ST MARY'S UNIVERSITY
SCHOOL OF GRADUATE STUDY
FACULTY OF BUSINESS

ASSESSMENT OF SUPPLY CHAIN MANAGEMENT SYSTEM OF MEDICAL LABORATORY SERVICES IN ETHIOPIA, THE CASE OF ART PROGRAM

BY

GIZACHEW KEDIDA RIKITU
SGS1/0050/2004

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ENDORSEMENT

This thesis has been submitted to St Mary's University, school of graduate studies for examination with my approval as a university advisor.

Dr Matiwos Ensermu, PHD	signature & Date

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ACCRONYMYS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy or Treatment
ARV	Antiretroviral
COP	Country Operation Plan
DHS	Demographic and Health Surveys
EHNRI	Ethiopian Health and Nutrition Research Institute
EID	Early Infant Diagnosis
FMoH	Federal Ministry of Health (Ethiopia)
FMHACA	Food, medicine and healthcare administration and control authority
GHTF	Global Harmonization Task Force
HAPCO	HIV/AIDS Prevention and Control Office
IVD	In-vitro Diagnostics
NLS	National Laboratory Systems
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Child Transmission
PSM	Procurement and supplies management
SPM	Strategic Plan for intensifying the Multi-sectoral HIV and AIDs response
UNDAF	UN Development Assistance Framework
VAW	Violence against Women
VCT	Voluntary Counseling and Testing
WHO	World Health Organization.

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ABSTRACT

There are people living with HIV in all parts of the world, from all walks of life and cultures, all ages and all genders where some are more affected than others, and some have better access to services than others. Acquiring HIV is no longer means certain death as it has been observed that a person on HIV treatment in a high-income setting now has nearly the same life expectancy as a person who does not have the virus. More than 78 million people have been infected with HIV and 39 million have died since the start of the AIDS epidemic at a global level and HIV/AIDS remained uncontrolled and continued to be a major public health problem at a global and national level.

Laboratory commodities are used in the provision of HIV/AIDS prevention, care and treatment services while efficient and effective procurement of laboratory items critically impacts the quality of all laboratory services albeit laboratory items are numerous and creates serious challenges to procurement agencies. Policies help set standards for laboratory practice, including the tests and techniques that will be used at each level in the system, which ultimately dictate the commodities that are required to support laboratory services where the unique characteristics of laboratory commodities impact the way in which the supply chain should be designed and managed to ensure the availability of these commodities. Testing results are only of value to those making clinical decisions if the test results reported are timely and correct The organization of laboratories in a country will be determined by local policies, administrative structure of the health system, geography, and population consideration where by the laboratory network is often or may be organized by administrative levels like other health services.

Assessment of the national SCMS of medical laboratory services for the ART program examines how well the system is organized and structured against the consensus of national framework indicators and how well the laboratory SCMS for ART monitoring is carried out against known ART SCMS indicators.

Checklists & interview were used to collect secondary and primary information respectively and descriptively analyzed for conformances.

The assessment showed the absence of most of the national laboratory program working frameworks and absence of important monitoring tools & practice to monitor the SCMS. Only limited laboratory tests are found to be used for ART patients monitoring while most of supplies for many testing services are found to be irregular and stock outs. The coverage of ART laboratory facility is also found to be less than 9% compared to number of health centers and hospitals across the country. Strong recommendations are drown to FMoH and other agencies to fulfill all the working frameworks and SCMS monitoring mechanisms to strengthen the laboratory program in general and the ART SCMS in particular.

CHAPTER I: INTRODUCTION

1.1. Background of the Study

There are people living with HIV in all parts of the world, from all walks of life and cultures, all ages and all genders. Some are more affected than others, and some have better access to services than others. At the end of 2013, there were 35 million [33.2 million–37.2 million] people living with HIV globally. Seventy per cent of the people living with HIV are located in sub-Saharan Africa. There are 3.2 million children and 2.1 million adolescents living with HIV. There are 4.2 million people 50 years and older living with HIV.

More than 78 million people have been infected with HIV and 39 million have died since the start of the AIDS epidemic at a global level. HIV/AIDS remained uncontrolled and continued to be a major public health problem at a global and national level.[10]

The 2011 UN High Level Meeting, at its Political Declaration on HIV/AIDS, set ten targets and commitments which among others include halving sexual transmission of HIV, ensuring that no children are born with HIV infection, increasing access to antiretroviral therapy to 15 million people and halving tuberculosis deaths in people living with HIV, by 2015. The Declaration also clearly underscores an urgent need to increase access to HIV services, particularly for those most at risk; and pledges to address gender-related inequalities without delay. It also called for monitoring of progress in implementation commitment and requires the UN General-Secretary to issues regular progress reports.

The world is embarking on a Fast-Track strategy to end the AIDS epidemic by 2030. To reach this visionary goal after three decades of the most serious epidemic in living memory, countries will need to use the powerful tools available, hold one another accountable for results and make sure that no one is left behind. HIV infections may not disappear in the foreseeable future, but the AIDS epidemic can be ended as a global health threat. To achieve this by 2030, the number of new HIV infections and AIDS-related deaths will need to decline by 90% compared to 2010.[14]

However, recent CDC reporting shows that only three Americans in 10 with HIV had the virus under control in a 2011 snapshot of the epidemic **"**and the great majority of those with infections

out of control had been diagnosed but were not still in care."And most of those whose virus remained out of control knew they had HIV but were not in medical care, according to a new Vital Signs analysis online "The findings are important because they show that we have much, much further to go," CDC Director Tom Frieden, MD, told reporters in a media briefing on the report.[15]

Acquiring HIV is no longer means certain death. A person on HIV treatment in a high-income setting now has nearly the same life expectancy as a person who does not have the virus. However, only two out of five people living with HIV have access to antiretroviral therapy. Among people who do have access, great inequities exist. Globally, only 38% [36–40%] of adults (15 and older) living with HIV and 24% [21–26%] of children living with HIV have access to treatment. As of 2013, 12.9 million people had access to antiretroviral therapy.[11]

The importance of quality laboratory services is indisputable. Medical laboratory services are an essential, yet often neglected, component of health systems in developing countries like Ethiopia. Their central role in public health, disease control and surveillance, and patient management is often poorly recognized by governments and donors. As developing countries strive to satisfy the United Nations Millennium Development Goals (MDG) and achieve universal access to HIV/AIDS treatment, establishing and strengthening functional national laboratory systems (NLS) as part of the overall health system will be critical. In many industrialized countries, functional NLS ensure a first-line response to support prevention, treatment, surveillance, and outbreak investigations; however, in developing countries, it has been financially neglected. [5]

Laboratory services support clinical practice by screening for different conditions and providing information for differential diagnosis, allowing clinicians to choose appropriate treatment regimens and monitor treatment. When diseases are diagnosed incorrectly, not only does the patient suffer, but valuable medicines are wasted treating a disease for which they are not effective. Correct diagnoses based on laboratory tests would prevent incorrect diagnoses and treatment, and the money saved could be used to purchase drugs and treat patients effectively. Monitoring tests enable clinicians to determine whether treatment is efficacious or toxicity is developing, enabling them to take action to protect the patient. In public health, laboratory tests are necessary to identify the causal agent of an epidemic (e.g., yellow fever, meningitis, severe acute respiratory syndrome); early identification of the causative agent allows rapid treatment and containment of the disease to prevent further spread.[6]

"Things happen...we can't be perfect" is a recent quote from a clinical laboratory workers in a hospital when asked on a survey why the critical results of patient's tests may not be properly reported. Unfortunately, this is not an uncommon issue in providing quality patient care in today's highly competitive, highly cost-conscious health care systems. "Laboratory processes are designed on the premise that nothing will go wrong." The importance and relevance of laboratory processes in improving the quality of clinical outcomes was emphasized by Dock when she stated that "70% of all information used by a clinician to diagnose and treat a patient comes from the laboratory." [2]

The laboratory component of the HIV/AIDS program in Ethiopia has been one of the most challenging areas of the program and the target of a National Master Plan developed and being implemented by EHNRI. The Master Plan achieved a standardization of laboratory equipment and testing supplies, and has overseen the roll out of laboratory testing capacity to more than **441** hospitals and health center laboratory sites. PEPFAR through CDC has been the principal provider of funds for laboratory reagents and supplies; laboratory equipments have also been purchased using both Global Fund and PEPFAR funds. Until December 2006, procurement and distribution of the ART testing sites was contracted to a private firm, the Private Laboratory Consortium (PLCU). The latter was also responsible for maintenance of equipments. SCMS is currently charged with handling the procurement of laboratory commodities; with PFSA managing distribution with technical support form SCMS. Currently, EHNRI has also taken over the oversight of equipment maintenance.[6]

1.2. STATEMENT OF THE PROBLEM

Ethiopia is the 2nd populous nation in Africa with about 100 million population as the estimate of July 2013. Addis Ababa is the capital city of Ethiopia and the residence for the head quarters of the African Union states (AU) as well as numerous of United Nations continental and regional headquarters including Economic Commission for Africa (ECA), tremendous international and diplomatic offices and residences. Ethiopian is responsible to provide a well organized healthcare system for its people and all these international dwellers.

A comprehensive and effective response to HIV/AIDS requires multi-sectoral and multi-programmatic coordination across a range of programs that rely on a diverse portfolio of commodities. Securing commodities for these programs and sustaining the continuity of commodities in rapidly growing programs necessitates strong supply chain management, resources, coordination and harmonization.[6]

The expansion of programs for human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), tuberculosis (TB), and malaria requires strong and supportive laboratory services. For antiretroviral therapy (ART) in particular, there has been a growing recognition of this importance, given the number of laboratory tests required to effectively monitor treatment. Well-functioning supply chains will enhance the availability of the commodities required to provide necessary laboratory services.

The main purpose of any supply chain management system is to get the right product, in the right quantity, with the right quality, to the right place, at the right time. There are usually two parts of supply chain management: supply chain planning – deciding what to do, and supply chain execution – communicating and executing the plan, as well as identifying and handling exceptions. Approaches to supply chain planning can be operational, planning the day-to-day operations; tactical, planning week-to-week or month-to-month; or strategic, which is conducted once a year or so and is focused on how the network is structured**.** Though tremendous international organizations experience has shown to strengthen laboratory supply chains, it is necessary to look at management practices, capacity, and services including the way laboratories function, like their human resource and equipment capacity that will impact the use of products.

The basic information in laboratory logistics may include; the function and organization of laboratory services, Commodities for laboratory services—reagents, consumables, durables, and equipment, and Supply chain considerations for management of laboratory commodities.

Resources mobilized for AIDS programmes continue to rise. In 2013, US$ 19.1 billion was invested in the AIDS response in low- and middle-income countries—an increase of about US$ 250 million over the amounts invested in 2012. Countries themselves have largely driven recent increases in AIDS investments, as international HIV assistance has flattened in recent years. As they increase domestic AIDS investments, more countries are adopting an investment approach, focusing resources on the most effective programmes and on the populations and geographical settings where need is greatest. With the dramatic increase in HIV resources over the past decade, the world is closing in on the target of mobilizing US$ 22–24 billion annually by 2015, although even more funding will be required to end the AIDS epidemic by 2030.[14]

Ethiopia is one of the highly benefiting countries globally for HIV/AIDS programmes acquiring a total fund of 199,924,923.30 USD in 2006 E.C. (2013/2014) Fiscal year mainly from global fund, CDC and IGAD, while the Ethiopian government has allocated 7,620,149.60 Birr. Earlier estimation of people living with HIV in Ethiopia was said to be about 1.5 million when ART was launched in 2004/2005. The federal HAPCO report shows that 805,948 people has been registered ever since the ART program launched and only 344,344 (42.7%) people are currently on ART indicates 561,604 (42.7%) of them are likely deceased. There were approximately 45,200 (36,500-55,200) AIDS related deaths in 2013 and about 898,400 (770,700 – 1,048,500) AIDS orphans in the same year. HIV adult prevalence is estimated at 1.5% in 2011, the year in which the last Ethiopian Demographic Health Survey (DHS) was conducted.[8]

Table 1: Six Years projected major indicators of HIV/AIDS burden in Ethiopia; Adopted from HIV Related Estimates and Projections for Ethiopia

Years	Positive Cases	New Infection	Annual Deaths	People in need of ART
2011	789,960	24,236	53,831	383,960
%		3.07	6.81	48.60
2012	759,268	20,158	41,444	398,686
%		2.65	5.46	52.51
2013	734,048	18,384	34,365	420,167
%		2.50	4.68	57.24
2014	711,446	16,849	30,378	443,121
%		2.37	4.27	62.28
2015	691,073	15,073	26,489	464,520
%		2.18	3.83	67.22
2016	671,941	14,405	24,813	485,025
%		2.14	3.69	72.18

Table 2: Current ART centers (HAPCO latest report)

Region	Governmental Hospitals	Governmental Health Centers	Private Health Facilities	Others	Total ART Health facilities
Tigray	14	86	2	0	102
Afar	5	16	0	0	21
Amhara	19	192	9	0	220
Oromiya	42	266	9	0	317
Somali	7	9	0	3	19
Benshangul	2	18	0	1	21
SNNP	22	155	5	0	182
Gambella	1	12	0	3	16
Harari	2	4	2	1	9
Addis Ababa	11	54	16	7	88
Diredawa	1	16	2	0	19
Armed Forces	0	0	0	33	33
Total	**126**	**828**	**45**	**48**	**1,047**

Table 3: ART Coverage since the commencement of ART Services in Ethiopia

Region	# of ART need in 2013/2014 (2006 E. C)	Cumulative # of Patients ever enrolled for ART	Cumulative # of Patients ever Started ART	Current # of Patients Under ART	% of Patients Currently Under ART	Current % of Patients Under ART Since the Start of ART
Tigray	33,224	72,783	46,098	31,949	96.2	69.3
Afar	10,864	9,972	5,920	3,320	30.6	56.1
Amhara	111,724	222,171	139,995	102,088	91.4	72.9
Oromiya	120,256	194,357	115,315	80,786	66.5	70.1
Somali	22,511	4,392	3,443	1,727	7.7	50.2
Benshangul	4,754	7,705	4,530	3,279	69	72.4
SNNP	58,726	68,327	38,841	26,260	44.7	67.6
Gambella	8,945	11,667	5,702	4,169	46.6	73.1
Harari	2,132	8,151	5,304	3,392	>100	64.0
Addis Ababa	52,983	173,120	105,638	74,661	>100	70.7
Diredawa	5,524	13,126	8,213	5,628	>100	68.5
Armed Forces		20,177	13,650	7,085		51.9
Total	**431,643**	**805,948**	**492,649**	**344,344**	**79.8**	**69.9**

The ART coverage should basically engage the mobilization, coordination, organization and utilization of multiples of resources including the human, infrastructure and supplies where the laboratory supplies are one of the major resources. The ART need projection in table 1 above shows 48% in year 2011 of the projection and it shows gradual increase coverage through the projection course to reach 72.18% in the year 2016 leaving significant coverage gap (28.88%) unmet.

