

Assessment of Medicines Expiry and its Contributing Factors in  
Public Health Facilities of South Gondar Zone, Amhara Region,  
Ethiopia



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This is to certify that the thesis prepared by Abraham Nigussie, entitled: ‘Assessment of Medicines Expiry and Its Contributing Factors in Public Health Facilities of South Gondar Zone, Amhara Region’ 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 with respect to originality and quality.

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## Abstract

### **Assessment of Medicines Expiry and its Contributing Factors in Public Health Facilities of South Gondar Zone, Amhara Region, Ethiopia**

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**Addis Ababa University, 2020**

**Introduction:** High availability of expired medicine is not only a burden to a health care system but it also shows existence of a supply chain gap. So, it is imperative to explore contributing factor for expiry at each stage of the supply chain. In Ethiopia, although there are reports that reveal the presence of expired medicines in the country, information on the type and extent of medicines expired as well as its contributing factor and disposal methods is scanty. The objectives of this study were therefore, to determine extent (including financial value) and type of expired medicines, to explore the reasons for expiry and to assess disposal practice of expired medicines in the health care facilities of South Gondar Zone.

**Methods:** A sequential explanatory mixed method where a descriptive cross-sectional study complemented by using qualitative approach was conducted from July 8-2017 to July 7-2018. For the quantitative part, Microsoft excel was applied for the analysis. For the qualitative part, data was collected through in-depth interview with the key informants and analyzed thematically. Previous records or reports of expired medicines in all health facilities were used to determine the type and financial value of expired medicine that were received by health facilities of South Gondar Zone during the fiscal year 2017/18. Eighteen key informants were also interviewed to explore main reasons for medicines expiry within the health facilities and the disposal practices applied.

**Results:** Medicines worth of 2,304,830.51 Ethiopian birr were expired in public health facilities of South Gondar during the study period, giving expiry rate of 6.45 %. Of these, anti-infectives were the most commonly expired group of medicines. Medicines delivered for various programs particularly for HIV/AIDS had the highest share in medicines expiry in term of value. Delivery of medicines through push system, delivery of near to expire medicines by supplier, and lack of communication and coordination in the health facilities were identified as major reasons for medicines expiry. Burning of unused medicines in open container and pouring iv fluids into the hole were commonly used methods to disposed unused medicines.

**Conclusion:** To reduce expiry: making delivery based on consumption that has longer shelf life with most effective communication between health care structures should take to promote regular supply, and rational use of medicines. Disposing expired medicine by adhering to the national standard on drug management protocols to stop contamination.

Keyword: Expired Medicine, Medicine Wastage, Disposal Methods, Public Health Facility, Ethiopia.

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## Abbreviation and acronyms

APTS	Auditable Pharmaceuticals Transaction and Service
ARHB	Amhara Regional Health bureau
ART	Anti-Retroviral Therapy
ARV	Anti-Retro Virus
ATC	Anatomical Therapeutic Category
CSA	Central Statics Agency
DTC	Drug and Therapeutics Committee
EFY	Ethiopian Fiscal Year
EPSA	Ethiopian Pharmaceutical Supply Agency
ETB	Ethiopian Birr
FEFO	First Expire First Out
FMHACA	Food, Medicine and Health Care Administration and Control Authority
FMOH	Federal Ministry of Health
GMOH	Ghana Ministry of Health
MSH	Management Science for Health
NAFDAC	National Agency for Food and Drug Administration and Control
NGO	Non-Governmental Organization
NMOH	Ministry of Health, Nigerian
OOP	Out of Pocket
RRF	Reorder Requesting Form
RDF	Revolving Drug Fund
SIAPS	System for Improved Access to Pharmaceuticals and Services

UNHCR	United Nation High Commissioner for Refugees
USAID	United State of America for International Development
WHO	World Health Organization
ZHD	Zonal Health Department

## **1. Introduction**

### **1.1. Background**

Medicines are substances intended to be used within the diagnosis, cure, mitigation, treatment, or prevention of disease and they play a major role in protecting, maintaining, and restoring people's health (WHO, 2008). Therefore, an uninterrupted supply of quality-assured medicines is critical for the continual delivery of health care services to patients by health facilities (Ejigu et al., 2012). However, the availability of medicines is a global concern until now.

Medicines comprise a major proportion of healthcare expenditure. According to the World Health Organization (WHO), the highest expense in each health care system in every country was money spent to avail medicines second to staff cost (WHO, 2006). Forty to sixty percent of the public sector health budget in any country is spent on buying medicines (Pérez-Casas et al., 2001). In Ethiopia, government expenditure for medicines in US\$ for the year 2009EFY was 148, 075,215.81 (WHO and EU, 2017) and the main cost drivers for primary hospitals are medicines and supplies, it accounts for 35% of the entire expenditure and is that the second higher expenditure next to human resources (FMOH, 2016). Even with spending such amount of resources, accessibility of essential medicines cannot attain for one-third of the world population, particularly up to one and a half in Asia and Africa (Hafeez et al., 2004).

In the activity of availing medicine to the client, there is a probability of medicine which will be damaged or expired and become unsafe for use (Ejigu et al., 2012). These medicines not dispensed to patients and those identified to be no use for patients, and leading to storing unfit for use medicines within the facility (Tong et al., 2011).

Many countries found in both the developed and developing world are suffering from revenue lost by the wastage of medicines (Sauls, 2016). Medicines wastage especially thanks expiry has been reported as one of the most important causes of a rise in health care costs (Dias, 2011). Within the United State of America and Switzerland, wastage rates due to expire are estimated at 16% and 29% respectively, with over \$1 billion (Toerper, et al., 2014) and \$436 million lost annually (Vogler et al., 2014).

Studies looking at revenue loss due to expired medicines are few in developing countries. In Ghana, 10% of the public dispensaries had expired medicines (Arhinful, 2009) and studies done in Nigerian in 2002 showed that from the available forty-six percent (46%) of key medicines, seven (7%) of them were expired (NMOH and WHO, 2002). In Ethiopia, there are large revenues lost due to the expiry of medicines, report during assessment baseline data for APTS indicated that the total value of medicines wasted in birr was 3,281,562.20 Ethiopian Birr (ETB) on 2004 E.C a by six hospitals, and 6,254,856.31 ETB of medicines on 2005E.C at eight of study hospitals (Tadeg et al., 2014).

Medication disposal is a hot topic in pharmacy today and it is rapidly gaining the attention of professionals and consumers. Medication wastes pose an environmental and a public health risk (Chasler and Subramaniam, 2011) since it increases the chance of uncontrolled use of the medication and subsequent poisoning, contribute to the development of antibiotic resistance and interfere with human hormonal system (Jonjić and Vitale, 2014; Barnett-Itzhaki et al., 2016). The environmental impact of improper medication disposal is expected in countries with poorly functioning waste management schemes: Middle Eastern, Asian and African countries (Paut Kusturica et al., 2017). Lack of proper mechanism to handle medication waste seems to be the main reason behind substandard medication waste management in developing

countries (Bound and Voulvoulis, 2005). This study aims to investigate the cause(s), extent, costs of drugs expiration, practice of disposal and drugs that are prone to expire in different public health facilities pharmacies.

## 1.2. Statements of the problem

Medicines and their management are a very important health system function. However, the shortage and expiry of essential medicine are still one of the foremost serious public health challenges (Tumwine et al., 2010). Medication wastage thanks to expiring at the health facilities might be a huge concern due to the wastage of potential useful medication additionally as costs related to the disposal of these medications (Daughton, 2003).

The expiry of medicines leads to significant wastage of resources which may cause reducing the availability of medicine. In countries that had a scarce resource for purchasing and delivery of medicine, the expire of medicines reduces the amount of medicines available to patients and the quality of health care they receive (Braund et al., 2009). Ethiopia is one of the countries with scarce resources that are struggling with health financing options, with a big number of the poor unable to afford out of the pocket health care. And it results in financial catastrophe to households due to out-of-pocket expenses resulting from a scarcity of access to medicines at a public health facility (Fenta et al., 2016). Therefore, inequitable access to medicines further highlights the necessity to continuously identify strategies to scale back avoidable expiry within the planning of medicines supply for retaining confidence within the health system by both patients and healthcare providers and improve equity in access overall.

In addition to the financial losses imposed on the health systems of countries and on individual patients, the disposal of these expired medications is equally problematic. If this expired medicine disposed of inappropriately there is a risk on the ecosystem and aquatic environment because they contain biologically active and sometimes toxic substances (Alnahas et al., 2020). Improperly disposed medicines contribute to the

loading of medicines and their metabolites to the environment potentially posing significant risk on the environment and humans (Braund et al., 2009). Accidental dispensing of expired medicines is additionally possible if they're not collected and stored in separate places until disposal. Furthermore, collected expired medicines that are not disposed at appropriate time intervals may end in inefficient use of cupboard space in health facilities, it results limiting available space for storage of usable medicines (MOHS, 2008).

Medicine expiry indicates an issue within medicine selection, quantification, procurement, storage, distribution, and use (UNHCR, 2006). So, study likes to search out reasons that end up in expiry medicines at each stage of the supply of medication and a design possible solution to reduce the matter.

The findings of the study would help to enhance the quality of health care services being delivered and to reduce the potential risk of improper disposal of medicines by the health facilities. Furthermore, the findings from this study will contribute to filling research gaps on identifying revenue loss, types of expired medicines, and factors associated with expiry as well as to assess disposal practices of these expired medicines in the health facilities.

## 2. Literature review

### 2.1. Extent medicine expires

Inadequacy of budget is experienced globally, but more so in the public health sector to attain required achievement everywhere there is a significant focus on improving workflow and reducing expenses (Agnelly, 2014). Such an inadequate budget became a complex global challenge due to expiry. Around the world, 3% to 5% of pharmaceutical inventory per annum was lost due to expiry (Dias, 2011). Studies conducted in England estimated about more than \$400million and in Spain, 8539.9-euro value of medicines was wasted (Langley et al., 2005; Coma et al., 2008). A similar study in Spain at community pharmacy from more than 50% of community pharmacies had expired medicines (Coma et al., 2008).

In developing countries, at facility-level in Nigeria to assess the availability of ARVs medicines in treatment centers found that 64% of the facilities had expired ARVs medicines worth more than \$146,000 (WHO, 2003). Similarly, a study done in Limpopo province of South Africa was found that an average of 0.07% expiry per month, but allowed limit of expiring was of 0.05% per month of pharmaceutical expenditure (Motlanthe, 2010).

