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Abbreviations

AA:	Addis Ababa
AHPSR:	Alliance for Health Policy and Systems Research
ADE:	Adverse Drug Events
BGR:	Benshangul Gumuz Region
CSA:	Central Statistics Agency
CBHI:	Community Based Health Insurance
DTC:	Drug and Therapeutic Committee
DDD:	Defined Daily Dose
DACA:	Drug Administration and Control Authority
EHIA:	Ethiopian Health Insurance Agency
EDHS:	Ethiopian Demographic and Health Survey
EFY:	Ethiopian Fiscal Year
EML:	Essential Medicines List
EFMHACA:	Ethiopian Food, Medicines and Health Care Administration and Control Authority
FSML:	Facility Specific Medicine List
GTP I & II:	Growth and Transformation Plan I & II
HSDP IV:	Health Sector Development Program IV
HSTP:	Health Sector Transformation Program
IPRs:	International Price Ratios.
LPGW:	Lowest Paid Government Worker
MSH:	Management Sciences for Health
MPRs:	Median Price Ratios
MOH:	Federal Ministry of Health

MOI:	Ministry of Industry
NMP:	National Medicines Policy
NCDs:	Non-communicable Diseases
NFM:	National Formulary Manual
OPDs:	Outpatient Departments
PFSA:	Pharmaceuticals Fund and Supply Agency
PMLU:	Pharmaceuticals, Medical Equipment and Logistics Unit
PMNCH:	Partnership for Maternal, Newborn and Child Health
PHFs:	Public Health Facilities
PMROs:	Private Medicine Retail Outlets
PSA:	Pharmaceutical Sector Assessment
SHI:	Social Health Insurance
SIAPS:	Systems for Improved Access to Pharmaceuticals and Services
STGs:	Standard Treatment Guidelines
SNNPR:	Southern Nation, Nationalities and Peoples Region
SDGs:	Sustainable Development Goals
UN:	United Nations
UHC:	Universal Health Coverage
WHO:	World Health Organization
WB:	World Bank

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Disclaimer

The views expressed herein are those of the Authors and cannot therefore in any way taken to reflect the official opinion of the European Union or the World Health Organization.

Executive summary

Background

This National Pharmaceutical sector assessment was conducted in Ethiopia in June 2016 with the objective of assessing and monitoring the impact of policies, strategies, regulation and activities in improving access to safe, effective and quality essential medicines and their rational use using WHO Level I and II indicators.

Methods

The survey employed WHO Operational Package for assessing, monitoring and evaluating country pharmaceutical situations (December 2007 Version). Purposive and stratified random sampling was used to select the study regions from the 9 Regional states and 2 City Administrations including the capital city. The selected areas/regions included: Addis Ababa (Capital City), Amhara, Oromia, Southern Nation Nationalities Peoples Region, Benshangul-Gumuz and Somali Regional States. In each region, 6 public health care facilities representing the three tier level of care, 6 private medicine retail outlets and 1 warehouse were surveyed. Data collection was done using forms developed by WHO with slight modification to include some variables of national interest and data entry and analysis were performed using SPSS statistical software (Version 21) and Microsoft Excel (v 2010). Results are expressed as percentages, mean, median, ratios, etc.

Key results

Level I Indicators:

Analysis of level I indicators suggested that the basic structures, regulatory framework and instruments for promoting access to quality assured medicines and their rational use are in place. However, the performance in certain areas still remains to be improved. The National Medicine Policy (NMP) designed to guide developments in pharmaceutical sector was developed before two decades and currently the revised version has not been endorsed and made available. The major health financing source including medicines' financing remains to be households.

Level II Indicators:

Access

Access to essential medicines is an integral part of meeting one of the fundamental human rights of citizens i.e. access to health care. There are, however, numerous reasons that hinder access including geographic inaccessibility of facilities supplying medicines, unavailability of medicines, high medicines price, and unaffordability by the majority of the population.

In the present survey, the overall indicators of access show that the median percent availability of basket of medicines selected in public warehouses was 70.7% and the public health facility

dispensaries had median availability of 72.4%. Availability was slightly lower at private medicine retail outlets (67.3%). The individual median availability of 14 medicines out of 29 assessed in Public Health Facilities (PHFs) and 10 out of 27 in Private Medicine Retail Outlets (PMROs) were less than 65% (considered low). The median availability of basket of medicines used for chronic illness including hypertension, diabetes and mental illnesses was found to be low (54.55%). The median percentage availability of medicines for non-communicable diseases in majority of surveyed regions/city administrations was very low (< 50%). The length of stock out duration was 19.6 and 26.6 days for public health facility dispensaries and warehouses supplying the public sector, respectively.

In the public health facilities, the procurement price was 1.60 times higher than international reference prices, indicating a need for improvement in the level of purchasing efficiency. Similarly in public health facilities and private medicines retail outlets, medicines were found to be sold at a price 1.8 and 4.94 times higher than International Reference Prices (IRPs), respectively.

The affordability of treatments for 4 tracer infectious diseases and 8 selected non-communicable diseases was investigated. In public health facilities, except for treatment of adult respiratory tract infection which required 1.27 days' wages, the cost of the standard treatments for the rest of tracer conditions was reasonable, requiring less than a day's wages. In private medicine retail outlets, although less than in public facilities, medicines had reasonable affordability for most infectious conditions. On the other hand, treatment affordability to most non-communicable diseases with medicines obtained from both PMROs and public health dispensaries were found to be compromised with minimum days' wages required to purchase a one month Defined Daily Dose (DDDs) ranged from 1.17 to 1.93 in PHFs and 1.19 to 6.69 in PMROs.

The present survey measured geographic access by time travelled to reach at the health facilities. In this regard, out of 1074 exit interviewed participants, 499 (47%) claimed that it took them less than 30min to reach to the PHFs; while 357(33%) said that they travelled greater than an hour to access the health facility. Nearly 90% of the respondents interviewed claimed that it took them under an hour to access private medicine retail outlets.

Quality

The median adequacy of conservation condition of medicines in stores of Pharmaceutical Fund and Supply Agency (PFSA) was found to be better than the conditions in public health facilities and private medicine retail outlets (81.8 vs. 72.7 vs. 70). It was also found that the adequacy of the conservation conditions declined with the level of private dispensing outlets.

Rational use of medicines

The average number of medicines per-prescription was 2.25, higher than the 2003 and 2010 figure. The proportions of antibiotics and injectable containing prescriptions were 30% and

10.49%, respectively. Out of the total prescribed medicines, 99.67% was from Essential medicine list/Facility specific medicine list and 96.42% were in generic names.

Fairly good results were observed in patient care indicators except adequacy of labeling practice which was found to be 19.9%. The extent of meeting FMHACA's labeling requirements ranged only from 1.78% to 52.63%.

The present survey also demonstrated that there was deviation from the guidelines with regard to the management of childhood diarrhea and non-pneumonia ARI. Antibiotic and anti-diarrheal uses were observed, respectively in 64.41% and 3.82% of the cases of acute watery diarrhea. And 13% of children with the same conditions did not receive ORS. Moreover prescribers in public health facilities were found prescribing an antibiotic to 73.89% of patients of any age with non-pneumonia ARI.

Additional indicators

The law concerning human resources requirements is not well followed by nearly half of the PHFs and 1/5th of the PMROs. The most commonly found senior prescriber in the public health facilities was health officers and only 11.1% participated in training related to rational use of medicines in the previous year.

The present survey also noted that, on the day of visit, standard prescription papers (for narcotic and psychotropic medications) distributed by EFMHACA were found only in slightly higher than 50% of the facilities (52.78% for narcotic and 55.56% for psychotropics). Moreover, the average availability of the instruments and support facilities to promote implementation of national medicine policy at the public health institutions was found to be below 50%.

IPLS was one of the interventions in place to ensure an efficient and high-performing healthcare supply chain in Ethiopia. However, the present assessment indicated that IPLS was reported to be non-functional in close to 1/3rd of the health facilities covered.

Conclusion and recommendations

The survey showed the existence of numerous positive and encouraging improvements in some areas of the pharmaceutical sector. However, there are areas which require further improvements in order to improve the sector and make quality, safe and affordable medicines more accessible. Although regions need to conduct assessment in their specific areas to get a more in-depth understanding of the underlying causes of specific deficiencies and inform decision making, the present national survey tried to outline recommendations for action to improve the performance of the sector.

1 Introduction

1.1 Background

"Ensuring healthy lives and promoting well-being for all at all ages" is one of the Sustainable Development Goals (SDGs) and founding concept of the World Health Organization and the Universal Deceleration of Human Rights (WHO, 2016). Realizing this goal requires the existence of a well - functioning Health Care System.

Use of medicines is a critical factor in health system efficiency. However, the ability of pharmaceuticals to save lives, reduce sufferings and improve health depends on their quality, safety, efficacy, availability, affordability and rational use. Cognizant of these, many countries in the world developed and implemented National Medicines Policy taking into consideration access, quality, safety and rational use as key strategic objectives. To monitor the progress of efforts to improve the global medicines situation, WHO has developed a system of indicators that measure important aspects of a country's pharmaceutical situation (WHO, 2007).

In line with this, EFMHACA, FMOH and WHO collaborated in the past (2003 and 2010) in assessing the pharmaceutical sector using level I and II indicators. The conclusion and recommendations made out of both surveys showed that most of the parameters measured were sub-optimal.

Ideally WHO recommends that indicator based assessment and monitoring of the pharmaceutical sector have to be made every four years to document meaningful changes. However in the case of the Ethiopian pharmaceutical sector, more than five years have elapsed since the 2010 survey. Many changes have occurred in the sector since the last survey. To mention some, the completion of GTP I and launching of GTP II, development and completion of HSDP IV which led to formulation of HSTP covering 2015 -2020 and launching of ten years national strategy and plan of action for pharmaceuticals manufacturing in Ethiopia (NSPA-Pharm 2015-2025). FMOH, EFMHACA and PFSA have also developed and started implementation of their respective transformational plans. All of the above plans, strategies and initiatives are believed to have impacts on the pharmaceutical sector. Hence the present survey attempted to measure progress made and also would serve as a baseline for measuring implementation of HSTP and GTP II.

This survey was a joint activity between government institutions EFMHACA, PFSA, PMLU (PFSA, FMHACA, PMLU and EHIA) and WHO. WHO provided technical and financial support as part of the 4th year work plan of the EC/ACP/WHO renewed partnership. USAID/SIAPS (MSH) were also involved in the survey as a member of Task Force.

1.2 Country background - Health and pharmaceutical sector

Ethiopia is a country in the horn of Africa and one of the oldest states. As of 2016, the country's projected population was nearly 102 million with a population growth rate of 2.5%, proportion of rural population was nearly 80% and life expectancy at births of 65 and 61.3 years for females and males respectively (UN, 2016). The general fertility rate was 160 per 1,000 women of age 15-49 years and maternal mortality ratio per 100,000 live births (LB) of 412 (CSA/ICF, 2016). The 2011 EDHS data showed that U5MR was 88/1000 LB (MOH/PMNCH/WHO/WB/AHPSR, 2015). The country follows federal system and is divided into 9 regional states and two administrative councils. These are further subdivided into 85 zones and 836districts (*woredas* in Amharic).

The healthcare service in Ethiopia has always consisted of a mixture of public, private and nongovernmental healthcare sectors. However, currently the public healthcare system is organized into a three-tier health care delivery system which was introduced in 2010 (FMOH, 2010). Level one is a *woreda* health system comprised of a primary hospital (for 60 000–100 000 people), health centers (for 15 000–25 000 population) and their satellite health posts (for 3000–5000 population), connected to each other by a referral system. The primary hospital, health centers and health posts form a primary health care unit. Secondary health Care is a general hospital for 1–1.5 million people and Tertiary Health Care is a specialized hospital for 3.5–5 million people.

One of the vital components of the healthcare is medicine. Medicines are crucial high value input for the health care systems that often make a difference in the health outcomes for the individual and the population (Fidler and Msisha, 2008). The pharmaceutical sector in Ethiopia is regulated by Food, Medicine and Healthcare Administration and Control proclamation No. 661/2009(FDRE, 2010). Accordingly, the Ethiopian Food, Medicines and Health Care Administration and Control Authority (EFMHACA) under the Ministry of Health (MOH) and its Regional Regulatory Counterparts are in charge of enforcement of the major regulatory functions

including marketing authorization, regulatory inspection, licensing of premises, marketing surveillance and control, pharmacovigilance, clinical trial oversight, etc. The Authority is aiming at ensuring that medicines marketed in Ethiopia are efficacious, safe and of high quality. The National Medicines Policy was issued in 1993 with a number of policy implementation instruments developed subsequently. For example, list of essential medicines, standard treatment guidelines and national formulary have been developed and used for promotion of rational use of medicines. As part of implementation, Pharmaceutical Logistic Master Plan was prepared, and Pharmaceuticals Fund and Supply Agency (PFSA) was established in September 2007 by Proclamation No. 553/2007 to assure uninterrupted supply of pharmaceuticals to the public at an affordable price.

In 2015, the annual pharmaceutical market in Ethiopia, was estimated at US$400 to US$ 500 Million and expected to reach at around US$ 1 billion by 2018 (MoH and MoI, 2015; Frost and Sullivan, 2012).

The number of pharmaceutical importers and wholesalers was 329 and 287, respectively and in 2007 E.C. there were 5136 medicine retail outlets including 780 pharmacies, 1030 medicine shops and 3266 rural medicine vendors. Most of the local pharmaceutical manufacturing companies operate below at lower capacity and could only cover about 20% of the local demand (MoH and MoI, 2015). In 2015, the Government of Ethiopia in collaboration with WHO has developed a national strategy and plan of action for pharmaceutical manufacturing development in Ethiopia that facilitates the development of the sub-sector and thereby increasing people's access to quality proven affordable medicines..

2 Objectives, Design and Methods

2.1 Objectives of the Assessment

2.1.1 General objective

- To assess and monitor the impact of policies, strategies, regulation and activities in improving access to safe, effective and quality essential medicines and their rational use using WHO Level I and II indicators.

2.1.2 Specific objectives

- To assess the existence and utilization of policies, strategic plans, regulatory frameworks, standards and structures for pharmaceutical sector.
- To assess the availability of key medicines in public and private establishments.
- To assess quality assurance of essential medicines.
- To assess affordability of essential medicines
- To assess rational uses of essential medicines from different dimensions.

2.2 Organization of the survey

Conducting such type of survey requires the involvement of stakeholders, which calls for the establishment of a platform for coordination with clear terms of reference. The stakeholders will bring their comparative advantage and resources to ensure an effective process and sound outcome that adopts the WHO guidance in undertaking such survey. To this effect, in the present assessment, two levels of coordination was established, namely, the Task Force (TF) and the Technical working Group (TWG).

The Taskforce was composed of representatives of managers of EFMHACA, PFSA, WHO and USAID/SIAPS and mainly responsible for supervision and monitoring of the overall survey process including coordination of logistical support from stakeholders, and develop TOR for recruitment of the consultant.

Technical working group consisted of professionals drawn from stakeholders EFMHACA, PFSA, FMOH, EHIA, WHO and USAID/SIAPS and closely works with the consultant in the development of the survey proposal, identification of data collectors, customization of survey questioners, and supervision of data collection activity. The consultant was in charge of design of the survey, training of data collectors, analysis of the data and report writing.

2.3 Survey Design and Methods

The survey employed WHO Operational Package for assessing, monitoring and evaluating country pharmaceutical situations (December 2007 Version). This package included three groups of indicators, namely, Level I, Level II and Level III indicators. The present assessment was limited to Level I and Level II indicators and focused in obtaining information on the existing structures and processes in a national pharmaceutical system, and the key outcome and impact of

strategic pharmaceutical programs such as improved access, quality and rational use of medicines (Table 1).

Data on national medicines policies and their components (including legislation and regulations, quality control of medicines, essential medicines lists, supply systems, financing, access to medicines, production, and protection of intellectual property rights were obtained by using key informant interviews and document reviews using WHO questionnaire on structures and processes of country's pharmaceutical situations (WHO, 2007).

Data on the availability, affordability and rational use was collected through visits to dispensaries of the public health facilities and private medicine retail outlets. The list of key medicines for the purpose of this survey was prepared based considering on the core list of medicines in use worldwide (WHO, 2007) and medicines of national importance obtained from List of Essential Medicines for Ethiopia and expert opinions (Annex 3). For each medicine, data were collected on the lowest-priced product found at each medicine outlet on the day of visit.Treatment affordability was estimated by comparing medicine costs to the daily wage of the lowest-paid unskilled government worker.

Data on level II indicators were collected using slightly modified forms of questionnaires and check lists developed by the world health organization.

Table 1: Objective, Indicators and Data Collection Methods Matrix, PSA, Level I & II, June 2016.

Objectives	Indicators	Data Collection Methods
Assess availability of Policies, plan of action, regulatory framework and structures	Existence and year of last update of a published NMP	Key informant interview and document review using WHO level I questionnaire
	Existence and status of NMP implementation plan	
	Existence and year of last update of a published national list of medicines.	
	Presence of key pharmaceutical sector legislation	
	Existence of ADE monitoring system	
	Number of ADE reports generated and validated.	
	Presence of guidelines and Legislation promoting generic prescribing and substitution	
	Product samples collected for regulatory purposes (pre and post market authorization) in one year period&% samples failed	
Assess accessibility of	Availability of key medicines in public health facility pharmacies, private pharmacies and regional warehouses	Observation check list, document/

quality essential medicines	Stock-out duration in public health facilities and regional warehouses	record review, key informant interview using WHO level II survey forms
	Affordability of treatment at public health facilities and private pharmacies	
	Percentage of prescribed medicines dispensed to patients at public health facility pharmacies	
	Price of key medicines in public health facilities and private pharmacies	
	Adequate stock record keeping at public health facilities and PFSA hubs	
	Geographic accessibility of dispensing facilities	
	Adequacy of storage conditions and handling of medicines in public health facility facilities and PFSA hubs.	
Assess Rational Use of Medicines	% of adequately labeled medicines dispensed in public health facilities' dispensaries	Exit interviews, observation check list, document review using WHO Level II Indicators survey Forms
	% of patients who know how to take medicines	
	Average number of medicines per-prescription in public health facilities	
	% of patients receiving antibiotics and injections in public health facilities	
	% of prescribed medicines on the EML/FSL at public health facilities	
	% of prescribed medicines prescribed by INN/generic name at public health facilities	
	Availability and utilization of standard treatment guidelines (STGs) in public health facilities	
	% of facilities with DTC	
	%of facilities with Narcotic/psychotropic drugs prescription papers	

2.4 Sampling survey areas and facilities

Both purposive and stratified random sampling was used to select the study regions from the 9 Regional states and 2 City Administrations including the capital city.

