

Assessment of the Pharmaceutical Sector in Ethiopia

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Assessment of the Pharmaceutical Sector in Ethiopia

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ACRONYMS

ADR	Adverse Drug Reaction
ANOVA	Analysis of Variance
ARTI	Acute Respiratory Tract Infection Company
DACA	Drug Administration and Control Authority
E. C.	Ethiopian Calendar
ECA	Economic Commission for Africa
EFY	Ethiopian Fiscal Year
EDL	Essential Drugs List
EDM	Essential Drugs and Medicines policy
ETB	Ethiopian Birr
FDRE	Federal Democratic Republic of Ethiopia
G. C.	Gregorian calendar
GMP	Good Manufacturing Practice
GDP	Gross Domestic Product
GNI	Gross National Income
HSDP	Health Sector Development Program
IMCI	Integrated Management of Childhood Illness
LIDE	List of Drugs for Ethiopia
Max	Maximum
Min	Minimum
MOH	Ministry of Health
NBE	National Bank of Ethiopia
NDL	National Drugs List of Ethiopia
NDP	National Drug Policy
NGO	Non-Governmental Organization
NHP	National Health Policy

ORS	Oral Rehydration Salt
PASS	Pharmaceutical Administration and Supply Service
PHARMID	Pharmaceuticals and Medical Supplies Service and Wholesale Share company
PHCF	Public Health Care Facility
PHCU	Primary Health Care Unit
PPD	Planning and Programming Department
PDRO	Private Drug Retail Outlet
RDS	Regional Drug Stores
RHB	Regional Health Bureau
SNNPR	Southern Nations, Nationalities, Peoples Region
STG	Standard Treatment Guideline
TGE	Transitional Government of Ethiopia
US\$	United States Dollar
WB	World Bank
WHO	World Health Organization

EXECUTIVE SUMMARY

The assessment of the pharmaceutical sector in Ethiopia was conducted from November – December 2002 G.C by PASS in collaboration with the World Health Organization Country Office. The assessment was mainly based on a cross-sectional survey carried out in five national regional states (Tigray, Amahra, Oromia, SNNPR, Benishangul–Gummuz) and Addis Ababa. It involved 7 hospitals, 19 health centers, 85 health stations, 5 regional drug stores of PHARMID, 24 private pharmacies/ drug shops and 490 households. This represents respective percentage sample sizes of 11.3%, 5.5%, 4.6% 71.4% and 5.4% of the hospitals, health centers, health stations, regional drug stores and private pharmacies/drug stores found in the surveyed regions.

The main objective of the study was to identify strengths and weaknesses in the pharmaceutical sector and give recommendations for improvement. Specifically, it was to see whether the target outcomes of the pharmaceutical sector (i.e. access, quality assurance and rational drug use) have been achieved and also determine whether Ethiopia has the necessary structures and mechanisms in place for improving its pharmaceutical sector.

The study has shown that the necessary structures and mechanisms required for the implementation of the NDP are more or less in place and a lot of achievements have been made. However, weaknesses in the implementation of the proclamation and some elements of the NDP were noted. For example, all manufacturers except one operate without having "certificate of competence" from DACA. Only drugs imported by the private sector are subjected to registration. The drug registration process is not linked to inspection of manufacturing sites abroad. The allocated drug budget was inadequate as revealed by a low per capita government drug budget of ETB 1.6(US\$ 0.18), which is much lower than the target set in HSDP I (US\$ 1.25) and the WHO's recommendation of US\$ 1.00. There is no proper stock management in health facilities as revealed by absence of stock control tools such as stock card in 60 % of the surveyed health facilities.

Moreover, there is no specific NDP implementation plan that sets responsibilities, budget and time line although some elements of the NDP are incorporated in HSDPI. Monitoring and evaluation of the NDP was not included as an element of the policy itself.

The results of the survey have also revealed the following short comings in relation to achievement of the major out come of the implementation of the policy:

Accessibility of drugs

The national average for availability of key essential drugs in health facilities was 70%, 85% and 91 % for public health facilities, regional drug stores and private drug retail outlets, respectively. The figures are lower than the ideal value of 100 % and the 100 % target set in HSDP I.

The affordability of adult and child preparations in public health care facilities was 135 % and 68 %, respectively. This means that approximately 1.4 days' and 0.7 days' salary of the lowest paid unskilled government employee is required to cover the cost of a single course of therapy of pneumonia in adult and children, respectively. On the other hand, affordability of adult and child preparations in private retail outlets was 195 % and 127 %, respectively and the same interpretation applies to this as well.

From the above data, we can conclude that drugs are less available but more affordable in public health facilities than in private drug retail outlets.

Average stock out durations in public health facilities and regional drug stores were 99.2 days, and 99 days, respectively. These figures are in stark contrast with the recommendation of zero stock out. Eighty-six percent of prescribed drugs are dispensed in public health facilities as compared with the ideal value of 100%.

It is obvious that all the above deviations from the standard norms have a cumulative negative impact on access to essential drugs.

Quality

On the average, the score for storage conditions were 6 and 8 on a scale of 0–11 in public health facilities and regional drug stores, respectively. These results are equivalent to an acceptable quality of drugs. However, the significant variations between health facilities and regions indicate the need for handling individual cases separately.

The national averages for presence of expired drugs in facilities were 8%, 2% and 3% in health facilities, regional drug stores and private drug retail outlets, respectively. Although the results are not alarming, the significant variation between health facilities and regions calls for precaution and further investigation.

In general, it is important to note that the factors investigated here are only indirect indicators of quality. It is difficult to make conclusion about the quality of drugs in the drug supply system since variables other than those investigated here also determine the quality of drugs.

Rational Drug Use

- The number of drugs prescribed per encounter was 1.9 and this is encouraging when compared with the ideal value of less than 2. However, the significant variations between health facilities and regions need careful investigation for future action.
- The percentage of antibiotic use was 58% and this is a bit high when compared with the ideal value of less than 20% and needs improvement.
- The percentage of injection use was 23% and this is an encouraging result when compared with the accepted norm of less than 15%.
- It was observed that on the average, 43% of drugs dispensed to patients in health facilities were inadequately labeled while the accepted norm is that 100% of them should have adequate label.
- The percentage of patients who knew how to take the drugs dispensed to them was 67% as compared with an ideal value of 100%.
- Only 39% of the health facilities surveyed had Standard Treatment Guidelines (STG) or list of essential drugs for the health facility or the region.

- Oral Rehydration Salt (ORS) was used in the treatment of uncomplicated diarrhea in children in 82% of cases as compared to an ideal value of 100%. Antibiotic and antidiarrhea/antispasmodic drugs use was 50% and 3%, respectively, compared to the ideal value of zero percent in both cases.
- Percentage use of antibiotics in the treatment of non-pneumonia Acute Respiratory Tract Infection (ARTI) was 61% compared to ideal value of zero percent.
- Percentage use of first line antibiotics in the treatment of mild/ moderate pneumonia was 54% compared with the recommendation of 100% use. Prevalence of use of more than one antibiotic in treating the same condition was 2% as compared to recommended value of zero percent.

Although some of the above values are close to the ideal values, most of them deviate from the ideal value and they require proper interventions as indicated in the recommendation section of this report.

Household Survey

The results show that the major health care providers (68%) were public health facilities. The percentage of people who did nothing about their illness (10%) was more than those who went to the private clinics (7%).

Public health facilities were the main sources of medicines (71%) followed by private pharmacies (18%) while the contribution of the informal sector as source of drugs was insignificant (< 1%). Forty-one percent of patients who could not get prescribed medicines mentioned the absence of medicine in public pharmacies as the main reason followed by lack of money (35%).

The level of compliance of patients to prescriptions was 91%, partial compliance 7% and absolute non-compliance 2%. The drug expenditure to income ratio has revealed that on the average 21% of estimated family weekly income or total weekly household expense is required to cover the cost of drugs to treat a single episode of illness.

Conclusion and recommendation

The study has shown both strengths and weaknesses in the pharmaceutical sector, which are related to policy/proclamation implementation and achievements of the target outcomes of the sector. To improve the situation, it is necessary to implement the interventions enumerated under the "recommendations" section of this report.

Chapter I: Introduction

1. Geographical and socio-demographic data

Ethiopia is located in the Eastern part of Africa, which is commonly known as the horn of Africa between 3 and 15 degrees north latitude and 33 and 48 degrees East longitude.

It has a surface area of 1.14 million square kilometers. With this area, Ethiopia stands as the fourth largest country in Africa. Ethiopia is bordered by the Sudan on the West, Somalia and Djibouti on the East, Eritrea on the North and Kenya on the South.

The population of Ethiopia was estimated to be 67.2 million in 2001/ 2002 G.C of which 85% live in rural area. The population growth rate is estimated at 2.64% (2002 G.C). The over all dependency ratio is 102% and average household size 4.8 (2001/ 2002 G.C). The total adult literacy was 36% (46%for males and 25% for females) (1).

Administratively, the Country is divided into nine National Regional States, namely, Tigray, Afar, Amhara, Oromia, Somali, Benishangul-Gumuz, Southern Nations, Nationalities and Peoples Region (SNNPR), Gambela, and Harari; and two administrative states (Addis Ababa City Administration and Dire Dawa

Council). The National Regional States as well as the Administrative States are further divided into 75 Zones, 551 Woredas (districts) and around 10,000 Kebeles. There are also 2 special Zones and 10 special Woredas (Annex I).

The economy is based on agriculture, and in 2002 this accounted for 52% of GDP, 85% exports and 80% of total employment. The contributions of other sectors to the GDP were industry (11%) and services (37%) (2).

In 2000, GDP was US\$ 6,304 million. In the same year, GNI (atlas method) was US\$ 6.7 billion representing a per capita of US\$ 100 while GNI (Purchasing power parity) was US\$ 42 billion representing purchasing power parity per capita of US\$ 660. Average annual percentage growth of GDP (1990–2000 G.C) was 4.6. (2).

2. The Health Sector

The health care delivery system is guided by a National Health Policy (NHP) which was issued in September 1993 and a Health Sector Development Program (HSDP) as of 1990 E. C. (1997/ 98 G. C.). The HSDP, which was designed for a period of 20 years with rolling five-year programs, has provided a long-term plan frame work for the health sector. The first phase of HSDP covered the period 1990 E. C. – 1994 E. C. (1997/98 – 2001/02 G.C.). The second phase (HSDPII) was started on July 2002 G.C and it covers a three year period, 1995 – 1997 E. C. (2002/03–2004/05 G.C) in order to synchronize it with the Five-year national development plan of the government. The HSDP has eight components one of which is *"Strengthening the Pharmaceutical Sector"*.

According 2001/ 2002 G.C estimate, 60 – 80% of the health problems of the country are due to infectious and communicable diseases and nutritional problem. Health service coverage was 51.8%, infant mortality rate 113 per 1000 live births, maternal mortality rate 871/100,000 live births, under 5 mortality rate of 188 per 1000 live births and life expectancy at birth of 53.4 years for males and 55.4 years for females.

In 2001/02, the health personnel to population ratio were 1:35,604 for physicians, 1:5,236 for nurses, 1:8249 for health assistants, and 1:569,661 for pharmacists and 1:84,767 for pharmacy technicians.

Total government health budget in 2001/ 2002 G.C was 1053.2 million ETB (US\$ 122.5 million) and of which 549.6 million ETB (US\$ 63.9 million) was recurrent budget. The per capita government recurrent health budget was 8.2 ETB (US\$ 0.95). (1).

The over all trend of government health budget allocation shows significant increase over 1985 EFY. (1993/ 94 G.C). (Table 1).

Table 1 Total health budget allocation before and 10 years after introduction of the NDP

EFY(G.C)	Recurrent health budget allocated	Per capita
	Million ETB(US\$)*	ETB(US\$)*
1985 (1992/93)	196.7 (39.3)	3.8 (0.76)
1994 (2001/2002)	549.6 (63.9)	8.18(0.95)
Change (%)	179 (62.6)	115(25)
Exchange rate	1US\$= ETB 5 (in 1985 E.C) and ETB= 8.6 (in 1994 E.C)	

Source: Health and health related indicators, PPD, MOH, 1992 E.C & 1994 E.C

* Author's conversion

The Ministry of Health is the major provider of health care followed by the private sector, Non-Governmental Organizations (NGOs) and other governmental organizations. The Federal Ministry of Health is the central body in charge of the health care system of the country. Each of the nine National Regional States and the two Administrative States has a Regional Health Bureau (RHB), Zonal Health Departments and District Health Offices.

However, as a result of the recent restructuring measures, the over all organization of the health services in each region or council is the responsibility of the Regional Health Bureau and the District Health Offices. Eventually, the Zonal health Departments are to be phased out

The actual delivery of health service is carried out by the different levels of health care facilities, which were structured in six-tier health care delivery system (Annex II).

The community health posts are the first contact points and act as bridge between the community and conventional health services. The health stations were the lowest level of the conventional health care system. In this organizational structure, each higher health care facility supports and serves as a referral health unit for the one below it.

The first phase of the Health Sector Development Program (HSDP I) had introduced a four-tier health service delivery system with primary health care units (PHCU) at the base followed by District Hospitals, Zonal Hospitals and Specialized Hospitals up the hierarchy in that order (Annex II). A PHCU consists of a health center and five satellite health posts. The health stations are to be either down graded to health posts or upgraded to health centers in course of time.

In 2001/ 2002 G.C, there were 155 hospitals, 412 health centers, 2,452 health stations, 1,311 health posts and 1,235 private clinics. Hospitals are further classified into three levels: specialized hospitals (5) zonal hospitals (40) and district hospitals (34) from higher to lower levels. In regard to training facilities, there are 5 universities which train different categories of mid-level to high level health personnel and other 22 training schools which also train low-level to mid-level health workers (1).

3. The Pharmaceutical Sector

Policy and regulation

The pharmaceutical sector is guided by a National Drug Policy (NDP), which was developed in 1993 G.C in line with the National Health Policy (3). There is no specific NDP implementation plan that set responsibilities, budget and timeline although some elements of the NDP are incorporated in the Health Sector Development Plan of the country.

The sector is regulated by the *"Drug Administration and Control Proclamation No. 176/199*, which was promulgated on 29 June 1999 G.C. This proclamation has superceded the former regulation called *"Pharmacy Regulation No. 288/ 1964"*, which formed the legal basis for official establishment of drug regulation in Ethiopia. *"The Pharmacy and Laboratory Department"* was the first drug regulatory body established under the Ministry of Health by the Pharmacy Regulation No. 288/ 1964. The department performed drug regulatory activities as well as the registration of pharmacy personnel.

Following the passage of proclamation No 176/ 1999, the pharmacy department was transformed to an independent drug control authority named *"Drug Administration and control Authority (DACA)"* which became operational on September 2001 G.C.

DACA inspects manufacturers, wholesalers, drug retail outlets as well as pharmacy units in health care facilities. It issues certificates of competence to private manufacturers, wholesalers and drug retail outlets while trade licenses are issued by the Ministry of Trade. DACA has different written guidelines and inspection check lists.