Managing supply chains in support of laboratory services is a formidable challenge, especially in developing countries and it seems worse in Ethiopia. Laboratory services play a significant role in a country's health system and in the delivery of quality health services. Expanding programs for human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), tuberculosis (TB), malaria, and other communicable and non-communicable diseases require strong and supportive laboratory services. Laboratory capacity depends on the availability of the required commodities to perform these tests, with most tests requiring multiple commodities to be available simultaneously. Well-functioning supply chains will enhance availability of the

commodities required to provide the necessary laboratory services.

The organization of laboratories in a country will be determined by local policies, administrative structure of the health system, geography, and population considerations. Like other health services, the laboratory network is often organized by administrative levels:

1. Central or national reference laboratories provide all laboratory services possible within the health system of the country.

2. Intermediate laboratory facilities provide less complex services.

3. Peripheral labs, which are usually located at the health centers and smaller service delivery sites, provide basic laboratory services.

There can be variations in this structure, and the relationships between these structures can vary between countries. For example, the expansion of HIV and AIDS and malaria programs has expanded the use of laboratory commodities out of traditional laboratory settings and by non-laboratory personnel. HIV tests may have once been administered only through laboratory scientists, but now can be administered by nurses, counselors, and health workers in voluntary counseling and testing (VCT) clinics and through mobile units.

Typically, higher-level laboratory facilities provide supervision, quality control, and technical support to lower-level facilities. Figure 1 illustrates a common organizational structure for laboratory services.

1.3. Research Questions

1.3.1. What are the levels of commitments of the FMoH, agencies and RHBs for the overall medical laboratory services in general and Laboratory supplies management system for the ART program in particular in Ethiopia?

1.3.2. Who is responsible to design the national and regional strategy of Laboratory supplies management system for the ART program in Ethiopia?

1.3.3. What is the strength of collaboration, support and information flow up and down between FMoH and RHBs?

1.3.3. Who is responsible to monitor and evaluate the effectiveness and efficiency in the strategic implementation of LSCMS of ART program functionality and operation?

1.3.4. What are the strengths and constraints of the national medical laboratory supplies strategy

and the system of implementing that strategy?

1.4. Objectives of the Study

1.4.1 General Objective

To assess the national plan and strategy of supply chain management system of medical laboratory services in Ethiopia for the ART program.

1.4.2 Specific Objectives

1.4.2.1 To review the commitment levels of FMoH and RHBs for the overall national and regional laboratory services in general and the ART supplies chain management system in particular in Ethiopia.

1.4.2.2 To assess the availability and implementation of national strategy and working framework of national laboratory operational program relevant to ART supplies chain management system in Ethiopia.

1.4.2.3 To assess and describe the monitoring mechanisms national laboratory supplies chain management system in various stakeholders.

1.4.2.4 To identify strengths and constraints of the national laboratory supplies chain management system.

1.5. Hypothesis

Not applicable.

1.6. Definition of Terms

Analyte: Substances that are identified or measured by the test e.g. antibodies or antigen.

CD4: Also known as T4 cells, CD4 cells are one of several types of T cells that are important to the immune response. They protect against viral, fungal, and protozoal infections and are the cells most susceptible to HIV. A CD4 count is an indicator of the health of patients' immune systems and thus their risk of developing opportunistic infection. Test results from a CD4 count can also be used to judge when antiretroviral therapy should begin (see T cell count).

Coefficient of variation: The coefficient of variation (CV) is a measurement of the precision (or reproducibility) of a laboratory test or process. Modern instruments have a CV of 3 percent to 5

percent. When all other parameters are equal, the lower the CV, the better the test.

Consumables: Items that are used once during testing and are not reused e.g. gloves, pipette tips, slides, cover slips, etc.

Device evaluation is the expert assessment of performance and function of a given device.

Diagnostics: In this document refers to an in vitro diagnostic medical device such as rapid diagnostic test, enzyme immunoassays, and other formats.

Equipment: Items such as analyzers that may be used for a range of specific tests and general laboratory equipment such as centrifuges, pipettes and incubators

External quality assessment: A program designed to assess laboratory performance, i.e. assessment of the quality of the entire testing process from collection of specimen, the testing procedure, to the reporting of testing results. Usually composed of one or more of the following activities: site visits, participation in external quality assessment schemes/proficiency testing and inter-laboratory comparison.

Good laboratory practice (GLP) includes the practices, processes, and conditions required for high-quality laboratory studies to be planned, performed, monitored, and reported.

IVD Medical Device: A device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Maintenance spares are often overlooked but are necessary for a functioning laboratory. Without adequate spare parts, the laboratory cannot provide reliable service. Most manufacturers can provide an accurate prediction of the type and number of parts required for a given instrument for one year.

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,

- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (ISO 13485:2003, 3.7; developed by GHTF)

Procurement is the process of obtaining what is required by the plans.

PSM plan: Procurement and supply chain management plan

Quality assurance: Planned and systematic activities to provide confidence that an organization fulfills requirements for quality, i.e. to ensure the quality of the testing process including quality of diagnostics and items/equipment.

Quality control: A measure to control of the quality of the test itself. QC does not totally control for the provision of correct testing results.

Quality management system: A management system, comprising an organizational structure, procedures, processes and resources, to direct and control an organization with regard to quality.

Reagents: Chemical and biological components used in the testing process

Test kits: Individual platforms or devices that include reagents required to carry out a test

Reagents are the chemical or biological substances used in laboratory testing to detect or measure an analyte (see definition). They vary widely in cost, stability, cold/cool chain requirements, availability, and associated hazards.

Recognized Standards: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Regulatory Authority (RA): A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Reliability of a test is measured in precision. Reliability is not directly related to the sensitivity of the technique but rather to its reproducibility. For example, automated instruments provide more reliability than manual techniques. As shown by the coefficient of variation—the measurement of precision reported in percentage—automated instruments typically have a CV of less than 8 percent while manual procedures may have a CV of 15 percent or more.

Sensitivity is the probability that a test is positive if the person being tested has the disease or condition. That is, high-sensitivity assays detect a high percentage of true positives. Screening tests, such as rapid HIV tests, must be highly sensitive. Screening tests may require confirmation with a highly specific test, such as the Western blot test.

Specifications: operational parameters from the manufacturer of a reagent, test, or instrument are defined in the specifications. Specifications may be found in package inserts and instrument manuals. National and international approval of reagents, tests, or instruments is based on meeting those specifications.

Specificity is the probability that if a test is negative, then the person being tested does not have the disease or condition. That is, high-specificity assays detect a high percentage of true negatives. A highly specific test should be used when a need exists to minimize the number of false negatives, for example, when diagnosing an infection in an individual.

Standard operating procedures (SOPs) explain step-by-step how to do a particular test, including specimen requirements, environmental conditions, reference ranges, and reporting units. SOPs should be defined or standardized across each level of the laboratory system. For example, every district lab should have the same set of SOPs for the test techniques carried out at the district level.

Standards are the concepts, procedures, and designs needed to achieve and maintain the required levels of compatibility, interchangeability, or commonality in the operational, procedural, material, technical, and administrative fields.

Standardization (in the laboratory context) is the process of ensuring that the:

. Same menu of laboratory tests, defined by level of the laboratory system (central, regional, district), is offered,

. Same techniques, defined by level, are used to carry out those tests,

. Same technical SOPs are followed for those techniques,

. Laboratory instrumentation, defined by level, is agreed upon.

Supply-chain is a term that describes how organizations (suppliers, manufacturers, distributors, and customers) are linked together.

Supply-chain management is a total system approach to managing the entire flow of information, materials, and services from raw-material suppliers through factories and warehouses to the end customer

Test menus describe the defined list of tests that should be offered at a specific laboratory or

level (central, regional, district, etc.) of the laboratory system.

Usage refers to the amount of laboratory commodities consumed during a set period of time.

Viral load is the measurement of the number of viral particles in the circulating blood. HIV and hepatitis C are often quantified with the viral load test. Viral load and CD4 counts are both predictors of the risk of HIV disease progression. Viral load testing is also used to determine when to initiate or change antiretroviral therapy.

WHO Prequalification of Diagnostics program: An assessment of the performance or operational characteristics and manufacturing quality of diagnostics, as performed by WHO.

1.7. Significance of the Study

Uninterrupted laboratory diagnostic services are highly crucial among other required improvements in health service functions at various government and non-government institutions for the overall improvement of health services nationwide. Access to accurate, safe and appropriate diagnostics and reliable laboratory services is paramount for diagnosis and disease management, surveillance and securing a safe blood supply. However, testing results are only of value to those making clinical decisions if the test results reported are timely and correct.[21]

An ART implementation status and outcome study carried out in Ethiopia in 2013 by HAPCO showed the absence of ART guideline in 27% of facilities and nearly half of the facilities under the study do not perform key laboratory tests for ART monitoring like complete blood count (CBC) (40%), renal function tests (49%), liver function tests (50%) and hepatitis surface B antigen test (49%). The study has identified significant gaps in the resources (inputs) for ART services implementation including unavailability of necessary guidelines, unavailability and non-functionality of laboratory services[18].

It is important to compare the type and frequency of laboratory tests being carried out in Ethiopia against internationally accepted HIV/AIDS benchmarking guideline if possible or that of at least the WHO guideline that would dictate the national, regional and health facilities SCMS plan.

Table 4: Current WHO Testing Guidelines for HIV/AIDS Positive Adult and Pediatric Patients

Test	Baseline	Month1	Month3	Month6	Month9	Month12	Thereafter
CD4	X			X		X	2
GOT	X			X		X	2
GPT	X			X		X	2
Creatnine	X			X		X	2
ALP	X			X		X	2
Urea	X			X		X	2
D. Bilirubin	X						
T. Bilirubin	X						
Hematology	X		X	X	X	X	2
Hematology pre Tx	X			X		X	2
Cryptococcus	X	PRN					
Syphilis	X	PRN					
Pregnancy	X	PRN					
TB - AFB	X	PRN					

Every HIV-infected patient entering into care should have a complete medical history, physical examination, and laboratory evaluation and should be counseled regarding the implications of HIV infection. The goals of the initial evaluation are to confirm the diagnosis of HIV infection, obtain appropriate baseline historical and laboratory data, ensure patient understanding about HIV infection and its transmission, and to initiate care as recommended in HIV primary care guidelines1 and guidelines for prevention and treatment of HIV-associated opportunistic infections.2 The initial evaluation also should include introductory discussion on the benefits of ART for the patient's health and to prevent HIV transmission. Baseline information then can be used to define management goals and plans. In the case of previously treated patients who present for an initial evaluation with a new health care provider, it is critical to obtain a complete antiretroviral (ARV) history (including drug-resistance testing results, if available), preferably through the review of past medical records.

Newly diagnosed patients should also be asked about any prior use of ARV agents for prevention of HIV infection.

The following laboratory tests may need to be performed during initial patient visits can be used to stage HIV disease and to assist in the selection of ARV drug regimens:

- HIV antibody testing (if prior documentation is not available or if HIV RNA is below the assay's limit of detection) (AI);
- CD4 T-cell count (CD4 count) (AI);
- Plasma HIV RNA (viral load) (AI);
- Complete blood count, chemistry profile, transaminase levels, blood urea nitrogen (BUN), and Creatnine, urinalysis, and serology for hepatitis A, B, and C viruses (AIII);
- Fasting blood glucose and serum lipids (AIII); and
- Genotypic resistance testing at entry into care, regardless of whether ART will be initiated immediately (AII). For patients who have HIV RNA levels <500 to 1,000 copies/mL, viral amplification for resistance testing may not always be successful (BII).

In addition, other tests (including screening tests for sexually transmitted infections and tests for determining the risk of opportunistic infections and need for prophylaxis) should be performed as recommended in HIV primary care and opportunistic infections guidelines. The baseline evaluation should also include a discussion of risk reduction and disclosure to sexual and/or needle sharing partners, especially with untreated patients who are still at high risk of HIV transmission.

A number of laboratory tests are important for initial evaluation of HIV-infected patients upon entry into care; during follow-up if antiretroviral therapy (ART) is not initiated; and before and after initiation or modification of therapy to assess the virologic and immunologic efficacy of ART and to monitor for laboratory abnormalities that may be associated with ARV drugs. Table 3 outlines the Panel's recommendations on the frequency of testing. As noted in the table, some tests may be repeated more frequently if clinically indicated.

Two surrogate markers are used routinely to assess immune function and level of HIV viremia: CD4 T-cell count (CD4 count) and plasma HIV RNA (viral load), respectively. Resistance

testing should be used to guide selection of an ARV regimen. A viral tropism assay should be performed before initiation of a CCR5 antagonist or at the time of virologic failure that occurs while a patient is receiving a CCR5 antagonist. HLAB* 5701 testing should be performed before initiation of abacavir (ABC). The rationale for and utility of these laboratory tests are discussed in the corresponding sections of the guidelines.

