FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA
MINISTRY OF HEALTH

ETHIOPIAN HOSPITAL SERVICES TRANSFORMATION GUIDELINES

Chapter 10: Pharmacy Service

Ethiopian Hospital Management Initiative

Version 1.0
August, 2017

Federal Democratic Republic of Ethiopia
Ministry of Health

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Forward

The earliest modern efforts to improve the quality of government hospitals throughout Ethiopia began in 2006 with the Ethiopia Hospital Management Initiative (EHMI), envisioned by the then Minister of Health, Dr. Tedros Adhannon, and supported by the Clinton Health Access Initiative in collaboration with the Yale Global Health Leadership Institute. The EHMI resulted in the creation of the Ethiopian Hospital Reform Implementation Guidelines (EHRIG), which built on both the Business Process Reengineering (BPR) and Hospital Blueprint efforts, as well as the Masters in Hospital and Healthcare Administration (MHA) degree program. Subsequently, the country developed a hospital performance monitoring system based on achievement of key performance indicators (KPI) and the Ethiopia Hospital Alliance for Quality (EHAQ) to spread best practices and promote collaborative learning in government hospitals nationally. EHAQ has focused on patient satisfaction, labor and delivery management, and provides a national framework for continuous quality improvement in hospitals across Ethiopia.

The Ethiopian Hospital Services Transformation Guidelines (EHSTG) build on and expand the Ethiopian Hospital Reform Implementation Guidelines (EHRIG) and are consistent with the Health Sector Transformation Plan (HSTP). The EHSTG, which is consistent with the national focus on quality improvement in health care, contains a common set of guidelines to help hospital Chief Executive Officers(CEOs), managers, and clinicians (care providers) in steering the consistent implementation of these transformational systems and processes in hospitals throughout the country. The EHSTG focused on selected management and clinical functions, including new individual service specific chapters for Emergency Medical, Outpatient and Inpatient Services, Nursing and Midwifery, Maternal, Neonatal and Child Health and Teaching Hospitals' Management. These guidelines also incorporate recent lessons from the operationalization of the EHRIG, as well as, new national initiatives such as the Guidelines for the Management of Federal Hospitals in Ethiopia, Hospital Development Army (HDA), Clean and Safe Hospital (CASH), and Auditable Pharmaceutical Transaction and Service (APTS).

It is expected that the guidelines will continuously evolve as new evidence emerges regarding improved hospital care and practices that are better tailored to needs and circumstances of different tiers of public hospitals.
We are grateful to all partners that have participated in the production of these guidelines. Special thanks go to our colleagues at the Clinton Health Access Initiative for their substantial contributions and support throughout the development of these guidelines as well as their dedicated efforts in support of our health reform efforts in so many other capacities.

Hon. Minister Kesetebirhan Admasu (MD, MPH)
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Abbreviations

ADR	Adverse Drug Reaction
APTS,	Auditable Pharmaceuticals Transactions and Services
AR	Analytic Reagent
DACA	Drug Administration and Control Authority
DIS	Drug Information Service
DSM	Drug Supply Management
DTC	Drug and Therapeutics Committee
FCC	Food Chemical Codex
FEFO	First Expiry, First Out
FMHACA	Food, Medicine and Healthcare Administration Control Authority
FMOH	Federal Ministry of Health
IPLS	Integrated Pharmaceutical Logistic System
LILO	Last in, Last Out
PFSA	Pharmaceuticals Fund and Supply Agency
PMP	Patient Medication Profile Card
RHB	Regional Health Bureau
STGs	Standard Treatment Guidelines
STI	Sexualy Trasmited Infections
MCH	Maternal and Child Health

Section I Introduction

Pharmacy service is an essential component of health care delivery in hospitals. It contributes to improved treatment outcomes through ensuring availability and rational use of quality, safe and effective medicines. Provision of effective pharmacy service is also crucial for early recognition & prevention of medication errors, adverse drug events and for the prevention and containment of antimicrobial resistance. It also promotes optimal use of meager resources thereby improving quality of care resulting in better health outcomes. Accordingly, pharmacy services should provide assurance that quality and safety is maintained at all stages of service provision and clients' satisfaction is given of utmost importance. Hospitals should establish convenient work environment and workflow that elicits confidence to patients and the staff.

Pharmacy chapter of the previous version of Ethiopian Hospital Reform Implementation Guideline (EHRIG) prepared in 2010, guided hospitals in the implementation of critical operational standards. It helped hospitals in the delivery of quality services and enabled Ministry of Health, Regional Health Bureaus and hospitals to evaluate their performance using predefined indicators. Consequently, commendable achievements have been registered in terms of improving pharmacy service delivery. Currently, many operational standards set in the first version have been achieved by majority of hospitals in the country.

Following the launching of the Health Sector Transformation Plan (HSTP) and its emphasis to increasing equity and quality of health care, hospital pharmacy services are expected to have substantial contributions in realizing this vision by rendering measurable and better quality services in a more responsible and accountable. Moreover, within the last five years, Ethiopian hospitals have been implementing number of initiatives including Accountable Pharmaceutical Transaction and Service (APTS) and Clinical pharmacy services which were not adequately addressed in the operational standards of the first version. Therefore, it is found necessary to update operational standards and implementation guidance so as to reflect these and other new developments such as chronic diseases management and

provision of poison information. In addition, there was a need to develop robust measurement approaches and applicable indicators that are in line with the health sector expectations in the coming five years. Therefore, the standards and guidance set in this chapter are designed to align with and support hospital pharmaceutical services to meet the demands of the health sector transformation plan of the nation.

Section 2 Operational Standards for Pharmacy Services

1. The hospital provides quality pharmaceutical products and effective services in its outpatient, inpatient, and emergency pharmacy service units.
2. The hospital has a functional Drug and Therapeutics Committee (DTC) that develops and implements interventions promoting the rational and cost-effective use of medicines
3. The hospital develops, utilizes and annually updates a comprehensive list of pharmaceuticals prioritized by Vital essential and nonessential (VEN}.
4. The hospital ensures execution of good dispensing practices at all dispensing outlets.
5. The hospital implements auditable, transparent and accountable pharmaceutical transactions and services (APTS).
6. The hospital provides clinical pharmacy services at inpatient, outpatient and emergency departments.
7. The hospital provides drug information services to health care providers, patients and the public.
8. The hospital has a functional compounding service.
9. The hospital selects, quantifies, procures, stores and distributes safe, effective and quality pharmaceuticals consistently to ensure uninterrupted supply.
10. The hospital regularly monitors medication use and safety.
11. The hospital conducts continuous segregation, documentation and safe disposal of pharmaceutical wastes.
12. The hospital pharmacy monitors and evaluates its performance on regular basis using implementation checklist and selected indicators.

Section 3 Implementation Guidance

3.1. Pharmacy Service Organization and Management

Pharmacy services should be organized and managed in such a way as to ensure patient safety, convenience, privacy and satisfaction. The organization and management should also improve performance and be convenient to practitioners.

3.1.1. Pharmacy Service Organization

Pharmacy services of the hospital should be organized as outpatient pharmacy services unit, inpatient pharmacy services unit, emergency pharmacy services unit, pharmaceutical supply management unit, drug information services unit, and compounding pharmacy services unit. Other units shall also be established depending on the hospital complexity and demand. Each unit should be directed by a registered pharmacist.

OPD Pharmacy Service Unit: shall be organized in one primary location that is accessible to all categories of patients. But, it may also be organized in multiple locations (e.g. general OPD pharmacy, ART pharmacy, chronic care pharmacy, MCH pharmacy, etc.) depending on the arrangement of the OPD clinics, proximity and complexity of the hospital so as to improve accessibility and convenience to patients. Patient waiting areas at the OPD pharmacy units should be fitted with adequate seats and shading to ensure patient safety and convenience.

Patients with chronic illnesses should be followed up at respective OPD pharmacy or separate Chronic Care Pharmacies. Depending on the hospital's level and service specialization, one or more chronic care pharmacies shall be established. All patients who have follow-up in these pharmacies shall have individual patient medication profile (PMP) records. The PMP should be updated by the dispensing pharmacist whenever a refill medication or other drugs are dispensed to the patient. When a patient presents to the pharmacy for a refill, the pharmacist must assess the patient for signs of compliance/adherence, effectiveness and safety of the therapy. Whenever the need arises, the pharmacist should communicate with the prescriber for any therapeutic modification.

Inpatient Pharmacy Service Unit: depending on patient load, number of beds, and accessibility, there should be adequate number of inpatient dispensaries and specialty pharmacies located near the major wards. These dispensaries should be led by pharmacists (preferably clinical pharmacists). Inpatient pharmacy services should function under unit dose dispensing system and work for 24 hours and 7 days a week.

Emergency Pharmacy Service Unit: should be organized within or near the emergency department. The dispensing process should be organized such that medicines reach to the patient as fast as possible. Emergency pharmacies should function for 24 hours and 7 days a week. The unit shall avail emergency pharmaceuticals as per the list indicated in this guideline (Annex 1). The unit also prepares ambulance kits for the hospital. The pharmacist in charge of the unit has to exert the necessary efforts to ensure continuous availability of pharmaceuticals at all times in adequate quantities for the emergency unit and hospital ambulances.

Besides the routine prescription based dispensing, emergency crash cart system shall be used to avoid delays in availing pharmaceuticals to emergency patients.

Orders received by word of mouth or through telephone during an emergency should later be endorsed by the prescriber and be documented in writing before the next shift. The quantity prescribed should be limited to emergency period only.

The emergency pharmacy, in addition to supply of pharmaceuticals, shall ensure safe and correct use of medications, as medication error is significantly high in this service area, by integrating clinical pharmacy services within the emergency team.