According to the above proclamation, DACA can establish its own branch offices in the regions. But, so far, no branch office is opened. Instead, the Regional Health Bureaus are delegated to undertake inspection and licensing of drug retail outlets.

Proclamation No. 176/ 1999 defines the objectives, powers and duties as well as organization of DACA. Products covered by the proclamation include human and veterinary drugs, traditional medicine, pesticides, animal food additives, poisons, blood and blood products, vaccines, sera, radio active pharmaceuticals, cosmetics, sanitary items, medical instruments and Medical supplies.

The proclamation has provisions for regulatory activities such as drug registration, inspection, quality control, post marketing surveillance, control of clinical trial, drug information and advertisement, packaging and

labeling of products. It also states the need for obtaining license for import, manufacture, wholesale and retail activity. But, it does not include requirements for obtaining such licenses. Regulations based on the proclamation have been drafted and submitted to the council of Ministers for approval.

The proclamation stipulates that any form of drug advertisement must be approved in advance by DACA. A drug information and Adverse Drug Reaction (ADR) monitoring unit has been established and ADR monitoring as well as dissemination of drug information to health professionals is recently initiated. Generic prescribing is advocated in both public and private sector but it is not obligatory. Generic substitution is also being practiced but has neither legal support nor prohibition.

Drug evaluation and registration system exists. The process involves assessment of the safety, efficacy and quality of products through clinical and Pharmaco-chemical data evaluation as well as laboratory quality control. Submission of WHO-type certificate is a requirement for products to be imported. There is a written guide line indicating the above and other requirements. However, the registration process is not linked to Good Manufacturing Practice (GMP) inspection of manufacturing plants.

According to article 16 of the proclamation, *"no drug, whether produced locally or imported, shall be put to use unless it is duly registered by the Authority"* (4). However, in practice, the registration focuses on products imported by the private sector. Locally manufactured products and those imported by the public sector are not subject to registration.

Delay in the registration process is a problem often mentioned by clients. The registration system is computerized and to date 3258 products are registered. But there is no list of registered products accessible to the public domain.

Quality assurance of pharmaceuticals

Following the promulgation of proclamation No. 176/1999, the old established drug quality control and toxicology laboratory was structured under DACA. It undertakes Physico-Chemical tests, Pyrogen tests, sterility test and toxicological tests. In 2001 G.C, a total of 294 samples were received by the laboratory: 2 taken from private pharmacies, 16 for public procurement, 31 for GMP inspection and 246 for registration purpose. 213 samples were tested the same year out of which 15 have failed the test.

Selection

There is a *"List of Drugs for Ethiopia (LIDE)"*, July 2002 G.C edition, and it is further classified by level of health care facility. The list consists of international non proprietary (generic) names of drugs that can be imported or locally produced and it is also the basis of drug registration (5).

A *National Essential Drugs list (EDL)* containing 234 chemical entities was prepared in 1987 G.C. as an extract from the LIDE which was called *"National Drugs List (NDL)"* at the time. But, the EDL has never been revised and published since then (6).

Import and distribution

Import and wholesale are done by the public sector, private sector, NGO's and international organizations.

The Pharmaceutical Administration and Supply Service (PASS) of the Ministry of Health and the Pharmaceutical and Medical Supply Import and Wholesale Share Company known as PHARMID (semi-governmental organization) are responsible for import and distribution to the public sector. PHARMID has eight wholesale distribution branches (2 in Addis Ababa and 6 in different regions). The public procurement is done through international and local tenders as well as by direct purchasing or negotiation. It is limited to the LIDE. Guideline on drug donation is prepared in the local language.

In the private sector, the total number of importers /wholesalers has increased from only 11 in 1993 G.C to 42 in 2002 G.C. Procurement in the private sector is done by direct order to manufacturers abroad and it is also limited to the LIDE.

The drug retail activity is done by the public sector, private sector, city councils, and the Red Cross society of Ethiopia. This sub-sector has also shown significant growth in number of outlets during the last decade. In 2000/ 2001 G.C, there were 311 pharmacies (run by pharmacy degree graduates), 249 drug shops (run by pharmacy diploma graduates or equivalent), and 1971 rural drug vendors (run by nurses or health assistants

or pharmacy technicians). Moreover, each health care facility has its own pharmacy unit / dispensary.

According to the Ministry of health, the potential coverage, defined as percentage of the population within 10 km of a health station (walking distance), is estimated at 51.2 % in 1993 E.C (2000/01 G.C). Indirectly, this shows that the percentage of the population which has *geographical access* to essential medicines is more than 51.2 %. (7)

Production

In 1993 G.C, there was only one local pharmaceutical manufacturing plant and it was owned by the government. Currently, drug production activity is being under taken by 13 local pharmaceutical manufacturing plants: One government owned, eleven private (unaffiliated with multinationals) and one private (affiliated with multinationals). Three of the factories are engaged in medical supplies production, one on empty gelatin capsule production and nine on finished product formulation using imported raw materials. However, only one of them has a certificate of competence from DACA.

There is no price control on pharmaceuticals. Both finished products and raw materials are subject to taxation, except anti retro viral drugs.

Drug financing

Sources of drug financing include government finance, private expenditure (i.e. user charges or out of pocket payments), external assistance, loan, and private health insurance. There are no updated figures on the contribution of each source although the National Health Accounts exercise in 1995/ 96 indicated that the private expenditure on drugs accounts for the largest share of the total estimated drug expenditure in the country.

In 2001/ 02 G.C, the total government drug budget was about 104 million ETB (US\$ 12.1 million) which is approximately 19% the recurrent government health budget and represents a per capita drug budget of ETB 1.6(US\$ 0.18). This is very low as compared with the target set in HSDP I (US\$ 1.25) and WHO's recommendation of US\$ 1.00 (8).

According to PASS, the total drug expenditure* of the Ministry of Health in 2002 G.C. was estimated at ETB 257.9 million (USD 30 million) representing a per capita drug expenditure of ETB 3.8 (US\$ 0.44). No reliable data is available on the drug expenditure of the private sector and other sectors. According to the National Bank of Ethiopia (9), the total value of import of "*medical and pharmaceuticals*" in 2001/02 G.C was ETB 421.3 million (US\$ 49 million). However, this category includes non-drug items as well and the value for drugs alone is lower than this figure.

* Includes: Regular MOH's drug budget of 104 million ETB, Loan 47.7 million ETB, and donation of 106.2 million ETB.

The government owned health facilities provide free health care including drugs to poor patients upon submission of letters from local administration offices. Anti-TB drugs are also provided free of charge to all patients.

Rational Drug use

The Ministry of Health has prepared Standard Treatment Guidelines (STG) for six types of diseases and has distributed them to health care facilities. A national formulary based on the LIDE (2001G.C) is under preparation by DACA.

The concept of essential drugs is part of the basic curricula of pharmacists and pharmacy technicians. Public education on rational use of drugs is being given by DACA through the mass media. There is no mandated continuing education program for health professionals, except that pharmacy and medical associations occasionally organize continuing education programs for their members.

Chapter II: Over all context of the study

1. The Problem

The national drug policy of Ethiopia has been in implementation over the last nine years. However, formal monitoring and evaluation of the implementation has not been undertaken in a comprehensive manner.

Previous studies conducted at different times focused either on specific issues or were limited in scope and size making national and international comparison difficult. This study aims at bridging this gap.

2. General objectives

To identify strengths and weakness in the pharmaceutical sector and give recommendations for future improvement

3. Specific Objectives

- To assess whether Ethiopia has the necessary structures and mechanisms in place for improving its pharmaceutical sector
- To examine the processes of implementing the pharmaceutical strategies
- To determine whether the target outcomes of the pharmaceutical sector (i.e. access, rational drug use and quality assurance) have been achieved
- To contribute to the international efforts to identify and examine trends of the global forces which affect the pharmaceutical sector.

4. Study design and Methodology

4.1 Sampling unit and sample size

The survey was carried out on 7 hospitals, 19 health centers, 85 health stations, 5 Regional Drug Stores (RDSs) owned by PHARMID, 12 private Pharmacies and 12 private drug shops collectively referred to as Private Drug Retail Outlets (PDROs), 5 special pharmacies and 490 house holds. This represents 11.3%, 5.5%, 4.6% 71.4%, 5.2% and 5.7% of the hospitals, health centers, health stations, regional drug stores, private pharmacies and private drug stores found in the surveyed regions in 1993 E.C(2000/2001G.C).

All the hospitals, health centers and health stations are owned by the Ministry of Health. Hereafter, they are collectively referred to as Public Health care Facilities (PHCFs).

These facilities were distributed in the six survey regions, namely, Tigray, Amhara, Oromia, SNNPR, Benishangul–Gumuz and Addis Ababa (the capital city). The summery of their distribution in the six survey regions is shown in annex III & IV.

4.2. Sampling Procedure

The five survey regions were randomly selected from 9 National Regional States in the country and the capital city–Addis Ababa was included according to the recommendation of the standard procedure.

The list of all PHCFs and PDROs in the survey regions was prepared and the required samples were selected using the lottery method. One RDS was taken from each survey region, except Benishangul–Gumuz region, which didn't have any RDS. Approximately 5 households were randomly selected in the vicinity of each PHCF surveyed.

4.3. Survey Instruments

Data on existing infrastructure and key processes in each component of the pharmaceutical sector were collected at a national level using WHO's standard questionnaire for level I indicators (Annex VII) and the salient points of the findings are summarized in the introduction section (see *'the pharmaceutical sector'*).

In order to gather systematic data on the degree of attainment of the NDP objectives: **access, rational drug use and quality of drugs**, a cross–sectional baseline survey was undertaken using WHO's standard survey formats for **outcome** (level II) indicators. A house hold survey was also carried out using a structured questionnaire. (Annex VIII).

4.4. Data collection and Co–ordination of the survey

Six data collection teams were formed (i.e. one team per survey region) and each team was composed of one medical doctor and one pharmacist officially assigned by the health bureaus in the survey regions.

The heads of the pharmacy teams in the health bureaus of the survey regions served as Supervisors. The over all activity was centrally coordinated by the head of the Pharmaceutical Administration and Supply Service (PASS) of the Ministry of Health and the National Professional Officer for Essential Drugs and Medicines policy(EDM) in the WHO country office.

Before the survey was started, the data collectors, supervisors and heads of health service & training departments in the health bureaus of the six regions were trained for four days (8–11 October 2002 G.C) in Addis Ababa. At the end of the training, field–testing of the survey tools was done. Two consultants sent from WHO Headquarter participated in the training as facilitators. The cross–sectional baseline survey was then conducted between November– December 2002 G.C and data collected from each region (each data collection form signed by the head of the facility surveyed and bearing the seal of the facility) were assembled and sent to the centre by each regional health bureau.

4.5. Data Management

Data collected from all the survey regions using the standard data collection forms were coded, checked for accuracy, consistency, omissions and irregularities. They were then entered into Microsoft excel 2002 and summarized using the standard summary forms.

All the required statistical analysis was done using excel 2002, except Analysis of Variance (ANOVA) which was done using Epi.Info version 6.

4.6. Scope and Limitation of the Data

The indicators used in the survey do not measure all aspects of the pharmaceutical sector. Moreover, most of the estimates are based on a one point in time observation.

Therefore, the results of the study must be understood as first–line indicators for further questioning and subsequent action (10).

Chapter III: Findings and interpretations of the results

1. Accessibility of key essential drugs

Access to essential drugs is a prerequisite for delivery of proper health care. The data on access, which were generated during the survey, are summarized in table 2 below and discussion on each access component follows.

Table 2 Summary of National indicators on access

Indicator	Public Health Care Facilities (PHCFs)		Regional Drug Stores (RDSs)		Private Drug Retail outlets (PDROs)	
	Mean	Median	Mean	Median	Mean	Median
Percentage availability	69.83 (n=111)	75	85 (n=5)	83	90.96 (n=24)	92
Affordability (adult)	135% (n=76)	141			195% (n=24)	188
Affordability (Children)	67.69% (n=96)	71.5			127% (n=24)	119
Average stock out duration (days)	99.22 (n=45)	91	99 (n=3)	103		
Percentage of prescribed drugs dispensed	85.48 (n=105)	94				

1.1. Availability of key essential drugs

To measure the physical availability of essential drugs, 12 key essential drugs, which are used to treat the most common health problems in the country, were selected at a national level (Annex IV). In order to collect the required data on physical availability of these drugs, a prospective survey was undertaken in Public Health Care Facilities, Regional Drug Stores and private drug retail outlets using standard survey forms. The essential drugs, which were physically available in the facilities, were identified and recorded in the format. The percentage availability of key drugs was calculated using the standard formula and the following results were obtained:

Table 2 above shows that the national average availability of key drugs was 70% in PHCFs (Min 0, Max 100), 85% in RDSs (Min 75, Max 92) and 91% in PDROs (Min 75, Max 100). The availability in PHCFs is lower than the ideal value (100%) and the 100% target set in HSDP I (11, 12). It is also lower than that of PDROs (Figure 1) with significant mean variation ($P < 0.05$).

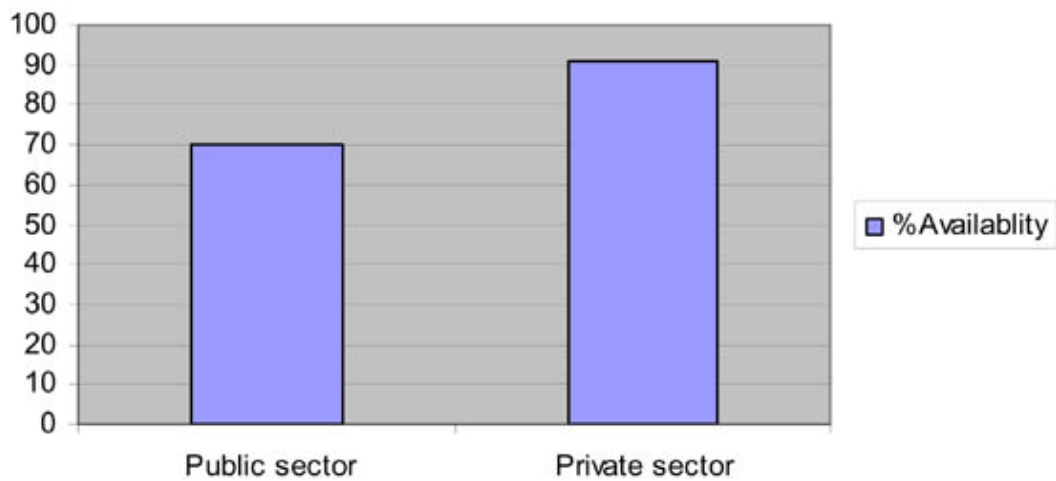


Figure 1 Availability of key essential drugs in the public and private sectors

Average availability of key essential drugs in PHCFs in the six regions (Figure 2) varied between 65 % (Amhara region) and 90% (Tigray region) showing relatively highest availability of essential drugs in Tigray region and lowest availability in Amhara region. However, the mean variations for both adult and children products were found to be insignificant ($P > 0.05$).

