
# Assessment of Leishmaniasis treatment commodities management and Leishmaniasis treatment pattern in public health facilities of Amhara Region, Ethiopia

Basazinew Mekuria

A thesis submitted to the Department of Pharmaceutics and Social Pharmacy, School of Pharmacy, College of Health Sciences, Addis Ababa University.

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## School of Graduate Studies

This is to certify that the thesis prepared by Basazinew Mekuria, entitled "*Assessment of leishmaniasis treatment commodities management and leishmaniasis treatment pattern in public health facilities of Amhara Region, Ethiopia*" and submitted in partial fulfillment of the requirements for the Degree of Master of Sciences in Health Supply Chain Management complies with the regulations of the University and meets the accepted standards for originality and quality.

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Examiner: Dr. Bruck Messele Signature _____Date_____

Advisor: Prof. Teferi Gedif Signature_____ Date_____

Advisor: Prof. Asrat Hailu Signature _____Date_____

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## Abstract

**Assessment of leishmaniasis treatment commodities management and treatment pattern in public health facilities of Amhara Region, Ethiopia**

**Basazinew Mekuria**

**Addis Ababa University, 2020**

**Background**: The Pharmaceutical logistics system in Ethiopia is consistently hindered by several systemic problems that cause frequent stockouts of critical pharmaceuticals. It is even worse when it comes to the supply chain management of neglected tropical diseases, including leishmaniasis.

**Objective**: To assess leishmaniasis treatment commodities' management and treatment pattern in public health facilities of Amhara Region.

**Method**: A descriptive cross sectional survey design was used for the study and a total of 18 health facilities found in Amhara Regional State were included in the study. Information on availability, inventory and storage practices of leishmaniasis treatment commodities and treatment pattern from health facilities were collected using structured questionnaires. In addition, in-depth interviews with key informants were conducted to identify challenges on leishmaniasis treatment commodities, and treatment pattern using interview guide. Three data collectors were trained and involved in data collection process. Data was entered and analyzed using Statistical Package for Social Sciences (SPSS) version 20. Descriptive statistics were used to calculate mean and percentage figures. The qualitative data was transcribed and summarized thematically.

**Results:** Utilization of bin cards and Receiving and Requisition Form (RRF) for leishmaniasis treatment commodities were reported in 10(55.6%) of the facilities, whereas 11(61.1%) health facilities used Internal Facility Report and Resupply (IFRR) for leishmaniasis treatment commodities. Fourteen (77.8%) and 7(38.9%) of the health facilities experienced stockouts of one or more commodities during the past one year and on the day of the visit, respectively. Five (100%) and 10(62.5%) facilities were stockout with mean frequency (range) of stockout 3.6(3-4) and 1.6(0-3) for Amphotericin B and rk39 test kit in the past one year, respectively. The mean number of days (and range) of stockouts of health facilities were 86(0-160) for Sodium Stibogluconate and 153(128-192) for Amphotericin B in the study period (March 2018-Feburary 2019). A total of 18221 leishmaniasis suspected patients in a period, from January 2016- December 2018, were tested by rk39, aspiration, and skin smear test, out of which 6261 were positive. Out of 6261 total leishmaniasis positive cases, the highest annual prevalence, 2414(38.6%), was reported in 2018. In the Amhara Region, 1245 in 2016, 1169 in 2017, and 1349 in 2018 leishmaniasis cases were managed. Out of 1147 patients with leishmaniasis treated in the study facilities in the period (March 2018-Feburary 2019) 122(76.2%) and 317(83.9%) were treated with Amphotericin B and combined Sodium Stibogluconate with Paromomycin for recommended duration respectively whereas 4(33.3%), and 155(26%) of patients treated with Paromomycin and Sodium Stibogluconate monotherapy were below the recommended duration respectively. The highest co-infection with leishmaniasis in the study period (March 2018-Feburary 2019) was severe acute malnutrition which is 38 patients. Out of the received leishmaniasis commodities, 5% of Sodium Stibogluconate, 8.6% of Paromomycin, and 7% of rK39 test kit were

expired in the study period (March 2018-Feburary 2019) while 69.3% and 35.8% of rK39 test kit and Paromomycin from stock on hand were near expiry. From the total assessed facilities, two hospitals, 88.2%, and 94.1% perform storage condition guideline criteria which is above the recommendation, and only 11.11% of health facilities maintain acceptable storage conditions.

**Conclusion:** The majority of health facilities had poor inventory management practice for leishmaniasis treatment commodities. Most health facilities experienced one or more commodities stocked out at the time of the visit and during the past year preceding the survey. Amphotericin B was the most frequently stocked out commodity in the health facilities. Some patients took treatment below the recommended duration which is contrary to established treatment guideline protocol. The storage condition of most health facilities was inadequate, and there was an expired and a large number of near expiry products in the health facilities. Generally, there was poorly organized leishmaniasis treatment commodities management in the region.

**Key terms**: Leishmaniasis treatment commodities, Management, treatment pattern, Public facility, Amhara region.

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## Abbreviation and Acronyms

| | |
|---|---|
| Amp B | Amphotericin B |
| ARHB | Amhara Regional Health Bureau |
| CL | Cutaneous Leishmaniasis |
| CSCMP | Council of Supply Chain Management Professional |
| DCL | Diffused Cutaneous Leishmaniasis |
| EPSA | Ethiopia Pharmaceutical Supply Agency |
| FEFO | First Expired First Out |
| FMHACA | Food, Medicine, and Health care Administration and Control Agency |
| FMoH | Federal Ministry of Health |
| HIV | Human Immune Virus |
| HMIS | Health Management Information System |
| IFRR | Internal Facility Report and Resupply |
| IPLS | Integrated Pharmaceutical Logistic System |
| LCP | Leishmaniasis Control Program |
| LMIS | Logistic Management Information System |
| MCL | Mucocutaneous Leishmaniasis |
| NTDs | Neglected Tropical Diseases |
| PKDL | Post-Kalazar Dermal Leishmaniasis |
| RHB | Regional Health Bureau |
| RRF | Receiving and Requisition Form |
| SCM | Supply Chain Management |
| SOPs | Standard Operating Procedures |
| SSG | Sodium Stibogluconate |
| TB | Tuberculosis |
| UK | United Kingdom |
| USAID | United States Agency for International Development |
| VL | Visceral Leishmaniasis |
| WHO | World Health Organization |

# 1. Introduction

## 1.1 Background

Leishmaniasis is a neglected tropical disease caused by protozoan parasites belonging to the genus *Leishmania (*Elnaiem et al., 2011). It is the third cause of disability from Neglected Tropical Diseases (NTDs) and the second cause of parasite-related deaths if untreated early (Bhargava and Sing, 2012). It exists in two primary forms in Ethiopia; visceral and cutaneous leishmaniasis (FMOH, 2016). There are different clinical manifestations of the leishmaniasis i.e. Visceral Leishmaniasis (VL), Post-Kala-azar Dermal Leishmaniasis (PKDL), Cutaneous Leishmaniasis (CL) and cutaneous leishmaniasis with the involvement of lesions of the mucous membranes, which is also called Mucocutaneous Leishmaniasis (MCL) (Stauch et al., 2012; Biswas et al., 2017). Diffuse Cutaneous Leishmaniasis (DCL) is the other clinical manifestation of cutaneous leishmaniasis, which is rarely occurred in some countries like South and Central America and Ethiopia (Lindoso et al., 2016; FMOH, 2013).

Worldwide around 700,000 to 1,000,000 new cases and 26,000 to 65,000 deaths occurred due to leishmaniasis annually. From these, 50,000 to 90,000 new cases are VL (WHO key fact, 2020). According to the World Health Organization (WHO) 2018 reports, more than 95% of VL new cases reported to WHO occurred in ten countries, including Ethiopia (WHO key fact, 2020). In 2015, 4000 new CL cases were from Ethiopia, Kenya, and Sudan, and in 2016, 11 000 new VL cases were reported to the WHO from six countries (Ethiopia, Kenya, Somalia, South Sudan, Sudan, and Uganda) (WHO, 2017).

Ethiopia is one of the high disease burden countries for leishmaniasis and estimated to have the highest burden of CL and the second-highest burden of VL in sub-Saharan

Africa (Alvar et al., 2012; Deribe et al., 2012). The spread of the disease to new areas of the country increases from time to time (FMOH, 2016). As a result, up to 2000 – 4,500 VL cases and 20,000 – 40,000 CL cases are reported each year. More than 85% of VL cases are reported from Amhara and Tigray Region (WHO, 2017).

The first line treatment regimens for the management of VL in Ethiopia are combination therapy of Sodium Stibogluconate (SSG) with Paromomycin (PM), SSG Monotherapy and Amphotericin B (Amp B) whereas the second line treatment are Amphotericin B, Miltefosine and Paromomycin. Currently, in Ethiopia combination therapy of SSG with PM were recommended in all VL patients except special groups i.e. pregnancy, sever illness, HIV/VL co-infection and for patients below the ages of 2 years and above 45 years at all treatment centers (FMoH,2016; FMoH, 2013). The systemic treatment management choices for CL includes Paromomycin, Miltefosine with Amphotericin B combination therapy and SSG monotherapy (FMHACA, 2014; FMOH, 2013)

According to the Council of Supply Chain Management Professionals (CSCMP)- " supply chain management (SCM) encompasses the planning and management of all activities involved in sourcing and procurement and all logistics management activities. Importantly, it includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third-party service providers, and customers. In essence, supply chain management integrates supply and demand management within and across companies" (CSCMP, 2013). Over time, the profession of SCM has evolved to meet the changing needs of the global supply chain. SCM comprises the logistics tasks and the coordination and collaboration of different levels and functions (USAID | DELIVER PROJECT, Task Order 1, 2011).

Commodity management controls the logistics activities of receiving, storing, transporting, and distributing commodities along with preparing necessary commodity reports and keeping commodity losses to ensure commodities availability and accessibility with high quality for patients (Walkowiak et al., 2008).

Logistics is the procedure of scheduling, applying, and controlling for the effective and efficient distribution and storage of commodities, including services, and related information from the point of origin to the point of consumption to conform to customer requirements (Raja and Mohamed, 2004).

## 1.2 Statement of the Problem

A reliable and uninterrupted supply of health commodities is a prerequisite to efficient healthcare delivery. Implementation of Integrated Pharmaceutical Logistic System (IPLS) tools is one of the methods to improve and strengthen the consistent supply of health commodities to all health facilities (PFSA, 2015). Investigating and assessing commodities management and supply chain practices determines important emerging trends and areas of concern that need corrective measures (MSH, 2012). To strengthen commodity supply chains, comprehensive assessments to identify the system's weaknesses, failures, and successes are of principal importance (Daniel et al., 2012).

Most leishmaniasis patients have limited access to care due to different reasons i.e. the disease high burden and endemic in developing countries, endemic countries had poor control system for leishmaniasis, and weak participation of the non-governmental organization in leishmaniasis control program (den Boer et al., 2011).

Delay in detection and treatment increases the risk of morbidity and mortality as well as the spread of the disease to others. If the patients do not get treatment early, VL expands, causing increasingly severe symptoms and, ultimately, death within two years, in most cases. Timely and appropriate availability of commodities, access to diagnosis, and care improve clinical outcomes and decreases disease spread and transmission from infected humans to others (Coulborn et al., 2018).

Effective commodity management ensures product safety and determines the achievement or failure of any public health program. Like in the business sector, decision-makers in the public sector progressively direct their commitment to improve supply chains, because commodity management developments convey significant,

quantifiable benefits. Uninterrupted and robust supply chains improve public health programs by increasing program impact, quality of care and improving effectiveness and efficiency (European Centre for Research Training and Development UK, 2015).

The supply chain practice of most countries, including Ethiopia for NTD commodities, including leishmaniasis, is often an ad hoc system. Temporary supply chain practice is the leading cause of supply disruption that leads to both overstock and under stock of commodities (Snow, 2015).

In Ethiopia, the pharmaceutical logistics system is weak, consistently being hindered by several systemic problems that cause frequent stockouts of critical pharmaceuticals, thus impeding continuous and quality treatment and testing (USAID | DELIVER PROJECT, Task Order 4., 2011).Currently, supply chain practice in Ethiopia progressed from weak, ad hoc, and program-based system to integrated system so that availability of essential commodities specially for integrated programs were improved but the supply chain challenges persists i.e. stock out of essential pharmaceutical, over and understock of commodities, wastage and imbalance of need and supply (USAID | DELIVER PROJECT, Task Orders 4 and 7., 2016). Although perception progressed, supply chain bottlenecks for leishmaniasis treatment commodities persist (Sunyoto et al., 2019). Supportive supervision conducted by FMoH and stakeholder on leishmaniasis program showed that the distribution of products and availability of leishmaniasis commodities in Ethiopia is weak, irregular, and not integrated (Bishaw et al., 2017). SSG availability was 4% nationally, and SSG or Amphotericin B was 2% in the Amhara region at the time of the visit (EPHI, 2016).

The Leishmaniasis Control Program (LCP) in Ethiopia was established in 2006, led by the FMoH. Following the 2005 Libo-kemekem outbreak, five VL treatment sites were established. Government policy for leishmaniasis control program is one plan, one budget, and one report (report through HMIS) (FMoH, 2016). Leishmaniasis products need identification (quantification) is based on obtained information without considering stock status and needs of the facilities. The LCP has neither a SCM team nor buffers stock at Ethiopian Pharmaceutical Supply Agency (EPSA) level. Leishmaniasis commodities, unlike other NTDs, should be available throughout the year because leishmaniasis cannot be managed without laboratory investigation and admission.

Since 2016, a combination of SSG and PM has been used as the treatment option instead of SSG only in most of VL treating sites in Ethiopia especially in highly endemic areas of the country, Northwest region. There is a plan to scale up the treatment in all VL treating sites, and the quantification of commodities is based on this plan (FMoH, 2016).

Leishmaniasis is one of the NTDs, and the supply chain of the program is not strong to fulfill the need. The program has a goal of controlling leishmaniasis by 2020 through maintaining a case fatality rate less than 3% from VL and Scale-up VL and CL treatment centers. Early diagnosis and treatment, improving diagnostic and treatment skills, and conducting operational research on the prevention of leishmaniasis are the approaches to achieve the goal (FMoH, 2016). Besides, the Federal Ministry of Health has a plan to integrate the leishmaniasis commodities supply chain. Assessing the leishmaniasis treatment commodities management is crucial to improve access and thus provide quality services. Little has been done in this regard. However supportive supervision done by Bishaw et al (2017) and readiness assessment done by EPHI (2016) tried to assess the

availability of leishmaniasis treatment commodities at the time of the visit but did not address the other components of the management. This study was therefore conducted with the aim of comprehensively assessing the leishmaniasis treatment commodities management in public health facilities of Amhara regional state, Ethiopia.