Table 5: Laboratory Monitoring Schedule for HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy[a]

Laboratory Test	Time point/Frequency of Testing								
	Entry into Care	Follow Up Before Initiation of ART	ART Initiation or Modification[b]	Follow-Up 2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
HIV	√								
Serology									
	If HIV diagnosis has not been confirmed								
CD4 Count	√	√ Every 3–6 months	√		√ During first 2 years of ART or if viremia develops while patient on ART or CD4 count <300 cells/mm 3		√ After 2 years on ART with consistently suppressed viral load: *CD4 Count 300–500 cells/mm3:* • Every 12 months *CD4 Count >500 cells/mm3:* • CD4 monitoring is optional	√	√
HIV Viral Load	√	Repeat testing is optional	√	√c	√d	√d		√	√
Resistance Testing	√		√e					√	√
HLA-B*5701 Testing			√ If considering ABC						
Tropism Testing			√					√	√
			If considering a CCR5 antagonist					If considering a CCR5 antagonist or for failure of CCR5 antagonist-based regimen	

Table 6: Laboratory Monitoring Schedule for HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy[a]

	Time point/Frequency of Testing								
	Entry into Care	**Follow Up Before Initiation of ART**	**ART Initiation or Modification[b]**	**Follow-Up 2 to 8 Weeks After ART Initiation or Modification**	**Every 3 to 6 Months**	**Every 6 Months**	**Every 12 Months**	**Treatment Failure**	**Clinically Indicated**
Hepatitis B Serology[f]	√		√ May repeat if HBsAg (-) and HBsAb (-) at baseline						√
Hepatitis C Serology, with Confirmation of Positive Results	√								√
Basic Chemistry[g,h]	√	√ Every 6–12 months	√	√	√				√
ALT, AST, T. bilirubin	√	√ Every 6–12 months	√	√	√				√
CBC with Differential	√	√ Every 3–6 months	√	√ If on ZDV	√				√
Fasting Lipid Profile	√	√ If normal, annually	√	√ Consider 4–8 weeks after starting new ART regimen that affects lipids		√ If abnormal at last measure-ment	√ If normal at last measurement		√
Fasting Glucose or Hemoglobin A1C	√	√ If normal, annually	√		√ If abnormal at last measure-ment		√ If normal at last measurement		√
Urinalysis[g]	√		√			√ If on TDF[i]	√		√
Pregnancy Test			√ In women with child-bearing potential						√

a This table pertains to laboratory tests done to select an ARV regimen and monitor for treatment responses or ART toxicities. Please refer to the HIV Primary Care guidelines for guidance on other laboratory tests generally recommended for primary health care maintenance of HIV patients.

b ART may be modified because of treatment failure, adverse effects, or for regimen simplification.

c If HIV RNA is detectable at 2 to 8 weeks, repeat every 4 to 8 weeks until viral load is suppressed to <200 copies/mL, and thereafter, every 3 to 6 months.

d In patients on ART, viral load typically is measured every 3 to 4 months. However, for adherent patients with

consistently suppressed viral load and stable immunologic status for more than 2 years, monitoring can be extended to 6 month intervals.

e In ART-naive patients, if resistance testing was performed at entry into care, repeat testing before initiation of ART is optional. The exception is pregnant women; repeat testing is recommended in this case. In virologically suppressed patients who are switching therapy because of toxicity or for convenience, viral amplification will not be possible; therefore, resistance testing should not be performed. Results from prior resistance testing can be helpful in constructing a new regimen.

f If HBsAg is positive at baseline or before initiation of ART, TDF plus either FTC or 3TC should be used as part of the ARV regimen to treat both HBV and HIV infections. If HBsAg, and HBsAb, and anti-HBc are negative at baseline, hepatitis B vaccine series should be administered. Refer to HIV Primary Care guidelines for more detailed recommendations.

g Serum Na, K, HCO3, Cl, BUN, creatinine, glucose (preferably fasting). Some experts suggest monitoring the phosphorus levels of patients on TDF. Determination of renal function should include estimation of Creatinine Clearance using the Cockcroft-Gault equation or estimation of glomerular filtration rate using the MDRD equation.

h For patients with renal disease, consult the Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America.

i More frequent monitoring may be indicated for patients with evidence of kidney disease (e.g., proteinuria, decreased glomerular dysfunction) or increased risk of renal insufficiency (e.g., patients with diabetes, hypertension).[9]

Key to Acronyms:

3TC = lamivudine, ABC = abacavir, ALT = alanine aminotransferase, ART = antiretroviral therapy, AST = aspartate aminotranserase, CBC = complete blood count, CrCl = creatinine clearance, EFV = efavirenz, FTC = emtricitabine, HBsAb = hepatitis B surface antibody, HBsAg = hepatitis B surface antigen, HBV = hepatitis B virus, MDRD = modification of diet in renal disease (equation), TDF = tenofovir, ZDV = zidovudine

1.8. Delimitation/Scope of the Study

This study is limited to qualitative review of the national strategy of SCMS where various stakeholders are taking part in designing, planning, implementing and evaluating the overall national laboratory services of ART management and hence the corresponding SCMS. It is limited to examining the mutli-sector collaboration and role of each sector in setting and implementation of the national SCMS strategy in addressing the need for ART supplies effectively.

CHAPTER II: LITERATURE REVIEW

For any business activity, such as supply chain management (SCM), which has strategic implications for any company, identifying the required performance measures on most of the criteria is essential and it should be an integral part of any business strategy. Many methods have been suggested over the years for SCM evaluation of any organization. However, a balanced approach to evaluate SCM is a source of increasing cost and concern to management as traditional methods focus only on well-known financial measures, which are best,

suited to measure the value of simple SCM applications. Unfortunately, evaluation methods that rely on financial measures are not well suited for newer generation of SCM applications. These complex supply chains typically seek to provide a wide range of benefits, including many that are intangible in nature. As a result, we suggest that it may be appropriate to use a balanced approach to measure and evaluate supply chains.

In recent years, a number of firms realized the potentials of SCM in day-to-day operations management. However, they often lack the insight for the development of effective performance measures and metrics needed to achieve a fully integrated SCM due to lack of a balanced approach and lack of clear distinction between metrics at strategic, tactical, and operational levels (Gunasekaran, Patel, & Tirtiroglu, 2001; Hudson, Lean, & Smart, 2001). Therefore, it is clear that for effective SCM, measurement goals must consider the overall scenario and the metrics to be used. These should represent a balanced approach and should be classified at strategic, tactical, and operational levels, and be financial and non-financial measures, as well.

Taking into account the above factors, a balanced SCM scorecard has been proposed and developed to discuss the several measures and metrics of SCM in contributing to important issues of SCM performance measurement theory and practices.

- It points out the importance of key players in the performance measurement of SCM, and the nature of roles they need to play.
- A balanced performance evaluation of SCM such as, balanced scorecard not only helps organizations in faster and wider progress monitoring of their operations but can also help them in improving their internal and external functions of business such as engineering and design applications, production, quality improvement, materials management, quick

response, gaining lost market shares, proper implementation of business strategies etc.

- Articulating the experiences of application of balanced SCM scorecard specific to SMEs, throwing light on the management of supply chain by conducting case studies. It focuses on critical factors that are likely to contribute for the successful performance measurement of SCM, particularly in SMEs sector.

The need of performance measurement systems at different levels of decision-making, either in the industry or service contexts, is undoubtedly not something new (Bititici, Cavalieri, & Cieminski, 2005). Kaplan and Norton (1992) have proposed the balanced scorecard (BSC), as a means to evaluate corporate performance from four different perspectives: the financial, the internal business process, the customer, and the learning and growth. Their BSC is designed to complement ‘‘financial measures of past performance with their measures of the drivers of future performance’’. The name of their concept reflects an intent to keep score of a set of items that maintain a balance ‘‘between short term and long term objectives, between financial and non-financial measures, between lagging and leading indicators, and between internal and external performance perspectives’’. The early image of the BSC serving the CEO like a control panel serves an aircraft pilot seems to have expanded to include mechanisms to alter the course of action as well. Now, the BSC seems to serve as a control panel, pedals and steering wheel (Malmi, 2001). Table 1 outlines the four perspectives included in a BSC.

Many companies are adopting the BSC as the foundation for their strategic management system. Some managers have used it as they align their businesses to new strategies, moving away from cost reduction and towards growth opportunities based on more customized, value-adding products and services (Martinsons, Davison, & Tse, 1999). A large number of methods of performance measurement systems have been reported in the literature (Bititici & Nudurupati, 2002; Chan & Qi, 2003a, 2003b; Chan, Chan, & Qi, 2006; Sharma, Bhagwat, & Dangayach, 2005). A comparison between the BSC approach and other approaches used to measure SCM performance is briefly described as follows:

- Strategic measurement analysis and reporting technique system: Wang Laboratories, Inc. (Cross & Lynch, 1989) developed this system and it consists of a four-level pyramid of objectives and measures: corporate vision/strategy, business unit market and financial objectives, business unit operational objectives and priorities, departmental level operational criteria and measures.
- Performance measurement questionnaire: It (Dixion, Nanni, & Vollmann, 1990) involves a

workshop to develop, revise, and refocus the set of performance measures. It has the advantage of providing a mechanism for identifying the improvement areas of the company and their associated performance measures. However, it cannot be considered a comprehensive integrated measurement system and does not consider continuous improvement.

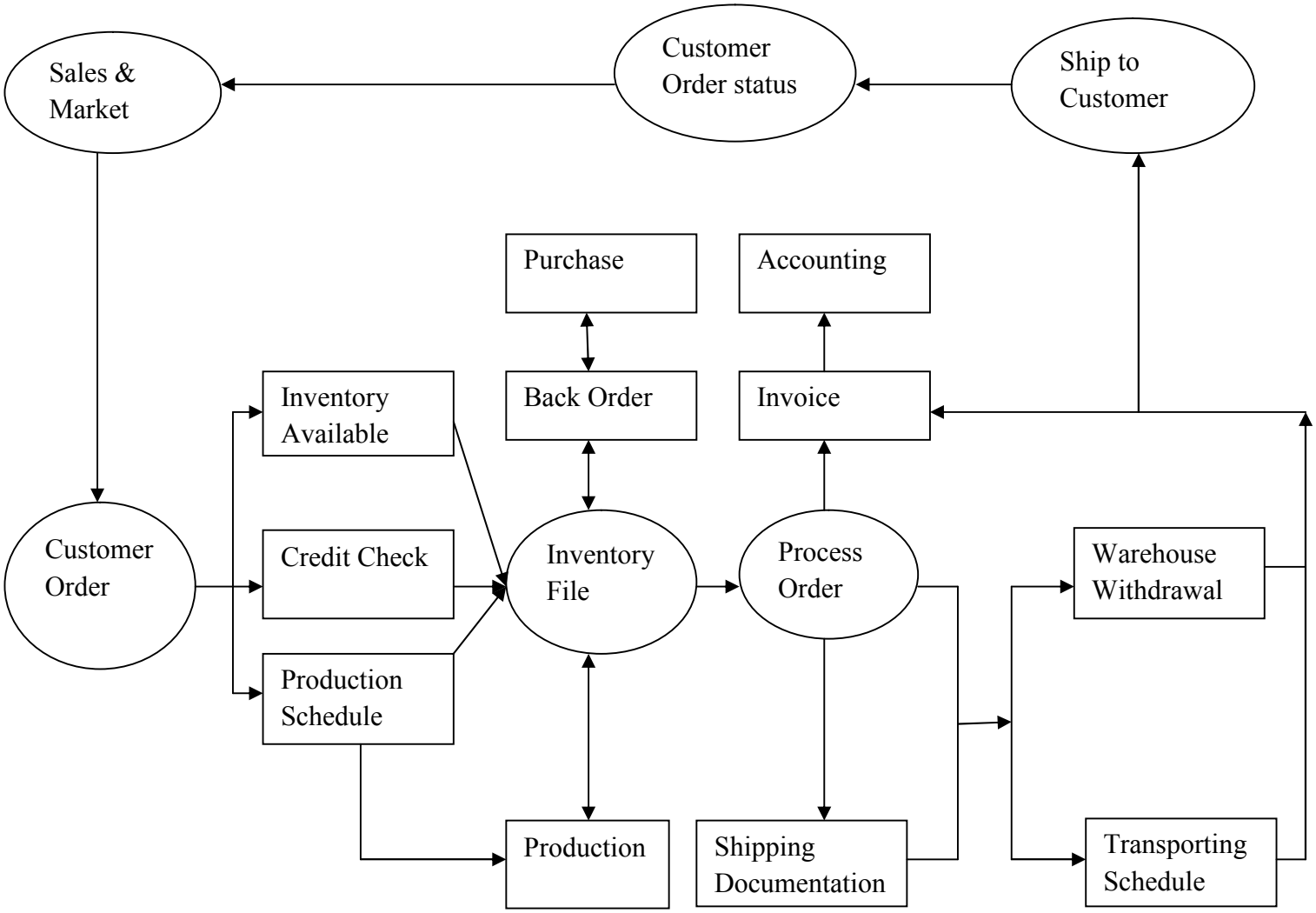
- Strategic performance measurement system: Vitale, Mavrinac, and Hauser (1994) presented an action-focused tool, which concentrates on the organization's strategies. The concepts and ideas were developed by hands-on experience.
- Integrated dynamic performance measurement system: Developed by Ghalayinin, Noble, and Crowe (1997) to achieve an integrated system by combining three main areas of the company: management, process improvement team, and factory shop floor.
- Holistic process performance measurement system: Kueng (2000) presented it especially for modern process-based businesses. It assesses the performance of the processes for five aspects: financial view, employee view, customer view, societal view, and innovation view.