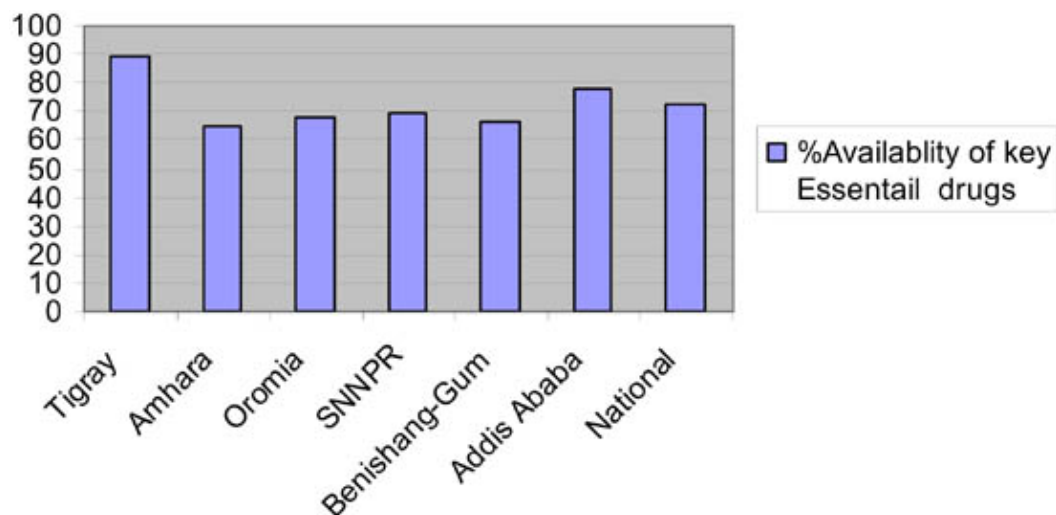


Figure 2 Availability of key essential drugs in PHCFs in six regions

The three levels of PHCFs were also compared (Figure 3) and average availability was found to be 88.3%, 76.8% and 66.7% in hospitals ($n=7$), health centers ($n=19$) and Health stations ($n=58$), respectively. But, the mean variation was insignificant ($P > 0.05$). The result indicates comparatively highest availability of essential drugs in hospitals but lowest availability in health stations.

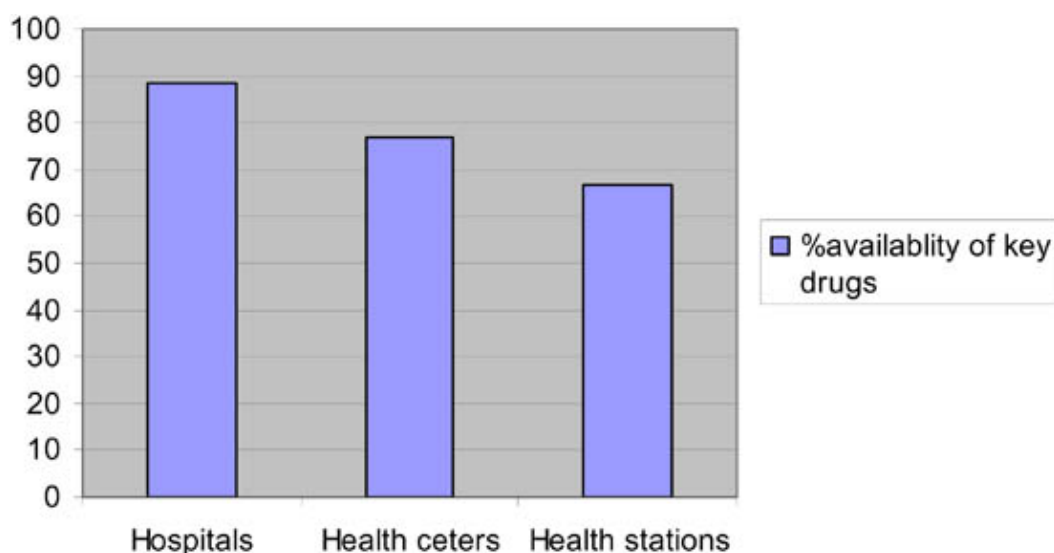


Figure 3 Availability of key essential drugs by level of PHCFs

Availability of the key essential drugs in the PDROs of the six regions varied between 83% (Addis Ababa) and 94.1% (Benishangul–Gumuz) with insignificant mean variation ($P > 0.05$).

1.2. Stock out duration

To measure the historical availability of key essential drugs to treat common health problems, a retrospective survey was undertaken by reviewing the stock cards of the facilities covering a period of 6–12 months. The number of days for which key essential drugs were not available (when the stock was zero) within the review period were recorded in the standard survey format. The average stock out duration was then calculated at each facility level, at regional and national level using the standard formula.

From table 2, the national average stock out duration in PHCFs ($n=45$) was 99.2 days (Min 0, Max 335). In the RDSs ($n=3$), it was 99 days (Min 81, Max 113.42). The above significant stock out duration compared with the objective norm of no stock out duration shows either inadequate finance and/or poor drug supply management.

Average stock out durations by level of health care facilities (Figure 4) were 22.3 days, 58.7 days and 121 days in hospitals ($n=3$), health centers ($n=11$) and health stations ($n=31$), respectively. The mean variation was also significant ($P < 0.05$).

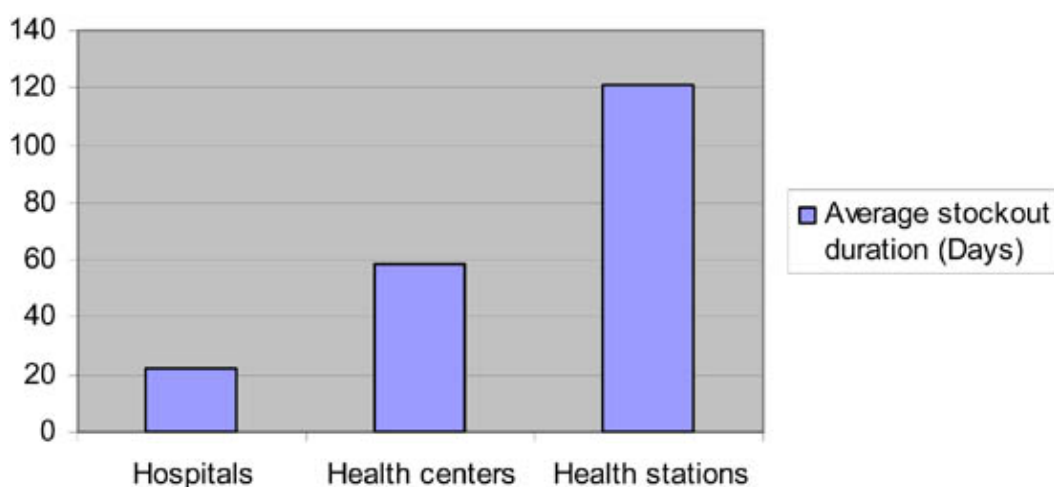


Figure 4 Key essential drugs stock out by level of PHCFs

On the other hand, average stock out durations in PHCFs varied in the four regions (Figure 5) between 49.7 days (SNNPR) and 139 days (Benishangul Gumuz) showing significant mean variation.

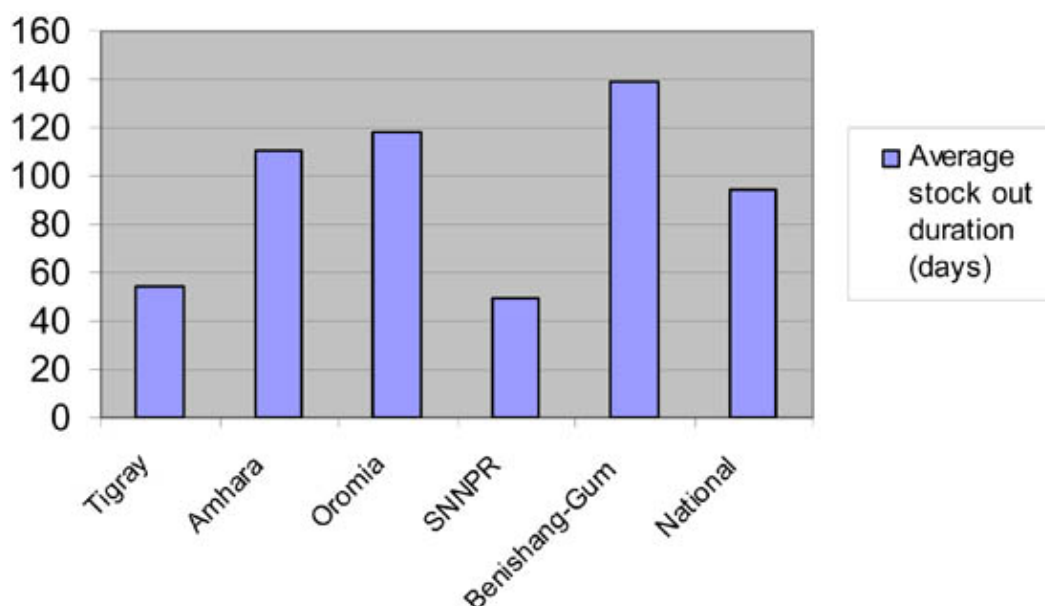


Figure 5 Key essential drugs stock out in PHCFs in five regions

1.3. Percentage of Prescribed drugs dispensed to patients

To measure the degree to which the facility is able to provide the prescribed drugs, exit interview was undertaken in PHCFs. Thirty out patients leaving the dispensing unit of each facility on the day of the survey were interviewed. Data collectors also checked the number of drugs dispensed to each patient out of the total prescribed drugs. Then, the percentages of drugs dispensed were calculated at facility level, regional level and national level using the standard formula. The results obtained are indicated below:

Table 2 above shows that the percentage of prescribed drugs that were dispensed in PHCFs was 85.5% and when compared with an ideal value of 100%, it shows lower ability of PHCFs to provide essential drugs. However, it is not different from situations in other developing countries (12).

The percentage of prescribed drugs dispensed varied in the six regions (Figure 6) between 63% (Addis Ababa) to 98.4% (Benishangul–Gumuz) showing relatively highest availability of prescribed drugs in Benishangul–Gumuz but lowest availability in Addis Ababa. The mean variation was also significant ($P < 0.05$).

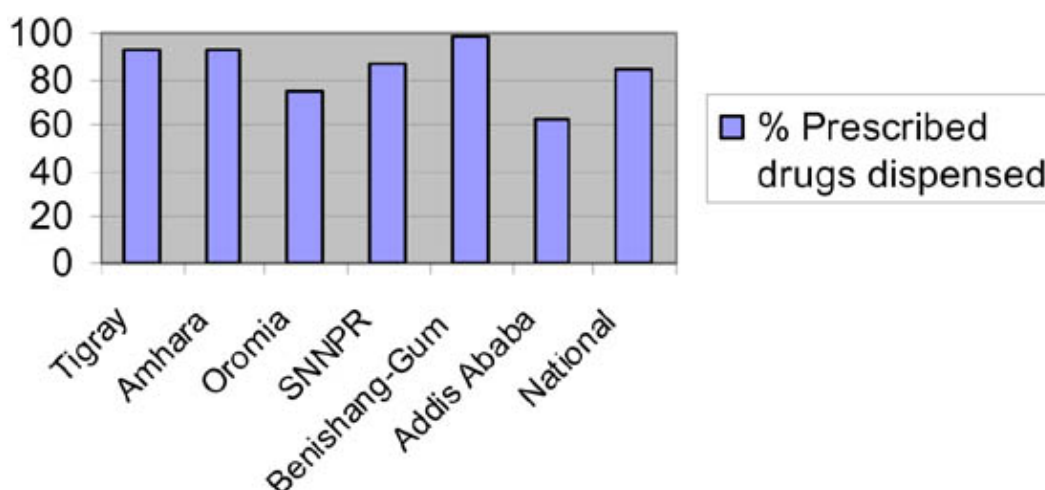


Figure 6 Extent of dispensing of prescribed drugs in PHCFs in six regions

The three levels of health care facilities were also compared (Figure 7) and the figures were 82.9%, 81.3% and 86.7% in hospitals ($n=7$), health centers ($n=19$) and health stations ($n=79$), respectively. But the variations were not significant ($P > 0.05$). In relative terms, health stations have shown the best ability to provide prescribed drugs while the health centers had the least ability

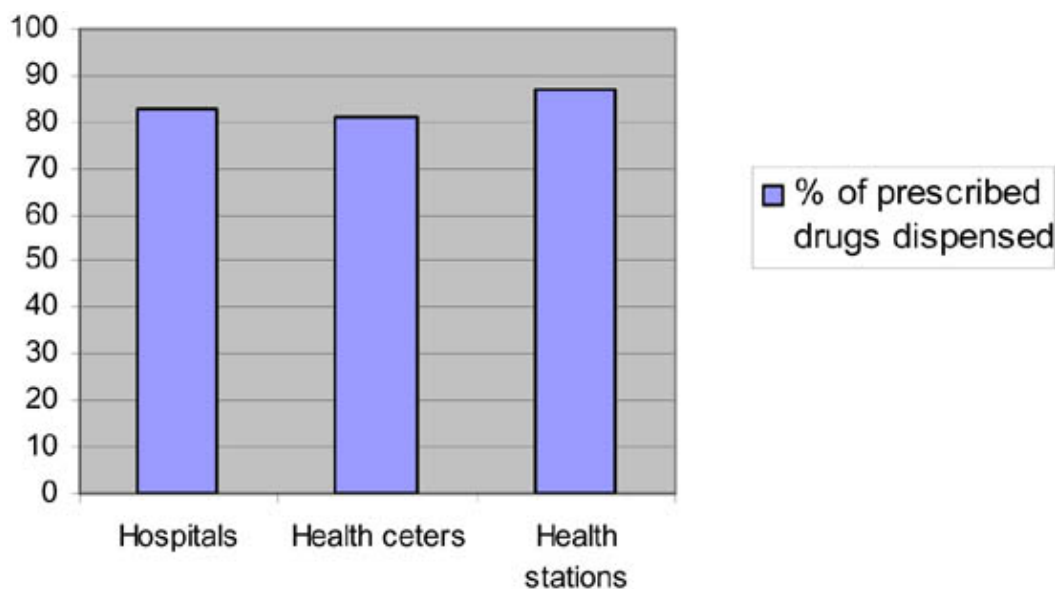


Figure 7 Extent of dispensing of prescribed drugs by level of PHCFs

1.4. Affordability of key essential drugs

The purpose of this indicator is to measure affordability of basic drug treatment as an indicator of access to essential drugs.

