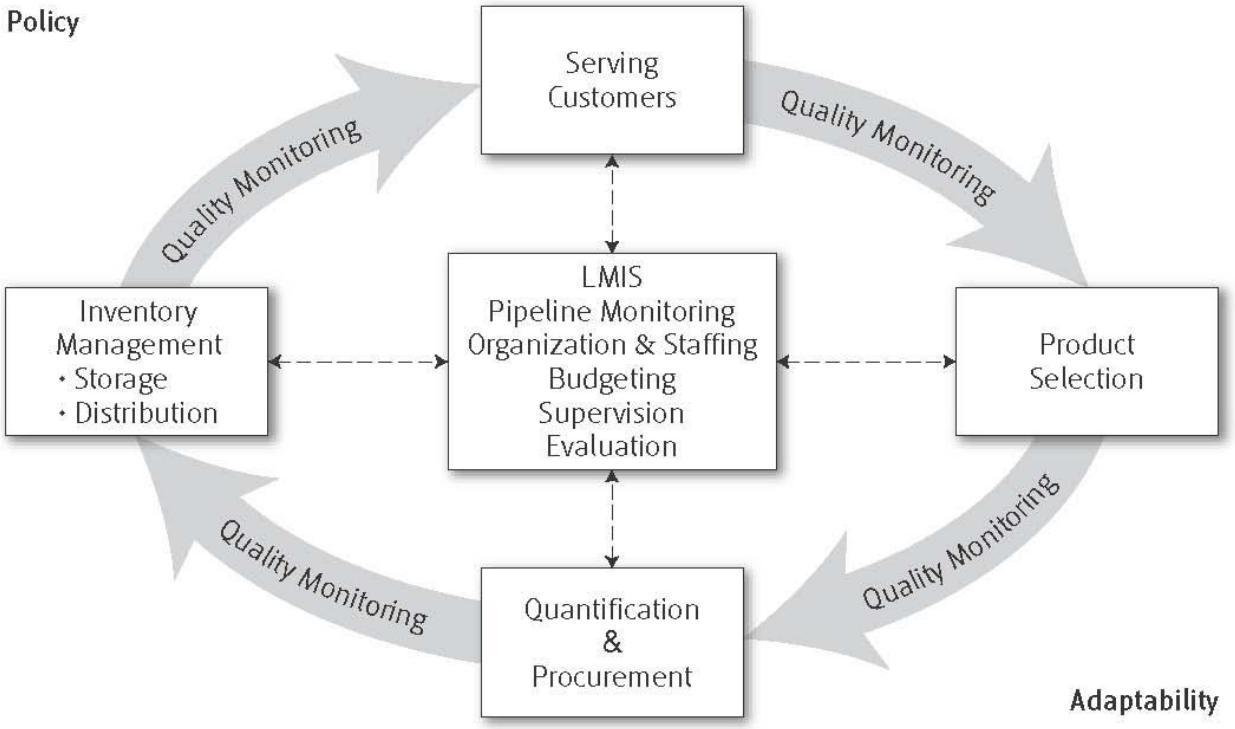


Figure 1: Pharmaceutical supply management framework (John Snow, Inc. and DELIVER, 2004)

In many low and middle income countries, the capacity of the pharmaceutical supply management (PSM) system has always been challenging and weak. The management of supplies used for chronic diseases such as HIV/AIDS becoming more increasingly difficult than other pharmaceuticals. The ARV supply chain management has become increasingly difficult due to

increasing number of people on ART, increasing number of sites providing ART and a greater diversity of different ARV regimen (Erik *et al*., 2011).

3.1. Selection and Quantification

Selection in the drug and health commodity management cycle involves: reviewing prevalent health problems and priorities; identifying interventions and treatments of choice; selecting needed drugs and dosages; selecting required health commodities, including laboratory tests and procedures; and making decisions about which drugs and health commodities will be available at what service levels. Program managers will have to prioritize choices during the selection process, particularly if resources are limited (Family Health International, 2008).

An accurate quantification is essential for all health commodities but of very importance for HIV/AIDS related commodities because quantification of drug and health commodity requirements for HIV/AIDS programs is complex and uninterrupted access for patients must be ensured (Family Health International, 2008). There are certain common challenges associated with the quantification of ARV drugs and supplies mainly in low and middle income countries. Data on ART services and ARV drug supply are limited and, when available, are often unreliable or insufficient to be used for quantifying ARV drug requirements. Multiple sources of funding, procurement mechanisms, and distribution channels used for ARV drugs are also posing a problem on quantification of ARVs and other commodities. Communication and coordination are lacking among key stakeholders and implementers (i.e., policymakers, program managers, service providers, funding sources, procurement agents, and suppliers) on issues related to the selection, quantification, and procurement of ARV drug (Allers *et al*., 2006).

An assessment of the HIV/AIDS related commodities supply chain in Lesotho showed that ARVs were quantified by HIV/AIDS prevention and control office (HAPCO) at the central level for all health care facilities receiving ARVs. There was generally poor reporting by health facilities, leading to incorrect quantities being distributed. A morbidity-based method of quantification was used for ARVs. The quantities for other medicines used for opportunistic infections were determined by the Disease Control Program which used a different consumption-based quantification method for that purpose (Pharasi, 2007).

A study done by Erik *et al*, in Malawi in 2011 showed that, they were using ceiling system to ensure forecasting for new patients. ART site were given ceiling of maximum number of patients they were allowed to start each month on treatment. Monitoring of patient outcome and ARV drug stocks were done quarterly which was also used to give rationale information for forecasting of drugs for patients who are already on ART. The ceiling system prevents stock outs in the first years of the program. However, as the number of people on ART increases the bulk of ARV consumption shifted to patients already on treatment rather than newly starting. Forecasting was then became difficult due to people shifting to alternative first line ART regimens and second line ART. This is difficult to predict. This led to oversupply of second line ARVs and contributed to shortages and stock outs of alternative first line ARVs (Erik *et al*, 2011).

A national assessment done in Sierra Leone on ARV drugs and test kits indicate that the quantification of ARV drugs involved few people; it didn't show the data source for quantification clearly. The expected percentage of patients to be on first and second line regimens was not quantified and also the percentage didn't add up to 100%. The quantification methodology of HIV test kits to be procured was not documented. The forecasting methodology of ARV drugs in Sierra Leone included assumption about the number of patients expected to continue treatment during the forecast period, the expected rate of drug substitutions within the regimen and switches first to second line regimens, and the number of new patients expected to initiate treatment during the forecast period according to scale up plans and service delivery capacity. There was no established forecasting methodology for HIV test kits except for PMTCT service. There was an established procedure for submission of monthly summary reports on ART, VCT, PMTCT, HIV Diagnostic Testing and Blood Safety, but logistics data was not reported and was not used in calculating the order quantities. A standardized procedure for correctly calculating order quantities based on logistics data from facilities did not exist. Re-supply of ARV drugs and HIV test kits to facilities was dependent on submission of a monthly summary report from each facility (Allers *et al*., 2007).

3.2. Inventory Management

One of the major reasons that medicines are wasted is that they may have expired without anyone noticing that the shelf life date was approaching. Failure to notice approaching expiry does might lead to the loss of a significant amount of resources, especially in resources limited countries. This type of loss is not acceptable to pharmaceuticals such as ARV drugs, which are very expensive. Expiry dates can be monitored by using different technique so that appropriate action can be taken on short dated product before they become unusable (RPM Plus, 2006).

An assessment done in Sierra Leone in 2007 showed that there was lack of a standardized inventory control system with procedures for monitoring and managing stock levels of ARV drugs and HIV test kits at all levels of the logistics system. Appropriate stock levels for ARV drugs and HIV test kits have not been established for the central warehouse in Laka, for hospitals, for district hospitals and primary health care units (PHUs). Stock outs of efavirenz(EFV), single stavudine(d4T) 30mg and second line drugs were noted and there were quantities of expired ARV drugs and HIV test kits (Allers *et al*., 2007).

A study done in Lesotho reveal that there were challenges in the drug supply system, which were mainly due to the lack of supervisory site visits, led to facilities over-stocking or under-stocking on certain items. Moreover, ARVs were expired on the shelves in some facilities where inventory was poorly managed (Pharasi, 2007).

A study done in Uganda showed that, ARV shortages affected all ART-providing facilities with considerable fluctuations regarding capacities to take up new patients. ARVs were available at 83%, diagnostic kits at 70% and paediatric ARVs at less than half of the health facilities surveyed. Patients were forced to switch to more complex and different drug regimens. Strategies to cope with stock-outs included lending and borrowing among facilities, late initiation of ART for new patients and treatment interruption. Health workers reported insufficient knowledge regarding safe drug substitution and a general lack of guidance to deal with shortages of ARVs. It also revealed that provision of ARVs suffers from both over and undersupply. According to findings from 2007 only a quarter of facilities receive ARVs on a monthly basis. In 2008 the estimated expired value was in the range of USD 1.3 - 2 million.

More than half (58%) of government facilities reported holding expired ARVs, compared to 29% of NGO facilities. According to a health facility survey in 2005 fewer than 25% of facilities were maintaining adequate stock levels on nevirapine (NVP), HIV test kits, and antibiotics. Health facilities on average reported 1 month of stock-outs of testing kits per year in 2005 (Ricarda *et al*., 2011).

The storage condition observed in district and PHUs of Sierra Leone was not generally in a good condition. The stock keeping practice in selected Sierra Leones' health facility was reported as not good. The Expired drugs and kits were stored together with the usable commodities which bring a shortage of space in the health facilities. While they used to meet the storage need by storing and issuing of ARV drugs integrated within existing hospital pharmacy stores or laboratory stores, or separate storerooms specifically assigned for storage of HIV/AIDS commodities, or in counseling room. No stock cards were available for ARV drugs or HIV test kits at any of the PHUs visited (Allers et al., 2007).

3.3. Drug use

Drug use is a complex subject involving the physician, the patient, and pharmaceutical institutions. Each of these is influenced by many factors that are often difficult to measure and quantify (Otoom S *et al*., 2002). Rational use of drug can be defined as patients receiving medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Irrational or non-rational use is the use of medicines in a way that is not compliant with rational use of drug (WHO, 2002).

A study done by Erik et al. showed that 91% of the patients were on standard first line regimen in Malawi by the end of 2010, which indicate good drug use pattern in country. (Erik et al., 2011).

3.4. Logistic Management Information System (LMIS)

A LMIS collects, processes, and reports supply chain data to the concerned body. The LMIS can be manual (paper-based), or partly or wholly computerized. For any supply chain system, the three essential LMIS data items are quantity of stock on hand, quantity of stock consumed and losses and adjustments (John Snow, Inc./DELIVER, 2005). Currently most LMIS are computer based since HIV/AIDS programs are complex and manage a broad range of commodities so paper-based systems for collecting, aggregating and analyzing data are burdensome (USAID/DELIVER PROJECT, 2008). But all the United States Government (USG) partners like DELIVER, SCMS, MSH and PEPFAR agree that 70% of the data collection should be done paper based even at location that had been using computerized ADT sometime (USAID/ The Global Health Technical Assistant Project, 2009).

The national ART programs in both Uganda and Ghana had chosen to implement vertical LMIS for ARV drugs. The LMIS have only one additional data item besides the three essential logistics data elements—quantities of drugs to order for estimated new ART patients (John Snow, Inc./DELIVER, 2005).

A study done by Wendy *et al*. on Computerizing LMIS for managing HIV/AIDS commodities identifies five factors as key to successful implementation of the computerized LMIS programs. These are ; Creation of a clear vision; Management of expectations of all users; Use of proper planning and implementation steps for software development; Committed and skilled staff designing, managing, programming and using the program and Ownership of the system by the users. While computerized LMIS can greatly facilitate the work of supply chain managers, the implementation of software packages can be costly and time-consuming, requiring planning and good management to achieve optimal outcomes. There was a need for user-friendly tools and software packages to support the management of logistics information that is critical in making decisions regarding forecasting for program needs and for managing supply chains to ensure successful HIV programs (Wendy *et al*., 2008).

3.5. Supply Chain Management of HIV/AIDS Related Commodities in Ethiopia

It has been almost a decade since ART and VCT services started in Ethiopia. VCT and ART services were first initiated at Zewditu memorial hospital in 2002 and 2003 respectively. ART service was then started at St. Peter (2004) and ALERT (2005) hospitals. Since then all governmental hospitals and HCs, some private hospitals and some NGO owned facilities started to provide VCT and ART and PMTCT service jointly or separately.

Ethiopia is among the countries most heavily affected by the HIV epidemic. The Government of Ethiopia adopted an HIV/AIDS National Policy in 1998 and established a multi-sectoral program coordinated by National and Regional HIV/AIDS Council Secretariats. In 2003, the ministry of health (MOH), drug administration and control authority (DACA) the current food medicine and health care administration and control office (FMHACA) and HIV/AIDS Prevention and Control Office (HAPCO) developed the National Guidelines on ARV and began providing ART training to teams of healthcare providers. (MOH, 2005). HIV/AIDS related commodities supply chain management in Ethiopia is vertical approach, dominated by partners with little government ownership. In most of the cases centralized procurement, distribution and LMIS activities had been managed by huge involvement of partners than the government (Alemayehu, 2009).

The number of people receiving ART continues to increase worldwide, with 6.65 million people getting treatment at the end of 2010 which is an increase of 27% from December 2009. In total 1,675,000 people initiated treatment in 2010. In sub-Saharan Africa treatment coverage increased from 41% to 49%, between 2009 and 2010 (PEPFAR, 2012). In Ethiopia, there were 222, 723 people receiving ART in 2010 and there was a 26% increment between 2009 and 2010. In 2011 there were 237,400 individuals receiving ART with a total budget of $293 million dollars in Ethiopia (PEPFAR, 2012; WHO, 2012).

On average the costs of ARV drugs account $202 per year per person in Ethiopia (Ali S.A., et al., 2011). There is also an additional cost associated with treatment of HIV/AIDS due to costs associated with diagnosis, prevention and treatment of OIs, STIs and other complications. The launching of the free ARV treatment initiative was characterized with a large infusion of commodities which require high logistic capacity (Alemayehu, 2009).

The unmet need for ART in Ethiopia is caused not by a shortage of drugs, but by health system constraints. Many health centers do not have the equipment for conducting CD4 cell counts and yet lack a vehicle for transporting samples quickly and safely to the nearest hospital having the required machine. Furthermore, hospitals are putting caps on the number of HC samples processed. The health system also lacks mechanisms for tracking pre-ART patients. Because of all these constraints, in Ethiopia some HIV-positive patients are started on ART on the basis of clinical staging without performing a CD4+ count, as a result of which some patients begin treatment when the count is already ≤ 200 cells/mm^3 (Elke *et al*., 2012)**.**

An evaluation done in Ethiopia showed that, at ART sites, inventory control systems were improved after implementation of newly designed ARV Logistic Management Information System (LMIS) by Supply Chain Management System (SCMS). Each ART store kept stock for maximum four months. The pharmacies/stores were expected to have a minimum of two week's stock. This evaluation states that inventory control in all surveyed ART sites was adequate. Stock outs had been non-existent or minimal for ARVs. Use of bin and stock cards was adequate. There were large quantities of combvir (ZDV300/3TC150) and Didanosine (ddi) 250 mg which expire shortly. There were also some expired second line drugs. Expired ARV drugs were kept together with active drugs at one study site. There were inadequate storage facilities, management, capacity, and temperature monitoring, especially for the cold chain in the selected health facilities. It also showed that the ART pharmacy stores were managed by using stock cards, generally manual, but it was computerized in some places. (USAID/ The Global Health Technical Assistant Project, 2009).

A study done in Oromia national regional state of Ethiopia showed that availability of first line ARV drugs were 100% and 95% at HCs and Hospitals respectively. Inventory control tools and Standard Operating Procedures and guidelines were barely used in both levels. Availability of expired OI drugs in store was 12% and 11% in health centers and hospitals respectively on the day of the visit (Alemayehu, 2009).

Regarding drug use an evaluation done in Ethiopia identified that, in the hospitals visited not only pre-ART, ART and PMTCT services were provided but they also served other ART and PMTCT sites. The study states that the services provided by the selected hospitals were

commendable. Patients on ART were resupplied with ARVs on a monthly, bimonthly, or quarterly basis, depending on their individual condition. There were great professionalism in the selected health centers and good quality of service. All the patients at the health center were kept on first-line, and second-line patients were referred to hospitals. One clinic managed dispensing of ARVs using the ARV dispensing Register prepared by RPM Plus/SPS even though they lack computerized automated dispensing tools (ADT) (USAID/ The Global Health Technical Assistant Project, 2009).

4. Objectives of the study

4.1. General objective

- To assess the supply chain management of HIV/AIDS related commodities in public hospital and Health Centers in Addis Ababa.

4.2. Specific objectives

- To assess quantification, ordering and receiving of HIV/AIDS related commodities in selected public hospitals and health centers in Addis Ababa.
- To assess inventory management procedures, storage conditions and distribution of HIV/AIDS related commodities within the hospital and Health Cs in Addis Ababa.
- To assess the utilization of HIV/AIDS related commodities in selected public hospitals and health centers in Addis Ababa.

5. Materials and Methods

5.1. Study area

Addis Ababa is the capital city of Ethiopia. Administratively Addis Ababa is divided into 10 sub cities and 116 woredas. It has a population of 3,146,999 (City government of Addis Ababa, 2012). In 2013, there were 11 governmental hospitals and 54 health centers (HCs) in Addis Ababa. There were a total of 74 ART sites, more than 202 VCT sites and 104 PMTCT sites in Addis Ababa. All the 11 governmental hospitals, 37 health centers, eight health facilities owned by non-governmental organizations and 18 private hospitals were reported providing ART and VCT services in Addis Ababa. Reports showed that as of June 2013, more than 125,994 patients had been enrolled in HIV/AIDS care, 74,986 patients had ever started ART and 53,677 patients were currently on ART (Addis Ababa City Administration Health Bureau, 2013). HIV/AIDS related care in Ethiopia was mainly dominated by partners with some involvement of national government and other stakeholders. The major donors and sources of HIV/AIDS funding in the country, among others, include the Global Fund, the US Presidential Emergency Program for AIDS Relief (PEPFAR) and the UN system (HIV/AIDS Prevention and Control Office, 2012). Pharmaceutical fund and supply agency (PFSA) is a governmental pharmaceutical importer and distributor which is mainly involved in the supply of ARV drugs and test kits to the health facilities. PFSA had 11 hubs in the country and 7 additional hubs are reported under construction in different parts of the country (Pharmaceutical fund Supply Agency, 2012). The Addis Ababa City Administration Health Bureaus (AACAHB) is responsible for distribution of test kits to regional hospitals and health centers.