According to Chan (2003), performance measurement describes the feedback or information on activities with respect to meeting customer expectations and strategic objectives. It reflects the need for improvement in areas with unsatisfactory performance. Thus efficiency and quality can be improved. Gunasekaran et al. (2001), and Gunasekaran, Patel, Ronald, and McGaughey (2004) have identified and discussed in the attempt to summarize some of the most appropriate performance metrics and measures of SCM.

For any firm, the first activity to begin with is to procure orders. A typical order path is shown in Fig. 1. From the figure, it is clear that the way the orders are generated and scheduled determines the performance of the downstream activities and inventory levels. Hence, the first step in assessing performance is to analyze the way the order-related activities are carried out. To do this, the most important issues – such as the order entry method, order lead-time and the path of order traverse – need to be considered.

The order entry method determines the way and the extent to which the customer specifications/requirements are converted into useful information, and are passed down along the supply chain. According to Mason-Jones and Towill (1997), such information connects all levels of supply chain and affects the scheduling of all activities. Proper control of the order is possible, provided that the order entry method is capable of providing timely, accurate and usable data at various entry levels, and hence, can be used as a metric of performance measure.

Figure 1: The path of a customer order (Source: Christopher (1992)).



The total order cycle time, which is called ‘‘order lead time ’’, refers to the time, which elapses between the receipt of the customer’s order and the delivery of the goods. This includes the following time elements:

Total order cycle time = Order entry time (through forecast/direct order from the customer) + Order planning time (Design + Communication + Scheduling time) + Order sourcing, assembly and follow up time + Finished goods delivery time.

A reduction in the order cycle time leads to a reduction in the supply chain response time (Gunasekaran et al., 2001). This is an important measure as well as major source of competitive advantage (Bower & Hout, 1988; Christopher, 1992). According to Towill (1997), it directly

influences the customer satisfaction level. Equally important is the reliability and consistency of the lead-time. Because of bottlenecks, inefficient processes and fluctuations in the volume of orders handled, there will be variations in activity completion times. The overall effect of this may lead to a substantial reduction in delivery reliability and customer service level. To deal with these, for example, the concept of ‘‘manufacturing cell’’ can be applied, in which well integrated actions are performed in parallel by cross functional teams to effectively decrease the order lead-time and reduce the redundancies (Schonberger, 1990). In fact, Schonberger notes that, in one case study, Ahlstrom, a Finnish company, was able to reduce the lead-time from one week to one day. Hence, therefore, measurement of total cycle time is very important in the context of customer service, and to serve as a feedback to control the day-to-day operations.

The path that order traverse is another important measure whereby the time spent in different routes and non-value adding activities can be identified, and suitable steps can be taken to eliminate them (Gunasekaran et al., 2001). For example, by tracing through the order path, the delays in the paperwork, time consumed while the product sits in the warehouse, time spent in checking and rechecking can be identified and eliminated using methods such as JIT, reengineering, and information technology (e.g. e-commerce, electronic data interchange (EDI) and Internet).

Recently, buyer–supplier partnership has gained a tremendous amount of attention from industries and researchers, resulting in a steady stream of literature promoting it (e.g. Ellram, 1991; Fisher, 1997; Graham, Dougherty, & Dudley, 1994; Gunasekaran et al., 2001; Landeros, Reck, & Plank, 1995; Maloni & Benton, 1997; McBeth & Ferguson, 1994; New, 1996; Thomas & Griffin, 1996; Toni, Nissimbeni, & Tonchia, 1994; Towill, 1997). Most of these studies stress the partnership for better supply chain operations. Accordingly, an efficient and effective performance evaluation of buyer and/or suppliers is not just enough; the extent of partnership that exists between them needs to be evaluated and improved, as well. The parameters that measure the level of partnership are summarized in Table 2.

Measuring customer service and satisfaction is aimed to integrate the customer specification in design, set the dimensions of quality and the feedback for the control process. They contain product/service flexibility, customer query time, and post-transaction service.

Being flexible refers to making available the products/services to meet the individual demand of customers. This has become possible as a result of the development of such technologies as flexible manufacturing systems (FMS), group technology (GT), and computer-integrated

manufacturing (CIM). In addition, other methods such as single minute exchange of die (SMED), as well as information technology (IT) and communication systems (CS), which provide online information, further facilitate quick response of the control system. The flexibility that these systems impart has a high impact on winning customers. For example, Toyota is using FMS and logistic principles to provide a high level of responsiveness to customer needs (Bower & Hout, 1988). Stewart (1995) presents a list of practices that world-class companies employ to improve flexibility. His analysis reveals a strong correlation of supply chain response time and flexibility. Hence, by defining flexibility as a metric and by evaluating it (Gunasekaran et al., 2001), companies can achieve what was previously impossible: rapid response to meet individual customer requirements.

The customer query time refers to the time it takes for a firm to respond to a customer enquiry with the required information. On several occasions, a customer enquires or needs to be informed about the status of an order, and the potential problems on stock availability or delivery. Providing such information genuinely helps the customers to schedule their activities, and helps the firm to retain them as customers. Thus, providing online information is an important element of customer service, and it can be evaluated for improving the same. To measure customer service, questions ‘‘what are the response times’’, and ‘‘what procedures exist to inform customers’’ should be considered.

The function of a supply chain does not end by providing goods to the customer. The post transaction activities play an important role both as part of customer service, and for valuable feedback for further improvements in the supply chain. For example, timely availability of spares helps companies to provide better customer service, and to trace the problems arising from warranty claims; then making improvements on them. Apart from these, there are other post-transaction elements that need to be evaluated as discussed hereunder:

- Service level compared to competitors: to be competitive, an organization must measure how well its service performance compares against the competitors’.
- Measuring customer perception of service: this is done primarily through direct interviews with customers. What are their needs? What is the service level they receive versus what are their expectations? These are the questions firms should ask the customers to improve on products/services, and for an increased confidence in the firm’s supply chain.

As an important part of SCM, the performance of the production process also needs to be measured, managed, improved, and suitable metrics for it should be established. This category

consists of range of product and services, capacity utilization, and effectiveness of scheduling techniques.

According to Mapes, New, and Szwejczewski (1997), a company that manufactures a wide range of products is likely to introduce new products at a slower rate than companies with a narrow product range. Based on a statistical analysis of ‘‘UK Best Factory Awards Database’’, these authors show that plants that manufacture a wide range of products are likely to perform poorly on added-value per employee, speed and delivery reliability. Furthermore, a company with an extensive product portfolio less frequently breeds new products of innovation. This indicates the impact of ‘‘product range’’ on supply chain performance, and so, it needs to be measured. The same analysis can be applicable for services, as well.

According to Fisher (1997), the selection of right supply chain strategy depends upon the nature of product variety and innovation. This also implies that the range of products and services acts as an important strategic metric, and hence, it should be considered in performance evaluation.

According to Wild (1995): ‘‘all the operations planning takes place within the framework set by capacity decisions.’’ From the above statement, the role of ‘‘capacity’’ in determining the level of all supply chain activities is clear. This highlights the importance of measuring and controlling the capacity utilization. According to Slack, Chambers, Harland, Harrison, and Johnston (1995), capacity utilization directly affects the speed of response to customers’ demand. Hence, by measuring capacity, gains in flexibility, lead-time and deliverability will be achieved.

Scheduling refers to the time or date at which activities are to be undertaken. Such fixing determines the manner in which the resources flow through an operating system. The effectiveness of this has a significant impact on the performance of supply chain (Gunasekaran et al., 2001). For example, scheduling based on JIT has tremendous influence on inventory levels. Similarly, computer generated schedules based on systems like MRP, and more recently ERP, provide a detailed and accurate bill of materials. These impact the effectiveness of purchasing, throughput time and batch size. However, the applications of such systems should not be limited to scheduling of shop floor activities and comparing their performance with others. In the case of supply chains, since scheduling depends heavily on customer demand and supplier performance, the scheduling tools/methods should also be viewed from that context. Based on these, it can be concluded that measuring and improving effectiveness of scheduling techniques will improve the performance of a supply chain.

These measures are designed to evaluate the performance of delivery and distribution cost in

supply chain. The typical measures for delivery performance evaluation are lead-time reduction in the delivery process, ontime delivery (delivery-to-request date, delivery-to-commit date and order fill lead-time), distribution mode, the delivery channel, vehicle scheduling, and warehouse location, the percentage of goods in transit, quality of information exchanged during delivery, number of faultless notes invoiced, flexibility of delivery systems to meet particular customer needs (Gelders, Mannaert, & Maes, 1994; Novich, 1990; Stewart, 1995).

In any typical delivery distribution mode, the delivery channel, vehicle scheduling, and warehouse location play an important role in delivery performance (Gunasekaran et al., 2001). An increase in delivery performance is possible by selecting suitable channel, scheduling and location policies. A survey conducted by Gelders et al. (1994) in Belgium shows that tremendous opportunities exist to improve the supply chain performance based on lead-time reduction in the delivery process. What is needed, according to Gelders et al. (1994), is an understanding of the link between delivery channels and organizational operating schedules. Another important aspect of delivery performance is on-time delivery. This determines whether a perfect delivery has taken place or not, and it acts as a measure of customer service level. Stewart (1995) identifies the following as the measure of delivery performance:

- delivery-to-request date;
- delivery-to-commit date; and
- order fill lead-time

His study reveals a trend in the reduction of lead-time as an operational strategy for improving delivery performance. Another aspect of delivery performance evaluation is the percentage of goods in transit. A higher percentage signifies low inventory turns, leading to unnecessary increase in tied up capital. Various factors that can be attributed to this are vehicle speed, driver reliability, frequency of delivery, and the location of depots. An increased effectiveness in these areas may well lead to a decrease in inventory levels under consideration. Like other activities, delivery heavily relies on the quality of information exchanged. For example, once the activities are scheduled, continuous monitoring is possible based both on information derived and information supplied across the channels of distribution. Thus, the quality and the way the information is presented determine the delivery performance to a large extent, which, therefore, can be used to measure and improve performance (Gunasekaran et al., 2004).

Moreover, the following aspects of delivery also reflect customer satisfaction:

- Number of faultless notes invoiced: An invoice shows the delivery date, time and the

condition under which goods are received. By comparing these with the previous agreement, it can be determined whether a perfect delivery has taken place or not. Also, the areas of discrepancy can be identified so that improvements in delivery performance can be made.

- Flexibility of delivery systems to meet particular customer needs: Nowadays, the delivery systems are becoming more flexible towards customer needs. By being flexible, a delivery system can positively influence the decision of customers to place orders, and hence, this can be regarded as a metric for winning and retaining customers. According to Novich (1990), customers can be grouped into different segments based on their needs. Thus, they can be grouped critically based on their economic profitability and flexibility.

Determining the total logistics cost can assess the financial performance of a supply chain. It is necessary to decide on a broad level of strategies and techniques that would contribute to the smooth flow of information and materials in the supply chain environment. They are used to assess the financial performance of supply chain, such as assets cost, return on investment, and total inventory cost.

Supply chain assets include accounts receivable, plant, property and equipment and inventories (Stewart, 1995). With increasing inflation and decreased liquidity, pressure is on firms to make the assets sweat, i.e. improve the productivity of their capital. In this regard, it is essential to determine how the costs associated with each asset, combined with its turnover, affects the ‘‘total cash flow time’’. According to Stewart (1995), this can be measured as the average number of days required transforming the cash invested in assets into the cash collected from a customer.

Once the total cash flow time is determined, it can readily be combined with profit with the objective of providing an insight into the rate of return on investment (ROI). This determines the performance that the top management can achieve on the total capital invested in business. As a corollary to this, the logistics management policies have a significant impact on ROI.

For example, superior customer service leads to improved sales and an increased profit, and subsequently, a higher ROI. Likewise, other areas of organization can be explored. By measuring ROI and the impact of the logistics policies on it, significant insights can be gained about the financial health of the supply chain.

In a supply chain, inventories range from raw materials, subassemblies and assemblies to finished products, as well as inventories held up in transit. What was traditionally perceived as a buffer in production to cope with uncertainties actually emerged to be one of the reasons for the increase in lead-time (Slack et al., 1995). As customer service requirements constantly increase,

effective management of inventory in a supply chain becomes increasingly critical and important. Hence, it is essential that costs associated with inventory should be evaluated, and proper trade-offs, with suitable performance measures, should be implemented.

In a supply chain, the total costs associated with the inventory (Christopher, 1992; Dobler & Burt, 1996; Lee & Billington, 1992; Levy, 1997; Slack et al., 1995; Stewart, 1995) consist of the following:

- Opportunity cost consisting of warehousing, capital and storage,
- Cost associated with inventory as incoming stock level, work in progress,
- Service costs, consisting of costs associated with stock management and insurance,
- Cost held up as finished goods in transit,
- Risk costs, consisting of costs associated with pilferage, deterioration, damage.
- Cost associated with scrap and rework.
- Cost associated with shortage of inventory accounting for lost sales/lost production.

In dealing with these costs, consideration should also be given to part/material size. A low cost part may have large size, and consequently, a large space requirement. Also, in deciding which cost should be tackled first, Pareto analysis can be used to prioritize the options. In addition, proper trade-offs should be considered in dealing with inventory at various levels in a supply chain. An excellent discussion on this, based on pitfalls and opportunities, is provided by Lee and Billington (1992). In particular, they point out that the cost of reworking stored components due to engineering changes and the risk of obsolescence could inflate the inventory holding costs by 40%. Clearly, not considering such factors may lead to inappropriate choices.

In dealing with inventory in transit, a trade-off is needed because changing the mode of transportation can significantly affect inventory investment and service performance. A faster and more expensive shipping mode may save enough in inventory investment to justify increase in shipping cost, but if inventory costs rates are appropriately chosen. According to Levy (1997), care must also be taken for longer lead-time due to longer distance as it increases the ‘‘volatility’’ of inventories, resulting in either too high or too low inventory levels. This, in turn, can lead to higher administrative costs being incurred, and can be the cause of costs due to lost sales.