In this study, the affordability of treating moderate pneumonia (without hospitalization) in both adults and children is assessed by comparing the total cost of a full course of therapy with the lowest daily government salary (approx. 6.7 ETB or US\$ 0.8). More formally, affordability is expressed as the ratio of the cost of treating moderate pneumonia to the lowest daily salary of unskilled government worker. Amoxicillin 250mg or 500 mg capsules and Cotrimoxazole (200+40) mg/5ml oral suspension were chosen as drugs of choice for pneumonia in adult and children, respectively. The treatment cost as % of the lowest daily salary of an unskilled government employee is calculated at facility level (both public and private), at regional and national level.

In PHCFs, the national average for affordability of treatment cost was 135% for adults and 67.7% for children (Table 2). These figures show that approximately 1.4 days' and 0.7 days' wage of the lowest paid unskilled government worker are required to cover the cost of a single course of therapy of pneumonia in adults and children, respectively.

In the PDROs, affordability for adult was 195% while for children it was 127% (Table 2). Comparison of affordability (both for adult and child) between the public sector and private sector (Figure 8) shows that treatment costs are more affordable in the public sector than the private sector. The mean variation was also insignificant ($P > 0.05$).

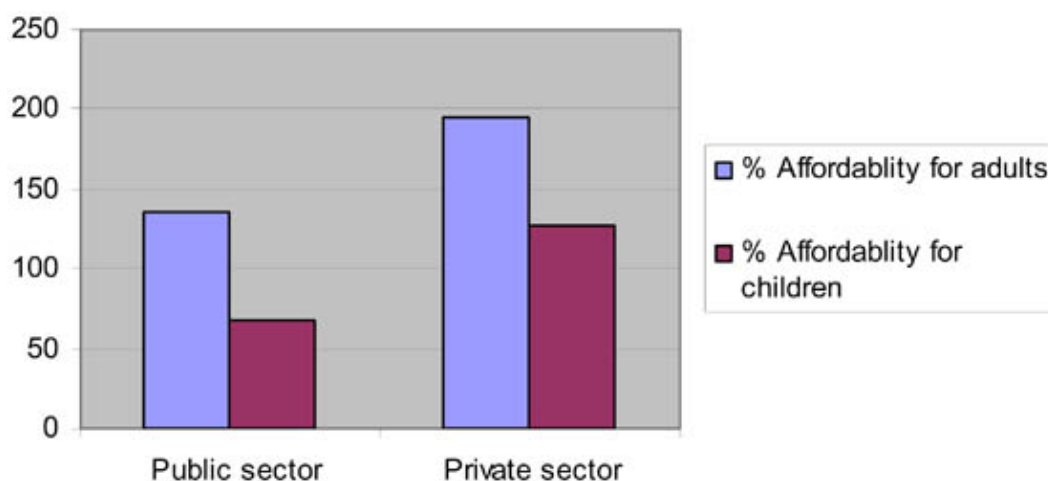


Figure 8 Affordability of key essential drugs in public and private sectors

Affordability for adult in PHCFs varied in the six regions (Figure 9) between 97% (Tigray) to 158% (SNNPR) while affordability for children varied between 33% (Tigray) to 99% (Benishangul–Gumuz). In both cases, treatment costs are lowest in Tigray. The overall mean variation between the regions was significant ($P < 0.05$).

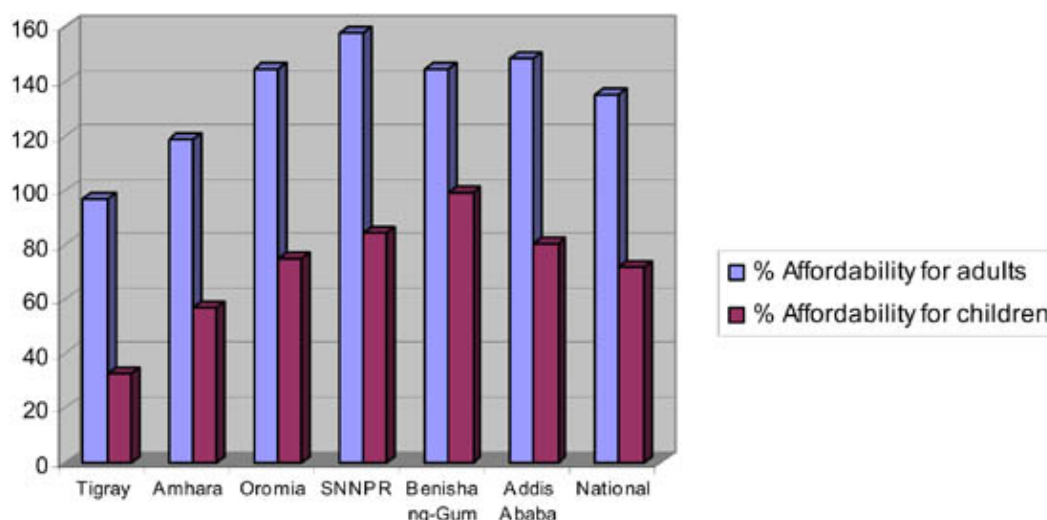


Figure 9 Affordability of key essential drugs in PHCFs in six regions

When considered by level of health care facilities, affordability for adult were 133%, 143.8% and 132.2% for hospitals ($n=7$), health centers ($n=18$) and health stations ($n=51$), respectively. This shows that adult treatment costs are best affordable in health stations but least affordable in health centers. On the other hand, affordability for children were 84.7%, 60.9% and 68.1% in hospitals ($n=6$), health centers ($n=19$) and health stations ($n=71$), respectively. It indicates that pediatric preparations are best affordable in health centers but least affordable in hospitals (Figure 10).

But, the mean variations in both cases (adult & children) were not significant ($P > 0.05$). It is also interesting to note that in all cases, irrespective of the sector and the level of health care facilities; pediatric preparations were relatively more affordable than adult preparations.

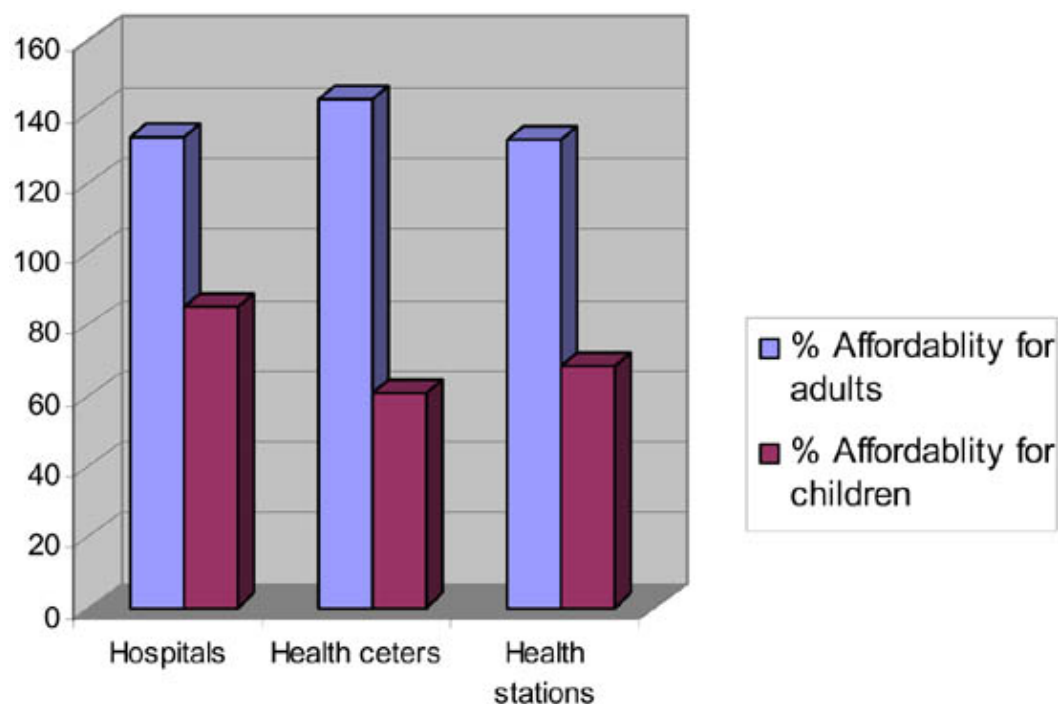


Figure 10 Affordability of key essential drugs by level of PHCFs

2. Quality

2.1. Adequacy of drug storage

The purpose of this indicator is to determine the status of essential drugs storage in public health care facilities and regional drug stores as one factor that affects drug quality.

The following eleven conditions were taken as ideal drug storage conditions:

- Availability of functional locks
- Cleanliness (absence of litter and dust)
- Absence of signs of pests
- Roof ceiling
- Availability of windows which can be opened or presence of Vents
- Protections from direct sunlight
- Freedom from moisture and absence of stocks on the floor
- Separation of storage and dispensing area
- Drugs placed/sorted in a systematic way
- Availability of stock record system
- Availability of cold storage with temperature chart.

The storage condition in both the drug store and dispensing unit/area were assessed against these criteria using a check list and rated according to the following scores:

Table 3 Storage condition rating

Storage condition	Rating	Equivalent rating for quality of drugs
Poor	0–3	Quality may be poor
Not adequate	4–5	Quality may be adequate
Moderately adequate	6–7	Acceptable quality
Adequate	8–10	Acceptable quality
More than adequate	11	Good quality

The average scores of the two compartments were taken as the total score for over all storage condition in each facility. Regional and national scores were also calculated by aggregating the scores of the facilities. The national data thus generated are summarized below:

Table 4 Summary of national indicators on quality

Indicators	PHCFs		RDSs		PDROs	
	Mean	Median	Mean	Median	Mean	Median
Storage condition rates (on a scale of 0–11 scores)	5.98 (n=111)	6	8 (n=5)	8		
Percentage of expired drugs	8.24 (n=111)	0	2 (n=3)	0	3 (n=24)	0

From Table 4 above, we can see that the overall facility storage scores for PHCFs was 6 (Min 3, Max 10) meaning a moderately adequate storage condition indicating acceptable quality of drugs. However, it was lower than the storage condition in RDSs, which had a score of 8 (min 5, Max 11) showing a relatively lower quality of drugs.

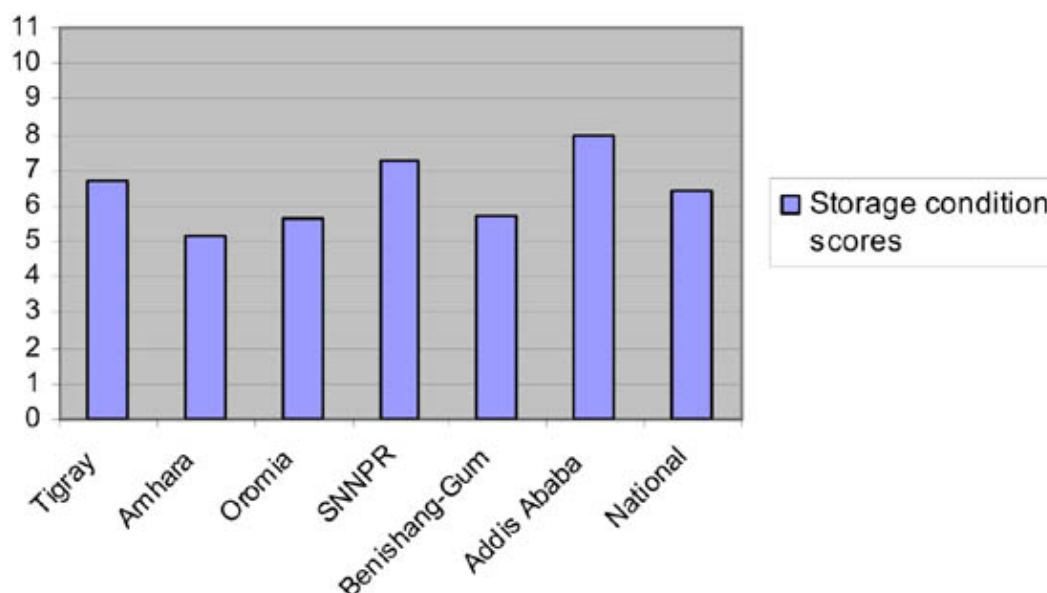


Figure 11 Storage Condition in PHCFs in six regions

Storage conditions varied in the six regions (Figure 11) between 5 (in Amhara region) to 8 (in Addis Ababa) showing significant mean variation ($P < 0.05$). In equivalent terms, the quality of drugs range from probable adequacy in Amhara region to acceptable quality in Addis Ababa.

Comparison of storage condition by level of health facilities also revealed that the scores for hospitals ($n=7$), health centers ($n=19$) and health stations ($n=85$) were 7.4, 7.5 and 5.5, respectively (Figure 12) showing significant mean variation ($P < 0.05$).

It shows that quality of drugs is least in health stations but best in health centers. However, it is important to note that the quality of all drugs at all levels is "acceptable".

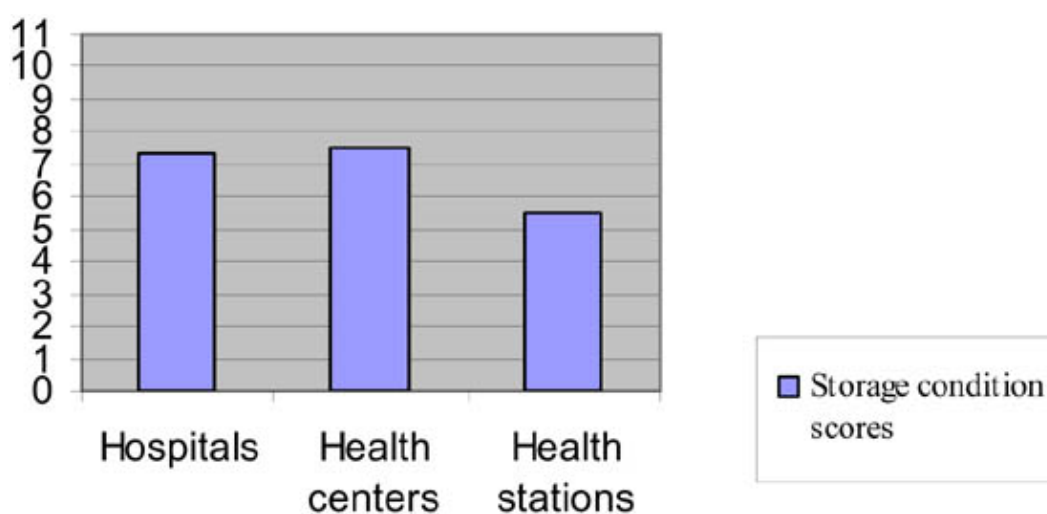


Figure 12 Storage condition by level of PHCFs

2.2. Presence of expired drugs at facility level

The Purpose of this indicator is to determine if expired drugs are being distributed or sold as one indicator of quality of drugs. The actual process involved checking the expiry dates of the 12 selected key essential drugs available in health facilities, regional drug stores or private retail outlets. Percentage of expired drugs was then calculated at facility level, regional level and national level.