Extemporaneous Compounding Unit: in order to respond to specific patient needs, the hospital pharmacy should have compounding services with separate premises, equipped with the necessary facilities/materials and meeting all other minimum requirements.

Pharmaceutical Supply Management Unit: to ensure uninterrupted supply of pharmaceuticals, the hospital pharmacy should have pharmaceutical supply management unit. The unit shall have separate pharmaceutical stores for medicines and supplies including consumable medical equipment and lab reagents. The overall operation of the unit (selection, quantification, procurement, inventory management, warehousing and distribution) should be coordinated by a dedicated pharmacist and stores should be managed by a separate store manager.

Drug Information Service (DIS) Unit: The hospital pharmacy should have a drug information service unit to effectively provide evidence based and up-to-date drug information for health care providers and patients/ clients.

Clinical Pharmacy Services: The hospital pharmacy shall provide clinical pharmacy services in its inpatient, outpatient and emergency departments. The service should be well integrated in all clinical departments. All services provided in these departments should be recorded, documented and reported.

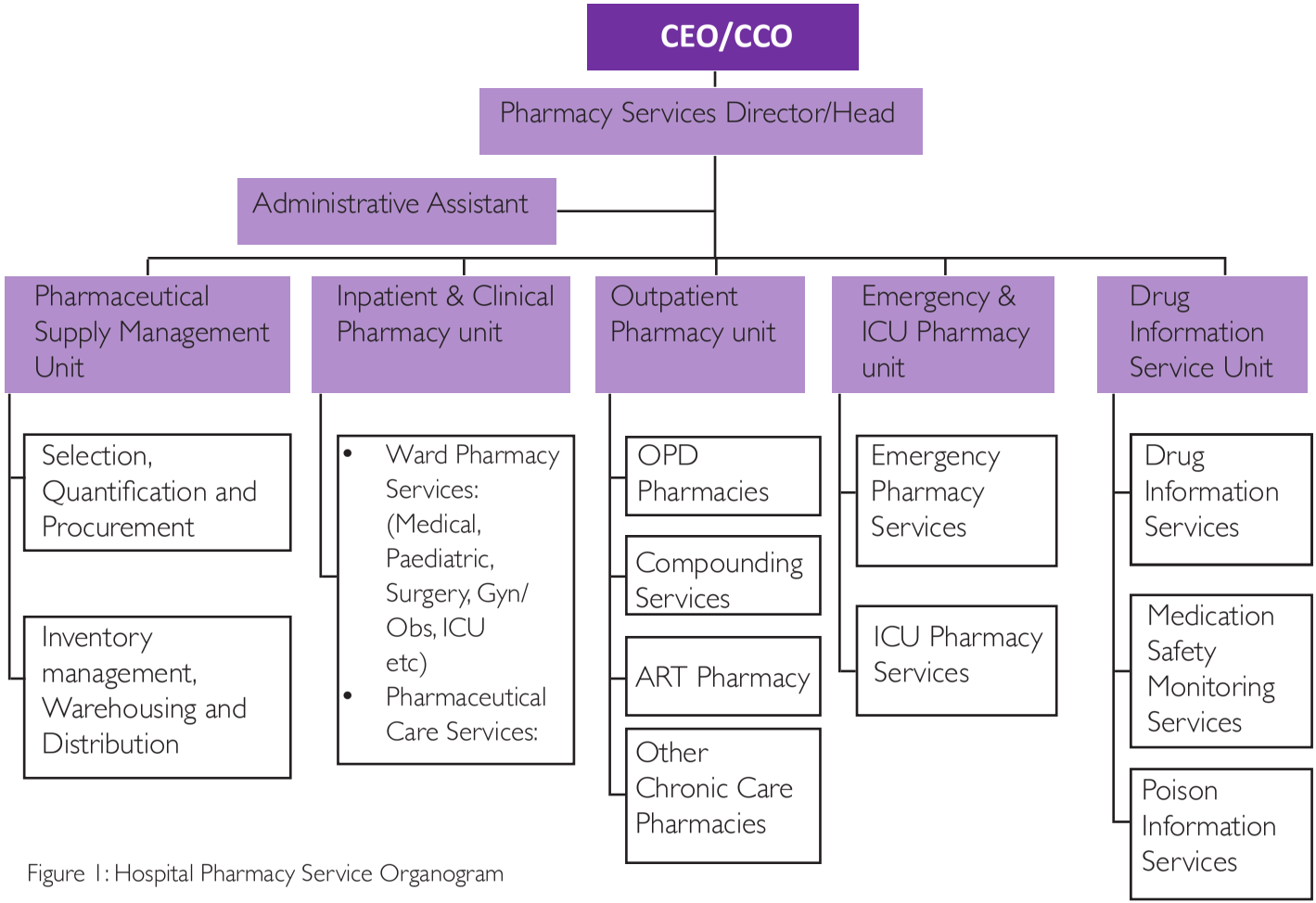

Figure 1: Hospital Pharmacy Service Organogram

3.1.2. Resources Needed for Pharmacy Services

Human resource: To deliver efficient and quality pharmaceutical services, the hospital pharmacy should be staffed by professionals with the required mix and number based on the type of services and workload. Hospital pharmacies should have at least the following positions and professional mix:

- Pharmacy Services Director/Head: in charge of overall activities of the pharmacy services
- Pharmacy Unit Coordinators: coordinates the overall activity in each unit. When necessary there may be team leaders under coordinators.
- Pharmacist: in charge of managing dispensing and related functions at the following service areas:
  - OPD pharmacist: include evaluators, processors and counselors. They dispense medicines to patients and manage assigned bins in dispensing areas. In addition, chronic care pharmacist provides pharmaceutical care to patients with chronic diseases.
  - Inpatient pharmacist: provides, records, documents and reports clinical pharmacy service for inpatients. In addition, he/she manages and dispenses in ward pharmacies.
  - Emergency pharmacist: provides pharmaceutical services in the emergency department.
  - Drug Information Pharmacist: provides up-to-date and unbiased drug information for the healthcare provider and patients/clients. He/she shall also monitor and evaluate medicine use and safety, conducts patient education and provide poison information services.
  - Compounding pharmacist: undertakes hospital based pharmaceutical preparations
  - Pharmaceutical supply management pharmacist: manages the selection, quantification, procurement, storage, inventory and distribution of pharmaceuticals.
- Pharmaceuticals Store Manager: manages the pharmaceuticals store/s.
- Pharmacy Accountants: in charge of aggregating and documenting pharmacy transactions and services.
- Cashiers: receives cash from clients and deposits in banks and delivers financial documents to accountants
- Porters: responsible for loading, unloading, delivering and arranging

pharmaceuticals under the supervision of pharmacy professionals in the respective unit.

- Cleaners: responsible to keep service delivery premises clean and tidy at all time.
- Patient assistant: responsible to keep order at dispensing outlets so that patients could be served in an orderly and secure manner
- Admin assistant: responsible for secretarial works and office management of the pharmacy director/head

Premises, Equipment and Facilities: The hospital should have sufficient space for the storage, compounding, counseling and dispensing of medicines and for the conduct of related administrative activities. Cashiers should be located within the dispensing room in a cubicle to ensure patient convenience. The pharmacy accountant office should be stationed adjacent or near to dispensaries. The store should be in an area that is accessible for trucks to facilitate loading and unloading activities. Separate office with office assistant should also be arranged for the director/head of pharmacy department.

The hospital should ensure availability of basic equipment and/or facilities to enable delivery of proper pharmacy services, including: tablet counters, packaging and labeling materials, refrigerators, thermometers, shelves, dispensing counters, lockable cabinets, tables, chairs, calculators, computers, printers, etc. All service areas should be clearly labeled. Access to storage and dispensing areas should be restricted to only authorized personnel. Only designated personnel shall have access to keys for entrance to medicine warehouses and dispensing units.

All pharmacy service units should have a sink with running water and continuous electricity with power backup (connected to hospital generator). Toilet should be available and appropriately located. Telephones and internet services should also be available within each service areas.

Note: Please refer the detail about pharmacy service workflow and cubicle sizes from APTS manual

3.1.3. Pharmacy Service Management

Hospital pharmacy services need be effectively managed so as to provide patient-centered services in a manner consistent with standards outlined in this guideline. To achieve this, the department shall be led by director/head who is assigned by the hospital management. The director/head in turn assigns unit coordinators; and team leaders may be formed to execute activities as deemed necessary.

The director/head of the department performs the following activities (in collaboration with respective service units):

- Develops, implements, and monitors annual action plans which are approved by the hospital management to fulfill the mission, vision, goals, and scope of services of the hospital.
- Continually monitor the evolving needs of health care units within the hospital and make the necessary adjustments in pharmacy services (including the selection, procurement, distribution and use of medicines) to respond to the emerging needs of clients.
- Follows new developments and trends in health care and hospital pharmacy practice, and communicates to everyone involved in the provision of pharmacy services
- Makes sure national service standards and guidelines pertaining to pharmacy practices are made available and implemented
- Continuously performs workload analysis and alerts the hospital management for possible action
- Participates in hospital committees and meetings representing the pharmacy department including drug and therapeutics committee (DTC)
- Makes sure that new staffs are properly oriented and supervised.
- Plans and implements professional development programs for all staff as appropriate to enhance their knowledge and skills.
- Organizes periodic meetings for discussion among staffs.
- Communicates and collaborates with other departments and services throughout the hospital
- Regularly evaluates the performance of pharmacy staffs and takes measures accordingly.

- Produces and communicates performance reports to the hospital management and relevant government bureaus and agencies

3.2. Drugs and Therapeutics Committee

Each hospital should establish a functional Drug and Therapeutics Committee (DTC) having multidisciplinary representative members. The DTC brings together all the relevant professionals to work jointly to improve health-care delivery. The DTC has an advisory role and discharges its responsibility of promoting the safe, rational and cost effective use of pharmaceuticals by providing guidance to pharmacy, clinical departments, and management of the hospital.