5.2. Study design

The study employed a cross sectional survey design and used both quantitative and qualitative data collection techniques to gather the required information.

5.3. Study participants

5.3.1. Source and study population

All public health facilities providing VCT, PMTCT and ART in Addis Ababa were the source facilities. All health care professionals and all documents that were used to manage the supply chain of ARV drugs in Addis Ababa were also sources of information. . All staffs working in the ART clinics, pharmacy and laboratory units of the nine selected public hospitals and 26 health centers which were operational before 2010/2011 and owned by the Addis Ababa City Administration Health Bureau and those under the Federal Ministry of Health were the study population. From the federal ministry of health hospitals, Amanuel Hospital was not included in the study population even though the hospital provides HIV/AIDS service. Since this hospital was specialized in psychiatric case and most of the ART patients were also psychiatric patients; so the supply chain of the HIV/AIDS related commodities in this hospital might be different from other general hospitals.

5.3.2. Sampling technique and sample size calculation.

Health facility selection

The sample of health facilities were calculated by using the Logistic Indicators Assessment Tool (LIAT) for ARV drugs and Test kits of USAID/DELIVER. This document suggested that it would be enough to take 15% of the targeted health facilities as sample for the study (USAID/DELIVER PROJECT, task 1, 2009). The selection of sample hospitals from all available hospitals in Addis Ababa considered ownership of the hospital and patient burden. Accordingly, the available public hospitals in Addis Ababa were grouped into two major categories i.e. those administered by the AACAHB and those under the Federal Ministry of Health (FMOH) The initial selection of the hospitals was followed by (extreme/deviant sampling) and accordingly four governmental hospitals, two from FMOH and two from AACAHB, and a total of 20 Health Centers, (two Health Centers from each of the ten sub cities were selected based on extreme/deviant sampling technique (one with high patient burden and the other with lowest patient burden) (For the details of the sampling of the health facilities see Annex VII).

Selection of health professionals

Heads of pharmacies, ART store managers/general store managers, ART dispensers, Laboratory heads, VCT staff and ART coordinator from the selected hospitals and health centers were the key respondents for the study.

Document review

ARV drugs and patient information sheets (PIS), ARV drugs dispensing register, patient tracking charts, drug and supply expiry date tracking charts, ARV drugs dispensing register for post exposure prophylaxis (PEP), ARV drugs dispensing register for emergency supply, VCT daily register and temperature recording charts, bin card and drug reporting and requisition format (RRF), Model 19 (receiving voucher), were the major documents checked and reviewed.

5.4. Data collection and management

5.4.1. Survey team and data collection period

The principal investigator (PI) collected the majority of the information used as input for the study. A research assistant (senior undergraduate pharmacy student) assisted the PI with collecting information from the hospital and health center pharmacy stores. The research assistant had half day training on the survey tool before being involved in the data collection. The data was collected on November 2013.

5.4.3. Data collection instruments

The LIAT for ARV drugs and test kits were used as a data collection tool (USAID/DELIVER PROJECT, 2009). A combination of semi-structured questionnaire and observation check list were used to collect data on the supply management of HIV/AIDS related commodities (Annex III and IV).

The semi-structured questionnaires in combination with observation check lists were used to collect data on quantification, receiving and distribution, use and inventory control procedures of HIV/AIDS related commodities from the different respondents including the head of the

pharmacy, ART dispenser, ART store manager/general store manager and laboratory head, VCT personnel and ART coordinator.

A total of 14 ARV drugs and five HIV test kits were selected for this assessment. A six month data (May 2013 to October 2013) were taken from bin card and VCT daily register to see the pattern of stock status and VCT service in hospitals and health centers.

5.5. Data quality assurance

The data collection tool was pretested prior to the data collection. The PI discussed with the research assistant on regular basis and reviewed the collected data for completeness. The collected data was summarized on the same day of the data collection.

5.6. Data entry and analysis

The collected data was manually checked for completeness and consistencies before being entered into the computer. The quantitative data was entered and analyzed by using excel 2007 and SPSS version 20. The qualitative data was analyzed thematically.

5.7. Ethical Consideration

Ethical approval was obtained from the Ethics Review Board of the School of Pharmacy, Addis Ababa University and AACAHB, Alert Hospital and St. Peter hospitals (Annex ix).

Verbal consent from all respondents was obtained before enrolling them as the respondents of the study. During the consent process, the respondents were provided with information regarding the purpose of the study, why and how they were selected as the respondents of the study, and what was expected of them. They were also informed that as they could withdraw from the study at any time during the interview process. Participants were also assured about confidentiality of the information that was obtained in the course of the study. To assure the anonymity of the respondents' personal identifiers were not used during the data collection.

5.8. Operational definitions

HIV/AIDS related commodities: refers to ARV drugs and HIV rapid Test kits.

Stock out: a commodity was considered as a stock out when the product was stocked out from the store on the day of visit and when the balance was zero on bin card (RPM Plus, 2006).

Discrepancy between quantities ordered and received: when the ordered quantity and received quantity have variation even by one pack.

Supply chain management: Management of material and information flow in a supply chain to provide the highest degree of customer satisfaction at the lowest possible cost (Business dictiionary.com 2012).

6. Result

A total of 24 health facilities were visited during this assessment; of which 4 were hospitals and 20 were HCs located in Addis Ababa. The selected HCs had an experience on VCT service provision for (9.1±1.4, (6, 11)) years and ART service provision for (6.9±0.8, (5, 8)) years, while hospital had an experience on VCT for (10.3±1.5, (9, 12)) years and ART service for (9±1.6, (7, 11)) years.

Since the beginning of the program in Ethiopia, both ART and VCT services were provided for free in all governmental health facilities. The HIV/AIDS service was integrated with other service in the health facilities. All health professionals involved in provision of HIV/AIDS care were employed by FMOH or AACAHB; while data clerks found both in ART clinic and pharmacy were employed by partners. Both HCs and hospitals had separate reporting and requisition formats for HIV/AIDS related commodities from other pharmaceuticals. Similarly, HCs and hospitals ordered, received, distributed and used the HIV/AIDS commodities separately from other commodities at the health facilities. But there was no a separate store for HIV/AIDS commodities in all of the facilities.

6.1. HIV/AIDS related services

All the selected facilities were providing VCT, PMTCT and ART services. In majority of the cases, HIV testing was done for VCT, PMTCT and clinical diagnosis. All of the selected facilities had a copy of HIV testing guideline in counseling room. Including the VCT and PMTCT staffs, all clinical workers working in ANC clinic, sexually transmitted infection (STI) and TB clinics, outpatient department (OPD) and sometimes laboratory personnel perform HIV testing for different purposes.

All of the facilities assessed were using rapid test kits KHB, stat-pack and uni-gold for testing. They followed serial testing algorithm that is; KHB for screening, stat-pack for confirmatory and Uni-Gold for tiebreaker test (Annex V). The facilities also used VCT daily register to record information on the quantities of HIV tests kits used. Only in 3(15%) of HCs, personnel working on VCT were recording information on the quantities of HIV tests in the stock at VCT service

delivery sites by using bin card and reagent consumption log sheet. The rest of the 17(85%) HCs and all of the hospitals didn't record the quantities of HIV test kits on hand at service delivery site.

Majority of the HCs, 13(65%) and half of the hospitals, 2(50%) were not providing VCT service on the day of visit. VCT service was interrupted once or more than once in 14(70%) of the HCs and 2(50%) of hospitals within six months prior to the survey date. When facilities are in short of HIV test kits, they were only doing a test for emergency cases or PMTCT purpose. The average duration where VCT service (HIV testing) was not provided during the past 6 months was very long for HCs, (39.8 ±32.8, (0, 98) days) compared to hospitals, (6.8 ±11, (0, 23) days). This study also revealed that the frequency where VCT service had been interrupted was 1.5 in HCs and 0.8 in hospitals with six months prior to the survey date. In most of the cases the interruption of this VCT service was associated with stock out of KHB. But in some instances shortage or lack of stat pack and blood lancet were mentioned as reasons for the service interruption.

Regarding the ART service, majority of the HCs 16 (80%) and all of the hospitals had document that lists recommended ARV drug regimens to be prescribed and dispensed. The major problem in ART dispensaries was absenteeism of data clerks at working hours during data collection time, who are mainly responsible for analyzing and reporting patient by regimen data. In addition to this, they were the one responsible for updating of PIS, daily ARV drugs dispensing registry and EDT in some of the facilities.

Looking at patient by regimen data, 16(80%) of HCs and one of hospital knew and reported their patient by regimen data. The rest, (4)20% of the HCs and 1(25%) of the hospitals were using ART clinic data to report to higher level. The remaining two hospitals were reporting the data from the ART pharmacy but they didn't know and lack patient by regimen data. This finding was evident by the following fact, the head pharmacist and the data clerk in the Zewditu Memorial Hospital said that since their Electronic Dispensing Tool (EDT) was not working appropriately, both the ART pharmacists and the data clerks face difficulties in handling (using) the patient data base. So they had to wait for an expert to come from the partner NGO (MSH) to analyze and collect the data for themselves. The ART pharmacist said, they didn't have the copy of the report

remaining with the pharmacy section and they didn't know their actual patient by regimen data. In addition to this, they said they didn't use any paper based format to register patient by regimen data because they mentioned high patient burden in their pharmacy made it difficult.

In Alert Hospital, both the head pharmacist and the ART pharmacist didn't know how the data clerks report and from where they did get the information. The ART pharmacist of this hospital said their EDT was not working properly. They mentioned that they were only able to enter patient information without analyzing the data for further reporting. In addition to this, they also mentioned that due to negligence of the professionals and other factor the data in EDT was not reliable. Even though they have been using PIS, they didn't use it appropriately. They didn't summarize it by daily ART register thus they couldn't know the exact figure. Both the head pharmacist and the ART pharmacist doubt the report of the data clerks. They said the data clerks report every time but they didn't have the copy of the report in the pharmacy so both the head and ART pharmacist didn't know the actual number of patient by regimen and their total number of active patients.

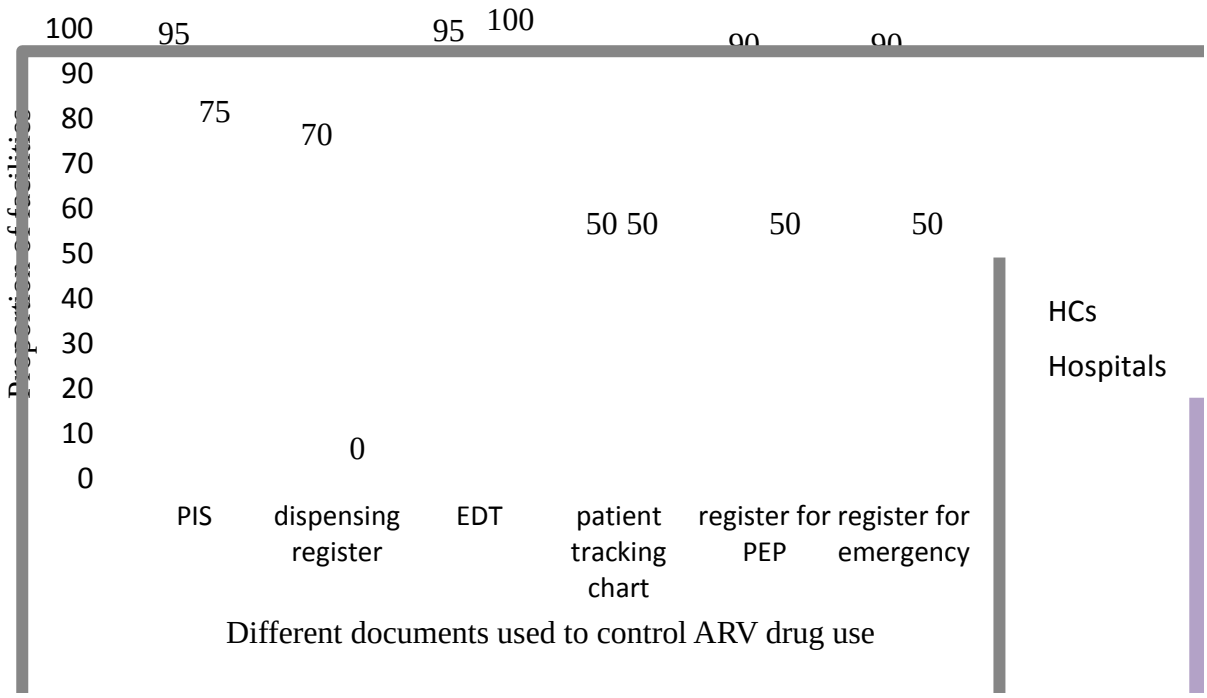


Figure 2: HCs and hospitals that had and used different patient information records, Addis Ababa, Ethiopia, 2013

All health facilities visited had EDT to dispense drugs to the patient. Except a single HC, all the hospitals and HCs used EDT in their daily work. They had been dispensing a dose that ranges from 15 days for beginners to 3 months depending on patients' condition. But some of the ART pharmacists mentioned that due to frequent stock out of drugs they were forced to dispense drugs for a week, 3 days and even for a day; especially for TDF/3TC based regimen. Sometimes, they mentioned that they referred patients to other health facilities. This was also evident that 2 (10%) of the HCs were dispensing daily doses of TDF/3TC/NVP on the day of visit.

The study also revealed that the ART pharmacists use bin card to control the quantity of the ARV drugs at the dispensary. In majority of the cases, 19(95%) of HCs and 3(75%) of hospitals used both EDT and patient information sheet to record the amount of drug dispensed to the patient and other information. But dispensing register was available and used only in 14(70%) of HCs and none of the hospitals. The study showed that 18(90%) of HCs and 2(50%) of hospitals used separate register for PEP. Only 10(50%) of HCs and 2(50%) of hospitals were using patient tracking chart (Figure 2). Despite the fact that they used patient tracking chart, due to lack of telephone they did not call to the patient though they knew the patient was missed. Those ART pharmacies which didn't use patient tracking chart complain patient load as a main factor but they also mentioned that since patient tracking is done by the clinic they think there was no need of tracking the patient by the pharmacy.

All the selected health facilities were providing PMTCT and PEP services in addition to ART and VCT. AZT/3TC/NVP and AZT/3TC were the choices of regimen for PEP in high and low risk patients, respectively. Based on the new guideline, all of the facilities had initiated HAART for pregnant mothers irrespective of their CD4 count. Mothers were treated using TDF/3TC/EFV while NVP and cotrimoxazole syrup was used to treat the infant.

6.2. Reporting and ordering ARV drugs and HIV Test Kits

Regarding the store data one HCs out of the 20 was taken as non-respondent since the store manager was not available during data collection time. Concerning the ARV drugs 23 health

facilities (19 HCs and 4 Hospitals) were using RRF to report consumption and to order ARV drugs needed. They submit the report to Pharmaceutical Fund and Supply Agency (PFSA) regional hub. They used facility personnel and vehicle to submit their report and request. The RRF is a pre-prepared format containing different logistic data which were classified as report part (Beginning balance, Quantity received, Loss/adjustment, Ending balance, Calculated consumption and Days of stock out) and requisition part (Maximum stock, Quantity needed to reach maximum and Quantity ordered)

In majority of the health facilities RRF was prepared and reported by the store manager alone. Despite the fact that they were supposed to submit the report every two months; between the 1st and the 10th day of the reporting month, there were few facilities which failed to do so. They had mentioned negligence as a main reason for not being able to submit their RRF on time. In line with this; they had recalled lack of the RRF and work load as additional factors for the delay in submitting the RRF. Majority of the facilities 18(94.7%) of HCs and 3(75%) of hospitals were able to submit their last report according to the schedule while 1(5.3%) of HCs and 1(25%) of hospitals failed to submit their report on time for the last report period. But on average the store managers of 15(78.9%) HCs and 2(50%) hospitals said that they were always able to send their report on time (Table 1).

Majority, 15(78.9%) of the store managers in HCs and 3(75%) in hospitals had on job training on integrated pharmaceutical logistic system (IPLS). They required average time of 10.3 hours (HCs) and 6.5 hours (hospitals) to complete and prepare the RRF. The store managers of 1 HC and 1 hospital said that they had been using only 1 and 3 hours respectively to finish the RRF. In all of the facilities the pharmacy department, specifically the store managers were responsible for determining the quantity of drugs. Majority of the store keepers, 78.9% in HCs and half of them in hospitals said they sent their report on time always (Table 1). They had standard formula to determine the quantity of drugs needed (Annex VII). They said number of patient was the main factor affecting the quantity of drugs that they ordered. But the study showed that store size was also another factor that affected the quantity of drug being determined.

Table 1: Professionals prepared report and requisition form, in health centers and hospitals of Addis Ababa, 2013.

Facility	RRF prepared by		Time needed to complete the RRF *(hr)	
	Store manager	Store manager +head pharmacist	Mean ± SD	(min,max)
HCs	17(89.5%)	2(10.5%)	10.3±6.2*	(1,24)*
Hospitals	75%	25%	6.5±2*	(2,8)*

*Except for 2 HCs and 1 hospital this was the average time required to prepare the RRF of program drugs and diagnostic agent including test kits.