From the two city administrations, the largest urban center, Addis Ababa, was purposively included in the survey. The rest of the regions were stratified into two based on the level of development. Accordingly the five Regions, namely, Tigray, Amhara, Oromia, SNNPR and Harari are classified as relatively developed regions as compared to Benshangul-Gumuz, Gambella, Somali and Afar Regions which are considered as developing Regions. Then from the five developed regions three were sampled based on random sampling and from the four developing regions two of them were chosen randomly.

In each survey Region, the sampling of the health facilities followed the Country's Three Tier Health Care delivery System. In all selected regions, the main Regional Referral Hospitals were purposively included. To select specific health facilities from the first and second Tier Level of the health care system, first Zones were classified into two based on their distance from the Regional Capital. Those Zones which are within 160 km radius are in the same stratum and the second group is those which are located greater than 160km from the regional capitals. Then one Zone was selected randomly from those which are located more than 160km. Thereafter, one general and one primary hospital, and three Health Centers were selected randomly. In situations where the selected zones did not have facilities from the specified tier level, equivalent number of additional facilities was considered from the next lower level. For each category of public health facilities selected, the nearest medicines retail outlets were selected for the assessment. Additionally, a PFSA hub that supplies the public sector was visited in each area, if available.

2.5 Data entry and analysis

SPSS statistical software (Version 21) and Microsoft Excel 2010 were used for data entry and analysis in the form of percentages, mean, median, ratios, etc.

2.5.1 Availability

Availability of 29 medicines was analyzed by determining the mean and median percentage availability in survey regions: PFSA hubs, public hospitals and health centers levels and in PMROs. The availability of medicines was considered regardless of innovator, generic or branded generic and measured at dispensaries and stores of the health facilities. Though different ranges have been used in different countries to describe availability, for the purpose of the present work, the following ranges have been used (Nyanwura and Esena, 2013):

- ≤ 50% very low
- 51-65% low
- 66-80% fairly high
- > 80% high

2.5.2 Determination of medicine prices

To determine the price of each medicine, the unit price was taken for most of the selected medicines except few where a unit package need to be bought such as amoxicillin 125mg/5ml

suspension bottle, mebendazole 100mg/5ml suspension, salbutamol inhaler, paracetamol 120mg/5ml syrup and normal saline 0.9% 1000 ml bag. The medicines prices collected in the survey were converted to median price ratios (MPRs) (a ratio of a medicine's median unit price to the international reference price obtained from Management Sciences for Health 2015 Price Indicator Guide (MSH, 2015). The international reference prices of medicines were converted to Ethiopian birr by using currency values of the National Bank of Ethiopia as of June 30/2016 (1 USD = 22.055ETB). An MPR of 1 or less indicates an efficient public sector procurement system and an MPR of 1.5 or less and 2 or less is considered acceptable level for patient prices in public and private sectors, respectively (Wang et. al., 2014).

2.5.3 Affordability

Affordability of four selected tracer conditions was calculated according to WHO/HAI standard methodology (WHO/HAI, 2008) by comparing the total cost of medicines prescribed at a standard dose (based on STGs) with the daily wage of the lowest paid unskilled government worker at the time of the survey (Birr 24.67). For assessing affordability of treatments of selected non-communicable diseases, defined daily dose (DDD) was taken, instead of standard prescribed dose, for a duration of one month.

3 Findings and discussion

The result and discussion part is organized into two parts. The first part is the Report on the findings of Level I indicators and the second part is on Level II indicators collected at facility levels.

3.1 Part I: Level I indicators

The information on the structure and key processes of the pharmaceutical sector in Ethiopia is presented in a completed WHO Level I assessment questionnaire annexed with this report. Below are the summary of the findings.

3.1.1 National Medicines Policy (NMP)

Ethiopia has an official National Medicines Policy since 1993. However, the policy has never been updated to reflect and accommodate some of the current priorities and developments of the country. For example, some of the main issues that emerged after issuance of the NMP that affect the national medicine policy components are the restructuring of the regulatory authority that led

establishment of EFMHACA with wider mandates, establishment of social insurance system, emergence of HIV/AIDS pandemic, development of multi-drug resistance infections, globalization that may impose TRIPS which may affects access to medicines, etc. Hence, the NMP should have been revised to guide actions related to these developments. According to the informant from FMOH, though the revision process has almost been finalized, its endorsement and launching is yet to be done.

In collaboration with WHO, two national surveys were conducted in 2003 and 2010 to assess the impacts of the NMP.

3.1.2 Medicine Regulatory System

In Ethiopia, the pharmaceutical sector is regulated in four dimensions, namely, medicines, premises, pharmacy professionals and practices. Currently, the EFMHACA in Federal Ministry of Health is mandated for regulatory activities related to product evaluation and registration, import and export control, licensing and inspection of pharmaceutical establishments, post-marketing surveillance and pharmacovigilance. It is also the mandated to control the quality and safety of food. The Regional Regulatory Counterparts, which are either under regional health bureaus or autonomous, are mandated to regulate licensing and inspection of medicine retail outlets, and premises involved in the wholesale of pharmaceuticals in their respective regions, EFMHACA has a regular budget from the government. In addition, some of its activities have also been technically and financially supported by its partners.

There are legal provisions for licensing manufacturers, importers, wholesalers and medicine retail outlets. In addition guidelines and requirements have been developed for registration and inspection of facilities. This information is being made accessible on the Authority's website.

As parts of market authorization process, EFMHACA uses WHO Certification scheme as a requirement. Non-preparatory names of medicines are used for the registration process. There is a functional formal committee responsible for assessing applications for registration of pharmaceutical products.

A total of 2000 products have been approved by EFMHACA to be marketed in Ethiopia and the list of registered products is posted on its website. However the authority does not have a computerized registration system and as a result timely updating of the list proved to be difficult.

On top of that due to lack of human resources and facilities, the efficiency of product registration process at times is reported to be delayed.

The country is signatory of the international convention on the control of narcotics, psychotropic substances and precursors. To this effect, legal provisions are in place for the control of these substances. The authority has in place quality control laboratory management and medicines are tested for registration, actual consignment and post marketing surveillances. For instances, in 2008 EFY, there were a total of 1342 samples tested; out of which 6.9% failed to meet the quality standards (Table 2).

Table 2: Testing facilities and number of sample tested in 2008 EFY, PSA- Level I, Ethiopia, June 2016.

Sample testing facilities	**Yes**	**No**
• Government quality control laboratory	✓	
• Local academic institutions		✓
• Private laboratory		✓
• Mini laboratories	✓	
• Quality control laboratory in another country	✓	
Tests	**Number**	
• Total number of samples quality tested in 2008 E.C.	1342	
• Total number of samples failed to meet quality standard quality tested in 2008 E.C.	92	

The country has an adverse drug E (ADE) monitoring system at central level and reports ADEs to Uppsala ADR Monitoring Center.

In Ethiopia, there are regulations, programs or procedures for detecting and combating counterfeit medicines and multiple sources of information such as National Authorities, *ad hoc* studies, and report from civic societies/NGOs are used to detect and combat counterfeit medicines.

Licensing and Practice of Pharmacy

Legal provision exists to practice pharmacy in the country. There is a policy of encouraging generic prescribing in both public and private institutions in Ethiopia but not obligatory. No incentive is given for generic dispensing in pharmacy retail outlets.

The country's legislation/regulations cover promotion and/or advertising of medicines.

3.1.3 Procurement

Public sector procurement is pooled at the national level and Pharmaceutical Fund and Supply Agency (PFSA) at Federal Ministry of Health is responsible for public sector medicines procurement and distribution. The procurement system is largely tender based. The procurement is overseen by a tender board/committee. Public sector medicines procurement is based on the WHO's prequalification system, PFSA procures pharmaceutical that are registered by EFMHACA and if there are products not registered by EFMHACA products registered by Stringent regulatory agency , WHO Prequalified, and manufactured by EFMHACA GMP inspected manufacturers are procured by PFSA. However the public sector procurement is not limited to medicines on the essential medicines list (EML) (Fig 1).

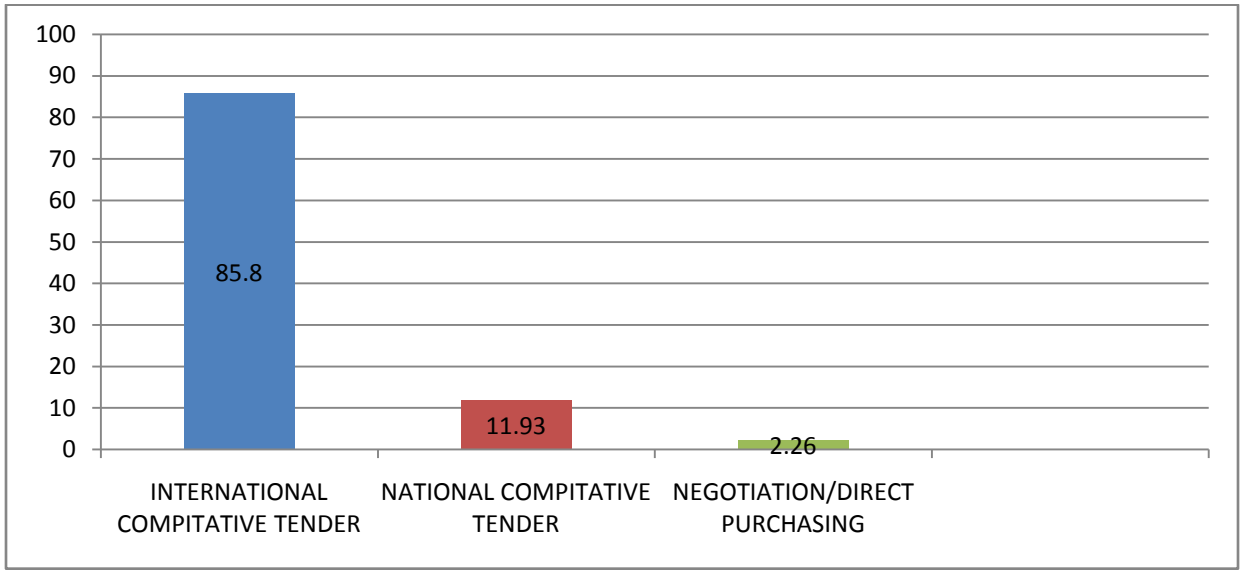


Figure 1: Type of tender process used for public sector procurement, PSA- Level I, Ethiopia, June 2016.

3.1.4 Medicines Financing

The total public or government expenditure for medicines in US$ for the year 2009EFY was 148, 075,215.81.

The country have a national policy to provide some medicines free of charge for patients who do not pay out-of-pocket for medicines used to treat malaria, tuberculosis, sexually transmitted diseases, HIV/AIDS and vaccines. In addition patients who cannot afford treatments of any diseases would get free treatment in government health facilities upon producing testimony letters from woreda offices (the lowest administrative units in government structure). The country have an official written guidelines on medicine donations that provide rules and regulations for donors and provide guidance to the public, private and/or NGO sectors on accepting and handling donated medicines.

One of the Health Sector Transformation Agendas of the Federal Ministry of Health is UHC. This can only be achieved when access to health services and financial risk protection are equitably addressed (African Strategies for Health, 2016).The SHI and CBHI are the two insurance schemes planned by the Government of Ethiopia to provide financial protection of households from catastrophic expenditures. The SHI scheme would provide financial coverage for formal sector employees, pensioners, and their families, while CBHI targeted informal sector employees and rural residents. The Community-based Health Insurance (CBHI) scheme has been already started as pilots since 2011. The overall enrollment rate in the pilot districts in 2013 reached approximately 52.4 percent of the target population (EHIA CBHI Scale-Up Strategy Document 2015). However SHI is yet to be implemented.

Currently, the contribution of the existing health insurance mechanisms to medicine financing pool is insignificant (SIAPS, 2016).

3.1.5 Production and Trade

The pharmaceutical production is at infancy stage and until now there is no research and development of new active substances as well as production of pharmaceutical starting materials. However there is formulation from pharmaceutical starting materials as well as repackaging of finished dosage forms. Patents for pharmaceutical products are granted by the Ministry of

Sciences and Technology of Ethiopia. Ethiopia is not a member of the World Trade Organization (WTO) and has only an observer status.

3.1.6 Rational Use of Medicines

According to WHO, rational use of medicines is when the patient receives medications appropriate to their clinical needs in doses that meet their requirements for adequate periods at a cost affordable to the individual and the society. The process of using medicines involves prescribing, dispensing and use by the patient. Hence promoting rational use of medicines should address the three elements. In Ethiopia, various interventions have been in place to promote rational use of medicines. These include:

3.1.6.1 Essential Medicines List

There is an essential medicines list (EML) in Ethiopia with 300 unique formulations. The EML was last updated in 2015. However, there is no separate essential medicine list for pediatrics group. The EML is reportedly being used for public procurement and public insurance reimbursements. The country has also list of medicine for public health insurance. However, there was no committee responsible for selection of products for EML.

3.1.6.2 Standard Treatment Guidelines (STGs) and National Medicine Formulary (NMF)

The EFMHACA has developed standard treatment guidelines to be used at national, hospital and primary care levels. The national STG was updated in 2013 and the hospital and primary level care STGs were both updated in 2014. Standard treatment guidelines for key pediatric illnesses were also developed and in use in the country.

There is also a national medicine formulary in Ethiopia which was revised in 2013 and covers products wider than included in EML. EFMHACA has also prepared good dispensing and prescribing manual in 2012 to promote rational use of medicines.

3.1.6.3 Use of EML, STGs and NFM for training health professionals

As shown in Table 3, there is pretty good coverage of the essential topics for implementing rational use of medicines across curricula of most health training institutions.

Table 3: Coverage of health professionals' training curricula on EML, STGs and NFM, PSA- Level I, Ethiopia, June 2016.

Category	EML	STGs	Problem based Pharmacotherapy	Rational Prescribing
Doctors	DK	Yes	yes	Yes
Nurses	DK	Yes	yes	Yes
Pharmacists	yes	Yes	Yes	Yes
Pharmacy Assistants	yes	yes	Yes	Yes
Paramedical staff	DK	DK	DK	DK

**DK – not known by the respondents*

Though non-commercially funded continuing education programs are encouraged by the government to all health professionals, they have never been a requirement for licensure or renewal for any category of the health professionals. However, currently the regulatory authority directive for continuing professional development and is preparing a guideline for an accredited obligatory continuing education programs in the country.

3.1.6.4 Prescribing personnel

Table 4: Extent of involvement of different health professionals in prescribing prescription only medicines at primary health care level in public sector, PSA- Level I, Ethiopia, June 2016.

Category	Extent of involvement in prescribing				
	Always	Frequently	Occasionally	Never	DK
Doctors	✓				
Nurses/Midwives/Health Officers		✓			
Pharmacists/Pharmacy Assistants				✓	
Paramedical staff				✓	
Personnel with less than 1 months training				✓	

3.1.6.5 National medicine information services and Public education on rational use of medicines

Rational use of medicine has been the subject of public education by Ministry of Health, Partners and professional associations in Ethiopia. The topics covered in most of the campaigns included proper use of antibiotics, safe use of injections, treatment compliance, antimicrobial resistance and others.

3.1.6.6 Pharmacy and Therapeutic Committee

According to the respondents from EFMHACA, establishing pharmacy and therapeutic committees at public health facilities has become a requirement. Currently, most of the Referral and General Hospitals across the country are said to have Pharmacy and Therapeutic Committees.

Ethiopia has a national strategy and plan of action on containment of antimicrobial resistance and there is also a national advisory committee where its members are drawn from different stakeholders including academic and research institutions, government ministries, partners and professional societies. Ethiopian Public Health Institute is mandated to coordinate the epidemiological surveillance of antimicrobial resistance in the country.

3.2 Part II: Level II Indicators- Key Findings and Discussions

The survey with Level II indicators is a very important part of monitoring the pharmaceutical sector as they provide measures related to the outcomes and impact of strategic pharmaceutical programs, namely: improved access, quality and rational use. Measurement of Level II indicators at facility level requires adequate record keeping. Hence in this survey, adequacy of record keeping both at PHFs and PFSA hubs were also assessed.

This section is based on the result of the study of outpatient records or outpatients from 36 public health facilities and its dispensaries (15 hospitals & 21 Health centers), 32 private medicines outlets (14 Pharmacies, 15 Drug shops and 3 Rural drug vendors) and records of 6 warehouses. A total of 2031 exit interviews were done in the above facilities. The detailed number of facilities and outpatient records per region is provided in Annex 1. The demographic characteristics of outpatients interviewed revealed that adults constituted the majority of patients (71.8%) and majority (51.5%) of them was also females (Annex 2).