# 2. Literature review

## 2.1 Availability of Essential Commodities and Challenges

Internationally, sustainable supply of leishmaniasis treatment commodities at the health facility or service delivery point is affected by administrative issues; inflexible tender mechanisms for public procurement; inadequate delivery systems; lack of safety stock and challenges in demand forecasting, inconsistent supply and lengthy lead time for production at the manufacturer (Sunyoto et al., 2018).

A report in Latin America indicated occasional stockouts (less than 5 days per month) occurred in the health facilities of essential medicines for chronic diseases and medicines used by disease control programs. It also showed in Honduras and Mexico continuous stockouts (more than 10 days per month) of essential medicines for chronic diseases and medicines used by disease control programs in health facilities (USID Delivery project, 2015).

Limited financial support; donation drug unavailability for patients during mass drug administration; inadequate availability of sensitive and specific rapid diagnostic tests to assess current infection and disease transmission and limited knowledge on how to triage, diagnose, confirm and report cases at the primary health care level are the reasons for poor accessing. Also, inadequate monitoring and evaluation practice to assess data quality in health facilities, inadequate health data reporting practice from service delivery point and inadequate health information system reporting formats are other problems of the program (Ortu and Williams, 2017).

## 2.2 Availability of Essential Commodities in Africa

A study conducted in Rwanda on the assessment of essential medicine in 2015 showed that up to 73% of health facilities faced a challenge of medium to high levels of stockouts, and the number of months with stockout for each drug ranged from 1.0-3.5 months and average delivery days after orders are made ranged 12-38 days (Nditunze et al., 2015). An assessment conducted in Tanzania in 2008 showed that of the twenty essential commodities, about 50% were stocked out, ranging from 1-120 days. This assessment also indicated that most respondents (78%) confirm that health facility professionals training on supply chain activities are insignificant. The study has also found that factors such as an error in forecasting and non-adherence first to expire first-out (FEFO) lead to both the un-availability and expiry of health products at the facility level. These, along with other factors such as receiving supplies with short expiry dates or supplies not based on what was demanded, had contributed to stockout of products (MOH and Social Welfare, 2008).

### 2.2.1 Inventory Management and Availability of NTD Commodities

The availability of SOPs, guidelines, or training materials for managing the NTD drugs supply chain affects its supply chain management and availability of commodities in health facilities. An assessment report in Ghana showed inventory management of NTDs commodities in the store was inaccurate data; i.e., the report does not include ending balances and loss/adjustment, physical inventory is not conducted, and recording formats in service delivery point were not adequately available (Snow, 2015).

### 2.2.2 Challenges to Accessing Leishmaniasis Commodities in Africa

There are different challenges for accessing leishmaniasis commodities to patients in Africa. The most significant obstacles to access leishmaniasis commodities in Africa are the drug supply mainly depend on NGOs; irregular production; long lead-times and quality problems or single-source manufacturers; lack of product registration in affected countries; poor reporting and lack of timely surveillance data; fluctuating caseloads and unexpected outbreaks; forecasting based on consumption only; unavailability of central buffer stocks/emergency stock; irregular distribution to treatment sites; lack of trained health workers that leads overuse or underuse of commodities; and emergency use of medications for outbreaks, e.g., SSG for CL (WHO, 2015).

## 2.3 Availability of Essential Commodities in Ethiopia

National Survey on IPLS for essential pharmaceuticals excluding leishmaniasis treatment commodities showed in average availability of essential selected pharmaceuticals was 89% on the day of the visit and 78.1% in the six months before the survey and facilities faced stockout of a product at least once in the six months prior to the survey. The survey showed that the frequency of stockout for essential pharmaceuticals was 1.5 times. The survey also showed the availability of formats is a challenge for 77% of hospitals, 20 % of health centers, and 50 % of health posts did not have bin cards and within 10% bin cards accuracy (Shewarega et al., 2015). A study conducted in Gondar town indicated that 22.4% of the health centers were stocked out for essential medicines, and the average length of stockout was 30.5 days with the average stockout frequency of 0.8 (Fentie et al., 2015).

The study conducted in 2015 in Amhara Region on availability of TB laboratory reagents showed that 40.2% of the health centers were below minimum quantity for at least one of the essential commodities, 13.4% health centers were below minimum quantity for all TB diagnostic reagents, 18.3% of health centers had stockout of at least one of the essential reagents and 3.7% health centers stocked out all TB diagnostic reagents (Sinishaw, 2015).

### 2.3.1 Challenges to Accessing Leishmaniasis Commodities in Ethiopia

A study conducted by Coulborn et al. (2018) showed transportation inaccessibility; low awareness among health professional and people; a few number of facilities that deliver the service; limited access to diagnosis and care; unavailability of treatment commodities at health facilities are significant challenges to access service to patients. A study conducted in eastern Africa indicated lack multisource manufacturer, small market volume for leishmaniasis treatment commodities, overwhelmed procurement due to forecasting difficulties, complex regulatory and distribution system and difficulties, weak communication and coordination between stakeholders, poor trust between different partners. limited political and resource commitment, and limited in-country capacity are barriers for leishmaniasis supply chain (Sunyoto et al., 2019). Other study showed lack of significant national or international donors for CL for control activities and decrease of funding, unavailability of simple and sensitive tests as well as the absence of safe and effective treatments; weak and outdated tools for diagnosis and treatments are challenges for the program (Mengistu, 2016). The availability of rapid treatment commodities has offered enhanced VL case detection and early diagnosis and treatment to prevent destructive mucosal disease in CL cases (Deribe et al., 2012).

## 2.4 Conceptual Framework

The conceptual framework shows that storage practices, distribution systems, inventory management, training, management support of the program, information management, and flow affect commodities management performance.

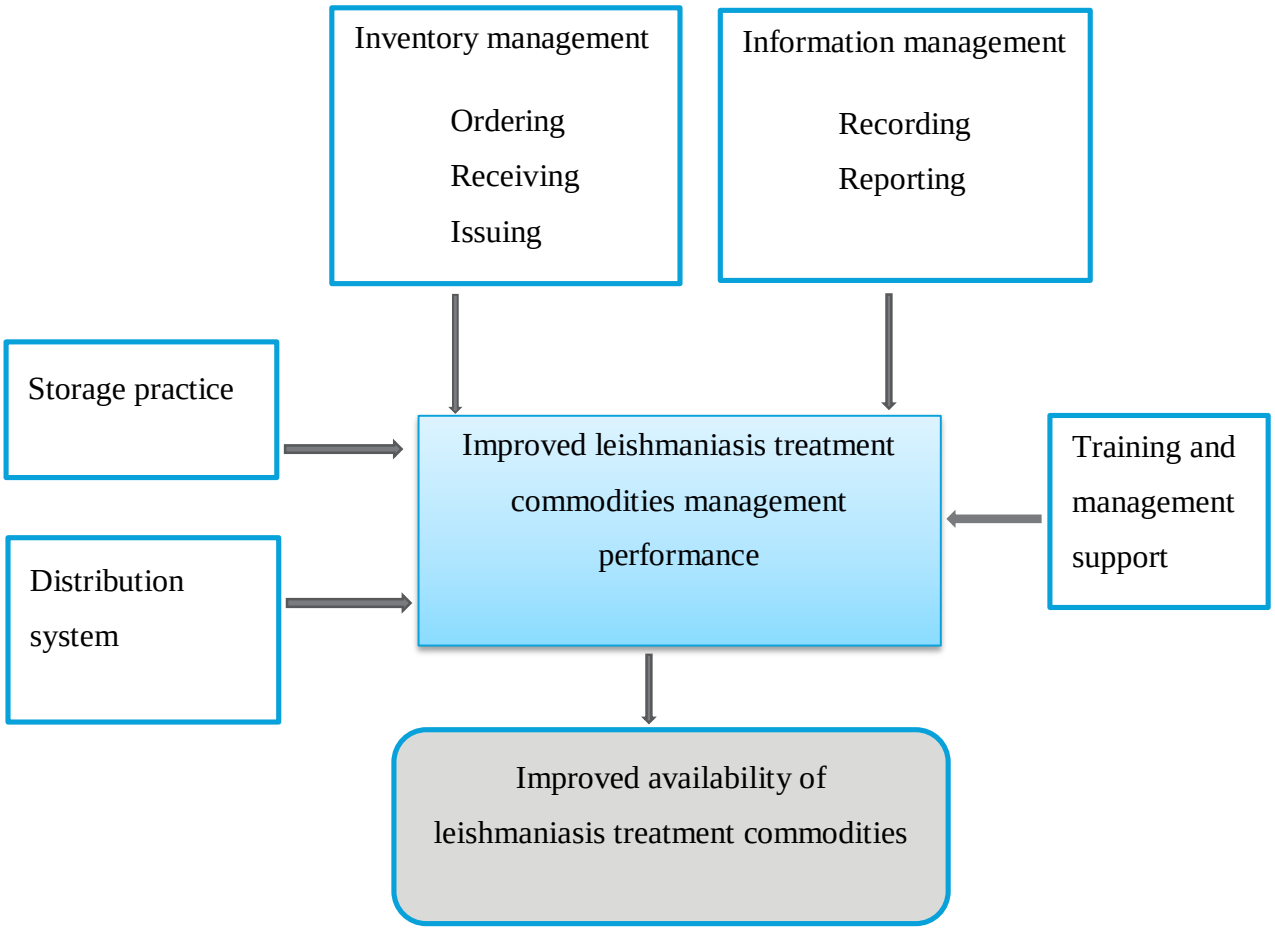



Figure 1: Conceptual framework for assessing leishmaniasis treatment commodities management in public health facilities of Amhara Region, 2019

## 3. Research Questions

- ✓ Do health facilities have consistent and proper supply and stock of leishmaniasis treatment commodities in Amhara Regional State?
- ✓ How are leishmaniasis treatment commodities stored and distribute in the study health facilities?
- ✓ How many cases of leishmaniasis were diagnosed and treated in the region since September 2015?
- ✓ What are the main challenges for leishmaniasis treatment commodities management?

# 4. Objective

## 4.1 General Objective

- To assess the leishmaniasis treatment commodities management and treatment pattern of patients with leishmaniasis in public health facilities in Amhara Region

## 4.2 Specific Objectives

- ✓ To assess the availability of leishmaniasis treatment commodities in public health facilities
- ✓ To assess storage, inventory, and distribution practices of leishmaniasis treatment commodities in the study facilities
- ✓ To identify the challenges of leishmaniasis treatment commodities management in the study facilities
- ✓ To assess the leishmaniasis treatment pattern in the study facilities in the region

# 5. Materials & Methods

## 5.1 Study Area

The study was conducted in Amhara Regional State, Ethiopia. According to the 2017 population projection, the Amhara Region has a population of 21,136,526, covers estimated area of 161,828.4 km2 (CSA, 2013; ANRS BoFED, 2011). The region has a total of 4269 health facilities (80 hospitals, 847 health centers, and 3,342 health posts) with potential health service coverage of 84.1% (FMOH, 2014; HSFR/HFG,2018). All parts of the region are at risk for cutaneous leishmaniasis and are at different risk levels for CL (Seid et al., 2014*)*. However, north and west parts of Gondar and areas around Lake Tana (West Belesa, Fogera, Libo-kemekem woredas) are high risks and endemic areas for visceral leishmaniasis (FMOH, 2016; Leta et al., 2014). In the Amhara Region, there are nine hospitals providing treatment services. Besides, three hospitals and eight health centers were providing only diagnostic services.

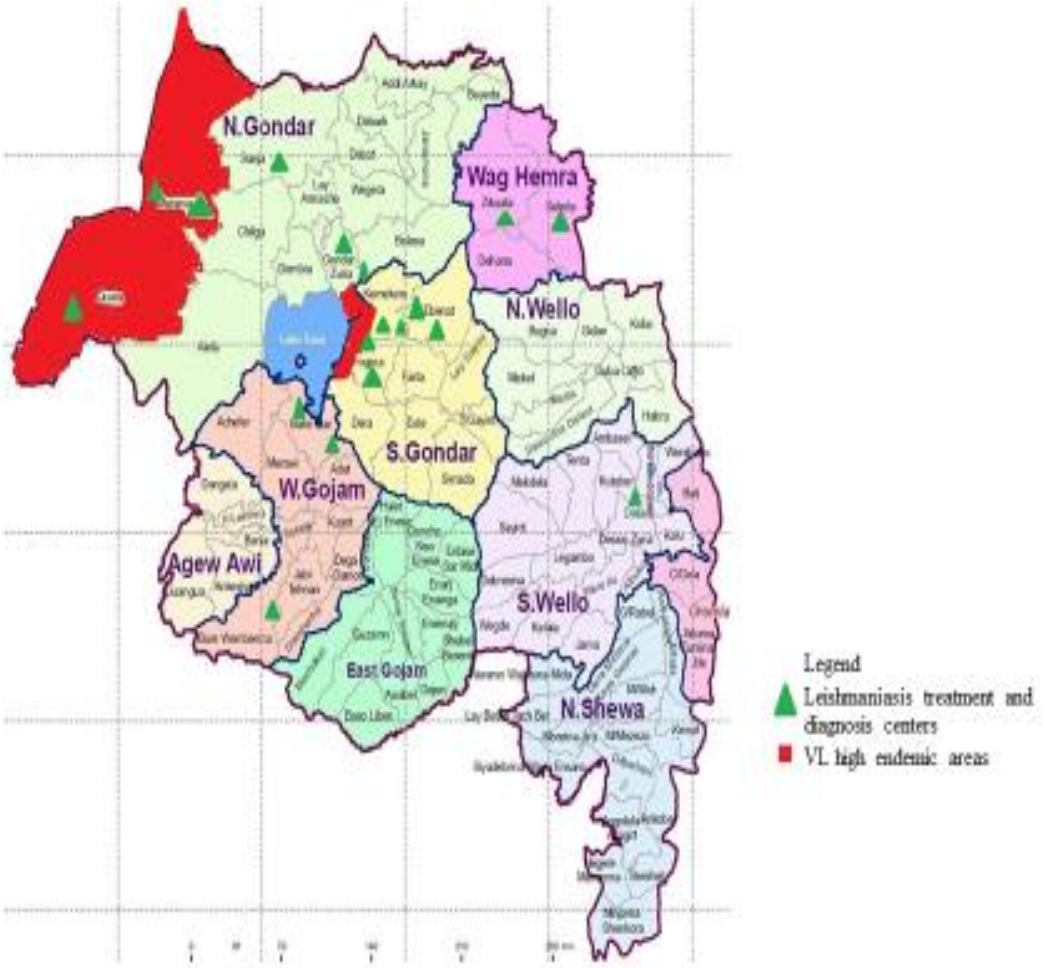



Figure 2: VL high endemic areas and leishmaniasis treatment and diagnosis centers in Amhara Region, 2019

The study area was chosen because it was the most endemic area for leishmaniasis in the country, and there is no prior study done on treatment pattern and leishmaniasis treatment commodities' management in Amhara Region.