The national averages expiry rate of medicines was found to be 8%, 2% and 3% in health facilities, regional drug stores and private drug retail outlets, respectively (FMOH and WHO, 2003). The baseline data for health sector development plan (HSDP IV 2010-2015) of Ethiopia was 8.24% and national target for HSDP IV average rate of medicines expiry to become lower than 2%. And in hospitals two years before start of APTS with rate of medicines expiry at Debre Markos were found to be 10%, Felege Hiwot Referral Hospital 9%, and that of Debre Berhan was found to be 15% (ARHB and USAID/SIAPS, 2014). A study conducted Southwest Shoa

Zone of Oromia region, 96% of wastage was due to medicine expiry it results in a loss of 480,501 ETB of revenue related to medicines and resulted wastage rate of 7.5% (Gebremariam et al., 2019b). Another study that was done in the Awi Zone of Amhara Region an average wastage rate of the hospitals was 4.4%; 1.53% at hospital 1, 2.38% at hospital 2, 2.5% at hospital 3, and 11.2% at hospital 4 (Ebrahim et al., 2019).

## **2.2. Type of medicines expired**

A study done in the world describes expired medicine in an enormous way, most commonly investigated in community settings either as home storage or returns to pharmacies of the public health facility.

Most studies presented expired medicines based on ATC (Anatomic therapeutic classification) category; studies conducted in Kuwait had respiratory medicines as the highest percentage (38%) of wastage (Abahussain and Ball, 2007). In Mexico, non-steroidal anti-inflammatory medicines were the commonest, representing 16.11% from the total (Gracia-Vásquez et al., 2015). Among the wasted medications in Taiwan, 25.93 % of gastrointestinal medicines were at the uppermost from the list, followed by 22.49% of cardiovascular medicines, and 12.15% anti-inflammatory medicines (Chien, et al., 2013). Antibiotics were also found in higher percentages, in Tanzania, it accounts for 61% (Mwita et al., 2019), in Kabul, it accounts for 46.5 % (Bashaar et al., 2017), and in Nigeria, it accounts for 16.8% (Auta et al., 2011). Similarly, a survey conducted in Serbia indicated expired medication belonged to three categories like antimicrobial for systemic use (16.7%), dermatological preparation (15.9%), and medications for alimentary tract and metabolism (14.2%) (Kusturica et al., 2016). And in South Africa, more than 80% of the expired medicines anti-infective for systemic use were on the essential medicine list and it accounts for

31 % from the total expired medicines (Sauls 2016). In Ethiopia, antimicrobial agents for systemic use accounts for 41% of the total wastage (Gebremariam et al., 2019b).

Some studies also present a type of expired medicines based on their characteristics and therapeutic use. Like a study conducted in Uganda presents medicine that is prone to expiry mostly those used for vertical programs, donated medicines, and those with slow turn over (Motlanthe, 2010). And Ugandan ministry of health report that medicines prepared for the emergency situation were commonly expired (Mwesige, 2006). And most of the medicines that expired in Rwanda central medical store were medicines used for treatment of HIV/AIDS (53.3%) and ant-malarial medication and essential medicines (22.5%) (Hakuzimana, 2019). In Ethiopian, at Tikur Anbessa Specialized Hospital; more than 87% of expired medicines were from program medicines (Wakjjira 2018).

In Ethiopia study done Southwest Shoa of region describe the most common wasted medicines based on single items had the highest value from the total wasted medicines like Hyoscine Butyl bromide 20mg/ml injection (Gebremariam et al., 2019b) and another study was done in Sheka zone, identify Paracetamol 125mg suppository, Amoxicillin Dispersible tablet, and Zinc sulfate 20mg tablet was the most common expired medicine from essential medicines list of a health facility (Belete, 2018).

### **2.3. Reason for the medicine to be expired**

Ineffective inventory control and management of available resources at public health facilities lead to loss of finance and delivery of non-quality health services at the facility due to the expire of required medicines (Nakyanzi et al., 2010). Principally in

developing countries, their national stores, and public health facilities contain large stocks of expired pharmaceuticals (Kamba et al., 2017).

Medicines became expired due to different reasons one in which related to organization and management includes: Poor management of medicines, shortage of human resources, and absence of accountability presented as the important causes of the expiry of medicines (WHO, 1998). If human resources inadequately trained and processes that do not take enough account of the local context leads to monitoring processes may be compromised (MSH, 2012). And lack of accountability in managing medicines has exposed the public healthcare system to wastage of medicines (Motlanthe, 2010). With available tools for better processes and effectively monitoring medicine procurement, use and financial resources, skills, and capacity are important pre-conditions (Tuwmine et al., 2010).

Another reason contributes to expiry associated with the selection, quantification, and distribution throughout countries. Poor quantification and forecasting of medicines will lead to overstocking medicines and overstocking medicines normally leads to a high number of expired medicines (MSH, 2012). Irrational procurement and provision of medicines not based on needs and requisition this elaborated by poor stock monitoring practice were factors that lead to expiry in Uganda (Nakyanzi et al., 2010). Non-participation of clinicians in medicine selection and quantification in hospitals and non-functional Drug and therapeutic committees contribute to the expiry of medicines (Motlanthe, 2010). When related to distribution, system related to delivery of medicines to health facility like push system of delivery in Uganda on shifting of medicines from pull system to push system results 63% of items to be oversupplied due to shifting of pull system of delivery to push system of delivery and it leads rate of expiry to 22% in oversupplied health centers (Bukuluki et al., 2013). Poor

communication between health professional was attributed to wastage medication in Saudi Arabia tertiary hospital (Al-Dhawali, 2011). Study conducted in Limpopo Province of South Africa reported that delivery of medicines with expire date of less than six month make problem on supply chain of the province (Mashishi and Dambisya, 2017),

In Ethiopia at the local level, a study done in Awi Zone hospitals the most common reason contribute to expiry medicines directly to Ethiopian Pharmaceuticals Supply Agency regarding pushing program products and also the delivery of near to expiry RDF items, other common reasons reported by the study were patterns of prescribers, quantification problems (especially for seasonal products), poor data quality, non-functional Drug, and Therapeutics Committee (DTC) and lack of inventory management skill by the store person (Ebrahim et al., 2019). Another study has done in South West Shoa of Ethiopia identifies that delivery of near expiry date medicines by suppliers and lack of a system to move nearly expired medicines from one facility to another was a major reason for wastage of medicines (Gebremariam et al., 2019a).

#### **2.4. Disposal of unused medicines**

Pharmaceuticals that are used for the treatment of diseases became poison to a human when present in the environment (Ngwuluka, et al., 2011). Expired or unused pharmaceuticals are potentially toxic substances and it should be disposed of effectively to avoid the accumulation of these substance in the environment (Michael, et al., 2019). The most common exposure routes of pharmaceuticals into the environment are manufacturing units and hospital wastes (Daughton, 2003). Most of the time pharmaceuticals get into the aquatic environment, and they directly affect organisms live in an aquatic environment and incorporated into food chains (Priya, 2017). Studies are done India shows, extremely high levels (mg/L) of several drugs

were found in sewage discharged into the river from local wastewater treatment plant (Ngwuluka, et al., 2011).

Studies on antibiotics have shown that up to 95% of antibiotic compounds can be released unaltered into the sewage system (Priya, 2017). This wide range of antibacterial substances observed in waters could possibly result in the formation of resistant microbes, which could pose a serious threat to human and animal health (Jovanović et al. 2016). Non-steroidal anti-inflammatory drugs (NSAIDs), for example, ibuprofen, naproxen, and diclofenac are widely being used and consequently are frequently detected in sewage, surface water and may be found in groundwater system (Patneedi et al., 2017).

The expiry of pharmaceuticals and their disposal cost in developing countries generates problems for the health care system and to the general economy of countries (Bekker, et al., 2018). In Ethiopia, the absence of good pharmaceutical management practices and the shortage of appropriate disposal facilities results in an extremely large accumulation of medicines waste and this leads to quite a large proportion of the space at the medicines store is occupied by expired and unfit for use pharmaceuticals (Ejigu, et al., 2012).

There are different approaches to the disposal of expired medicine around the world. Buried and open dumped, are the cheapest and the most common practice for solid waste management especially in low lying areas (Al-Salem and Lettieri, 2009; Obara and Ouko, 2011). In addition to buried and landfill, burning and incineration methods are also common waste management practices, even with their negative impact on the environment, it also depends on numerous factors, especially the burning temperatures (Nunavut Department of Environment 2012). The burning of unused medicines which is implemented in many countries is not an environmentally friendly

method (Alnahas et al., 2020). This due to the organic nature of the most pharmaceutical product it requires sufficient time, oxygen, and temperature for ultimate burning (Department of Environment Government of Nunavut 2012). Burning of such pharmaceutical and pharmaceuticals contains halogens in their respective structure is environmentally unfriendly due to the production of toxic air pollutants when burnt at low temperatures in open dumps (WHO, 2009). Some pharmaceuticals also contain heavy metals such as iron, zinc, manganese, selenium, and molybdenum which do not incinerate easily (Alnahas et al., 2020). Burning of pharmaceutical waste should be precisely controlled; otherwise the leftovers from the burning sites and increase the tendency of remnants discharged into the ecosystem (Kadam and Vasantrya, 2016).

Lack of proper mechanism to handle medication waste seems to be the main reason behind substandard medication waste management in developing countries (Bound and Voulvoulis, 2005). A study was done in identifying methods in the management of pharmaceutical waste in the health facilities of Lagos state; expired drugs are mostly returned directly to the supplier (40.4%) while expired drugs are mostly returned to manufacturers (41.2%), the rest is disposed of by the hospital using medical waste bin (37.5%), while 15.1% buried them in the hospital premises, and 12.3% burn them openly. 31.4% of returned expired drugs to the supplier is a controlled drug (Adesina and Felix, 2018). Another study that was done in Nigeria community pharmacies: 31.8% of pharmacies dispose of through NAFDAC by using incineration, 21% return to drug distributors, and 9.1% through the rubbish bin for solid dosage form drug. However, 7.1% of them used the sink to dispose of liquid dosage form drugs (Michael et al., 2019). In Tanzania, majority of facilities (41.4%) in the study used methods such as the pouring of unfit medicines into the sink and into the dustbin (Mwita et al.,

2019). And 38.2% of drug retail outlets in Jimma city disposed their damaged, expired or unused medicines disposed of by burning at retail outlets (Gudeta and Assefa, 2020).

When related to frequency of disposal of unused medicines. In Tanzania, majority of facilities (41.4%) in the study used methods such as the pouring of unfit medicines into the sink and into the dustbin (Mwita et al., 2019).

In Ethiopia, some guidelines prepared to protect the public and the environment from health risks and hazards of medicines waste ensured by safely managing and disposing of medicines is required and medicines which are unfit for use shall not be stored for more than six months. This guideline presents those disposal methods of medicines waste varies with the class of medicines and dosage form: such class of medicines like controlled drugs or substances, anti-neoplastic or cytotoxic/anti-cancer medicines and other toxic medicines, radiopharmaceuticals, anti-infective medicines, etc. The disposal sites shall be environment and society friendly and shall be approved by an appropriate organ in accordance with environmental impact assessment, for this purpose; any health institution which does not have a disposal facility approved by the appropriate organ shall not carry out medicines waste disposal and shall use disposal referral system of licensed disposal firms, respective medicines suppliers or central disposal sites to make (FMHACA 2011).