3.2.1 Adequacy of Record Keeping

The national average percent of adequate record keeping was 65.61% and median value of 81.03%. As shown in Fig 2 below, there were regional variations in recording keeping practices and the mean percentage of adequate record keeping ranged from 35% in Oromia to 86.78% in Amhara Region. Record keeping practice was relatively better in PFSA Hubs as compared to Hospitals and Health centers with the respective median values of96.55%, 95.55% and 58.62%, respectively (Fig 3). Although the expected value for adequate record keeping is 100%, there was improvement in the practice in PHFs as compared to 2010 survey result (median 46.7 vs. 81.03).However there is a slight decrease in median value of adequate record keeping from 100% in 2010 to the present value 96.55% in PFSA Hubs (MOH/WHO, 2010).

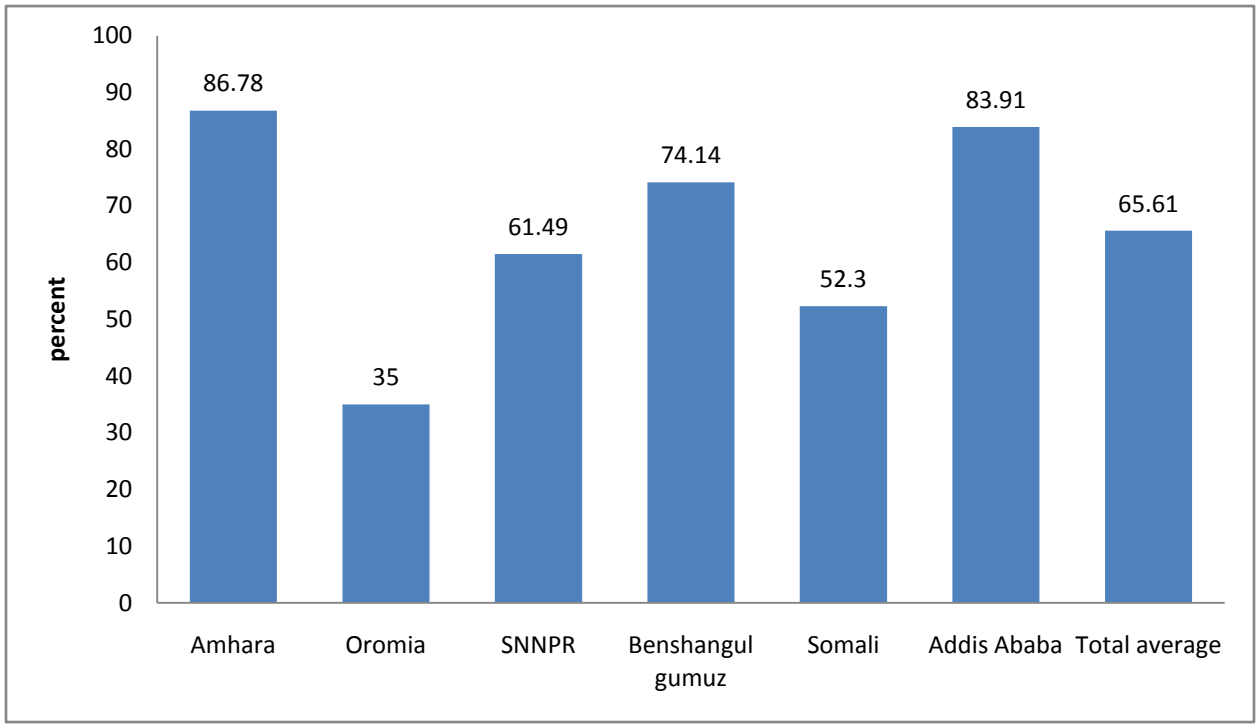


Figure 2: Percent of adequate record keeping at PHFs, PSA-HFS Level II, Ethiopia, June 2016.

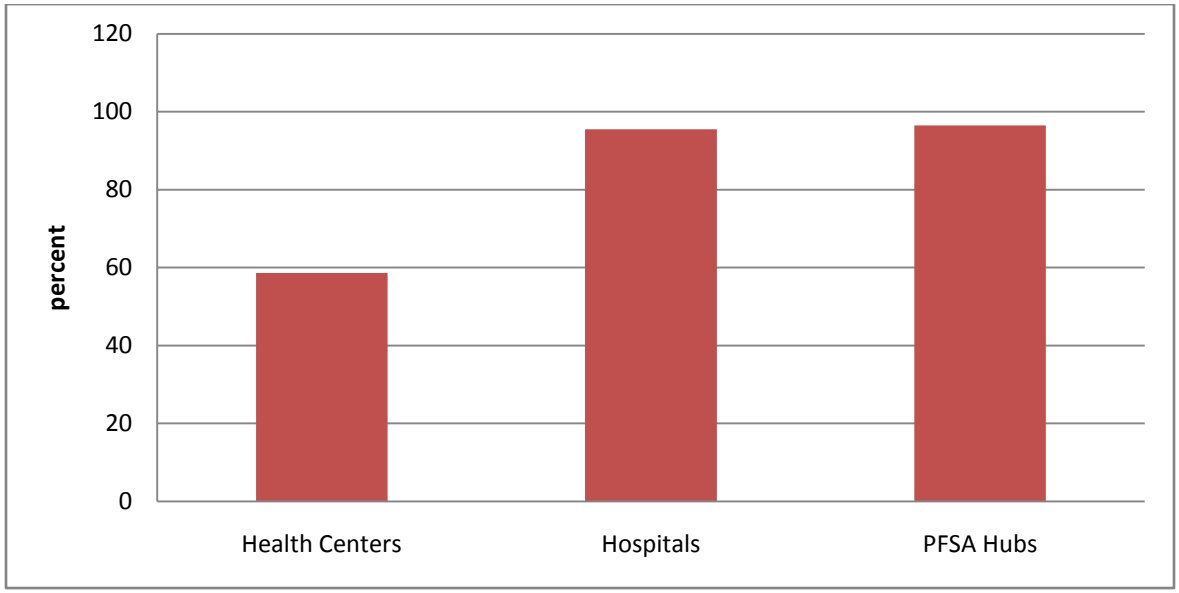


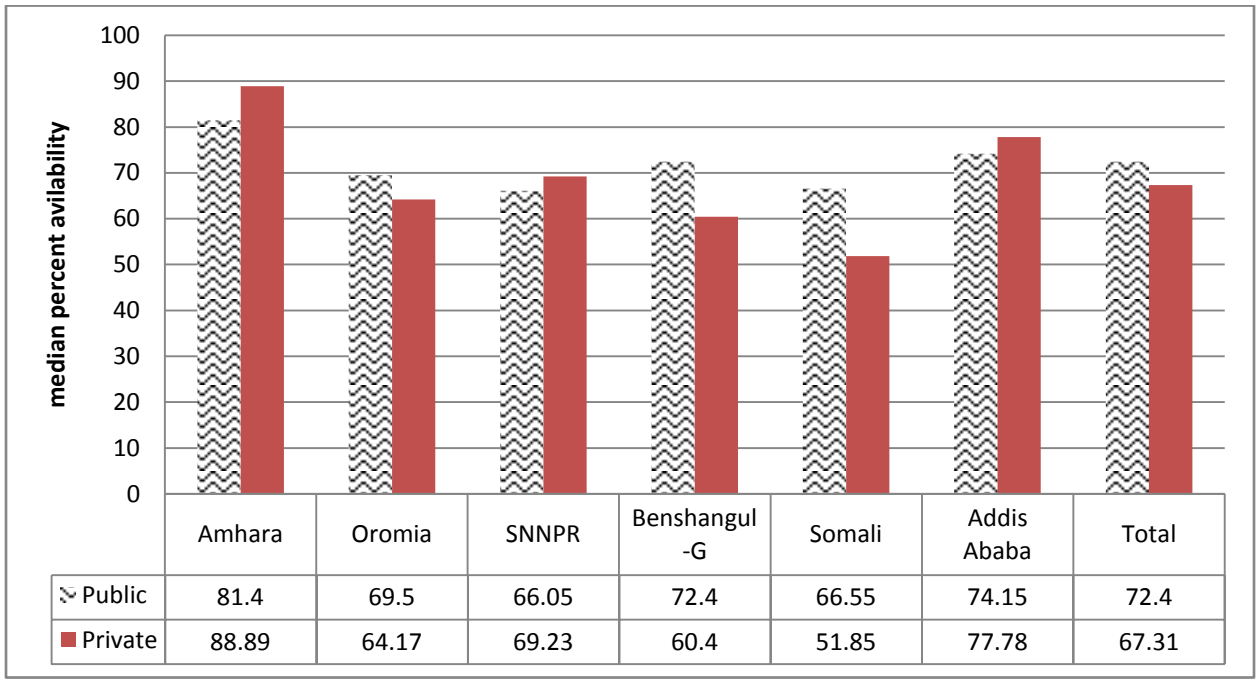
Figure 3: Percent adequate record keeping in PHFs and PFSA hubs, PSA-HFS Level II, Ethiopia, June 2016.

3.2.2 Access

Access to essential medicines is an integral part of meeting the fundamental human rights of citizens in a particular country. There are, however, numerous reasons that hinder access including geographic inaccessibility of facilities supplying medicines, unavailability of medicines, high medicines price, and unaffordability by the majority of the population.

3.2.2.1 Availability of medicines in the public and private sectors

The median percentage availability of basket of medicines in the public health facilities' dispensaries and stores was found to be 72.4% and 70.69%, respectively. In the private medicines retail outlets, the median availability was 67.31% which is lower than the percentage availability in public facilities (Fig 4, 5and 6).The national average median percent availability both in PHFs and in PMROs could be considered fairly high. It was encouraging also to note that availability of program medicines and medicines for treating infectious diseases was >80%. However as medicines included for analysis were mostly first choices for the most prevalent problems, the expected result should have been nearly 100%. Moreover, the availability was still short of the target set in HSTP for 2009 EFY (MOH, 2010).



	Amhara	Oromia	SNNPR	Benshangul -G	Somali	Addis Ababa	Total
Public	81.4	69.5	66.05	72.4	66.55	74.15	72.4
Private	88.89	64.17	69.23	60.4	51.85	77.78	67.31

Figure 4: Availability of basket of medicines in public health facilities and private medicine retail outlets, PSA-HFS Level II, Ethiopia, June 2016.

The median availability in PHFs among survey areas ranged between 66.05% to 81.4%; while in private medicine retail outlets, it ranged from 51.85% to 88.89%. The individual median availability of 14 medicines out of 29 assessed in PHFs and 10 out of 27 in PMROs were less than 65% (considered low).

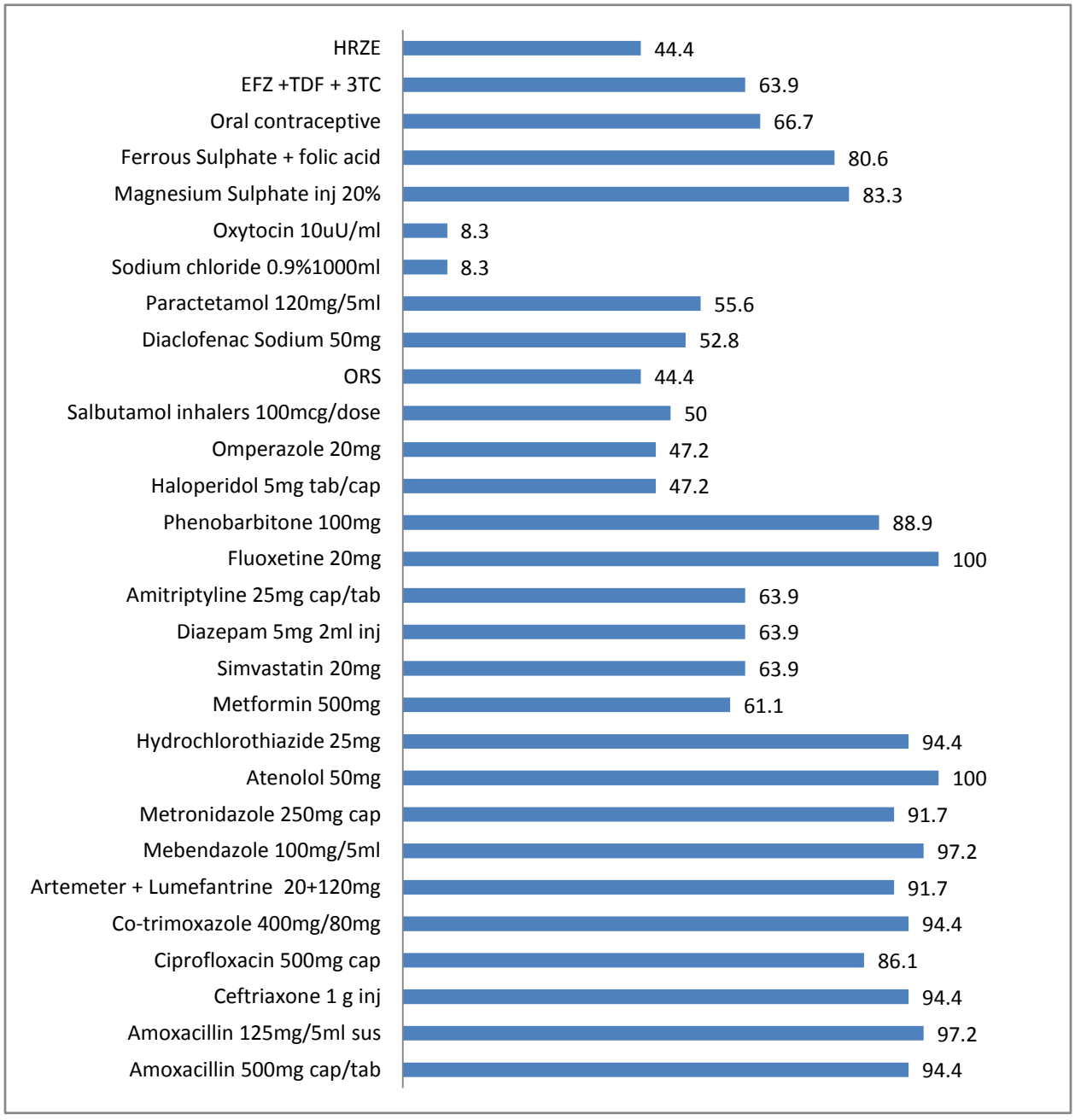


Figure 5: Availability of basket of medicines in Dispensaries of Public Health Facilities, PSA-HFS Level II, Ethiopia, June 2016.