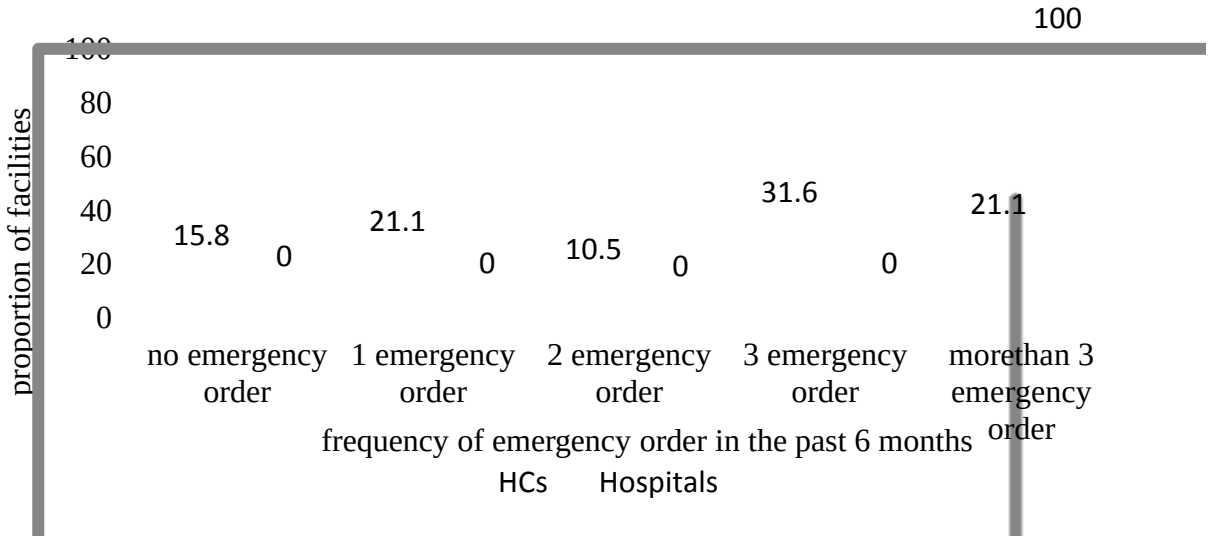


Figure 3: Frequency of emergency order for ARVs in hospitals and health centers, Addis Ababa. 2013

Although they had been using standard formula to quantify ARV drugs needed and reported as per schedule, majority of the facilities had emergency orders in the past 6 months. Only 3(15.8%) of the HCs didn't have emergency orders of ARV drugs in the past 6 months. While all of the hospitals reported that they had emergency order for more than 3 times in the past 6 months (Figure 3).

The reporting and requisition of test kits was done in combination with the ARV drugs by the main store manager in all the studied health facilities except one hospital and two HCs. The hospital had a separate store for test kits, so the RRF was prepared by two separate store managers. In the two HCs the report and requisition was prepared by the laboratory head that never had training on how to complete the form.

All hospitals used RRF to report and request test kits from PFSA every two months. However, two of the regional hospitals reported previously sending their report to AACAHB. But starting from June 2013 they begin to report to PFSA. But both of the hospitals didn't receive the order from PFSA till the study period. All of the HCs had been using facility based reporting formats to report either to their respective sub city health offices or to AACAHB every month. But starting from June 2013, they started to directly report to PFSA. About a quarter, 5(26.3%) of HCs reported have sent their report only to PFSA every two months starting from July 2013, even though PFSA never respond to them. So these HCs were forced to ask their respective sub city health offices or the AACAHB for emergency order by telephone or through letter. Seven (36.8%) of the HCs had sent their report both to PFSA and AACAHB yet they were able to get the test kits from AACAHB. The remaining 6(31.6%) HCs report only to AACAHB; while only one HC sent the report neither to PFSA nor AACAHB. The respondent said that since the supply chain of these items was not stable for the past 8 or 9 months, they simply ordered the test kits orally by telephone or by written letter from sub-city.

The quantity of HIV test kits were determined using a standard formula in a few 9(47.3%) of HCs but in all hospitals (Annex VIII). However, the majority of the respondents in the HCs said that they take a rough estimation of the needed quantity of the HIV test kits to be ordered. They said they were unable to calculate the exact quantity of test kits required due to frequent supply

interruption. Generally, the reporting and the requisition of HIV test kits were more organized in hospitals compared with HCs.

Except one HC, all the health facilities had emergency order of test kits in the past six months. All of the hospitals and nearly half (47.4%) of the HCs had an emergency order for more than three times in the past six months. They all agreed that in the majority of the cases they received the test kits on emergency order (Figure 4).

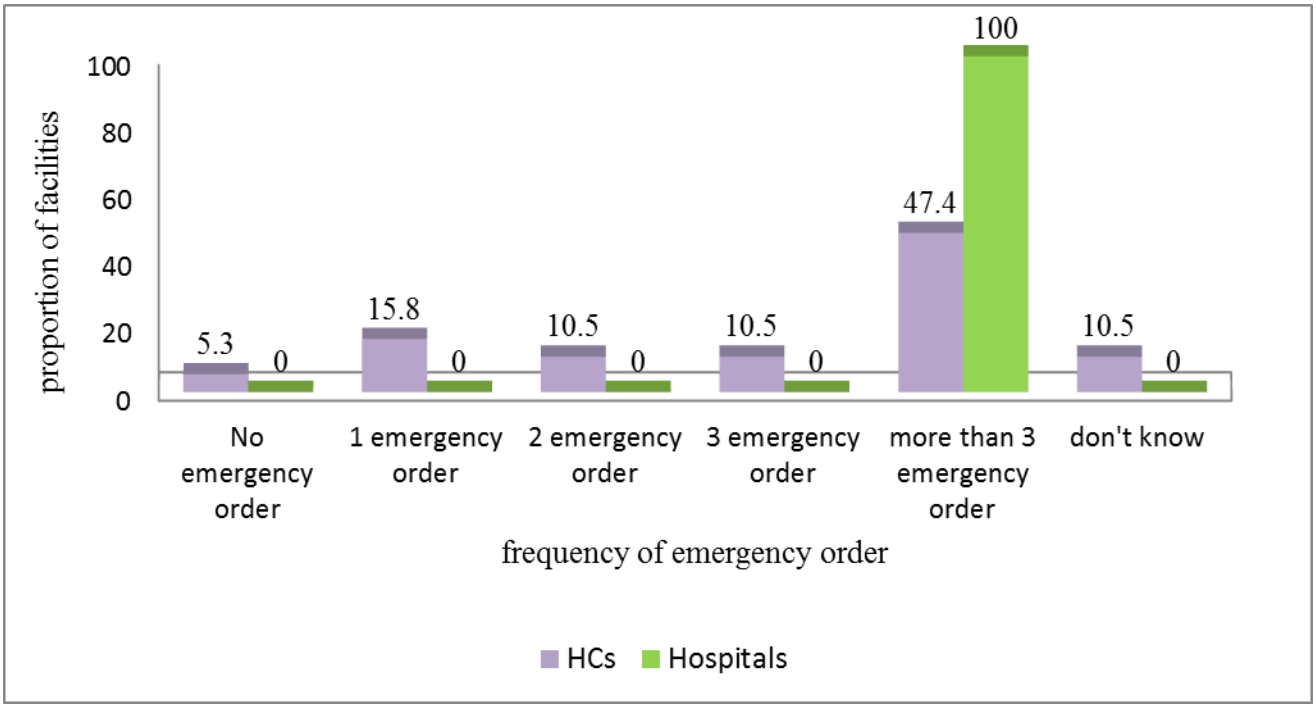


Figure 4: Frequency of emergency order for HIV test kits in hospital and health centers, Addis Ababa, 2013

6.3. Receiving/ distribution and transportation of ARV drugs and Test Kits

All health facilities had been expecting PFSA to bring the ordered ARV drugs between the 11th and the 20th days of the reporting month. All the store managers had kept the invoice as a proof of delivery. Majority of the store managers of hospitals, 3(75%) said that they received the quantity of drug they ordered sometimes, while 12(63.2%) of HCs said that they received the quantity of the drug they ordered most of the time (Figure 5).

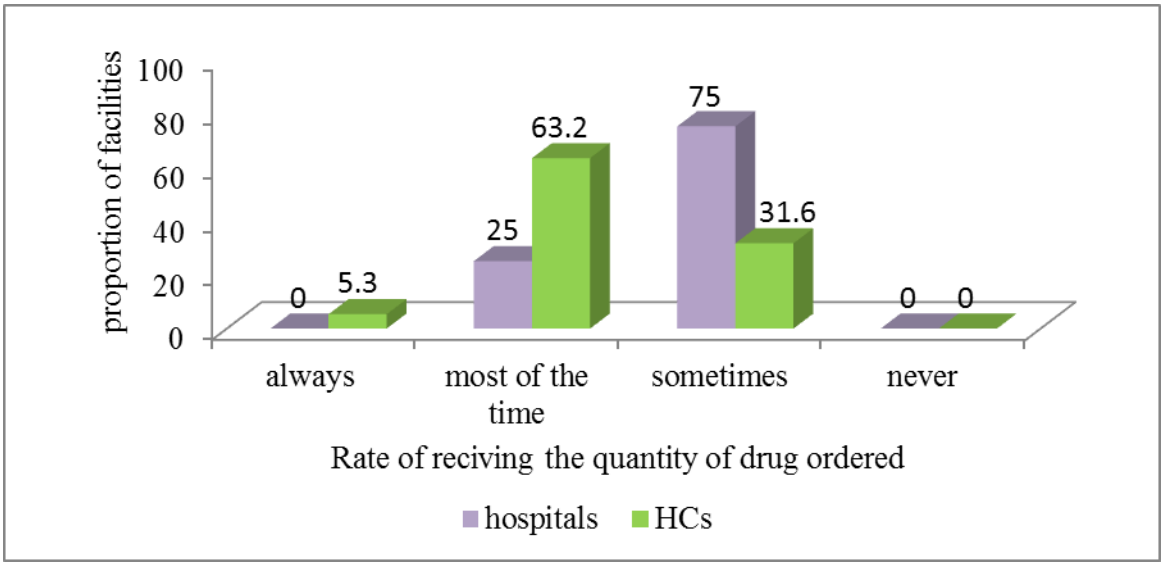


Figure 5: Hospitals and health centers receiving quantity of ARV drugs they ordered, Addis Ababa, 2013

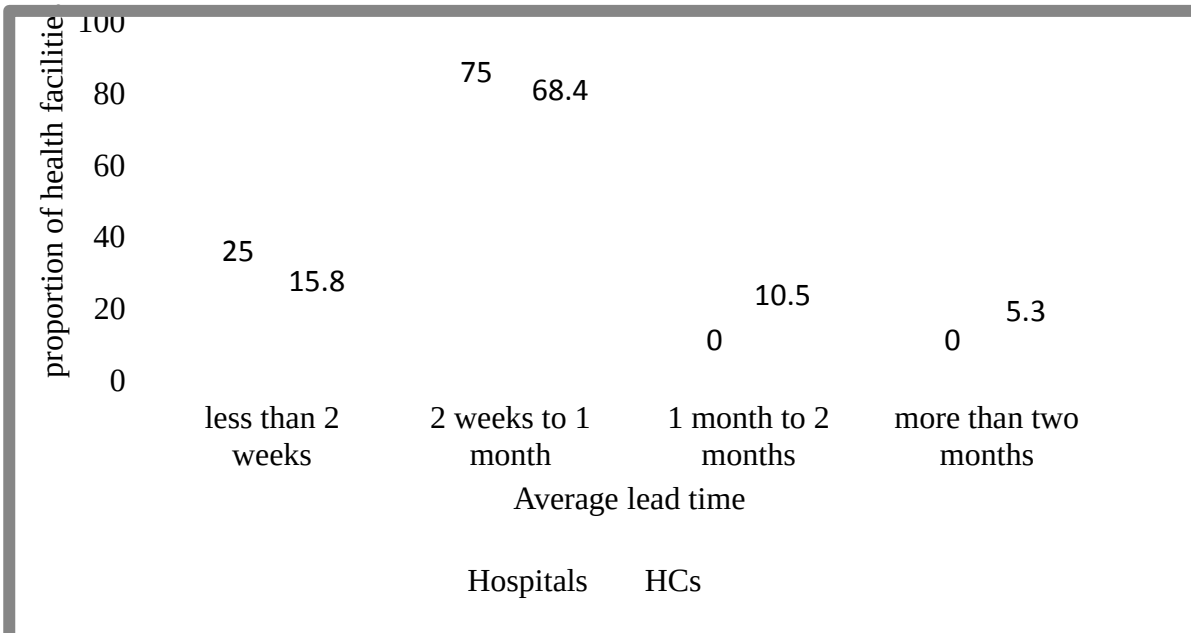


Figure 6: Average lead time for ARVs in hospitals and health centers, Addis Ababa, 2013

The majority of the hospitals, 3(75%) and 13(68.4%) of the HCs described, on average they received their ordered products between two weeks to one month of their order point (Figure 6). Even though majority of the respondent said the average lead time was two weeks to one month, the review of the last report had showed that, the time that often takes between the order and delivery of the order was more than a month. On average the lead time was 37.5 and 34.2 days in hospitals and HCs respectively for last report period. Only 4(21.1%) of the HCs received their last order quantity within 20 days (Table 2).

Table 2: Average lead time for ARVs for the last order period in hospitals and health centers, Addis Ababa, 2013

Facility type	Mean lead time ± SD, for last order(days)	(Min,max) days
HCs	34.2±18	(14,85)
Hospitals	37.5±17.1	(22,61)

There were on average more than 6 ARV products ordered per facility during last order period both in hospitals and HCs. This study showed that HCs and hospitals received 53.1% and 59.2% the quantity of ARV drugs ordered as per ordered quantity, respectively and they didn't receive 15.3% and 5% of the products that they ordered in last report period respectively. For the rest of the cases they either received in lesser or excess quantity than ordered (Table 3).

Table 3: ARVs received and not received by health centers and Hospitals in last report period, Addis Ababa, 2013

No	Variable	Facility type			
		HCs		Hospitals	
		Mean ± SD	(min,max)	Mean ± SD	(min,max)
1	Mean no of ARVs ordered	6.5±2.4	(2,10)	7.8±2.6	(5,10)
2	% of ARVs not received	15.3±15.8	(0, 44.4)	5±10	(0, 20)
3	% ARVs received as per the order	53.1±25.1	(0, 100)	59.2±6.9	(50, 66.7)
4	% of ARVs received with discrepancy	31±23.7	(0, 66.7)	35.8±12.6	(20, 50)
5	% of ARVs received in less quantity	23±18.9	(0, 66.7)	33.3±9.4	(20, 40)
6	% of ARVs received in excess quantity	8.6±18.2	(0, 66.7)	2.5±5	(0, 10)

The mean percentage difference between quantity ordered and received was high for 3TC300/TDF300 (69.6% ± 17%, (55%,93%)) and d4T12/3TC60 (69.4% ± 33.4%, (45.8%,93%)) in hospitals while it was high for d4T6/3tc30/nvp50 (110.9% ± 193.8%, (0%,400%)) and followed by 3TC300/TDF300 (51.7% ± 33.8%, (0%, 99%)) in HCs for last report (Table 4).

Table 4: Percentage difference between ordered and received quantities of ARVs in health centers and hospitals, Addis Ababa, 2013

ARV drugs	HCs		Hospitals	
	Mean percentage difference ± SD	(min,max)	Mean percentage difference ± SD	(min,max)
efv 50	0	0	*	*
efv 200	9.5 ± 21.2	(0, 47.6)	0	0
efv 600	47 ± 32.3	(0, 80.7)	2.9 ± 2.7	(0, 11.5)
3tc300/tdf300	51.7 ± 33.8	(0, 99)	69.6 ± 17	(55, 93.4)
nvp200	0	0	0	0
zdv300/3tc150	27.1 ± 43.1	(0, 143)	34 ± 29.5	(0, 52)
zdv300/3tc150/nvp200	14.8 ± 33.6	(0, 93.6)	50 ± 0	(50,50)
3tc30/zdv60/nvp50	0	0	0	0
Nvp 240ml	5.9 ± 16.6	(0, 47.1)	0	0
d4T12/3tc60/nvp100	27.8 ± 83.5	(0, 290)	0	0
d4T6/3tc30/nvp50	110.8 ± 193.8	(0, 400)	0	0
3tc30/zdv60	25.4 ± 35.9	(0, 50.8)	45.7±12.7	(36.7,54.7)
d4T12/3tc60	0	0	69.4±33.3	(45.8,93)
d4T6/3tc30	*	*	0	0

* the product was not ordered by the health facility in reviewed requisition and report format

There were some cases where the facility received greater amount of drug than their ordered quantity. Only one HC received three ARV drugs; efv600 (1000 of 30 tabs), d4T12/3tc30/nvp100 (10 of 60 tabs) and d4T6/3tc30/nvp50 (10 of 60 tabs) without ordering the product. This HC ordered only three products in last report period and out of these products they

received only one product as in a quantity in the report. For the other two products i.e. zdv300/3tc150 and zdv300/3tc150/nvp200, they received 143% and 93% in excess respectively.

Upon reporting and requisition by RRF, PFSA was responsible for transporting ARV drugs to the facilities at regular order. However, during emergency order, the facilities took the responsibility for transporting ARV drugs by using their own vehicle. All the facilities had a pre-prepared internal facility reporting and requisition format (IFRR) to facilitate the distribution of the ARV drugs within the facility.

Concerning the test kits, both hospitals and HCs were supposed to receive test kits together with the ordered ART drugs between 10^{th} and 20^{th} day of the reporting month. But this study showed that the two regional hospitals and 100% of the HCs never received the ordered test kits from PFSA starting from July 2013. Even the remaining two federal hospitals had been complaining on PFSA regarding the supply of the test kits. The HCs and the two of the regional hospitals mentioned that, before June 2013; in most of the cases they collected the ordered quantity from AACAHB on the day of reporting or sometimes AACAHB or sub-cities health administration had supplied them within a week. But they said once they started reporting to PFSA, they received very few test kits from AACAHB and sub city only by emergency order.