## **2.5. Conceptual Framework**

The conceptual framework reveals the connection between the variables of the study; a variable is a measurable characteristic that assumes specific values among topics. The relationships between the variables of the analysis are shown in the following figure

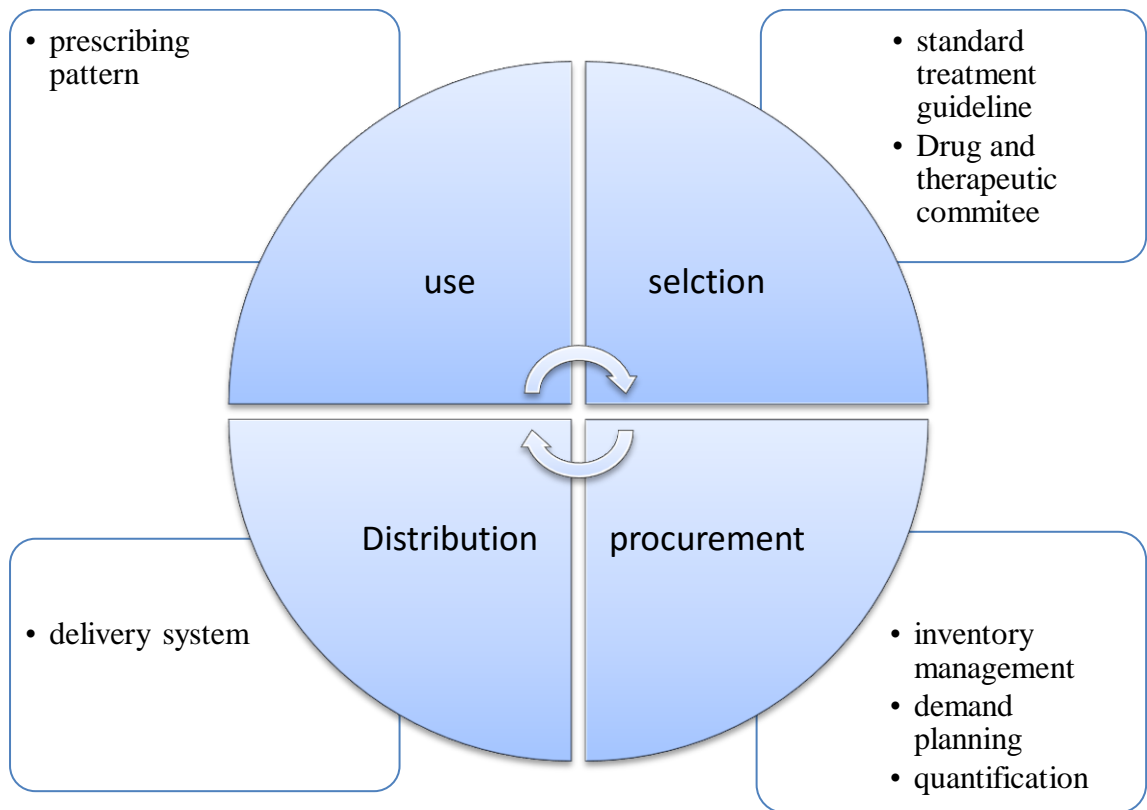


Figure 1: Theoretical framework

### **3. Objective of the study**

#### **3.1. General objective**

To assess medicine expiry, its contributing factors and disposal practices in public health facilities of South Gondar Zone, Amhara Region.

#### **3.2. Specific objectives**

- To determine the extent of medicines expiry in public health facilities, South Gondar Zone, Amhara Region Ethiopia.
- To determine the type of medicine expired in public health facilities, South Gondar Zone, Amhara Region, Ethiopia.
- To explore the reason for medicine expiry in public health facilities, South Gondar Zone, Amhara Region, Ethiopia.
- To explore expired medicine disposal practices in public health facilities, South Gondar Zone, Amhara Region, Ethiopia.

## **4. Methods and Materials**

### **4.1. Study area**

This study was conducted in public health facilities located in South Gondar Zone, which is one of the most populated zones in the Amhara Regional State of Ethiopia with an estimated population of 2,239,077 according to 2017 estimation (CSA 2017). Debre Tabor, the capital town of the zone, is located 113 km away from Bahir Dar and 666 km away from Addis Ababa. According to the report by the zonal health department, during the surveying time the zone had 8 public hospitals (1 general and 7 primary hospitals), 55 health centers, 465 health posts, 15 pharmacies, 35 drug stores and 27 rural drug vendors (SGZHD, 2017).

### **4.2. Study design and period**

A sequential explanatory mixed method where a descriptive cross-sectional study complemented by using qualitative approach. Data collection was carried out between April 7 and May 21, 2019.

### **4.3. Source and study population**

The source population for this study was all hospitals, health centers and health care professionals who were working in these health facilities in South Gondar Zone. And the study populations are selected hospitals and health centers which became functional before 2010 EFY and had recording of model 19, annual inventory of 2009 EFY and report of expired medicines and professionals willing and available in health facility and also involved in medicine supply management.

## 4.4. Sample size determination and sampling techniques

### 4.4.1. Sample size determination

The required numbers of health facilities to be included in the survey were determined based on the Logistics Indicators Assessment Tool (LIAT) (USAID|DELIVER PROJECT, 2008). The indicator recommends a minimum of 15% of the health facilities. Accordingly, the targeted number of health centers and hospitals within the zone gives 96. At the time of the survey 25 number of health facilities were included.

### 4.4.2. Sampling techniques

A sequential explanatory multi-stage stratified sampling technique was used to select the 25 health facilities. First, health facilities were stratified by level in to health centers, primary hospitals and general hospitals. Of these, two Primary hospitals were selected using a lottery method, one General hospital was selected purposely, and the remaining 11 health centers were selected by using two-stage sampling and the design effect of 2 and became the total health centers became 22. The woredas and city administration were selected randomly and the health centers are then selected randomly proportionate to the size. Tach gaynit, Libo-kemkem, Guna begemidir, Farita, Fogera, Ebinat, and Debretabor city administration were the study woredas/city administration (Table 1).

Table.1. Selected district (Woreda) and number of health centers.

Selected district (woreda)	Total no of health center	Number of the selected health center in each district (woreda)
<i>Debre tabor city administration</i>	3	2
<i>Ebinat</i>	5	2

<i>Farita</i>	7	4
<i>Guna begemidir</i>	3	2
<i>Libo kemkem</i>	8	4
<i>Fogera</i>	9	5
<i>Tach gaynit</i>	6	3
<i>Total</i>	41	22

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For the qualitative part of the study, chief executive officers of each facilities (CEO), pharmacy head, pharmacy store person and dispensary pharmacists of the selected health facilities and those working in Ethiopian Pharmaceutical Supply Agency (EPSA) hubs as forecasting and capacity building and distribution officers were selected purposely as a key informant.

#### **4.5. Data collection and management**

##### **4.5.1. Data collection instrument**

Data abstraction format for assessing extent and type of medicine expiry was prepared based on previous literatures (EPSA, 2017; Motlante, 2012). An interview guide was also prepared to explore current situation, identify the reasons for medicine expiry, measures taken to prevent problems of medicine expire and current practice of disposing expired medicines. The interview guide was developed after reviewing different literature (Sauls, 2016; Kagashe et al., 2012; MSH, 2012; FMHACA, 2011).

##### **4.5.2. Data collection procedure**

The principal investigator collected both quantitative and qualitative data from April 7 up to May 21, 2019.

For the quantitative part, after communicating with a head of pharmacies or CEO of health facilities, Then, guided by a store manager and head of pharmacies, review and took secondary data of expired medicines such as name of the drugs, dosage forms, buying cost ...etc. on records of expired medicines or disposal report and value of medicines received at 2017/2018 on Model 19 and beginning balance on annual inventory (beginning balance).

The study was conducted over a period of one month from April 7 to May 21, 2019. The researcher conducted in-depth face-to-face interviews with selected health professionals. All interview sessions were recorded by the use of a voice recorder. A total of eighteen health professionals were interviewed, a pilot study was conducted at woretta health center. Arrangements were made to conduct interviews with the participants through the office of the chief executive officers (CEOs) of the hospitals based on their convenient times. The office was arranged such that there was no interference from noise such as people coming in and out of the office, telephones were off the hook and a “DO NOT DISTURB” sign was posted on the door where the interviews were conducted. Questions during an interview were not only limited to the ones mentioned on the interview guide. Questions were asked based on the role and involvement of the participants. Each interview session took less than fifteen minutes per interviewee.

### **The Principal Investigator Status as an Insider:**

The principal investigator having two years of personal working experience in the one of health facilities within study as department head and working as quality officer for health facilities under cluster of hospital offers certain strengths and insights into the phenomena that were explored. He was operated with an awareness of insider bias and the nature of his conflicting roles. The issues concerning competing roles related

to the concept of insider bias, which has both advantages and disadvantages when conducting this study. In this case, the advantages included being able to use existing system for gaining information related to health facilities and contacts with health official have information on occurrences under the study. On the other hand, the disadvantages related to position of principal investigator and his work area within health facility under the study makes challenge to give honest perceptions and opinions specially those facilities under his quality supervision and also the response influenced by his knowledge gained from his work experience, and also from his current academic level.

#### **4.6. Data quality control and analysis**

##### **4.6.1. Data quality control**

For the quantitative part, data was collected by principal investigator. The principal investigator discussed with the research supervisor on the instruments before the data collection, collected data reviewed for completeness, summarized and record on the computer for each facility on the same day of data collection was carried out.

For the qualitative part, the validity of the findings was enhanced by; sharing the transcript to respondents if they agree the transcript is what they forwarded and quoted. Whereas, the consistency of the finding was indicated by repeated reading of the transcription.

##### **4.6.2. Data analysis**

The quantitative data were entered and analyzed using the Microsoft excel. The analysis was performed in aggregate using descriptive (Frequency, mean Standard deviation (SD), percentage and graph) statistics.

To determine the extent of medicines expiry, recording of expired medicines by its quantity and unit price in each health facility was done and its total price was calculated. The total value (by multiplying quantity and unit buying price) of the received medicines and beginning balance, received and expired medicines was calculated based on model 19 and annual inventory of 2017. For non-priced medicine the monetary value was calculated estimated based on the unit price obtained from EPSA in 2017/18 from the same health facility. When medicines had different prices, we took median value from the possible price list. Medicines with similar generic name but differ in dosage forms and strength like amoxicillin 250 mg suspension, amoxicillin 250 mg capsules and amoxicillin 250 mg dispersible tablet were considered as different medicines. Extent of medicines expired for each health facilities was calculated by using usable medicine (beginning balance and received medicine) on denominator and value of expired medicines on nominator multiplied by 100.

Expired Medicines were presented, according to World Health Organization ATC classification and RDF/program category: program medicines were classified as ART, anti- malaria, Family planning, MNCH and TB and leprosy based on form used for stock status report of pharmaceutical health facilities to EPSA (annex 8).