Table 4 above shows that the national percentages of expired drugs were 8.2% in PHCFs (min 0, Max 67), 2% in RDSs (Min 0, Max 8), and 3% in PDROs (Min 0, Max 25). In relative terms, the quality of drugs appears to be best in RDSs and least in PHCFs.

The percentage of expired drugs varied in the six regions (Figure 13) between 3% (in Tigray) to 38% (in Benishangul–Gumuz) showing very significant mean variation ($P < 0.05$).

This means that, in relative terms, quality of drugs is best in Tigray but least in Benishangul–Gumuz.

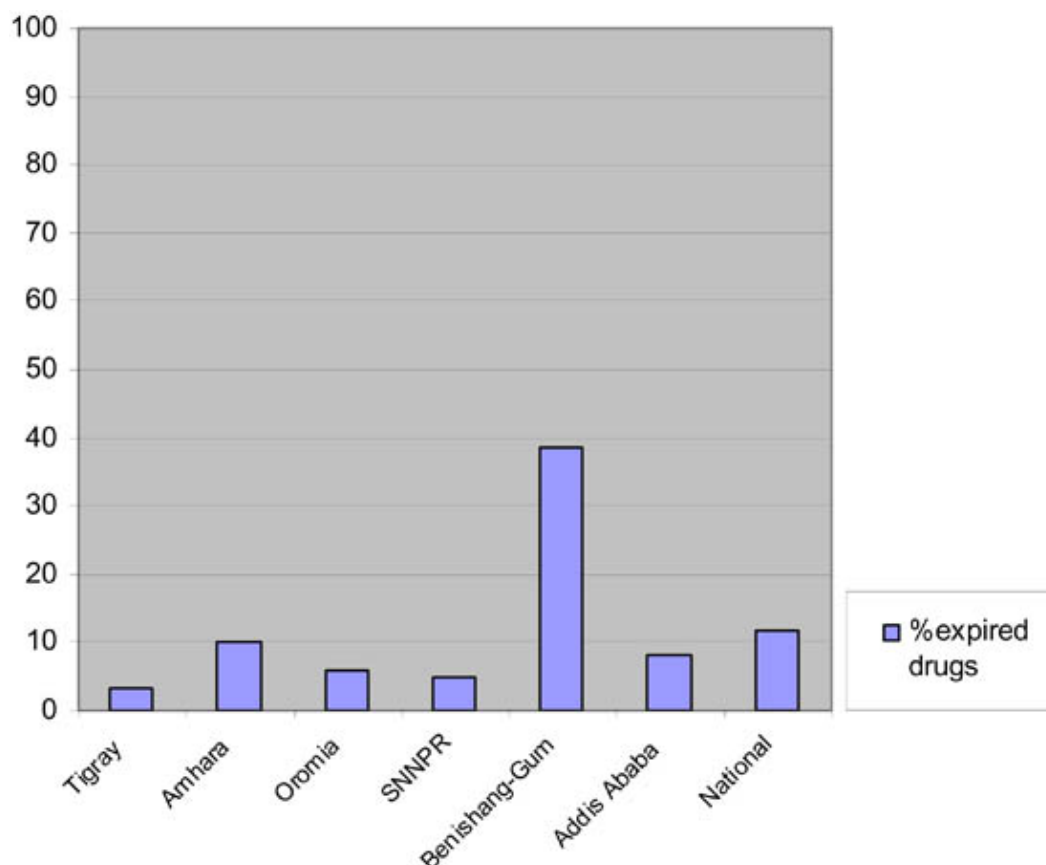


Figure 13 Magnitude of expiry of key essential drugs in PHCFs in six regions

When compared by level of health facilities, percentages of expired drugs were 13.1, 9.7 and 7.5 in hospitals ($n=7$), health centers ($n=19$) and health stations ($n=85$), respectively (Figure 14). But the mean variation was insignificant ($P > 0.05$). The figures show that quality of drugs is relatively best in health stations but least in hospitals.

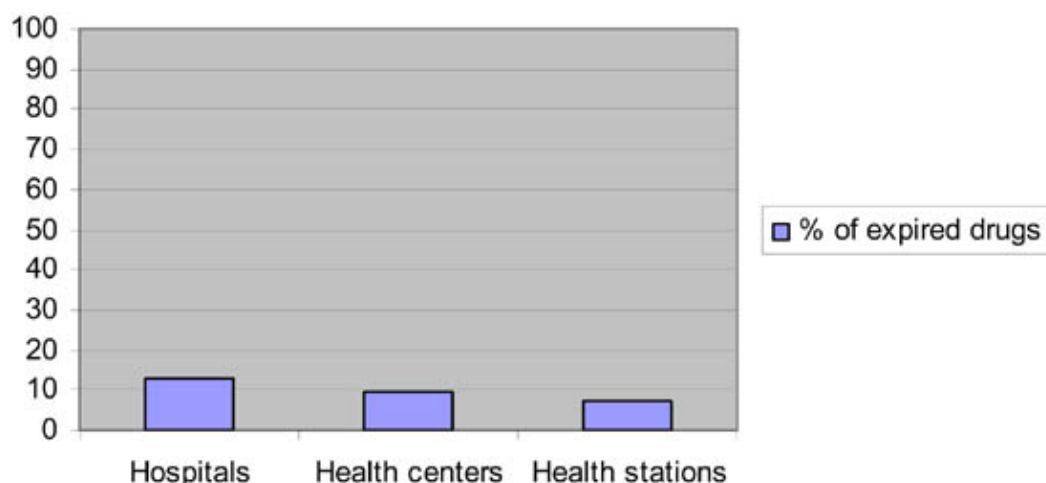


Figure 14 Magnitude of expiry of key essential drugs by level of PHCFs

3. Rational Drug Use

To assess the drug use situation in Public Health Care Facilities, the records of 30 general outpatients seen within the last 6–12 months in each health facility were selected following a standard selection procedure and

the following common drug use indicators were calculated (Table 5).

Table 5 Summary of national indicators on rational drug use in PHCFs

Indicators	Therapy	Mean	Median	Min	Max
Treatment of diarrhea (watery, non bloody) in children	Percentage of ORS use	81.87 (n=107)	90	10	100
	Percentage of antibiotic use	49.63 (n=107)	50	0	100
	Percentage of anti-diarrhea and/or antispasmodic drugs use	2.55 (n=102)	0	0	40
Treatment of Non-pneumonia ARTI	Percentage of antibiotic use	60.69 (n=106)	70	0	100
Treatment of mild/moderate pneumonia	Percentage of use of any one of the first line antibiotics (procaine penicillin injection, Amoxicillin, Cotrimoxazole)	54.1 (n=106)	50	0	100
	Percentage of use of more than one antibiotic	2.36 (n=106)	0	0	30
Average number of drugs per encounter		1.99 (n=111)	1.97	0.8	3.33
Percentage of antibiotic(s) per encounter		58 (n=111)	57	3	100
Percentage of injection(s) per encounter		26.98 (n=111)	23	0	90
Percentage of drugs adequately labeled		42.66 (n=105)	46	0	100
Percentage of patient with adequate knowledge		67.36 (n=106)	70	0	100
Percentage availability of STG		39 (n=108)	0	0	1
Percentage availability of regional or facility EDL in the facility		1< (n=105)	0	0	1

3.1. Average number of drugs prescribed per encounter

In order to determine the prevalence of poly pharmacy, which is one measure of unnecessary prescribing, the number of drugs prescribed for each case was counted and the average number of drugs per encounter at facility level, regional level and national level calculated. In this process, a drug given in different forms (e.g. paracetamol tablet/syrup) or two names (brand/generic) of the same chemical entity, and combinations were counted as one.

The national average number of drugs prescribed per encounter was approx. 2.0 (Min 0.8, Max 3) and this shows acceptable prescribing practice when compared with the ideal maximum value of 2 (12).

Similar studies conducted in 1991/92 (13) and in 1997 (14) have reported 1.82 and 2.1 drugs per encounter, respectively.

The current figure shows a slight decline from the former result but an improvement over the later finding.

Average numbers of drugs per encounter by level of health facility were 1.7, 2 and 2 for hospitals (n=7), health centers (n=19) and health stations (n=85) showing a better prescribing behavior in hospitals as compared with health centers and health stations, which have equal standing.

On the other hand, average numbers of drugs per encounter varied in the six study regions between 1.6 (Addis Ababa) and 2.3 (Benishangul Gumuz) showing significant mean variation ($P<0.05$). The figures show that prescribing behavior is relatively best in Addis Ababa but least in Benishangul–Gumuz.

3.2. Percentage of antibiotic use

Drugs belonging to the following categories in the 4th edition of the Lists of Drugs for Ethiopia (July 2002) were considered as antibiotic: Penicillins (AI 101), Other anti bacterials (AI 102), Topical anti infectives that are similar to the drugs in the previous two groups (DE100), and ophthalmic anti bacterials (OP300).

To determine the prevalence of antibiotic prescribing (over prescribing of antibiotics is one common type of inappropriate use), the number of cases for which antibiotics were prescribed was counted and the percentage of antibiotics prescribed was calculated at facility level, regional level and national level. In this process, a case with one or more antibiotics order was counted as one.

The national average for percentage of antibiotic per encounter was 58% (Min 3, Max 100) with a very wide range of 97.

Previous studies conducted in 1991/92 and 1997 (13, 14) have found 58.34% and 53.60%, respectively, which are similar to the current study result.

By level health facility, the average percentage antibiotic use was 55.43%, 62.26% and 57.26% for hospitals (N=7), health centers (n=19) and health stations (n=85), respectively. The mean variation was insignificant ($P>0.05$). (Figure 15)

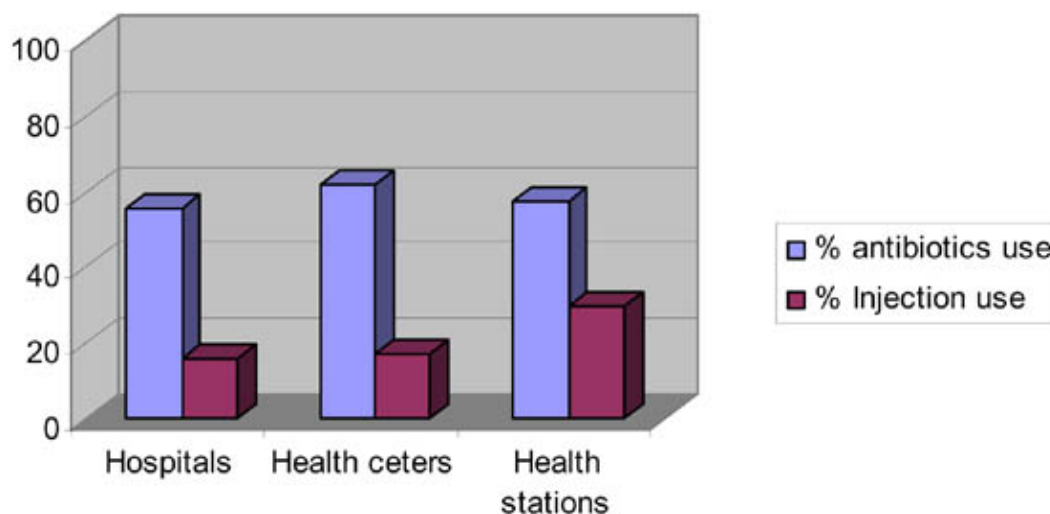


Figure 15 Prevalence of antibiotic and injection use by level of PHCFs

The figures imply a relatively best prescribing behavior in hospitals but least in health centers.

The average percentage antibiotic use also varied in the six regions (Figure 16) between 44.2% (Benishangul–Gumuz) to 87.7% (Addis Ababa) showing significant mean variation ($P<0.05$). The results indicate relatively best prescribing behavior in Benishangul–Gumuz but least in Addis Ababa.

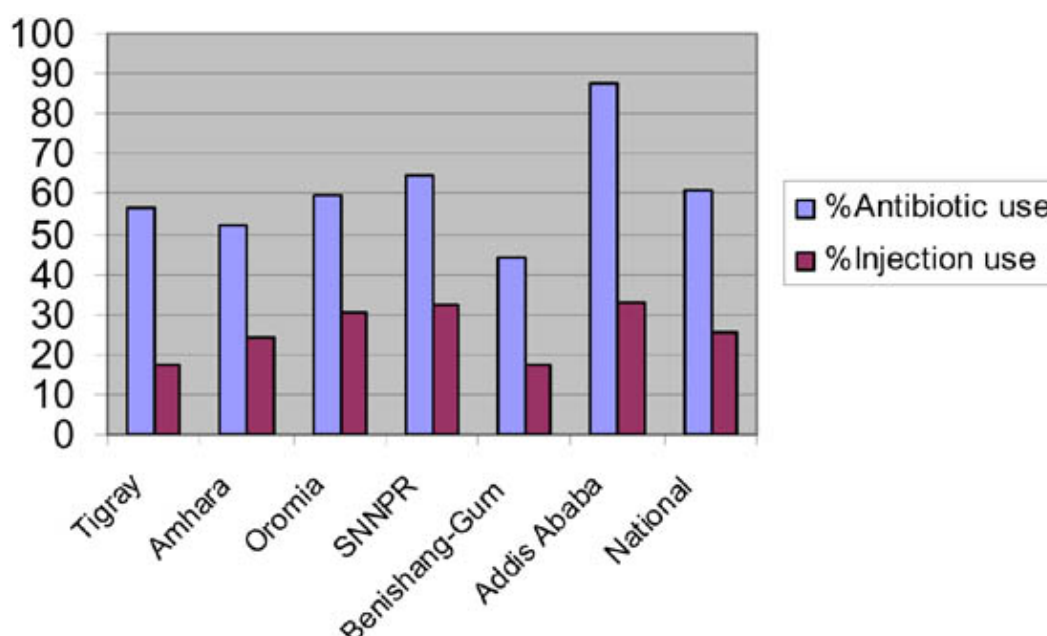


Figure 16 Prevalence of antibiotic & injection use in PHCFs in six regions

3.3. Percentage of injection use

To determine prevalence of injection use, the number of encounters in which one or more injections is prescribed was counted (excluding immunizations and injectable contraceptives) and the percentage use of injections calculated at facility level, regional level and national level.

The national average for percentage of injections per encounter was 23% (Min 0, Max 90) with a very wide range of 90. However, it is very close to the ideal maximum value of 20% showing nearly acceptable prescribing behavior. Moreover, it shows an improvement over the result of previous studies conducted in 1991/92 (12) and 1997 (13), which reported 39.43% and 31.06% respectively.

By level of health facility, the average percentages of injections per encounter were 15.9%, 17% and 30.1% in hospitals (n=7), health centers (n=19) and health stations (n=85), respectively (Figure 15). The mean variation was significant ($P < 0.05$). From these figures, we can deduce that, in relative terms, hospitals have the best prescribing practice followed by health centers.