## 5.2 Study Design

A cross-sectional descriptive study design supplemented by a qualitative approach was used to conduct the study on leishmaniasis treatment pattern and leishmaniasis treatment commodities' management in Amhara Regional State.

## 5.3 Source and Study Population

The source population was all health facilities in the Amhara region receiving leishmaniasis treatment commodities from EPSA. This includes 20 public health facilities delivering leishmaniasis treatment and/or diagnosis services in Amhara Regional State. Central and EPSA hubs and the regional health bureau were included in the assessment.

The study facilities were all public health facilities found in the region that fulfill the inclusion criteria (one federal specialized teaching hospital, nine hospitals and eight health centers under Amhara Regional Health Bureau were included in this study

A Purposive sampling technique was employed to select in-depth interview study participants from 9 institutions (three EPSA hubs found in Amhara Regional State, central EPSA, ARHB, three Health facilities found in Amhara region, and FMoH) were included.

## 5.4 Eligibility Criteria

### 5.4.1 Inclusion Criteria

Eighteen facilities providing leishmaniasis treatment and/or diagnosis services for at least one year and receiving commodities from EPSA were included in this study.

## 5.5 Data Collection Techniques

Both quantitative and qualitative data collection methods were employed to collect data on the management of leishmaniasis treatment commodities and treatment patterns in

health facilities providing leishmaniasis treatment and/or diagnosis services found in Amhara Regional State and EPSA hubs.

### 5.5.1 Quantitative data collection

A structured questionnaire and observation checklist were used to collect quantitative information from the health facilities. A modified version of the Logistic Indicator Assessment Tool (LIAT) for leishmaniasis treatment commodities was used as a data collection tool (USAID. DELIVER PROJECT ,2008)**.** The data were collected in the English language as recorded, but the interview was conducted in Amharic. Leishmaniasis treatment commodities data were collected from health facilities using document review and physical count using an observation checklist from March 2018 to February 2019. Data related to treatment pattern was collected from health facilities using document review from January 2016 to February 2019**.**

The sources of data for the assessment were physical counts of leishmaniasis treatment commodities, stock ledgers and bin cards. In addition, order and receiving forms between dispensary unit within the facility (IFRR) and order and receiving forms between facilities and higher level (RRF) and observation of facilities' store were used. Essential commodities for the management and diagnosis of leishmaniasis included in Ethiopia Guideline (FMHACA, 2014; FMOH, 2013), including SSG, Paromomycin, Amphotericin B, and rK39 were covered in the assessment. Indicators measured and data sources used are summarized in table 1.

Table 1: Indicators measured and data sources used for assessing leishmaniasis treatment commodities management and treatment pattern in the study facilities, Amhara region, 2019.

| Indicators | Data sources |
|---|---|
| **1. Product Availability** | |
| Percentage of facilities stocked out of leishmaniasis treatment commodities at the time of the visit | stock card, a physical inventory of leishmaniasis treatment commodities |
| Percentage of facilities stocked out of leishmaniasis treatment commodities within one year before the assessment | Respondent, stock records of the leishmaniasis treatment commodities |
| Mean frequency(range) of stockouts of leishmaniasis treatment commodities within the last one year | Respondent, stock records of the leishmaniasis treatment commodities |
| Mean (range) of days of stockout of the leishmaniasis treatment commodities within the last one year | stock records of the leishmaniasis treatment commodities |
| **2. Storage practice** | |
| Percentage of facilities adhering to storage Guidelines | Observational checklist |
| **3. Supportive supervision on leishmaniasis** | |
| Percentage of facilities' store managers receiving supportive supervision within a specified schedule | interview |
| Percentage of facilities' receiving supportive supervision on treatment protocol according to the schedule | interview |
| **4. Inventory Management Practices** | |
| Percentage of facilities with bin card | Observational checklist |
| Percentage of facilities using bin cards | Observation |
| Percentage of facilities store with bin card updated | observation |
| Percentage of facilities having product issue form(IFRR) | Interview/observation |
| Percentage of facilities having a form for ordering (requisition) commodities from a higher level(RRF) | Interview/observation |

| | |
|---|---|
| **5. Personnel** | |
| Average work experience of facility storeman | interview |
| Percentage of facilities' with store man trained in commodities management | interview |
| Number of facilities managing leishmaniasis commodity by non-pharmacy professional | interview |
| **6. Treatment pattern** | |
| Number of leishmaniasis cases screened | Laboratory records of leishmaniasis patients |
| Number of leishmaniasis cases treated | Treatments records of leishmaniasis patients |
| Types of leishmaniasis medication started | leishmaniasis patients chart |
| Duration of leishmaniasis treatment | leishmaniasis patients chart |

### 5.5.2 Qualitative Data Collection

The in-depth interviews were conducted with distribution officers at central EPSA, Bahir Dar, Gondar, and Dessie EPSA hubs. Besides NTDs logistic officer at FMoH, ARHB NTDs officer and physicians from selected hospitals, were interviewed using flexible probing techniques to understand the challenges facing leishmaniasis treatment commodities management and treatment pattern, and to obtain a clarification on the management system for leishmaniasis treatment commodities.

The principal investigator was graduated from wollo university in clinical pharmacy in 2016. Since September 2016, I worked at Metema hospital as clinical pharmacist focal person and pharmacy head. When I was in Metema hospital I noticed suffering of leishmaniasis patients with development of severe symptoms and stayed lengthy days in the hospital. I also faced frequent stockout of leishmaniasis treatment commodities in the hospital and there was no response for this problem from higher level at that time. In February 2018, I joined Addis Ababa university to study my postgraduate in health supply chain management. So the above problems inspired me to do my thesis on leishmaniasis treatment commodities management and treatment pattern.

The principal investigator conducted the interviews. The English version data collection tool was translated to Amharic version and the interview was conducted in Amharic. The interview was audio-recorded and it was taken on average below an hour. The tool and the data were translated by two MSc holder pharmacists and principal investigator. The in-depth interviews focused on challenges in the management of leishmaniasis commodities, program integration, coordination, communication, and information flow.

Table 2: In-depth interview participants to identify challenges of leishmaniasis treatment commodities management and treatment pattern in Amhara region, 2019.

| Participants | Number |
|---|---|
| Central EPSA program product distribution officer | 1 |
| EPSA Gondar hub program products' distribution officer | 1 |
| EPSA Bahir Dar hub program products' distribution officer | 1 |
| EPSA Dessie hub program products' distribution officer | 1 |
| FMoH NTDs logistic officer | 1 |
| ARHB NTDs logistic officer | 1 |
| Physicians | 3 |
| Total | 9 |

## 5.6 Data Collectors

Two nurses and one pharmacy professional (who has experience in pharmaceutical management) collected the data from the study health facilities.

## 5.7 Data Quality

The data collection tools were tested on one health facility not included in the actual study to ensure that the tools were consistently communicated and understood. Data collectors were trained for half day and provided written explanations about study variables. The principal investigator has provided frequent checks on the data collection

process to ensure the completeness and consistency of the gathered information. Critically avoided leading/biased questions i.e. yes/no in qualitative data collection tools to improve data quality and to decrease biased. The principal investigator was avoided from asking leading and indicating question during the interviews.

## 5.8 Data Analysis Procedures

The quantitative data were entered and analyzed using the Statistical Package for the Social Sciences version 20 (SPSS) and excel. Descriptive statistics were used to calculate mean and percentage, and results were presented using tables and graphs. Audio-recorded interviews were transcribed word for word, and the raw data was grouped under themes and sub-themes. The qualitative data were reviewed in order to identify critical points for data analysis. A thematic analysis was then used to analyze the data.

## 5.9 Ethical Considerations

Ethical approval was obtained from Addis Ababa University (AAU) School of Pharmacy Research Review Board (Ref. No. ERB/SOP/49/02/2019), and then a letter was written to the Amhara Regional Health Bureau (ARHB). ARHB written a letter to health facilities administrators so that permission was granted and facility administrators were informed. No health facility name and participating subjects were revealed in the results. Only the aggregated result of the facilities and summary results of the in-depth interview was presented.

## 5.10 Operational Definitions

**Leishmaniasis treatment commodities: -** are used for the treatment or diagnosis of leishmaniasis which includes medicines and/or test kits (rK39)

**Stockout on the day of the visit:** - facilities not having stock of products on the day that the data collector arrived

**Frequency of stockout:** - how often a leishmaniasis treatment commodities was not available at health facilities during the review period (on-off product availability)

**Lead-time: -** time taking between reporting and receiving of leishmaniasis treatment commodities and are made ready to use

**Applicable facility**- a facility that manages leishmaniasis treatment commodities

.

# 6. Results

## 6.1 Quantitative Findings

### 6.1.1 Leishmaniasis Treatment Commodities Management

#### 6.1.1.1 Characteristics of Study Health Facilities and Study Participants

A total of 18 public health facilities were covered in this study. From these, 7(38.9%) facilities were providing both diagnosis and treatment services while the remaining 11(61.1%) were managing only diagnostic services. In majority 13(72.2%) of the health facilities, the principal persons managing leishmaniasis treatment commodities were pharmacy technicians followed by pharmacists in 4(22.2%). The mean numbers of years of work experience of those managing the commodities were 5.5, ranging from 1-13 years. The majority 10(55.6%) of those who were managing leishmaniasis treatment commodities were reported to have taken training related to commodity management (Table 3).

Table 3: Types of study facilities and professionals involved in managing leishmaniasis treatment commodities in Public Health Facilities, Amhara Region, 2019.

| Variables | Number(n=18) | (%) |
|---|---|---|
| **Types of health facilities** | | |
| Health centers | 8 | 44.4 |
| Primary hospitals | 8 | 44.4 |
| Referral hospitals | 2 | 11.2 |
| **Types of services** | | |
| Diagnosis only | 11 | 61.1 |
| Diagnosis and treatment | 7 | 38.9 |
| **Services provided by disease category** | | |
| Visceral leishmaniasis(VL) | 12 | 66.2 |
| Cutaneous leishmaniasis (CL) | 2 | 11.1 |
| Both VL and CL | 4 | 22.2 |
| **Professionals involved in commodity management at the facility** | | |
| Pharmacist | 4 | 22.2 |
| Pharmacy technician | 13 | 72.2 |
| Nurse | 1 | 5.6 |
| **Trained professionals that mange leishmaniasis treatment commodities** | | |
| Yes | 10 | 55.6 |
| **Supportive supervision** | | |
| Yes | 14 | 77.8 |
| **Mean number of (range) of storeman work experience in years** | 5.5(1-13) | |

#### 6.1.1.2 Leishmaniasis Treatment Commodities Management

Stock status and assessment of management activities for commodities for leishmaniasis treatment were made to evaluate product availability and stockouts in selected study health facilities. Consequently, a total of 10(55.6%) facilities used bin cards for leishmaniasis treatment commodities. Fourteen (77.8%) and 7(38.9%) of health facilities had an experience of stockouts for one or more of leishmaniasis treatment commodities during the past one year and on a day of the visit, respectively. From the total 18 health facilities,10(55.6%) facilities were found requesting leishmaniasis treatment commodities by RRF integrated with other program commodities to EPSA hubs (Table 4).

Table 4: Practice of leishmaniasis treatment commodities' management activities at the health facilities of the Amhara Region, 2019

| Variables | Number(n=18) | Percent |
|---|---|---|
| Bin card used | | |
| Yes | 10 | 55.6 |
| Report and requisition(RRF) form used | | |
| Yes | 10 | 55.6 |
| Internal facility report and requisition (IFRR) form used | | |
| Yes | 11 | 61.1 |
| Facilities stockouts of one or more leishmaniasis treatment commodities | | |
| At the time of the visit | 7 | 38.9 |
| In the past year | 14 | 77.8 |
| Way of sending requests to EPSA hubs | | |
| Integrate with other programs | 10 | 55.6 |
| Other method | 3 | 16.7 |
| Not sent | 5 | 27.7 |
| When supportive supervision received on leishmaniasis treatment commodities | | |
| Never received | 4 | 22.2 |
| Within the last month | 8 | 44.4 |
| 1-2 months | 1 | 5.6 |
| 3-6 months | 5 | 27.8 |

** Other methods- requested separately by the letter*

#### 6.1.1.3 Utilization of Stock Keeping and Reporting Forms

The majority of health facilities, 5(71.4%) and 10(62.5%) used bin cards for SSG, and rK39 respectively. In contrast, a few numbers of facilities 2(20%) were used for Amphotericin B. Almost half of health facilities from bin card using facilities 1(50%) and 5(50%) updated bin card for Amphotericin B and rK39 test kit commodities respectively. Three (60%) facilities used IFRR for Paromomycin and Amphotericin B and 4(57.1%) facilities used for SSG, but only 2(66.7%) from IFRR used facilities reported and received Paromomycin and Amphotericin B by scheduled IFRR (Table 5).