3.2.1. Membership of DTC

While deciding number of DTC members, the hospital shall consider that fewer DTC members will enable to reach consensus more easily while more DTC members provides greater expertise, reduce workload for individuals and increase chances of DTC decision implementation. Considering this, DTCs shall have the following members, as a minimum:

- Chief Clinical Officer or equivalent (Chairperson)
- Pharmacy director/head (Secretary)
- Head of laboratory service
- Head of nursing service
- Head of clinical departments (internal medicine, surgery, pediatrics, gyn-obs, etc.)
- Head of finance department
- Representative from other services as deemed necessary

Other non-voting, non-executive participants can be invited to attend DTC meetings to discuss specific issues that require their particular expertise. All DTC members, especially the chair and secretary, should be given sufficient time for their DTC functions and this should be included in their job descriptions.

Sub-committees of the DTC may be formed to address specific issues as the need arises (for example a policy on the use of antimicrobials, etc.).

3.2.2. Procedures of DTC meetings

The DTC should meet at a minimum every two months, or more often as the need arises. Minutes should be kept for all DTC meetings. The agenda, supplementary materials and minutes of the previous meeting should be prepared by the secretary and distributed to members for review in sufficient time before the meeting. These documents should be kept as permanent records of the hospital and recommendations should be circulated to hospital management and concerned units/departments. Seventy-five percent of the members will constitute a quorum for any meeting and 50% plus members' support will approve decisions of any discussed issue.

3.2.3. Roles and responsibilities of the DTC

The DTC should develop terms of reference (TOR) detailing the objectives, scope, meeting frequency, membership, and roles and responsibilities of the DTC and each member. The DTC is expected to develop and implement annual action plan in line with its roles and responsibilities. The DTC should have the following roles and responsibilities:

The DTC develops and maintains the hospital's specific list of pharmaceuticals: The DTC coordinates all relevant departments of the hospital to take part in the selection and prioritization of pharmaceuticals needed by the hospital. Pharmacy, medical, laboratory, medical equipment management and imaging departments should take part in the process.

Preparation of SOPs and guidelines needed to ensure provision of proper pharmacy services: SOPs should be developed for drug supply management, disposal, drug information services, generic substitution and therapeutic interchange, use of specific medications such as narcotics and psychotropic agents, high-alert medications, chemotherapeutic agents, highly expensive medications, etc.

The DTC promotes the adoption and utilization of standard treatment guidelines (STG): The DTC should promote utilization of national STGs. Specialized hospitals may also develop their own STGs based on availability of required expertise, facilities, etc.

The DTC establishes mechanisms to identify and address drug use problems: The DTC should establish policy/procedures for identifying and managing drug use problems. The DTC follows the implementation of these activities by itself or by setting up a subcommittee composed of relevant departments. When problems are identified, the DTC should devise specific interventions to improve practices. Interventions may be educational, managerial and/or regulatory.

Establishing Antimicrobial Stewardship Program (ASP): The DTC should establish Antimicrobial Stewardship Program (ASP) to promote rational antimicrobial use and contain antimicrobial resistance (AMR). The program should be implemented through a multidisciplinary approach containing physicians, pharmacists, nurses, laboratory professionals, infection prevention committee and others as needed.

Support and oversee establishment and functioning of Drug Information Services (DIS): As part of improving access to unbiased and current information on medicines, the DTC should support establishment of a functional Drug Information Service (DIS) that serves both health professionals, patients and the public at large.

For further details, please refer the DTC manual

3.3. Hospital Specific Pharmaceuticals List

All hospitals shall develop hospital specific pharmaceuticals list comprised of medicines, medical supplies, medical equipment and laboratory reagents which are prioritized as vital (V), essential (E) and non-essential (N). This list is developed based on the national formulary. The hospital should use the list for procurement purposes and for monitoring prescribing and use. In addition, specialized hospitals may have formulary manual for specific medicines used for their specialty services. These hospitals may include pharmaceuticals not included in the national list.

Hospital specific pharmaceuticals list should be prepared by multi-disciplinary team of health professionals drawn from medical, pharmacy, laboratory, and imaging departments.

The selection of pharmaceuticals should be based on:

- The local pattern of disease
- National standard treatment guidelines (STGs)
- The recent national drug list (List of drugs for Ethiopia)
- Type of health services given by the hospital
- Availability of expertise in the hospital (specializations)
- Diagnostic capacity of the hospital

The description of pharmaceuticals in the list should contain generic names, dosage form, and strength. The list is recommended to include a limited number of drugs so as to improve drug availability, adherence to treatment, focused prescribing, and to simplify supply management.

The pharmaceuticals list should be reviewed and updated at least annually. The list should be available in clinical departments, the pharmaceuticals store, dispensaries, laboratory, finance, etc. to be used as references.

3.4. Good Dispensing Practice

Good dispensing practice refers to the delivery of correct medicines to the right patient, in the required dosage and quantities in a package that maintains acceptable potency and quality for the specific duration with clear labelling instruction and drug use counseling. The six dispensing steps are described below:

Step 1: Receiving, interpretation and evaluation of a prescription
Step 2: Billing and recording transactions
Step 3: Selection, manipulation or compounding of the medicine
Step 4: Packaging and labeling of the medicine
Step 5: Provision of medicines to the patient with counseling
Step 6: Filing the prescription and transaction documents

Step 1: Receiving, interpretation and evaluation of a prescription

The pharmacist receives prescriptions in a professional manner and validates for completeness, legality and legibility. He/she should also correctly interpret

type of treatment and the prescriber's intentions, abbreviations and brands. Then, the pharmacist evaluates the appropriateness of the drug choice, dosage form, strength, dose, frequency, and duration of treatment with the diagnosis. The pharmacist is also required to identify any medicine interactions, contraindications, ADR and treatment duplications giving special attention to pregnant and lactating mothers and children.

The pharmacist should identify the patient, the prescriber and the entity responsible for payment (as applicable). The pharmacist informs the patient about the benefits and implications of substitution (if any) including branded medicine and therapeutic alternatives. The pharmacist should also help patients to solve problems with prescriptions that cannot be dispensed due to cost, religion, culture and lifestyle. Any problems identified should be discussed and solution should be solicited in consultation with the prescriber, pharmacists and patient. All hospitals should use standard prescription paper and the pharmacist shall fill orders written only on standard prescriptions with complete information (Annex 2).

Step 2: Billing and recording of transactions

The pharmacist should perform the necessary calculations related to quantity and cost of medicines to be dispensed. Billing and recording of transactions (products and services) should be conducted using serially numbered sales tickets and registers approved by Ministry of Finance and Economic Development or respective regional finance bureaus. For drugs that are not available in the pharmacy, those items should be copied on a blank prescription and signed by the dispenser with a word 'copied' on the prescriber's signature space. On the original prescription, which is retained by the pharmacy, '√' mark should be placed adjacent to those items which have been dispensed and 'X' for items that are not dispensed. Medicines dispensed should be recorded and documented as proof of transaction between the patient and the pharmacy professional. Prescriptions can therefore be traced back if the need arises.

Step 3: Selection, manipulation or compounding of medicines

Medicines should be selected carefully using the prescription at hand. Counting of tablets and capsules should be done on a clean counting

tray. Compounding of extemporaneous preparations should be done in a separate room by the appropriate staff; equipment and procedure (see details in compounding standard sub topic).

Step 4: Packaging and labeling of medicines

The packaging materials for dispensing must maintain quality and potency of medicines. It should provide protection from moisture, light, and contamination. Capped bottles are preferred over plastic and paper bags. All medicines to be dispensed should be labeled and the labels should be clear, legible and indelible. Printed labels are advisable for patient safety. The following information must be indicated on the label:

- Patient name
- The generic name of the product or (active ingredients, for compounding) with strength and dosage form
- Dose, route, frequency of administration, duration of treatment and total quantity
- The directions for use and special precautions as applicable
- Expiry date/Beyond use date
- Storage condition
    * Auxiliary labels such as 'keep out of reach of children'

Step 5: Provision of medicines to the patient with counseling

All drugs should be dispensed with adequate and appropriate counseling. Information must be structured to meet the needs of individual patients. Written information should be provided to supplement counseling. Counseling should ensure that the patient has adequately understood the instructions and any distinct characteristics or requirements of the medicine. Counseling should include the following, as appropriate:

- Name and description of the medicine
- Intended use of the medicine and expected benefit
- Dose, frequency, and route of administration and actions to be taken if a dose is missed
- Duration of therapy with emphasis given to completing the entire course, e.g. antibiotics,
- Expected time to see a response of the medication and instructions on

what to do if the desired effect is not obtained
- The time the drug should be taken in relation to other drugs, food, life style, etc.
- Clear instructions on measurement and administration of medicine (liquid, aerosol, topical preparations and suppositories)
- Techniques for self-monitoring of medication therapy
- How to prevent, identify, and manage common and severe adverse effects
- Clinically significant interactions (drug-drug, drug-food, drug-disease)
- For patients who need special counseling such as those taking suppositories and pessaries, psychiatric patients, non-adherent patients, patients with STI, stigmatized patients, etc. should be counseled in dedicated counseling rooms
- Storage instructions including advice regarding keeping medicines out of reach of children
- Any other information as appropriate

Step 6: Filing the prescription and transaction documents

Each prescription (signed by evaluator and counselor), sales tickets and registers should be filed. All registers and prescriptions, patient and medication related records and information should be documented and kept in a secured place that is accessible only to authorized personnel. Filing will include:

- At the close of each day all dispensed prescriptions should be organized into normal or special prescriptions (e.g. Narcotic drugs) and filed separately.
- Prescriptions should be filed sequentially by date in a single container/ carton for each month. The container should be labeled with the month and year.
- Containers should be arranged on a monthly basis.
- Normal prescriptions should be filed securely for two years and special prescriptions for five years.