6.4. Supportive Supervision

More than half of the HCs 11(55%) and 2(50%) hospitals had been supervised in the past month and past 3months respectively. All of the HCs and 3(75%) of the hospitals were supervised during the past 6 months (figure 7).

The sub-city health administration, AACAHB and USAID/DELIVER were mentioned as a direct supervisor of HCs while AACAHB, FMOH and USAID/DELIVER were the direct supervisors for the hospitals. All the respondents said that their last supervision include review of stock cards and bin cards, different reports, physical stock count, storage condition, review of HCMIS and EDT, PIS and dispensing register book, VCT tally and VCT daily register and etc. They also discussed and facilitate removal of expired products from the store. The respondents said, most of the time the supervisors gave feedbacks after the supervision but sometimes they forced the

facilities to do certain things accordingly; e.g. feeling patient card, use of dispensing register, patient tracking chart utilization and etc.

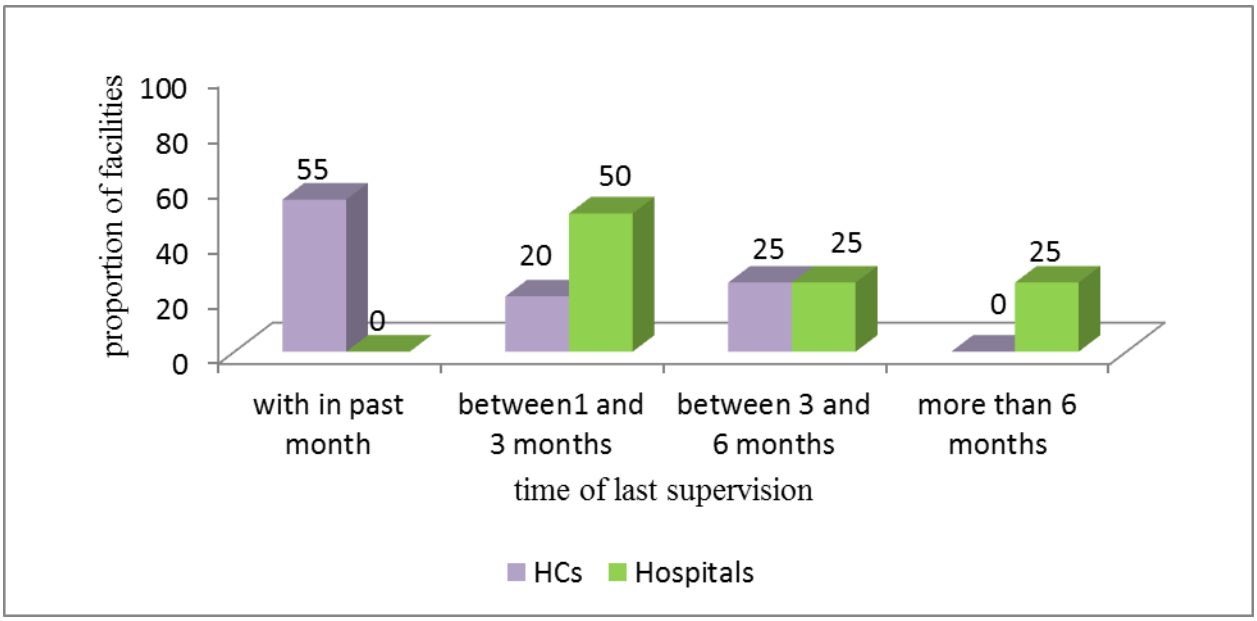


Figure 7: Health centers and Hospitals have their last supervision, Addis Ababa, Ethiopia, 2013

6.5. Storage condition of ARV drugs and Test kits

The stores of 19 HCs and 4 hospitals were assessed during the study time. There were 2 HCs which didn't have bin card for ARV drugs and not included in the calculation of percentage of bin card updated. There were also 2 hospitals, which had updated bin card with 1 month and 2 months transaction; which were included in the calculation of availability of bin card for ARV drugs and bin card updated. But these two hospitals didn't have complete transaction for the past 6 months. Store manager of one of the hospital said that she didn't have the previous bin card with her. She said she only gets the bin card of 9 ARV drugs when she received the store from the previous store manager, so only the bin card of the 9 products were used in the past 6 month stock status. The store manager of the second hospital didn't record the past 14 month's transaction neither on bin card nor on the HCIMS. They used the bin card to record some

physical count data. But the new store manager started to use both HCMIS and bin card to control stock movement of ARV drugs. So this hospital was excluded in the calculation of past six months of stock status of ARV drugs. The stock status was calculated with this limitation. In addition to these, the major challenge was some of the store keepers were unavailable during the study period.

Overall 14(73.7%) of the HCs and 3(75%) of the hospitals reported faced stock out of one or more ARV drugs on the day of visit, while in the past six months all of hospitals and HCs faced stock out of 1 or more ARV drugs. Efv600, nvp200, nvp240 and d4t6/3tc30/nvp50 was stocked out both at hospitals and HCs. Stock out was high for nvp200 in hospitals 2(50%) and it was high for tdf300/3tc300 in HCs 7(36.8%) on the day of visit (Table 5).

Table 5: ARVs stocked out on the day of visit in health centers and Hospitals, Addis Ababa, 2013

ARV drugs	HCs stocked out of each ARV drug N (%)	Hospitals stocked out of each ARV drug N (%)
efv 50	0(0%)	0(0%)
efv 200	4(23.1%)	0(0%)
efv 600	1(7.1%)	1(25%)
3tc300/tdf300	7(36.8)	0(0%)
nvp200	2(14.3)	2(50%)
zdv300/3tc150	1(7.1)	0(0%)
zdv300/3tc150/nvp200	0(0%)	1(25%)
3tc30/zdv60/nvp50	5(26.3%)	0(0%)
Nvp 240ml	1(7.1)	1(25%)
d4T12/3tc60/nvp100	4(21.4%)	0(0%)
d4T6/3tc30/nvp50	4(21.4%)	1(33.3%)
3tc30/zdv60	0(0%)	1(25%)
d4T12/3tc60	2(11.1%)	0(0%)
d4T6/3tc30	2(11.1%)	0(0%)

The mean no of products stocked out on the day of visit was 1.6 and 2 in HCs and hospitals respectively, whereas the percentage of ARV drugs stocked out on the day of visit was as high as 6 and 4 in HCs and Hospitals respectively. Mean number of products stocked out in the past six months was 5.1 and 6.5 in HCs and hospitals respectively (Table 6). TDF300/3Tc300 was most frequently stocked out item in the past 6 months prior to the study both in hospitals and HCs.

Table 6: ARVs managed and stocked out in health centers and hospitals on the day of visit and within 6 months prior to the study, Addis Ababa, 2013

	On day of visit				Past 6 months			
	HCs		Hospitals		HCs		Hospitals	
	mean±SD	(min, max)	mean±SD	(min, max)	mean±SD	(min, max)	mean±SD	(min, max)
No. of ARVs managed	12.2 ± 2	(8,14)	13.2±3.8	(8,16)	12.2 ± 2	(8,14)	13.2 ± 3.8	(8,16)
No. of ARVs stock out	1.6 ± 1.5	(0,6)	2 ± 1.6	(0,4)	5.1 ± 2.6	(1,11)	6.5 ± 2.1	(5,8)
% of ARVs stock out	12.8 ±11.3	(0,42.8)	17 ± 13.7	(0,30.8)	46.3±23.3	(9.1,91.7)	56.3 ±8.8	(50,62.5)

The mean duration of stock out was longer for d4t6/3tc30 (55.8 ±45days, (0, 109)) and tdf300/3tc300 (45.9±4.5 days, (0, 165)) in HCs while it was long for tdf300/3tc 300 (42.5±6 days, (0, 85))) and Nvp200 (36.5±2 days, (23, 50)) (figure 8). The mean duration of stock out was more than a month for almost quarter 3(21.4%) of the ARV drugs in both HCs and hospitals, respectively.

Decreasing the ordered quantity of ARV drugs and test kits by the supplier was mentioned as a main reason for the stock outs of these pharmaceuticals. In addition to this for tdf300/3tc300, transfer of patients from d4T based regimen to tdf/3tc based regimen was mentioned as a factor for frequent stock outs of these drugs in majority of the health facilities. Overall majority of the store managers believed that this stock outs were mainly due to the problem associated with the suppliers.

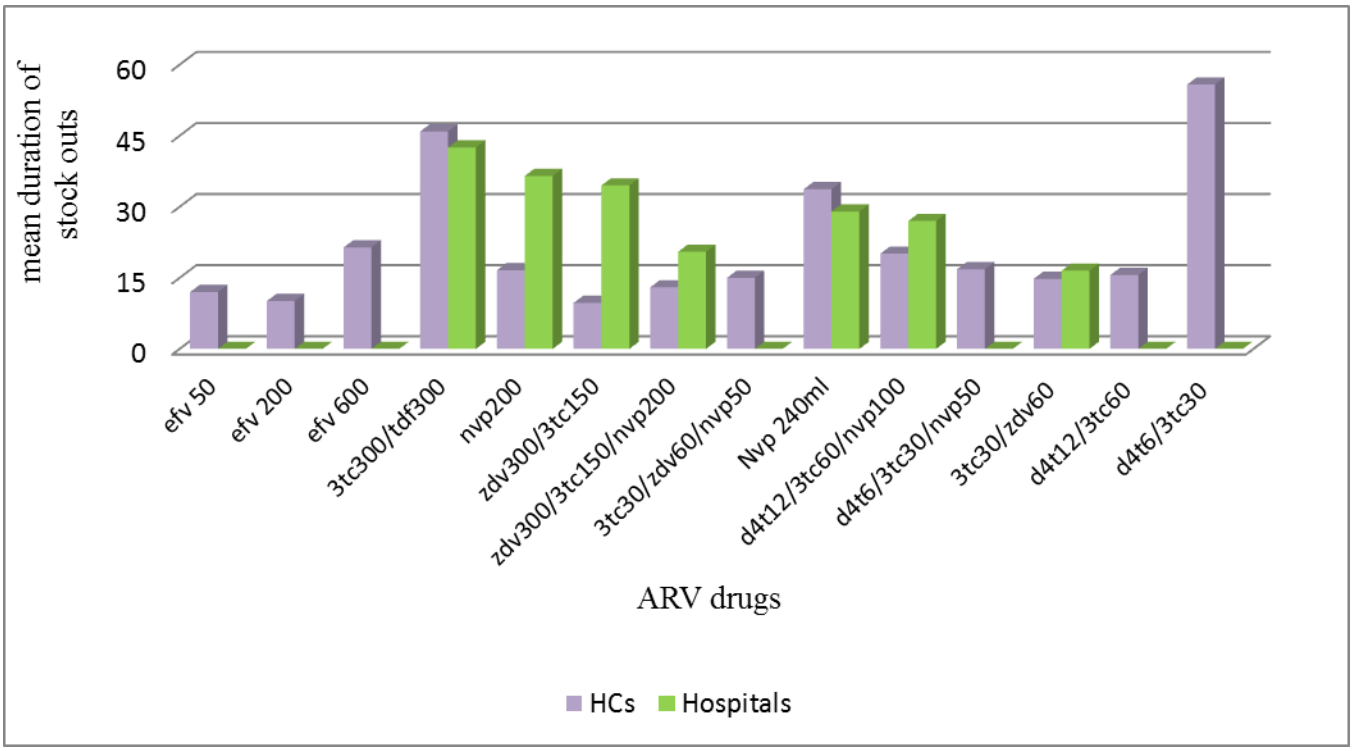


Figure 8: Stock out days of ARVs within 6 months prior to the study in health centers and hospitals, Addis Ababa, 2013

Majority of the store manager of the health facilities said that they controlled the stock movement both by bin card and an electronic system called HCMIS. Except 2 (10.5%) of HCs; all HCs and hospitals used bin card on the day of visit. However this study revealed that there were few cases where the facilities lack bin card for one or more products. On average, 83.9% and 97% of the drugs had bin card in HCs and hospitals. Only 9(47.4%) of the HCs and 3(75%) of the hospitals had bin card for all of the ARV products that they managed on the day of visit (Figure 9). All of the facilities used maximum minimum stock control system to manage the stock of ARV drugs. They had four months of maximum stock, two months of order interval and 15 days of minimum stock.

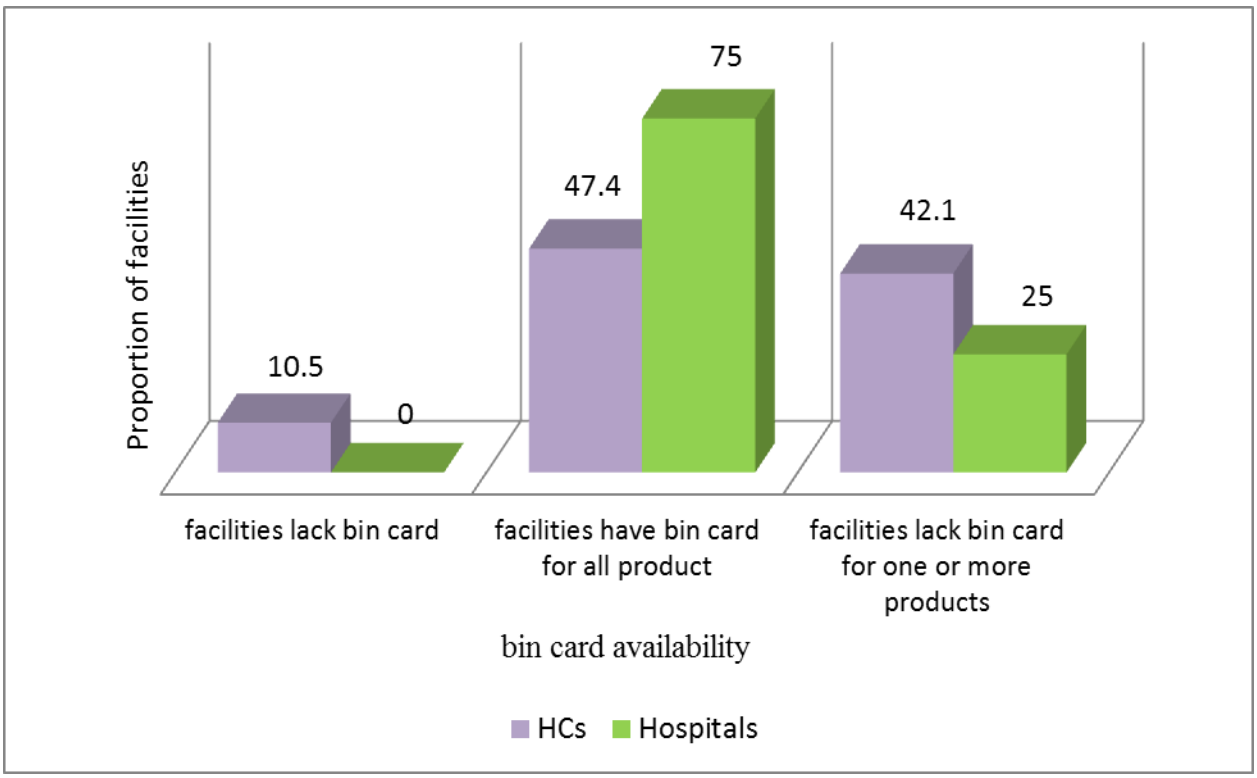


Figure 9: Health centers and hospitals had bin card for ARV drugs in health centers and hospitals, Addis Ababa, 2013

The average percentage of updated bin card of ARV drugs was 85.7% and 96.9% in HCs and Hospitals respectively. Percentage of bin card updated varies from facility to facility with a range of 22.2% - 100% in HCs and 87.5% - 100% in hospitals. The study showed that, in the past 6 months the mean number of data on bin card were 7.9 and 8.1 in HCs and hospitals respectively hence both HCs and hospitals on average update their bin card approximately every month, where it may extend up to two months for HCs (Table 7). All bin cards were updated in 3(75%) of hospitals and in 10(58.8%) of HCs on the day of visit. While the remaining hospitals and HCs have one or more not updated bin cards.

Table 7: Updated ARV bin cards and approximate days of update in health centers and hospitals, Addis Ababa, 2013

Bin card status	HCs		Hospitals	
	Mean±SD	(min,max)	Mean±SD	(min,max)
% Bin card updated	85.7 ±24.6	(22.2,100)	96.9±6.3	(87.5, 100)
% Bin card not updated	14.3±24.6	(0, 77.8)	3.1±6.3	(0, 12.5)
Number of data on bin card in the past 6 month	7.9±2.7	(3.3, 13.9)	8.1±2.1	(6.6, 9.6)
Number of days where bin card updated	26.4±10.8	(12.9, 54.5)	23.2±6.3	(18.8, 27.5)

With regard to the inventory control system of test kits, any of the facilities were using minimum maximum inventory control system. Since bin cards of test kits was filled but incomplete in majority of the hospitals and HCs, only bin card availability and stock status on the day of visit was calculated and presented as follow. Percentage difference between the ordered and received for test kits was not also calculated since all HCs and 2 of the hospitals were not receiving the quantity of test kits order at regular order since July 2013.

There were 5 test kits selected for this assessment i.e HIV rapid test. These were KHB, stat-pack, uni-gold, blood lancet and EDTA capillary tube. Unlike ARV drugs only 10(52.6%) of HCs and 2(50%) of hospitals had bin card for the test kits on the day of visit while the remaining 9(47.4%) of HCs and 2(50%) of hospital didn't have bin card for test kits.

The stock status of test kits on the day of visit showed that; 7(36.8%) of the HCs were fully stocked on the day of visit while 2(10.5%) of them reported stock out of all the five test kits (Figure 10).