Average percentage of injections per encounter varied in the six regions (Figure 16) between 17.5% (Tigray) to 32.7% (Addis Ababa) but the mean variation was insignificant ($P > 0.05$). The figures indicate relatively best prescribing practice in Tigray but least in Addis Ababa.

3.4. Percentage of prescribed drugs included in the EDL

Ethiopia does not have current national EDL. Therefore, it was not possible to measure the degree to which prescribing practices conform to the national EDL.

3.5. Adequacy of Labeling of drugs

A national consensus was reached that "**adequate label**" means a label bearing the **name, strength, quantity, dosage and duration of treatment** of the drug dispensed.

Adequacy of labeling was assessed by checking the labels of drugs dispensed to 30 outpatients in the health facility on the day of the survey. A label would be considered adequate if it conforms to all the above requirements. The percentage of drugs adequately labeled was then calculated at facility level, regional and national level.

The national average for percentage of drugs adequately labelled was 42.7% (Min 0, Max 100) with a very wide range of 100. The figure shows significant deviation from the ideal value of 100%

Average percentages of drugs adequately labeled by level of health facilities were 59.7%, 53% and 38.7% for hospitals (n=7) health centers (n=19) and health stations (n=79), respectively (Figure 17). However, the mean variation was not significant ($P>0.05$). The figures show that hospitals and health centers have better performance than the national average. The labeling practice is also least in health stations but best in hospitals.

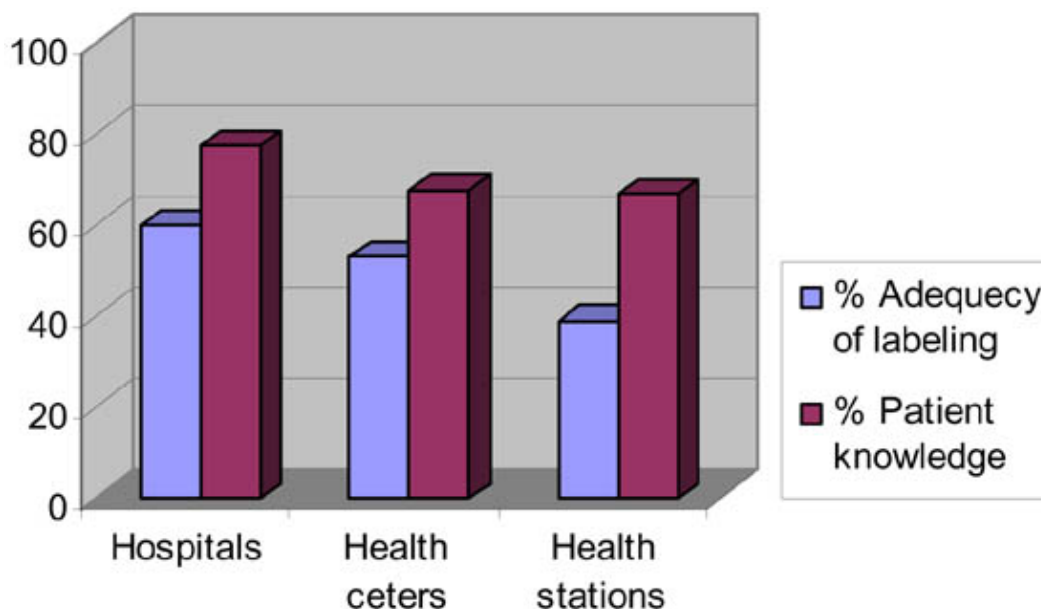


Figure 17 Adequacy of labeling & patient knowledge by level of PHCFs

On the other hand, the average for percentage of drugs adequately labeled varied in the six regions (Figure 18) between 12.4% (Benishangul –Gummuz) and 89.3% (Addis Ababa) showing extremely significant variation ($P<<<0.05$). From the above, we can deduce that PHCFs in Benishangul–Gumuz have least labeling practice but best in PHCFs of Addis Ababa.

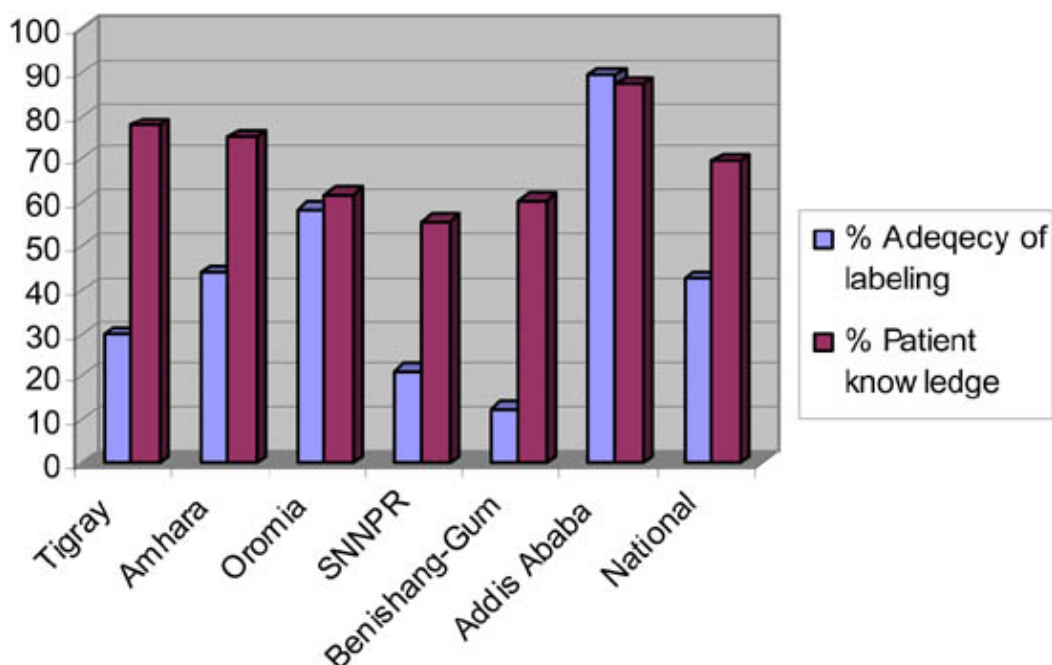


Figure 18 Adequacy of labeling and patient knowledge in six regions

3.6. Patient Knowledge

To assess if patients have adequate knowledge on how to take the drugs dispensed to them, 30 outpatients leaving the dispensing unit of each facility on the day of the survey were interviewed. Knowledge about the drug constitutes ability to tell *dose, frequency of administration and length of therapy fully*. Then, the percentage of patients who had adequate knowledge was calculated at facility level, regional level and national level.

The national average for percentage of patients who had adequate knowledge about the drugs dispensed to them was 67.4% (Min 0, Max 100) and it was much lower than the expected ideal value of 100%.

By level of health facilities (Figure 17), the average percentages were 77.1%, 67.6% and 66.4% for hospitals (n=7), health centers (n=19) and health stations (n=79), respectively. But, the mean variation was insignificant ($P>0.05$).

3.7. Availability of STGs/EDLs in health facilities

The Ministry of Health has prepared and distributed Standard Treatment Guidelines (STGs) for six disease conditions, namely, Tuberculosis/Leprosy, Sexually Transmitted Diseases, Malaria, Acute Respiratory Tract Infection (ARTI), diarrhoeal diseases, and opportunistic infections related to HIV/AIDS. Out of these, availability of treatment guidelines for Malaria (adults), Tuberculosis (adults) and Integrated Management of Childhood Illness (IMCI) was selected as criteria of assessment due to report of their wider distribution. Moreover, availability of regional and facility EDL was also taken as additional criteria of assessment. A facility would be considered to have STGs and EDLs if any of the STGs or EDLs mentioned above was physically available.

The survey revealed that only nearly 39% of the 108 health facilities surveyed had one or more of the STGs. It shows that majority of the health personnel are working without any standard guideline giving a way to irrational drug use.

When considered by level of health facilities (Figure 19), 67% of the hospitals (n=6), 50% of the health centres (n=18) and 35% of the health stations (n=84) had at least one of the STGs showing significant percentage variation ($P<0.05$).

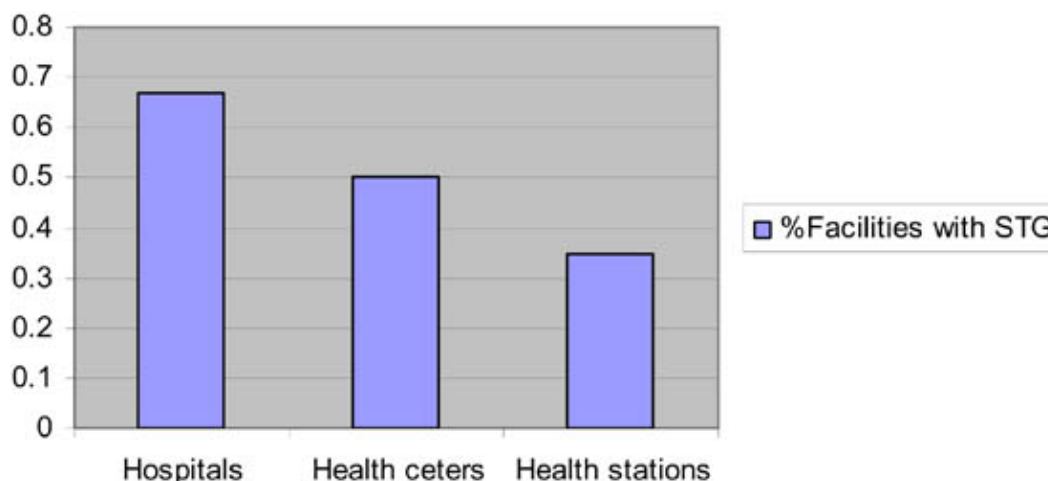


Figure 19 Availability of Standard Treatment Guidelines by level of PHCFs

The percentage availability of STGs varied in the five regions (Figure 20) between 3% (Oromia) to 75% (Tigray) reflecting very significant percentage variation ($P<0.05$).

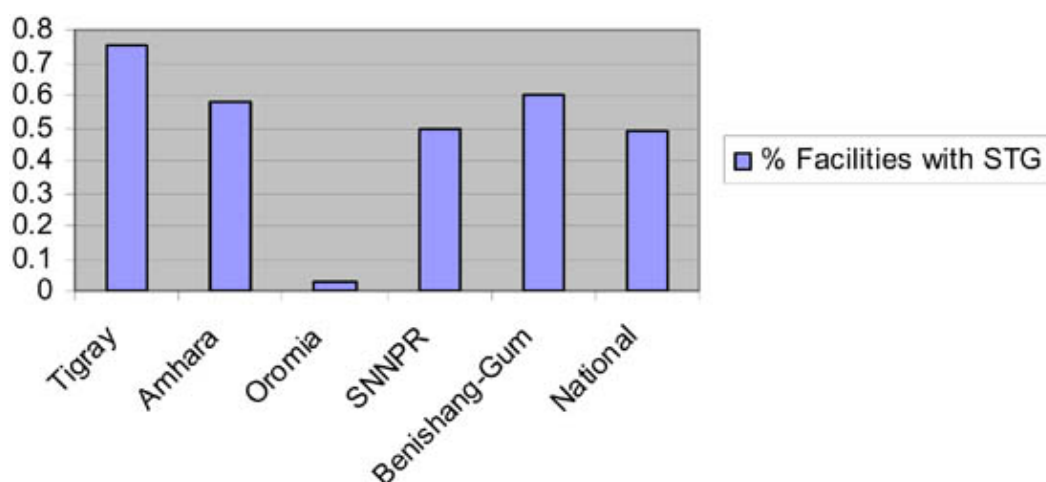


Figure 20 Availability Standard Treatment Guidelines in PHCFs in five regions

On the other hand, it was learnt that only one health facility had facility EDL out of the 108 facilities surveyed and this would have a negative impact on the selection of essential drugs in the health facilities.

3.8. Assessment of Treatment Practices

To measure the quality of care for common disease conditions with clear standard treatment guidelines, the utilization of STGs in health facilities was assessed by checking whether the chosen tracer diseases had been treated according to the treatment schedules recommended in the STGs.

For this purpose, three disease conditions, namely, diarrhoeal disease in children (watery, non-bloody), non-pneumonia Acute Respiratory Tract Infection (ARTI) and mild/moderate pneumonia were chosen. *The recommended treatments are: ORS for watery, non-bloody diarrhea; non – use of antibiotic for non-pneumonia ARTI and use of any of the first line antibiotics for Mild/Moderate pneumonia (Procaine Penicillin, Amoxicillin or Cotrimoxazole).* The records of 30 out-patients (10 patients for each disease) treated in the facility were selected randomly from the records of the day prior to the survey; when the number of cases was insufficient, by going back one day at a time until 10 cases were found for each disease condition. The records of the thirty patients were examined to determine if the treatments complied with their respective recommendations in the STGs. Then, the percentage of cases treated according to STGs was calculated at facility level, regional level and national level.

3.8.1 Treatment of diarrhea (non-bloody, watery) in children

Prevalence of ORS use

The national average for percentage of ORS use in 107 health facilities was 81.9% (Min 10, Max 90) and it is close to the ideal value of 100%.

By level of health facilities (Figure 21), the percentages of ORS use were 68.6% for hospitals (n=7), 72.1% for health centers (n=19) and 85.3% for health stations (n=81) showing significant mean variation ($P < 0.05$).

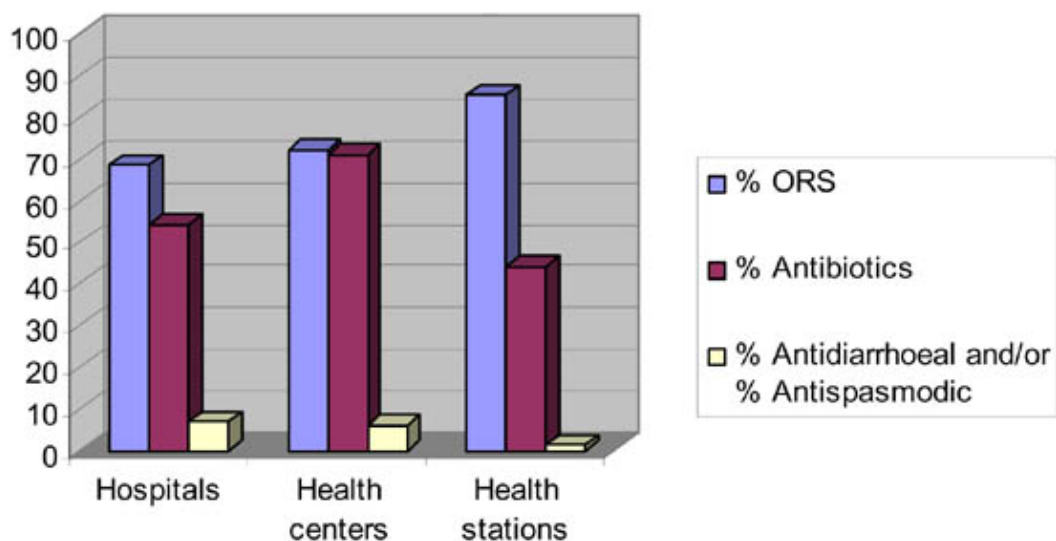


Figure 21 Pattern of treatment of uncomplicated diarrhoea by level of PHCFs

According to the above figures, health stations have shown better compliance to STG followed by health centres.