Another factor that needs to be measured and dealt with regarding inventory is the accuracy of forecasting techniques. According to Fisher (1997), supply chain in many industries suffers from

inventory, owing to their inability to predict demand. A new demand forecasting system that takes sales data from distributor's computer and combines with on-hand inventory could serve as a technique to deal with this problem. Harrington (1996) shows that using such techniques, Microsoft has been able to keep production schedules open until one week, and make what the market will accept.

Therefore, measuring inventory at supply, production, distribution and scrap levels as well as accuracy of forecasting techniques, can provide an insight into the cost performance and reduce the lead-time in a supply chain.

Although there is an ever-increasing amount of literature addressing theories and practices of supply chain management, the existing performance measurement methods fail to provide significant assistance in supply chain development and an effective method is lacking (Chan & Qi, 2002). Many methods and techniques have been suggested over the years for SCM evaluation. Traditional methods focus on well-known financial measures, such as the return on investment (ROI), net present value (NPV), the internal rate of return (IRR), and the payback period. These methods are best suited to measure the value of simple SCM applications. Unfortunately, evaluation methods that rely on financial measures are not well suited for newer generation of SCM applications. These complex supply chains typically seek to provide a wide range of benefits, including many that are intangible in nature. There is, however, a greater need to study the measures and metrics in the context of following reasons (Gunasekaran et al., 2001):

(I) *Lack of a balanced approach. Financial measures*, which are required for examination by external stakeholders, are generally well developed. However, operational measures are typically ad hoc and lack formal structure (Hudson et al., 2001). Many firms have realized the importance of financial and non-financial performance measures. However, they failed to understand them in a balanced framework. According to Kaplan and Norton (1992), while some managers and researchers have concentrated on financial measures of performance, others have concentrated on operational measures. Such equality does not lead to metrics that can present a clear picture of the organizational performance. As suggested by Maskell (1991), for a balanced approach, companies should bear in mind that, while financial performance measurements are important for strategic decisions and external reporting, day-to-day control of manufacturing and distribution operation is better handled with non-financial measures.

(II) *Lack of understanding on deciding on the number of metrics to be used*. Quite often,

companies have a large number of performance measures to which they keep on adding based on suggestions of employees and consultants, and fail to realize that performance measurements can be better addressed using a good few metrics.

(III) *Lack of clear distinction between metrics at strategic, tactical, and operational levels*. Metrics that are used in performance measurement influence the decisions to be made at strategic, tactical, and operational levels. Using a classification based on these three levels, each metric can be assigned to a level where it would be most appropriate.

Therefore, it is clear that for effective management of supply chain, measurement goals must consider the overall scenario and the metrics to be used. These should represent a balanced approach and should be classified at strategic, tactical, and operational levels, and be financial and non-financial measures, as well.

This being the background, Gunasekaran et al. (2001) illustrated the above discussed performance measures and metrics of the SCM with help of a framework that gives cohesive picture to address what needs to be measured, and how it can be dealt with. The framework developed is shown in Table 3.

The metrics discussed in this framework are classified into strategic, tactical and operational levels of management. The metrics are also distinguished as financial and non-financial so that a suitable costing method based on activity analysis can be applied. Such a classification helps in signifying which metric should be used where, and which can together act as a fair indication of the problems persistent in respective links. These metrics are extracted from the mainstream supply chain management literature as well as the emerging literature on other related SCM practices. Table 5 shows the high performance metrics that target broader functional areas of supply chain.

A balanced scorecard approach is proposed to evaluate these measures and metrics for SCM in the section that follows. These measures are generic in nature; because each corporate mission and the strategic goals are related to it will require a unique set of measures (Barua, Lee, & Whinston, 1996; Kaplan & Norton, 1996; Letza, 1996).

Table 7: A framework of metrics for the performance evaluation SCM (Gunasekaran et al., 2001)

Level	Performance Metrics	Financial	Non-financial
Strategic	Total supply chain cycle time		√
	Total cash flow time		√
	Customer query time	√	√
	Level of customer perceived value of product		√
	Net profit vs. productivity ratio	√	
	Rate of return on investment	√	
	Range of products and services		√
	Variations against budget	√	
	Order lead time		√
	Flexibility of service systems to meet particular customer needs	√	√
	Buyer–supplier partnership level		√
	Supplier lead time against industry norms		√
	Level of supplier's defect free deliveries		√
	Delivery lead time		√
	Delivery performance	√	√
			√
Tactical	Accuracy of forecasting techniques		√
	Product development cycle time		√
	Order entry methods		√
	Effectiveness of delivery invoice methods		√
	Purchase order cycle time		√
	Planned process cycle time		√
	Effectiveness of master production schedule		√
	Supplier assistance in solving technical problems		√
	Supplier ability to respond to quality problems		√
	Supplier cost saving initiatives	√	
	Supplier's booking in procedures		√
	Delivery reliability	√	
	Responsiveness to urgent deliveries		√
	Effectiveness of distribution planning schedule		√
Operational	Cost per operation hour	√	
	Information carrying cost	√	√
	Capacity utilization		√
	Total inventory cost as: • Incoming stock level • Work-in-progress • Scrap value • Finished goods in transit		√
	Supplier rejection rate	√	√
	Quality of delivery documentation		√
	Efficiency of purchase order cycle time		√
	Frequency of delivery		√
	Driver reliability for performance		√
	Quality of delivered goods		√
	Achievement of defect free deliveries		√

Medical laboratory services in developing countries can be strengthened by leveraging funding from other sources of HIV/AIDS prevention, care, surveillance, and treatment programs. Strengthening these services will require coordinated efforts by national governments and partners and can be achieved by establishing and implementing national laboratory strategic plans and policies that integrate laboratory systems to combat major infectious diseases. These plans should take into account policy, legal, and regulatory frameworks; the administrative and technical management structure of the laboratories; human resources and retention strategies; laboratory quality management systems; monitoring and evaluation systems; procurement and maintenance of equipment; and laboratory infrastructure enhancement. [5]

National (regional) laboratory policy is crucial to systematically outline the major issues that need to be addressed, including organizational and management structure, human resources, laboratory infrastructure, care and maintenance of equipment, provision of laboratory supplies, a functional information management system, a quality management system (QMS) and adequate financial support.

QMS in medical laboratory comprises 12 major conventional quality system essential including organization, personnel, SCMS (equipment, purchasing & inventory management), process control, information management, documents and record management, occurrences management, assessment, process improvement, customer service and facility and safety whereby SCMC is one of the critical quality system essentials (QSEs).

The existence of a national health laboratory policy and national health laboratory plan are an indication of the commitment of a government to provide quality health services to its people by ensuring that systems are established for the management and operation of laboratory services, and adequate and sustainable financing is available.

Laboratory services need to be considered as an integrated program, and not fragmented with only parts of the system strengthened to support specific disease control initiatives. A vertical approach may lead to disorganization of the laboratory and neglect of other components of the laboratory services. Laboratory services should be recognized as a vital and integral part of a quality health service at all levels of the health system. This requires all stakeholders to undertake operational planning and allocate adequate and sustainable resources.

National medical laboratory management program; a coherent national framework for health laboratory services includes a well-organized and managed structure, the important components of which are as follows:

(a) National laboratory focal point (department) and national laboratory coordinating committee: The terms of reference for the national laboratory focal point (department), and the composition and terms of reference for the national laboratory coordinating committee should include responsibility and accountability for steering and monitoring the health laboratory services.

The medical laboratory shall meet the management requirements of the International Standard (ISO 15189:2012 when carrying out work at its permanent facilities, or in associated or mobile facilities, where detail management requirements and the for the professional management role as a laboratory director or manager however it is called, with a detail responsibilities are strongly emphasized.[22]

(b) National regulatory mechanism

Regulation is the legal means of governing or controlling health service provision, including laboratories, laboratory staff, equipment, test kits and reagents, and reporting of essential information to meet the required standards. Regulation is a tool for ensuring competent performance as well as confidence in the laboratory services.

There are several internationally Recognized accreditation and regulatory Standards are available like ISO 15189, ISO13485, ISO 17043 and other that are relevant and deemed to offer the presumption of conformity to the overall medical laboratory management in general and IVD in particular that may need to be adopted by RAs to be followed and implemented at each health facility. These standards recommend that IVD medical devices should be designed and manufactured in such a way that the performance characteristics support the intended use, based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy which is trueness and precision (repeatability and reproducibility), control of known relevant interference and limits of detection. These performance characteristics need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.

Diagnostic devices and devices with a measuring function, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device, based on appropriate scientific and technical methods. The limits of accuracy should be indicated by the manufacturer.

Unlike pharmaceutical products, methods for selection and procurement of diagnostics have to be tailored to the end user, hence, procedures may differ between the types of diagnostics. In particular, the desired testing throughput, staff competencies and training requirements, and site

infrastructure will greatly impact the choice of diagnostic in a particular health facility.[21]

The IVD medical devices are allocated to one of four classes, using a set of rules as defined in the guidance documents of Principles of in Vitro Diagnostic (IVD) Medical Devices Classification.

Table 8: IVD medical devices risk and conformity assessment elements

IVD medical device classification	**Risk**	**Conformity assessment elements (RA/CAB)**
Class A	lowest risk devices	the quality management system for a Class A or Class B device shall be either a full quality management system or one without design and development control, the manufacturer must choose the one that it believes to be most suitable.
Class B	moderate to low risk	
Class C	moderate to high risk	Establish and maintain a full QMS
Class D	highest risk	Establish and maintain a full QMS
The level of scrutiny and evidence needed to demonstrate that the IVD Medical Device meets the Essential Principles for Safety and Performance and conformity assessment procedures shall be proportional to the risk class of the IVD Medical Device.		

Source: GHTF recommendation on harmonized conformity assessment system for IVD medical devices

The laboratory shall have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service. The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfill this requirement. Criteria for selection shall be established. The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned. Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before use in examinations.[22]

(c) Laboratory structure and network.

A well-defined laboratory structure must be established, which identifies key management and technical roles and responsibilities at each level, and establishes a functional laboratory network and referral system. The laboratory network should include a disease monitoring and response system where the ART and other laboratory SCMS can be effectively addressed while addressing other QSEs.

The main purpose of any supply chain management system is to get the right product, in the right quantity, to the right place, at the right time. There are usually two parts of supply chain management: supply chain planning – deciding what to do, and supply chain execution – communicating and executing the plan, as well as identifying and handling exceptions.

Approaches to supply chain planning can be operational, planning the day-to-day operations; tactical, planning week-to-week or month-to-month; or strategic, which is conducted once a year or so and is focused on how the network is structured. Since most of the work for the Ethiopia public sector supply chain systems has been of an operational and tactical nature, this study was planned to focus on the strategic analysis.

The tools and techniques used for the strategic analysis include:

- Network optimization – what is the most effective network, subject to rules of "constraint".
- Inventory optimization – profile the demand and supply and determine the optimum safety stock required for the system.
- Supply chain simulation – evaluate how the network will perform in the real world, including impact on service rates and analysis of the real-time inventory.
- Comparative benchmarking
- GIS mapping of the network – including transportation routes, customers, warehouses etc.

The purpose of the national or regional PSM manual for Procurement of Diagnostics and Related Laboratory Items and Equipment is to provide information essential to ensure high quality testing services on procurement processes specific to general and HIV related diagnostics, laboratory items and equipment.

.Monitoring and evaluation are used to assess a system's strengths and weaknesses. Monitoring should cover all components of a procurement and supplies management (PSM) system, and

monitoring and evaluation should trigger correction of all aspects that do not reach the target. Monitoring can therefore ensure continuous quality assurance of a national PSM system. Implementation of an effective monitoring and evaluation program requires trained personnel, financial and other resources, which should be well planned.

There are conventional indicators commonly utilized in many countries for the purpose of monitoring and evaluation of PSM with the following rationale:

- The performance of PSM systems must be monitored and evaluated regularly in a timely manner in order for corrective actions to be taken and to control quality.
- Core PSM indicators are needed that are relevant for all national laboratory supplies programs, donors and institutions.
- Harmonized indicators will highlight the most critical problems; avoid duplication of effort and complement monitoring and evaluation by multiple stakeholders.
- The 12 core indicators presented are common to all aspects of national PSM systems and are not specific to a donor or country program.
- They are common to the multiple bodies within a country that are responsible for contributing data (e.g. partners and stakeholders involved in the national PSM system, ministries of health, the national AIDS program and principal recipients).

Valuable information about PSM systems is routinely collected and stored but is often not used to analyze a system's performance. The SCMS indicators seek to make use of this information without an additional burden on already overwhelmed human resources.

Therefore, the aims of these indicators are to:

- Provide information about the factors associated with stock-outs and overstocking (e.g. lead time, insufficient quantities procured);
- Analyze routinely collected data to determine what is required to prevent stock-outs or overstocking;
- Provide timely evidence to prevent stock-outs or overstocking and to measure the per-formance of national PSM systems (e.g. countries with positive results); and
- Provide opportunities for:
    - enhancing collaboration among different levels in the national distribution system and

among relevant sectors and stakeholders working in national programs to supply ARVs and tuberculosis and malaria medicines;

- strengthening data quality assurance and regular data reporting; Data on consumption and stocks should be analyzed for real-time decision-making and further discussed in regular meetings with care providers and data managers; and
- Enhancing information-sharing and fostering partnerships among the various procurement stakeholders to achieve greater efficiency, problem-solving and synergy and thus improve the performance of national PSM systems.

The Organization for Economic Co-operation and Development (OECD) notes that four "pillars" are required for a good procurement system:

- Legislative framework
- Integrity and transparency
- Institutional and management capacity
- Operations and markets[20].

An effective public procurement system allows suppliers to provide satisfactory quality, service and price within a timely delivery schedule. The basic tenet of public procurement is contained in what are described by Bailey as the "five rights": the right product or service of the right quality and right price, and the right quantity, at the right place and time. Although this formula is simple, it involves questions of accountability, integrity and value, with effects far beyond the actual buyer and seller transactions at its centre.