Free and credit registers should be filed for at least two years:

3.5 Auditable Pharmaceutical Transactions and Services (APTS)

APTS is a data driven package of interventions designed to establish accountable, transparent and responsible pharmacy practice. It enables health facilities to optimize utilization of medicines budget, improve access to medicines, and decrease wastages. APTS continuously monitors the number, mix & performance of pharmacy workforce. It also improves pharmacy premise design and workflow. Through improving recording and documentation, it generates reliable and consistent information for decision making. As a result, APTS improves overall quality of pharmacy services thereby increasing patient knowledge and satisfaction. Ultimately it contributes to better health outcomes.

APTS has five result areas: efficient budget utilization, transparent and accountable transactions, reliable information, effective workforce development and deployment, and improved customer satisfactions. In order to achieve these results, hospitals are expected implement selected interventions. The following list provides guidance on what needs to be done to achieve each of these results.

3.5.1. Efficient Budget Utilization

- All hospitals should develop facility specific drug list prioritized by VEN and enforce its use
- Regular ABC value analysis should be conducted and reconciled with VEN categorization and results should be used for guiding decisions during subsequent procurements
- Procurement should be conducted only from hospital medicines list
- Regular stock status and consumption to stock analysis is conducted to identify medicines at risk of expiry
- The hospital should measure wastage rate of medicines on monthly basis. The hospital identifies medicines having near expiry date and take preventive measures to reduce wastage/expiry to less than 2%.
- Establish effective mechanisms for managing sales of medicines and/or increasing revenue by increasing turnover rate, improving availability and reducing misappropriations.

3.5.2. Transparent and Accountable Transactions

The process of receiving, issuing and dispensing pharmaceuticals in hospitals should be transparent and accountable. Transactions include: receiving at store, issuing to dispensing units, receiving at dispensing units and dispensing to patients. To achieve transparent and accountable transactions hospitals should perform the following activities.

- Use standard financial vouchers, sales tickets, registers and forms that can clearly identify and document medicines transacted.
- All pharmaceuticals are coded and all transacted medicines should be traced by using uniquely identifying codes.
- At the time of transactions, complete description of medicines, i.e., name, strength, dosage form, batch number and expiry date, should be recorded.
- All medicine sales should be supported by a record/document and actual cost of medicines should be reconciled by applying adjusted sales method on daily basis (separating the over and under sales).
- Hospitals should implement bin management at all dispensing units and create individual accountability.
- Hospitals should also apply collective responsibility for professionals working in one dispensing unit to achieve participatory effort in managing medicines and transactions.
- All hospitals should conduct random product audits, monthly financial audits and quarterly service audit.

Pharmaceuticals are received at the pharmaceuticals store from PFSA and other sources. The pharmaceuticals received by the store are issued to dispending outlets. From the dispensing outlets medicines are dispensed to patient on cash, for free or on credit basis. All transactions should be conducted using legally approved and pharmaceuticals-specific models, sales tickets, and dispensing registers. The flow of pharmaceuticals from distributers to end users in the hospital shall include:

Receiving: All pharmaceuticals (medicines, lab reagents, medical supplies, and equipment) should be received and managed by the hospital Pharmaceuticals

Store. At this step pharmaceuticals must be assessed for quality and quantity through physical inspection and added into the inventory of the store.

Note that pharmaceuticals should be requested using standard format (RRF) from PFSA every two month.

Issuing: Each dispensing unit should have an agreed list of pharmaceuticals including the maximum (one month) and minimum (two weeks) quantity to be stocked in the dispensing unit. The stock list of each dispensing unit should be approved by pharmacy department director/head or pharmaceuticals supply management unit head before they are issued to dispensaries. Each dispensing unit should maintain Bin Cards for all pharmaceuticals in the unit with shared responsibility by bin owners.

Dispensary transactions: The sale of pharmaceutical products is an important source of hospital income. With the exception of exempted health programs (Immunization, TB, Leprosy, ART and MNCH) pharmaceuticals can be sold at a price that covers the actual cost of the medicine plus a service charge. Transparent and uniform procedures should be established for managing the sales of medicines.

The retail price of each pharmaceutical should come from the store in issue vouchers (model 22/health). Each dispensing unit should sale pharmaceuticals at the stated price. All pharmaceuticals should be dispensed/sold using a standard sales ticket designed for the purpose and approved by Federal Ministry of Finance and Economic Development or respective regional finance bureau. The pharmacy professional is responsible to record each medicine with full descriptions, uniquely identifying codes, retail prices in the sales tickets or registers. The pharmacist should also to record all service provided, drug therapy problems (DTP) identified by prescription evaluators, and counseling made for clients.

In order to facilitate the prescription evaluation, billing, cash collection and patient counseling, the following actions are important:

- Prepare adequate number of counters used for prescription evaluation/

billing, cash payment and counseling based on the daily number of patient served in the hospital

- Arrange waiting area for dispensaries as per the patient load in a day
- Arrange workflow in dispensaries (prescription evaluator and biller, cashier and medicines use counselor) in such a way that a patient enters through an entrance/door on one side, passes through successive stages of services (prescription evaluation/billing by a pharmacist, payment to a cashier and finally medicines use counseling by a second pharmacist) and exits on the other side.This arrangement combines all services together in one room so that the patient gets one stop shopping service.

The dispensing workflow shall be designed to realize the six dispensing steps. The dispensing workflow begins when the pharmacist receives and evaluates the prescription. Then the pharmacist should calculate the price of the medicines and inform the same to the patient/care giver. He/she then writes the medicines with uniquely identifying codes and retail prices on a sale ticket. Then the sale ticket is given to the cashier. Once payment is effected, the cashier transfers the prescription to the processor pharmacy professional. He/she selects, counts, assembles and delivers medicines with the prescription to the counselor pharmacist.Then the counselor pharmacist, packs, labels, checks whether the payment is effected, and gives the medicine with verbal and written counseling to the patient. The dispensing workflow is shown below.

Finally, the pharmacy accountant summarizes all transactions (financial value,

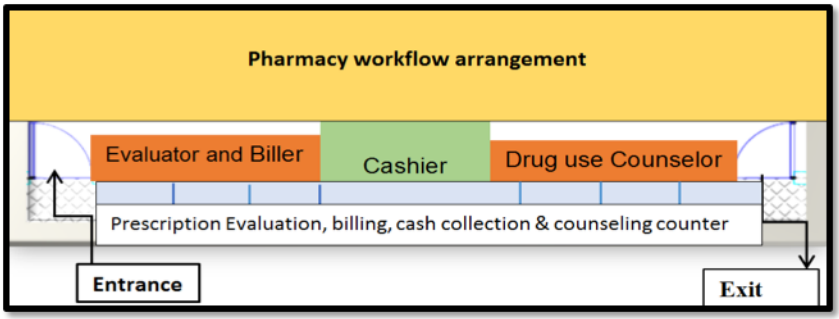

Figure 2: Pharmacy Workflow Arrangement

dispensed medicines and services) on daily basis and prepares report on monthly basis as per the APTS guideline. Auditors in collaboration with pharmacy professionals and DTC members should use the document for auditing of the above transactions and services and making decisions to improve the service.

3.5.3. Effective Work Force Development and Deployment

All hospitals should develop detailed job description for all staffs in the pharmacy department. The level of effort for each unit should be measured and workload should be calculated. Based on the workload, hospitals should take subsequent measures.

The following assumptions are used for workload analysis:

- For dispensaries, 1000 prescription (or 1500 counseling episodes) per pharmacists per month;
- For clinical pharmacy services in wards, 25, 30, 35 beds per pharmacist per day for tertiary, secondary and primary hospitals, respectively;
- For chronic pharmacies, 30 prescriptions per day per pharmacist
- For accountants practical experience showed that 5000 patients per month.
- For cashers the number of patient served by one cashier at dispensary is up to 500 per day.
- Other services units shall deploy staffs as per their workload

Note: see details about mix of professional needed in resource needed for pharmacy service sub topic

3.5.4. Reliable Information for Decision Making

All hospitals should produce reliable information on product, financial values of medicines transacted, and pharmaceutical services rendered on monthly basis. The report of the pharmacy should be linked to the serial numbers of financial tools for ease of documentation, reference and validation. Information concerning the financial values includes value of medicines sold on cash, credit and for free.

Service related information includes the total number of patients served per health facility, per dispenser per month segregated by service type which may

include services rendered for paying, credit and free patients; outpatients, inpatients and emergency patients; mothers and children; patients with chronic illnesses, patients taking medicines for OIs and so on.

This information should be used for decision making. Hospitals should also use product information like consumption to stock ratio analyses, availability of medicines for top ten diseases, rate of expiry and affordability to take subsequent measures for improving services.

3.5.5. Improved Customer Satisfaction

The eventual success of hospital pharmacy service is to achieve overall patient satisfaction through improving availability of medicines, premises and work flow and providing quality pharmaceutical services. Reducing patient travels between dispensing and finance units by providing one stop shopping is critical for enhancing patient convenience and reducing waiting time. Moreover, increasing the number of dispensing cubicles based on patient load dramatically reduces patient waiting time, promotes privacy and increases care time (for prescription evaluation and counselling). Such services create the environment whereby patients are empowered to properly adhere to prescribed medicine by improving their knowledge and attitude. Moreover, they save patients from unnecessary harm associated with irrational use of medicine. The hospital should measure patient satisfaction of pharmacy services on a regular basis.