Qualitative aspects of the study, all in-depth interviews were typed in Microsoft word and analyzed in Microsoft Excel, which was used to help with the coding and thematic analyses of the data. A code book was developed and analyzed deductively and also inductively allowing for themes to emerge from the participants themselves. Texts were coded across all transcripts were drawn on as part of the analysis. The information was analyzed thematically in a systematic way using an exploratory

approach in order to explore in-depth the reasons why medicines expire and disposal method.

#### **4.7. Ethical considerations**

Ethical approval was obtained from the Ethics Review Committee of the School of Pharmacy, Addis Ababa University (Annex 5). Also, permission to conduct the research was obtained from the Amhara Public Health Institute, South Gondar Health Office and Woreda Health Office and also from Central EPSA, EPSA Bahir Dar and Gondar hub.

Participants of the study were asked for verbal consent before participating in the study. During the consent process, the study participants were informed about the purpose of the study and the importance of their participation in the study. The study participants were also informed that they could skip question/s that they did not want to answer fully or partly and also to quit the process at any time if they wanted to do so and their participation was voluntary. Participants were also assured about the confidentiality of the information obtained in the course of the study by not using personal identifiers.

## 5. Results

A total of 25 public health facilities (1 General hospital, 2 Primary hospitals, and 22 health centers) were surveyed. The results are presented in two sections as quantitative and qualitative findings.

### 5.1. Quantitative findings

#### 5.1.1. The extent of medicines expiry

In all surveyed health facilities, medicines worth of 44,465,809.54 ETB (34,493,675 ETB received and 9,972,134.54 ETB beginning balance). From these, total of 2,304,830.5 ETB (average expiry rate of 6.45%) worth of medicines was expired (Table 2).

Table 2: Extent of medicines expiry (2017/18) in surveyed public health facilities, South Gondar Zone, Amhara Region.

Code of Health Facility	Total received in ETB at 2017/2018	Beginning balance at 2017/18	Total annual for expiration at 2017/18	% Expired at 2017/18
GH1	8,378,450	1,861,039.39	730,564.02	7.13
PH1	2,496,641.56	761,638.41	164,890.31	5.06
PH2	4,461,682.49	961,260.4	97,935.02	1.81
HC3	3,268,431.39	1,006,733.68	143,707.93	3.36
HC5	1,190,860.26	525,456.57	60,792.39	3.54
HC9	986,446.69	764,334.78	124,661.74	7.12
HC6	2,917,500.80	199,065.30	129,041.16	4.14
HC1	354,792.29	64,981.84	6,664.84	1.59
HC8	514,430.51	124,273.91	29,214.39	4.57

HC12	737,727.61	94,596.45	177,753.84	2.13
HC7	300,693.23	89,474.60	74,032.32	18.97
HC21	377,491.87	244,006.47	50,976.44	8.2
HC14	803,717.99	210,419.88	28,891.67	2.85
HC10	367,762.13	178,965.13	8,073.86	1.48
HC16	595,955.73	390,448.15	26,493.92	2.69
HC20	369,570.70	177,572.40	136,642.82	24.97
HC15	360,150.29	240,533.93	26,561.67	4.42
HC22	386,150.29	363,185.39	54,911.78	7.33
HC11	391,476.31	339,885.84	42,224.15	5.77
HC18	1,596,886.03	275,972.65	42,167.47	2.25
HC19	791,765.12	202,445.51	95,387.93	9.59
GH13	340,818.32	219,197	86,135.58	15.38
HC17	744,462.00	268,598.53	69,800.31	6.89
HC4	365,558.00	198,497.08	44,380.49	7.87
HC2	394,069.57	209,581.68	12,924.84	2.14
<b>Average</b>	<b>1,333,747.00</b>	<b>398,885.38</b>	<b>92,193.22</b>	<b>6.45</b>

## 5.1.2. Commonly Expired Medicines

### 5.1.2.1. Description of expired medicines based on RDF or Program medicines

One hundred ninety-three medicines from RDF and 136 medicines from the Program were expired. In terms of monetary value, program medicine covers 62.3% of the total expired medicines; when categorizing these medicines based on health programs: medicine for HIV/AIDS (42.62%), maternal neonatal & child health (33.09%),

Malaria (14.92%), TB-Leprosy (5.73%) and Family Planning (3.59%) were expired within the facilities of South Gondar (Figure 3).

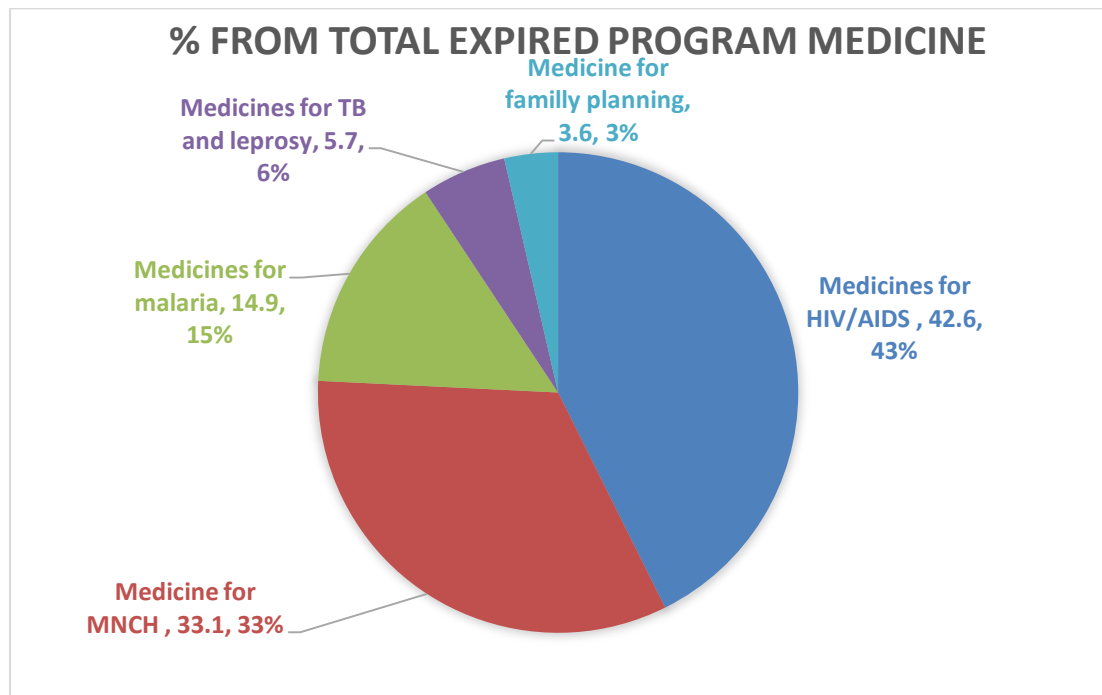


Figure 1: Expired Program Medicines based on health program in surveyed public health facilities (2017/18), South Gondar Zone, Amhara Region.

#### 5.1.2.2. Top expired medicines based on value

From the RDF category, the top three expired medicines in terms of value lost (ETB) were paracetamol 125mg suppository (47,740.89) followed by ampicillin 250mg cap (28,138.36) and bisacodyl 5mg suppository (15,185.59) (Figure 5).

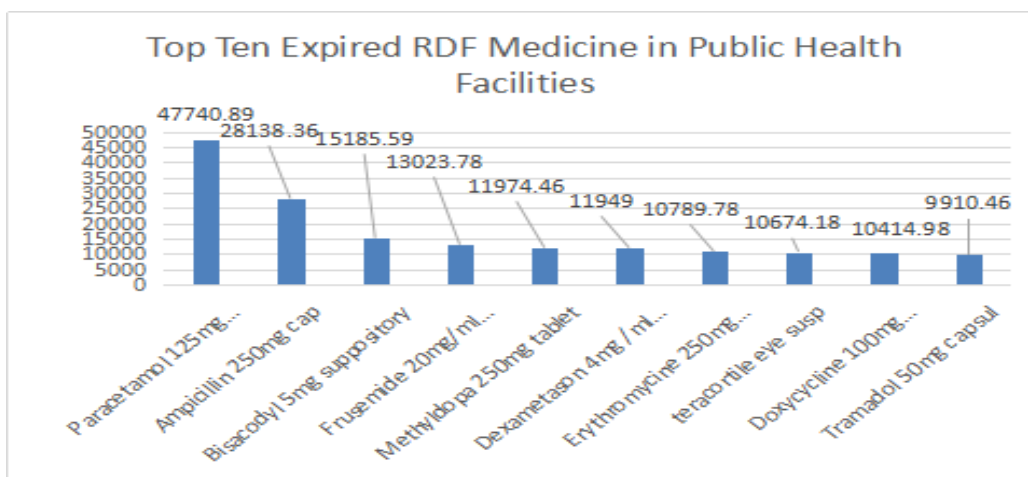


Figure 2: Top ten expired RDF medicines in the surveyed public health facilities (2017/18), South Gondar Zone, Amhara Region.

From program medicines: -Arthemeter+Lumafantrine (20mg+120mg) tablet (186,228.87) followed by zinc sulphate 20mg tablet (144,818.31) and Lamivudine + Tenofovir (300mg+300mg) tablet (144,336.79) were the first three commonly expired medicines (Figure 6).

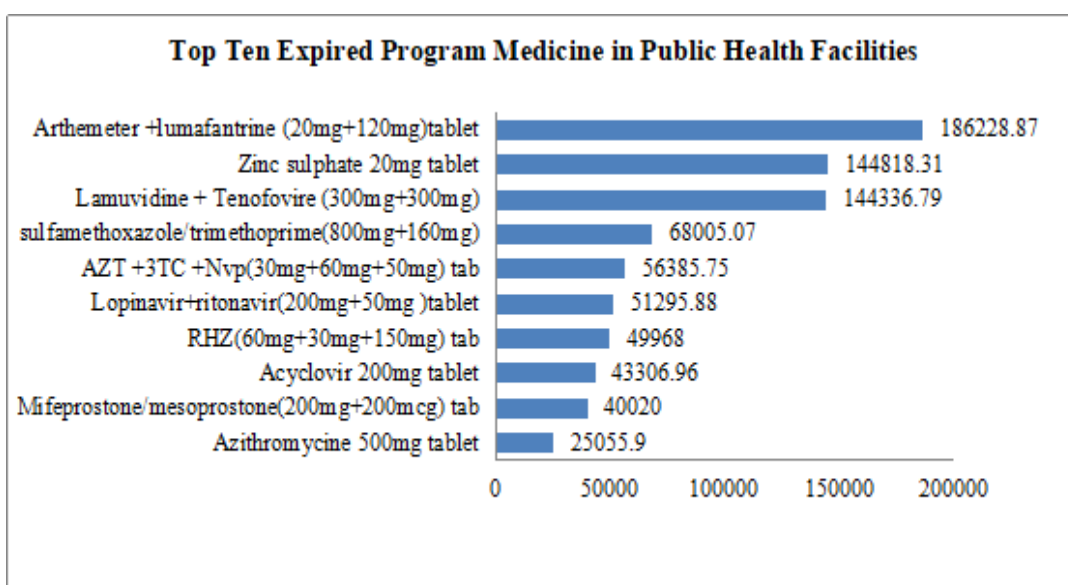


Figure 3: Top Ten Expired Program Medicines in in the surveyed public health facilities (2017/18), South Gondar Zone, Amhara Region.