It also varied in the six regions (Figure 22) between 66% (Benishangul– Gumuz) and 85% (SNNPR) with insignificant mean variation ($P>0.05$).

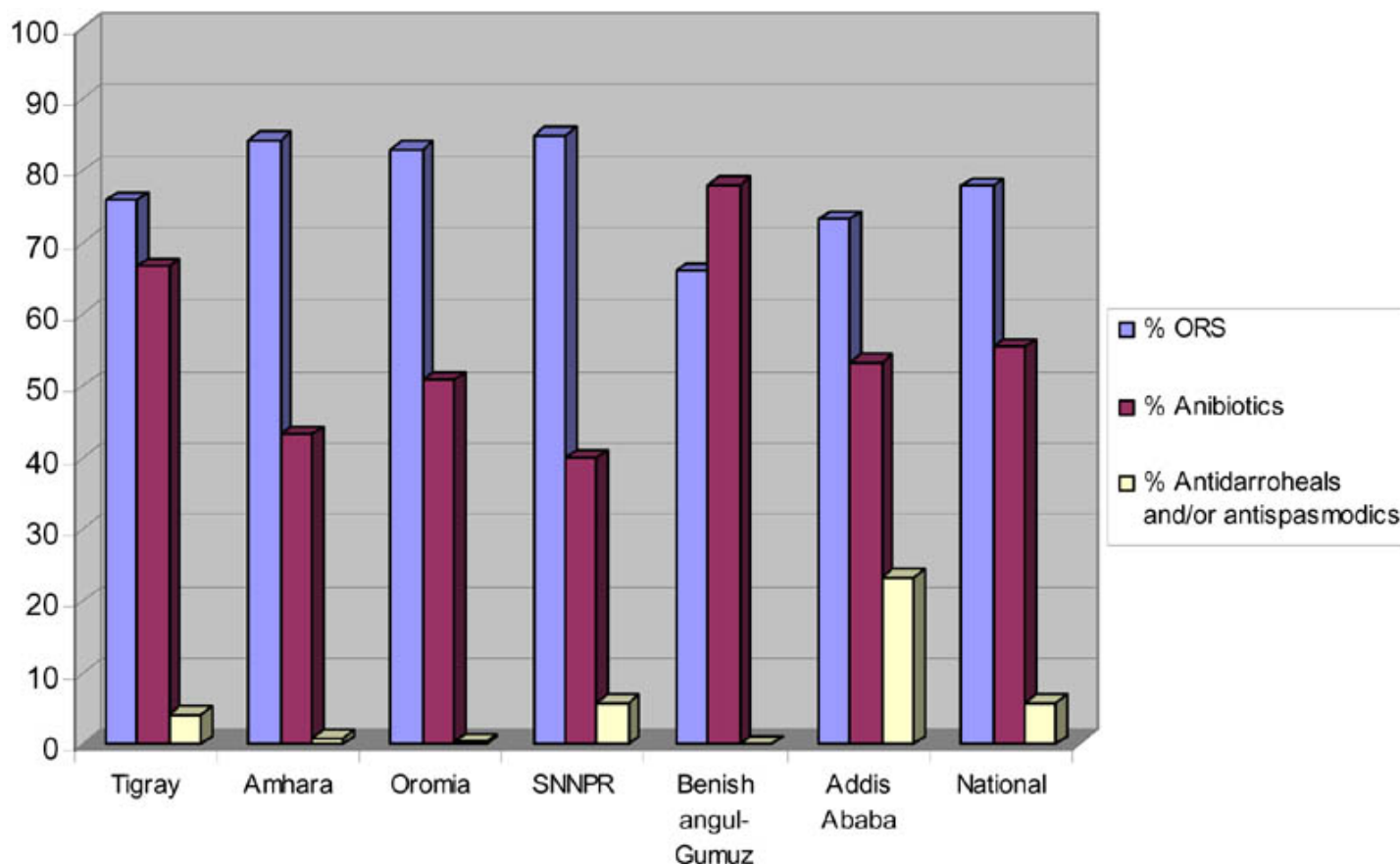


Figure 22 Pattern of treatment of uncomplicated diarrhoea in children in six regions

Prevalence of use of antibiotic

The national average for percentage of antibiotic use in 107 health facilities was 49.6% (Min 0, Max, 100). This is a bad practice since the norm is not to use any antibiotic in watery, non–bloody diarrhea.

When seen by level of health facilities, it was 54.3% for hospitals (n=7), 71.1% for health centers (n=19) and 44.2% for health stations (n=81) showing significant

mean variation ($P < 0.05$). Even though all practices deviate significantly from the STG, in relative terms, health stations have shown better compliance followed by hospitals (Figure 21).

The percentage varied in the six regions (Figure 22) between 40% (SNNPR) to 78% (Benishangul Gumuz) with insignificant mean variation ($P > 0.05$).

Prevalence of use of anti-diarrhea and or anti-spasmodic drugs

The national average for percentage of this mode of treatment in 102 health facilities was 2.6% (Min 0, Max 40) and this is not very far from the ideal value of zero use.

By level of health facilities, the percentages were 7.1% for hospitals (n=7), 6.1% for health centers (n=18) and 1.3% for health stations (n=77) with significant mean variation ($P < 0.05$). In relative terms, health stations have shown the best compliance followed by health centers.

Across the six regions, it varied (Figure 23) between 0% (Benishangul-Gumuz) to 23.3% (Addis Ababa). The situation in Addis Ababa needs further investigation.

3.8.2 Treatment of non-pneumonia ARTI

The national average percentage use of antibiotic in 106 health facilities was 60.7% (Min 0, Max 100) and this is a significant deviation from the STGs.

By level of health facilities (Figure 23), the percentages were 55.7% for hospitals (n=7), 66.8% for health centers (n=19) and 58.9% for health stations (n=80). But the mean variation was insignificant ($P > 0.05$).

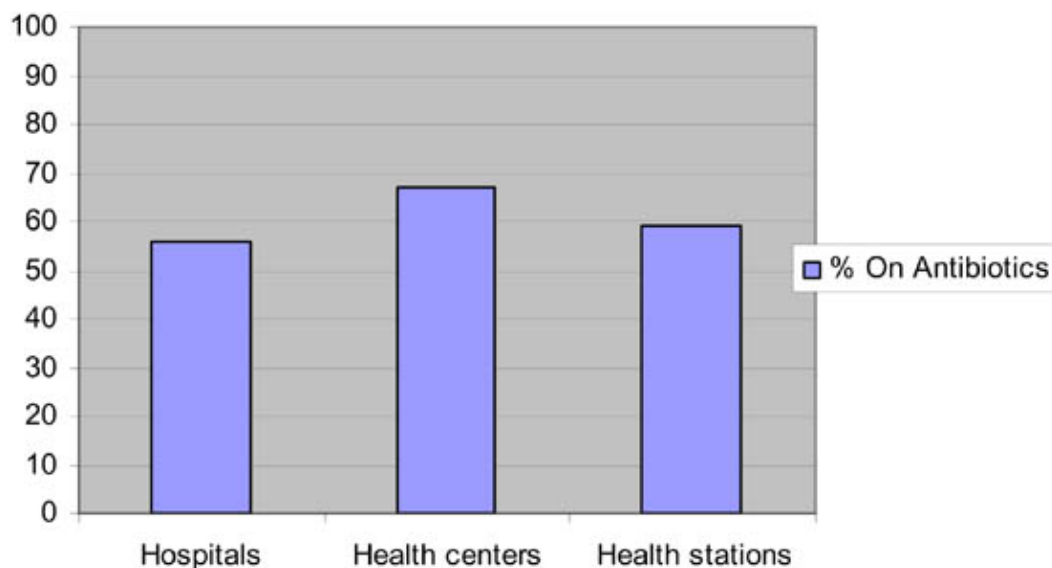


Figure 23 Prevalence of antibiotic use in the treatment of Non-Pneumonia ARTI by level of PHCFs

The percentage varied in the six regions (Figure 24) between 33.9% (Amhara) and 80% (Benishangul-Gumuz) showing better compliance with STGs in the Amhara region and least compliance in Benishangul-Gumuz region. The mean variation was also significant ($P < 0.05$).

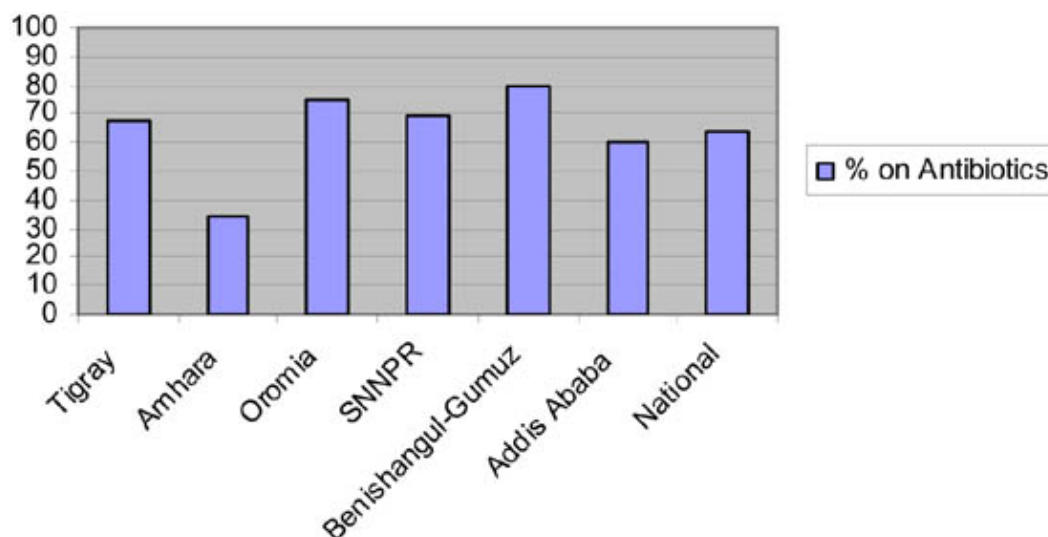


Figure 24 Prevalence of antibiotic use in the treatment of non-pneumonia ARTI in six regions

3.8.3 Treatment of Mild/Moderate pneumonia

Prevalence of use of first-line antibiotics

The study has shown that the national average percentage use of any of the first line antibiotics was 54.1% (n=106) with a minimum of 0% and maximum of 100% showing a wide range of 100. The practice is unsatisfactory as compared with the recommendations in the STG.

At the level of health facilities, the percentage was 53.3% for hospitals (n=6), 57.4% for health centers (n=19) and 53.4% for health stations (n=81) with insignificant mean variation ($P>0.05$) (Figure 25).

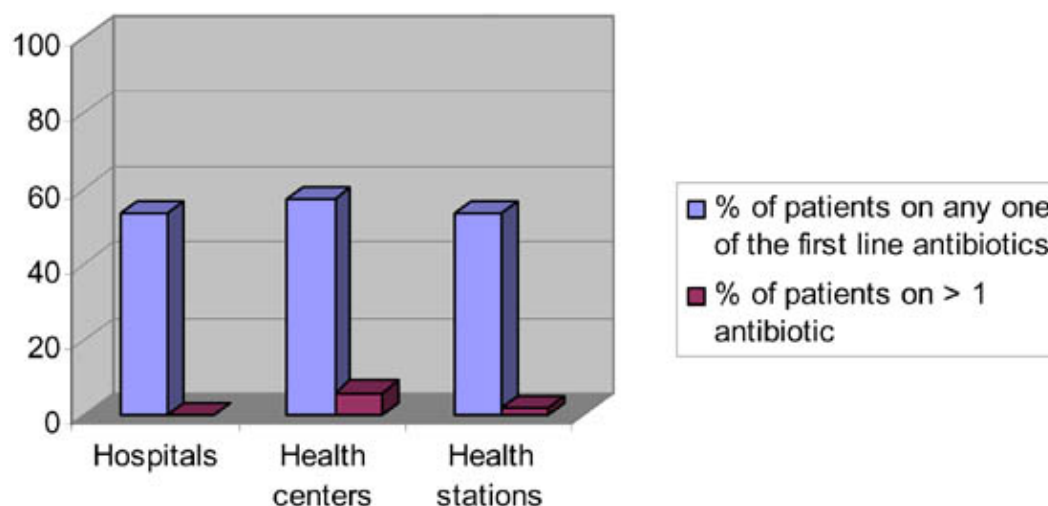


Figure 25 Pattern of treatment of Mild to Moderate pneumonia by level of PHCFs

The percentage varied in the six regions (Figure 26) between 28% (Amhara) and 99.1% (Oromia) showing extremely significant mean variation ($P<<<0.05$). In relative terms, Oromia has shown the best compliance to STG and Amhara region the least compliance.

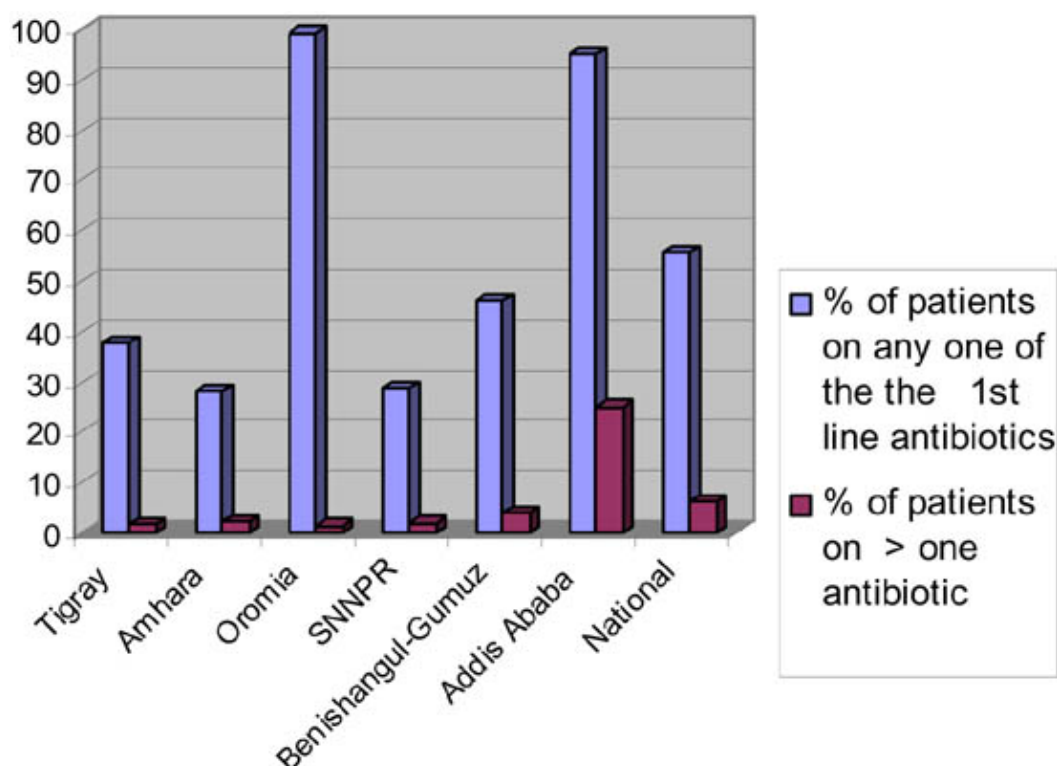


Figure 26 Pattern of treatment of Mild to Moderate pneumonia

Prevalence of use of more than one antibiotics

At the national level, the percentage of use of more than one antibiotic in the treatment of Mild/moderate pneumonia was 2.4% (n=106) with a maximum of 30% and minimum of 0%. The results show a very good overall compliance to STG and needs to be maintained, if not improved.