Table 5: Availability and use of bin cards, RRF and IFRR for leishmaniasis treatment commodities in the health facilities, Amhara Region, 2019

| Leishmaniasis treatment commodities | No of applicable facilities, n (%) | No of Facilities bin card used, n (%) | No of Facilities bin card updated, n (%) | No of Facilitie s IFFR used, n (%) | No of Facilities scheduled IFRR used, n (%) | No of Facilities RRF used, n (%) |
|---|---|---|---|---|---|---|
| SSG | 7(38.9) | 5(71.4) | 2(40) | 4(57.1) | 3(75) | 5(71.4) |
| PM | 5(27.8) | 3(60) | 2(66.7) | 3(60) | 2(66.7) | 3(60) |
| Amp B | 5(27.8) | 2(20) | 1(50) | 3(60) | 2(66.7) | 5(100) |
| rK39 | 16(88.9) | 10(62.5) | 5(50) | 8(50) | 3(37.50) | 10(62.9) |

The majority,10(55.6%)of health facilities used RRF for the management of leishmaniasis treatment commodities, but the duration between reporting and receiving

commodities (lead-time) varied. Mostly 2(28.6%), 1(20%), 3(60%) and 3(27.3%) for SSG, Paromomycin, Amphotericin B and rK39 took for two to three months of duration respectively, and only one facility took Amphotericin B in a lead-time greater than three months (Table 6)

Table 6: Lead-time of leishmaniasis treatment commodities in the health facilities, Amhara Region, 2019

| Leishmaniasis treatment commodities | No of applicable facilities, n (%) | Lead-Time <1month, n (%) | 1-2 Months, n (%) | >2-3 Months, n (%) | >3 Months, n (%) |
|---|---|---|---|---|---|
| SSG | 7(38.9) | 1(14.3) | 4(57.3) | 2(28.6) | 0(0.00) |
| PM | 5(27.8) | 1(20) | 3(60) | 1(20) | 0(0.00) |
| Amp B | 5(27.8) | 0(0.00) | 1(20) | 3(60) | 1(20) |
| rK39 | 16(88.9) | 2(18.2) | 6(54.5) | 3(27.3) | 0(0.00) |

#### 6.1.1.4 Availability of Leishmaniasis Treatment Commodities

As shown in table 7, from applicable health facilities, 4(80%) and 2(28.6%) of facilities reported stockout of Amphotericin B and SSG respectively on the day of the visit, whereas 5(100%) and 10(62.5%) of facilities were stockout for Amphotericin B and rK39 test kit during the last one year respectively. However, only 1(20%) facility was stockout for Paromomycin both on the day of the visit and in the past one year. The mean number of duration of stockouts in days was found to be highest for Amphotericin B (153 days)

followed by SSG (86 days), while the lowest average duration of stockout was for Paromomycin (26 days). The mean number of stocked out frequency within the last year was 3.6, 3.3, and 1.6 times for Amphotericin B, SSG, and rK39 test kit, respectively. Thirty (6%) pack of 25 strips of rK39 and 930(8.6%) ampoule of Paromomycin commodities were expired in the past one year while 97(69.3%) pack of 25 strips of rK39 and 1700(35.8%) ampoule of Paromomycin were near expiry within two months.

Table 7: Percentage of facilities stock out for leishmaniasis treatment commodities on the day of the visit, during the last one year, mean duration of stockouts and mean number of stockouts, number of near expiry and expired products in the past one year (March 2018- February 2019), Amhara Region

| Commodities | No of applicable facilities, n (%) | Facilities stockout on day of the visit, n (%) | Facilities stockout in the past 1year, n (%) | Mean # of days (range) of stockouts in the past1 year | Mean # of times (range) of stockouts in the past 1 year | Expired quantity in the past one year from total received quantity, n (%) | Near expiry (below two months) quantity from the sock on hand, n (%) |
|---|---|---|---|---|---|---|---|
| SSG | 7(38.9) | 2(28.6) | 3(42.9) | 86(0 – 160) | 3.3(0-4) | 300(5) | 200(1.4) |
| PM | 5(27.8) | 1(20) | 1(20) | 26(0 – 130) | 0.4(0-2) | 930(8.6) | 1700(35.8) |
| Amp B | 5(27.8) | 4(80) | 5(100) | 153(128 – 192) | 3.6(3-4) | 0(0.00) | 0(0.00) |
| rK39 | 16(88.9) | 2(12.5) | 10(62.5) | 73(0 –180) | 1.6(0-3) | 30(6) | 97(69.3) |

*SSG in a vial; PM in ampoule; rK39 of 25 test strip*

### 6.1.1.5 Storage Practice of Leishmaniasis Treatment Commodities

#### 6.1.1.5.1 Storage Practice of Health Facilities for each indicator

As shown in Table 8, the majority of the health centers, primary, and referral hospitals were not using the standard storage guideline for the storage of leishmaniasis treatment commodities. Of these, in 7(85.7%) health centers and primary hospitals, and in 2(100%) referral hospitals leishmaniasis treatment commodities were stored separately from insecticides and chemicals.

Table 8: Storage conditions for leishmaniasis treatment commodities in Health facilities in Amhara Region, 2019

| Storage condition indicators | Health centers, n (%) | Primary hospital, n (%) | Referral hospitals, n (%) | Total, n (%) |
|---|---|---|---|---|
| Products arranged that labels and expiry dates are visible. | 6(75) | 4(50) | 0(0.00) | 10(55.6) |
| Products stored in FEFO manner | 4(50) | 7(87.5) | 1(50) | 12(66.7) |
| Products stored in good condition | 5(62.5) | 6(75) | 2(100) | 13(72.2) |
| Separation of expired and damaged products | 4(50) | 4(50) | 0(0.00) | 8(44.4) |
| Products are protected from direct sunlight | 5(62.5) | 4(50) | 1(50) | 10(55.6) |
| Products are protected from water & humidity | 6(75) | 8(100) | 2(100) | 16(88.9) |
| Storage area is free from harmful insects | 2(25) | 5(62.5) | 2(100) | 9(50) |
| The storeroom is secured | 8(100) | 8(100) | 2(100) | 18(100) |
| Products are stored at an appropriate temperature | 4(50) | 5(62.5) | 0(0.00) | 9(50) |
| The roof is in good condition | 7(87.5) | 8(100) | 2(100) | 17(94.4) |
| The storeroom is in good condition | 2(25) | 6(75) | 1(50) | 9(50) |
| The store is sufficient for current products | 7(87.5) | 4(50) | 0(0.00) | 11(61.1) |
| Availability of fire safety equipment | 4(50) | 4(50) | 1(50) | 9(50) |
| Products stored separately from insecticides and chemicals | 7(87.5) | 7(87.5) | 2(100) | 16(88.9) |
| Products stacked 10cm of the floor | 6(75) | 7(87.5) | 0(0.00) | 13(72.2) |
| Products stacked 30 cm of the wall | 0(0.00) | 0(0.00) | 0(0.00) | 0(0.00) |
| Products stacked 2.5m high | 8(100) | 7(87.5) | 0(0.00) | 15(83.3) |

#### 6.1.1.5.2 Percentage of Facilities that Maintain Acceptable Storage Conditions

Two hospitals (hospital 9 and hospital 10) fulfil 88.2% and 94.1% of storage guideline criteria for leishmaniasis treatment commodities, respectively (Figure 3). The percentage of facilities that maintain acceptable storage conditions for leishmaniasis treatment commodities in the Amhara Region was 11.11%.

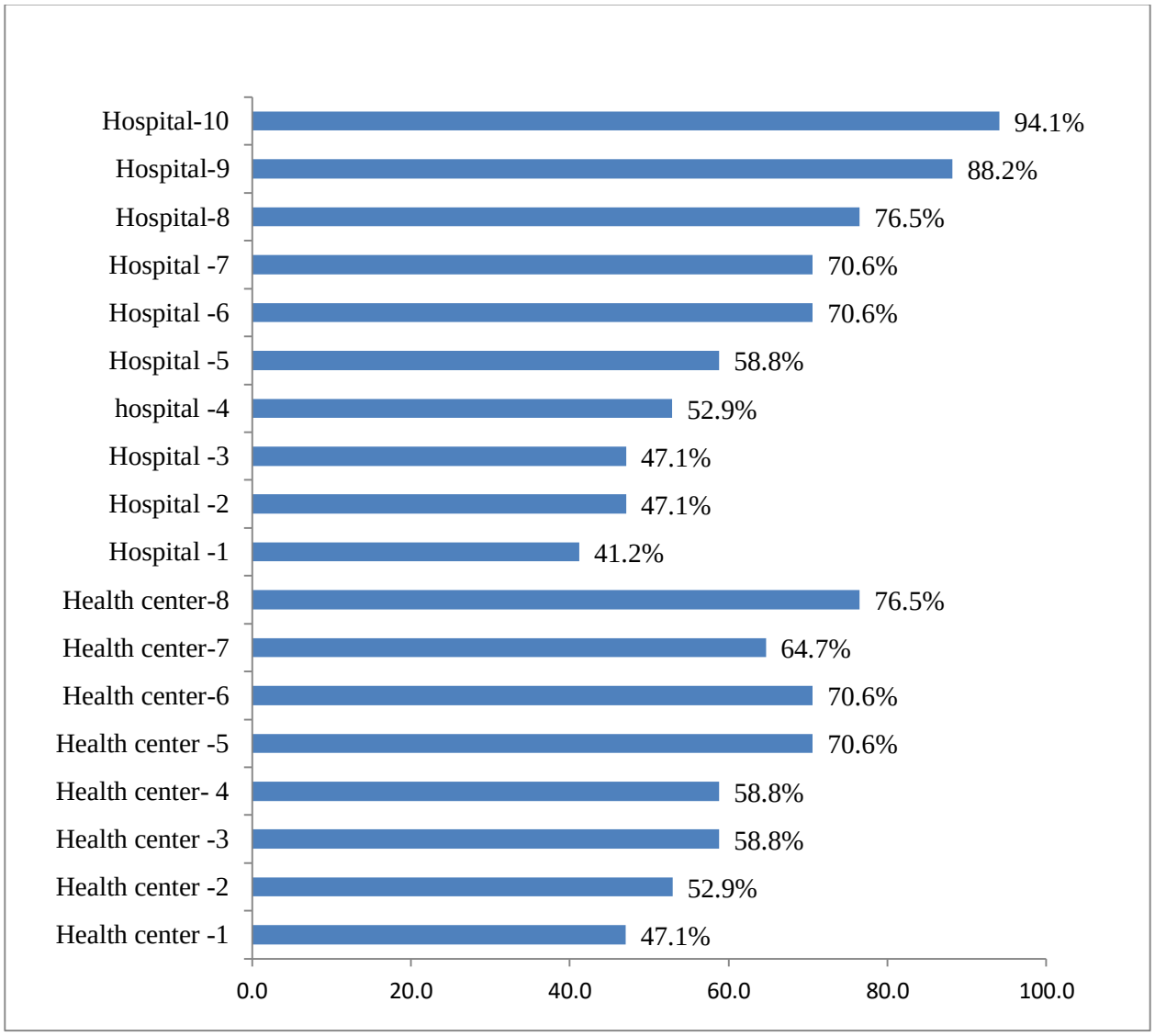



Figure 3: Storage conditions of leishmaniasis treatment commodities at each health facility, Amhara Region, 2019

### 6.1.2 Leishmaniasis Treatment Pattern

#### 6.1.2.1 Number of Leishmaniasis Cases Screened

A total of 18221 leishmaniasis suspected patients in a period, from January 2016-December 2018, were tested by rk39, aspiration, and skin smear test, out of which 6261 were positive. The overall prevalence of leishmaniasis was 6261(34.4%). Of the 6261 total leishmaniasis positive cases, the highest annual prevalence, 2414(38.6%), was reported in 2018. Majority of positive cases were screened by rK39 (n= 3949) and aspiration (n= 11552) (Table 9). A total of 3126 and 15095 cases were tested in health centers and hospitals, respectively, and the load was higher in hospitals (Figure 4).

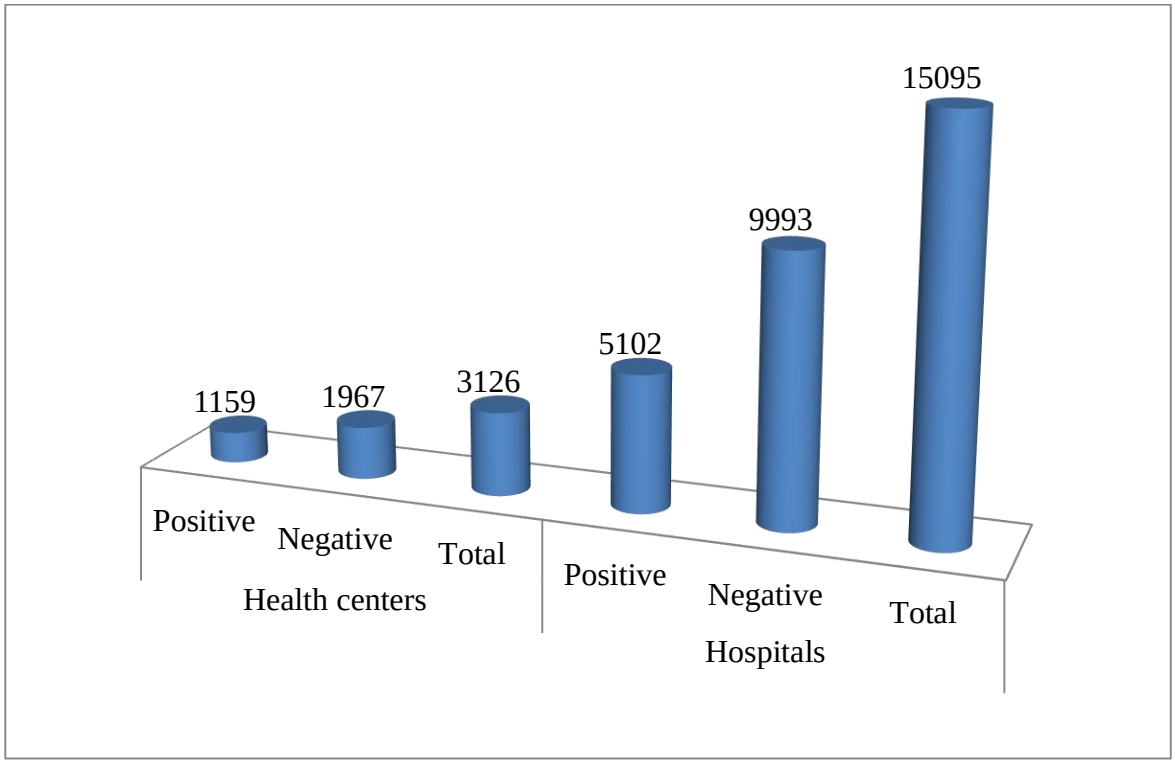



Figure 4: Total number of cases screened in health centers and hospitals from January 2016- December 2018, Amhara Region