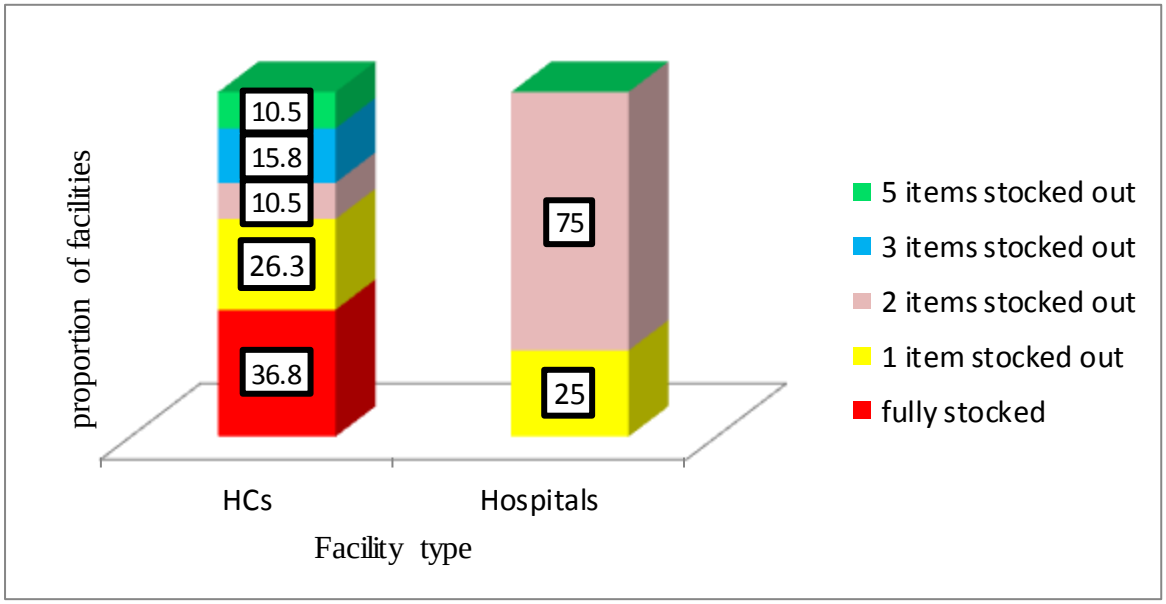


Figure 10: Test kits stock status in HCs and hospitals on the day of visit, Addis Ababa, 2013

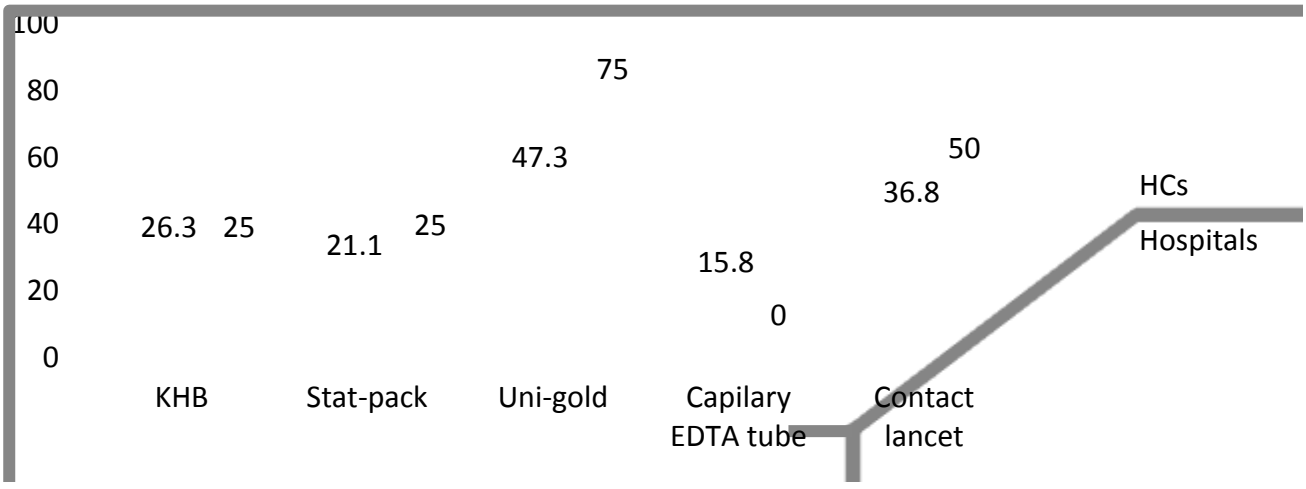


Figure 11: HCs and hospitals stocked out of HIV test kits on the day of visit. Addis Ababa, 2013

Uni-Gold was stock out in majority of HCs and Hospitals on the day of visit compared to the other kits (Figure 11). Average percentage of test kits stocked out on the day of visit was 29.5% and 35% in HCs and hospitals respectively (table 8).

Table 8: Test kits stocked out in health centers and hospitals on the day of visit, Addis Ababa, Ethiopia, 2013

Facility type	Test kits stock out			
	Percentage		Number	
	Mean ± SD	(min, max)	Mean ± SD	(min,max)
HCs	29.5±32.9	(0,100)	1.5±1.6	(0,5)
Hospitals	35 ±10	(20,40)	1.8±0.5	(1,2)

Except one hospital all the facilities had one store for ARV drugs and test kits. The qualitative data obtained by observation checklist showed that appropriate arrangement of products with visible expiry dates and identification labels, FEFO organization of product and accessibility of products for counting; cleanliness of the store, and thermometer usage were the major challenges in the majority of the HCs and hospitals. Ventilation and lightness of the store room and storage space were additional demanding requirements in the majority of the HCs while only few hospitals had these problems as a challenge. The stores of majority of the HCs were highly overstocked so that there was not sufficient space to move; in addition to this, products were kept in the floor without palate. Additionally there was sign of rodents and insects in the majority of HCs and few of Hospitals. Utilization of expiry tracking chart was also very minimal both in HCs and hospitals and expired ARV drugs including test kits were found on the shelves of few HCs and single hospital on the day of visit.

Unlike this, majority of the HCs and hospitals maintained the outer cartoon of the product in good condition and they were able to separate expired and damaged product from usable product either in the store room or in separate store. Moreover, the observation revealed that cartoons and products were protected from direct sunlight; stores were locked and the keys were maintained with the store manager, roofs were maintained in good condition to avoid sunlight and water penetration.

6.6. Logistic management information system

In all of the selected health facilities they used both computerized and paper based recording and reporting tools. They used computerized EDT and HCMIS at dispensary and store respectively. In addition to these RRF and Internal Facility Reporting and Requisition (IFRR) were used to facilitate and control stock movement between PFSA and facility and within the facility itself.

The study showed that EDT reduces the work load of the pharmacists and the data clerk at ART dispensary. Majority of the client both in HCs and Hospitals mainly used EDT to record patient information than paper based format like PIS and Daily ARV drug register even though there was risk of power interruption and risk of losing the patient data. EDT contains all the drugs currently dispensed at facilities unlike HCMIS. The EDT could mark the patient as lost or dropped if the data of the patient was not entering appropriately or the patient was actually missed. Since there is large number of HIV/AIDS patients this computerized software eases the work of the health professionals. But the professionals complained that this software had its own drawbacks. Some of them said it was not easy to manipulate patient data. They said they were unable to get patient by regimen data from it. So they relied on the data obtained from the clinic which had also some shortcomings. They also mention it was difficult to get the data from the EDT. They also mentioned that sometimes the program stuck without knowing the exact reason. Even some of them complained about they may missed patient data from the EDT by an unknown reason.

The other software was HCMIS, used in the store to control stock movement. Respondents said that this software has many advantage. Firstly they mentioned that it makes their job easy. They also acknowledged it for summarizing their data, preparing different reports, having its own expiry tracking chart and it helped them to understand the utilization pattern of the drug. In contrary to these they said this software was not user friendly. They said they couldn't update the software by themselves; instead they call up for USAID/DELIVER personnel to update the software. They mentioned that this software can't be used to control the stock movement of new drugs like TDF/3TC/EFV, TDF/3TC, Atz-R, plumpy sup and etc. So they only used paper based bin card for this items. In addition to this they also complained that this software can issue in

negative value once the old batch drug is expired, even after entering of new batch with new expiry date.

RRF and IFRR were paper based format used to report, order and control stock movement. RRF was used to report and order both ARV drugs and test kits either from PFSA or AACAHB. Instead IFRR was used to facilitate movement of products within the facility itself.

About LMIS data quality, it was only done for ARV drugs because as indicated above the majority of the facilities lack bin card for test kits.

LMIS data quality was checked by using last LMIS report (RRF) and bin cards of ARV drugs. Ending balance according to most recent RRF was checked with ending balance on bin cards from the time of LIMs report. If there is a difference of ending balance for one or more items the respondent was asked to explain the discrepancy. In 13(76.5%) of HCs and all of hospitals the store managers report ending balance as the SOH kept in the store room only. Only one HC report the ending balance as the SOH found in the store room and all other places. A single HC had unexplained discrepancy, while in another HC the discrepancy between LMIS report and bin card was due to the fact that the store manager didn't count the products in opened boxes though the HC used SOH found in the store room only and negligence (forgetting different brands). The remaining one HC explained the discrepancy as deliberate. They used stock on hand (SOH) in store room as ending balance but they deliberately manipulate the data. The store keeper of the health center said that the supplier sometimes send excess ARV drugs and sometimes decreased the ordered ARV drugs. So to prevent and minimize the fluctuations made by the supplier the store manager of the HC increased or decreased the balance to be reported accordingly.

7. Discussion

Knowing patient taking ARV by regimen data is crucial for the supply chain of ARV drugs. This finding showed that all ART pharmacies were supposed to report patient by regimen data to an NGO (MSH), AACAHB or their respective sub city health offices. But despite this fact, only 16(80%) HCs and 1(25%) of hospital pharmacies were able to appropriately report and knew their patient by regimen data. They mention the problem with operation of the EDT as a main factor. Some of them use ART clinic data as an alternative. But the report from the ART clinic lack patient on TDF/3TC/EFV and TDF/3TC/NVP; where these two drugs might account for quarter or more of the patients in the health facility and other second line ARV drugs. So this lack of adequate and accurate data; might affect the decision of national ARV drugs quantifiers.

Similarly, a study done by Aler *et al*, showed that, there are certain common challenges associated with the quantification of ARV drugs and supplies mainly in low and middle income countries. The study mentioned that data on ART services and ARV drug supply are limited and, when available, are often unreliable or insufficient to be used for quantifying ARV drug requirements (Allers *et al.*, 2006). Another literature stated the importance of information in drug supply chain to ensure that there are no interruptions in treatment and tests (AVERT, 2012).

Almost all of the facilities had EDT and used it for recording patient information daily. Due to this only 14(70%) of the HCs used paper based ARV drugs dispensing register as a backup. All of the hospitals and 6(30%) of HCs stopped the use of the paper based register. The respondents believed this as a duplication of work and not applicable when the patient load increases. A single HC and one of hospital didn't use patient information sheet; where they thought it was wastage of time and duplication of work. The ART dispensers believed registering on EDT was enough though the EDT in the majority of the health facility was not working adequately. Thus, lack of dispensing register might be associated with the risk of not having patient by regimen data mainly in hospitals and in some HCs. So having paper based backup might help in the improvement of the supply chain with in the health facility and national level as a whole. Moreover paper based backups were also recommended by all the USG partners where they agree that 70% of the data collection should be done paper based even at location that had been

using computerized EDT sometime (USAID/ The Global Health Technical Assistant Project, 2009).

Adherence is an important issue in any antibiotic therapy but it is of a special concern when it comes to drugs like ART so that, HIV patients should be monitored and followed with much of concern. As result of this utilization of patient tracking chart is vital in ART treatment and it is also recommended by the SOP for management of ART drugs in health facilities (RPM Plus, 2006). This study showed that only 50% of (10) HCs and (2) hospitals used patient tracking chart, but they didn't use it effectively. After identifying that the patient was missed, they failed to trace the patient. They mentioned lack of telephone in ART pharmacies and negligence as a main factor for the observed problem. In those facilities which didn't use patient tracking chart they simply dispense for the patients that came to their dispensary. They didn't know how much of their patient were missed. So this might contribute to default of more patients, probably emergence of drug resistance and above all loss of lives.

Generally the ART dispensers were dispensing doses that range from 15 days for beginners to 3 months depending on patient condition. Another study done in Ethiopia similarly states that patients on ART were resupplied with ARVs on a monthly, bimonthly, or quarterly basis, depending on their individual condition (USAID/ The Global Health Technical Assistant Project, 2009). But some of the respondents mentioned that due to frequent stock out of drugs they were forced to dispense drugs for a week, 3 days and even for a day; especially for TDF/3TC based regimen. Since d4T based adult regimen is currently out dated, the shortage of TDF/3TC was might be associated with transfer of high number of patients from d4T based adult regimen to this drug. This kind of practice might exhaust the patients and contribute for default. This kind of drug interruption might have a serious impact on the patients, the professionals and the health care system. Similarly a study done by Erik *et al*, in 2011 showed that, forecasting has become difficult in Malawi due to people shifting to alternative first line ART regimens and second line ART. This was difficult to predict and led to oversupply of second line ARVs and contributed to shortages and stock outs of alternative first line ARVs (Erik *et al*, 2011).

Within six months prior to the study 14(70%) of HCs and 2(50%) of hospitals stopped VCT service. This might shows that there was shortage of HIV test kits in the health care market. This

shortage might be associated with the reporting system of utilization of test kits in different health facilities which seriously affect forecasting at national level. The average duration of time and the frequency where VCT service was stopped was very greater for HCs compared to hospital. The high average duration and frequency in HCs was possibly associated with the facts that starting from July 2013 HCs were not supplied by PFSA at regular order; they get less quantity than they ordered from AACAHB by emergency order. The other probable reason was that ALERT Hospital was doing VCT only for five patients per day so this hospital was not counted as a hospital not providing VCT service on the day of visit, so this might contribute for the fact that hospitals had less frequent and shorter VCT service interruption compared to HCs.

All the 23 health facilities used RRF to report consumption and order ARV drugs and test kits. 3(75%) of hospitals and 18(94.7%) of HCs were able to submit their report according to the schedule. The average time needed to prepare and report the RRF was higher in HCs (10.3 hrs) compared with hospitals (6.5hrs). But the work load and the product to be managed was much higher in hospitals than HCs. In addition to this the range of time that is needed to complete the form was 23 hrs in HCs while it is 6 hrs in hospitals. So this result showed that there might be some controversies or negligence in the preparation of this form either in hospitals or HCs.

Even though both HCs and Hospitals control their inventory by maximum minimum stock inventory system there were frequent emergency order of ARV drugs in the six months period prior to the study. Majority of HCs 16(84.2%) had one or more emergency order while all of hospitals had emergence order of ARV drugs more than three times in the past six months. This might be associated with that the number of patient in hospitals are relatively higher than HCs. more over this emergency order might be associated with inadequate quantification and supply from central level. Literature said that an accurate quantification is essential for all health commodities but are of very importance for HIV/AIDS related commodities because quantification of drug and health commodity requirements for HIV/AIDS programs is complex and uninterrupted access for patients must be ensured (Family Health International, 2008).

Number of patients was the main factor affecting the quantity of drugs that the health facilities order. But this study also showed that store size was also another factor that affects the quantity

of drug being ordered. Since it was not practical and safe to decrease the quantity of ARV drugs to be ordered even though the storage area was not sufficient; the facilities came up this problem by reducing bulk items like plumpy nuts and harvest blend.

Only 4(21.1%) of the HCs received their last order within 20 days from the order date while the rest of the HCs and the hospitals needs more than 20 days to receive their order. This indicates that only 21.1% of the HCs received their order as per the proposed schedule set by the PFSA so this is also an indicative for the interruption of the supply from the central level.

The percentage difference between quantity ordered and received was zero for 4(30.8%) and 7(53.5%) of the ARV drugs in all of HCs and hospitals respectively. The mean percentage difference between quantity ordered and received was high for 3TC300/TDF300 (69.6%) and d4T12/3TC60 (69.4%) in hospitals while it was high for d4t6/3tc30/nvp50 (110.8%) followed by 3TC300/TDF300 (51.7%) in HCs for last report. Both in HCs and hospitals the percentage difference was high for TDF/3TC this was because of inadequate supply at central level and there was change of regimen towards this regimen from d4t based. Regarding d4t6/3tc30/nvp50 it was high in HCs because of the fact that HCs had small number of pediatric patients so they order very minimal amount of the drug so slight increase in the ordered quantity ends up with high percentage difference. This percentage difference between ordered and received quantity was an indicative of interrupted supply chain and it showed that the current supply chain was not strong enough to fill the gaps.

Two of the regional hospitals and all of the HCs were supposed to receive test kits together with the ordered ART drugs between 11th and 20th day of the reporting month starting from July 2013. But this study showed that the two regional hospitals and all of the HCs never received the ordered test kits from PFSA starting from July. In Addition this study showed that there was stock outs of test kits both in HCs and hospitals so it is indication that the stock at central level might not be sufficient. So it showed that there was a serious interruption test kits in supply chain.

This study showed that 2(50%) of hospitals and 5(25%) of HCs had their recent supervision more than 3 months ago. So lack of supportive supervision was also a challenge for adequate

supply chain of ARV drugs and HIV tests. Frequent supervision is good practice since it can prevent interruption of supplies, overstocking and under stocking of products. A study done in Lesotho similarly reveal that there were challenges in the drug supply system, which were mainly due to the lack of supervisory site visits, led to facilities over-stocking or under-stocking on certain items (Pharasi, 2007).

One of the major reasons for wastage of medicines is that they may have expired without anyone noticing that the shelf life date was approaching. Failure to notice approaching expiry date might lead to the loss of a significant amount of resources, especially in resources limited countries. This type of loss is not acceptable to pharmaceuticals such as ARV drugs, which are very expensive. Expiry dates can be monitored by using different technique so that appropriate action can be taken on short dated product before they become unusable. Tracking expiry date of a product prior to its expiry helps and important to prevent and minimize wastage of resources. (RPM+, 2006). Unlike this fact, this study showed that utilization of expiry tracking chart was minimal both in HCs and hospitals thus on the day of visit expired drugs and test kits were found on the shelves in few HCs and a single hospital. Similar to this finding, a study done in Lesotho showed that, ARV drugs were expired on the shelves in some facilities where inventory was poorly managed (Pharasi, 2007).