By level of health facilities, the percentages were 0% for hospital (n=6), 5.8% for health centers (n=19) and 1.7% for health stations (n=81) with insignificant mean variation ($P < 0.05$).

In relative terms, hospitals have shown absolute compliance with the STG followed by health stations (Figure 25).

The percentages varied in the six regions (Figure 26) between 1.5% (Oromia) and 25% (Addis Ababa). The results in Oromia are very encouraging while the situation in Addis Ababa needs further investigation

4. House Hold Survey

In order to assess the provision and use of drugs in the community, 490 households (approximately 5 households per health facility) were surveyed; out of which only 383 households reported that at least one member of the household was sick (excluding hospital admission) in the last two weeks before the day of the survey. Only one illness episode was considered per household. When the sick person was a child, the parents or caretakers were interviewed using a structured questionnaire (Annex IX).

4.1. Demographic Characteristics

The demographic characteristics of the people interviewed are shown in the table below:

Table 6 Age and Sex distribution of respondents (n=371)

Characteristic	Number	Percent
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Age:		
< 1 year	14	3.71
1–5 year	66	17.79
6–15 Year	57	15.36
16–54 Year	210	56.6
55+ Year	24	6.47
Sex:		
Female	188	50.67
Male	183	49.33

Majority of the respondents (50.7%) were females while the 16–15 yr age group represented the largest percentage (56.6%) of the respondents.

4.2. Disease Symptoms

The pattern of disease symptoms experienced by the respondents (Table 7) shows that most of them (40.7%) had symptoms other than diarrhea, cough or fever. Fever was the next common symptoms (30%) followed by cough (18.2%) and diarrhea (11.1%).

Table 7 Disease Symptoms (n=560)

Symptom	Number	Percent
Diarrhea	62	11.02
Cough	102	18.21
Fever	168	30
Other	228	40.71

4.3. Types of Consultations

A closer look into the types of consultations, which the patients have opted for (Table 8) shows that majority of them (68.2%) had consulted public health facilities, followed by people who did nothing (10.1%) about their illness. Private health care facilities were the third sources of consultation (7.3%).

Table 8 Types of Consultations (n=368)

Type	Number	Percent
Consulted traditional healer	11	2.99
Consulted public health clinic/hospital	251	68.21
Consulted private health clinic/hospital	27	7.34
Consulted pharmacist	2	0.54
Consulted drug seller	18	4.89
Sought advice from friend/neighbor/family	4	1.09
Bought medicine without consultation	14	3.80
Used medicine without consultation	4	1.09

Did nothing	37	10.05
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4.4. Extent of Drug therapy

The outcomes of the consultations (Table 9) revealed that medicines were prescribed for majority of the respondents (98.4%).

Table 9 Outcomes of consultations (n=317)

Outcome	Number	Percent
Medicines prescribed	312	98.42
No Medicines prescribed	5	1.58

4.5. Extent of dispensing of prescribed Medicines

Table 10 shows that all the prescribed drugs were dispensed to most of the patients with prescriptions (94.9%) indicating a very good availability of the required drugs.

Table 10 Extent of dispensing of prescribed medicines (n=315)

Variables	Number	Percent
All prescribed medicines were dispensed	299	94.92
Some of the prescribed medicines dispensed	10	3.17
None of the prescribed medicines were dispensed	6	1.90

4.6. Reasons for not obtaining the prescribed Medicines

Absence of the required medicines in public pharmacies was the major reason (41.2%) for not getting the prescribed medicines followed by lack of money (35.3%) on the part of the patient (Table 11).

Table 11 Reasons for not obtaining Prescribed Medicines (n=17)

Reasons	Number	Percent
Price was too high	0	0
Did not have enough money	6	35.29
Not able to borrow enough money	0	0
Too many medicines were prescribed	0	0
Did not believe all the medicines were needed	1	5.88
Started to feed better	0	0
No time to get all the medicines	1	5.26
Traditional healer did not have all the medicines	0	0
Public pharmacy did not have all the medicines	7	41.18
Private pharmacy did not have all the medicines	1	5.26
Drug seller did not have all the medicines	0	0

Already has some of the medicines at home	0	0
Others	1	5.88

4.7. Level of compliance to prescribed Medicines

Assessment of the level of compliance to prescribed medicines has shown that majority of the patients (90.8%) complied with the order. The percentages of partial compliance and absolute non-compliance were 7.2 % and 2 %, respectively (Table 12). The results of this study differ from the results of previous study conducted on out patients of a teaching hospital (15), which had reported compliance rate and non-compliance rate of 73.9% and 20.1%, respectively. The differences of the findings may be due to differences in the subject populations.

Table 12 Compliance status (n=305)

Variables	Number	Percent
All of the medicines taken	277	90.82
Some of the medicines taken	22	7.21
None of the medicines taken	6	1.97

4.8. Sources of Medicines

Analysis of sources of medicines used by the respondents (Table 13) indicates that the main sources (71.1%) were public health facilities followed by private pharmacies (17.7%). The contribution of informal sources such as local stores/market places, friends/neighbors/family, etc. was in significant (<1%). The results of this study is in stark contrast with the findings of other studies carried out in developing countries (16, 17), where it was reported that more than half of the medications used in the community are obtained from informal sources such as village grocery stores, and house hold stocks.

Table 13 Sources of medicines used by the respondents (n=345)

Source	Number	Percent
Traditional healer	9	2.61
Public Health centre/hospital	245	71.01
Private health centre/hospital	13	3.77
Public pharmacy	8	2.32
Private pharmacy	61	17.68
Local store/market place	3	0.87
Friends/neighbor/family	2	0.58
Medicines already owned	3	0.87
Others	1	0.29

4.9. Drug expenditure to Income ratio

Further look into the drug expenditure to income ratio of 250 respondents has revealed that on the average 20.9% (Minimum 0%, Maximum 3300%), of estimated family weekly income or total weekly household expense is required to cover the cost of drugs to treat a single illness episode.

Chapter IV: Conclusion and Recommendation

1. CONCLUSION

The assessment of the pharmaceutical sector using level I and Level II core indicators has shown both strengths and weaknesses in the implementation of the National Drug policy.

Some of the **strengths** include:

- Strong commitment of the government to the implementation of the national drug policy;
- Establishment of an independent drug regulatory authority supported by a quality control laboratory.
- Promulgation of current proclamation for control of the pharmaceutical sector
- An improvement in resource allocation for regulatory and drug supply activities
- Growth in the number of local pharmaceutical factories from one to thirteen and also an increase in the number of importers, wholesalers and retail outlets.
- Various training sessions and public education programs conducted by DACA, PASS and professional associations to improve drug supply management skill of health personnel and to promote rational drug use
- Initiation of new activities such as drug information dissemination and monitoring of adverse drug reaction.

On the other hand, the policy implementation had numerous **shortcomings**, among which were the following:

Policy & regulation

- Absence of regulations for the implementation of proclamation No. 176/1999;
- Absence of specific NDP implementation plan that sets responsibilities, budget and timeline;
- Absence of monitoring and evaluation of the elements in the NDP
- Double standard in the implementation of the proclamation with respect to product registration;
- Weak regulation of local manufacturers in terms of licensing
- Failure to link drug registration with inspection of manufacturing sites abroad

Out comes of policy

Failure to achieve some of the recommended targets for *access, quality and rational drug use*:

- Inadequate drug budget allocation;
- In availability of STGs and current EDL at health facilities;
- Poor dispensing and prescribing practices;
- Low level of patient knowledge about drugs dispensed to them;
- Long stock-out period of essential drugs in public health care facilities;
- Wide variation in storage conditions of public health care facilities, some of them falling below acceptable level

2. RECOMMENDATIONS

To improve the existing situation, the following measures are recommended:

Policy & regulation

- Proclaim current legislation for the implementation of proclamation 176/199.
- Revise the NDP and national EDL in the light of current developments.
- Develop NDP implementation plan that sets responsibilities, budget and time line.
- Apply uniform registration requirements on both locally produced and imported products, irrespective of the sector;
- Ensure that local manufacturers comply with GMP requirements through proper certification ;
- Establish linkage between product registration and GMP inspection of manufacturers abroad

Accessibility

- Increase drug budget allocation to improve availability of essential drugs
- Upgrade the drug supply management skills of health personnel working at different levels

Quality

- Improve storage conditions in health facilities.
- Undertake post marketing quality monitoring of essential drugs

Rational Drug Use

- Conduct training on rational use of drugs for prescribers and dispensers
- Improve the dispensing practice by allocating enough resource for dispensing inputs
- Distribute STGs, EDL and other reference materials to improve prescribing practices and drug selection in facilities
- Strengthen the public education and drug information dissemination initiatives;
- Establish/revitalize Drugs & Therapeutic Committees in Public Health Care facilities
- Introduce audit & feed back systems on the practice of prescribers & dispensers

General

- Undertake further in depth study on areas where shortcomings were noted in order to explore underlying causes and design specific interventions;

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Annex I: National Regional States of Ethiopia



Annex II: Six-tier and four-tier health care delivery systems

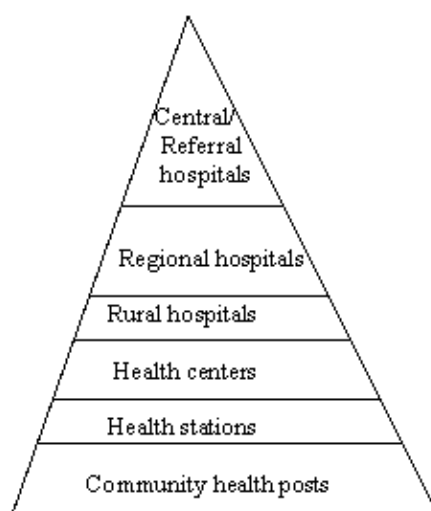


Figure 1 Six-tier health care delivery system in Ethiopia

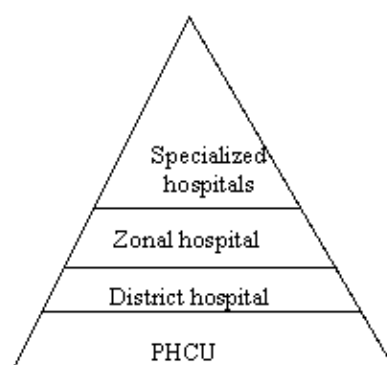


Figure 2 Future Four-tier health care delivery system

Annex III: Distribution of Health Facilities and House Holds Surveyed

Sr. No.	Region	Hospitals (DH+ZH)	Health Centers	Health Stations	Private Pharmacy	Private Drug shops	Special Pharmacy	Regional Drug Store	House Holds
1.	Amhara	14(1)*	77(4)	518(28)	29(2)	39(2)	1	2(1)	165
2.	Oromia	19(2)	111(5)	787(31)	42(3)	94(5)	–	1(1)	108
3.	Tigray	12(1)	29(2)	158(9)	14(1)	10(1)	3	1(1)	62
4.	SNNPR	10(1)	103(6)	299(13)	22(1)	24(1)	–	1(1)	100
5.	Benishangul Gumuz	2(1)	7(1)	65(3)	–	2(1)	–	–	25
6.	Addis Ababa	5(1)	20(1)	8(1)	125(5)	42(2)	1	2(1)	30
Total		62(7)	347(19)	1835(85)	232(12)	211(12)	5	7(5)	490
Sample size (%)		11.3%	5.5%	4.6%	5.2%	5.7%		71.4%	

* Figures in brackets show sample size

Acronyms:

DH District Hospital

ZH Zonal Hospital

Annex IV: LIST OF KEY ESSENTIAL DRUGS

Health problem	Key essential drugs
Acute Respiratory Tract infection	Amoxicilin capsule or tablet Co-trimoxazole tablet Procain penicillin injection
Diarrhea	Oral Rehydration Salt (ORS) Co-trimoxazole
Malaria	Chloroquin tablet Sulphadoxine-Primethamine tablet
Worm infestations	Mebindazole tablet
Conjunctivitis	Tetracycline eye ointment
Skin disinfection	Denatured alcohol
Anemia	Ferrous salt + Folic Acid
Pain	Paracetamol tablet
Scabies	Benzyl benzoate lotion

Annex V: Summary of National Indicators

Ser. No.	INDICATORS	VALUE
Public Health Care Facilities		
1.	Percentage availability of key essential drugs	69.83
2.	Percentage of expired drugs	8.24
3.	Average stock out duration (days)	99.22
4.	Affordability (adult)	135 %
5.	Affordability (children)	67.69 %
6.	Adequacy of storage	5.98
7.	Average number of drugs per encounter	1.99
8.	Percentage of antibiotic per encounter	58
9.	Percentage of injection per encounter	26.98
10.	Percentage of prescribed drugs dispensed	85.48
11.	Percentage of drugs adequately labeled	42.66
12.	Percentage of patients who have adequate knowledge	67.36
13.	Percentage of health facilities with STG	39%
14.	Percentage of health facilities with EDL (facility or regional EDL)	< 1 %

Treatment of Cases:			
15.	Diarrhea	ORS	81.87
		Antibiotic	49.63
		Antidiarrheal and/ or antispasmodic drugs	2.55
16.	Acute respiratory tract infection:		
17.	Non-pneumonia ARTI	Percentage of antibiotic use	60.09
18.	Mild/ moderate pneumonia	Percentage of use of first line antibiotic	54.1
		Percentage use of > one antibiotic	2.36
Private retail Outlets:			
	Percentage affordability (Adult)		195
	Percentage affordability (Children)		127
	Percentage availability of key essential drugs		90.96
	Percentage of expired drugs		3
Regional Drug Stores			
	Percentage availability of key essential drugs		85
	Average stock out duration (days)		99
	Storage condition rates (on a scale of 0–11 scores)		8
	Percentage of expired drugs		2