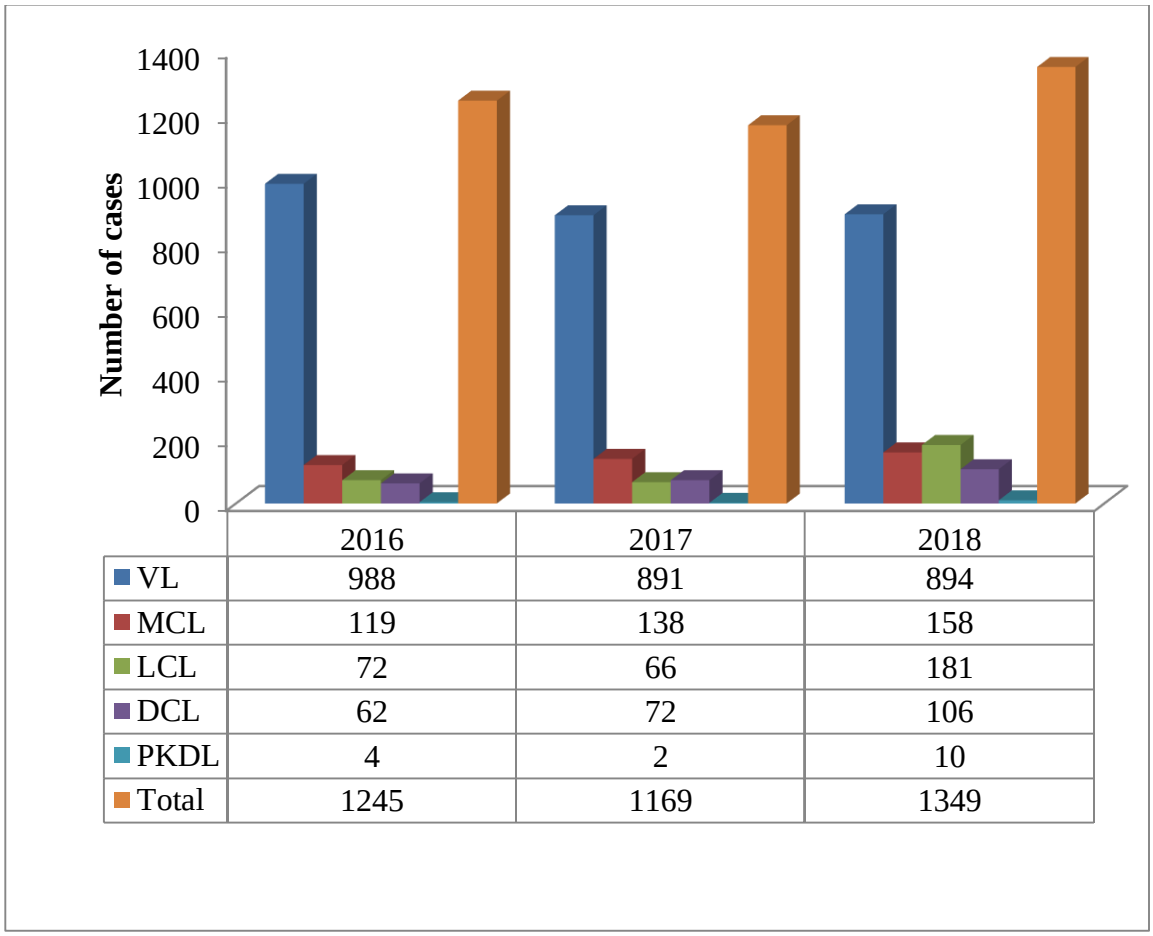
Table 9: Number of cases screened by rK39 test kit, aspiration and skin smear test (January 2016- December 2018), Amhara Region

| Health facilities | Cases | Screened years | | | | | | | | | TC screened by rK39 | TC screened by Asp | TC screened by SST | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 2016 | | | 2017 | | | 2018 | | | | | | |
| | | rK39 | Asp | SST | rK39 | Asp | SST | rK39 | Asp | SST | | | | |
| Health | Positive | 236 | 0 | 0 | 399 | 0 | 0 | 524 | 0 | 0 | 1159 | 0 | 0 | 1159 |
| centers | Negative | 414 | 0 | 0 | 683 | 0 | 0 | 870 | 0 | 0 | 1967 | 0 | 0 | 1967 |
| | Total | 650 | 0 | 0 | 1082 | 0 | 0 | 1394 | 0 | 0 | 3126 | 0 | 0 | 3126 |
| | PC (%) | 36.3 | 0 | 0 | 36.8 | 0 | 0 | 37.6 | 0 | 0 | 37.1 | 0 | 0 | 37.1 |
| Hospitals | Positive | 829 | 502 | 173 | 906 | 535 | 267 | 1055 | 515 | 320 | 2790 | 1552 | 760 | 5102 |
| | Negative | 1751 | 980 | 346 | 1995 | 823 | 529 | 2099 | 755 | 715 | 5845 | 2558 | 1590 | 9993 |
| | Total | 2580 | 1482 | 519 | 2901 | 1358 | 796 | 3154 | 1270 | 1035 | 8635 | 4110 | 2350 | 15095 |
| | PC (%) | 32.1 | 33.9 | 33.3 | 31.2 | 39.4 | 33.5 | 33.4 | 40.6 | 30.9 | 32.3 | 37.8 | 32.3 | 33.8 |
| Total cases screened | | 3230 | 1482 | 519 | 3982 | 1358 | 796 | 3548 | 1270 | 1035 | 11761 | 4110 | 2350 | 18221 |
| Total positive cases | | 1740(27.8%) | | | 2107(33.7%) | | | 2414(38.6%) | | | | 6261(34.4%) | | |

**Asp_ aspiration* **SST_ skin smear test* **PC- positive cases* ** TC- total cases*

### 6.1.2.2 Number of Leishmaniasis Cases Treated

Since January 2016, a high number of visceral leishmaniasis (988) treated in 2016, whereas 181, 158, 106, and 10 cases of localized cutaneous, mucocutaneous, diffused cutaneous, and post-kala-azar dermal leishmaniasis was treated in 2018, respectively. In the Amhara Region, 1245 in 2016, 1169 in 2017, and 1349 in 2018 cases were managed (Figure 5).




| | 2016 | 2017 | 2018 |
|---|---|---|---|
| VL | 988 | 891 | 894 |
| MCL | 119 | 138 | 158 |
| LCL | 72 | 66 | 181 |
| DCL | 62 | 72 | 106 |
| PKDL | 4 | 2 | 10 |
| Total | 1245 | 1169 | 1349 |

**VL_ visceral leishmaniasis *DCL_ diffused cutaneous leishmaniasis *MCL_ mucocutaneous leishmaniasis *LCL_ localized cutaneous leishmaniasis *PKDL_ post-kala-azar dermal leishmaniasis*

Figure 5: Total number of leishmaniasis cases treated (January 2016 - December 2018), Amhara Region

### 6.1.2.3 Types of Starting Medication Used and Relapsed Leishmaniasis Cases

A total of 1147 patient charts from seven health facilities were reviewed from March 2018 to February 2019. From 1147 patients, 938 of them were males. The mean age was 25.97 years and ranged from 1 to 74 years.

Table 10 showed, out of a total of 1147 leishmaniasis cases treated in one-year period (March 2018-February 2019), 600(52%), 375(33%), and 160(14%) started taking SSG monotherapy, SSG with Paromomycin combination therapy and Amphotericin B, respectively. The majority of VL 375(61%) initiated therapy with a combination of SSG and Paromomycin, while most localized cutaneous leishmaniasis 197(96.1%), diffused cutaneous leishmaniasis 55(96.5%), mucocutaneous leishmaniasis 263(98.5%) and all post-kala-azar dermal leishmaniasis started therapy with SSG monotherapy. From the total number of VL cases treated in the past year, 17(2.8%) were relapsed cases.

Table 10: Treatment pattern of leishmaniasis patients in the past year (March 2018-February 2019), Amhara Region

| | Treatment initiated with | | | | |
|---|---|---|---|---|---|
| Leishmania type | SSG + PM, n (%) | SSG, n (%) | PM, n (%) | Amp B, n (%) | Total, N (%) |
| VL | 375(61) | 82(13.3) | 0(0.00) | 158(25.7) | 615(100) |
| LCL | 0(0.00) | 197(96.1) | 8(3.9) | 0(0.00) | 205(100) |
| DCL | 0(0.00) | 55(96.5) | 0(0.00) | 2(3.5) | 57(100) |
| MCL | 0(0.00) | 263(98.5) | 4(1.5) | 0(0.00) | 267(100) |
| PKDL | 0(0.00) | 3(100) | 0(0.00) | 0(0.00) | 3(100) |
| Total | 375(33) | 600(52) | 12(1) | 160(14) | 1147(100) |
| Relapsed cases treated from total VL | | | | | 17(2.8%) |

### 6.1.2.4 Duration of Leishmaniasis Treatment

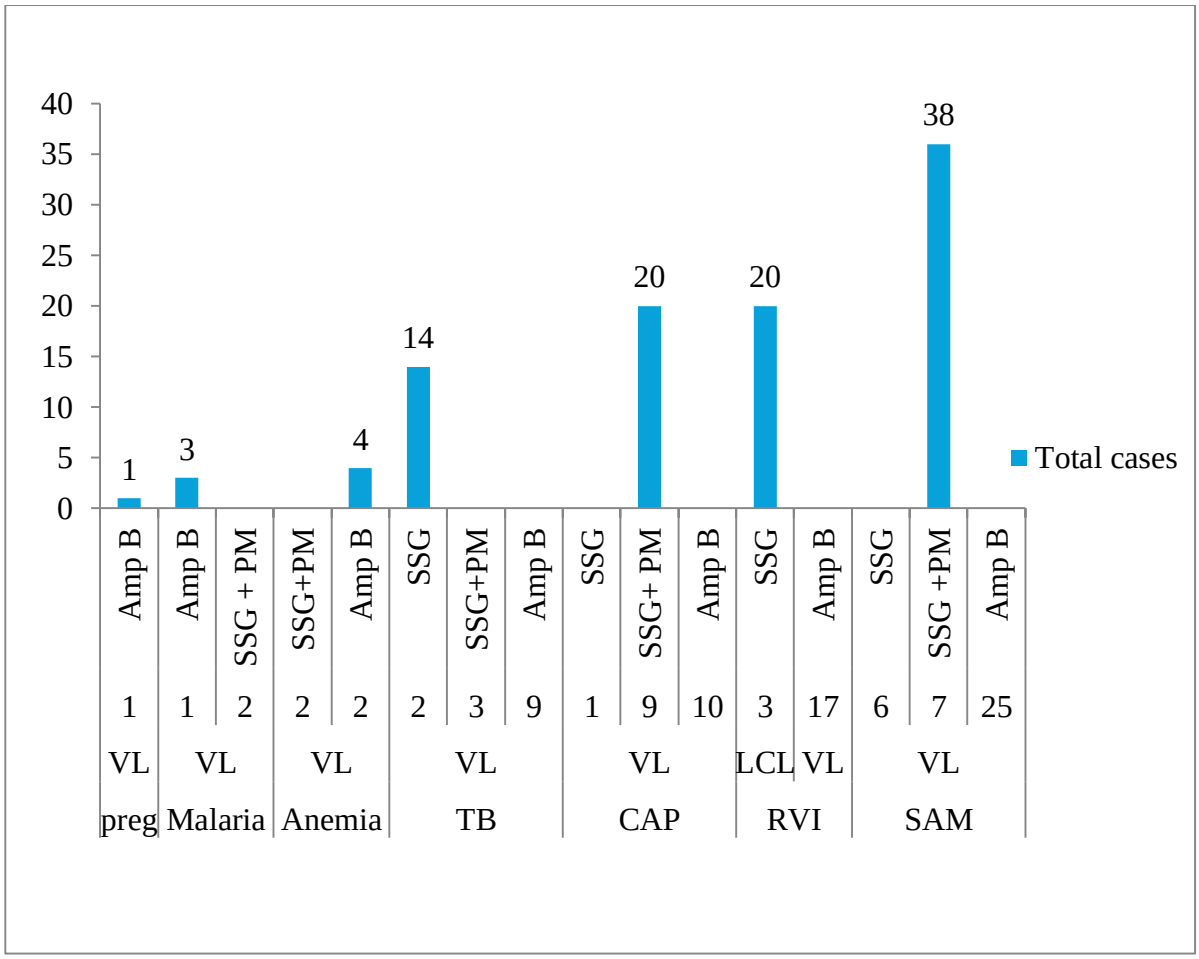
Table 11 indicated that out of 160 leishmaniasis cases treated with amphotericin B only 122(76.2%) received 6 days' standard duration while 25(15.6%) of the cases received the treatment for less than the standard duration. From the total 375 leishmaniasis cases treated with combination therapy of SSG with PM only 316(84.3%) took 17 days' standard duration, out of 600 leishmaniasis cases treated with SSG monotherapy only 314(52.3%) received 30 days standard duration and from the total 12 leishmaniasis cases treated by Paromomycin only 8(66.7) took 20-30 days' standard duration

Table 11: Treatment duration of each regimen for patients treated in health facilities (March 2018- February 2019), Amhara Region.

| Leishmaniasis treatment commodities | Treatment Duration in days | Number of cases | Percent (%) | Standard treatment duration | |
|---|---|---|---|---|---|
| | | | | For primary | For Relapse |
| Amphotericin B | <6 | 25 | 15.6 | | |
| | 6 | 122 | 76.2 | 6 days | 6-14 days |
| | >6 | 13 | 8.1 | | |
| SSG plus PM | <17 | 53 | 14.1 | | |
| | 17 | 316 | 84.3 | 17 days | SSG for 30 days |
| | >17 | 6 | 1.6 | | PM for 17 days |
| SSG | <30 | 157 | 26.2 | | |
| | 30 | 314 | 52.3 | 30 days | 40-60 days |
| | >30 | 129 | 21.5 | | |
| PM | <20 | 4 | 33.3 | | |
| | 20-30 | 8 | 66.7 | 20-30 days | - |
| | >30 | 0 | 0 | | |

### 6.1.2.5 Common Co-Infections with Leishmaniasis and Special groups

Severe acute malnutrition (38), retroviral infection (20), and community-acquired pneumonia (20) were significant co-infections with leishmaniasis in the past one year. Most co-infections were with VL (Figure 6).




*Preg-pregnancy, TB-Tuberculosis, CAP- community-acquired pneumonia, RVI- retroviral infection, SAM-severe acute malnutrition*

Figure 6: Number and types of co-infections, regimen used, and types of leishmaniasis (March 2018 - February 2019), Amhara Region.

## 6.2 Qualitative Findings

In-depth interviews were conducted at EPSA Central, EPSA Gondar, Dessie, and Bahir Dar hubs with program drug distribution officers, FMoH NTDs logistic officer, Amhara Region Health Bureau NTDs logistic officer, and physicians from selected health facilities. From 9 respondents, 8 of them were males and with a mean age of 34.4 years (28 to 45 years). Most of them 6 (66.7%) had a masters' degree. Their mean work experience was 8.2 years (1 to 12 years) (Table 12). Responses from key informant interviews are categorized into four thematic areas.