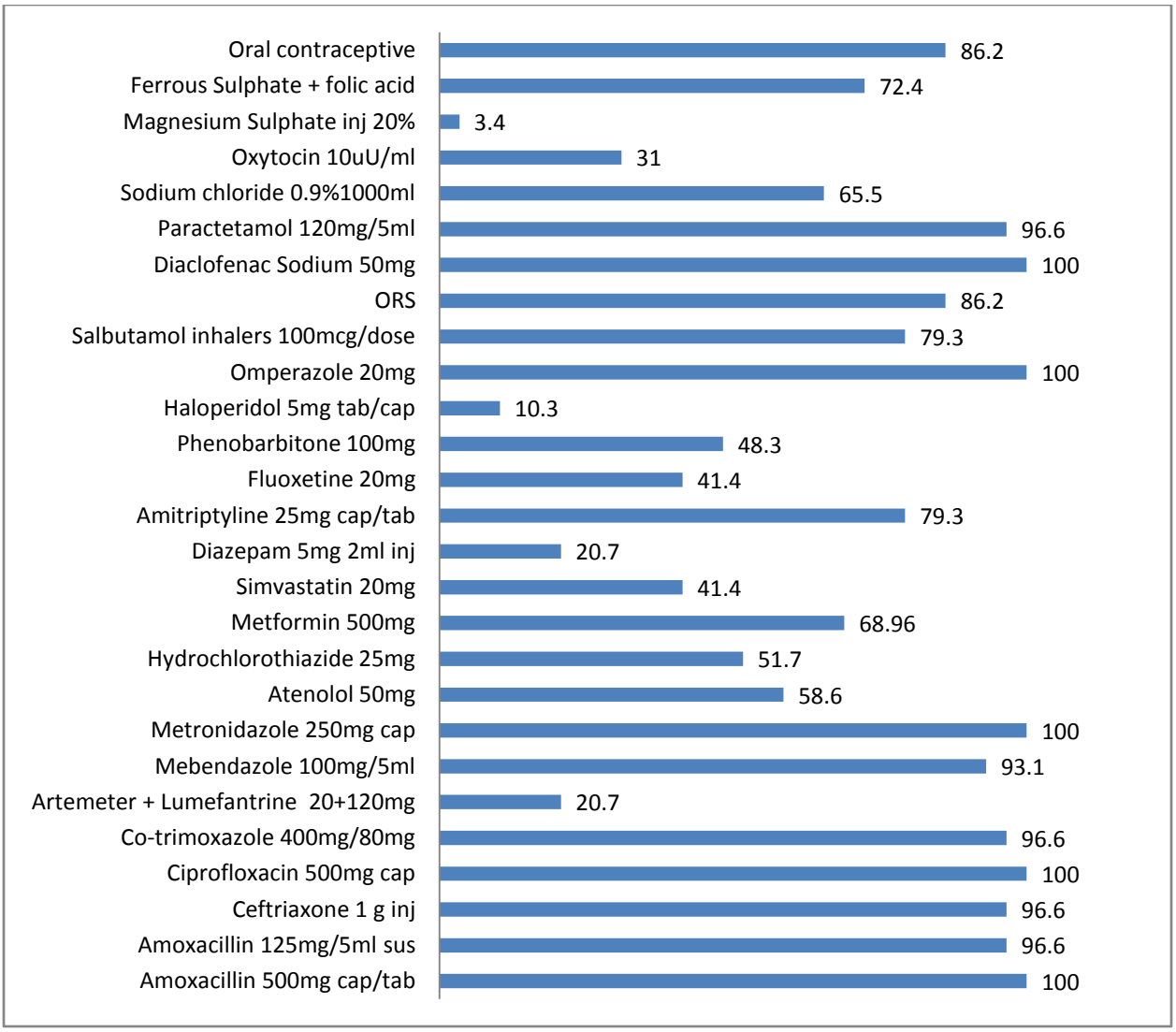
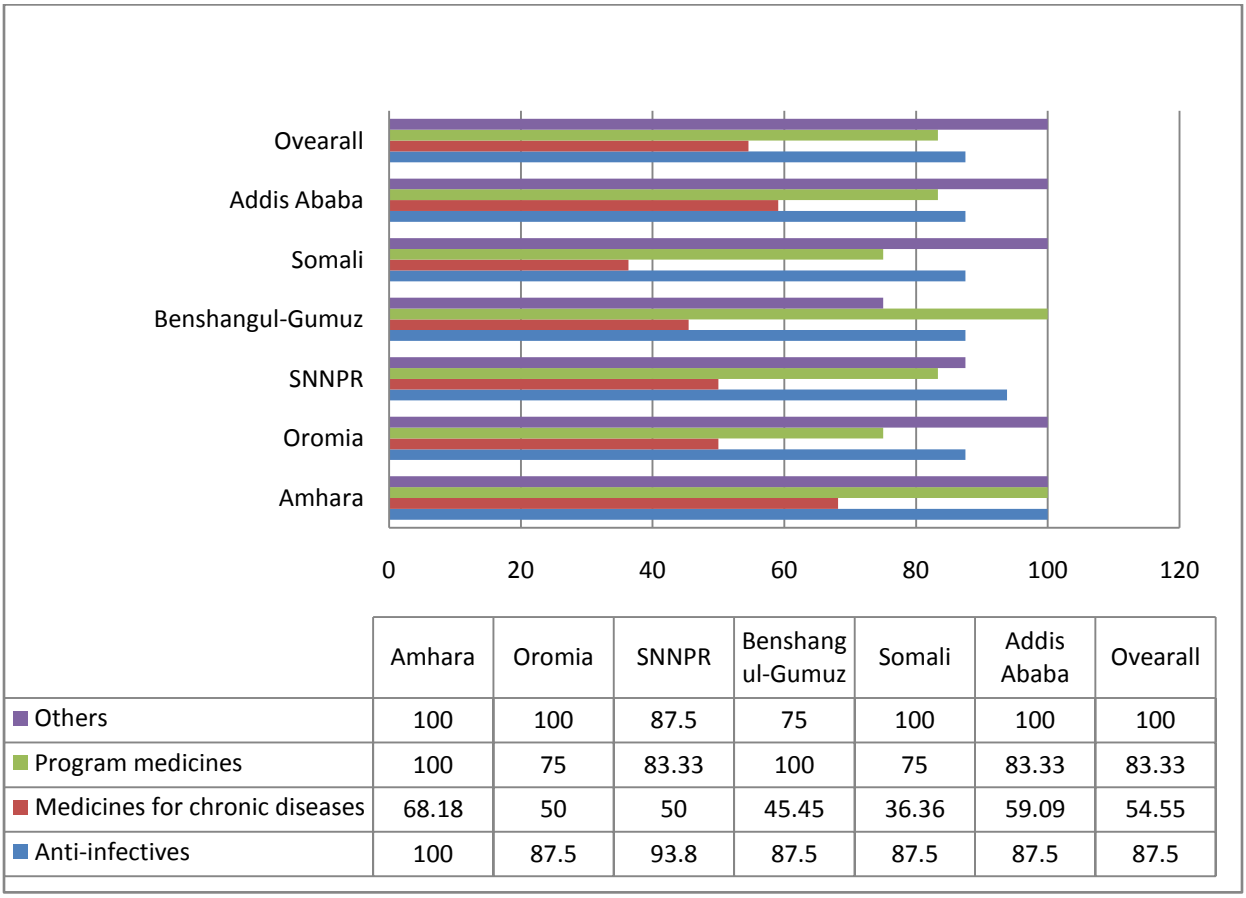


Figure 6: Availability of baskets of medicines in Private Medicine Retail Outlets, PSA-HFS Level II, Ethiopia, June 2016.

As shown in Fig 7, the median availability of basket of medicines used for chronic illness including hypertension, diabetes and mental illnesses was found to be low (54.55%). The median percentage availability of medicines for non-communicable diseases in majority of surveyed regions/city administrations was very low (≤ 50%). It ranged from 36.36% to 68.18%. Given the fact that NCDs and injuries are already major contributors to the high morbidity and mortality burden of the country (WHO/AFRO, 2016), this figure is alarming. WHO set a target of 80% availability and affordability of essential medicines for NCDs in both public and private facilities that would enable to reducing premature mortality and achieve the wider aim of universal health care coverage (WHO, 2013). Though difficult to do a conclusive comparison of findings of

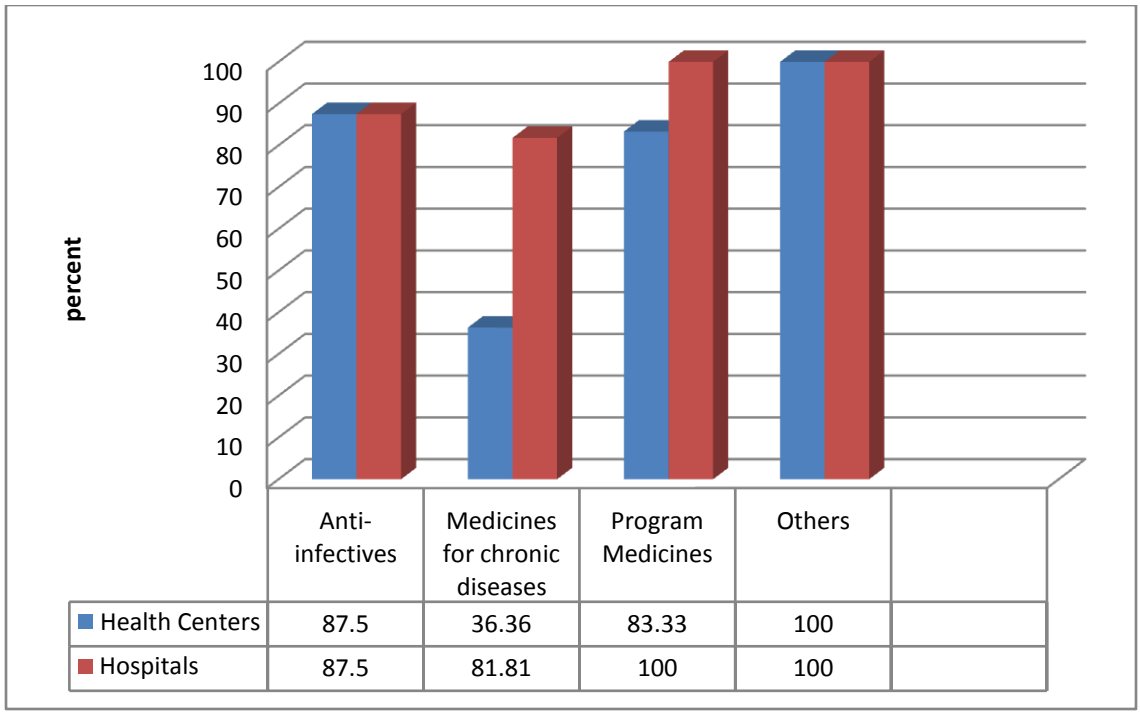
different national surveys regarding access due to differences in the number and kinds of medicines considered in each survey, the median availability found in the present survey both in public and private sectors decreased from 2010 figures (MOH/WHO, 2010).



	Amhara	Oromia	SNNPR	Benshangul-Gumuz	Somali	Addis Ababa	Ovearall
Others	100	100	87.5	75	100	100	100
Program medicines	100	75	83.33	100	75	83.33	83.33
Medicines for chronic diseases	68.18	50	50	45.45	36.36	59.09	54.55
Anti-infectives	100	87.5	93.8	87.5	87.5	87.5	87.5

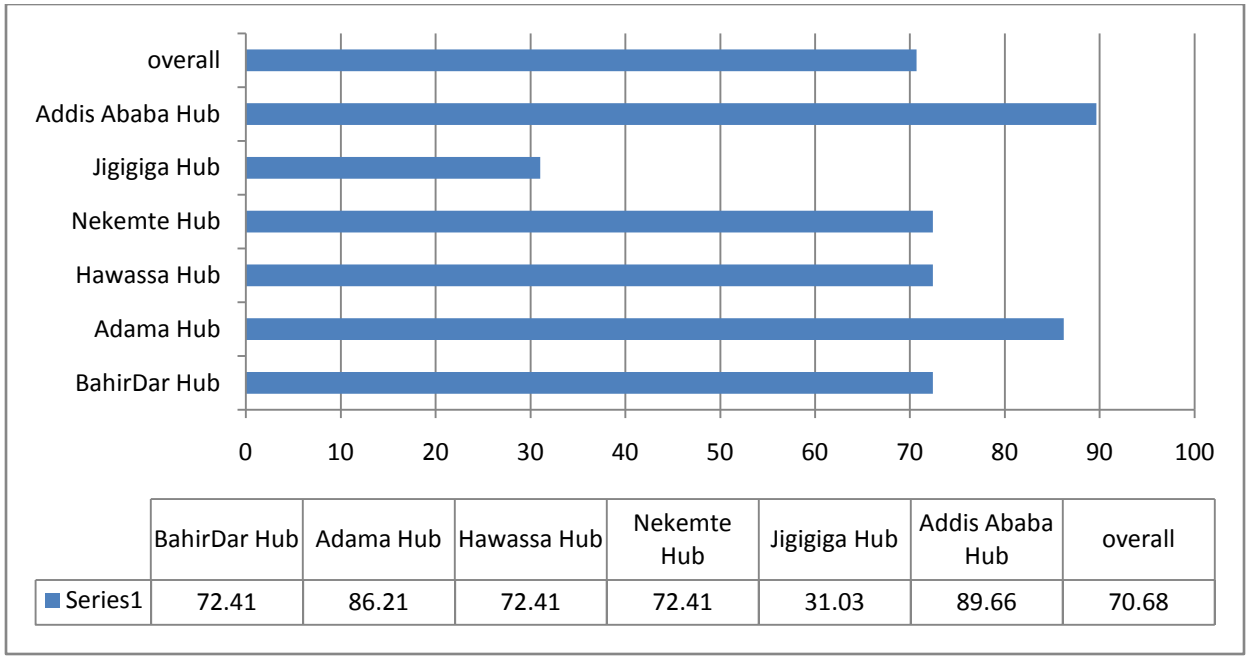
Figure 7: Median percentage availability by class of medicines in public facilities dispensaries, PSA-HFS Level II, Ethiopia, June 2016.

As Fig 8indicates the median percent availability was higher in hospitals than in health centers. The mean availability of basket of medicines in the public procurement agency (PFSA) was 70.68% which was slightly lower than the median value of 72.41% and might be because of the outlier Jigjiga branch with a very low availability figure of 31% (Fig 9).



	Anti-infectives	Medicines for chronic diseases	Program Medicines	Others	
Health Centers	87.5	36.36	83.33	100	
Hospitals	87.5	81.81	100	100	

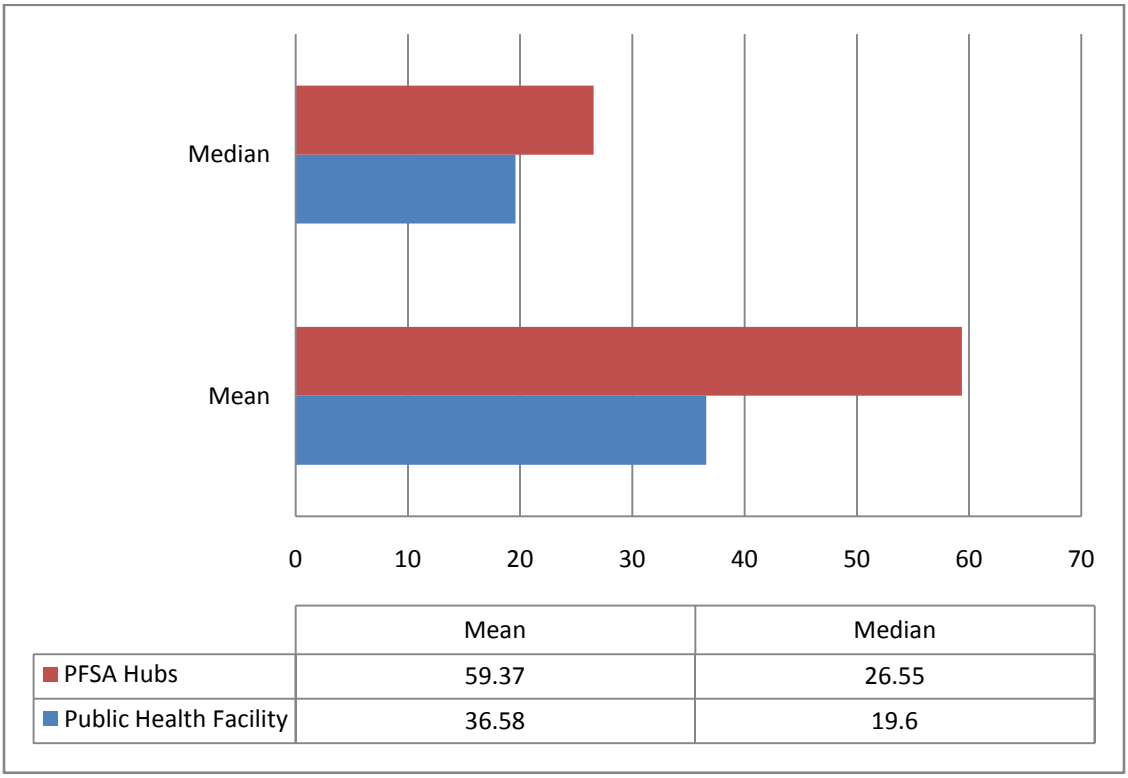
Figure 8: Median percent availability of category of medicines in the dispensaries of public facilities, PSA-HFS Level II, Ethiopia, June 2016.



	BahirDar Hub	Adama Hub	Hawassa Hub	Nekemte Hub	Jigigiga Hub	Addis Ababa Hub	overall
Series1	72.41	86.21	72.41	72.41	31.03	89.66	70.68

Figure 9: Percent availability of basket of medicines in PFSA Hubs, PSA-HFS Level II, Ethiopia, June 2016.

Historical availability of basket of medicines was retrospectively assessed using stock cards of the health facilities and PFSA hubs covering the period of 6 to 12 months based on WHO's recommendation. Accordingly, the national median stock out duration (in days) in public health facilities was 19.6 (Min 6.59, Max 118.88); while in PFSA hubs it was 26.55 (Min 2.78, Max 225.95).



	Mean	Median
PFSA Hubs	59.37	26.55
Public Health Facility	36.58	19.6

Figure 10: Mean and Median stock- out duration (days) in public health dispensaries and PFSA hubs, PSA-HFS Level II, Ethiopia, June 2016.

3.2.2.2 Medicines prices

3.2.2.2.1 Price mark ups

The final price of medicines can be strongly determined by the high add-on costs in the supply chain. A key contributor to these add-on costs are wholesaler and retailer markups (Mhlanga and Suleman, 2014). As shown below in Table 5, during the time of the study the national average retail markup in public health facilities was found to be 25.2%. The mark ups in public health facilities across regions varied and ranged from average of 18.2% in Somali Region to 29.6% in Oromia region. This indicated that there is no uniform pricing policy in the country and retail

price markup is decided at the health facilities level in most instances. Markups were also found to vary from medicine to medicine. It is worth noting at this point that though generating revenue from sales of medicines may be used to expand services and replenish the stock, it is important to consider the affordability issue when setting up patients' price markups.

Table 5: Price Mark ups in Public Health Facilities, PSA-HFS Level II, Ethiopia, June 2016.