3.6. Clinical Pharmacy Services

Clinical pharmacy services are patient-oriented services developed to promote the rational use of medicines, and more specifically, to maximize therapeutic benefits, minimize risk, and reduce cost. Pharmacists assume responsibility for managing medication therapy in direct patient care settings (inpatient, outpatient and emergency). They assess patients, identify drug therapy needs and problems, propose care plan, recommend choices, and monitor outcomes. The service should be well integrated with all clinical departments.

The following activities need to be performed during the provision of clinical pharmacy services in inpatient settings:

3.6.1 Admission Medication History Taking

Using an In-patient Medication Profile Form (Annex 3), a pharmacist takes admission medication history either together with the admitting physician or independently. The pharmacist also uses the treatment chart to take relevant information. The information collected on In-patient Medication Profile Form will be part of patient medical chart.

3.6.2 Provision of Pharmaceutical Care

The delivery of pharmaceutical care involves the following processes:

- Assess the patient's drug therapy needs and identify actual and potential drug therapy problems (DTPs).
- The pharmacist establishes the existence of any needs and/or problems with the drug therapy by interpreting information collected from patient, caregivers, medical records and other healthcare professionals.
- Develop a care plan to prevent and/or resolve the DTPs.
- Based on the assessment, the pharmacist establishes goals of therapy, develop appropriate interventions to resolve DTPs, achieve goals, and prevent new problems by considering therapeutic alternatives and selecting patient-specific pharmacotherapy, patient education, and other nondrug interventions.
- Implement the care plan.
- The care plan is implemented with the agreement of the patient and within the context of the overall care of the patient, in cooperation with other members of the health care team.
- Evaluate and review the care plan
- The pharmacist evaluates effectiveness and safety of pharmacotherapy and judgment is made as to the clinical status of the condition being managed. Patient compliance is also assessed and new DTPs are identified, if any. Finally next follow-up evaluation is scheduled.

Although all patients benefit, it may be necessary to select patients that would benefit most from a pharmaceutical care plan. Hence the following group of patients should be prioritized:

- Those with multiple conditions/drugs
- Those whose age, weight or clinical state may affect drug pharmacokinetics

(PK) and pharmacodynamics (PD)
- Patients taking medicines known to have a high risk of toxicity
- Patients taking medicines with a narrow therapeutic index
- Patients taking medicines which may interact
- Patients whose therapy is changed frequently
- Patients who have advanced disease state and/or develop complications
- Patients who failed to respond with initial therapy and continue to deteriorate

3.6.3 Patient Monitoring and Follow-up

The pharmacist monitors the outcome of drug therapy for its effectiveness and toxicity based on relevant laboratory, radiological, physical, and subjective findings. The Pharmaceutical Care Progress Note Recording Form (Annex 4) is used to record these findings.

The activities include:
- Assessing whether goals of therapy are achieved or not
- Identifying existing or potential adverse reactions and/or treatment failures and recommend management approaches.
- Identifying drug incompatibilities and interactions having clinical significance and discuss potential solutions.
- Applying pharmacokinetic dosing principles in dosing of selected drugs such as injection (IV) to oral (PO) switch

3.6.4 Ward Rounds, Morning Sessions and Seminars

The pharmacist should actively engage in ward rounds, morning sessions and seminars to contribute to patient care decisions. These activities are performed both as part of the multidisciplinary team (MDT) and as pharmacy only activities. In pharmacy only rounds, the pharmacists are also expected to communicate patients and provide patient medication counseling. They will participate in grand rounds and death reviews, as applicable.

3.6.5 Medication Reconciliation Services

All patients should have their medication reconciled as soon as possible after admission or presentation. If medication reconciliation cannot be completed for all patients, prioritize patients that most likely are to obtain maximum

benefit. The service should be documented using Medication Reconciliation Form (Annex 5).

Medication Reconciliation is a formal three-step process that includes:

- Obtaining a complete and accurate list of each patient's current medications (including name, dosage, frequency and route)
- Comparing the physician's admission, transfer or discharge medication orders to that list
- Resolving any discrepancies that may exist between the medication list and physician order before an adverse drug event (ADE) can occur

Medication reconciliation is important, especially at transition points. Care transition points include:

- Admission to the hospital
- Transfers within the hospital (Intra-hospital transfer)
- Discharge from the hospital

3.6.6 Drug Information Provision

As part of the routine clinical pharmacy service provision in the inpatient setup, pharmacists should provide verbal and/or written drug information timely. The service is given proactively or when posed by the healthcare team. It should be recorded appropriately.

3.6.7 Discharge Medication Counseling

Pharmacists need to involved in discharge planning and provide medications counseling to ensure continuity of care after patients are discharged from hospital. The pharmacist will record discharge medications and counseling provided using Inpatient Medication Profile Form (Annex 3). Discharge medication counseling includes informing the name of drugs, dose, frequency and specific time of administration, and how to administer. The counseling should also include clear benefit and outcome of each drug therapy, expected major side effects and their management, pertinent drug-drug and drug-dietary interactions, warnings if any, and storage conditions.

3.6.8 Documentation of Clinical Pharmacy Services

Clinical pharmacy services should be properly recorded on standard formats, filed properly and reported periodically to relevant bodies. The recording forms should be part of the permanent medical record (treatment chart) of the patient. The formats include:

- Inpatient Medication Profile Form
- Pharmaceutical Care Progress Recording Form
- Medication Reconciliation Form

Data on clinical pharmacy interventions are summarized on Clinical Pharmacy Intervention Daily Summary Form and reported on Clinical Pharmacy Intervention Monthly Summary and Reporting Form.

3.6.9 Unit Dose Dispensing in Ward Pharmacies

Through the establishment of different ward pharmacies, a unit dose dispensing system shall be implemented to reduce drug wastage, improve drug availability, achieve efficient use of pharmacy and nursing staffs, and to promote rational drug use. Unit dose system is a single dose package of medicines, in a ready to administer form, dispensed for 24 hours, and with a pharmacy specific documentation.

In this system, the pharmacist reviews all medication orders written by the physician (patient chart). Then the pharmacy professional prepares the medications and makes ready to be taken to patient care areas by the nurses. The nurse then administers the dose to the patient and records on the Medication Administration Record (MAR).

3.6.10 Advanced Clinical Pharmacy Services

Depending on availability of expertise and resources, advanced clinical pharmacy services can be provided particularly in specialized hospitals. These include therapeutic drug monitoring, total parenteral nutrition, oncology, anticoagulation, dialysis, and transplantation clinical pharmacy services.

3.7. Drug Information Services

Access to authoritative, unbiased and well-referenced drug information is fundamental for the rational and effective use of drugs. However, due to the vast number of medicines and the information related to them, it would be

very difficult for the health professional to search for all credible sources of information and use it in routine practice. Hence, all hospitals should establish and provide drug information services (DIS).

The DIS provides information for health professionals, patients and members of the public. The service generally responds to drug information queries received from the health care team or patients. It also provides education and training to health professionals and/or the public regarding appropriate and safe use of medicines. Regular drug information publications such as drug alerts, newsletters, monographs, and therapy updates shall be prepared and distributed to keep the health care team up-to-date. It also notifies availability of pharmaceuticals to the hospital staff.

The DIS should have a dedicated room that has sufficient space and appropriate furniture and equipment including telephone, computer, printer, filing cabinets and internet access. The DIS should have a current collection of national and international authoritative reference materials such as books, journals, guidelines, formularies, and databases. The DIS should be staffed by appropriately skilled drug information pharmacists that are trained in the provision of drug information.

The operations of the drug information service should be guided by appropriately formulated standard operating procedures (SOPs)/guidelines prepared in line with national documents. The guidelines/SOPs should be established for receiving and answering drug information queries, developing and distributing educational materials and information publications, documentation activities, education and training activities. It also needs to guide monitoring and evaluation activities, participation in other clinical pharmacy services, supporting DTC activities and conducting research. The center is a resource for the DTC in formulary preparation and revision. The DIS should be open during normal working hours.
Educating patients on the rational use of medicines through different mechanisms is a crucial activity of the DIS. All relevant staffs of the pharmacy department should be involved in the provision of education for the patient as appropriate. Under the hospital health education program, the unit will

have periodic breakdown of topics assigned to responsible pharmacists.

The DIS should develop annual action plan on each activities and should be communicated to the director/head of pharmacy department. All services provided should be documented and performance report should be sent to the director/head of the pharmacy department regularly.

The DIS shall also provide poison information services.This service will support emergency and critical care departments for both adults and pediatrics in providing consultation to healthcare professionals in the management of poisoning, drug overdose and envenomation.The premise of this service can be set up either within the DIS or independently if resources allow.

3.8. Compounding Services

A hospital pharmacy should prepare non-sterile preparations such as prescription based ointments and creams and bulk preparations (e.g. hand rubs, hydrogen peroxide, alcohol of different strengths, and gentian violet) which are not available commercially but needed for patient care. Small scale manufacturing of sterile preparations such as intravenous fluids and total parental nutrition (TPN) could also be initiated depending on the need of the hospital and feasibility. Both sterile and non-sterile preparations in the hospital should fulfill efficacy, safety, and quality parameters. These can be achieved through employing standards, protocols and procedures that guide the preparation of these products.

Compounding should be performed by pharmacists.The Compounding Services Unit should develop compounding SOP and secure approval by the DTC.The SOP includes:

- The name, strength and dosage form of the preparation
- All ingredients and the quantities needed
- Requirement for premises for the compounding
- Equipment needed for preparation,
- Instructions including order of mixing, mixing temperature, duration of mixing, etc
- Beyond-use date

- The packaging or container to be used for dispensing
- Storage requirements
- Labeling instructions
- Quality control procedures (e.g. checking the adequacy of mixing, odor, color, consistency, clarity or pH of preparation as appropriate).

A list of equipment and materials for compounding is presented in Annex 6. Further details on the compounding process are described in Annex 7.

A Compounding record should be kept of all compounding activities. Sample format for recording of the compounding process and Compounding Prescription Register are presented in Annex 8 and 9, respectively.