Table: 12 Characteristics of in-depth interview participates involved in the study

| **Variables** | | **Number** | **percent** |
|---|---|---|---|
| **Sex** | Male | 8 | 88.9 |
| | Female | 1 | 11.1 |
| **Age** | <30 | 2 | 22.2 |
| | 30-35 | 5 | 55.6 |
| | >35 | 2 | 22.2 |
| **Mean number (range) of participants age in years** | | | 34.4(28-45) |
| **Profession** | Pharmacist | 6 | 66.7 |
| | Physician | 3 | 33.3 |
| **Level of education** | Degree | 3 | 33.3 |
| | Master Degree | 6 | 66.7 |
| **Work experience** | <5 | 2 | 22.2 |
| | 5-10 | 4 | 44.5 |
| | >10 | 3 | 33.3 |
| **Mean number (range) of participants work experience in years** | | | 8.2(1-12) |

**Epidemiological Significance of Leishmaniasis in Amhara Region**

Though the number of cases seen in each diagnostic and treatment center in the Amhara Region is decreasing due to the opening of some additional diagnosis and treatment centers, the regional and national burden of leishmaniasis is increasing each year. A high number of leishmaniasis cases screened and treated each year nationally, and most cases are from Amhara Region. These show that the region is highly endemic for leishmaniasis. One physician has illustrated this as follows:

*"Our area is highly endemic for leishmaniasis, but numbers of cases treated in our hospital decrease because the government opens many treatment centers."* (Physician 1)

Another respondent adds on this:

"*The burden of leishmaniasis in the country is increasing from year to year, and the majority of cases are reported from two regions. Amhara region is one of the high burden and endemic regions for leishmaniasis in the country*." (Program Distribution Officer 1)

Since 2006, the government established many treatments and diagnosis centers in the country, especially in the Northern part after the leishmaniasis outbreak in *Libo-kemekem* woreda in 2005. Since then, awareness, diagnosis, treatment and reporting of leishmaniasis cases from health facilities increase from year to year (FMoH, 2016). The reports' from health facilities and leishmaniasis treatment commodities requests' shows the epidemiological significance of leishmaniasis in the region is high and increasing from year to year. One respondent has illustrated this:

*"Health facilities' leishmaniasis case reports and leishmaniasis treatment commodities requests increase from time to time. This shows that the epidemiological significance of leishmaniasis in the area is high and increasing."* (Program Distribution Officer 2)

**The distribution system of NTD commodities and Information**

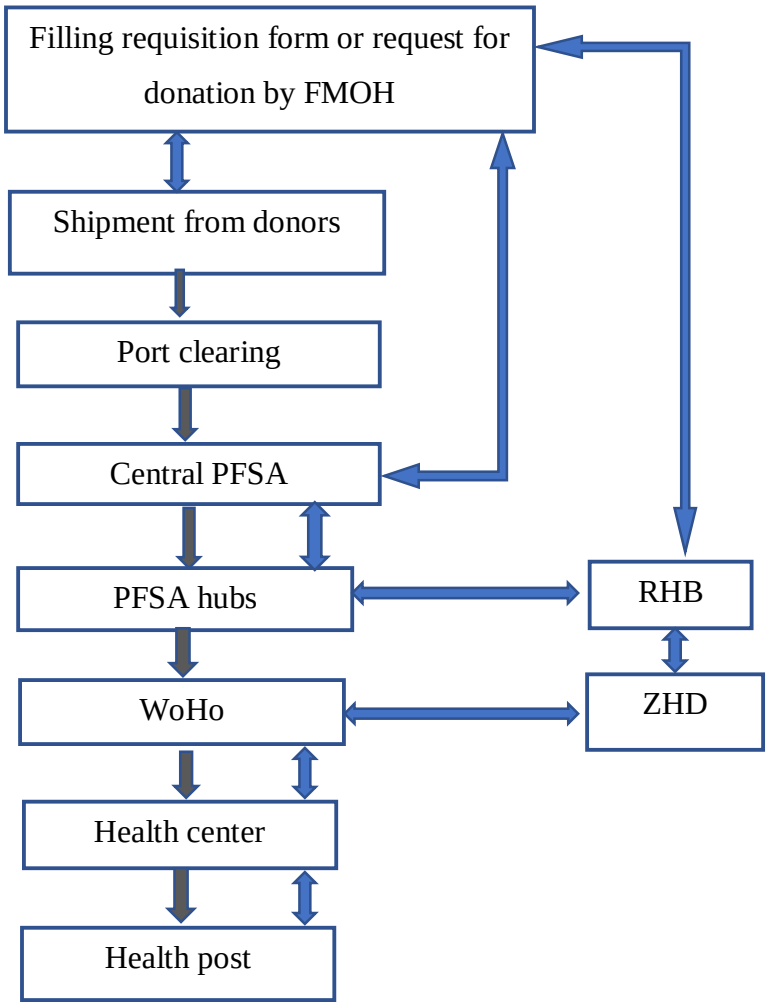



Figure:7 Pharmaceutical medical supplies management chain for NTD (FMoH, 2016)

**The distribution system of leishmaniasis treatment commodities**

In Ethiopia, the distribution of leishmaniasis treatment commodities is unscheduled. FMoH quantifies based on number of leishmaniasis cases screed and treated. Donors, especially WHO procures leishmaniasis treatment commodities based on the FMoH quantification report then distributes it to central EPSA. Central EPSA distributes to EPSA hubs (Gondar, Bahir Dar, and Dessie hubs) based on allocation by FMoH allocation. From each EPSA

hubs, the commodities were distributed to each diagnosis and treatment health facilities based on allocation. The EPSA at all levels is primarily responsible for distribution to diagnosis and treatment health facilities and are used as transient and temporary storage for leishmaniasis treatment commodities. They are not participating in other leishmaniasis treatment commodities management activities i.e. quantification and procurement, and they do not have information about consumption and stock on hand of the health facilities. Stockouts of leishmaniasis treatment commodities are not managed at EPSA hubs. Even if most of the health facilities forward their request for leishmaniasis treatment commodities to EPSA hubs, the hubs were not used the information because leishmaniasis treatment commodities distributions were based on allocation by FMOH. In addition, the hubs do not use the information that health facilities submitted, and refilling is not based on the requested quantity and on time. There is no leishmaniasis treatment commodities buffer stock at EPSA hubs.

Leishmaniasis treatment commodities distribution to health facilities is a challenge because leishmaniasis treatment commodities are a small amount inline item and the program is not integrated. Information and leishmaniasis treatment commodities flow are in different lines (Figure 8). This distribution system is different from NTDs commodities distribution system in the guideline (Figure7). One respondent from Ethiopian pharmaceutical supply agency stated that:

*"Our mandate at EPSA is only to distribute the allocated commodities to health facilities. We are not participating in other supply chain management activities, and HFs consumption information is not using by us. Distribution to health facilities is difficult and unscheduled because the program is not integrated."* (Program distribution Officer 3)

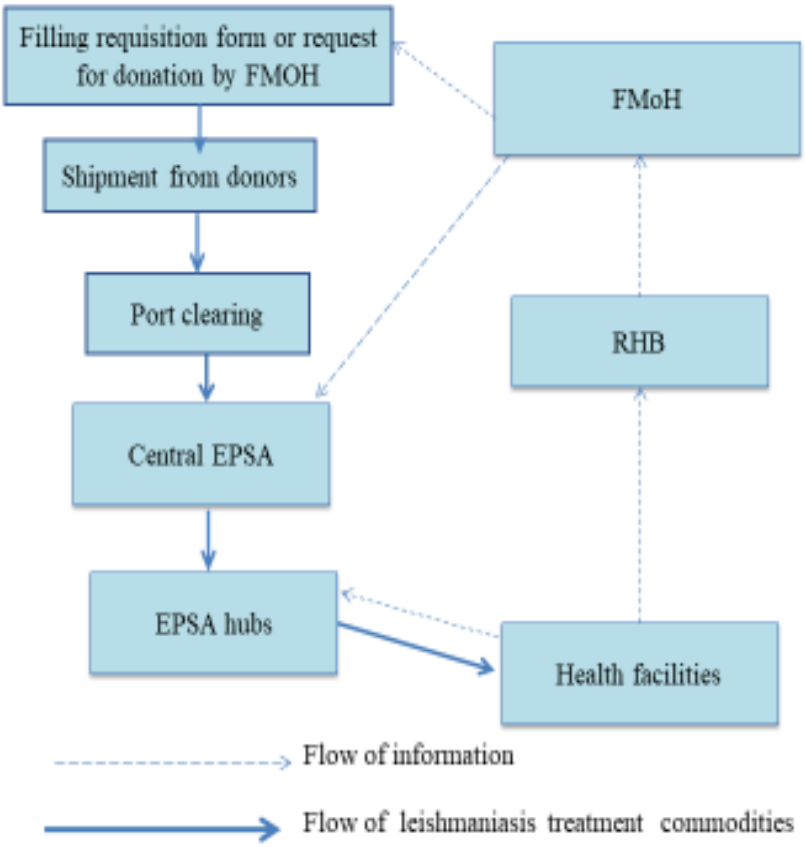



Figure 8: Flow of information and leishmaniasis treatment commodities, Amhara Region, 2019

**Stockout of leishmaniasis treatment commodities**

Health facilities (HFs) frequently experienced stockout of almost all leishmaniasis treatment commodities in the region. Amphotericin B medicines are the most frequently stockout commodities in health facilities that are supposed to handle it. Currently, in Ethiopia, only two options are available for leishmaniasis management. Physicians are forced to shift from one regimen to another because of stockouts. Sometimes leishmaniasis treatment commodities were stocked out at HFs even if available at EPSA stores because

line items are few in making a separate distribution less feasible. This has been stated by one physician that:

*"...only two options are available for disease management that we must return to other options after starting one option due to stockout of commodities like shifting from Amphotericin B to Sodium Stibogluconate with Paromomycin combination therapy including HIV and Leishmaniasis co-infected patients. Sometimes products stockout at health facilities while available at EPSA hubs"* (Physician 2)

Another respondent adds that:

*"----- There is supply interruption in health facilities even while available at EPSA hubs due to difficulty distributing on time alone because leishmaniasis treatment commodities are a small inline item, and the distribution system is irregular. From leishmaniasis treatment commodities, Amphotericin B is frequently stoked out nationally."* (NTDs Logistic Officer 1)

**Challenges and Proposed Solution**

Challenges of leishmaniasis treatment commodities' management are disruption of commodities, lack of buffer stock at EPSA hubs, lack of communication between professionals at different levels, irregular ordering and request, lengthy procurement and distribution system. Most professionals do not know the owner of the program, a limited option to treat the disease like other cases and common stockout of commodities, poor communication and coordination between stakeholders, medicines side effect, poor infrastructure at health facilities i.e., some treatment centers had no separate leishmaniasis ward, unavailability of the committee at EPSA level to manage leishmaniasis treatment commodities and limited supportive organizations like other programs.

Proposed solution from key informant interviews was established easy and short distribution system with the involvement of all stakeholders, integration of the program, improve communication and coordination between stakeholders, more research required to strengthen the program, train the professionals at a different level about the treatment protocol and commodities management, scheduled supportive supervision and follow up for the program.

## 7. Discussion

In this assessment, leishmaniasis treatment commodities management was assessed using indicators. Besides, the number of leishmaniasis cases treated, screened, and treatment practice at health facilities was also assessed.

Reliable and accurate use of bin cards is critical for commodities availability and stock management. Utilization of bin cards and RRF for leishmaniasis treatment commodities were reported in 10(55.6%) of facilities, whereas 11(61.1%) health facilities used IFRR for leishmaniasis treatment commodities. The study results were lower than a national survey conducted on essential pharmaceuticals in which bin card utilization was 73% in hospitals and 64% in health centers, RRF was 97% in all health facilities, and IFRR utilization was 91% and 87% in hospitals and health centers respectively (Shewarega et al., 2015). This might be due to leishmaniasis treatment commodities were a small amount inline items and not integrated like other programs. Besides, most professionals are not seriously managing the commodities, and the follow up by higher-level management has been weak.

Bin cards is considered to be updated if it is updated within the past 30 days or last updated with the balance of 0, and a facility has not received any of those products since the date of that entry (Shewarega et al., 2015). In the present study, 2(40%), 2(66.7%), 1(50%), and 5(50%) of facilities had updated bin cards for SSG, Paromomycin, Amphotericin B and rk39 test kit, respectively. This is different from a study conducted in Addis Ababa Ethiopia on HIV/TB laboratory commodities and a national survey on essential pharmaceuticals in which 60% and 61.5% of facilities had updated bin cards, respectively (Shewarega et al., 2015; Tilahun et al., 2016). This might be due to irregular

distribution leishmaniasis treatment commodities to health facilities and lack of well-organized systems like IPLS for these commodities.

To maintain sufficient availability of commodities in health facilities: maximum months of stock, minimum months of stock, and an emergency order point should be implemented in each health facility (PFSA, 2015). The present assessment indicated that 14 (77.8%) of health facilities experienced one or more commodities stocked out during the last one year. This is higher than an assessment conducted in Pakistan, in which 50 % of the facilities had uninterrupted leishmaniasis treatment commodities (POHA, 2015). Seven (38.9%) health facilities stocked out at least one commodity at the time of the visit. This is different from a supportive supervision report on leishmaniasis treatment commodities in the Amhara region (Bishaw et al., 2017), where most health facilities experienced stockout at least one commodity at the time of the visit. This is due to leishmaniasis treatment commodities that were not managed based on maximum-minimum months of stock and emergency order point method at health facilities in the region.

This study indicated that 2(28.6%) and 4(80%)of facilities were stocked out SSG and Amphotericin B at the time of the visit, respectively. This is lower than the national assessment report, in which SSG and Amphotericin B availability was 2% in the Amhara region at the time of the visit (EPHI, 2016). The difference is due to leishmaniasis treatment commodities distribution system, which is irregular in the Amhara region, and the visit time might be a factor. This study also showed that 42.9% and 100% of health facilities were stocked out with the mean frequency of stockouts as 3.3 and 3.6 for SSG and Amphotericin B in the past one year, respectively. These are higher stocked out than National Survey on IPLS conducted on essential commodities that average availability of

essential selected commodities was 78.1% with a frequency of stocked out 1.5 times in the six months preceding the survey (Shewarega et al., 2015). The discrepancies showed management and follow up for essential pharmaceuticals in the health facilities were stronger than leishmaniasis treatment commodities management and follow up. The study also showed a range of stocked out in days were 0-160, 0-130, 128-192, and 0-180 for SSG, Paromomycin, Amphotericin B, and rk39 test kit commodities, respectively. This is higher than an assessment conducted in Rwanda and Tanzania that essential commodities stockout was at a range of 30-105 and 1-120 days, respectively (Nditunze et al., 2015; MOH and Social Welfare, 2008).