Region/City	% mark ups
Amhara	25.61
Oromia	29.64
SNNPR	28.60
Benshangul-Gumuz	23.03
Somali	18.17
Addis Ababa	22.04
Overall	25.17

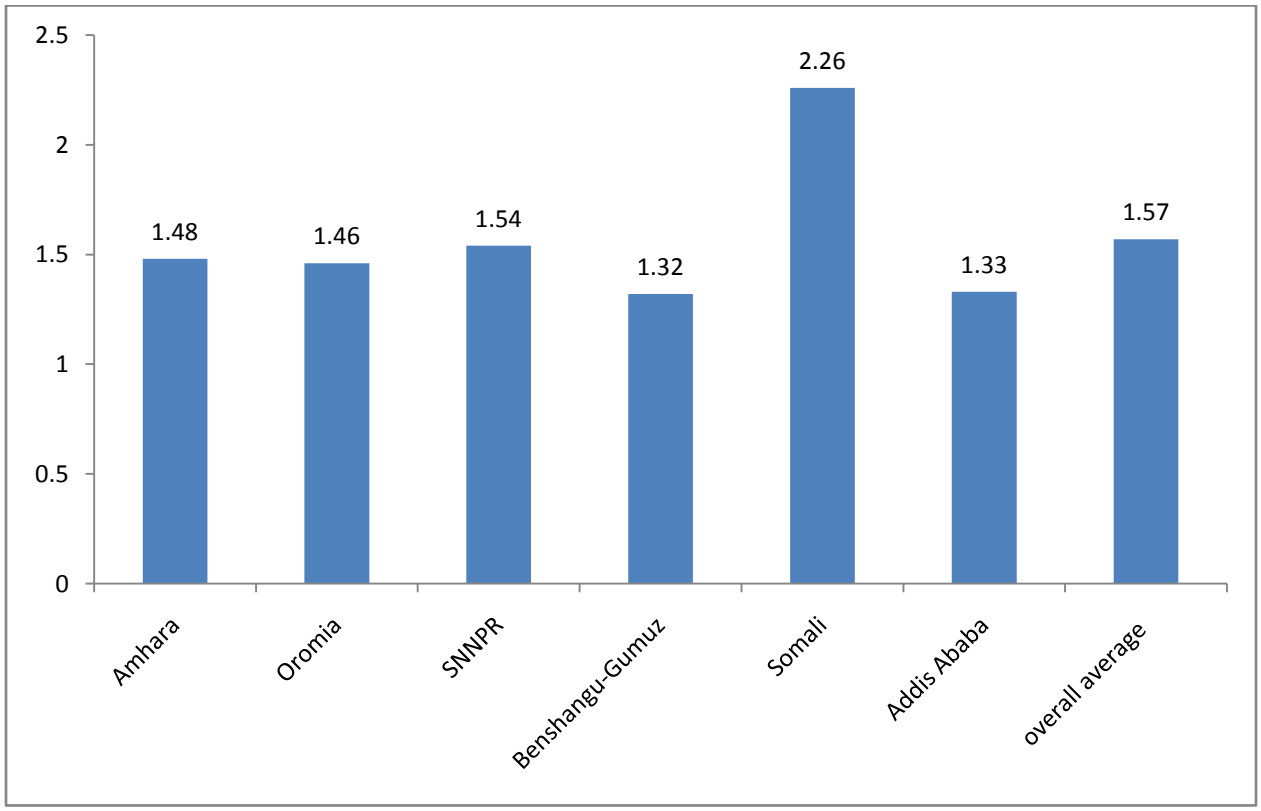


Figure 11: Regional variations in average procurement MPRs in public health facilities, PSA-HFS Level II, Ethiopia, June 2016

3.2.2.2.2 Public health facilities' procurement and patients' prices

Based on the MPRs' results for the 22 medicines for which the prices were obtained, the public health facilities procured medicines at a higher price than the IPRs (average procurement MPR=1.6).The average PMPR's varied across regions and ranged from 1.3 to 2.3 (Fig 11). This clearly indicated that public procurement efficiency is suboptimal requiring a detailed investigation to find out the underlying causes.

When public health facilities medicine prices were compared with IRPs, the medicines were found to be priced 1.8 times the IRPs. Within the basket this varied from 0.14 for omeprazole 20mg to 4.93 for haloperidol 5mg. In the private medicines retail outlets, medicines were found to be sold at 4.94 times the IRPs and within the medicines covered in the survey, MPRs varied from 0.19 for omeprazole to 57.99 for hydrochlorothiazide 25mg. The result indicated also that basket of medicines cost 274.4% more, on the average, at PMROs than in public health facilities (Fig.12).Though median MPR in PHFs was lower than in PMROs, both MPRs were higher and above the acceptable levels (Gelders et al., 2006). According to World Health Organization and Health Action International (2003), medicine price is identified to be an important obstacle to ensuring access. In a country like Ethiopia where out of pocket expenditure for health care including medicines constituted the lion share, understanding the reasons for high price of medicines and developing pricing policies would ensure affordability of medicines.

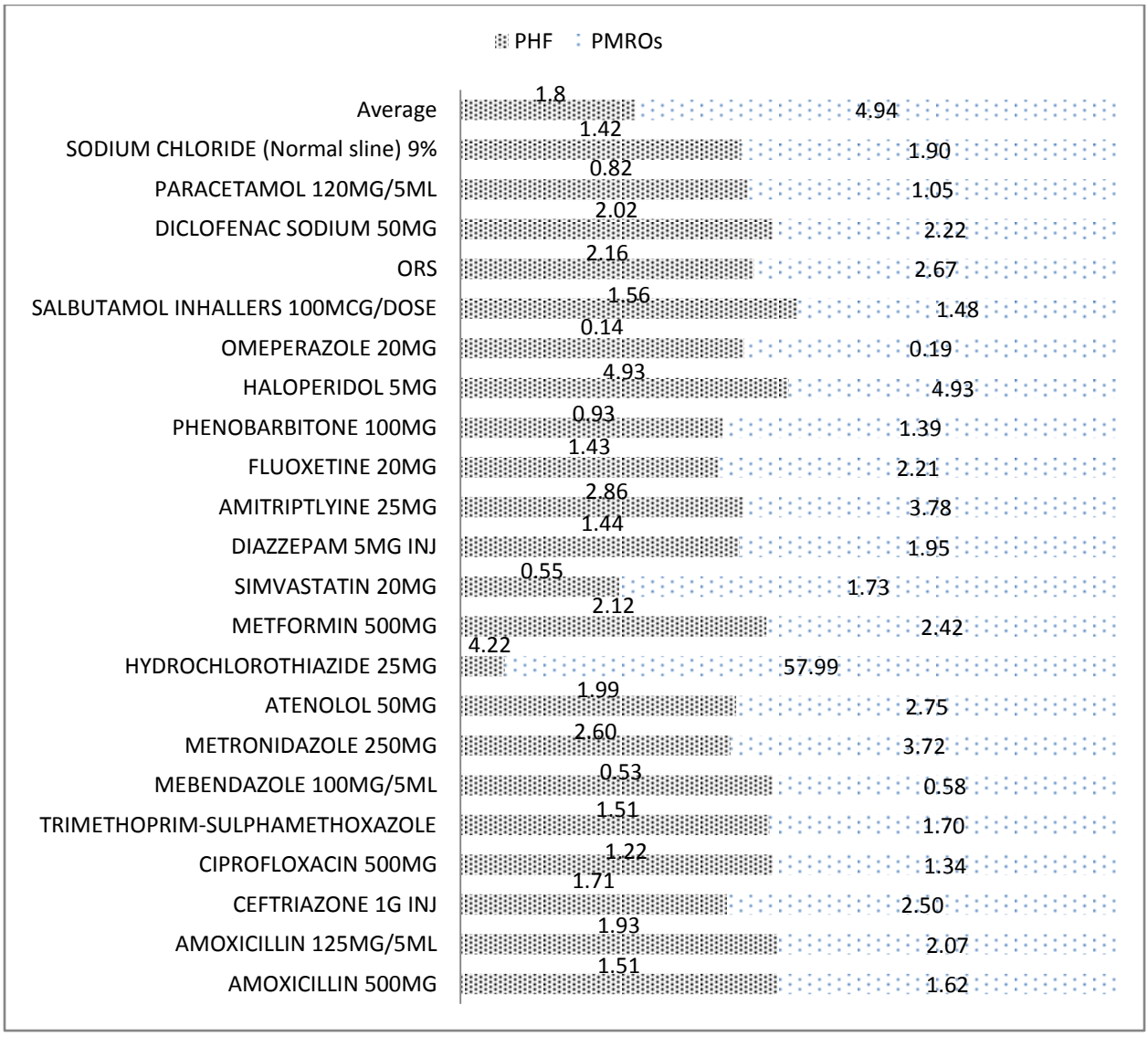
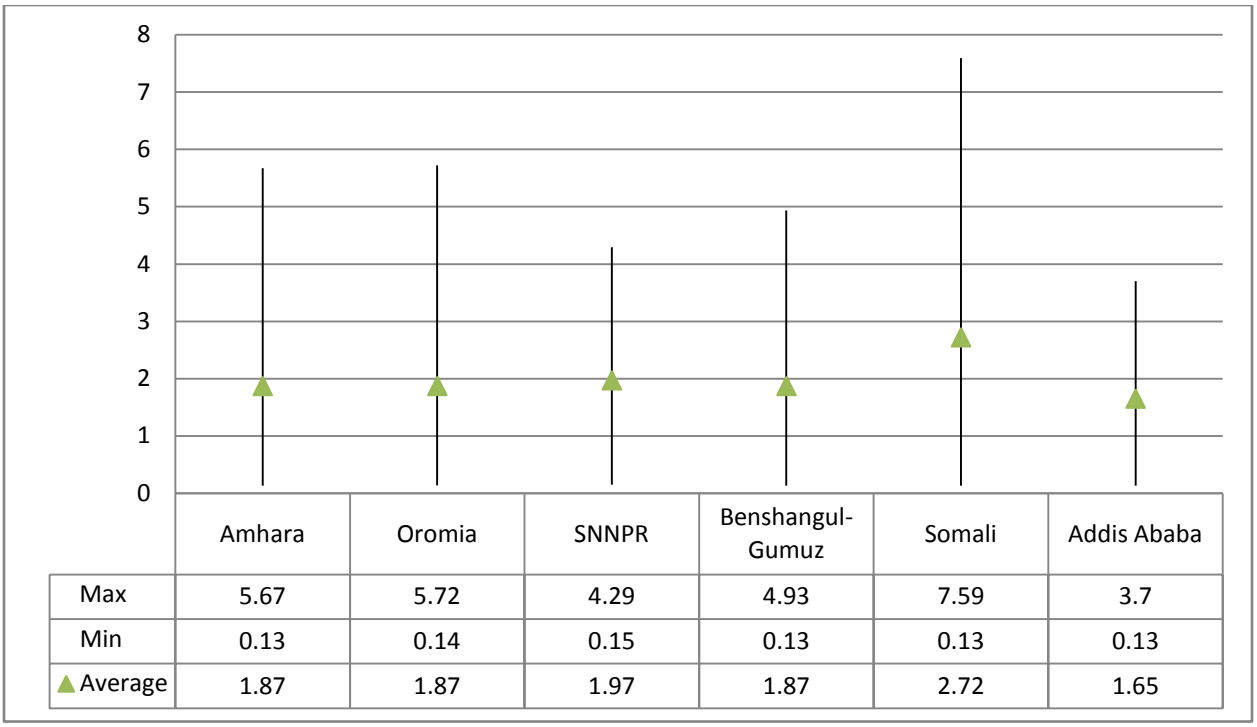


Figure 12: Median MPRs for selected medicines in surveyed public and private dispensaries, PSA-HFS Level II, Ethiopia, June 2016.

Not only there were regional variations in MPRs, but also there were variations across health facilities within the same region. For example as shown in Fig 13, in Addis Ababa MPRs ranged from 0.13 to 3.7 and in Somali it ranged from 0.13 to 7.59.



	Amhara	Oromia	SNNPR	Benshangul-Gumuz	Somali	Addis Ababa
Max	5.67	5.72	4.29	4.93	7.59	3.7
Min	0.13	0.14	0.15	0.13	0.13	0.13
▲Average	1.87	1.87	1.97	1.87	2.72	1.65

Figure 13: Average, max-min median price ratios of a basket of medicines in the public sector, PSA-HFS Level II, Ethiopia, June 2016.

3.2.2.3. Affordability

The affordability of treatments for 4 tracer infectious diseases and 8 selected non-communicable diseases is shown in Tables 6 and 7. In public health facilities, except for treatment of adult respiratory tract infection which required 1.27 days' wages, the cost of the standard treatments for the rest of tracer conditions was reasonable, requiring less than a day's wages. In private medicine retail outlets, although less than in public facilities, medicines had reasonable affordability for most infectious conditions. While hydrochlorothiazide and atenolol (for hypertension) were affordable only in PHFs, diclofenac (for arthritis) and omeprazole (for ulcer) were found to be affordable both in PHFs and PMROs. Though slightly better in PHFs, treatment affordability to most other non-communicable diseases with medicines obtained from both PMROs and public health dispensaries were found to be compromised with minimum days' wages required to purchase a one month DDDs ranged from 1.17 to 1.93 in PHFs and 1.19 to 6.69 in PMROs. For example, treating diabetes with metformin 500mg required 1.7 days' wages in PHFs and 2.43 in PMROs; while treating depression with amitriptyline 25mg cost 1.93 and 2.55 days' wages, respectively in PHFs and PMROs.

Table 6: Number of days' wages of the lowest paid government worker needed to purchase standard treatments of tracer diseases, PSA-HFS Level II, Ethiopia, June 2016.

Tracer diseases	Drug name	Strength	No Units in a day	Duration	Day's wages in PHFs	Day's wages inPMROs
Adult respiratory infection	Amoxicillin	500mg	3	7 days	1.27	1.51
Adult uncomplicated UTI	Cotrimoxazole	400mg/80 mg	4	5 days	0.40	0.60
Pediatric respiratory infection (non-severe Pneumonia)	Amoxicillin	125mg/5ml	-	7 (100ml)	0.78	1.40
Watery diarrhea	ORS		-	2 sachets	0.32	0.67

Table 7: Number of days' wages of the lowest government worker needed to purchase DDDs of medicines for selected non-communicable diseases for one month duration, PSA-HFS Level II, Ethiopia, June 2016.

Diseases	Medicine name	Strength	No of DDD	Duration	Day's wages in PHFs	Day's wages in Private MROs
Diabetes	Metformin	500mg	4	30	1.70	2.43
Hypertension	Atenolol	50mg	1.5	30	0.86	1.19
	Hydrochlorothiazide	25mg	1	30	0.49	6.69
Hypercholesterolemia	Simvastatin	20mg	1.5	30	1.17	3.65
Depression	Amitriptyline	25mg	3	30	1.93	2.55
	Fluoxetine	20mg	1	30	1.65	2.55
Schizophrenia	Haloperidol	5mg	1.5	30	1.82	1.82
Arthritis	Diclofenac	50mg	2	30	0.49	0.54
Ulcer	Omeprazole	20mg	1	30	0.55	0.73
Asthma	Salbutamol inhaler	0.1mg/dose	0.8	30	3.08	2.92

Affordability became very much less for treating chronic diseases particularly with concomitant illnesses. For example, treatment of type II diabetes with hypertension using metformin 500mg and atenolol 50mg would require days' wages ranging from 3.56 to 6.87 in PHFS across study areas. This range increased to 4.69 to 17.38 in PMROs (Fig 14 and 15).

"The affordability of chronic diseases treatments is further constrained by the frequent need of more costly combination therapies, and by the ongoing nature of treatments."(Cameron et. al., 2008).

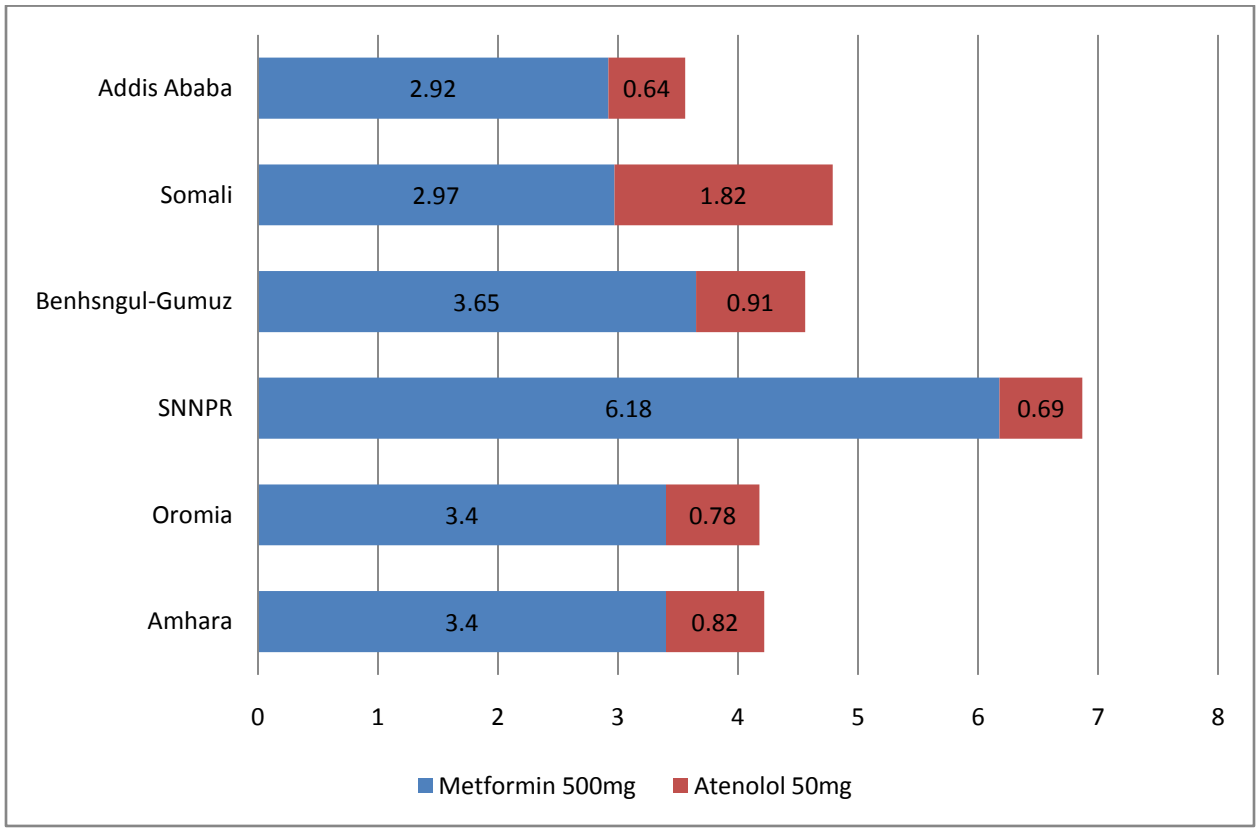


Figure 14: Treatment affordability for type II diabetes with concomitant hypertension (expressed as the number of days the lowest paid government worker needs to pay for a 1-month supply of medicines in DDDs) from the public health facilities, PSA-HFS Level II, Ethiopia, June 2016.