Right quality:

- The right description and specifications, with the appropriate quality inspections.
- The description, specifications and inspections set the minimum standard acceptable.
- The description or specifications are generic, and are not suited or aligned to one particular firm or group of firms.
- The description or specifications are unambiguous.
- All tender respondents have equal opportunity in obtaining all relevant details.
- Specifications avoid stating that items will be procured "as per sample", to ensure transparency.

Right price:

- Rate estimation or justification is based on tangible factors; for example, last purchased rates, published maximum retail price, raw material cost, prices of similar or alternative products, or prevalent industry unit rate price.
- Negotiations or counter offers are rare and, if used, have specific guidelines, criteria and precautions. The tender system aims to obtain the best possible price, and not an unreasonably low price.
- Due diligence is exerted to look at all pages of all the offers received, to ensure that any price implications in the offer are identified.
- Vigilance is maintained, especially in cases of closely competitive tenders and unhealthy, cartel-type situations. Anti-fraud or anti-corruption software is applied when available. Protocols exist for declaring conflicts of interest and tracing accountability for all decisions.

Right quantity:

- Right quantity for procurement is justified, taking into consideration all the stocks available. As many requirements for the same item as possible are consolidated, taking into account the shelf-life of items and the lead time for procurement.
- No major change to the tendered quantity occurs after submission, because this raises suspicion and creates a lack of transparency.
- There is vigilance when it is necessary to distribute quantities among more than one tender respondent.

Right time and place:

- The right time and place for delivery are specifically and exactly stated in the tender (these have a bearing on the price), and the final accepted offer conforms to these factors.
- Logistics of issues such as supply and mode of transport are clearly specified.
- Terms of payment are outlined.

Laboratory strategic planning was believed to be the means for resource-poor countries to define direction, set standards, and make decisions on allocating capital and persons to achieve sustain-

able standards for quality laboratory services and formulated at the early stage of ART initiation in Ethiopia. Establishing an effective NLSP includes situational analysis of the existing laboratory network in the country by using a combination of standard approaches, including the existing strengths, weaknesses, opportunities, and threats to identify gaps that need strengthening. An effective NLSP has seven key components, which include the following: (1) policy, legal, and regulatory framework; (2) institutional and management framework that outlines the administrative and technical management structure of the national, regional, and district laboratories; (3) human resources, including issues related to training and retaining appropriate and adequate personnel to support a tiered laboratory network; (4) laboratory quality management

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

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

machine failures, and PFSA's limited capacity to deliver reagents to facilities, were among the major problems that affected the national laboratory logistic system in the country. [12]

The efficient and effective procurement of laboratory items critically impacts the quality of all laboratory services. Laboratory items are numerous and create serious challenges to procurement agencies. Important issues were noted on the need for adaptation of international guidelines, standard operating procedures (SOPs) which suit the national environment, training of human resources, quality assurance and advocacy for strengthened laboratory services. Different funding is often provided for different disease programmes in a vertical manner e.g. Global Fund, UNITAID, PEPFAR, etc and hence the same items may be purchased by several partners at country level. Quantifying needs is difficult to perform and especially if there are multiple procurement systems and vertical programmes in the country. A nationally-agreed list of laboratory items to be used and purchased, coordinated procurement planning among partners at country level and improving stock management of laboratory items could be the way forward to overcome such difficulties. [13]

Supply chain is a network of interconnected organizations or organizational entities developed with the goal of getting the right product to the right place at the right time. Supply chain encompasses every effort involved in producing and delivering a final product, from the supplier's supplier to the customer's customer. These efforts include managing supply and demand, sourcing raw materials and parts, manufacturing and assembly, warehousing, information management, distribution and delivery to customers. Supply chain management is the management of flows between and among supply chain stages to maximize total supply chain profitability.

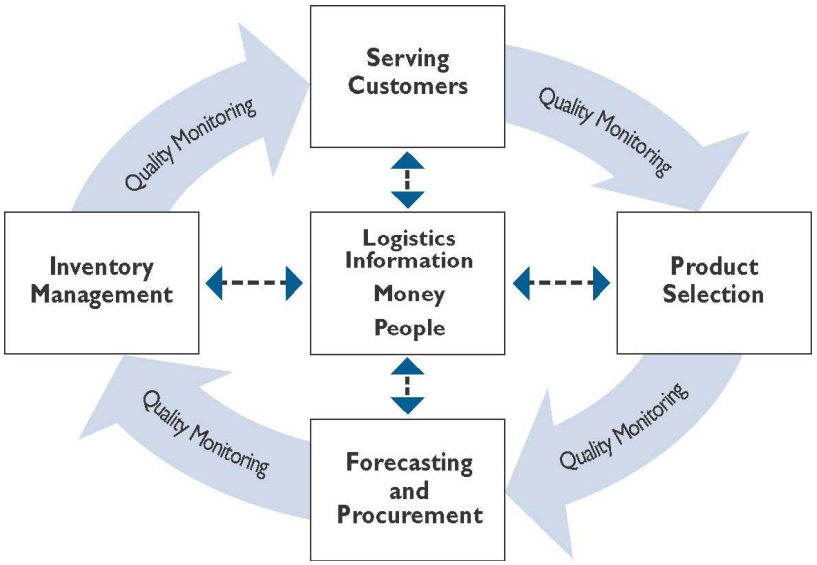
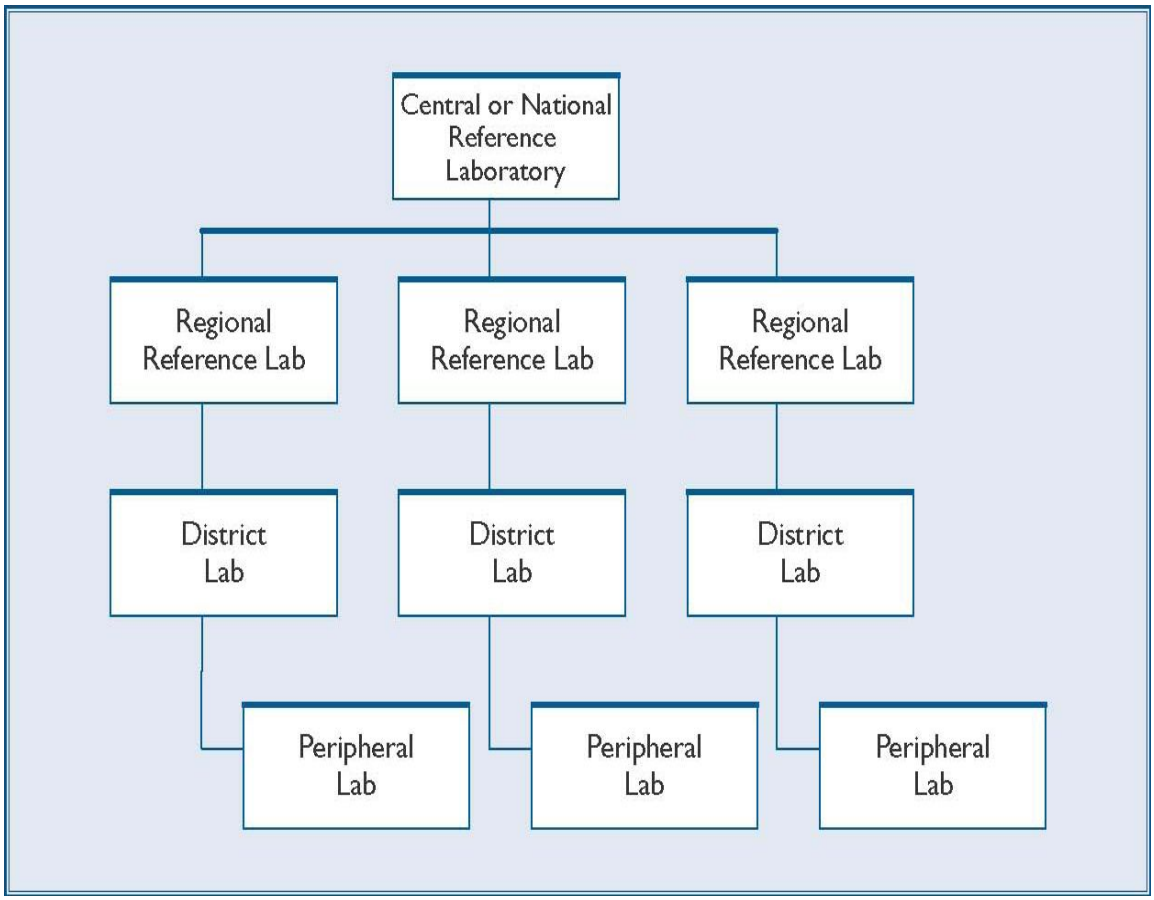


Figure 2: The logistics cycle, WHO procurement guideline

In most developing countries the organization of laboratory services usually includes a central or national-level laboratories, intermediate-level laboratories, and peripheral laboratories. Policies help set standards for laboratory practice, including the tests and techniques that will be used at each level in the system, which ultimately dictate the commodities that are required to support laboratory services. The unique characteristics of laboratory commodities impact the way in which the supply chain should be designed and managed to ensure the availability of these commodities. These characteristics include the need for large numbers of commodities that depends on the levels of the logistics system and variety of testing services provided, the various types preparation, packaging, and shelf lives.

Figure 3: Organization of Laboratory Services



CHAPTER III: RESEARCH DESIGN AND METHODOLOGY

3.1. Research Design

The entire SCMS involves suppliers of raw materials and other inputs, manufacturers, distributors, consumers and stakeholders in order to make avail right products, in right qualities and quantities and at right place and right time. However, the ART SCMS in our country is limited to procurement of equipments, reagents and consumable supplies from around the world, import, store and distribute to more than 350 ART laboratory health facilities in the nation.

For capturing relevant quantitative and qualitative data from those key actors of the SCMS this paper used non-experimental research design, specifically descriptive sample survey design was employed and only qualitative research methods was used.

The objectives of the study and the nature of variables necessitated the collection of some quantitative data from close ended and mixed questionnaires and more qualitative data using open ended questions in cross sectional study of stakeholders with a descriptive sample survey method which involved sample survey and interviewing was used to those research questions thereby addressing the objective of the study.

Regarding qualitative research methods, the research will apply semi-structured interviews with key information that will be identified and contacted with the help of guards and focus group discussion with a total of xx organizations and agencies working at a national level as a key stakeholders playing as a strategic key points. In addition, observations of the SCMS in some health facilities and facilitators setting will be conducted to see on how the implementation of the national strategy effectively and efficiently.

In order to analyze data generated by those above stated research methods, detailed documentary analysis will be made by locating relevant policy documents on strategy and guidelines, published journals, articles, dissertations and thesis, web based files from the internet etc,. are used.

3.2. Population and Sampling Techniques

Currently, there are a total of more than 1.065 ART centers all over the country most of which are governmental health facilities. This study was conducted in Addis Ababa mainly at the national owners and procurement agencies, regulatory authorities, donors, partners and other

stakeholders engaged in various leadership roles like setting national SCMS strategic planning and implementing guidelines, leading and managing various SCMS activities, financial and technical support, monitoring and evaluation of the SCMS implementation for a continuous improvement as required and other direct or indirect involvement at national and regional levels. These institutions include FMoH, HAPCO, EPHI, PFSA, private importers, FMHACA, few regional health bureaus or laboratories, donors (USAID/CDC, global fund & WHO), MSH/SCMS, commercial banks, insurance companies, custom authority, and transit firms (freight forwarders). 18 organizations and group of organizations which may have a national responsibility to design, plan and implement the national LSCMS of the ART program in Addis Ababa and other regions are included into the survey.

Based on those issues stated above, the author applied the assessment in all the national agencies and other stakeholders which are known to play a vital role in designing, planning, implementing and evaluating the LSCMS in Ethiopia. These institutions are chosen because they have a known authority and expected to play an overall responsibility in designing, planning, implementation and evaluation of the national LSCMS. Assessment of the existing system may be important for how the system functions and for effectiveness and efficiency of the SCMS against internationally recognized SCMS as a national laboratory program.

3.3. Types of Data and Tools/Instruments of Data Collection

In this study, some quantitative and more qualitative data were collected by the student researcher generated from both primary sources such as the respondents, informants, institutions and health facilities, and secondary sources i.e., official documents on health policy, strategy, guidelines, progress reported on ART program, published and/or unpublished journal articles, PHD dissertations, master's thesis, web-based files and similar other documents.

A structured questionnaire which is originally developed by other researchers and/or institutions but locally tailored was adopted and used to collect quantitative and qualitative data from the respondents. In order to triangulate those data collected using the questionnaire; the researcher employed interview guide/protocol, checklist/schedule, observation checklist, and documentary analysis template to collect the two types of data from both primary and secondary sources.

3.4. Procedures of Data Collection

The survey draft structured questionnaire was carefully developed based on a review of the

published international studies and then revised based on the comments and criticism of experts and professional colleagues who have been involved in conducting studies, managing and implementing the SCMS of the ART program.

In addition, the survey questionnaire was pretested after initial draft has been revised in response to the experts and professionals constructive suggestions. In what follows, the revised questionnaire was then be assessed by a focus group discussion of seven from both sexes to make sure that the items are relevant and understandable to the respondents in the actual sample survey and phrased in culturally appropriate terms. However, these FGD participants will be excluded from the main study undertaken later to avoid biases.

After the researcher has incorporated all relevant comments and suggestions, a pilot study was conducted using the modified questionnaires. In the pilot study, ten voluntary respondents who met the criteria were invited to participate in the miniature survey. In addition, the total time to complete the questionnaire was recorded. In the pilot study, the researcher facilitated the filling in the responses of all questions in the questionnaire by the respondents. By doing so the researcher obtained their feedback on the items, data for checking the reliability of the survey instruments and to receive their feedback and suggestions for improving the quality of the final questionnaire.