3.9. Drug Supply Management

To ensure uninterrupted supply of safe, effective and quality pharmaceuticals, the hospital pharmacy shall have effective and efficient drug supply management (DSM). Drug supply management at hospitals involves the following basic functions: selection, quantification, procurement, storage, distribution and use. Effective DSM needs well organized and functioning Logistics Management Information Systems.

3.9.1 Selection

Hospital pharmacy should have DTC approved list of medicines, medical supplies, equipment and laboratory reagents categorized by VEN. The pharmaceutical supply management unit in consultation with the various departments in the hospital selects the required medicines for procurement as per the approved list. Whenever there is a need for procuring pharmaceuticals which are not included in the list, it is necessary to demonstrate their significance for safe and effective care of individual patients, and secure approval from the DTC.

3.9.2 Quantification

After the list is prepared, the quantity of each product required by the hospital for a given period of time should be determined. Two main methods for quantification are consumption and morbidity methods.

Any quantification method should aide in:

- Setting the maximum, minimum and reorder stock levels
- Identifying what to quantify (develop drug list)
- Considering the impact of lead time
- Adjusting for service growth and losses due to wastage and theft
- Estimating total procurement cost
- Adjusting and reconciling final quantities

Consumption Method: The Consumption Method is the most reliable predictor of future consumption. Therefore, this method is the preferred option for quantifying the requirements for pharmaceuticals. Since the Consumption Method relies on accurate records of past drug consumption, each hospital should have a reliable system to track drugs from the store to each dispensing unit and to the patient. Consumption at different outlets of the hospital should be recorded, compiled and analyzed for the appropriate supply and use of pharmaceuticals.

This method is most suitable when there is:

- a representative pattern of morbidity and patient attendances
- an acceptable pattern of rational prescribing
- adequate and uninterrupted drug supply
- complete and accurate data on stock-on-hand and issues/consumption, and
- data on wastage and losses

Table 1:Quantification Steps Using Consumption Method

Quantification Steps:
Step 1: Prepare list of pharmaceuticals to be quantified
Step 2: Determine the period of time to be reviewed for consumption
Step 3: Collect and enter consumption data for each pharmaceutical
Step 4: Calculate average monthly consumption
Step 5: Forecast the quantity of each drug required for the next pro curement period
Step 6: Adjust for expected changes in consumption patterns
Step 7: Adjust for safety stock requirements and estimated losses
Step 8: Estimate costs for each pharmaceutical and total costs
Step 9: Compare total costs with budget and make adjustments

Note: Forecasting involves quantifying beyond the next procurement period.

Morbidity method: This method uses morbidity data to determine the quantity of pharmaceuticals required. It may be the most appropriate method of quantifying drug requirements when:

- consumption data are incomplete or not available
- prescribing patterns are not cost effective
- budget is unlikely to be sufficient to meet estimated requirements, and
- health facilities or services are new

Table 2: Quantification Steps using Morbidity Method

Quantification Steps:
Step 1: Specify the list of health problems
Step 2: Establish standard or average treatments for each health problem
Step 3: Establish the list of drugs to be quantified
Step 4: Collect morbidity data for each problem for the review period
Step 5: Estimate the number of treatment episodes for each health problem
Step 6: Forecast the quantity of drugs for each health problem
Step 7: Combine the estimates for each drug from the various health problems into a master procurement list
Step 8: Adjust quantities to cover other health problems
Step 9: Adjust for current stock position and expected losses
Step 10: Estimate costs for each drug and total cost
Step 11: Compare total costs with budget and make adjustments

Note: Forecasting involves quantifying beyond the next procurement period.

3.9.3 Supply planning

Based on the above quantification, the pharmaceutical supply management unit prepares supply plan every two months regarding the product, supplier (if the product is unavailable from PFSA), budget, quantities, procurement method and its lead time, distribution related costs, current stock status, and minimum and maximum stock levels. It prepares a supply plan that outlines quantities and delivery schedules.

3.9.4 Procurement

Procurement involves acquiring of pharmaceuticals through purchasing, donation or hospital manufacturing. As per the public procurement policy of the country and the proclamation of PFSA, the pharmaceutical supply management unit procures the required pharmaceuticals and also assesses its

performance periodically. All hospitals should procure preferentially through PFSA and the payment can be made on credit/cash based on the signed agreement between PFSA and the hospital. During procurement, principles of good pharmaceutical procurement practice and procedures should be followed.

Whenever pharmaceuticals are not available at PFSA and out of stock certificate is secured from the agency, procurement from private suppliers can be considered as per the conditions set in the procurement policy of the hospital. The policy should be in line with the Public Procurement Agency of Ethiopia and approved by DTC. The methods of procurement include: request for quotation, restricted tendering, open bidding and direct procurement. Additionally, for products that cannot be supplied by PFSA but their timely purchase and delivery are critical for hospital services, the hospital may consider establishing preferred supplier arrangements as an option by signing flexible framework agreements each year. This process of selecting preferred supplier(s) should be done in an open bid and competitive process.

General principles and procedures that should be followed during in procurement include:

- Procurement by generic name
- Procurement limited to products specified in the drug list
- Procurement in bulk
- Procurement based on quantification and available funds
- Flexibility to respond to emergency situations
- Compatibility with the regional and national laws
- Product quality assurance
- Supplier selection: PFSA or private (registered by FMHACA)
- Contract terms (delivery time, payment terms, etc.)
- Batch recall of pharmaceuticals, when necessary
- Audit and monitoring of the procurement process
- The pharmacist must not purchase any medicinal product where he/she has any reason to doubt its safety, quality or efficacy.
- The pharmacist must ensure that both the supplier and the source of

any medicine purchased are reputable and registered by the regulatory body.

3.9.5 Receiving, Storage and Distribution

The procured pharmaceuticals shall be received by the Pharmaceutical store manager. Before receiving pharmaceuticals, the store manager shall assure their type, quality, usability and quantity. Once confirmed that these pharmaceuticals fulfill the minimum requirements, the store manager should receive using Model 19/health, and give signed and sealed copy of confirmation for the deliverer. At the time of delivery, the truck should wait while products are counted and assessed in order to obtain proof of delivery and to take note of any discrepancies with the shipment. If there is any discrepancy, it should be noted and informed to PFSA or the supplier.

The received pharmaceuticals should be stored at central pharmaceutical store until they are issued to dispensing/service delivery units of the hospital. The pharmaceutical store manager should properly store pharmaceuticals following guidelines for good storage practices for pharmaceuticals. Alphabetical, pharmacological, pharmaceutical orders, or high/low usage systems, or a logical combination of one or more of these methods can be used while arranging pharmaceuticals in the store. The store manager also determines the available warehouse space before ordering pharmaceuticals for the next procurement period according to Pharmaceutical Storage Guideline (Annex 10).

Up on issuing, the dispensing/service delivery unit should fill Internal Facility Report and Resupply Form (IFRR) and the store manager should issue using model 22/health. The distribution of pharmaceuticals should always be based on first expire first out (FEFO) principle. After issuing, the store manager updates Bin Card (Annex 11) and stock card clerk update stock card (Annex 12) and files appropriately. There should be a system approved by DTC for returning of expired, damaged, leftover and empty packs from the dispensing unit and other service areas to the Central store.

The pharmaceutical store manager should establish a resupply schedule for each of the dispensing units, preferably not less than two weeks to not more

than four weeks unless in emergency situations. Each dispensing unit should have a designated date to receive its resupply. Bin owners in the dispensing unit should complete their part of the Internal Facility Report and Requisition Form (IFRR) (Annex 13) and compile before sending it to store. The request should be approved by the Director/Head of pharmacy department or by pharmaceutical supply management unit coordinator. The store resupplies to each dispensary as per the approved request.

Note: Refer detail transactions tools and process in the APTS vouchers and manual

3.9.6 Inventory control systems

The purpose of an inventory control system is to maintain appropriate stock levels to meet the needs of patients. A well designed inventory control system informs personnel when and how much of a commodity to order and helps to reduce shortages, oversupply, and expiry of commodities. To do so, both manual and computer based inventory management system can be implemented.

Effective inventory management is underpinned by a Logistics Management Information System (LMIS). The purpose of LMIS is to support the management of all pharmaceuticals by collecting, organizing and reporting information to other levels in the system. Three essential data items that must be captured by the LMIS are stock on hand, consumption data and losses/ adjustments.

An effective inventory control system has three key elements: maximum months of stock, the minimum months of stock and the emergency order point. To help maintain adequate levels of stock, these three key elements shall be followed as per the Integrated Pharmaceuticals Logistics System (IPLS) of the country.

Standardized forms for inventory management are described below:

Bin Card: A Bin Card should be prepared for each product in the Pharmaceutical Store. The Bin Card should be kept with each product inside the store. All transactions of the product to or from the store should be recorded on the Bin Card. The Bin Card should also include a column for the loss/adjustment of stock and a column for the stock balance. The stock balance should be updated after each and every transaction or adjustment. (See Annex 11)

Stock Record Card: The Stock Record Card is similar to the Bin Card but is used to track stock based on issuing and receiving orders. It should be kept in the Pharmaceutical Supply Management Unit. The totals on the Stock Record Card should be checked against those on the Bin Card and the results of the physical count. Any discrepancies should be investigated. A combined Bin/Stock Card System provides a measure of internal control that helps to minimize leakages of stock due to theft or loss. Paper based or electronic systems can be used. If an electronic system is installed there should be regular back up of data. (See Annex 12)

Internal Facility Report and Resupply Form (IFRR):: The IFRR is used to report the internal transfer of items between the hospital pharmaceutical store and Dispensing Units. The IFRIR also calculates the quantity of each item that should be provided to the Dispensing Unit to reach maximum stock levels. (See Annex 13)

Report and Requisition Form (RRF): The RRF is used to order health commodities from PFSA. Orders should be placed every two months. The quantity to be ordered is calculated as follows: Quantity requested = quantity issued from the store room in the previous reporting period x 2 minus stock on hand. All requisitions/orders shall carry a unique order number so that they can be official documents (replacing MOFED Models 19 to 22). If an order is placed to PFSA by telephone this should immediately be confirmed in writing. (See Annex 14)

Record for Returning Unusable Commodities (RRUC): The RRUC form is used to track the transfer of supplies back to PFSA. The form should be submitted to PFSA every second month. (See Annex 15)
The recommended inventory control for the new national system is a Forced Ordering Maximum/ Minimum inventory control system. This means that all facilities are required to report on a fixed schedule, and PFSA is expected to supply on a fixed schedule. Facilities will place orders to return their stock levels to the maximum determined for each pharmaceutical. All products are resupplied each time a report and order is completed and sent to PFSA. In emergencies, an emergency order can be placed.