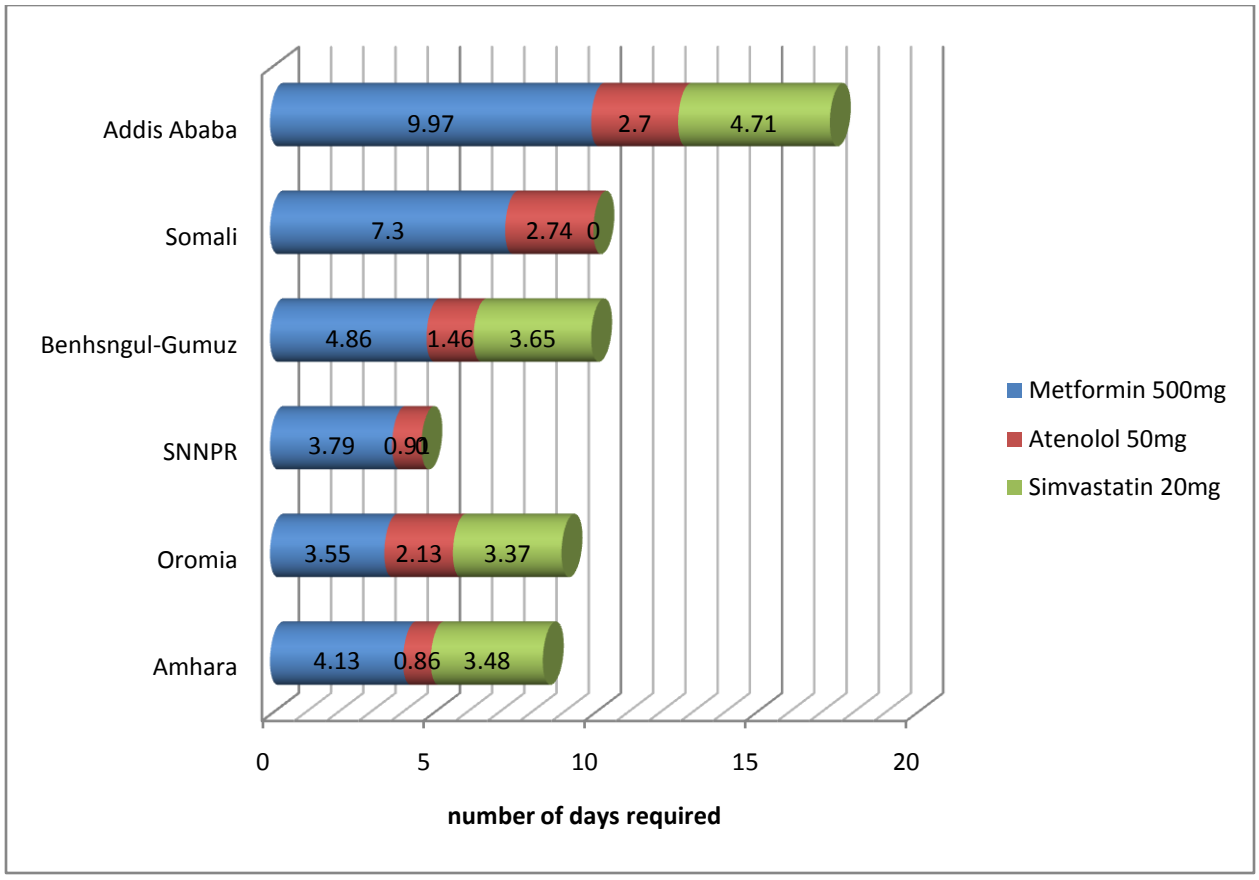


Figure 15: Treatment of type II diabetes with concomitant hypertension and hypercholesterolemia for a month treatment in DDS from private medicine retail outlets, PSA, Ethiopia, June 2016.

Generally, though treatment for most of the tracer infectious diseases selected such as adult uncomplicated UTI, child non-complicated pneumonia and watery diarrhea might be affordable, the monthly cost of treatment of chronic illnesses can clearly exceeds several days' wages of the lowest paid government employee. It should also be noted that affordability in the present study reflected medicines costs only and did not include fess for consultation and diagnostic tests. Moreover even if individual medicines for certain disease conditions appear to be affordable, households which need multiple medications would be unable to afford treatments.

3.2.2.4. Geographic accessibility

Geographic (physical) access "is understood as the availability of good health services within reasonable reach of those who need them and of opening hours, appointment systems and other aspects of service organization and delivery that allow people to obtain the services when they need them" (Evans et.al., 2013). Even though, distance and time are both important factors of

accessibility, World Health Organization (WHO) recommends using travel time, rather than distance, to assess geographical accessibility. The present survey measured geographic access by time travelled to reach the health facilities. In this regard, out of 1074 exit interviewed participants, 499 (47%) claimed that it took them less than 30min to reach to the PHFs; while 357(33%) said that they travelled greater than an hour to access the health facility (Fig 16).

"Disparities in the geographic accessibility to health care may be due to the location/distribution of the population and the characteristics of the transportation infrastructure relative to spatial arrangement of the health care delivery system within a region" (Yerramilli and Fonseca, 2014).

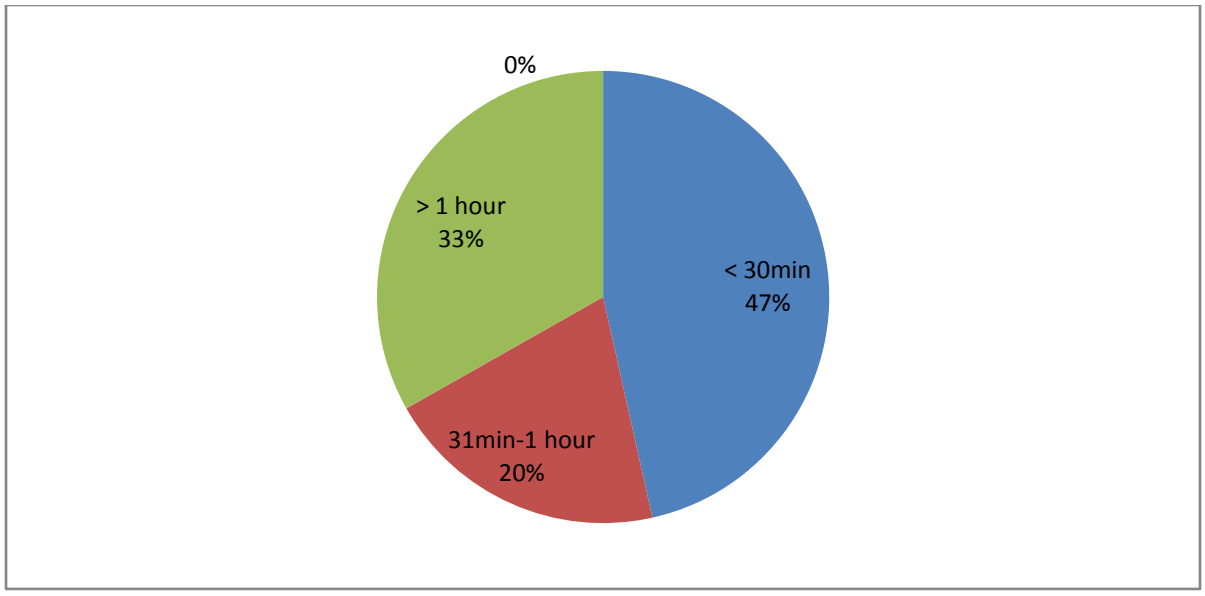
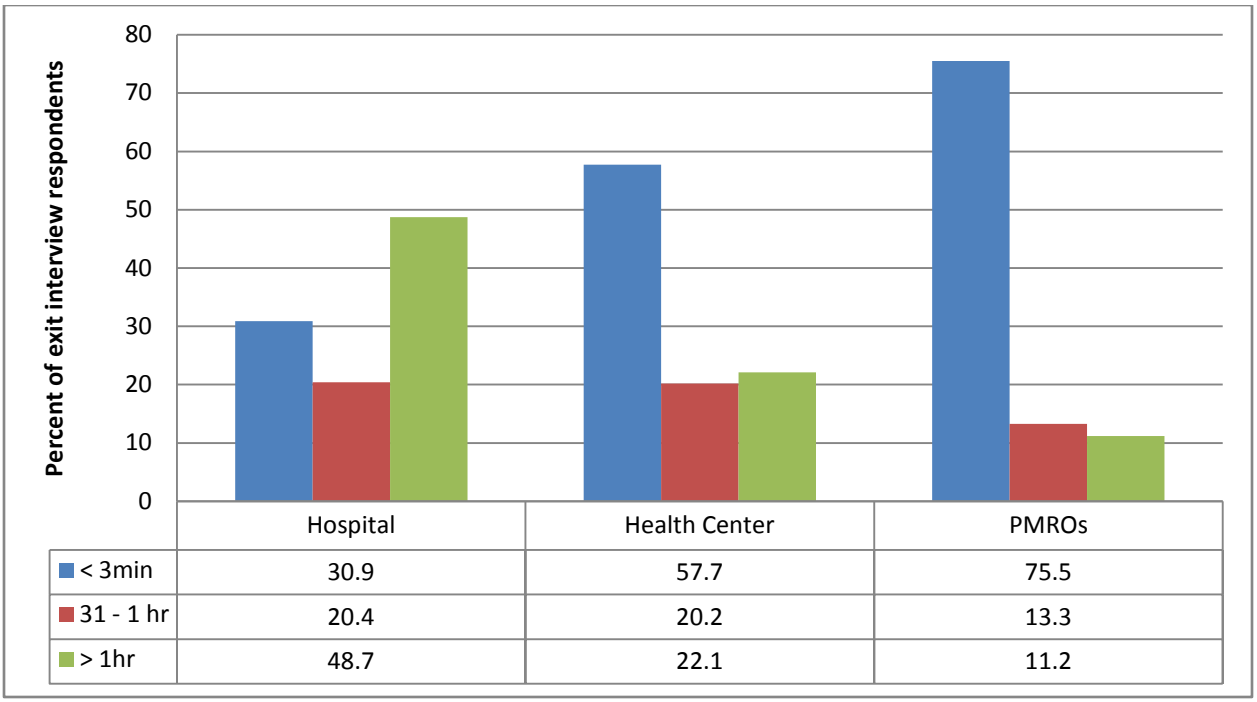


Figure 16: Geographic accessibility of PHFS, PSA-HFS Level II, Ethiopia, June 2016.

As shown in Fig 17 below, when different dispensary units are compared, PMROs were found to be more accessible to the population as compared to public health facilities. While 48.7% travelled greater than an hour to reach at the hospitals and 22.1% to the health centers, only 11.2% had to travel greater than an hour to the nearby PMROs to purchase medicines.



	Hospital	Health Center	PMROs
< 3min	30.9	57.7	75.5
31 - 1 hr	20.4	20.2	13.3
> 1hr	48.7	22.1	11.2

Figure 17: Comparison of geographic accessibility of Medicine Dispensaries, PSA-HFS Level II, Ethiopia, June 2016.

3.2.3 Rational use of medicines

According to WHO, the target for indicators measuring the extent of adequate labeling, proportion of prescribed medicines dispensed, adherence to treatment guidelines and availability of key medicines is ideally 100%. However, internationally valid standards for other indicators, such as average number of medicines per prescription, and the percentage use of antibiotics and injections, are more complex and have not been empirically established. Targets may require modification over time and between countries, but are currently recommended to be below 2, 30% and 20%, for the average number of medicines per prescription, percentage use of antibiotics and percentage use of injections, respectively. The optimal indicator values in these cases largely depend on disease patterns, policies and treatment guidelines and therefore may vary from country to country and over time.

3.2.3.1 Prescribing indicators

Prescribing indicators were assessed by retrospectively sampling 30 prescription papers per facility. As presented in Table 8, a total of 1080 prescriptions containing 2430 medicines were analyzed and indicated that the average number of medicines per-prescription was 2.25. The

proportions of antibiotics and injectable containing prescriptions were 30% and 10.49%, respectively. Out of the total prescribed medicines, 99.67% was from EML/FSML and 96.42% were in generic names. As compared to 2003 and 2010 figures, the average number of medicines per prescription which was documented in the present survey is higher (1.99, 2, and 2.25). Though the optimal values for this indicator largely depend on disease patterns and standard treatment guidelines, the currently recommended target is below 2 (WHO, 2007). It is encouraging to note at this point that in terms of the extent of use of injectable, Ethiopia is close to meet WHO target of 10%. When it comes to the proportion of the use of antibiotics, though the present survey revealed 30% which is WHO target, further improvement is required to attain the target of 25 % set in HSDP IV (MOH, 2010). However, when the present figure is compared with the two previous national pharmaceutical sector assessment results, a huge progress has been observed in terms of the use of antibiotics (MOH/WHO, 2010).

Table 8: Prescribing indicators, PHFs- PSA-HFS Level II, Ethiopia, June 2016.

Indicators	**N**	**%**
Total prescriptions assessed	1080	
Total number of medicines prescribed	2430	
Average number of medicines per prescription	2.25	
Proportion of prescription containing antibiotics	729	30.00
Proportion containing injectable	255	10.49
Proportion of medicines on EML/FSML	2422	99.67
Proportion with generic (INN) name	2343	96.42

3.2.3.2. Patient care indicators

Patient care indicators were assessed by interviewing patients/clients as the exited from the health facilities or private medicine retail outlets. The recorded data of the patient care indicators revealed fairly good results (Table 9, Fig 18). However, the proportion of adequate labeling was found to be very low (19.9%). According to EFMHACA (2010), the minimum information that should be included on the label of dispensed medicines is patients' name; generic name (with

strength and dosage form) of the medicines; dose, frequency and duration of use; quantity and how to take the medicines; and storage conditions. The extent of meeting these requirements varied from region to region; it was 1.78% in Oromia and 52.63% in Addis Ababa.

Table 9: Patients care indicators, PHFs- PSA-HFS Level II, Ethiopia, June 2016.

Area	No of medicines prescribed	% dispensed	% adequately labeled	% of Patients knowing how to take
Amhara	395	93.16	24.18	88.9
Oromia	374	90.37	1.78	88.3
SNNPR	389	94.86	5.96	93.9
Benshangul-G	362	90.06	23.05	72.8
Somali	361	94.18	14.41	100
Addis Ababa	352	91.76	52.63	97.7
National average	2233	92.43	19.9	90.22

As shown in Fig 18, when key patient care indicators were compared across different levels and set of health facilities, it revealed that the extent of adequacy of labeling was better in private medicine retail outlets followed by public hospitals and health centers with proportion fulfilling the minimum requirements sent by EFMHACA 36.7%, 22.9% and 17.9%, respectively. Encouraging result has been obtained as far as adequacy of patient knowledge is concerned in across health facilities considered. Patient knowledge was better in PMROs (92.7%) as compared to PHFs (90.2%). Generally it showed improvement from 2003 to 2010 and then in 2016; 67.36%, 84% and 90.22% respectively. It was however less than the ideal value and target set in HSDP IV document, 100% (MOH, 2010). There were slight variations across regions with regard to the proportion of exit interviewed participants' knowledge on how to take the medicines.

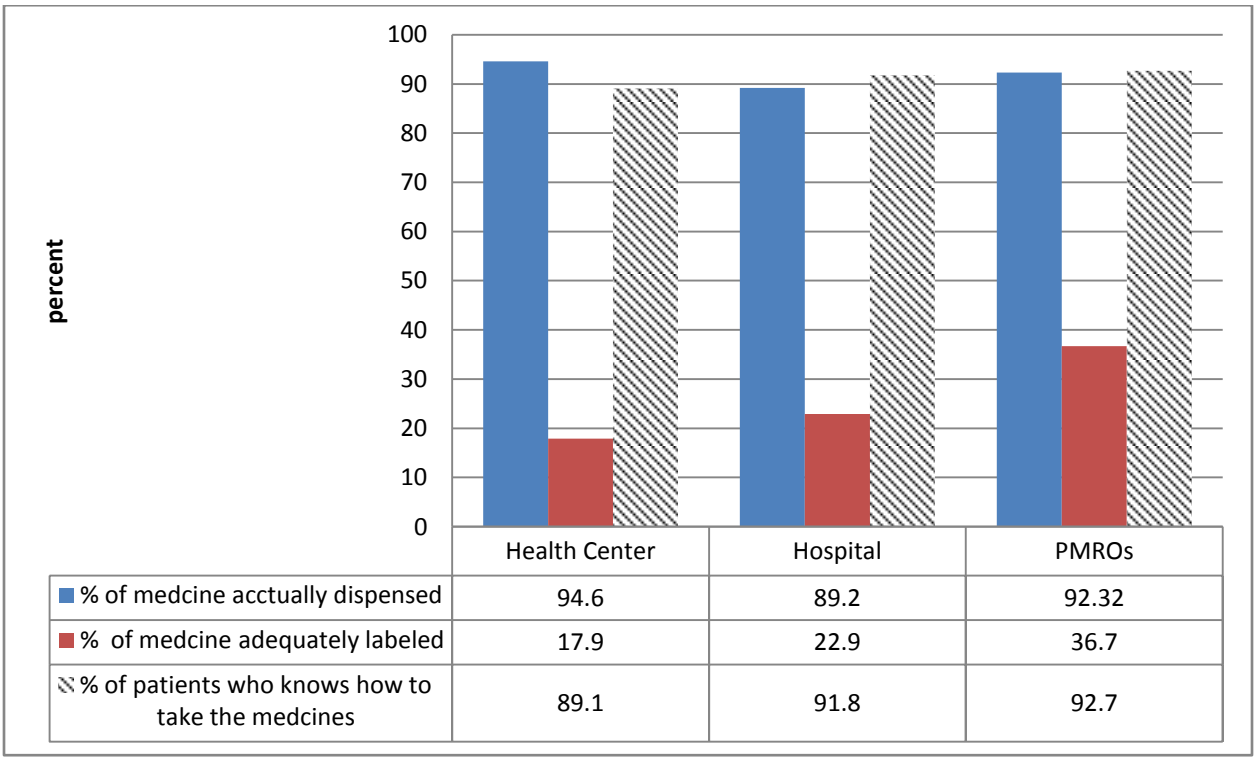


Figure 18: Patient care indicators by type of health facilities, PSA-HFS Level II, Ethiopia, June 2016.