3.5. Methods of Data Analysis

Having completed the data collection of quantitative and qualitative data, the structured questionnaire was verified for accuracy and completeness. To address the study objectives, some descriptive statistics are used to assess all variables in the questionnaire to produce frequency distribution tables, measures of central tendency, measures of variability/dispersion and other types of relevant description. Regarding the qualitative data analysis, the researcher has first gone through the field notes, identified relevant issues, categorized them into different themes in line with the objectives of the study, and then put each theme into different labeled folders. Finally, these folders were consulted and used while writing the MBA thesis.

3.6. Ethical Considerations

This study was carried out mainly on the existing laboratory SCMS for ART program which didn't involve human being as a study cases and ethical clearance was not required.

4.0. Results and Discussions

4.1. Results/findings of the Study

Table 9: National Laboratory Program Operational Framework Indicators

		Survey Participant I													
S. No	**National Laboratory Program Operational Framework Indicators**	**FMoH**	**EPHI**	**FMHACA**	**PFSA**	**MSH/SCMS**	**Private Importers**	**GF/UNOPS**	**WHO**	**USAID**	**CDC**	**UNAIDS**	**RHBs**	**Health Fac. & Prof.**	**UNICEF**
1	Role	**Owner**	**Owner**	**Regulatory**	**Procurement**	**Procurement**	**Procurement**	**Donor**	**Donor/TS**	**Donor/TS**	**Donor/TS**	**Donor/TS**	**Owner**	**Owners**	**Donor/TS**
2	National Laboratory policy - Government commitment	-	-	NR	-	-	-	NR	-	NR	NR	NR	-	-	NR
3	National Laboratory program - Government commitment	-	-	NR	-	-	-	NR	-	NR	NR	NR	-	-	NR
4	National ART laboratory guideline - System productivity	2	2	NR	2	2	2	NR	2	NR	NR	NR	2	2	NR
5	Laboratory expertise utilization for ART SCMS - System productivity	2	2	NR	2	2	2	NR	2	NR	NR	NR	2	2	NR
6	National ART SCMS regulatory standard	-	-	NR	-	-	-	NR	-	NR	NR	NR	-	-	NR
7	National (regional) medical laboratory SCMS manual/guideline;	-	-	NR	-	-	-	NR	-	NR	NR	NR	-	-	NR
8	Methods and products validation (verification) practice; Quality	-	-	NR	-	-	-	NR	-	NR	NR	NR	-	-	NR
9	Equipments and devices management, maintenance and repair system: System productivity	-	-	NR	-	-	-	NR	-	NR	NR	NR	-	-	NR
10	National (regional) budget allocation system; Commitment	-	-	NR	-	-	-	NR	-	NR	NR	NR	-	-	NR
	Total point out of 40	**4**	**4**	**0**	**4**	**4**	**4**	**0**	**4**	**0**	**0**	**0**	**4**	**4**	**0**
	Percentage of Compliance (%)	**10**	**10**	**0**	**10**	**10**	**10**	**0**	**10**	**0**	**0**	**0**	**10**	**10**	**0**

Key of Responses: Full (4), Partial (2), Noncompliance (0), No Response (NR), Not applicable (NA)

Table 8 above shows ten national working framework indicators in which the national and regional laboratory programs are expected to operate in an optimized and systematized conditions. Each agency is rated from a total point of 40 which can be converted into 100% where all the institutions rated very low.

The main sectors actively participating directly or indirectly in the ART SCMS are owners (FMoH, HAPCO, EPHI, Regional health bureaus and health facilities), regulatory agencies, procurement agencies, donors & other partners, financial sectors and facilitators. A total of 25 indicators (check lists) were used under two main groups to assess whether these indicators are in place or not and their actual implementation level: The first ten (10) indicators were used to assess the overall national laboratory operational strategic framework which are supposed to be in place to design, plan, implement and evaluate the overall laboratory activities including the SCMS in Ethiopia. The second groups of 15 indicators were used to assess the ongoing monitoring and evaluation of the SCMS activities.

FMoH is the main owner of the laboratory program at a national level where by EPHI and regional health bureaus are mainly expected to play as the program operational role for ART and all healthcare programmes. The HIV/AIDS prevention and control (clinical response) case team is responsible to coordinate the overall national HIV/AIDS related activities and intersectoral collaboration matters. The case team is also responsible to develop policies and directions and review what may be developed by other agencies that are related to decision making at the FMoH including the laboratory programs and all other resources required for ART program. However there was no appropriate response to the interview and questionnaire on the laboratory program in general which are categorized under the national laboratory framework indicators as well as the second group of indicators related to SCMS in particular from the case team where there is no single laboratory expert in the team.

There are over 20,062 health service delivery points in Ethiopia with 311 governmental hospitals, 3500 health centers, and 16,251 health posts. The number of hospitals and health centers in the nation is 3,811 where at least ART services including part of the ART laboratory services can be offered. An overall of 1065 (27.95%) ART sites whereby 327 (8.58%) of ART sites with laboratory services are found offering ART services.

Table 10: Primary Health Service Coverage (Source: FMoH Website)

S. No	Institution	Before 1939	Before 1966	Before 1983	1984-1993	1994-2006
1	Hospitals	46	84	72	110	311
2	Health Centers	-	93	153	382	3500
3	Health posts	-	-	223	1023	16251
Total		46	177	448	1515	20062
Primary Health service Coverage		-	-	38%	50%	100%

HAPCO is the main federal agency mandated to coordinate the overall National HIV/AIDS Prevention and Control program within a multi-sectored approach including the coordination and management of resources for the ART program in receiving the funds and other resources donations from most donors and hence appropriate provision on the basis of national plan.

FMHACA is established and mandated by the proclamation number 661/2009 to carryout overall healthcare activities regulation in Ethiopia. However, there was no specific regulatory guideline or other document for medical laboratory supplies until September 2014. Moreover the authority is found to offer acquiesce to the request for interview and questionnaire in principle but reluctant to properly respond to the survey. Moreover, it is known that laboratory professionals are not assigned to carry out their professional expertise in the area of IVD registration, import permit approval and inspection where only pharmacists or other professionals are assigned to practice. Furthermore, private IVD importers are complaining that FMHACA is enforcing to hire a pharmacist who has no insight of these products instead of properly trained laboratory professionals.

EPHI has been said to be mandated to provide support and strengthen regional, federal and peripheral laboratories in order to enable them to accomplish their responsibilities and with a mission to establishing and maintaining a quality laboratory system. There is a dedicated directorate known as “Regional Laboratory Capacity Building Directorate” to carry out the strengthening role for many of the laboratory program components where there is a unit for the SCMS issues. The role of the SCMS unit is to participate in the specification and quantification

and advisory activities for the national procurement program of laboratory supplies in general and ART supplies in particular by PFSA.

PFSA is established and mandated by the proclamation No. 553/2007 of the federal people's representative council mainly "to establish and implement efficient and effective procurement and distribution systems to deliver, by using the drug fund and focusing on the country's major health problems, quality assured pharmaceuticals at affordable prices sustainably to public health institutions" among other powers and duties. PFSA uses the integrated pharmaceutical logistics system guideline (IPLS) which is meant to guide the management of all medical and pharmaceutical products and supplies. Procurement is carried out by the procurement directorate while forecasting, storage & distribution directorates are also carrying out their respective duties. However, there are two laboratory case teams are working separately in PFSA; where the "chemicals and laboratory reagents case team" is working under the procurement directorate for the regular health program supplies procurement, the other team which has been seconded by MSH/SCMS is working separately under the forecasting, distribution & storage directorates for the programmatic projects including ART and other programs. It is also known that these programmatic supplies are directly procured by the united states of America international aid (USAID)'s management contractor known as Management Sciences for Health (MSH) under the project known as Supply Chain Management System (SCMS) and delivered to PFSA main warehouse from where supplies are distributed to PFSA regional hubs that is said to be located within a maximum of 120 kilometers distance from ART services health facilities.

Table 11: Number of ART sites with supporting ART Laboratories

	# of ART sites	# of ART and ART lab Monitoring sites	# of Laboratory service only sites
	738	**327**	**17**
Total ART Sites	**1,065**		
Total ART Laboratories		**344**	
Total ART Laboratories (%)			**32%**

Source: SCMS, COP 14 procurement plan for 2015

MSH/SCMS project is mainly responsible to carry out the procurement of laboratory

commodities for the ART and other related programs carrying out quantification and procurement responsibilities. It uses an annual plan called Country Operation Plan (COP) carried out by all HIV/AIDS program related agencies, donors and other stakeholders usually on the basis of ART national target estimates with considerations of yearly ART services expansions. The annual plan is approved by FMoH and the budget is approved by USAID whereby the donation agreement is signed between these both parties. This document shows only estimated quantities of commodities to be procured in the COP for each program area and estimated procurement costs adjusted within the available funds where the procurement decision is guided by the direction from the USAID mission as summarized in the following table. No clear procurement criteria guideline is found to be followed in the selection of laboratory equipments and supplies either by PFSA or MSH/SCMS. Moreover, laboratory personnel at health facilities and other level of the health system have complained that they have very low or no access in either the bid or other form of procurement process while the bid procedure usually favors the low cost principle at the expense of quality.

Table 12: Summary of ART Laboratory Supplies Budget

Supply Item	**Budget allocated**	**% of Budget by Supply Item**
CD4 Reagents	$5,694,871	63.28
Chemistry Reagents	$784,896	8.72
Hematology Reagents	$1,244,331	13.83
Viral Load	$1,049,998	11.67
ARV Drug Resistance Supplies	$28,312	0.31
Microbiology	$47,590	0.53
Laboratory machines	$150,000	1.67
Total:	$8,999,998	100.00

Source: SCMS, COP 14 procurement plan for 2015

Most of the budget (more than 63%) goes to CD4 supplies while the least proportion (0.53% & 0.31%) goes to microbiology and ARV drug resistance testing supplies respectively. In principle, the procurement of Laboratory commodities is said to be based on the bi-monthly consumption report and requests from health facilities. However, the interview response shows that significant discrepancy is usually encountered between forecasting based on the compiled health facilities consumption report and that of the national target ART cases estimation of the laboratory commodities that poses difficulty to reconcile the discrepancies. Moreover, there is no compiled data found to compare the mentioned discrepancy as there is no regular reporting from health facilities be sent to zonal health offices and nearby PFSA hubs despite it has been designed to fill the IFRR. Regular consumption reporting is found to be irregular with frequent interruption between health facilities, & zonal health offices and no report is made to regional health bureaus, EPHI and hence FMoH due to the absence of clear laboratory operational plan including the ART SCMS nationwide.

Only two of the procurement and SCMS performance indicators were found to be practiced by MSH/SCMS project namely the procurement cycle time for international suppliers & supplier performance for local suppliers among many other important indicators like System Productivity, Efficiency, products quality, procurement integrity, payment efficiency, timeliness and cost.

The main donors and partners like USAID, CDC and UNAIDS refused to respond to the research questionnaire and interview request. Global fund has no office in Ethiopia and it carries out its donation through a local fund agency (LFA) which is not in a position to respond to this survey as it is not dealing with technical issues. It is also learned that experts are usually coming to Ethiopia whenever needed and WHO guidelines are used regarding the procurement and management of laboratory supplies and other medical supplies.

WHO is found to be one of the major stakeholders in the ART program by actively participating in system design, system development, implementation and monitoring of various normative documents, policy advices and guidelines. It is also playing an active role in the national ART planning (quantification) and forecasting of ART laboratory commodities. WHO is also known by developing and implementing international standards of laboratory and other medical SCMS across the world mainly for the poor setting health facilities in the developing countries. It is found operating all these contributions without having a single laboratory professional.

There is also no clear national guideline on the type and frequency of laboratory tests for HIV/AIDS patients before and after the initiation of ART, despite physicians are claiming that

they use WHO guideline to treat the ART patients.

Table 13: SCMS ongoing monitoring indicators

		Participant II																
S. No	**Laboratory SCMS Continuous Monitoring Tools (Indicators)**	FMoH	EPHI	FMHACA	PFSA	MSH/SCMS	Private Importers	GF/UNOPS	WHO	USAID	CDC	UNAIDS	RHBs	UNICEF	Health Facilities & Professionals	Custom	Com. Banks	Insurance
		Owner	Owner	Regulatory	Procurement	Procurement	Procurement	Donor	Donor/TS	Donor	Donor	Donor/TS	Owner	Donor/TS	Owners	Regulatory	Finance	Finance
1	Product Price Variance	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
2	Effective Contract Utilization -	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
3	Procurement mechanisms	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
4	Expiration Management	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
5	Supplier Performance	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
a	Supplier delivers the correct goods & on time	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
6	Procurement Cycle Time, timeliness	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
7	Payment Processing Time	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
8	Emergency Procurement,	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
9	Procurement Cost,	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
10	Staff Training, – system productivity	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
11	Transparent Price Information,	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
12	Transparent Tendering,	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
13	Financial transaction and payment processes	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	2	NA
14	Insurance service	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	4
15	Customs taxation and clearance processes -	-	-	-	-	-	-	NR	-	NR	NR	NR	-	-	-	NA	NA	NA
	Total Point out of 60	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**4**
	Percentage (%)	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**50**	**100**

Key of Responses: Full (4), Partial (2), Noncompliance (0), No Response (NR), Not applicable (NA)

MSH/SCMS and private suppliers and venders have commonly complained on regulatory authority (FMHACA), bank, custom and cargo warehouse with frequent and continuing difficulties listed as follows:

Regulatory (FMHACA):

- Too much time and resources wasted in the process or product registration.
- Same for approval of purchase orders of registered products.
- Again time and resources wasted upon arrival of goods.
- A lot of resource is wasted on imported products due to "short shelf life" expected by the authority while the reagents are to be consumed in a short span of time.
- Disposal process is too long, complicated, involves too many people and not transparent.
- Pre-import approval required for warranty and modification parts.
- Proficiency testing samples, quality control and consumable materials are treated like other products while they do not naturally fulfill the actual product qualification.