Physical Inventory: A Physical Inventory/Count is an actual count of each pharmaceutical in the stock at any given time. A Physical Inventory should be done regularly in the store and at each dispensing unit, at a minimum of once per year. Bin Cards and Stock Record Cards should be updated at the end of each physical count. See details on the APTS manual for the activities conducted pre, during and after physical inventory.

Pharmaceutical supply performance monitoring and reporting: The pharmaceutical supply management unit collects, analyzes and interprets data on the hospital's pharmaceutical supply management performance and prepares report for the hospital management.

3.10. Monitoring Medication Use and Safety

Medication use involves a multistep process including prescribing, transcribing, dispensing, administering, and monitoring. It is crucial to ensure patient safety through the implementation of safe medication use practices. Each hospital should implement medication safety programs including adverse drug event (ADE) monitoring and reporting, performing medication reconciliation activities, identifying high alert medications, and implementing new and existing national standards and systems. The DIS is responsible for monitoring medication use and safety, presenting the findings and recommendations to the DTC, following interventions proposed by the DTC, and measuring outcomes.

3.10.1. Monitoring Medication Use

To monitor the use of medications in hospitals, the pharmacy department in collaboration with the DTC should implement the following activities periodically.

- Monitoring of prescriptions
- Aggregate data methods (ABC, VEN)
- Indicator study methods
- Drug use evaluation methods

Prescription Monitoring: Prescriptions should be regularly monitored to identify prescribing trends and problems and to promote proper prescribing and dispensing practices in the hospital. The monitoring schedule should be set at a frequency suitable for the patient mix and prescribing practice in the hospital. The results should be communicated to the DTC for proper implementation and follow-up.

Prescriptions should be monitored for:

- Legality, legibility and completeness of prescription
- Appropriateness of prescription papers used (NPS)
- Appropriateness of the medication for the diagnosis
- Compliance with the hospital formulary or applicable treatment guidelines
- The appropriate dose and route of administration
- The appropriate duration of therapy
- Significant interactions (drug-drug, drug-disease and drug-food)
- Duplication of therapy

ABC-VEN Analysis: ABC and VEN analysis are aggregate data methods that are used to identify medication use problems. Each hospital should employ these methods annually to monitor drug use and take interventions accordingly.

ABC Analysis is a method for determining and comparing pharmaceutical costs within the formulary system. It follows the Pareto principle "separating

the vital few from the trivial many". ABC analysis can be explained in terms of budget consumed and number of drugs in the budget list as follows:

Category	Percentage of Budget Share	Percentage of Drugs
"A" Drugs	70-80%	10-20%
"B" Drugs	15-20%	10-20%
"C" Drugs	5-10%	60-80%

"A" medicines:

- High percentage of funds spent on large-volume or high-cost items
- Greatest potential for savings
- Greatest potential for identifying expensive medicines that are overused

"B" medicines:

- Moderate cost and moderate number of items; important items

"C" medicines:

- Small amount of funds spent on the majority of the inventory

Steps in performing ABC analysis:

Step 1. List all items purchased and enter the unit cost.
Step 2. Enter consumption quantities for each item.
Step 3. Calculate the value of consumption for each item.
Step 5. Calculate the percentage of total value represented by each item.
Step 6. Calculate the cumulative percentage of total value for each item.
Step 7. Choose cut-off points for A, B, and C.

Note: The results of ABC should be reconciled with that of VEN.

VEN Analysis is a method to prioritize for medicine purchase. This analysis is used to identify high priority medicines for procurement and low priority medicines that the DTC should analyze carefully for deletion from the formulary.

VEN stands for:

V = Vital: potentially lifesaving and crucial to providing basic health services.
E = Essential: effective against less severe but significant illness; not vital.
N = Non-essential: effective for minor illness but have high cost and low therapeutic advantage.

Steps for conducting a VEN analysis are as follows:

Step 1. Classify all medicine on the list as V, E, or N
Step 2. Analyze the "N" items. Where possible, reduce quantities to purchase or eliminate them.
Step 3. Identify and limit therapeutic duplications.
Step 4. Reconsider proposed purchase quantities.
Step 5. Find additional funds if needed or possible.

Indicator study methods

In indicator studies, a selected indicator is set and performance against this indicator is measured. Indicators can be developed to assess prescribing, patient care or facility practices. The following table presents possible indicators that could be used for an Indicator Study.

Selected indicators to assess prescribing, patient care and facility practices

Table 3: Selected indicator to assess prescribing, patient care and facility practices

Prescribing Indicators	Patient Care Indicators	Facility Indicators
• Average number of medicines per encounter • % of medicines prescribed by generic name • % of encounters with an antibiotic prescribed • % of encounters with an injection prescribed • % of medicines prescribed which are from the essential medicines list or formulary list	• Average consultation time • Average dispensing times • % of medicines actually dispensed • % of medicines that are adequately labeled • % of patients who know how to take their medicines	• Availability of essential medicine list or formulary • Availability of key set of indicator medicines • Availability of standard treatment guideline (STG)

Table 4: Steps to be taken when conducting a drug use indicator study

Step 1: Determine objectives of study, **Step 2:** Define indicators and data collection procedures, **Step 3:** Determine study design and sampling methods, **Step 4:** Pilot test, **Step 5:** Train data collectors, **Step 6:** Collect data as per the time line, **Step 7:** Compile and analyze data, **Step 8:** Prepare report and recommendations based on findings of study, **Step 9:** Present report and recommendations to DTC and relevant hospital staff, and implement recommendations arising from study, repeat study to assess impact

Drug Use Evaluation (DUE): Drug Use Evaluation studies can be undertaken to measure the use of a specific drug and/or adherence to standard treatment guidelines (STGs). DUE studies are particularly important to investigate:

- Perceived overuse or underuse of medications
- Problems identified by indicator and aggregate methods
- High numbers of ADRs
- Excessive amounts of non-formulary medicines used
- Use of high-costs medicines when less expensive alternatives exist
- Use of excessive numbers of medicines within a therapeutic category.

Table 5:Steps to be undertaken in conducting a DUE study

Step 1:	Define appropriate medicine use (for example medicine use de scribed in national or local STGs)
Step 2:	Audit actual prescribing practice against the set criteria
Step 3:	Analyze data, prepare report and recommendations based on findings
Step 4:	Present report and recommendations to DTC and relevant staff
Step 5:	Implement recommendations arising from study, repeat study to assess impact

Problems identified by aggregate methods, Indicator Study and DUE studies may be further investigated using the following qualitative methods: In-depth interviews, Focus Group Discussions, Structured Observations, and Structured Questionnaires.

3.10.2. Monitoring Medication Safety

Adverse Drug Event Monitoring and Reporting: The pharmacy department shall coordinate, in cooperation with medical and nursing staff an adverse drug event (ADE) program. The program shall include: prevention, identification and reporting of ADR, medication errors and product defects.

Vigilance is required to detect ADRs. Individuals susceptible to an ADR include:

- Those with multiple diseases
- Those on multiple drug therapy
- Geriatric or pediatric patients
- Those receiving medicines that are known to be associated with serious adverse effects
- Those receiving drugs with a low therapeutic index or potential for multiple interactions
- Those with organ impairment that may alter drug pharmacokinetics, and
- Those who have had a previous ADR

An ADR focal person should be appointed by the DTC. He/she will be part of the drug information services unit and will be responsible to:

- Ensure that all health professionals are involved in detecting, assessing, managing and reporting potential ADRs
- Ensure that ADR report forms are readily available in all clinical areas and that health professionals are familiar with the form and how to complete it
- Receive ADR report forms from clinical staff
- Investigate potential ADRs
- Analyze ADR data and compile reports
- Provide regular reports to the DTC/and Hospital Management on ADRs in the facility
- Report all ADRs to the Regulatory Body

The DTC should receive regular reports from the ADR focal person and make any necessary decisions regarding the use of medicines in the hospital. Where necessary the hospital formulary should be amended to take account of detected ADRs.

Suspected ADEs should be investigated, managed and reported as follows:

1. Assess Suspected ADR with Respect to:

a **Patient details:** age, gender, organ function, height, weight; diagnosis and other relevant co-morbidities prior to reaction; previous exposure to suspected drug(s) or related drug(s).

b. **Medicine details:** non-prescription drugs, alternative treatments, recently ceased medicines; name, dose, route of administration, manufacturer, batch; date and time commenced; date and time discontinued (if applicable); indication.

c. **Comprehensive adverse reaction details:** description of the reaction; time of onset and duration of reaction; complications and sequelae; treatment and outcome of treatment; relevant investigation results or autopsy report.

2. Perform Causality Assessment

To assess likelihood of the drug causing the observed reaction. A literature review may be undertaken to assess the likelihood that a suspected ADR was caused by a particular drug and/or the advice of other health professionals may be sought.