3.2.3.3Adherence of prescribers to Standard Treatment Guidelines

Irrational use of medicines is a huge problem globally (WHO, 2011). It would result in poor patient outcome, adverse drug reactions, increasing antimicrobial resistance and wasted resources. One of the strategies to promote rational use of medicines is to develop and make use of standard treatment guidelines. When practitioners fail to prescribe medicines in accordance with standard treatment guidelines, it may end up with non-rational use of medicines (WHO, 2013; MSH, 2012). In developing and transitional countries, in primary care less than 40% of patients in the public sector and 30% of patients in the private sector are treated in accordance with standard treatment guidelines (WHO, 2011). As shown below in Table 10, the present survey demonstrated that there was deviation from the guidelines with regard to antibiotic and anti-diarrheal use in the management of childhood diarrhea. Antibiotics were prescribed in 64.41% of cases, and anti-diarrheal in 13.82% of cases. According to the guidelines, however, neither of these should have been prescribed at all. Moreover 13% of children with the same conditions did not receive ORS.

Most respiratory tract infections are self-limiting and antibiotic treatment only slightly modifies their course (Arroll and Kenearly, 2002). However, prescribers in public health facilities were found prescribing an antibiotic to 73.89% of patients of any age with non-pneumonia ARI.

Table 10: Adherence to Standard Treatment Guidelines in treating tracer conditions at PHFs, PSA-HFS Level II, Ethiopia, June 2016.

Tracer conditions	Indicators	Percent
Non-bacterial diarrhea in children under the age of 5	Total cases	340
	% ORS	86.76
	% antibiotics	64.41
	% anti-diarrheal /or anti-spasmodic	13.82
Non-severe (outpatient) pneumonia in children under age 5	Total cases	350
	% receiving any 1st line antibiotic	63.43
	% receiving more than one antibiotic	11.14
Non-pneumonia upper respiratory tract infection (Common cold, Pharyngitis, Laryngitis) in patients of any age	Total cases	360
	% receiving any antibiotics	73.89

3.2.4 Quality of Medicines

Since direct quality assessment of medicines is expensive and time consuming, it is difficult to conduct in such types of national surveys. Instead some proxy indicators could be used. In the present survey, very basic quality standards for storage conditions verified in this study were measured.

The collected data show that the storage conditions were better in the warehouses than the public health facilities and private medicine retail out-lets (Figures 19& 20).

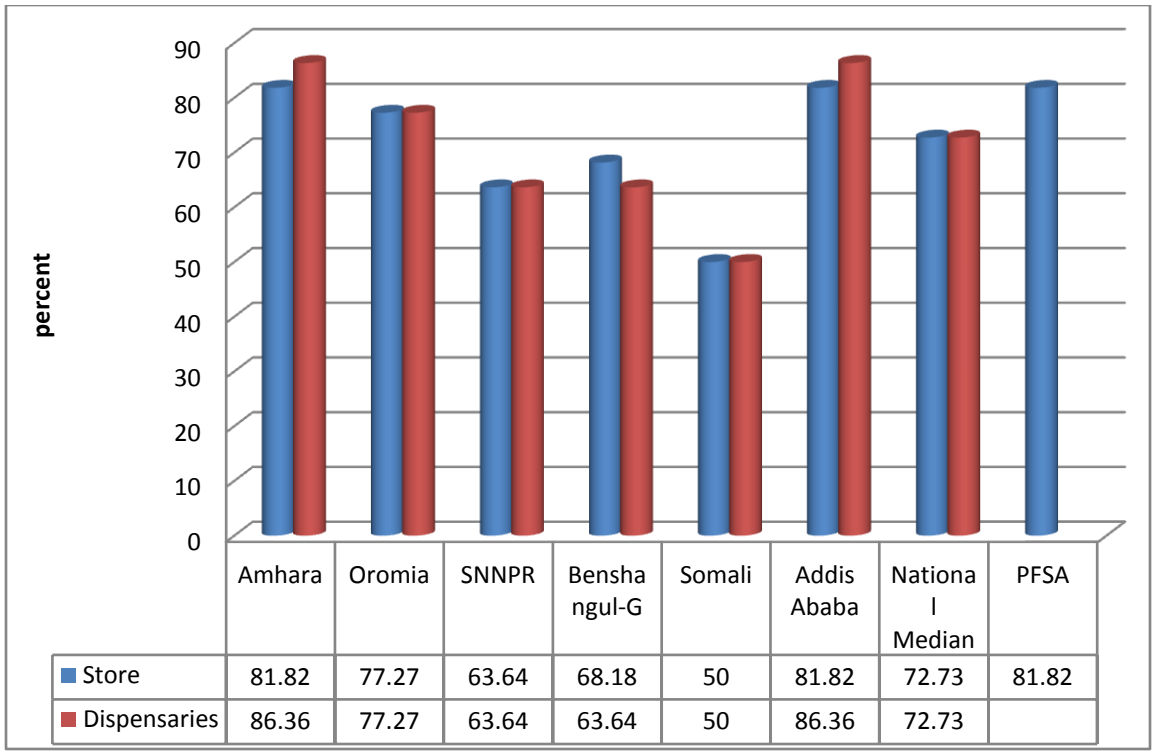


Figure 19: Adequacy of infrastructure for conservation conditions of medicines, PHFs and PFSA Hubs-PSA-HFS Level II, Ethiopia, June 2016.

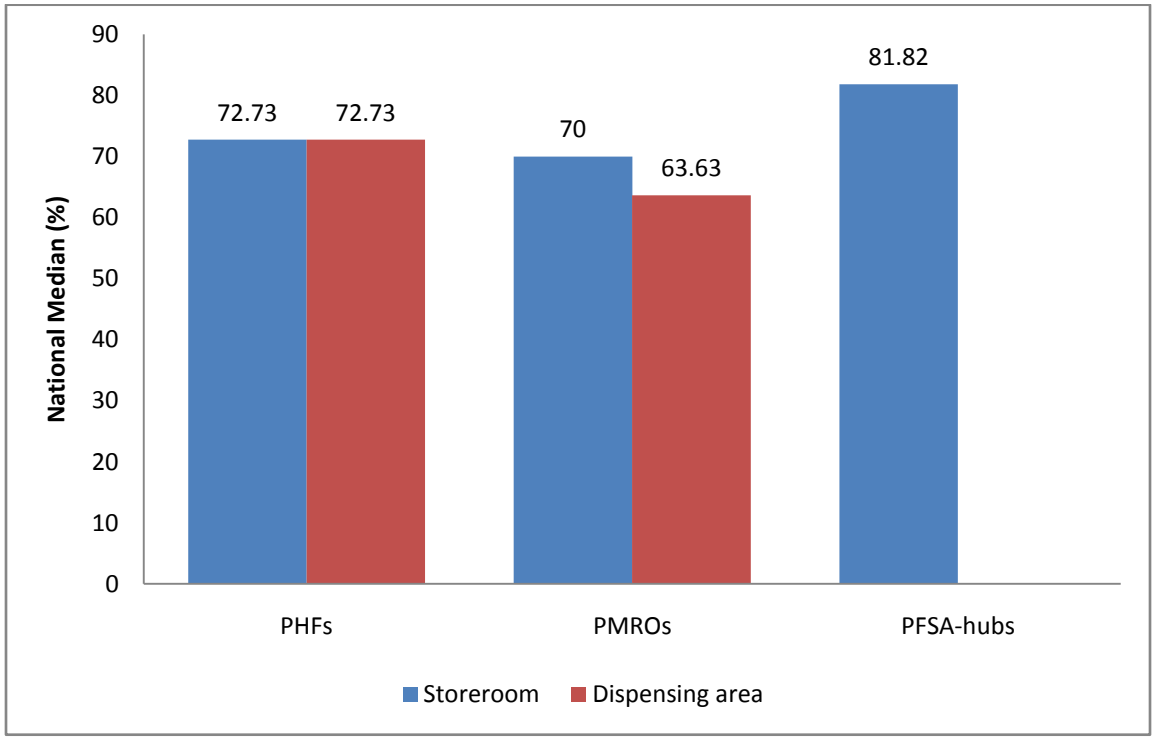


Figure20: Adequacy of infrastructure of conservation conditions of medicines, PSA-HFS Level II, Ethiopia, June 2016.

As shown in Fig 21 below, the adequacy of the conservation conditions declined with the level of private dispensing outlets. In this regard, pharmacies had better infrastructure for adequate storage conditions of medicines as compared to drug shops and rural drug vendors.

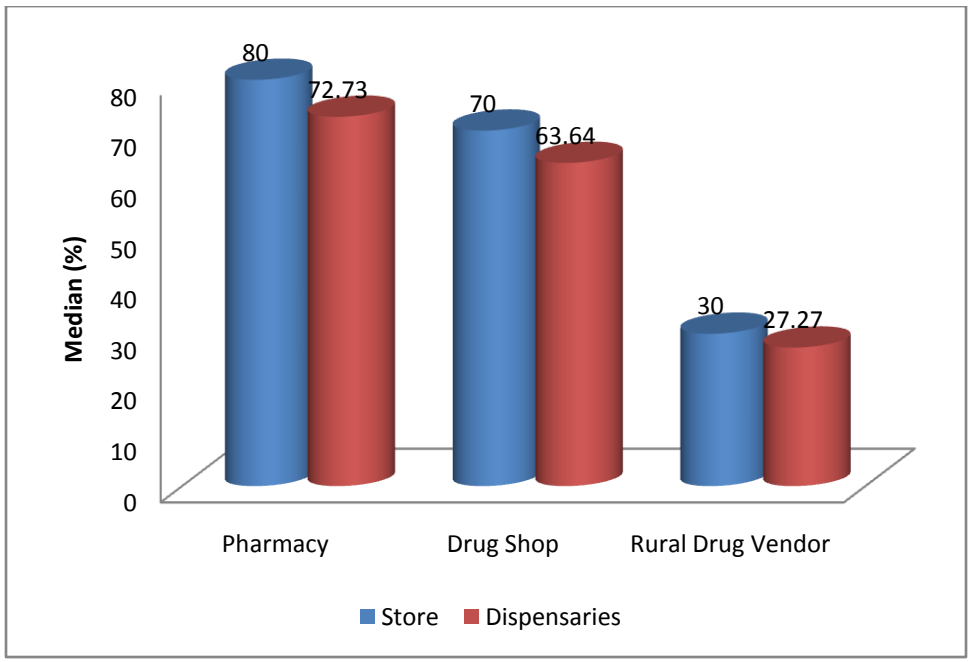


Figure 21: Adequacy of infrastructure of conservation conditions of medicines in PMROs, PSA-HFS Level II, Ethiopia, June 2016.

3.2.5 Compliance with human resources requirements

Appropriate pharmacy professionals were found in 52.8% and 78.1% of the public health facilities and medicine retail outlets, respectively; suggesting that the law concerning human resources requirements is not well followed by nearly half of the PHFs and 1/5th of the PMROs. Pharmacist was found in 33.3% and 80% of public dispensaries at the health centers and hospitals, respectively (Table 12, Fig 22).

The most frequent prescriber found in the public health care facilities was the health officer (47.2%) followed by physician (36.1%). The most senior prescriber found was also the health officer36.1%; of whom only 11.1% participated in training related to rational use of medicines in the previous year (Table 13).

Table 11: Dispenser profile and compliance with the Law, PHFs and PMROs, PSA-HFS Level II, Ethiopia, June 2016.

Professional dispensing during the day of visit	PHFs	PMROs
Pharmacist	38.9	50
Druggist/Pharmacy Tech	38.9	28.1
Nurse/HA	19.4	21.9
Facilities with appropriate pharmacy professionals as per the law	52.8	78.1

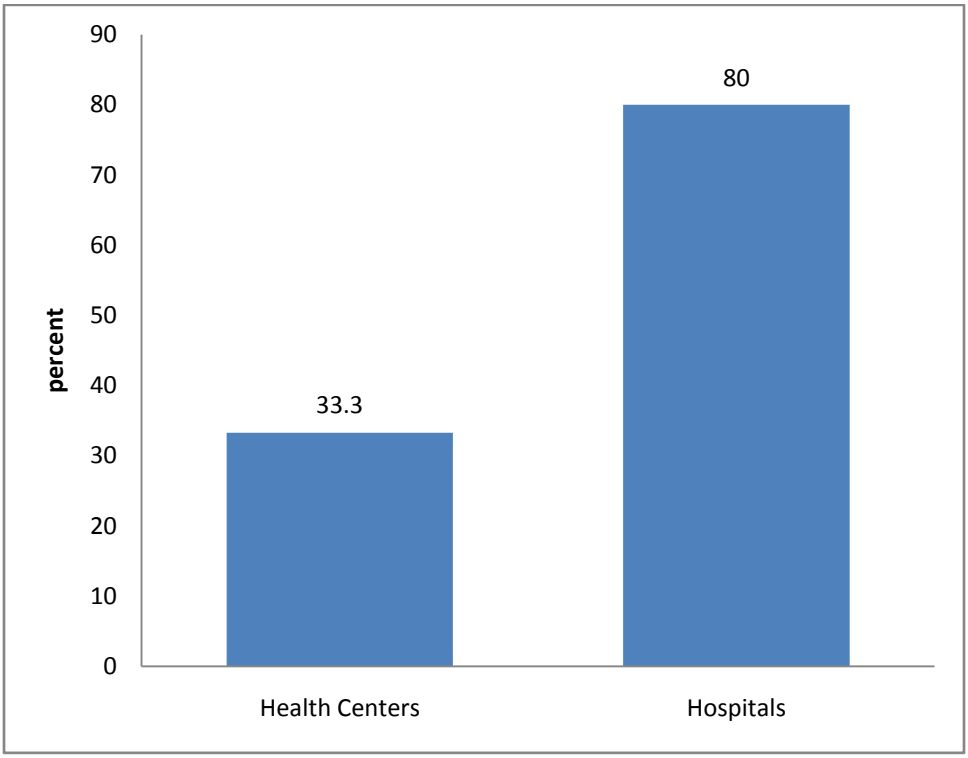


Figure 22: Presence of the pharmacist during the day of visit, PHFs-PSA-HFS Level II, Ethiopia, June 2016

Table 12: Prescriber profile in the PHFs, PSA-HFS Level II, Ethiopia, June 2016.

% Facilities where	Doctor	Health Officer	Nurse
The professional was present during the visit	36.1	47.2	16.7
The most senior professional present	33.3	36.1	30.6
The most senior professional attended RDU-related	11.1		

3.2.6 Availability of Forms and services for implementation of NMP strategies

The use and abuse of dependence producing substances has become a matter of concern. As a result the international community and governments have been urged to develop mechanisms to control illicit use of these substances and promote their rational use in clinical practice. The international drug control treaties are instruments which provide a framework for the regulation of a number of defined narcotic drugs and psychotropic substances, the most dangerous of which are eliminated from use. The potentially beneficial ones are subjected to controls in production, manufacture, trade and distribution so that their use can be limited exclusively to scientific and medical purposes. Furthermore, the conventions embody a policy and indicate the type of controls needed in legislation and drug regulatory work, thus helping to promote the rational utilization of the controlled substances and the prevention of their abuse and to counteract illicit international traffic.

Ethiopia is a party to the different UN Drug Convention and Protocols. In connection with this, a number of steps have been taken to promote appropriate utilization of narcotics and psychotropic medications in the country which include development of formulary for narcotic and psychotropic medications (DACA, 2004), and introduction of special prescription papers for these medications to limit their use. EFMHACA have been engaged in distributing these prescription papers. However, as shown in Table 13 below it was only in slightly higher than 50% of the facilities where standard prescriptions were available on the day of the visit (52.78% for narcotic and 55.56% for psychotropics).

Though assessment of Level I indicators indicated that the Ethiopian pharmaceutical sector possesses a satisfactory enabling policy and necessary instruments for implementation of the strategies, the average availability of the instruments and support facilities at the public health institutions was found to be below 50%. In some instances even if they were available in the health facilities surveyed, they were not found in a section they are most needed. For example, STG for pneumonia was found in 55.6% of the facilities; while only in 27.8% of the cases where they were located in the OPDs. Similarly, STG for malaria was available in 52.8% of the survey health institutions but it was only in 30.6% of the cases where this guideline was placed in OPDs (Table 13).

Health Supply Chain is the blood line of a well-functioning health care system. To ensure an efficient and high-performing healthcare supply chain, various interventions have been initiated by the Ethiopian Federal Ministry of Health (FMOH). To this effect, IPLS has been one of the many interventions in place since 2009 (Shewarega et. al., 2015). The present survey, however, indicated that IPLS was reported to be non-functional in close to 1/3rd of the health facilities covered.

Table 13: Availability of forms, guidelines and services in PHFs- PSA-HFS Level II, Ethiopia, June 2016.

Variables	Yes (%)
Standard prescription paper for narcotics medications	52.78
Standard prescription paper for psychotropic medications	55.56
National medicine Formulary	63.89
ADE reporting form	50.00
Medicine Supply Management Unit	36.00
Implement IPLS	63.89
Medicine Information services	33.33
STG for pneumonia	55.6
STG for malaria	52.8
Both STGs	47.2
STG for pneumonia in OPD	27.8
STG for malaria in OPD	30.6
List of Medicines for Ethiopia	58.3
National Essential Medicines List	30.6
Facility Specific Essential Medicines List	58.3

4 Conclusion and Recommendations

"Sustainable improvements in pharmaceutical sector depends on high level national commitments to improvements, technically sound plans based on an accurate situation assessment, and technical and financial resources to implement proposed changes" (MSH, 2012). The present national pharmaceutical sector assessment (PSA) survey was the third of its kind in the country and it is believed that it would provide an insight on the progress made in terms of implementation of the national medicine policy and the various initiatives which have been in place to improve the pharmaceutical services in particular and the health care system in general. It would also provide baseline information to measure the impacts of the different reforms and measures taken in relation to implementation of HSTP.