The current study showed that the refill time for most health facilities was 30-60 days. This is higher than a report conducted in Rwanda and a national survey in Ethiopia that average refill days of essential commodities ranged 12-38 days and below 30 days, respectively. This assessment also showed that some facilities' Amphotericin B lead time was more than 90 days after ordering, which had significant difference than this report (Nditunze et al., 2015; Shewarega et al., 2015). The discrepancy might be due to the refill system, where leishmaniasis treatment commodities refill system is irregular in Ethiopia, while essential pharmaceuticals' refill is regular, and facilities can also procure essential pharmaceuticals using revolving drug funds.

The current study showed that 8.6% of Paromomycin and 7% of rK39 test kit were expired in the past one year, while 69.3% and 35.8% of rK39 test kit and Paromomycin from stock on hand quantity were near expiry in health facilities. These showed some facilities were stockout while others overstocked that leishmaniasis treatment commodity expired, and a large number of commodities are near expiry. This result is supported by a supportive

supervision report in the Amhara region, where most rK39 test kits and other commodities were near-expired (Bishaw et al., 2017). The reason might be that commodities allocation for health facilities is based on the number of cases treated and tested in the previous time without considering consumption, stockout duration, and stock on hand. Besides, leishmaniasis treatment commodities' inventory management at health facilities is overlooked by most professionals, and the transfer of commodities for stockout facilities was not done, and there are poor communication and information exchange between health facilities and stakeholders.

Drug resistance is a significant international challenge in leishmaniasis treatment (Rita et al., 2019). Monotherapy and inadequate use of leishmaniasis treatment medicines, either inappropriate regimen or short treatment duration, are some of a serious cause for drug-resistance. The use of combination therapies is less likely to develop resistance than Monotherapy (Ponte-Sucr et al., 2017; Singh et al., 2016). In the Amhara region, the average duration of treatment for leishmaniasis cases in health facilities is not as per the treatment guidelines. This study indicated that only 316(84.3%) patients received combination therapy for 17 days as per the recommendation in the guideline for combination therapy (FMHACA, 2014; FMOH, 2013), while 53(14.1%) of the cases received the treatment for less than the standard duration. The study also showed that from the total 160 leishmaniasis cases treated with Amphotericin B 25(15.6%) of cases received treatment below 6 days' duration, from 600 leishmaniasis cases treated with SSG monotherapy 155(26%) of cases took treatment below 30 days' duration, and from the total 12 leishmaniasis cases treated with Paromomycin 4(33.3%) of cases received treatment below 20 days' duration. These are different from the guideline's recommendations

(FMHACA, 2014; FMOH, 2013). The difference may be due to many reasons, i.e., lack of training for professionals, stockout of medication, and poor practice to the updated treatment protocol. Besides, these indicated that the program's attention, leishmaniasis treatment commodities' distribution, and management were weak and unorganized.

Mostly relapse is occurring in VL with in the first 6 months of the first treatment (FMOH, 2013). This study showed that 20 leishmaniasis patients are co-infected with HIV, and 17(2.8%) of patients were relapsed cases treated in the past year. This is lower than expected from number of VL cases treated, expected number of up to 5% relapse in immune-competent patients, and up to 50% in HIV/VL co-infected individuals (FMOH, 2013). This might be due to the number of HIV/VL co-infection cases is low in the region.

Storing is the secure handling of commodities to avoid damage, expiry, and theft in order to maintain high-quality products. The quality and effectiveness of commodities can be improved by storing pharmaceutical commodities in a good storage setting (PFSA, 2015). This assessment showed that the majority of health facilities did not adhere to the standard storage guidelines. Similarly, a study was done in Addis Ababa stated that the storage of commodities at health facilities was inadequate (Berhanemeskel et al., 2016). The current study indicated 16(88.9%) of facilities stored products protected from water and humidity, and separately from insecticides and chemicals. This proportion is smaller as compared to the result shown in a study conducted in Addis Ababa, where 100% of HFs stored products separately from insecticides and chemicals (Tilahun et al., 2016). This assessment also indicated that 87.9% of primary hospitals stored products in the FEFO manner. This is similar to a study conducted in Addis Ababa on IPLS implementation that 88.3% of facilities adhere to the FEFO system (Tilahun et al., 2016). If the facilities fulfilled at least

80% of storage conditions as stipulated in the guideline, the facilities' storage condition is adequate (PFSA, 2017). The present assessment showed that only two facilities fulfilled the minimum criteria (88.2% and 94.1%). The percentage of facilities that maintain acceptable storage conditions for leishmaniasis treatment commodities in the Amhara region was 11.11%, which is inadequate.

## 8. Limitation of the Study

The study's quality depends on the accuracy of the documentation system in health facilities and the study was conducted in Amhara regional state only.

# 9. Conclusion and Recommendations

## 9.1 Conclusion

Leishmaniasis treatment and diagnosis services started in Ethiopia a long time ago. However, the management for leishmaniasis treatment commodities is still not organized. The present study indicated that most health facilities had poor practice in inventory management of leishmaniasis treatment commodities. One or more commodities were stocked out at least once in last year for fourteen (77.8%) of health facilities. Of all leishmaniasis treatment commodities, Amphotericin B was the most frequent stockout commodity in the health facilities. Some patients took treatment below the recommended duration which is contrary to established treatment guidelines. The storage condition of most health facilities were inadequate, and there were expired and a large number of near expiry products in the health facilities.

## 9.2 Recommendations

- ARHB and stakeholders should improve leishmaniasis treatment commodities distribution system by involving all levels in the system.
- FMoH and central EPSA should available safety stock at Ethiopian pharmaceutical supply agency branches.
- Health facilities' management and professional should improve leishmaniasis treatment commodities management to improve its quality and efficacy by decreasing expirations.
- Health facilities should develop system for transferring commodities before they expire to other facilities providing similar service.
- FMoH and partners should integrate the program for better availability and management of leishmaniasis treatment commodities.

- All health professionals involved in treatment practices should implement the updated treatment protocol.
- ARHB and FMoH should conducted regular supportive supervision and follow up to improve the leishmaniasis treatment commodities management and treatment pattern.

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# 11. Annex

## I. Questionnaire

Assessment of leishmaniasis treatment commodities' management and treatment pattern in public health facilities of Amhara Region, Ethiopia Data Collection Tool

"Good day. My name is _______. My colleague and I representatives of this research team. We are conducting a survey regarding leishmaniasis treatment commodity management system to determine the availability of commodities, treatment pattern and challenges of leishmaniasis treatment commodity management and treatment pattern. We are looking at the availability of leishmaniasis commodities and information about how you order and receive those products. We are visiting selected health facilities throughout the region; this facility was selected to be in the survey. The objectives of the survey are to collect current information on commodity management and treatment pattern performance and stock status of leishmaniasis commodities. This is not a supervisory visit and the performance of individual staff members is not being evaluated. The results of this survey will provide information to EPSA, FMoH, ARHB and stakeholders to make decisions and to promote improvements. All of the information collected is strictly confidential. We will not refer to individual facilities in the report, but rather will describe the overall picture of all facilities. Do you have any questions? May we proceed?

First, ask the following questions of the person in-charge or pharmacy head/store manager. After asking questions visit the storeroom, or storage area where the leishmaniasis commodities are managed. If you are referred to another staff member for the stocktaking exercise, introduce the survey goals and objectives as you did during the introduction. Hand the respondent the list of products that are included in the survey, and explain that we will refer to the list for some of the following questions.

Assessment form 1: Facility Services and Infrastructure

| **No** | **Facility Identification** | **Code classification** | **Comments** |
|---|---|---|---|
| 01 | Name of the facility _____ | | |
| 02 | Region _____ | | |
| 03 | Zone _____ | | |
| 04 | Woreda_____ | | |
| 05 | City/town: _____ | | |
| 06 | Supplying Hub: _____ | | |
| 07 | Facility Code: _____ | | |
| 08 | Types of center | Treatment center------1<br>Diagnosed center------2 | |
| 09 | Type of facility | Health center --1<br>Primary Hospital—2<br>General hospital---3<br>Referral hospital----4 | |
| 10 | Types of service | VL----1<br>CL-----2<br>Both VL and CL-----3 | |

Assessment form 2: Public health facility pharmacy/dispensary

Facility: _____ Date: _____ Region: _____

Data collector: _____ Public Health Facility #_____

**Background Characteristics of the Respondent**

| **No** | **Question** | **Code Classification** | **Comments** |
|---|---|---|---|
| 01 | Can we continue? | Yes_____ 1<br>No----------0 | |
| 02 | Title of person interviewed for this survey | Title:_____ | |
| 03 | Number of years and months you have worked at this facility? | Years: _____<br>Months: _____ | |
| 04 | Are you the principal person responsible for managing drugs and medicine products at this facility? | Yes_____ 1<br>No----------0 | |
| 05 | Who is the principal person responsible for managing leishmaniasis commodities at this facility? | Nurse---------- 1<br>Clinical Officer----------2<br>Pharmacy Technician------- 3<br>Pharmacist---------- 4<br>Medical Assistant----------5<br>Other (Specify) ----------9 | |
| 06 | Is the principal person trained for commodity management? | Yes ------1<br>No---------0 | |

Assessment form 3: Public health facility pharmacy/dispensary

Facility: _____ Date: _____ Region: _____

Data collector: _____Public Health Facility #_____

**Inventory management of leishmaniasis commodities**

| No. | Questions | Code Classification | Comments |
|---|---|---|---|
| 1 | Do you use stock keeping logistic forms for leishmaniasis treatment commodities | Yes ----------1<br>No----------0 | |
| 2 | What stock keeping logistic forms do you use for leishmaniasis treatment commodities? | | |
| | A. Stock card/bin card/inventory control card | Yes-------1<br>No---------0 | |
| | B. Stock ledger | Yes--------1<br>No---------0 | |
| | C. others | Yes--------1 No---------0 | |
| 3 | What LMIS forms do you use for reporting/ordering of leishmaniasis treatment commodities? | | |
| | A. RRF | Yes_____ 1<br>No---------- 0 | |
| | B. IFRR | Yes_____ 1<br>No---------- 0 | |
| | C. other | Yes (specify)------1<br>No---------- 0 | |

| | | | |
|---|---|---|---|
| 4 | Do LMIS report forms include the following? | | |
| | A. stock on hand | Yes_____ 1<br>No----------0 | |
| | B. quantities used | Yes_____ 1<br>No----------0 | |
| | C. losses and adjustments | Yes_____ 1<br>No----------0 | |
| 5 | Does a completed LMIS report include the following? (must be verified with completed report) | | |
| | A. stock on hand | Yes_____ 1<br>No---------- 0<br>Completed report not available--------9 | |
| | B. quantities used | Yes_____ 1<br>No---------- 0<br>Completed report not available------ 9 | |
| | C. losses and adjustments | Yes _____1<br>No----------0<br>Completed report not available------ 9 | |
| 6 | How often are these LMIS reports | Monthly----------1 | |

| | | | |
|---|---|---|---|
| | sent to the higher level? | Bimonthly-------2<br>Quarterly----- 4<br>Semi-annually------- 5<br>Annually----------6<br>Others ----------9 | |
| 7 | When was the last time you sent an order/report for leishmaniasis commodities at this facility? | Never -------1<br>Within the last month-----2<br>2 months ago ----------3<br>3 months ago ----------3<br>More than 3 months ago ----4 | |
| 8 | How the LMIS report sent? | Separately----------1<br>Integrate with other program---2<br>Others---------3 | |
| 9 | Does the commodities refill based on request on time? | Yes---------1<br>No----------0 | |
| 10 | On average, approximately how long does it take between | Less than 1 month------1 | |

| | | | |
|---|---|---|---|
| | ordering and receiving of leishmaniasis treatment commodities? | 1 month to 2 months -----2<br>Between 2 and 3 months -----3<br>More than 3 months -------4 | |
| 11 | How did you learn to complete the forms/records used at this facility? | During a logistics workshop ---1<br>On-the-job training ---------2<br>Never been trained-----3<br>Other (specify)_____9 | |
| 12 | How many emergency orders for leishmaniasis commodities have you placed in the last 1 year? | None-------0<br>1----------1<br>2----------2<br>3----------3<br>More than 3-------4<br>NA------9 | |
| 13 | Who determines this facility's resupply quantities? | The facility itself -----1<br>Higher-level facility --2<br>Other---------9 | |
| 14 | How are the facility's resupply | Formula (any calculation) | |

| | | | |
|---|---|---|---|
| | quantities determined? | -- 1<br>Don't know ---------2<br>Other means-------9 | |
| 15 | When did you receive your most recent supervision visit?<br>***Check visitors book, if necessary.*** | Never received-------1<br>Within the last month -----2<br>1 - 3 months ago--------3<br>3 - 6 months ago -------4<br>More than 6 months ago ------5<br>Other (specify) ---------9 | |
| 16 | Did your last supervision visit include drug management (e.g., stock cards checked, reports checked, expired stock removed, storage conditions checked)? | Yes---------- 1<br>No-------- 0<br>Don't know------ 9 | |
| 17 | Do you have a functioning refrigerator(s) to store Amphotericin B (liposomal)? | Yes---------- 1<br>specify number_____<br>No---------- 0<br>*Not applicable*--------9<br>_____ | |
| 18 | To record the actual temperature, look at the internal thermometer | Temperature (in | |

| | | | |
|---|---|---|---|
| | inside the refrigerator—ideal temperature is between 0 and +8 degrees centigrade. (Note if thermometer is broken or missing.) | centigrade) _____ | |
| 19 | Are refrigerators located away from any surrounding objects (approximately ½ meter)? | Yes---------- 1<br>No---------- 0 | |
| 20 | Is the temperature chart up-to-date? (to be up-to-date, there must be an entry for the day before the visit). | Yes---------- 1<br>No----------0<br>..... | |

Assessment form 4. Product availability (stock status) (Yes-------1, No--------0)

Facility: _____ Date: _____Region: _____Data collector: _____Public Health Facility #_____

| Products | Units of count | Managed at this facility? | Physical inventory | Stock out today? | Quantity of expired products | Bin card available? | Bin card updated? | IFRR Used | Schedule IFRR used | RRF used | Balance on bin card | Stock out most recent one year | Number of stock outs | Total number of days stocked out | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SSG | | | | | | | | | | | | | | | |
| PM | | | | | | | | | | | | | | | |
| Amp B | | | | | | | | | | | | | | | |
| rK 39 | | | | | | | | | | | | | | | |