More than three fourth of the hospitals and HCs had stock out of one or more ARV drugs on the day of visit. The percentage of products stocked out was 12.8% and 17% in HCs and hospitals on the day of visit respectively. Regarding the stock status of test kits; 7(36.8%) of the HCs were fully stocked on the day of visit while 2(10.5%) of them were stock out of all the five test kits selected. All of the hospitals were stocked out one or more test kits on the day of visit. Different from this study, a study done in Oromia National Regional State showed that availability of first line ARV drugs was 100% and 95% at HC and Hospitals respectively and another study done in Ethiopia showed that stock outs had been non-existent or minimal for ARVs (Alemayehu, 2009, USAID/ The Global Health Technical Assistant Project, 2009). This study showed in the past 6 months, all of hospitals and HCs faced stock out of 1 or more ARV drugs. TDF300/3Tc300 was most frequently stocked out item in the past 6 months both in hospitals and HCs. Mean number of products stocked out in the past 6 month was 5.1 and 6.5 in HCs and hospitals respectively.

Strategies to cope with stock-outs included lending and borrowing of test kits and ARV drugs among facilities, doing VCT by quota, doing HIV test for PMTCT and emergency purpose and decreasing the amount of drugs dispensed were the major one. An assessment done in Sierra Leon similarly showed that there were stock outs of EFV and second line drugs in ART providing facilities. (Allers *et al*., 2007). In line with this finding, a study done in Uganda showed that, ARV shortages affected all ART-providing facilities with considerable fluctuations. ARVs were available at 83% and diagnostic kits at 70% of the health facilities surveyed (Ricarda *et al.,* 2011).

The mean duration of stock out was longer for d4t6/3tc30 (55.8 days) and tdf300/3tc300 (45.9 days) in HCs while it was longer for tdf300/3tc 300 in hospitals (42.5 days). The mean duration of stock out was more than a month for 3(21.4%) of the products in HCs and hospitals. The mean duration of stock out was longer for majority of the products which is mainly associated with the shortage of supplies from the central level. Both HCs and hospitals faced longer duration of stock outs for tdf/3tc300, which is mainly associated with the large number of patients transferred to this regimen and lack of adequate drug in the supplier store. Similarly, a study done by Jonathan *et al*, showed that interrupted supplies and stock outs are the major challenges in the supply chain of ARV drugs in Africa (Jonathan *et al.,* 2005). This ARV drugs interruption put individual patient at risk of disease progression and death, in drug resistance development, hampers progress towards universal access, and diminishes the credibility of ART programmes in the eyes of patients, community and healthcare providers and generally put the public health in danger (Pasquet *et al.,* 2010). So to prevent this kind of interruption, there has to be efficient supply chain. Effective drug supply management and inventory control avoid stock out, loss due to unnecessary expiry, theft and ensure that the desired pharmaceutical products are available at all times in adequate quantity (RPM Plus, 2006)

Except 2 (10.5%) of HCs; all HCs and hospitals used bin card on the day of visit. However this study reveals that there were few cases where the facilities lack bin card for one or more products. Both HCs and hospitals on average update their bin card every month, where it may extend up to 2 months for HCs. Generally, availability and update of bin card for ARV drugs was relatively better in hospitals than HCs. Unlike ARV drugs only 10(52.6%) of HCs and

2(50%) of hospitals had bin card for the selected test kit on the day of visit. Any of the facilities used minimum maximum inventory control system for test kits. They said since the supply chain fluctuates every time they couldn't use this controlling mechanism. In contrary to this finding an evaluation done in Ethiopia in 2009 states that the inventory control in all surveyed ART sites and use of bin cards and stock cards as an adequate (USAID/ The Global Health Technical Assistant Project, 2009). In line with this finding a study done in Sierra Leone reported that , the stock keeping practice in ART providing health facilities was not good. No stock cards were available for ARV drugs or HIV test kits at any of the PHUs visited (Allers *et al.*, 2007).

To provide clients with high –quality products, each facility must have safe, protected and organized storage areas to ensure efficient handling and use of products; in contrary, this assessment revealed that the storage condition of both hospitals and HCs were not adequate so it leads to inefficient handling and use of drugs. Comparing hospitals with HCs, hospitals had relatively better storage condition. Appropriate arrangement of products with visible expiry dates and identification labels, cleanliness of the store room and thermometer usage were a challenge both in hospitals and HCs. The store premises were better in hospitals and over stocking was a major problem in HCs compared to hospitals. Similarly a study done in Sera Leon also states that the storage condition observed in district and PHUs was not generally in a good condition. Expired drugs and kits were stored together with the usable commodities which bring a shortage of space in the health facilities. (Allers *et al.*, 2007) An evaluation done in Ethiopia similarly showed that there was inadequate storage facilities, management, capacity, and temperature monitoring, especially for the cold chain in the selected health facilities (USAID/ The Global Health Technical Assistant Project, 2009).

There were both computerized and paper based LMIS both in the visited HCs and hospitals. It was reported that the computerized LMIS help facilities to perform their day to day task in a facilitated manner. Similarly literature said that most LMIS related with HIV/AIDS are computer based since HIV/AIDS programs are complex and manage a broad range of commodities so paper-based systems for collecting, aggregating and analyzing data are burdensome (USAID/DELIVER PROJECT, 2008). But this study revealed that there were problems with the use of the automated LMIS. Majority of the facilities complain that they were unable to

manipulate and fix EDT and HCMIS. It was said that some of the features of this software were not easy to manipulate. So there was not adequate and accurate data in both dispensary and store since majority of them rely on the computerized LMIS. A study done by Wendy *et al*. on Computerizing LMIS for managing HIV/AIDS commodities suggest that, computerized LMIS can greatly facilitate the work of supply chain managers. Similarly this study suggests that there was a need for user-friendly tools and software packages to support the management of logistics information that is critical in the supply chain of ART drugs (Wendy *et al.*, 2008). In addition to this inadequate training to the professionals who are going to manage this LMIS might be associated with the difficulty of manipulation and update of the software.

In 13(76.5%) of HCs and all of hospitals the facilities report ending balance as the stock on hand kept in the store room only. These facilities considered the stock moved from the store as an actual consumption which might not reflect the actual consumption so ultimately affects forecasting at national level. There were some cases; where the consumption of some of the drugs were 0 (zero) during the past 6 months from the store e.g. zdv300/3tc150. But there was actual consumption in the facility. This was evidenced that the store keeper said there was large quantity of drugs at the dispensary. So this kind of practice can seriously affect drug supply chain and which might contribute the current shortage of ARV drugs and test kits. In addition to this there was a discrepancy which couldn't be justified by the respondent. Only a single HC report the ending balance as the stock on hand found in the store room and all other places. Generally the quality of the data on LMIS was not adequate.

8. Limitation of the study

- Lack and incomplete bin cards for ARV drugs and test kits in the visited health facilities.
- The study didn't include major stakeholders in the supply chain HIV/AIDS related commodities; PFSA, AACAHB and donors.
- The study didn't include all the components of supply chain management mainly selection, and legal point of view in the country.

9. Conclusions and Recommendations

Even though it has been a decade since ART and VCT services were started but there was not adequate data on patient by regimen and stock status of ARV drugs and Test kits. Majority of the facilities didn't have and utilize patient tracking chart and it seems they left the issue of adherence to the patients themselves.

There was difference between quantity of ARV drugs ordered and received both in hospitals and HCs especially for tdf300/3tc300. The reporting and receiving system of ART drugs were organized compared to HIV test kits both in hospitals and HCs. Almost all of the facilities were not providing VCT service mainly due to lack of KHB on the day of visit. All of the facilities had computerized LMIS in the store and ART pharmacy. There was shortage of ART drugs and test kits both in HCs and hospitals. The stock status of ART drugs were controlled relatively in better way than HIV test kits in HCs and Hospitals. Both HCs and hospitals utilized maximum minimum inventory control system for ARV drugs while they didn't use for HIV test kits due to frequent stock outs. The supply chain of ART drugs and test kits was interrupted and not stable. There were frequent stock outs of ARV drugs and HIV test kits, which are an indicator of weak supply chain. TDF/3TC, KHB and unigold were the major items stocked out in the supply chain. Generally the storage condition was not good but it was relatively better in hospitals than HCs. Regarding the computerized LMIS, in majority of the cases the professionals were unable to manipulate and operate as they desired.

Based on the findings of this assessment the following recommendation can be forwarded for professionals, facilities, supplier and other concerned bodies.

- ART pharmacies in HCs and hospitals should have full and reliable ARV patient information, which is the back bone of any supply chain that flow throughout the supply chain accordingly.
- Facilities should use both paper based and computerized LMIS to minimize loss of patient and drug information and to minimize wastage and shortage of resources.
- All facilities should prepare and send reports regularly, since it is the main factor that affects the supply chain quantification of ARV drugs and test kits.

- All facilities should have expiry tracking chart to prevent and minimize expiry of very expensive ARV drugs and test kits.
- Storage condition of all the facilities should be improved so that safety and efficacy of drugs can be maintained while damage and expiry of products can be minimized.
- Change of regimen should be done by consulting all the stakeholders (prescribers and dispensers) to prevent stock outs like the one that happened on tdf/3tc.
- Adequate training should be given to ART dispensers, data clerks and store manager regarding the computerized LMIS.
- The computerized LMIS should be user friendly, easy to manipulate and fix in cases of minor problem by the professionals themselves.
- Research should be done on the utilization of the computerized LMIS by the health professionals.

References

Addis Ababa City Administration Health Bureau (2013); HIV care and ART, Addis Ababa, as of June 30/2005 E.C (unpublished).

Alemayehu L (2009). Assessment of Supply Management Current Status for Antiretroviral Therapy (ART) in Oromia National Regional State, Ethiopia. Ethiopian Pharmaceutical Associasion, Book of Abstract.

Ali SA, Menzies N, Kenyon T, Melaku Z, Gadisa T, et al, (2011). Scenario-based cost projections for PEPFAR resource requirements for the ART program in Ethiopia from FY2011-FY2015. : 19th International AIDS Conference: Abstract no. TULBE06

Allers C, Timothy O, Meba K (2007). Sierra Leone: Supply Chain Assessment for ARV Drugs and HIV Test Kits. Arlington, Va.:USAID | DELIVER PROJECT Task Order 1.

Allers C and Yasmin C. (2006). Guide for Quantifying ARV Drugs. Arlington, Va.: DELIVER, for the U.S. Agency for International Development.

AVERT (2012).Universal Access to HIV/AIDS Treatment. Available at: http://www.avert.org/universal-access.htm Accessed on: 2/12/12

Business dictiionary.com (2012). Supply chain management (SCM). Available at: http://www.businessdictionary.com/definition/supply-chain-management-SCM.html#ixzz39j7aF7Ch Accessed on: 17/07/2014

City government of Addis Ababa (2012). City Profile, Addis Ababa. Available at: http://www.addisababacity.gov.et Accessed on: 2/12/12

DACA (2010). Standard Treatment Guidelines for General Hospital. Addis Ababa, Ethiopia, 2nd ed.

Elke K, Yirga A, Katherine D, Peter G, Tesfaye A, et al, (2012). Implications of adopting new WHO guidelines for antiretroviral therapy initiation in Ethiopia. Bulletin of the World Health Organization 90:659-663.

Erik JS, Andreas J, Anne BS, Simon DM, Anthony DH, et al, (2011). Antiretroviral drug supply challenges in the era of scaling up ART in Malawi. Journal of the International AIDS Society 14(suppl 1).

Family Health International (2008). Strategies for an expanded and comprehensive response (ECR) to national HIV/AIDS Epidemic, Module 7: Mnanaging the supply of drugs and commodities. Available at: http://www.fhi360.org/en/HIVAIDS/pub/guide/ecrhndbk/mod7.htm Accessed on: 15/12/12

Helena W and Douglas K (2009). Managing Medicines and Supplies for HIV/AIDS Program Scale-up. Washington, DC: Elizabeth Glaser Pediatric AIDS Foundation**.** Available at: http://ftguonline.org Accessed on: 15/01/12

HIV/AIDS Prevention and Control Office (2012). Country Progress Report on HIV/AIDS Response, 2012. Federal Democratic Republic of Ethiopia.

Jonathan D, Nana-Adjoa B, James R, Romuald JM (2005). Medicines supply in Africa. BMJ 331(7519): 709–710.

John Snow, Inc./DELIVER (2004). HIV Test Kit Selection: Operational Considerations for VCT and PMTCT Services. Arlington, VA: John Snow Inc. and DELIVER, for United States Agency for International Development (USAID).

John Snow, Inc./DELIVER (2005). Guidelines for Managing the HIV/AIDS Supply Chain. Arlington, Va.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development.

Keiser O, Orrell C, Egger M, Wood R, Brinkhof MWG, et al, (2008). Public health and individual approaches to antiretroviral therapy: Township South Africa and Switzerland Compared. PLoS Med 5(7): e148. doi:10.1371/jornal.pmed.0050148.

MOH (2005). Guideline for Implementation of Antiretroviral Therapy in Ethiopia. Addis Ababa.

MSH (2000). Managing Drug Supply Training Series, 2nd ed, Participant's Guide. Available at: http://erc.msh.org/newpages/english/drugs/intro_pg.pdf. Accessed on: 22/12/2012

Otoom S, Batieha A, Hadidi H, Hasan M, Al-saudi K (2002). Evaluation of drug use in Jordan using WHO patient care and health facility indicators. East Medit Health J 8:537–543

Pasquet A, Messou E, Gabillard D, Minga A, Depoulosky A, et al, (2010). Impact of drug stock-outs on death and retention to care among HIV-infected patients on combination antiretroviral therapy in Abidjan, Côte d'Ivoire. PLoS One15;5(10):e13414.

PEPFAR (2012). Partnership to Fight HIV/AIDS in Ethiopia. Available at: http://www.pepfar.gov/countries/ethiopia/index.htm Accessed on: 25/12/12

Pharasi B (2007). Assessment of the HIV/AIDS Medical Supplies and Laboratory Commodities Supply Chain in Lesotho. Arlington, VA: Management Sciences for Health.

Pharmaceutical Fund and Supply Agency (2012). Message from director general. Available at: www.pfsa.gov.et Accessed on 14/07/2014

Ricarda W**,** Peter W**,** Florian N**,** Florian S and Don de S (2011). Scaling up antiretroviral therapy in Uganda: using supply chain management to appraise health systems strengthening. Globalization and Health **7**:25

RPM Plus (2006). Standard Operating Procedures for Antiretroviral Drug at Health Facilities: Guidelines for Forms. Arlington, VA: Management Sciences for Health.

USAID/DELIVER PROJECT (2008). Computerized Logistic Management Information System (LMIS) for managing HIV & AIDS Commodities. Available at: http://www.deliver.jsi.com Accessed on: 29/12/12

USAID | DELIVER PROJECT, Task Order 1 (2009). Logistics Indicators Assessment Tool (LIAT): Antiretroviral Drugs. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.

USAID | DELIVER PROJECT, Task Order 1 (2009). Logistics Indicators Assessment Tool (LIAT): Test Kits. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.

USAID/ The Global Health Technical Assistant Project (2009). RPM+/SPS and SCMS in Ethiopia: An Evaluation. DELIVER, for the U.S. Agency for International Development. Available at: http://www.ghtechproject.com/resources.aspx . Accessed on: November 29/2012

Walensky RP, Wood R, Ciaranello AL, Paltiel AD, Lorenzana SB, Anglaret X, Stoler AW and Freedberg KA (2010). Scaling Up the 2010 World Health Organization HIV Treatment Guidelines in Resource-Limited Settings: A Model-Based Analysis. PLoS Med 7(12): e1000382.

Wendy N, Yasmin C, Anubha B, Mimi W and Sarah A (2008). Computerizing LMIS for managing HIV/AIDS commodities. : AIDS 2008 - XVII International AIDS Conference: Abstract no. MOPE0647

WHO (2002). Promoting rational use of medicines: core components. WHO Policy Perspectives on Medicines. Geneva: WHO.

WHO (2009). Fast facts about HIV treatment. Available at: http://www.who.int/hiv/treatment/en/index.html Accesses on: 01/12/2012

WHO (2011). Universal access to HIV/AIDS prevention, treatment and care. Geneva: WHO.

WHO (2012). Global HIV/AIDS Response - Epidemic update and health sector progress towards Universal Access - 2011 Progress Report. Geneva: WHO.

WHO (2012). World health statistics 2012: Indicator compendium.

Yasmin C, Barbara F, Allers C, David A, Marilyn N, and Alexandra Z (2006). Supply Chain Management of Anitretroviral Drugs: Considerations for Initiating and Expanding National Supply Chains. Arlington, Va.: DELIVER, for the U.S. Agency for International Development.

Yasmin C, Eric T, Allers C, and Colleen M (2009). HIV/AIDS Drug Procurement and Supply Chain Management. Washington, DC: Elizabeth Glaser Pediatric AIDS Foundation; 2009. Available at: http://ftguonline.org. Accessed on: December 1/12/2012

List of Annexes

Annex I. Information Sheet

Introduction

Good day and thank you for agreeing to receive us today. My name is Eyerusalem Berhanemeskel. My colleague is _____.I am a student in AAU, school of pharmacy and doing my MSc thesis on the assessment of HIV/AIDS related commodities supply chain management in Addis Ababa public health facilities. Us you know the number of people receiving ART continues to increase through time, so this type of research can be used to assess the current supply chain and it will provide an input for future improvement. We are visiting selected health facilities throughout the city and this facility and you were selected to be included in the assessment.

Purpose

The purpose of the visit today is to assess the availability of HIV/AIDS related commodities at this facility, and to collect information on the supply chain management of these commodities in order to better understand how the logistics system for managing HIV/AIDS related commodities is functioning. This assessment may be conducted again in the future to measure changes in the logistics system over time.

Procedure

After I get your permission my colleague and I will collect the data confidentially. In addition, I would like to visit the storage areas to actually count the products you have in stock today and observe the general storage conditions.