When categorizing expired medicines based on their function in human body system (ATC), anti-infective for systemic use (47 %) followed by alimentary tract and metabolism (17.2%), and Nervous system (6.1%) constituted the lion share of in terms of value medicine expiry (Figure 7).

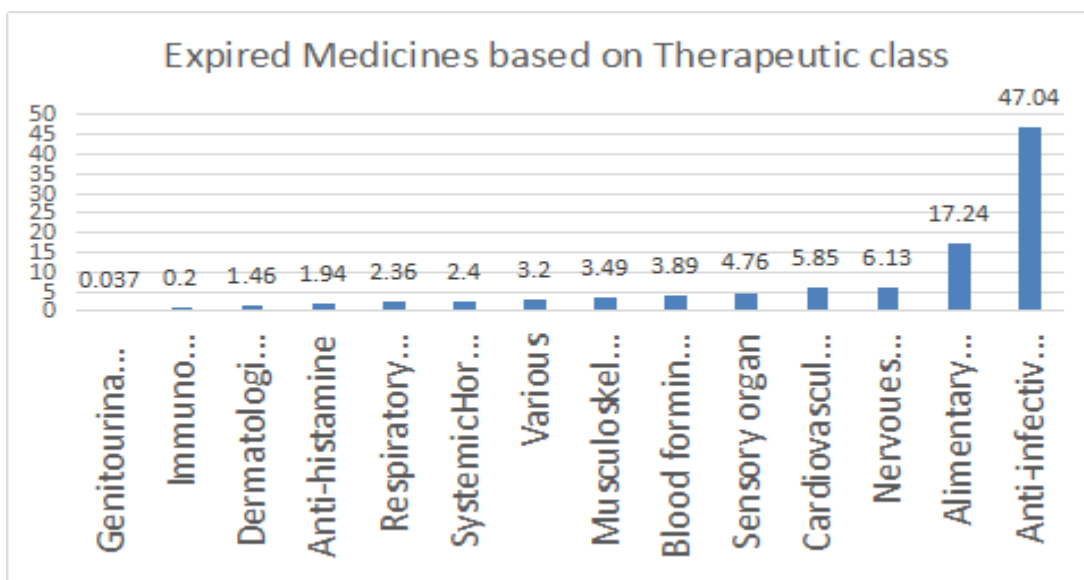


Figure 4: Expired medicines based on therapeutic class in the surveyed public health facilities (2017/18), South Gondar Zone, Amhara Region.

The first top expired medicines in each surveyed health facility were from program medicines. Accordingly, as shown in Table 3 below, Lamivudine + Zidovudine /300mg+300mg/ tablet accounted the highest value followed by Lamivudine + Tenofovir /300mg+300mg/ tablet.

Table 3: Top first expired medicines in each surveyed public health facilities (2017/18), South Gondar Zone, Amhara Region.

Code of Facility	Top First Top Expired Medicine in each Surveyed Health Facilities	Value (ETB)	Program /RDF
GH1	Lamivudine+ Zidovudine /300mg+300mg tablet	123,811.2	Program

HC9	Lamivudin(3TC) +Tenofovir (TDF)/300+300/mg	110,119.6	Program
HC8	ZT+3TC+NVP (60mg+30mg+50mg) tablet	49,490	Program
PH2	Acyclovir 200mg tablet	40,014.2	Program
HC10	Zinc Sulphate 20mg tablet	35,958	Program
HC17	Artemether 20mg+Lumafantrine 120mg tablet	27,017.3	Program
HC14	Albendazole 400mg tablet	25,187.7	Program
HC3	Misoprostol + Mefiprostol/200mg+200mcg/	24,650	Program
HC18	Misoprostol + Mefiprostol/200mg+200mcg/	20,010	Program
HC11	Artemether 20mg+Lumafantrine 120mg tablet	18,906.1	Program
HC21	Misoprostol + Mefiprostol/200mg+200mcg/	17,400	Program
HC5	Praziquantel 600mg tablet	17,113.3	Program
PH1	Zinc Sulphate 20mg tablet	15,878.9	Program
HC7	Artemether 20mg+Lumafantrin120mg) tablet	12,107.4	Program
HC4	Artemether 20mg+Lumafantrine 120mg tablet	10,928.3	Program
HC15	Ampicillin 250mg capsule	8,668.3	RDF
HC16	Zinc Sulphate 20mg tablet	7,421.7	Program
HC22	Praziquantel 600mg tablet	7,200	RDF
HC2	Methyldopa 250mg tablet	7,079.4	RDF
HC1	Artemether 20mg+Lumafantrine 120mg tablet	6,071.3	Program
HC13	Artemether 20mg+Lumafantrine 120mg tablet	5,020.1	Program
HC12	Paracetamol 125mg suppository	4,488.4	RDF
HC20	Methyldopa 250mg tablet	3,407.7	RDF
HC19	Ampicillin 250mg capsule	1,237.4	RDF
HC6	Diazepam 5mg/ml in 2ml injection	1,185.8	RDF

## 5.2. Qualitative finding

Interviews were conducted with key informants who were working in the hospitals and health centers to explore reasons for medicine's expiry and disposal practice. Eighteen interviews were carried out between April 7 and May 21, 2019. Of 18 key informants interviewed, 15 of them were males. The age of the respondents within the range of 25 to 56 years, one with a Master's degree, six with a bachelor's degree, and the rest with Diploma. Their work experience ranged from 3 to 26 years. Nine participants were currently working as a store person, 3 of them as CEO of a health facility, 2 of them in the dispensary, and 1 of them as pharmacy head and the rest three working in Ethiopian Pharmaceutical Supply Agency (EPSA) hubs as forecasting and capacity building and distribution officers. . Key themes to emerge were: situation of medicines expire, reasons for medicines to expire and recommendation for reduce medicines expire and disposal practice of expired medicine.

### **The situation of medicine expires**

All key informants agreed that medicine expiry is a problem in their facilities. They also said that program medicines expire more than RDF medicines. In relation to this a key informant said:

*“Program medicines expire commonly particularly those used for the treatment of opportunistic infection, for HIV/AIDS, and MNCH. Specifically, sulphamethoxazole / trimethoprim (800mg+ 160mg) tablet, STI kit, and zinc 20mg dispersible tablet frequently expire.” (Store person#1)*

### 5.2.1. Reasons for medicine expiry

Major reasons mentioned by key informants were: pushing medicine without a health facilities request, delivery of near to expire medicines and ineffective communication and coordination.

#### Delivery of near expiry products

Delivering near expiry products (i.e. left with two or three months to expire) by the suppliers was believed by the key informants as one of the major the reason for expiry. For example, one of the key informants expressed as follows:

*“In our facility most of the time EPSA deliver medicine with short shelf life, mostly having only two or three months left for expiry date.”* (Store person #2).

#### Delivery of medicine by pushing system

Majority of the key informants were of the opinion that medicines received from the suppliers without request were mostly expired. One of the key informants stated that

*“Most of the program medicines expired in this facility is medicines that we received without our request.”* (Store person#3)

This argument was, however, refuted by a key informant from supplier (EPSA) side by saying

*“Delivery of medicines to health facilities is based on the needs as per the average monthly consumption reported in RRF.”* (Forecasting and capacity building officer #1)

Another key informant from the EPSA said:

*"We are distributing medicines to health facilities from the agency based on the FEFO principle. So, some medicines with a short expiry date (i.e. less than 6 months)*

*could be supplied to the health facilities based on the RRF, by cross-checking the remaining shelf life and the requested quantity, and hence we deliver only the amount of medicines health facilities are able to finish it before the expiry date.”* (Distribution officer # 1)

### **Ineffective communication and coordination**

According to majority of the key informants, prescribers in the surveyed health facilities prescribe drugs based on their choice without considering availability in the health facilities and without referring to facility specific medicines list.

One participant said:

*"I think lack of communication between prescribers and pharmacy professionals about available medicines and prescriber not concerned to prescribe according to available medicines in the facility make expiry of medicines.”* (Store person #2)

### **Delivery of medicines through the woreda health office**

Some participants mentioned that delivering medicine through the woreda health office created additional bureaucratic level and reduce chance of using short expiry medicines before the expiry date. One participant said:

*“Program medicines are obtained from woreda health office. The program medicines are stored in woreda health office for some time until distribution plan is prepared, then issued to health centers. As a result, the chance of using medicines with short expiry would be reduced.”* (Pharmacy head #1)

### **Shortage of pharmacy professionals**

Key informants also identified unavailability/shortage of pharmacy professionals as a reason for expiry.

*“In our woreda, most of the health centers’ stores are run by either clinical nurses or midwifery due to shortage of pharmacy professionals. They are not interested in and committed to the management of medicine supply.” (CEO #3)*

## **Key Informants Recommendation to Reduce Expiry**

### **Updating top disease**

Updating facility specific medicine list based on the current diseases pattern, particularly ten top diseases seen in each and availing the required medicines uninterruptedly is the recommendation made by most participants. One respondent said:

*“List of facility specific medicines was prepared based on previously selected top ten diseases. This may not be relevant at present due to epidemiological shift from infectious diseases to other non-communicable diseases. So, we need medicines based on the current top ten diseases of the facilities. This could contribute to a reduction of stock out and expiry of medicines.” (CEO# 2)*

### **Framework for donated medicines to use for revenue generation**

At lower levels of health, the facility gives special attention to medicines that sold at a dispensary but lose attention to donated medicines not system allow to be sold.

One respondent said:

*“Most of the medicines that come through donation have no price, it makes lost attention by professionals because of some professional gives special attention to medicine incurred by facility resource and finance, and sold at a dispensary.” (CEO #2)*

### **Redistribution of overstocked and unneeded medicines**

Medicines those are consumed in fewer amounts in one facility but vital for the service of another facility. To avail this medicine, it needs redistribution from one area to another.

One participant said:

*“.... Some medicines like Artesunate 60mg injection, it needs redistribution by national or regional level because in some health facilities especially in our health centers not needed much but other health facilities especially like hospital needed much or vital for service and stock out for long period time.”* (Store person #3)

### **Consumption-based delivery**

Delivery of medicines without the need for health facilities results in the overstock of medicine and expires.

One of the participants said:

*“Commodity like Zinc Sulfate 20mg tablet stock was oversupply so we need these medicines to be supplied based on consumption.”* (Store person #7)

### **6.2.2. Disposal practice**

From 15 key informants within health facilities, only five participants aware the disposal practice of their health facilities and were involved in disposal committee.

### **Selection of disposing area**

The selection of the area for disposing of medicines was done by a sanitary professional coming from the woreda health office and the zone health department.