- **Quantity of products received in the past one year.**

1. SSG----------vial
2. PM----------ampoule
3. Amphotericin B ----------ampoule
4. Rk39----------kit

- **Stock on hand**

1. SSG ---------- Vial, Exp date ---------- Bach number ----------
2. PM ---------- Amp, Exp date ---------- Bach number ----------
3. Amp B ----------Vial, Exp date ---------- Bach number----------
4. rK39 ---------- kit, Exp date ----------Bach number ----------

Assessment form 5. Storage Conditions (PFSA, 2017)

Facility: _____ Date: _____ Region: _____

Data collector: _____Public Health Facility #_____

All facilities should be assessed for products that are ready to be issued or distributed to SDPs and for store rooms in all SDPs. Place a check mark in the appropriate column based on visual inspection of the storage facility; note any relevant observations in the comments column. To qualify as "yes," all products and cartons must meet the criteria for each item.

| No | Description | Yes = 1, No=0 | Comment |
|---|---|---|---|
| 1 | Products that are ready for distribution are arranged so that identification labels and expiry dates and/or manufacturing dates are visible. | | |
| 2 | Products are stored and organized in a manner accessible for first-to-expire, first-out (FEFO) counting and general management. | | |
| 3 | Cartons and products are in good condition, not crushed due to mishandling. If cartons are open, determine if products are wet or cracked due to heat/radiation (fluorescent lights in the case of condoms, cartons right-side up) | | |
| 4 | The facility makes it a practice to separate damaged and/or expired products from usable products and removes them from inventory. | | |
| 5 | Products are protected from direct sunlight. | | |
| 6 | Cartons and products are protected from water and humidity. | | |
| 7 | Storage area is visually free from harmful insects and rodents. (Check the storage area for traces of bats and/or rodents [droppings or insects].) | | |

| | | | |
|---|---|---|---|
| 8 | Storage area is secured with a lock and key, but is accessible during normal working hours; access is limited to authorized personnel. | | |
| 9 | Products are stored at the appropriate temperature according to product temperature specifications. | | |
| 10 | Roof is maintained in good condition to avoid sunlight and water penetration. | | |
| 11 | Storeroom is maintained in good condition (clean, all trash removed, sturdy shelves, organized boxes). | | |
| 12 | The current space and organization is sufficient for existing products and reasonable expansion (i.e., receipt of expected product deliveries for foreseeable future). | | |
| 13 | Fire safety equipment is available and accessible (any item identified as being used to promote fire safety should be considered). | | |
| 14 | Products are stored separately from insecticides and chemicals. | | |
| 15 | Products are stacked at least 10 cm off the floor. | | |
| 16 | Products are stacked at least 30 cm away from the walls and other stacks. | | |
| 17 | Products are stacked no more than 2.5 meters high. | | |

Assessment form 6. Number of cases screened from January 2016 - December 2018

Facility: _____ Date: _____ Region: _____

Data collector: _____ Public Health Facility #_____

| **No** | **Years** (G.C) | **Methods** | **Positive cases** | **Negative cases** | **Total** | **comments** |
|---|---|---|---|---|---|---|
| 1 | 2016 | rK39 | | | | |
| | | SST | | | | |
| | | ASP | | | | |
| 2 | 2017 | rK39 | | | | |
| | | SST | | | | |
| | | ASP | | | | |
| 3 | 2018 | rK39 | | | | |
| | | SST | | | | |
| | | ASP | | | | |

*ASP-aspiration SST_ skin smear test*

Assessment form 7. Total Number of cases treated from January 2016 – December 2018

Facility: _____ Date: _____ Region: _____

Data collector: _____ Public Health Facility #_____

| **No** | **Leishmaniasis type** | **Years(G.C)** | | | **comments** |
|---|---|---|---|---|---|
| | | **2016** | **2017** | **2018** | |
| 1 | Visceral leishmaniasis(VL) | | | | |
| 2 | Localized cutaneous leishmaniasis (LCL) | | | | |
| 3 | Diffused cutaneous leishmaniasis(DCL) | | | | |
| 4 | Mucocutaneous leishmaniasis(MCL) | | | | |
| 5 | Post kalazar dermal leishmaniasis(PKDL) | | | | |

Assessment form 8. Medication use assessment

1. Health facility name----------Card number----------
2. Age----------Sex----------KG----------Kebele----------
3. Indication or Dx ---------- a. Primary b. Relapse

b. leishmaniasis type----- a. VL (1) b. LCL (2) c. MCL (3) d. DCL(4) e. PKDL(5)

c. other indication----------

4. medications

i. At admission (leishmaniasis starting medication)

a. SSG+PM (1) duration--------days d. Amphotericin B (4) duration-----days

b. SSG (2) duration----------days c. PM(3) duration----------days

ii. Is there any discontinued medication? a. Yes-------1 b. No------0

iii. If there is discontinued medication

a. What is the medication?

1. SSG + PM (1) 3. PM (3)
2. SSG (2) 4. Amphotericin B (4)

b. The reason for discontinuation----------

iv. Is there any added medication? A. Yes-------1 B. No ------0

v. If there is added medication

a. What is the medication

1. SSG + PM (1) ----------days 3. PM (3) ----------days
2. SSG (2) ----------days 4. Amphotericin B (4) ----------days

vi. Is the patient: a. referred in? i. Yes-----1 ii. No-------0

1. Reason for referred in----------

b. Referred out? i. Yes-----1 ii No------0

2. Reason for referred out----------

**II. Semi structured guiding for key informant interview (English Version)**

Introduction

I want to thank you for taking time to meet with me today. My name is Basazinew Mekuria. I came from Addis Ababa University School of Pharmacy attending a post graduate study in Health supply chain management. I am the principal investigator for the study entitled "Assessment of leishmaniasis treatment commodities management and treatment pattern in public health facilities of Amhara Region, Ethiopia". And I would like to talk with you about significance of leishmaniasis, flow of information and commodities, shortage of commodities and challenges. The aim of this study is to assess leishmaniasis treatment commodities management system and treatment pattern in public health facilities of Amhara Region. Considering that the findings and recommendations emanated from this study will help the policy makers and other organizations to design intervention activities, you are kindly requested to participate in this study. The interview should take less than an hour. I will be taping the session because I don't want to miss any of your comments. Although I will be taking some notes during the session, I can't possibly write fast enough to get it all down. Because we're on tape, please be sure to speak up so that I don't miss your comments. All responses will be kept confidential. This means that your interview responses will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the respondent. Remember, you don't have to talk about anything you don't want to and you may end the interview at any time.

Are you willing to participate in this interview? ☐ Yes ☐ No

If yes, the interview will be continued

Assessment form 9: Key Informant interview guide

Facility: _____ Date: _____ Region: _____

**a. Back ground information of the key informant**

1. Age----------
2. Sex----------
3. Position in HF----------
4. work experience----------
5. Educational level----------
6. Profession----------

**b. Key Informant interview guide**

- How do you see the epidemiological significance of Leishmaniasis in your area?
- How do you assess the leishmaniasis treatment commodities supply system in the country, region and local?
  - Ownership on leishmaniasis treatment commodities management?
  - Leishmaniasis treatment commodities distribution to service delivery point? (Probe: Periodically, with other products, based on order…, flow of information and product at different level).
  - Shortages of medicines? Other supplies?
- What are the main leishmaniasis treatment commodities management challenges? Proposed solutions?

- Any additional comment?

Thank you for your time

አዲስ አበባ ዩኒቨርሲቲ

የፋርማሲ ትምህርት ቤት

የፋርማሲዩቲክስና ሶሻል ፋርማሲ ዲፓርትመንት

በአማራ ብሔራዊ ክልላዊ መንግስት ባሉ ጤና ተቋማት ዉስጥ ያለውን የሌሽማኒያሲስ መድኃኒት አስተዳደር እና የሌሽማኒያሲስ ሕክምና አገልግሎት ሁኔታን በተመለከተ ከሚመለከታቸው አካላት ጋር የሚደረግ ቃለ-መጠይቅ የተዘጋጀ መመሪያ።

መግቢያ ጤና ይስጥልኝ ስሜ ባሳዝነው መኩሪያ ይባላል። በአሁኑ ሰዓት በአዲስ አበባ ዩኒቨርሲቲ የመድኃኒት ሰንሰለት አስተዳደር የሁለተኛ ዲግሪ ተማሪ ስሆን በአማራ ብሔራዊ ክልላዊ መንግስት ባሉ ጤና ተቋማት ዉስጥ ያለውን የሌሽማኒያሲስ መድኃኒት አስተዳደር እና የሌሽማኒያሲስ ሕክምና አገልግሎት ሁኔታን የሚገመግመው ጥናት ዋና ተመራማሪ ነኝ። በመጀመሪያ ውድ ጊዜዎን ሰውተው ለቃለ መጠይቁ ፍቃደኛ ስለሆኑልኝ ከልብ አመሰግናለሁ።

የዚህ ጥናት ዋና ዓላማ በአማራ ብሔራዊ ክልላዊ መንግስት ባሉ ጤና ተቋማት ዉስጥ ያለዉን የሌሽማኒያሲስ መድኃኒት አስተዳደር እና የሌሽማኒያሲስ ሕክምና አገልግሎት ሁኔታን ማወቅ እና በሌሽማኒያሲስ መድኃኒት አስተዳደር እና በሌሽማኒያሲስ ሕክምና አገልግሎት አሰጣጥ ሂደት ውስጥ ያጋጠሙ ችግሮችን ማወቅ እና መለየት ነው። ይህ ደግሞ ወደፊት ፖሊሲ አውጪዎች እና ሌሎች ጉዳዩ የሚመለከታቸው አካላት አስፈላጊውን የማሻሻያ እርምጃ እንዲወስዱ ከፍተኛ አስተዋፅኦ ያደርጋል:: በመሆኑም በጤና ተቋማቹ ውስጥ የተገለፀውን ሁኔታ በሚመለከት ያለዎትን የግል አስተያየት በግልፅ እንዲነግሩኝ በአክብሮት እንጠይቃለሁ።

በቃለ-መጠይቁ ወቅት የሚያነሱዋቸውን ነጥቦች ሙሉ በሙሉ ለማስቀረት ይረዳን ዘንድ የርሶ ፍቃድ ከሆነ ይህ ቃለ-መጠይቅ በመቅረጸ-ድምጽ የሚቀዳ ይሆናል። ይህም በመሆኑ ድምፅዎን በሚሰማ መልኩ ጮክ ብለው እንዲናገሩ አሁንም በማክበር እጠይቃለሁ። ይህም ከጊዜዎት ከአንድ ሰዓት ያልበለጠ ጊዜ ይወስዳል። በዚህ የቃለ-መጠይቅ ሂደት የሚገኙ ማናቸውም መረጃዎች በምስጢር የሚጠበቁ ይሆናል። ይህም ማለት የሚሰጡንን መረጃ ከጥናት ቡድኑ አባላት ውጭ ለማንም ግልፅ የማናደርግ ሲሆን የሚዘጋጁት የቃለ መጠይቁ ዘገባዎችም እርስዎን እንደመረጃ ሰጪ የማይጠቅሱ ይሆናል። እርስዎ መናገር ስለማይፈልጉት ነገር ለመናገር እንደማይገደዱ እና ቃለ-መጠይቁን በማንኛውም ጊዜ ማቋረጥ እንደሚችሉም ላስታውስዎት እወዳለሁ። በቃለ- መጠይቁ

ለመሳተፍ ፍቃደኛ ነዎት? አዎ _ አይደለሁም በቃለመጠይቁ ለመሳተፍ ፍቃደኛ ከሆኑ ቃለ-መጠይቁ ይቀጥላል::

1. **የመነሻ መረጃ**

1.1. እድሜ _____ 1.2. ፆታ _____

1.3. የትምህርት ደረጃ _____ 1.4. የስራ ልምድ _____

1.5. የስራ ድርሻ _____ 1.6. ሙያ _____

2: **ቃለ-መጠይቅ መረጃ መሰብሰቢያ ነጥቦች /የመነሻ ጥያቄዎች**

2.1. እርሶ በሚሰሩበት አካባቢ የሌሽማኒያሲስ በሽታ ስርጭት ሁኔታን እንዴት ያዩታል?

2.2. በአካባቢዎ፣ በክልሉ ብሎም በሀገሪቱ ያለዉን የሌሽማኒያሲስ ህክምና የመድኃኒት ግባት ስርዓትን እንዴት ይገመግሙታል ወይም ያዩታል?

ሀ. የሌሽማኒያሲስ ህክምና መድኃኒቶችን በባለቤትነት የሚያስተዳድር አካል ማን ነዉ?

ለ. የሌሽማኒያሲስ ህክምና መድኃኒቶች ወደ ጤና ተቋማት ያለዉ ስርጭት ምን ይመስላል?

(በፕሮግራም፣ ከሌሎች መድኃኒቶች ጋር፣ በትዕዛዝ ሲጠየቅ ፣….)

ሐ. በየደረጃዉ ያለዉ የመረጃ እና የመድኃኒቶች ፍሰት ምን ይመስላል?

መ. የሌሽማኒያሲስ ህክምና መድኃኒቶች እና ሌሎች ግባቶች እጥረት ምን ይመስላል?

2.3 የሌሽማኒያሲስ ህክምና እና መድኃኒቶች አስተዳደር ላይ የሚያጋጥሙ ዋና ዋና ፈተናዎች ምን ምን ናቸዉ? የሚወሰዱ የመፍትሔ እርምጃዎችስ?

የሚሰጡት ተጨማሪ አስተያየት ካለዎት?

ስለትብብራችሁ ከልብ አመሰግናለሁ።

## III. Ethical Clearance

አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

ፋርማሲትምህርትቤት
የኢትዮጵያሪቪውቦርድ

School of Pharmacy
Ethical Review Board

ቀን Date: March 04, 2019

ቁጥር Ref. No: ERB/SOP/49/02/2019

To: **BasazinewMekuria**
School of Pharmacy

Re: **Ethical Clearance**

It is to be recalled that you submitted a study proposal entitled ***"Assessment of anti-leshmaniasis commodities management in public health facilities of Amhara Region, Ethiopia"*** for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Arebulssa
Chairperson, ERB

00251156 07 12 1176 ቴሌፋክስ Telex: 21205 ፋክስ Fax: 00251(11)1558568 ቴሌግራም Cable: AAUNIV