Justice

This facility and you are selected purposively. I am going to visit 23 more facilities based on patient number. I select 12 facilities with high patient burden and 12 facilities with low patient burden.

Risk

Since you are involving in this study I may take 30 – 60 minutes of your time. But this study doesn't have any additional discomfort.

Benefit and compensation

By participating in this study you may not get any compensation or benefit right now. But the results of the assessment will provide information for developing recommendations and planning improvements in the logistics system for these products.

Confidentiality

This is not a supervisory visit and the performance of individual staff members is not being evaluated. We are not going to take any personal identifiers. The collected data will be analyzed in aggregate without making any personal manipulation.

Right to withdraw

If you feel any discomfort or harm, you can withdraw from the study at any time. In addition to this, you are not obliged to answer every question. You have the right not to answer those questions that you do not want to answer.

Contact address

If you have any question or comment, you can contact me by this address.

Eyerusalem Berhanemeskel

Tel: 0912053967

Email: jerabmk@gmail.com

berhanemeskele@yahoo.com

Annex II. Verbal consent

Previously I tried to clear out the purpose of the study, the procedure of the data collection and why you are included in the study. I also discuss the risk, compensation and benefit associated with the study. Finally I illustrate for you how much this study is confidential and how your voluntarism is important for this study. I would first like to ask you about your willingness for this study. Then, with your permission, I would like to speak with you about how the HIV/AIDS related commodities are managed at this facility; particularly I will ask you based on your major task. Your participation is completely voluntary. You can refuse to answer any questions and/or withdraw from the study at any time without any problem. Your name will not be recorded on the questionnaire, and your responses will not be linked to your personal identity at any time.

In addition, I would like to visit the storage areas to actually count the products you have in stock today and observe the general storage conditions. So my colleague and I will collect the remaining data confidentially.

For your part, do I have your permission to continue? Yes ☐ No ☐

If Yes, Continue to the interview, If No, Skip to the next Respondent

Annex III. ARV Drugs Questionnaire and Observation Check List

Addis Ababa University

School of Pharmacy

Department of Pharmaceutics and Social Pharmacy

Date: _____
Facility type: _____
Level of facility: federal_____ regional:_____
Name of the facility:_____

First ask to speak to ART coordinator and Head of the pharmacy . After explaining your purpose asks the questions, visit the warehouse, storeroom, or other storage area where the ARV drugs and test kits are stored. If you are referred to another staff member keep telling the prpose of the visit before data collection.

No	ART service	Answers	Go to/comment
1.	How long have ART services been offered at this facility		
2.	Is the copy of the updated standard treatment guideline available at this facility? If yes ask to see the copy of it	Yes No	
3.	Is there a document that lists all the recommended ARV drug regimens to be prescribed and dispensed at this facility? (	Yes No	
4.	Are the data on the total number of patients on ART at this facility reported to a higher level?	Yes No	
5.	Are the data on the number of patient on ART by regimen reported to higher level?	Yes No	
6.	From where did you get the data	ART pharmacy ART clinic D0n't know	
7.	What report do you use for reporting this information to a higher level? (ask to see		

	a copy of the report)		
8.	Who is the principal person responsible for managing ARV drugs at this facility	Pharmacist Druggist Pharmacy technician Other	
No	**ART pharmacy**	**answers**	**Go to /Comment**
9.	Do you have training (specify)	Yes No	
10.	How much of a supply is dispensed to patients when they come for resupply	Months Days	
11.	Where do you record information on the quantities of ARV drugs dispensed (consumption)?	Daily ART Register Patient Information sheet EDT Not Recorded Other	
12.	What do you say about the general features of EDT? Advantage and dis advantage		
13.	Where do you record information on the quantities of ARV drugs in stock (stock on hand)?	Stock Card Bin Card Not Recorded Other	
14.	Where do you record patient by regimen information?	Daily ART Register EDT Not Recorded	

		Other	
15.	what drug you used for PMTCT and PEP	PMTCT regimen • ..... Mother _____ • ..... Infant _____ PEP • ..... High risk _____ • ..... Low risk _____	
No.	Reporting and ordering	Answers	Go to/comment
16.	What report do you use for reporting to higher level? Ask to see the copy of the report) write the name of LMIS here.		
17.	Verify the type of data collected in the LMIS report (look at the LMIS report to verify)		
a	Received		
b	Issues	Yes No	
c	Consumption	Yes No	
d	Stock on hand	Yes No	
f	Losses/adjustments	Yes	

		No	
i	others(specify)		
18.	Who prepares the orders/reports for ARV drugs for this facility?	head of the pharmacy store manager Other	
19.	When was the last time you submitted the report on consumption and stock on hand of ARV drugs at this facility?	Never Within the last month 2 months ago More than 2 months ago	
20.	How often are you supposed to submit reports to the higher level?	Monthly Bimonthly Quarterly Semi-annually Annually Other	
21.	Are you able to submit you report on time?	Always Most of the time Sometimes Never	
22.	What factors influence not being able to submit your report on time?	Takes too long Not enough time between reports Don't have the form Approval process is too long	

		Difficulties in transmitting reports (mail, email, telephone, collection) Other_____	
23.	How long does it take you to complete your report/order?	Days:_____ Hours:_____	
24.	How did you learn to complete the forms?	On job training Never been trained Other (specify)	
25.	Who determines the quantities of ARV drugs to order? (Circle all that apply.)	Pharmacy department The facility itself Higher level facility Other	
26.	How are the order resupply quantities determined? (ask interviewee to explain the formula used to arrive at the order quantity and note here)	Formula Don't know Other means (specify)	
27.	What factors affect the quantities you order?	No of patients on ARV Size of the store Other	
28.	How many emergency orders for ARV drugs were placed in the past 6 months?	None 1 2 3 More than 3	

		Don't know	
29.	How do you transmit your report/order to the higher level?	Send by facility vehicle Picked up by higher level Other *(specify)*	
30.	**Receiving/ Distribution/ Transportation**	**Answer**	**Go to/comment**
	How often do you receive supplies?	Weekly Biweekly Monthly Bimonthly Other (specify)	
31.	Do you keep a copy of your proof of delivery?	Yes No Don't know	
32.	Do you receive the quantities of ARV drugs that you order?	Always Sometimes	

		Never	
33.	Who is responsible for transporting ARV drugs to your facility?	Supplier This facility collects Other (specify)	
34.	What type transportation is most often used for ARV drugs?	Facility vehicle Supplier vehicle Other (specify)	
35.	On average, approximately how long does it take from the time the facility places an order until the ARV drugs are received?	Less than 2 weeks 2 weeks to 1 month Between 1 and 2 months More than two months	
36.	**Supervision**	**Answers**	**Go to/ Comments**
	When did you receive your most recent supervision visit from your direct supervisor?		
37.	Did your last supervision visit include management of the ARV drugs supply at this facility (e.g. review of stock cards, reports, physical stock count, removal/disposal of expired stock, storage condition)?	Yes No	

38.	**Storage condition, stock keeping practice, physical inventory**	**Answers**	**Go to/comments**
	Do you have a training related to your job? Please specify	Yes No	
39.	Do you use HCMIS in your store?	Yes No	
40.	Can you tell me how HCMIS contributed on your daily job? Advantage and disadvantage		
41.	Are bin cards completed using the smallest unit of count?	Yes (Always) No (not always)	

Storage condition

Ask where the main storage area for ARV drugs is located. Ask for permission to visit the storage area. Assess storage conditions of main storage area *only*. Place a check (tick) mark in the appropriate column based on visual inspection of the storage area; note any relevant observations in the comments column**.** To qualify for a Yes response, all products must meet the criteria for each item.

No	Description	Yes	No	Comments
1.	Products are arranged on shelves with arrows pointing up, and with identification labels, expiry dates, and manufacturing dates clearly visible.			
2.	ARV drugs are stored and organized to FEFO procedures and are accessible for counting and general stock management.			
3.	Outer cartons are in good condition (not crushed, perforated, stained, or otherwise visibly damaged).			
4.	There is separate store for expired and damaged products, and procedures exist for removing them from inventory			
5.	Damaged and expired products are separated from usable products in the storeroom, and procedures exist for removing them from inventory.			
6.	ARV drugs are stored in a dry, well-lit, well-ventilated storeroom. (Visually inspect roof, walls, and floor of storeroom.)			
7.	Expired products are stored with other products haphazardly			
8.	Cartons and products are protected from direct sunlight			
9.	There is no evidence of rodents or insects in the storage area. (Visually inspect the storage area for evidence of rodents [droppings] or insects that can damage or contaminate the products.)			
10.	Storage area is secured with a lock and key but is accessible during normal working hours; access is limited to authorized personnel.			

11.	Roof is maintained in good condition to avoid sunlight and water penetration.			
12.	Storeroom is clean, with all trash removed, no evidence of food and drinks, products stored on sturdy shelves/bins, and boxes organized neatly.			
13.	Current storage space is sufficient for existing products.			
14.	Expiry date tracking chart			

Stock Data for ARV Drugs (for the past 6 months and day of the visit)

INSTRUCTIONS

Column:

1. Name of each ARV drug that will be checked.
2. Whether or not the product is available, is this facility supposed to manage this product? Answer Y for yes or N for no. If the facility has been stocked out of a particular product for a long time, it may report as "not managing." Make sure to ask if the facility is actually supposed to manage the product.
3. Record if the facility is experiencing a stock out of the product on the day of the visit, according to the physical inventory; answer Y for yes or N for no.
4. Check if the bin card is available for each product; answer Y for yes or N for no. If another type of record is used (e.g., stores ledger), note, and continue to gather stock information using another type of record.
5. Check if the bin card has been updated within the last 30 days; answer Y for yes or N for no. Note: If the balance was 0 the last time the bin card was updated and the facility has not received any resupply of ARV drugs, consider the bin card up-to-date.
6. Record whether the facility has had any stock outs of the product during the last six complete months before the day of the visit: answer Y for yes or N for no.
7. Record how many times the product stocked out during the six complete months before the day of the visit according to the bin cards.
8. Record the total number of days the product was stocked out during the last six complete months before the day of the visit.
9. Record the number of days for which any data are recorded on the bin cards, including 0.
10. Reason(s) for stock outs. For any product that experienced a stock out in the last six complete months before the survey, record the specific reason(s) for the stock out.
11. If a Maximum/Minimum Inventory Control System has been established, fill in the maximum and minimum months of stock and order interval in the spaces provided at the bottom of the table

Table 1. Stock Data for ARV Drugs (for the last 6 months and day of the visit)

Product	Managed at this facility? (Y/N)	Stockout today? (Y/N)	bin card available? (Y/N)	bin card updated? (Y/N)	Stockout most recent 6 months? (Y/N)	Number of stockouts (most recent 6 months)	Total number of days of stockout(s)	Number of days of data available on stock card
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
efv 50								
efv 200								
efv 600								
3tc300/tdf300								
nvp200								
zdv300/3tc150								
zdv300/3tc150/nvp200								
3tc30/zdv60/nvp50								
Nvp 240ml								
d4t12/3tc60/nvp100								
d4t6/3tc30/nvp50								
3tc30/zdv60								
d4t12/3tc60								
d4t6/3tc30								

Comments:

10* - Reason for stock out:

1, didn't receive order,

2, did not order on time,

3, don't know how to order,

4, didn't receive the quantity ordered,

5, stock out at the central level,

6, transportation not available for delivery

11. other maximum months of stock _____minimum months of stock_____

Table 2. Difference between quantity ordered and quantity received

INSTRUCTIONS

Column:

1. List the same products as in table 1. (Note: Do this before finalizing the questionnaire and making photocopies.)
2. Enter the date the last order was placed for the regular order period (do not enter date/ quantities for emergency orders or other orders outside of the established order period).
3. Enter the quantity ordered of each product for the last order period for which products were received (do not include quantities on order that have not yet been received).
4. Enter the date the last delivery was received.
5. Enter the quantity received.

Product	Date last order placed	Quantity ordered for last order period	Date last delivery received	Quantity received in last order period
1	2	3	4	5
efv 50				
efv 200				
efv 600				
3tc300/tdf300				
nvp200				
zdv300/3tc150				
zdv300/3tc150/nvp200				
3tc30/zdv60/nvp50				
Nvp 240ml				
d4t12/3tc60/nvp100				
d4t6/3tc30/nvp50				
3tc30/zdv60				
d4t12/3tc60				
d4t6/3tc30				

Table 3. LMIS Data Quality: Usable Stock on Hand at Time of Most Recent LMIS Report

On the basis of the standard operating procedures, determine whether health facilities report stock on hand (SOH) that is kept in the storeroom only or in the storeroom *and* all other places. If the SOH in the LMIS report includes ARV drugs kept in the storeroom and all other places, there will always be a discrepancy between the balance according to the LMIS form (2) and the balance from the bin card (3).

INSTRUCTIONS
Column:

1. List the same products as in table 1. (Do this before finalizing the questionnaire)
2. Obtain the most recent LMIS report for the selected products, and record the SOH from the LMIS report.
3. Write the quantity of usable SOH from the stock records at the time of the selected LMIS report.
4. Note the reasons for any discrepancy.

	Usable Stock on Hand at Time of Most Recent LMIS Report		
Product	Ending balance on recent LMIS report	balance on bin card from time of LMIS report	Reasons for discrepancy
1	**2**	**3**	**4**
efv 50			
efv 200			
efv 600			
3tc300/tdf300			
nvp200			
zdv300/3tc150			
zdv300/3tc150/nvp200			
3tc30/zdv60/nvp50			
Nvp 240ml			
d4t12/3tc60/nvp100			
d4t6/3tc30/nvp50			
3tc30/zdv60			
d4t12/3tc60			
d4t6/3tc30			

Table 4. Observation check list

Ask for the availability of the following documents (hard copy or soft copy) which are recommended by the SOP for ARV drug management for health facilities prepared by RPM plus in 2008. See the copy of them. If the document is not available, not updated ask their reason and fill in the remark boxes.

No	Document/ form	Yes	No	Remark
1	Patient tracking chart			
3	ARV drugs dispensing register for PEP			
4	ARV drugs dispensing register for emergency supply			

Ask the participant(s) if they have any questions or would like to make any comments.

Participant Comments:

Thank the person/people who talked with you.

Additional data collectors Comments:

Brief Analysis of Findings from the Facility Visit

Annex IV. Test Kits Questionnaire and Observation Check List

Addis Ababa University

School of Pharmacy

Department of Pharmaceutics and Social Pharmacy

Date: _____
Facility type: _____
Level of facility: federal_____ regional:_____
Name of the facility:_____

No.	HIV Testing Program Information	Answers	Go To/comments
1.	Do you have a training which relate to your current job? Specify		
2.	How long have HIV counseling and testing services been offered at this facility?	Years: _____ Months: _____	
3.	Do you have a copy of the HIV testing guidelines? *(Ask to see a copy of the guidelines. Mark Yes only if you see the guidelines.)*	Yes No	
4.	For what purposes is HIV testing being provided at this facility? *(Circle all that apply.)*	VCT PMTCT Laboratory/Clinical Diagnosis Other *(specify)*	
5.	Which facility staff is qualified to perform HIV tests at this facility? *(Circle all that apply.)*	Medical doctor Nurse/Counselor laboratory staffs VCT Counselor Other *(specify)*	
6.	Where is HIV testing performed at this facility? *(Circle all that apply.)*	Laboratory ANC Clinic Counseling Room STI Clinic TB Clinic VCT	

No.	HIV Testing Program Information	Answers	Go To/comments
		Other *(specify)*	
7.	Where are HIV test kits stored and managed at this facility? *(Circle all that apply.)*	central medical store separate store other(specify)	

HIV TEST KITS

First, ask to speak to staff member(s) responsible for performing HIV testing and for managing the HIV test kit supply. After asking the questions in this section, visit the warehouse, storeroom, laboratory, or other storage areas where the HIV test kits are stored. If the test kits are stored with ARV drugs then use same storage condition observation check list.