One of the participants said:

*“Sanitary professional that comes from woreda health office or zone health department with disposal committee select area that is not easily reachable by human and considering the absence of an electric line.” (Pharmacy head #1)*

### **Methods of disposal**

In addition to buried and landfill, burning and incineration methods are also common waste management practices, even with their negative impact on the environment, it also depends on numerous factors, especially the burning temperatures. The burning of unused medicines which is implemented in many countries is not an environmentally friendly.

Most key informant suggested that burning pharmaceuticals in the open dumps as an open container with fires and pouring IV (intravenous) fluid and fluid chemical into a prepared hole to run down were a commonly applied method of disposing of unused pharmaceuticals.

One participant said:

*“We perform disposing of pharmaceutical by burning pharmaceutical able to burn and pouring liquid pharmaceutical like intravenous fluid and liquid chemical into the dump.” (Store person #2)*

### **Frequency of disposal**

Most of the key informants were involved in disposing of Expired pharmaceuticals as a committee member and indicated that disposal of unused pharmaceuticals was done every two or three years. One participant said:

*“Because of fears of blame from the community, we dispose of pharmaceuticals every two years. They correlate the disposal of unused medicines with the unavailability of medicines.”(Pharmacy head #1)*

## 6. Discussion

Few countries have adequate administrative provisions for writing-off pharmaceutical stock. In the public sector, medicines are the property of the state, for which strict accounting procedures are necessary (WHO, 2001). Especially in developing countries like Ethiopia scarce resource for the delivery of health and selling of medicines use as a source of revenue for expansion of their health service within the facility, expire of those medicines result loss of revenues that were used for ensuring a consistent supply of affordable priced essential medicines and generating additional resources for quality improvement of health. There is limited information on the extent of expiring, sort of medicines commonly expired medicines within the health facility, and reasons cause to medicines to expire. This study focused on the determination of medicines expire rate, sorts of medicines expired and reasons contribute to medicines to expire in public health facilities found and disposal practice for those expired medicines in South Gondar Zone, Amhara Regional State, Ethiopia from July 8,2017, until July 7, 2018.

### **The Extent of Medicines' Expiry**

The value and average expire rate of expired medicines for 2017/18 was 2,304,830.51 ETB and 6.45%. The average expires rate of medicine during this study is less than the finding reported on the baseline data for the health sector development plan (HSDP IV 2010-2015) of Ethiopia with an average rate of 8.24% in the health facility (FMOH and WHO, 2003) and another study that was done in Southwest Shoa Zone of Oromia Region with a rate of 7.5% (Gebremariam et al., 2019b). This might be because within the previous finding they take received medicines only as usable medicines in the calculations of the rate. But higher than the extent reported in Awi Zone of Amhara Region with reported rates of 4.4% (Ebrahim et al., 2019). This

could be attributed to the differences in the dispensing unit included in the study of these health facilities and the number of health facilities included within the study. This finding also higher than the finding of the study carried out in hospitals assessing the outcome of Auditable Pharmaceutical Transaction Services (APTS) with a rate of 1.1% (Fenta et al., 2016) and there is also a higher rate of expiry found on facilities within this study that apply APTS, its rate 7.13%, and 3.36% in one hospital and health center, respectively. This higher difference might happen due to exclusion of facilities failed to fulfill the minimum requirements for APTS in the previous study. The average expires rate of 6.45% indicates that the zone is above the target of 2% set on HSDP IV (FMOH, 2010). The rationale behind not being under the national target of 2% might be poor communication and coordination between different stockholders involved within medicines supply chain management of the Zone.

### **Type of Expired Medicines**

According to this study, more than 61.26% of the expired medicines were program medicines. The same result was obtained in Tikur Anbessa Specialized Hospital; more than 87% of expired medicines were from program medicines (Wakjjira, 2018). But the proportion was much higher than what was found in this study, this might due to differences within the level of service/ amount of medicines managed. Additionally, from this category, 42.62 % of expired program medicines were medicines used for HIV/AIDS patients. These might be due to their price above the remainder type of medicines and also the key informant interview showed that HIV/AIDS medicines delivered in large quantities without their request that have only a three months' time period. This makes a great loss of health resources and the incapability of health service. Similarly, a facility-level study in Nigeria to assess the availability of ARVs

medicines in treatment centers found that 64% of the facilities in the study had expired ARVs medicines worth more than \$146 000 (WHO, 2003).

The top ten expired medicines in the study (in terms of value) were Artemether + lumefantrine and are one of the essential medicines for the World Health Organization (WHO, 2019) and within the tracer medicines list of Ethiopia (FMHACA, 2014). The expire of those essential medicines increases fears due to they are available through donations and aid for the fulfillment of Millennium Development Goals (MDGs) directly associated with health that set by the United Nations (WHO, 2010). This medicine only buys from the international market. Expiry of this medicine would likely have an impact on the standard of management of malaria especially the health facilities found within the malarias' area of the zone.

Anti-infective medications were the commonly expired (wasted) medications (47%). Which is higher than reported by a study conducted in Awi zone of the Amhara region and Southwest Shoa of Oromia region, in which anti-infective medicines wasted was 36.4% (Ebrahim et al., 2019) and 40% (Gebremariam et al., 2019b), respectively from the entire medicines expired (wasted). This might be due to the difference within the number of health facilities and types of medicines assessed. This finding also higher than the finding of the study carried out in Serbia, Kabul, and Nigeria: anti-infective were also found in higher percentages, it accounts for 16.7% (Kusturica et al., 2016), for 46.5 % (Bashaar et al., 2017), and for 16.8% (Auta et al., 2011), respectively. This could be attributed to the differences in the types of disease prevalence (morbidity) in the areas and kinds of services provided by the health facilities.

### **Reasons for Medicines Expiry**

In the current study, participants identified the delivery of medicines through a pushing system, delivery medicine nearly to expire (< 2 or 3 months) by the supplier, and ineffective communication and coordination system were major reasons provided by key informants for expiring of medicines within the South Gondar Zone health facilities. Finding from the study is delivery of medicines through a push system by suppliers was a significant reason behind medicines' expiry. The key informant interview showed that delivery of medicines while not their demand/needs by suppliers ensuing overstocking of unwanted medicines. This finding is like a study that was done in Uganda on shifting from pull system to push system of delivery, it presents that 63% of items to be oversupplied due to shifting of pull system of delivery to push system of delivery and it leads rate of expiry to 22% in oversupplied health centers (Bukuluki et al., 2013). Another similar study done in Ugandan hospitals was identified as a push system that possibly causes medicines expiry (Tuwmine et al., 2010). In Ethiopia, studies in Awi Zone hospitals (Ebrahim et al., 2019) and Southwest Shoa Zone health facilities (Gebremariam et al., 2019a), identified that push delivery of medicines was the foremost common problem and contributes to the expiry of medicines. A study that was done in Zone identified that program products were commonly legible for a push system of delivery (Ebrahim et al., 2019). Similarly, during this study, 62.3% of medicines in value expired was program medicines. However; at both the suppliers (EPSA), the amount of expiry is 13.3% and 23.3% for program medicines. This is able to possibly indicate push delivery of program medicine by suppliers is that the rationale behind the expiry of medicines within the health facilities of South Gondar Zone. Medicines that are ordered by the health facility was done based on the pattern of endemic diseases as well as the kind and level of services provided by the health facility, as a result,

suppliers must deliver based on the requirements and demand of the health facility. The study also reported that the delivery of nearly to expiry medicines (< 2 or 3 months) to the health facilities by the suppliers as one of the reasons for medicines' expiry. The result of this study is analogous to the study conducted in health facilities of Awi Zone of Amhara Region (Ebrahim et al., 2019), Southwest Shoa Zone of Oromia (Gebremariam et al., 2019a), Limpopo Province of South Africa (Mashishi and Dambisya, 2017), and in Uganda (Tumwine et al., 2010), these studies presented as medicines expired was due to delivery of medicines that were close to expire. This study suggests that suppliers should ensure all medicines delivered to health facilities expected to be used before they expire. The participants also mentioned that lack of communication and coordination among dispensers, prescribers, store managers, and managers of the facility also a major reason for medicines' expiry. A similar study shows that due to the shortage of communication about available medicines and medicines have short expiry date among different departments became a challenge for efficient and effective management of medicine (Sauls, 2016). Another similar study conducted on wastage of medication in King Khalid University Hospital of King Saud University, Riyadh, Saudi Arabia, found that poor communication between pharmacists and nurses was attributed to wastage of intravenous medication (Al-Dhawali, 2011). Communication and coordination between different departments about available medicines before medicines expired important for efficient and effective use of resources.

### **Disposal practice**

Inappropriate disposal of pharmaceutical waste would be dangerous if it pollutes the water supplies or local sources employed by the overall public or wildlife. Additionally, Pharmaceuticals waste could even be diverted to the marketplace for the

illegal resale and to be extensively consumed by scavengers or children if the disposal is improper (WHO, 2009).

In the present study, the whole participant suggested that open burning and pouring of liquid unused pharmaceutical was the foremost common methods of removing for pharmaceutical. Findings within the present study are different from other studies that were conducted within the health facilities of Lagos state experiencing returning of expired drugs on to the supplier (40.4%), while only 12.3% health facilities burn them openly in their premises (Adesina and Felix, 2018). This might happen thanks to the difference in their advanced systems for reverse logistics at a lower level. But are in line with other studies conducted among drug retail outlets found in Jimma city, 38.2% of drug retail disposed of their damaged, expired, or unused medicines by burning at retail premises (Gudeta and Assefa, 2020). This due to the similarity of the country study conducted. According to the World health organization report burning of unused pharmaceuticals at low temperatures in open dumps is environmentally unfriendly (WHO, 2009). The possible reason for this improper disposal might be the infrequent inspection of the disposal practice of health facilities by the regulatory body. The regulatory body should be controlling the disposal practice of health facilities and prepare high-temperature incineration achieves the prevention of unwanted effects related to improper disposal of pharmaceuticals.

## **7. Strength and limitation of the study**

The accuracy of the study is dependent on the accuracy of the document used in the study and the study limited to the public health facilities and excludes health posts and private health facilities. The study doesn't show the extent of expired medicines separately program and RDF. And the findings of this study were from only health facilities perspective and did not include other stakeholders to identify the reason for delivery of near to expired medicines to health facilities such as zonal and woreda health offices and partners.

## 8. Conclusion

The main aim of this study was to assess the extent and type of medicines that are expired within health facilities as well as reasons for medicines expiry and disposal practice for expired medicines at public health facilities.

The average expiry rate of medicines at public health facilities of South Gondar Zone was 6.45%. This study identifies anti-infective and medicines acting on the gastrointestinal tract were commonly expired medicines based on ATC classification. Medicines managed as Program medicines in health facilities were the type of medicines expired, from which medicines for the treatment of HIV/AIDS expired in higher portion and Artemether and lumefantrine combined medicines were the first top expired medicines.

Delivery through pushing system, delivery of medicines near to expiry by the supplier, absence of communication and coordination, medicine distribution through woreda health office, and shortage of pharmacy professionals were identified as major reasons for medicines expiry.