The NMP in Ethiopia is over 2 decades old, as well as EML, STG, Formulary and others requiring updating. Though the revision is said to be completed, its formal launching is yet to be done. Analysis of level I indicators also suggested that the basic structures, regulatory framework and instruments for promoting access to quality assured medicines and their rational use are in place. However, the performance in certain areas still remains to be improved. The major health financing source including medicines' financing remains to be households.

"People lack access to medicines where they cannot obtain the products they need to prevent or treat a medical condition. This might be because a product is either unavailable or is not offered or because it is unaffordable" (DIFID, 2004). The fundamental objective of the Ethiopian National Medicine Policy was to provide Ethiopians with safe, effective and affordable medicines that are of good quality.

This PSA revealed that the national median availability of key medicines at public health dispensaries was 72.4%, better than availability in PMROs (67.3%). The median availability across regions varied from 66.1% to 81.4% and availability of the 48.3% of key medicines was less than 65%; which was considered to be low. Of particular concern is the fact that the median percentage availability of medicines for non-communicable diseases in majority of surveyed regions/city administrations was very low (< 50%). The median stock-out durations were 19.6 and 26.6 days in PHFs and PFSA hubs, respectively. This indicated the need to double our effort to ensure that medicines are in stock 100% of the time.

Medicine price was found to be one of the main obstacles to access in many developing countries. The efficiency of public sector procurement appears to be sub-optimal as evidenced by the higher median procurement price ratio (60% higher than IPR). Similarly, the patient MPR was 1.8, which is higher than the acceptable level of 1.5. The MPRs was even higher in PMROs (4.9 times the IRP). Similarly, the average retail mark up in PHFs was documented to be 25.2%.

One of the components of access framework is affordability. Medicines for the treatment of most of the tracer conditions selected were often affordable. However, the treatments of chronic diseases such as diabetes, hypercholesterolemia, depression, schizophrenia and asthma were found to be unaffordable. Affordability was seriously compromised when treating chronic conditions with concomitant illnesses.

Irrational use of medicines remains a major issue facing most health systems across the world (WHO, 2011). The key factors contributing to inappropriate medicines use are likely to change over time and policy makers need to get updated information on the issue to implement appropriate measures (Ofori-Aseno and Agyeman, 2016). From the present survey it was concluded that there was improvements in terms of the extent of use of antibiotics and injections from the two national studies conducted in 2003 and 2010 and very close in achieving the target set in HSDP IV. Analysis of patient care indicators also revealed that 90.2% of patients in PHFs and 92.7% in PMROs had knowledge on how to take medicines prescribed to them. As compared to the previous national survey there has been an increment from 67.4% to 84% to 90.2% respectively for 2003, 2010 and 2016 surveys. However, the figure is short of the 100% target indicated in HSDP IV. The present survey also documented irrational dispensing practice with only 19.9% of dispensed medicines adequately labeled. While the high level (87%) of use of ORS for watery diarrhea was encouraging, the use of antibiotics (64.4%) and anti-diarrheal (13.8%) for the treatment of non-bloody diarrhea was not in accordance with the STGs. The same deviation was observed in the treatment of non-Pneumonia ARI where antibiotics were used in 73.9% of the patients.

Though assessment of Level I indicators indicated that the Ethiopian pharmaceutical sector possesses a satisfactory enabling policy and necessary instruments for implementation of the strategies, the average availability of the instruments and support facilities at the public health institutions was found to be below 50%. For example greater than 40% of the facilities did not

have standard prescription papers for narcotics and psychotropic medications, 1/3rd of facilities did not implement IPLS, and STGs for pneumonia was found only in 55.6% of the facilities.

The law concerning human resources requirements was not well followed by nearly half of the PHFs and 1/5th of the PMROs. Only 1/10th of the existing prescribers reported to have had any forms of training in rational use of drugs.

Finally, although the survey showed the existence of numerous positive and encouraging improvements in some areas of the pharmaceutical sector, there are also areas which require further improvements in order to improve the sector and make quality, safe and affordable medicines more accessible. Based on the findings the following recommendations are made:

1. Based on the findings of the national survey, regions need to conduct assessment in their specific areas to get a more in-depth understanding of the underlying causes of specific deficiencies and inform decision making.
2. The revised version of the NMP need to be launched and made available to the stakeholders to guide efforts to strengthen the pharmaceutical sector.
3. Ethiopia used pooled procurement based on competitive tender for multisource products and price negotiations for single source items since the establishment of PFSA. These strategies claimed to have resulted in considerable savings. However, the routines of procurement, stock handling and distribution, and their impact on the availability and affordability should be assessed.
4. Generating revenue from sales of medicines may be used to expand services and replenish the stock, it is important to consider the affordability issue when setting up patients' price markups. Sound and clear regulation of mark ups particularly in public health facilities is required to reduce the higher price ratios in most of the medicines studied.
5. System should be in place to continuously engage importers/wholesalers and local producers to identify how best they can contribute to enhancing accessibility and affordability of medicines.
6. Availability, affordability and prices should be regularly measured.
7. Attention should be given to increase availability and affordability of medicines particularly to patients with chronic diseases due to the fact that their medication is for life time. In this regard, strengthening and encouraging pooled and prepaid financing of medicines is needed.

8. Prescribers' adherence to standard treatment guidelines for managing common conditions like diarrhea and non-pneumonia respiratory conditions was poor. Only 11% of the senior prescribers interviewed on the day of visit reported to have taken training on rational use of medicines. There is therefore a need for an official continuing education system on rational use of medicines for prescribers and dispensers as this is one of the most cost-effective ways to improve rational use of medicines.
9. Evaluating and strengthening of mechanisms of distribution of support instruments for promoting rational use of medicines such as STGs, Standard Prescription Papers for narcotics and psychotropics, EML/FSML, IPLS and their usages need to be done.

The findings of this survey were presented to stakeholders in a-two day validation workshop. The following key points were raised by the participants:

- The findings would serve as baseline for measuring the performance of different initiatives including the broader HSTP implementation.
- To get a full picture of the pharmaceutical situation in the country, private clinics and hospitals should have been included as their contribution is significant.
- Standard list of basket of tracer medicines should be prepared with a wider consultation for future monitoring of pharmaceutical sector.
- Measuring affordability based on GDP per capita could have been better than using lowest wages of the unskilled government worker.
- Problem of stock out and low availability of medicines requires attention. In this regard, increasing medicines' budget and improve storage facilities at the health facilities were recommended.
- Deficiencies in recording at health facilities level affected the forecasting accuracy and should be improved.
- Local manufacturing capacity should be strengthened to ensure availability and affordability.
- Regulation of narcotics and psychotropic medications seems to be inefficient. Alternative design for the distribution and availability of standard prescription paper needs to be considered.
- Detailed studies should be done to identify the underlying causes of suboptimal performances in relation to the major objectives of NMP.

5 Strength and Limitations of the Survey

The survey used WHO methodology for monitoring of country's pharmaceutical sectors which is standardized that would allow comparison with the findings from other countries. Moreover the data generated in the present survey was validated in a workshop conducted in June 2017 where professionals from stakeholders both at federal and regional levels, health institutions covered and from partners were in attendance. However, availability for basket of medicines was determined with only one strength and dosage form, without considering the alternate strength and dosage forms, which might possibly undermined availability."Availability may change depending on the time of the year" (Dabare et al., 2014). This assessment was conducted in June, the end of the Ethiopian Budget Year. This might positively or negatively affected the procurement process consequently influencing availability.

Affordability was measured taking into consideration the salary of the lowest paid unskilled government workers without regard to the household size and possibility of existence of multiple morbidities in a household which may render even the lowest priced medicines unaffordable to the family. Moreover as many studies indicated, calculating affordability based on government workers' wages would lead to over optimistic estimate since a significant proportion in most countries earn less than this (Jiang, et. al., 2013; Ahmed et. al., 2008; Nyanwura and Esena, 2013).

6 References:

Ahmed H., Ibrahim M., Babar Z. (2013). Affordability of essential medicines used for treating chronic diseases in Malaysia: an academic perspective. Journal of Third World Medicine, 8(1):1-8.

Arroll B, Kenealy T (2002). Antibiotics for the common cold. Cochrane Database Syst Rev: CD000247.

Cameron A., Ewen M., Ross-Degnan D., Ball D., Laing R (2008). Medicines prices, availability, and affordability in 36 developing and middle income countries: a secondary analysis. The Lancet.com, DOI: 10.1016/S0140-6736 (08) 61762-61.

Central Statistics Agency of Ethiopia and ICF (2106). Ethiopian Demographic and Health Survey 2016: Key Indicator Report. Addis Ababa, Ethiopia and Rockville, Maryland, USA.CSA and ICF.

Dabare PRL, Wanigatunge CA and Beneragama BVSH (2014).A national Survey on availability, price and affordability of selected essential medicines for non-communicable diseases in Sri Lanka. BMC Public Health; 14:817.

Drug Administration and Control Authority. Formulary of narcotic drugs and psychotropic substances for Ethiopia. Drug Administration and Control Authority: Addis Ababa, February 2004.

Ethiopia Health Sector Financing Reform/Health Finance and Governance Project, Year One – Annual Performance Report, August 1, 2013–June 30, 2014. Bethesda, MD: Health Finance & Governance Project, Abt Associates, Inc.

Evans DB, Hsu J, & Boerma T (2013).Universal health coverage and universal access. Bulletin of the World Health Organization 2013; 91:546-546A. doi: http://dx.doi.org/10.2471/ BLT 13.125450

Federal Democratic Republic of Ethiopia. The Federal NegaritGaztea16th Year No. 9, Addis Ababa, 13th January, 2010.

Fidler, A. & Msisha, W. (2008).Governance in the pharmaceutical sector. EuroHealth-London, 14, 25.

Gelders S, Ewan M, Noguchi N, Laing R. (2006). Price, Availability, and Affordability: an international comparison of chronic diseases medicines. World Health Organization and Health action International: Cairo.

Jiang M., Yang S., Yan K., Liu J., Zhao J., Fang Y. (2013). Measuring Access to Medicines: A Survey of Prices, Availability and Affordability in Shaanxi Province of China. Plos One, 8(8):1-8.

Management Sciences for Health (2015).International Drug Price Indicator Guide 2014 Edition. Medford, Mass: MSH.

Management Sciences for Health (2012). Supply system management available at: http//www.msh.org/mds3-ch36-supply system mar2012pdf.

Mhlanga BS., Suleman F. (2014). Price, Availability and Affordability of Medicines. Afr J. Prim Health Care Fam Med. 6(1): http://dx.doi.org/10.4102/phcfm.V6i1.604.

MOH (2010).Health and Health Related Indicators2009 EFY. Federal Democratic republic of Ethiopia, Ministry of Health, Addis Ababa.

MOH/WHO. Assessment of the pharmaceutical sector in Ethiopia. Addis Ababa: WHO Country Office, 2010.

MOH, PMNCH, WHO, World Bank, AHPSR and participants in the Ethiopia multi-stakeholder policy review (2015). Success Factors for Women's and Children's Health: Ethiopia.

MOH and MOI. National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015-2025). Federal Democratic Republic of Ethiopia (Ministry of Health and Ministry of Industry), World Health Organization, July 2015.

Nyanwura EM, Esena RK (2013). Essential medicines availability and affordability: a case study of the ten top registered diseases in Bulisa district of Ghana. International Journal of Scientific and technology research, 2(8): 2008-219.

Ofori-Asenso R and Agyeman AA (2016).Irrational Use of Medicines – A Summary of Key Concepts. Pharmacy, 4, 35; doi: 10.3390/pharmacy4040035.

Rexed B., Edmondson K., Khan I., Samson RJ (1984). Guidelines for the Control of Narcotic and Psychotropic Substances in the context of the international treaties. World Health Organization: Geneva.

Shewarega, Abiy, Paul Dowling, Welelaw Necho, Sami Tewfik, and Yared Yiegezu (2015). Ethiopia: National Survey of the Integrated Pharmaceutical Logistics System. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4, and Pharmaceuticals Fund and Supply Agency (PFSA).

SudhaYerramilli, Duber Gomez Fonseca. Assessing Geographical Inaccessibility to Health Care: Using GIS Network Based Methods. Public Health Research 2014, 4(5): 145-159 DOI: 10.5923/j.phr.20140405.01

Systems for Improved Access to Pharmaceuticals and Services (2016). Ethiopian National Health Insurance Scale-Up Assessment on Medicines Financing, Use, and Benefit Management: Findings, Implications, and Recommendations. Submitted to the United States Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

United Nation Statistics Division (2016).World Statistics Pocketbook .http://data.UN.org/ country profile/Ethiopia. Accessed on June 2016.

Wang X., Fang Y., Yang S., et.al, (2014). Access to pediatric essential medicines: A survey of prices, availability, affordability and price components in Shaanxi Province, China. PLOS ONE, 9(2):1-7.

World Health Organization and Health Action International (2003).Medicine prices: a new approach to measurement. World Health Organization & Health Action International; 2003. Available from:http://apps.who.int/iris/bitsstream/10665/67911/WHO.EDM-PAR-2003.2.

World Health Organization and Health Action International (2008).Measuring medicine prices, availability, affordability and price components. Geneva: World Health Organization & Health Action International; 2008. Available from: http://www.haiweb.org/ medicine prices/manual /documents.html.

WHO. SDG 3: Ensure healthy lives and promote wellbeing for all at all ages. Available at http://www.who.int/sdg/targets/en/

WHO-AFRO (2016). Country Profile: Ethiopia analytical summary - Non-communicable diseases and conditions. Brazzaville, World Health Organization Regional Office for Africa, 2016.http://www.aho.afro.who.int/profiles_information/index.php/Ethiopia:Analytical_summary Non-communicable_diseases_and_conditions. Accessed on 13 August 2017.

WHO (2013).Global action plan for the prevention and control of non-communicable diseases 2013-2020. Geneva: World Health Organization, 2013.

WHO (2011). The World Medicines Situation 2011: Rational Use of Medicines. WHO Press, World Health Organization: Geneva, 2011. WHO/EMP/MIE/2011.2.2

WHO (2007). WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors. WHO/TCM/2007.2

Annex 1: Characteristics of the surveyed facilities and number of exit interviews conducted, PSA-HFS Level II, Ethiopia, June 2016.

Region	Category of facilities	No of facilities covered	No of exit interviews
Region 1: Amhara	Public Hospital	3	90
	Public Health Centers	3	90
	Private Medicine Retail outlets	5	150
	PFSA warehouse	1	N/A
Region 2: Oromia	Public Hospital	3	90
	Public Health Centers	3	90
	Private Medicine Retail outlets	4	117
	PFSA warehouse	1	N/A
Region 3: SNNPR	Public Hospital	3	90
	Public Health Centers	3	90
	Private Medicine Retail outlets	5	150
	PFSA warehouse	1	N/A
Region 4: Benshangul-G	Public Hospital	2	60
	Public Health Centers	4	120
	Private Medicine Retail outlets	6	180
	PFSA warehouse	1	N/A
Region 5: Somali	Public Hospital	2	60
	Public Health Centers	4	119
	Private Medicine Retail outlets	6	180
	PFSA warehouse	1	N/A
Region 6: Addis Ababa City	Public Hospital	2	60
	Public Health Centers	4	115
	Private Medicine Retail outlets	6	180
	PFSA warehouse	1	N/A

Annex 2: Age and sex distribution of exit interviews participants, PSA-HFS Level II, Ethiopia, June 2016.

Category of Health Facilities	Number of exit interviews	% Females	Age (%)	
Hospitals	450	50.2%	Under 5 yrs.	8.9
			5 to 15 yrs.	7.8
			16 to 60 yrs.	73.8
			Greater than 60 yrs.	9.6
Health Centers	624	50.8%	Under 5 yrs.	17.6
			5 to 15 yrs.	13.5
			16 to 60 yrs.	66.2
			Greater than 60 yrs.	2.7
Private Medicine Retail Outlets	957	52.5%	Under 5 yrs.	12.3
			5 to 15 yrs.	8.3
			16 to 60 yrs.	74.5
			Greater than 60 yrs.	4.9
Total	2031	51.5%	Under 5 yrs.	13.2
			5 to 15 yrs.	9.8
			16 to 60 yrs.	71.8
			Greater than 60 yrs.	5.3

Annex 3: List of basket of medicines

Key medicines
Amoxicillin 500mg cap
Amoxicillin 125mg/5ml suspension
Ceftriaxone 1g inj.
Ciprofloxacin 500mg caps/tab
Trimethoprim-Sulphamethoxazole 400mg/80mg tab
Artemeter + Lunfantrine 20mg + 120mg tab
Mebendazole Oral Suspension,100mg/5ml
Metronidazole 250mg cap/tab
Atenolol 50mg tab
Hydrochlorothiazide 25mg tab
Metformin 500mg tab
Simvastatin 20mg tab
Diazepam 5mginj
Amitriptyline 25mg tab
Fluoxetine 20mg tab
Phenobarbitone 100mg tab
Haloperidol 5mg
Omeprazole 20mg
Salbutamol inhalers 100mcg/dose
Oral Rehydration Salts (ORS)
Diclofenac Sodium 50mg
Paracetamol 120mg/5ml
Sodium Chloride0.9%(Normal Saline) 1000ml
Oxytocin 10uU/ml
Magnesium sulphate inj.
Ferrous sulphate + folic acid tab
Oral contraceptives
EFZ + TDF + 3TC
HRZE