<table>
<tr><th>No.</th><th>Data Collection</th><th>Answers</th><th>Go To/ Comments</th></tr>
<tr><td>1.</td><td>Which HIV test kits are used at this facility?</td><td>KHB
Uni Gold
Stat-pack
others (specify)</td><td></td></tr>
<tr><td>2.</td><td>What is the HIV teting algorithm followed at this facility? (if other, please specify)

KHB……..01
Uni Gold……02
Stat-pack……..03
others (specify)……04 Other (specify)…… …..05</td><td><table><tr><th>Type of test</th><th>no</th></tr><tr><td>Screening</td><td></td></tr><tr><td></td><td></td></tr><tr><td>Confirmatory</td><td></td></tr><tr><td rowspan="2">Tiebreaker</td><td></td></tr><tr><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td><td></td></tr>
<tr><td>3.</td><td>Is the testing algorithm parallel or serial?</td><td>Parallel ___
Serial____</td><td></td></tr>
<tr><td>4.</td><td>Where do you record information on the quantities of HIV tests used?</td><td>VCT daily register
Laboratory Register
Stores Ledger
bin card
Other
Not recorded</td><td></td></tr>
</table>

5.	Where do you record information on the quantities of HIV tests in stock? (Stock on hand)	VCT daily register Laboratory Register Stores Ledger Stock Card Other Not recorded	
6.	Are you providing VCT service today?	Yes No	
7.	Was there any point that you quit providing VCT in the past 6 months	Yes No	
8.	How many times and for how long you stopped provision of VCT service?		
No.	**Reporting and Ordering**	**Answers**	**Go To/ Comments**
	NOTE: If the person performing HIV tests is not responsible for compiling and submitting facility reports on consumption and stock levels of HIV test kits, ask to speak to the appropriate person to answer the following questions in this section.		
9.	What report (LMIS forms) do you use for reporting to a higher level? *(Ask to see a copy of the report.)*		
a.	Insert name of country-specific standard LMIS report here:		
b.	Other *(specify)* _____		
	Record the type of data collected on the LMIS report *(look at the LMIS report to verify):*		
a.	Received	Yes No	
b.	Issues	Yes No	
c.	Consumption	Yes No	
d.	Stock on hand	Yes No	
e.	Losses/Adjustments	Yes No	

10.	Who prepares the orders/reports for HIV test kits for this facility? *(Circle all that apply.)*	store manager head of the pharmacy other(specify)	
11.	When was the last time you submitted the report on consumption and stock levels of HIV test kits to the higher level?	Never Within the past month 2 months ago 3 months ago More than 3 months ago	
12.	How often are you supposed to submit reports to the higher level?	Monthly Quarterly Semi-annually Annually Other	
13.	Are you able to submit your report on time?	Always Most of the time Sometimes Never	
14.	What factors influence not being able to submit your report on time?	Takes too long Not enough time between reports Don't have the forms Approval process takes too long Difficulties in transmitting reports (mail, email, telephone, no one came to collect the report) Other	
15.	How long does it take you to complete your order/report?	Days: _____ Hours: _____	
16.	How did you learn to complete the forms for collecting and reporting data on HIV test kits at this facility? *(Circle all that apply.)*	During a training workshop On-the-job training Never been trained Other *(specify)*	
17.	Who determines the quantities of HIV test kits to order? *(Circle all that apply.)*	The facility itself Higher-level facility Other	

18.	How are resupply quantities determined? *(Ask interviewee to explain the formula used to arrive at the order quantity and note here.)*	Formula Don't Know Other means *(specify)*	
19.	What factors affect the quantities you order?	No of possible clients Size of the store Other	
20.	How many emergency orders for HIV test kits were placed in the past 6 months?	None 1 2 3 More than 3 Don't Know	
21.	How do you transmit your report/order to the higher level? *(Circle all that apply.)*	Send by facility vehicle Picked up by higher level Other *(specify)*	
No.	**Receiving/Distribution/ Transportation**	**Answers**	**Go To/ Comments**
22.	How often do you receive supplies?	Weekly Monthly Bimonthly Quarterly Biannually Annually other(specify)	
23.	Do you keep a copy of your proof of delivery (POD)?	Yes No Don't Know	
24.	Do you receive the quantities of HIV test kits that you order?	Always Sometimes Never	
25.	Who is responsible for transporting HIV test kits to your facility? *(Circle)*	Local supplier delivers This facility collects Other *(specify)*	

26.	What type of transportation is most often used for HIV test kits?	Facility vehicle supplier vehicle Other *(specify)*	
27.	On average, approximately how long does it take from the time the facility places an order until the HIV test kits are received?	Less than 2 weeks 2 weeks to 1 month Between 1 and 2 months More than 2 months	
No.	**Supervision**	**Answers**	**Go To/ Comments**
28.	When did you receive your most recent supervision visit by your direct supervisor for the HIV testing program? *(Check visitors' book, if necessary.)*	Never received Within the past month Within the past 3 months Within the past 6 months More than 6 months ago Other *(specify)*	
29.	Did your past supervision visit include management of test kits at this facility (e.g., review of stock cards, reports, physical stock count, removal/disposal of expired stock, storage conditions)?	Yes No	

If there is separate store

No.	**Stock-keeping Practices/Physical Inventory**	**Code Classification**	**Go To**
1.	Do you have a training related to this job? (specify)		
2.	Are bin cards completed using the smallest unit of count? *(Count HIV tests, not kits.)*	Yes *(always)* No *(not always)*	

Table 1. Storage Conditions

No	Description	Yes	No	Comments
1	Products are arranged on shelves with arrows pointing up, and with identification labels, expiry dates, and manufacturing dates clearly visible.			
2	HIV test kits are stored and organized to FEFO procedures, and are accessible for counting and general stock management.			
3	Outer cartons are in good condition (not crushed, perforated, stained, or otherwise visibly damaged).			
4	There is separate store for expired and damaged products, and procedures exist for removing them from inventory			
5	Damaged and expired products are separated from usable products in the storeroom, and procedures exist for removing them from inventory.			
6	Expired and damaged products are store with other products haphazardly			
7	HIV test kits are stored in a dry, well-lit, well-ventilated storeroom. *(Visually inspect roof, walls, and floor of storeroom.)*			
8	Cartons and products are protected from direct sunlight.			
9	There is no evidence of rodents or insects in the storage area. *(Visually inspect the storage area for evidence of rodents [droppings] or insects that can damage or contaminate the products.)*			
10	Storage area is secured with a lock and key, but is accessible during normal working hours; access is limited to authorized personnel.			
11	Roof is maintained in good condition to avoid sunlight and water penetration.			
12	Storeroom is clean, with all trash removed, no evidence of food and drinks, products stored on sturdy shelves/bins, and boxes organized neatly.			

13	Current storage space is sufficient for the existing products			
14	Expiry tracking chart			

Stock Data for HIV Test Kits (for the past 6 months and day of the visit)

1. Name of each test kits that will be checked.
2. Whether or not the product is available, is this facility supposed to manage this product? Answer Y for yes or N for no. If the facility has been stocked out of a particular product for a long time, it may report as "not managing." Make sure to ask if the facility is actually supposed to manage the product.
3. Record if the facility is experiencing a stock out of the product on the day of the visit, according to the physical inventory; answer Y for yes or N for no.
4. Check if the bin card is available for each product; answer Y for yes or N for no. If another type of record is used (e.g., stores ledger), note, and continue to gather stock information using another type of record.
5. Check if the bin card has been updated within the last 30 days; answer Y for yes or N for no. Note: If the balance was 0 the last time the bin card was updated and the facility has not received any resupply of test kits, consider the bin card up-to-date.
6. Record whether the facility has had any stock outs of the product during the last six complete months before the day of the visit: answer Y for yes or N for no.
7. Record how many times the product stocked out during the six complete months before the day of the visit according to the bin cards.
8. Record the total number of days the product was stocked out during the last six complete months before the day of the visit.
9. Record the number of days for which any data are recorded on the bin cards, including 0.
10. Reason(s) for stock outs. For any product that experienced a stock out in the last six complete months before the survey, record the specific reason(s) for the stock out.
11. If a Maximum/Minimum Inventory Control System has been established, fill in the maximum and minimum months of stock and order interval in the spaces provided at the bottom of the table

Table 1. Stock Data for HIV Test Kits (for the last 6 months and day of the visit)

Product	Managed at this facility? (Y/N)	Stockout today? (Y/N)	bin card available? (Y/N)	bin card updated? (Y/N)	Stockout most recent 6 months? (Y/N)	Number of stockouts (most recent 6 months)	Total number of days of stockout(s)	Number of days of data available on stock card
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
KHB								
Stat pack								
Uni-Gold								
Capillary EDTA ?Tube								
Contact Lancet								

Comments:

10* - Reason for stock out:

1, didn't receive order,

2, did not order on time,

3, don't know how to order,

4, didn't receive the quantity ordered,

5, stock out at the central level,

6, transportation not available for delivery

11. maximum months of stock _____minimum months of stock_____

Table 2. Percentage Difference between Quantity Ordered and Quantity Received

INSTRUCTIONS

Column:

1. List the same products as in table 1. (Note: Do this before finalizing the questionnaire and making photocopies.)
2. Enter the date the last order was placed for the regular order period (do not enter date/quantities for emergency orders or other orders outside of the established order period).
3. Enter the quantity ordered of each product for the last order period for which products were received (do not include quantities on order that have not yet been received).
4. Enter the date the last delivery was received.
5. Enter the quantity received.

Product	Date Last Order Placed	Quantity Ordered for Last Order Period	Date Last Delivery Received	Quantity Received in Last Order Period
1	2	3	4	5
KHB				
Stat pack				
Uni-Gold				
Capillary EDTA Tube				
Contact Lancet				

Table 3. LMIS Data Quality: Usable Stock on Hand at Time of Most Recent LMIS Report

On the basis of the standard operating procedures, determine whether health facilities report stock on hand (SOH) that is kept in the storeroom only or in the storeroom *and* all other places. If the SOH in the LMIS report includes ARV drugs kept in the storeroom and all other places, there will always be a discrepancy between the balance according to the LMIS form (2) and the balance from the bin card (3).

INSTRUCTIONS

Column:

1. List the same products as in table 1. (Do this before finalizing the questionnaire)
2. Obtain the most recent LMIS report for the selected products, and record the SOH from the LMIS report.
3. Write the quantity of usable SOH from the stock records at the time of the selected LMIS report.
4. Note the reasons for any discrepancy.

	Usable Stock on Hand at Time of Most Recent LMIS Report		
Product	Ending balance on recent LMIS report	balance on bin card from time of LMIS report	Reasons for discrepancy
1	**2**	**3**	**4**
KHB			
Stat pack			
Uni-Gold			
Capillary EDTA Tube			
Contact Lancet			

Ask the participant(s) if they have any questions or would like to make any comments.

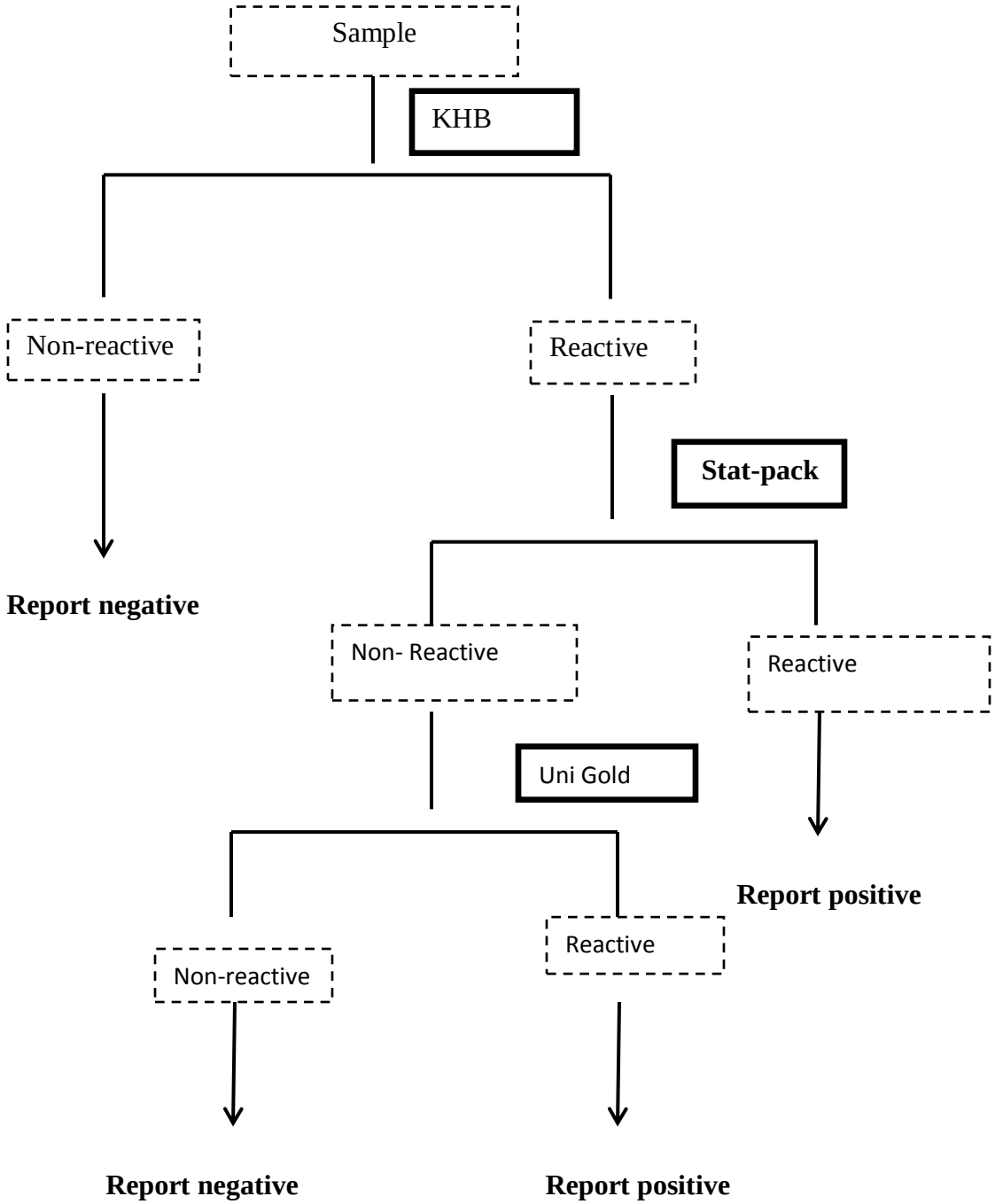
Participant Comments:

Thank the person/people who talked with you.

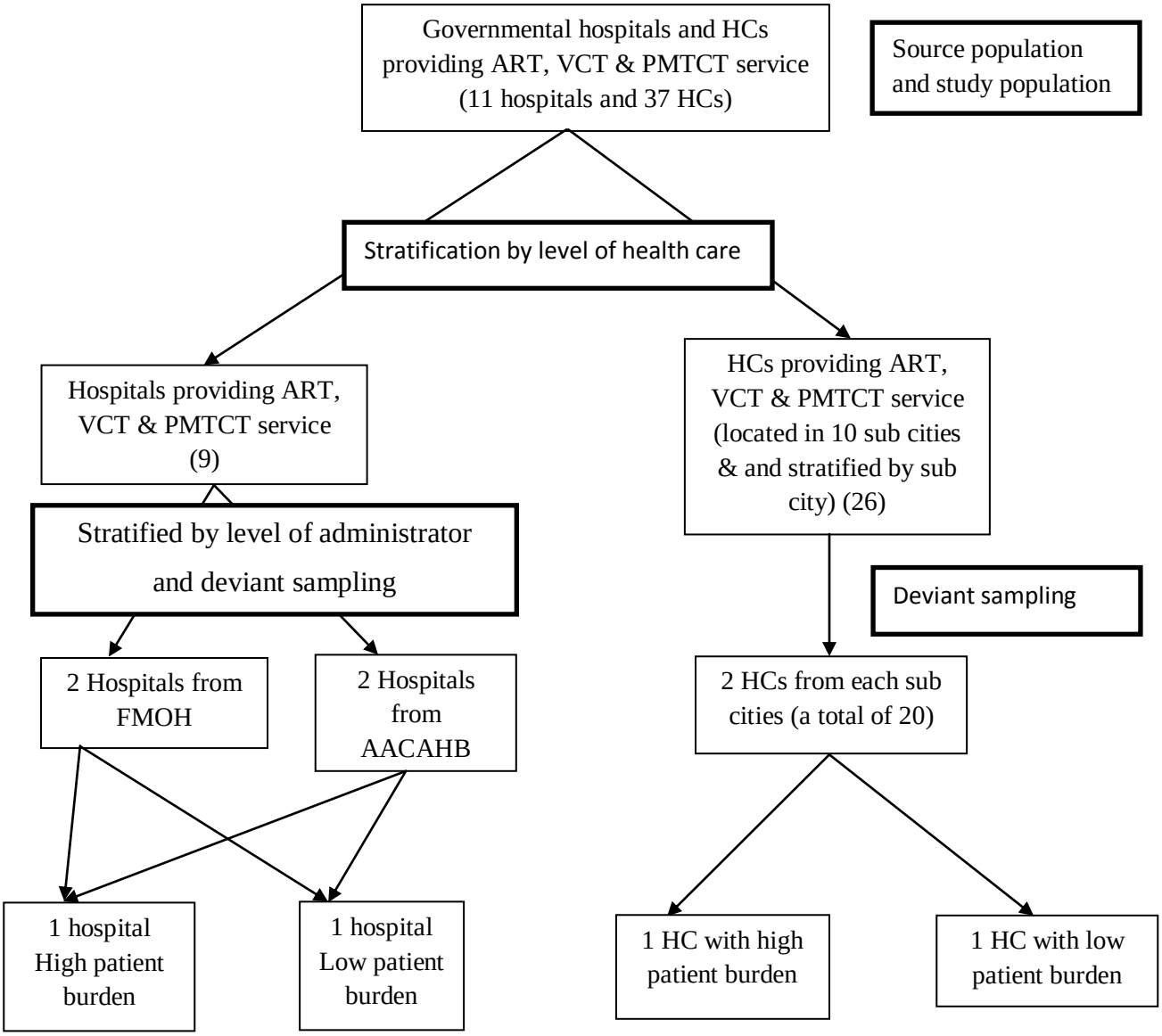
Additional data collectors Comments:

Brief Analysis of Findings from the Facility Visit

Annex V: HIV testing algorithm, Addis Ababa, Ethiopia, November 2013



Annex VI. Sampling frame for the health facilities providing ART, VCT, PMTCT service in Addis Ababa, Ethiopia, 2013



Annex VII: List of Health Facility Visited

Level of facility	Administrator	Patient burden	
		High Patient burden	Low patient burden
Hospital	FMOH	Alert Hospital	St. Peter memorial hospital
	AACAHB	Zewditu memorial hospital	Gandi memorial hospital
Health centers	Arada	Arada Health center	Kebena health center
	Gulele	Shiromeda health center	Selam health center
	Lideta	Teklehaymanot health center	Lideta health center
	Nifas Silik	Woreda 3 health center	Woreda 9 HCs
	Kirkos	Kirkos health center	Meshualekia HCs
	Yeka	Kotebe health center	Entot no.1 health center
	Bole	Bole 17 health center	Bole 17/20 health center
	Kolfe	Kolfe health center	Woreda 24/9 health center
	Addis ketema	Woreda 7 health center	Addis Ketema health center
	Akaki kality	Kality health center	Akaki Health center

Annex VIII: Standard Formula That All of the Professionals Used to Determine The Quantity to be Ordered

Beginning Balance	Quantity Received	Loss/ Adjustment	Ending Balance	Calculated Consumption	Days of Stock Outs	Maximum Stock Quantity	Quantity Needed to Reach Max	Quantity Ordered
A	B	C	D	E (A+B) ± (C-D)	F	G $\frac{120*E}{(60-F)}$	H G-D	I

Annex IX: Copy of Ethical Clearance Letters