Disposing of expired pharmaceuticals in every two or three years by burning in open containers and pouring liquid pharmaceuticals into the prepared hole were commonly used methods for disposing of these pharmaceuticals.

## 9. Recommendations

Based on the finding the following recommendations were made:

To Health facilities

- Make procuring and ordering of medicines to be done by personnel trained in medicine supply management.
- Replace other professionals in a storeroom by pharmacy professional.

To Amhara Regional State Health Bureau

- Create strategies for redistribution of nearly expire and over supplied medicine between health facilities.
- Set system for disposing of unused medicines at central level.
- Adequate law enforcement strategies disposal to be perform according to FMHACA guideline.

To Ethiopian Pharmaceutical Supply Agency (EPSA)

- Make direct delivery to facilities
- Delivery to health facilities based on their requested demand and item type.

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## Annex 1: Data abstraction format

### Section I: General information

1. Date.....
2. Facility code:
3. Type of facility; 1.for hospital 2.for health center
4. When the facility was established (E.C) .....

### Section II: Data Abstraction formats

#### Instruction:

Communicate the head pharmacist. Then be guided by the store manager, review and take secondary data from the facility pharmaceutical records; such as expired medicine registration book, disposal registration (if expired medicines were disposed), and Model 19 documents.

1. Data abstraction format to gather fiscal year amount beginning balance and received medicine.

#	Required Data	From July-8-2017-July-7-2018
1	Total Value of Expired	
2	Total Value of beginning balance	
3	Total Value of received	

2. Data abstraction format for expired medicine (**July /8//2017) - July/7/2018)**

#	Name of Pharmaceutical	Strength /Size /Specification	Value of Pharmaceutical	Type of Pharmaceutical	RDF/Program	Therapeutic Category
1						
2						
3						
4						

5						
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## **Annex 2: Semi-structured guide for key informant interview (English version)**

Addis Ababa University

School of Pharmacy

Department of Pharmaceutics and social pharmacy

### Introduction

I want to thank you for your time. My name is Abraham Nigussie. I came from Addis Ababa University, School of Pharmacy, department of pharmaceutics and social pharmacy attending a post-graduate study in Health Supply Chain Management. I am the principal investigator for the study entitled "Assessment of medicines expire and its contributing factors in selected public health facilities in South Gondar Zone, Amhara Regional State, Ethiopia".

This study aims to determine the medicines expire rate and to identify its contributing factors in selected public health facilities of South Gondar Zone, Ethiopia. By considering the findings and recommendations emanated from this study will help the policymakers and other organizations to design intervention activities, you are kindly requested to participate in this study.

I will be taping the session because I don't want to miss any of your comments. Because we are on tape, please be sure to speak up so that I don't miss your comments. The interview would take less than an hour.

The study is purely for academic purposes and will remain confidential and therefore not affects you in any case. Your participation is voluntary and you have the right not to answer any question and stop the interview at any time if you have any doubts. Moreover, your name will not be written and your responses are identified only by codes. However, your genuine, honest and timely response is vital for the successfulness of the study. Therefore, I kindly request you to respond to each item of the question very carefully. Would you be willing to participate?

1. Yes. Thank you! Let's begin.

2. No.

Semi-structured guiding for key informant interview

1: Background information of the key informant

1.1 Age .....

1.2 Sex .....

1.3 Highest level of education .....

1.4 Total Work experience .....

1.5 Current position.....

2. Guiding questions for the interview

2.1. Do you think medicine expiry is a problem in your facility?

2.2. What are the commonly expired medicines? Why?

2.3. What measure is taken in your facility? What solution suggests for preventing expiration of medicine?

2.4. Are you involved in the disposing of expired medicines in your facility? How method disposed this medicine

### Annex 3: Semi-structured guide for key informant interview (Amharic version)

አዲስ አበባ ዩኒቨርሲቲ

የፋርማሲ ትምህርት ቤት

የፋርማሲዩቲክስና ሶሻሌ ፋርማሲ ዲፓርትመንት

መግቢያ

ስለ ውድ ጊዜዎ አመሰግናለሁ ። ስሜ አብርሃም ንጉሴ ይባላል። በአሁኑ ሰዓት በአዲስ አበባ ዩኒቨርሲቲ በፋርማሲዩቲክስና ሶሻሌ ፋርማሲ ዲፓርትመንት በህክምና ግብአት አስተዳደር የሁለተኛ ዲግሪ ተማሪ ስሆን በደቡብ ጎንደር ዞን ውስጥ በሚገኙ የመንግስት ጤና ተቋማት ውስጥ ያለውን የሽረት ጊዜ ያለፈባቸውን መድኃኒቶች ሁኔታ የሚገመገመው ጥናት ዋና ተመራማሪ ነኝ። በመጀመሪያ የሽረት ጊዜ ያለባቸው የመድኃኒቶች ዙሪያ ለመነጋገር ውድ ጊዜዎን ሰውተው ፍቃደኛ ስለሆኑ ከልብ አመሰግናለሁ።

የዚህ ጥናት ዋና ዓላማ በደቡብ ጎንደር ዞን ውስጥ በሚገኙ በተመረጡ የመንግስት ጤና ተቋማት ውስጥ ያለውን የሽረት ጊዜ ያለፈባቸው የመድኃኒቶች መጠን ማወቅና ለሽረት ጊዜ ማለፍ መንስኤ የሆኑ ችግሮችን መለየት ነው። ይህ ደግሞ ወደ ፊት ፖሊሲ አውጪዎች እና ሌሎች ጉዳዩ የሚመለከታቸው አካላት አስፈላጊውን የማሻሻያ እርምጃ እንዲወስዱ ከፍተኛ አስተዋፅኦ ያደርጋል። በመሆኑም በጤና ተቋማቱ ውስጥ ያለውን የሽረት ጊዜ ያለፈባቸውን መድኃኒቶች ሁኔታ በሚመለከት ያለውን የግል አስተያየት በግልፅ እንዲነግሩኝ በአክብሮት እጠይቃለሁ።

በቃለ-መጠይቁ ወቅት የሚያነሱዎቸውን ነጥቦች ሙሉ በሙሉ ለማስቀረት ይረዳን ዘንድ የርሶ ፍቃድ ከሆነ ይህ ቃለ- መጠይቅ በመቅረጹ-ድምጽ የሚቀዳ ይሆናል። ይህም በመሆኑ

ድምፅዎን በሚሰማ መልኩ ጮህ ብለው እንዲናገሩ አሁንም በማክበር እጠይቃለሁ። ይህም ከጊዜዎት ከአንድ ሰዓት ያነሰ ጊዜ ይወስዳል። በዚህ ቃለ-መጠይቅ ሂደት የሚገኙ ማናቸውም መረጃዎች በምስጢር የሚጠበቁ ይሆናል። ይህም ማለት የሚሰጡንን መረጃ ከጥናት ቡድኑ አባላት ውጭ ለማንም ግልፅ የማናረግ ሲሆን የሚዘጋጁ የቃለ መጠይቆች ዘገባዎችም እርስዎን እንደ መረጃ 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 \_\_\_\_\_

በቃለ-መጠይቁ ለመሳተፍ ፍቃደኛ ከሆኑ ቃለ-መጠይቁ ይቀጥላል።

1. የመነሻ መረጃ

1.1. እድሜ \_\_\_\_\_

1.2. ፆታ \_\_\_\_\_

1.3. ትምህርት ደረጃ \_\_\_\_\_

1.4. የስራ ልምድ \_\_\_\_\_

1.5. የስራ ድርሻ \_\_\_\_\_

2: ቃለ-መጠይቅ መረጃ መሰብሰቢያ ነጥቦች / የመነሻ ጥያቄዎች

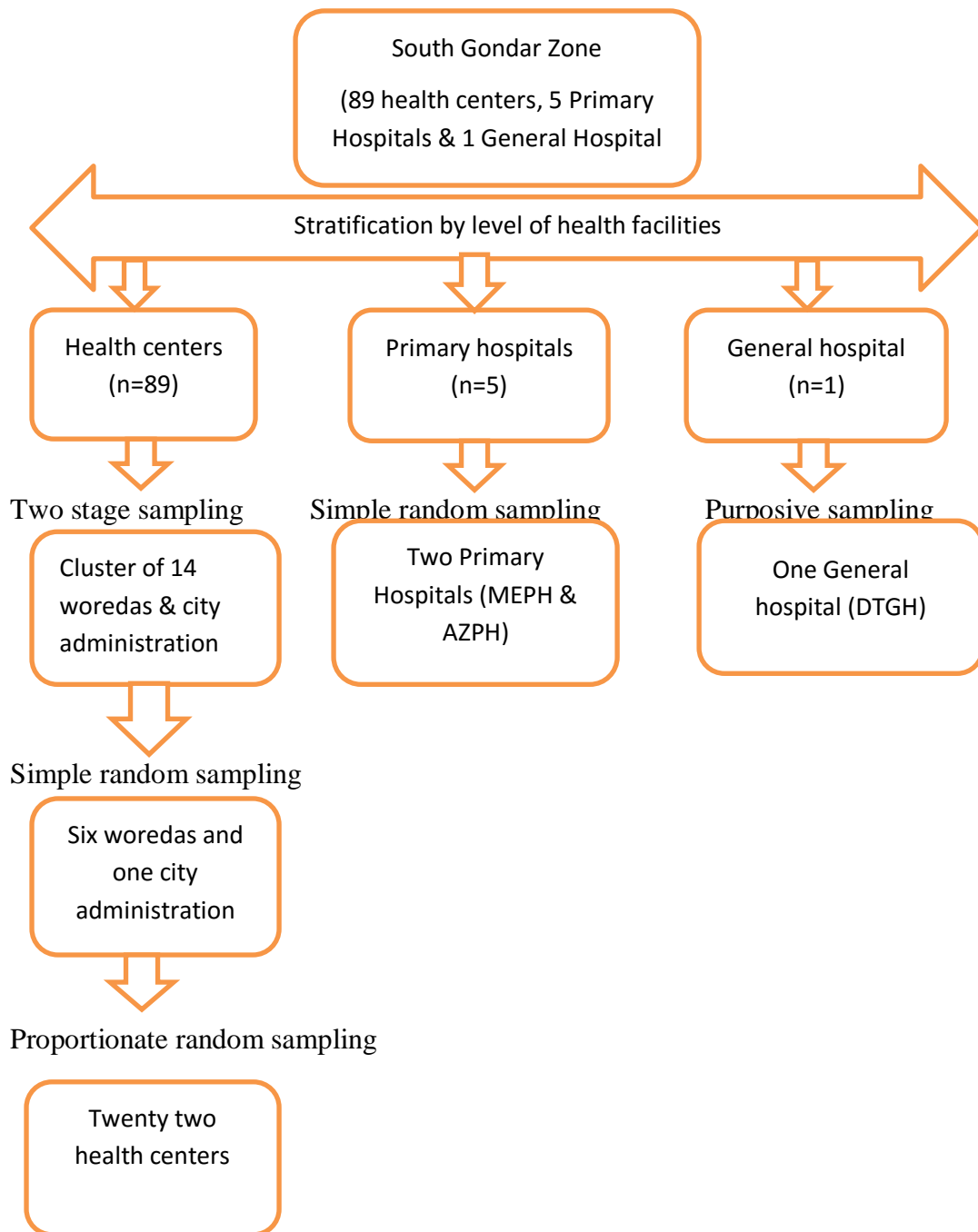
2.1. በጤና ተቋማቹ ውስጥ ያለውን የሽረት ጊዜያቸው ያለፈባቸው መድኃኒቶች እንዴት ይገመገሙታል?