Customs:

- Process to clear goods takes too long (2 to 4 weeks).
- Excess tariff of 5 to 30% charged on some products imported purely for IVD purposes.
- Excess duty claimed over and above invoice value legalized by Chamber of Commerce, claimed "under invoiced".

Banks only for private importers:

- Banks take too long to avail foreign currency. It is common to queue for one month and at times as long as three months.
- Banks block full amount of proforma invoices for however long it takes goods to arrive.
- Bank permit and document for customs clearing take too long.
- Documents required by the bank e.g. Certificate of origin is a must for the same products imported for more than 15 years.

MSH/SCMS project has no problem of foreign currency as the PEPFAR donation fund and procurement arrangements are actually managed by the procurement management office (PMO)

at it's headquarter in the United States.

Inland Revenue only for private importers:

- Profit tax is charged on goods returned from customers for various reasons, and even when the products are unused and in inventory as expired stock.

Airline (cargo):

- Location of shipments sometimes not found.
- Warehouse charges are too high.

Insurance:

- Marine insurance premiums are too high for expensive but safe means of air transport.

The response from commercial banks shows that there are directions to focus on three priority areas for foreign currency permit every fifteen (15) days to import good including fuel, industrial projects and health commodities while other commodities are also allowed by committee decisions intermittently.

The response from customs authority shows that there is no significant problem in handling healthcare products as it has a guideline and procedure to release many of the perishable products imported or to be exported including pharmaceuticals and other healthcare products. The authority claimed that taxation of healthcare products is as small as 5% or even free of taxes in some cases. It also claimed that products are released even before declaration is made when products are imported by PFSA & MSH/SCMS project while private importers are required to fulfill all custom clearance requirements before the release of goods.

Information from health facilities and professionals show that CD4 test is the only monitoring surrogate used in most case for patients' ART decision and ongoing monitoring while viral load and resistance testing services are almost not available. Furthermore, there are consistent shortage of many other testing services used for screening and monitoring of drug toxicity, adverse effect, concomitant and opportunistic infections.

High turnover in almost all health facilities and shortage of laboratory personnel in many of district health facilities are also known to be among other problems which is also found to be the main factor affecting the practice of quality management system of each facility laboratories and hence the reason for poor quality services.

4.2. Discussion

National health agencies, the regulatory authority, donors and other partners, regional health bureaus, health facilities & professionals and private importers are found working with a very least and inconsistent laboratory management operational frameworks and guidance and inappropriate regulatory impositions for the laboratory program in general and laboratory ART program in particular. This can be illustrated by the absence of national laboratory policy, clear national laboratory operational system and program, a well-defined laboratory structure to identify key management and technical roles and responsibilities at each level, clear regulatory guideline for laboratory SCMS, clear laboratory SCMS guideline, clear ART guideline and absence of known operational budget in carrying out their respective role in the national laboratory program and ART supplies management.

FMHACA's establishment and mandate proclamation number 661/2009 defined "Medicine" as "any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in human and includes narcotic drugs, psychotropic substances and precursor chemicals, traditional medicines, complementary or alternative medicine; poisons, blood and blood products, vaccine, radioactive pharmaceuticals, cosmetics and sanitary items and medical instruments;" And

"Medical instrument" is defined as any instrument or supply that may be used on the inner or outer part of the body for diagnosis or treatment of a disease in human, and includes various diagnostic laboratories, surgery, dental medical instruments and suturing materials, syringes and needles."

These definitions are very vast and comprehensive that may need for disambiguation and all medical and technical terms need to be clearly defined to their relevant application to avoid ambiguity in the day to day regulatory activities that can impact the activities of suppliers, vendors and eventually the end user institutions, professionals and the patients at large as a result of inappropriate regulatory imposition. For instance FMHACA has been following its "Guideline for registration of medicine" which is practically dealing with drugs that has been used for the registration of IVDs and other medical equipment until September 2014 which are actually different products with different standards and requirements. Basically, drugs requirements are dealing with the in-vivo studies while that of IVDs are dealing with in-vitro studies.

The current FMHACA guideline for registration of medical devices outlines various IVD classification and compliance requirements based in international IVD standards for registration.

Moreover, it outlined further requirement in part I as; "*Where applicable, a sample of actual products may be requested for the purpose of visual confirmation and/or for the purpose of laboratory testing or analytical performance evaluation of the device. Also, as ample specimen of the packaging materials may be requested, when applicable*."

However, it is not satisfactory in contrast to the ISO 15189 medical laboratory equipments and supplies requirements for device and method verification terms, WHO guideline and other standards for the performance evaluation of laboratory supplies before use as there is no obligation to enforce the standard that is important for quality. Furthermore, the verification procedure requires an advanced center of excellence where highly trained various laboratory scientists are practicing in their respective specialties and properly recognized standards are available if not "Gold Standards" against which any new method or device can be verified, evaluated and assured for quality and performance before use. Malpractice

Moreover, the FMHACA regulatory standard has given very little attention to mandatory enforcement of professional role and scope of practice including its importance in the laboratory regulation at all level of laboratory practices where it is common to observe many non-laboratory personnel malpractice the laboratory practices in many places including governmental, nongovernmental and private institutions that also shows that the regulatory measures are not addressing the professional abuse. Besides, the authorities and responsibilities given to the laboratory manager or director however it is called, by the FMHACA laboratory standards is almost unnoticeable as it gives all the responsibilities to the governing board which is also different in governmental and private facilities. In contrast, all authorities and responsibilities of the laboratory management and leadership is bestowed upon the laboratory manager or director in most of the international accreditation and regulatory standards including ISO15189 so that would enable the laboratory management issues including SCMS are properly carried out in a professional manner.

The absences of most of the national working frame works for the laboratory program including national laboratory focal point (department) at FMoH, the national laboratory coordinating committee with the responsibility and accountability for steering and monitoring the health laboratory services, laboratory policy and other SCMS related guideline, national and regional laboratory operational budget allocation, proper regulatory functions to ensuring competent performance as well as confidence in the laboratory services, proper procurement function and many others shows that the national laboratory program is not in place yet. The absence of

proper reporting of SCMS and other laboratory activities from health facilities to zonal and regional health bureaus and hence to FMoH also substantiates the absence of national program that would necessitate regular supervisions and follow-ups on each facility laboratory performances.

The student researcher acknowledges the unprecedented contribution of the global fund, the PEPFAR program through USAID, CDC and other donors and supporting partners as they are playing the major role in the Ethiopian ART rollout, the improvement of the laboratory and other health services by introducing internationally recognized standards and providing technical and financial supports in many ways.

PFSA's role is known to receive, store and distribute the laboratory supplies and equipment procured by MSH/SCMS project to health facilities for the ART program. However, the agency's structure and organization for the laboratory SCMS in general and ART commodities in particular is found to be weaker in that there is no integration of functions and efforts when one case team (with inappropriately name, chemicals and reagents case team) is working under the procurement directorate, other case team is working under two other directorates namely forecasting and storage and distribution while there is also another team for the equipment procurement and management. Furthermore, the agency has been carrying out the procurement of medical laboratory equipment and supplies without proper professional expertise until recent times and still it has no laboratory professionals at its regional hubs for supplies handling and distribution.

Supplies storage and distribution activities are also found to be another major challenges where there are no proper storage condition for those supplies requiring freezing temperature like the viral load kits, some calibrators and other supplies prohibiting the provision of laboratory services to be done by these supplies. Inappropriate distribution of supplies are also found to be common, where some of the kits meant to do a single test are taken to some health facility the remaining would go to other health facility where it would end up in neither of the facilities could perform the given laboratory test because of impartial supply distribution. The other identified distribution problem is when laboratory reagents and consumables are distributed to health facilities where the laboratory equipments are already down and the supplies would expire and wasted while many other health facilities are suffering shortage of supplies.

Equipment repair and maintenance is also found to be major challenges of laboratory performances while there is a national program at EPHI to manage these functions. These

problems are emanated from the absence of trained maintenance personnel for all sources of devices which is impossible to accomplish by the government on one hand and the lack of capability and accountability of local vendors to take responsibilities for all the devices they sold.

Most of the private importers and agents assume exclusive agent ship and they make huge margin on equipment and supplies that is eventually imposed on the end-users.

5.0. Conclusions and Recommendations

5.1. Conclusions

This assessment shows a clear lack of commitment from the FMoH and regional health bureaus for the fact that most of the national laboratory working frameworks are not in place including national laboratory operational program plan, National Laboratory policy, national ART laboratory guideline, effective laboratory expertise utilization for ART SCMS, national (regional) medical laboratory SCM and regulatory manual/guideline, national ART SCM and regulatory standard, equipment and devices management, maintenance and repair system, and national (regional) budget allocation system. Moreover, there is no or very little system to monitor the efficiency and effectiveness of the laboratory SCMS in general and ART commodities in particular.

Most importantly, medical laboratory SCMS monitoring activities including System Productivity, staff training, Efficiency, products quality, procurement integrity, payment efficiency, timeliness and cost are found to be not practiced by the procurement agencies.

The overall assessment of the existing national laboratory SCMS indicates very low level of supplies provision in quantity and quality where the overall laboratory service facility for ART is found to be poorly functional are 8.59% of the total 1065 ART service delivery points while supplies shortage are common even for these existing laboratories. There is very long way to go!

5.2. Limitations of the study

This study is strictly limited make the survey of the national laboratory ART SCMS qualitatively on how well the system had fulfilled important working frameworks and how well the ART SCMS is monitored and evaluated continuously.

The impact of the existing national SCMS couldn’t be examined quantitatively because of the

fact that the scope of the study is very wide and resource demanding.

5.3. Recommendations

1. Commitment of FMoH and RHBs is strongly recommended by allowing and providing appropriate working ground, infrastructure and resources for the overall laboratory program and SCMS mainly in the following area but not limited to:
   A. National and regional laboratory operational program and plan
   B. Setting national laboratory policy
   C. Establishing a well-defined laboratory structure functional networking starting a department at the FMoH downward to RHBs and zonal health offices while strengthening regional and district laboratories.
   D. Allocating defined budget for all laboratory operational activities and running costs at all level down to the health facilities.
   E. Setting national laboratory SCMS guideline.
   F. Setting national laboratory ART guideline.
   G. Fostering strong intersectoral collaboration among all concerned government agencies and other stakeholders to minimize or avoid those limiting factors that may create hindrance and delay in SCMS.
   H. Creating strong employee retention mechanisms at all level.
   I. Allowing and encouraging as many as possible internationally recognized and leading IVD manufacturers to open their branches in Ethiopia by improving some hindering policies in collaboration with other stakeholders for the provision of goods and supplies at a competitive quality and costs to reduce lead time, service interruption, equipment maintenance problems and unnecessary government investments and costs.
2. Commitment of FMHACA is strongly recommended to have a well organized and functional laboratory department for all the regulatory activities with all internationally recognized regulatory standards and tools to cope up with the demand of regulatory functions for the overall laboratory components where the SCMS regulation would be solved all together of this huge country, Ethiopia.

3. Commitment of PFSA is also strongly recommended to properly organize a functional department at all level of its facilities to carry out effective laboratory SCMS for the given mandate.
4. Complete and detail survey is strongly recommended.

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Annex 1: National Laboratory Services SCMS Performance Indicators (Checklist)

1. The function of the organization/unit/person being assessed regarding HIV/AIDS & ART
2. National medical laboratory policy and plan available and implemented: government dedication & commitment:
3. National (regional) medical laboratory management program available and implemented: Leadership, System functionality and integrity
4. National (regional) ART laboratory guideline: practical framework and direction
5. Professional manpower assignment (laboratory expertise utilization)
6. National (regional) medical laboratory products regulation program; Quality
7. Methods and products validation (verification) practice; Quality
8. Equipments and devices management, maintenance and repair system; Quality
9. National (regional) budget allocation system; Commitment
10. Product Price Variance, Percentage price variance between contract unit price and international unit price for focus products - Prices paid for focus goods are in alignment with international prices – cost
11. Effective Contract Utilization, Percentage by value of purchases made under simple purchase orders, annual contracts, and multi-year contracts
12. Efficient procurement mechanisms are being used – cost
13. Expiration Management, Annual dollar value of expired products or percentage value of expired products
14. Good supply chain practices are being used, including inventory management, demand management, and the timely supply of good quality products – quality
15. Supplier Performance, Percentage of orders in compliance with contract criteria &
16. Percentage of orders delivered on time
    A) Supplier delivers the correct goods - quality
    B) Supplier delivers goods on time – timeliness
17. Procurement Cycle Time, Percentage of procurements completed (placed) within standard time guidelines
18. There are no delays in executing procurements – timeliness

19. Payment Processing Time, Percentage of supplier payments made within the payment period called for in the contract - There are no delays in processing payments to suppliers – timeliness
20. Emergency Procurement, Percentage, by value and number, of purchase orders or contracts issued as emergency orders - Good supply planning practices are being used – systems productivity
21. Procurement Cost, Ratio of annual procurement unit cost-to-value of annual purchases
22. Level of efficiency of operations in procurement unit – systems productivity
23. Staff Training, Key training program components are in place and the percentage of staff who receive training annually - An effective training program is in place to improve procurement staff skills – system productivity
24. Transparent Price Information, Percentage of products with prices posted on publicly accessible website - The level of product pricing information that is available to the public – system productivity
25. Transparent Tendering, Percentage of total value of contracts that were awarded through an open and competitive process - The level of competition achieved through a competitive bidding process - integrity
26. Easy and efficient financial transaction processes and procedures:
27. Easy and efficient financial insurance service processes and procedures:

DECLARATION

I, the undersigned, declare that this thesis is my original work, prepared under the guidance of St Mary's University. All sources of materials used for the thesis have been duly acknowledged. I further confirm that the thesis has not been submitted either in part or in full to any other higher learning institution for the purpose of earning any degree.

Gizachew Kedida

Signature& Date