2.2. በጤና ተቋማት ውስጥ በብዛት የሸረት ጊዜ የሚያልፍባቸው የመድኃኒቶች እነማን ናቸው? ለምን?






2.3. የችግሩን መጠን ለመቀነስ በፋርማሲ ክፍሌ / በጤና ተቋማት በኩል የተወሰደ እርምጃ ካለ ይጥቀሱ? ለወደ ፊትስ ምን መደረግ አለበት ብለው ያስባሉ?

2.4. መድኃኒቶች ሲወገዱ ተሳትፈህ ታውካለህ? በምን መንገድ ነበር ያስወገዳቸው?

## Annex 4: Sampling frame



## Annex 5: Copy Ethical Clearance Letter

በ ፋርማሲ ት/ቤት የኢትዮጵያ ሪፐብሊክ ቦርድ	አዲስ አበባ ዩኒቨርሲቲ Addis Ababa University	School of Pharmacy Ethical Review Board
		
		ቀን Date April 05, 2019
		ቁጥር Ref. No. ERB/SOP/58/04/2019
To: <b>Abraham Nigussie</b> School of Pharmacy		
Re: <b>Ethical Clearance</b>		
<p>It is to be recalled that you submitted a study proposal entitled "<b>Assessment of medicine expire and its contributing factor in public health facilities of south Gondar, Amhara Region, Ethiopia</b>" 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.</p>		
With best regards,		
Arebu Issa  Chairperson, ERB		
		
 00251156 02 12	 1176	ቴሌክስ Telex: 21205
		ፋክስ Fax: 00251(11)1558566
		ቲሌግራም Cable: AAUNIV



## Annex 7: Program medicines

MNCH commodity-Medicines		
<i>A. Neonatal and Child Health (NCH) Commodities- Medicines</i>		
1	Albendazole 400mg Tablet	50X2
2	Amoxicillin 125 mg Dispersible Tablet	10X10
3	Amoxicillin 250 mg Dispersibl Tablet,	10X10
4	Ampicillin 250mg Injection	50
5	Chlorhexidine 4% Gel	21gm
6	Gentamicin 10mg/mL in 2 ml Injection, with syringe	50
7	ORS (Sodium Chloride + Trisodum Citrate dihydrate + Potassium Chloride + Glucose) (3.5 g + 2.9 mg + 1.5 mg + 20 mg) Powder	100X10
8	Tetracycline 1% Eye Ointment	4gm
9	Zinc- ORS Co-pack (2 sachet ORS + 10-tab Zinc)	Kit
10	Zinc 20mg Dispersible Tablet	10X10
<i>B. Maternal Health (MH) Commodities- Medicines</i>		
1	Adrenaline (Epinephrine) 1mg/ml Injection	10X10
2	Amoxicillin 500mg Capsule	50X10
3	Ampicillin 500 mg powder for Injection	50
4	Atropine 1mg/ml Injection	10X10
5	Bupivacaine 0.5% 10 ml Injection	5
6	Calcium Gluconate 10% 10ml Injection	10
7	Ceftriaxone 1 gm powder for Injection	Vial
8	Dextrose in Sodium chloride (DNS), with giving set	1000ml
9	Diazepam 5mg/ml, 2ml Injection	100
10	Diclofenac 25mg/ml 3ml Injection	100
11	Doxycycline 100mg Capsule	20X10
12	Ergometrine 0.25mg/ml in 1ml Injection	10X10
13	Ferrous sulphate + Folic Acid (200mg + 0.4 mg) Tablet	100X10
14	Gentamycin 40mg/ml, 2ml Injection	10X10

15	Halothane 250ml Inhalation	Bottle
16	Hydralazine Injection 20mg/ml in 2 ml Injection	5
17	Ibuprofen 400mg Tablet	10X10
18	Ketamine HCl 50mg/ml in 10ml Injection	25
19	Lidocaine 1% without epinephrine 20 ml Injection	25
20	Magnesium Sulfate 50% in 20ml Injection	100
21	Methyldopa 250mg Tablet	100X10
22	Metronidazole 250mg Capsule	100X10
23	Metronidazole Injection 5mg/ml in 100ml Infusion	Bottle
24	Mifepristone -Misoprostol copack (200mg Tablet + 200mcg, 4 Tablet)	Kit
25	Misoprostol 200mcg Table	28
26	Misoprostol 25mcg Tablet	4
27	Nifedipine 10mg Tablet	10X10
28	Oxytocin Injection 10IU/ml in 1ml Injection	50
29	Pethidine, 50mg/ml in 2ml Injection	10
30	Ringer lactate solution (Na 147 mEq + K 4 mEq + Cl 155 mEq), With giving set	1000ml
31	Sodium Chloride 0.9% (NS) IV Solution, with giving set	1000ml
32	Suxamethonium chloride 50mg/ml in 10ml Injection	Ampule
33	Water for Injection, 10ml	100
<b>HIV/AIDS COMMODITIES-Medicines</b>		
<i>Anti Retrovirals (ARVs)- Medicines</i>		
1	Abacavir 300mg Tablet	60
2	Abacavir 60mg + Lamivudine 30mg Tablet	60
3	Atazanavir + Ritonavir (300+100) mg Tablet	30
4	Efavirenz 200mg Capsule	90
5	Efavirenz 50mg Capsule	30
6	Efavirenz 600mg Tablet	30

7	Lamivudine 150mg Tablet	60
8	Lamivudine 300mg/Tenofovir 300mg Tablet	30
9	Lamivudine 300mg/Tenofovir 300mg/Efavirenz 600mg Tablet	30
10	Lamivudine 30mg/Zidovudine 60mg/Nevirapine 50mg Tablet	60
11	Lamivudine 30mg/Zidovudine 60mg Tablet	60
12	Lopinavir 100mg+ Ritonavir 25mg Tablet	120
13	Lopinavir 200mg/Ritonavir 50mg Tablet	120
14	Lopinavir/Ritonavir 80/20mg/ml Solution	60ml
15	Nevirapine 10mg/ml Suspension	240ml
16	Nevirapine 200mg Tablet	60
17	Zidovudine 300mg/Lamivudine 150mg Tablet	60
18	Zidovudine 300mg/Lamivudine 150mg/Nevirapine 200mg Tablet	60
<i>Opportunistic Infection-Medicines</i>		
1	Sulphamethoxazole + Trimethoprim (200mg +40mg) /5ml suspension	100ml
2	Sulphamethoxazole + Trimethoprim (400mg + 80mg) tablet	100x10
3	Sulphamethoxazole + Trimethoprim (800mg + 160mg) tablet	100x10
4	Sodium stibogluconate 30ml	
5	Azithromycine 500mg tablet	
6	Acyclovir 200mg tablet	
7	Acyclovir 250mg iv infusion	
<i>Sexually Transmitted Infection (STI) Kits</i>		
1	UL Cure	Kit
2	Addis Cure	Kit
3	Addis Cure Plus	Kit
4	Male condom	Piece
<i>Nutrition</i>		
1	Plumpy Nut	Sachet
2	Plumpy Sup	Sachet
<i>Family Planning Program Pharmaceuticals</i>		
1	Etonogestrel - 68mg - Capsule (Subdermal Implant)	Each

2	IUCD (Intrauterine Contraceptive Device) - Long acting (CU380 A)	Each
3	Levonorgestrel - 75 mg/rod of 2rods - implant rods (Sub dermal) with sterile insertion trocar (Jaddle)	Each
4	Levonorgestrel (D-Norgestrel) - 0.03mg - Tablet	Cycle
5	Levonorgestrel (D-Norgestrel) - 0.75mg - Tablet	Cycle
6	Levonorgestrel(D-Norgestrel) +Ethinylestradiol + Ferrous Fumerate - (0.15mg + 0.03mg +75mg) - Tablet	Cycle
7	Medroxyprogesterone Acetate - 150mg/ml in 1ml Vial - Injection (Aqueous suspension) with syring (3 or2ml ) 21G needle.	Vial
<b>TB and LEPROSY PHARMACEUTICALS</b>		
<i>Drug Sustainable Anti-Tuberculosis Medicine</i>		
1	Ethambutol - 100mg - Tablet	10x10
2	Isoniazide -(INH) 300mg -Tablet	24x28
3	Isoniazide -(INH) 100 mg -Tablet	10x10
4	RH(Rifampicin + Isoniazid) - (75mg+50mg) - Tablet	28x3
5	RHZ( Rifampicin+Isoniazid+pyrazinamide) -(75mg+50mg+150mg) - Tablet	28x3
6	RHZE(Rifampicin+Isoniazide+pyrazinamide+Ethambutol)- (150mg+75mg+400mg+275mg) Of 6x28 + RH(Rifampicin+ Isoniazid)- (150mg+75mg) of 12x28	Kit
7	Pyridoxine HCL (Vitamin B6)-25mg-Tablet	100
Drug Resistance (Second line Anti TB medicines)		
1	Aminosalicyclic Acid Delayed Release granules,4gm solution	30
2	Amoxicillin + Clavulanic acid 500mg+125mg Film coated tablet(s)	3x5
3	Capreomycin-1gm vial-powder for injection	Vial
4	Cycloserine-250mg-capsule	100
5	Clofazimine - 100mg - Capsule	100
6	Ethambutol - 400mg - Tablet	24x28
7	Kanamycin 1g/4ml inj	10
8	Levofloxain 250mg tablet	100
9	Moxifloxacin-400mg-tablet	100
10	Prothionamide 250mg tab	100
11	Pyrazinamide-400g-Tablet	24x28

<i>Anti-leprosy medicines</i>		
1	Multibacillary-(MB) adult of 6 blister- Tablet	Pack
2	Multibacillary-(MB) child of 6 blister - Tablet	Pack
3	Pousebacillary- (PB) adult of 6 blister - Tablet	Pack
4	Pousebacillary- (PB) child of 6 blister - Tablet	Pack
5	Prednisolone - 5mg - Tablet	Pack
ANTI-MALARIAL-Medicines		
1	Artemether + lumefantrine (20 +120)mg	30
5	Artesunate 60mg vial injection	vial
6	Chloroquine 150mg tablet	10x10
7	Chloroquine 50mg base 5ml syrup	60ml
8	Quinine Sulphate 300mg tablet	10x10
9	Premaquine 7.5mg tablet	1000