The ADR should be classified as:

- **Certain**: a clear temporal association is established between medicine administration and the reaction; and/or the results of investigations confirm that there is a relationship between the administration of the medicine and the reaction; and/or the reaction recurs upon re-exposure to the drug; and/or the reaction is commonly known to occur with suspected drug;
- **Probable**: the reaction is known to occur with the suspected drug, and there is a possible temporal association between the reaction and medicine administration; and/or the reaction resolves or improves upon withdrawal of the suspected medicine and other medicine therapy remains unchanged; and/or an uncommon clinical event occurs in the absence of other potentially causative factors;
- **Possible**: an alternative explanation for the reaction exists; and/or more than one medicine is suspected; and/or recovery follows withdrawal of more than one drug; and/or the temporal association between the reaction and administration of the medicine is unclear; or
- **Doubtful**: another cause is more likely to have accounted for the clinical event, e.g. underlying disease.

3. Make Recommendations on Treatment Options

Including possible alternative treatments taking into consideration:

- The likelihood of the suspected drug(s) having caused the reaction
- The clinical significance of the reaction
- The condition of the patient
- The requirement for therapy
- The risks and benefits associated with continuing therapy
- The relative efficacy and safety of other therapeutic options, and
- The prophylactic use of other medicines to prevent future adverse reactions.

4. Document the ADR and Provide Follow up Advice

All ADRs should be clearly highlighted in the patient's case notes. Any patient who has experienced an ADR should receive advice about the drug and reaction, should be advised to avoid the drug in the future and should be given an 'alert card' that states the drug involved and nature of the reaction. He/she should be advised to show this card at any future clinical consultation to prevent the same drug being prescribed again.

5. Report ADR Reporting Mechanism

The Hospital Pharmacy department should avail reporting form, retain the necessary documentation and also mail the ADE report to regulatory authority (FMHACA).

A standardized form should be used to record and report ADRs. This should include:

- Patient name, sex, age, medical record number
- Clinical diagnosis
- Current medication
- History of previous ADR if any
- Details of adverse reaction
- Causality assessment
- Recommendations given

A sample of the reporting form is presented in Annex 16.

High alert medications

High-alert (or high-hazard) medications are those that are most likely to cause significant harm to the patient, even when used as intended. Although mistakes may not be more common in the use of these medications, when errors occur the impact on the patient can be significant. Some medications that have been considered as high-alert medications include: anticoagulants such as heparin and warfarin, narcotics and opiates, insulins, and sedatives.

General Principles for Reducing Harm from High-Alert Medications

Hospitals and other care settings should employ the following principles of a safe system:

1. Methods to prevent harm include:
   - Develop preprinted order forms and protocols to reflect a standardized approach to treat patients with similar problems, disease states, or needs.
   - Minimize variability by standardizing strengths
   - Include reminders and information about appropriate monitoring parameters in the order forms and protocols
   - Consider protocols for the elderly, pediatric, and pregnant patients.
2. Methods to identify errors and harm include:
   - Include reminders and information about appropriate monitoring parameters in the order forms and protocols
   - Ensure that critical lab information is available to those who need the information and take action.
   - Implement independent double-checks where appropriate.
   - Instruct patients on symptoms to monitor and when to contact a health care provider.
3. Methods to mitigate harm include:
   - Ensure that antidotes and reversal agents are readily available.
   - Have rescue protocols available.

3.11. Pharmaceutical Waste Management

Pharmaceutical wastes are all wastes that are generated from the hospital in the use of pharmaceuticals during diagnosis, treatment, immunization, compounding and manufacturing. Handling, transportation and disposal of pharmaceutical wastes should be guided by FMHACA's pharmaceutical wastes disposal guideline to protect patients, health workers, supportive staff, community, and environment.

Each hospital should establish a pharmaceutical disposal committee comprised

of representatives from pharmacy, finance/audit, and sanitation services to ensure the proper disposal of pharmaceutical wastes in accordance with the country laws. The pharmaceutical supply management unit shall prepare an SOP which contains the schedule, methods, materials and equipment required for disposal that will be used by the committee. The SOP should also clearly identify the responsible person for the proper management of pharmaceutical waste. The SOP need to be approved by the DTC.

Pharmaceuticals which are eligible for disposal include the following:

- All expired/damaged pharmaceuticals,
- All unsealed syrups or eye drops (expired or unexpired),
- All cold chain products not stored as per manufacturers' recommendations (e.g.: insulin, hormones, gamma globulins and vaccines),
- All bulk or loose tablets and capsules with containers which are not sealed, properly labelled or within broken blister pack, and
- All unsealed or damaged tubes of creams, ointments, lotions and related products.

The following key steps are performed in pharmaceutical waste management:

Step 1: Pharmaceuticals that are expired/damaged or unfit for use should be counted, recorded and placed separately from the other pharmaceuticals in the hospitals.

Step 2: List of pharmaceuticals expired or unfit for use should be submitted to the hospital management and responsible body. The list should clearly state trade name and/or generic name, strength (where applicable), dosage form, pack type and size, quantity, batch number, expiry date, and product price.

Step 3: The pharmaceuticals should be sorted out based on the pharmaceutical dosage form and chosen disposal method.

Step 4: The pharmaceuticals should be disposed of in accordance with the appropriate method and in the presence of delegates from the responsible body.

Step 5: Signed and stamped certificate of disposal format should be issued

by the authorized body entitled to dispose the drugs.

Step 6: Adjustments for each disposed drug should be made in the available inventory management system.

Hospital pharmacy and cleaning staff should be well informed about the potential risks of hazardous pharmaceutical wastes and their management. Disposal of pharmaceuticals should be supported by proper documentation including the price of products for audit and other legal requirements.

General Disposal Methods

Return to donor or manufacturer: Whenever practical, the possibility of returning unusable drugs for safe disposal by the manufacturer/donor should be explored; particularly for drugs which present disposal problems, such as anti-neoplastic agents.

Waste immobilization/encapsulation: This involves immobilizing pharmaceutical wastes in a solid block within a plastic or steel drum filled to 75% capacity. The remaining space should be filled and sealed with cement or cement/lime mixture and water in proportions 15:15:5 by weight. The sealed drums are then placed at the base of a land fill and are covered with fresh municipal solid waste.

Landfill: Place the expired or 'unfit for use' pharmaceuticals directly into a land disposal and cover it with municipal waste to prevent scavenging. It should be noted that discarding in open, uncontrolled dumps with insufficient isolation from water courses can lead to pollution.

Sewer: Some liquid pharmaceuticals, e.g. syrups and intravenous fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental effect. Fast flowing water courses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics. In this case, disposal should be done in consultation with the hospital sanitarian/environmental health specialist.

Burning in open containers: Pharmaceuticals should not be disposed by burning at low temperature in open containers as toxic pollutants may be released into the air. Paper and cardboard packaging, if they are not to be recycled, may be burnt but polyvinyl chloride must not be. It is strongly recommended that only very small quantities must be disposed in this way.

Incineration: Expired solid form of pharmaceuticals are burned using a two chamber incinerator that operates at a minimum temperature of 850^{0}C.

3.12. Monitoring and Evaluation

Monitoring and evaluation are an integral part of the management cycle, providing a link between planning and implementation. To monitor and evaluate the overall pharmacy operations, implementation checklist and indicators are listed under section 4.

Section 4

Implementation Checklist and Indicators

4.1 Operational Standards Assessment Checklist

In order to determine if the Operational Standards for Pharmacy Services have been met by the hospital, the following assessment checklist should be used. It describes operational standards, method of evaluation and rating (met, unmet). This tool can be used by hospital management or by an external body such as RHB or FMOH to measure attainment of each Operational Standard.

Table 6:Operational standard assessment checklists

SN	Standard	Method of evaluation	Met	Unmet	Remark
1	The hospital provides quality pharmaceutical products and services in its outpatient, inpatient, and emergency pharmacy service units.	Presence of pharmacy services near-by outpatient, inpatient and emergency departments			
		Presence of pharmaceutical supply management unit			
		Presence of compounding service unit			
		Presence of drug information service unit			
		Presence of separate medicines store			
		Presence of store for medical supplies, lab reagents, and medical equipment			
		Presence of specialized pharmacy services (for specialized hospitals only)			
2	The hospital has a functional Drug and Therapeutics Committee (DTC)	Presence of DTC annual plan for the fiscal year			
		Presence of terms of reference (TOR)			
		Presence of official letter of assignment for members			
		Presence of at least 6 signed meeting minutes in the last 12 months			
		Presence of performance report of DTC activities of the last fiscal year			

SN	Standard	Method of evaluation	Met	Unmet	Remark
3	The hospital develops, utilizes and annually updates a comprehensive list of pharmaceuticals prioritized by VEN.	Availability of annually updated pharmaceutical list			
		The list is prioritized by VEN			
4	The hospital ensures good dispensing practices	Dispensers use prescription evaluation checklist			
		Presence of waiting area with seats in OPD pharmacies			
		Presence of signed prescriptions by evaluator and counselor (hint: see randomly selected 10 prescriptions)			
		Presence of records for identified DTPs and measures taken			
		Presence of report on patient knowledge on correct dosage and satisfaction			

SN	Standard	Method of evaluation	Met	Unmet	Remark
5	The hospital implements auditable, transparent and accountable pharmaceutical transactions and services (APTS).	Workflow organized as:			
		Evaluator » Biller » Casher » Counselor (Entrance and Exit)			
		Presence of properly recorded and filed vouchers at store			
		Presence of properly recorded and filed prescriptions, sales tickets and registers at dispensaries			
		Adequate human resource is deployed in each pharmacy services units (hint: based on workload analysis: number of prescriptions and bed size)			
		Pharmacy premises are arranged so as to keep patient safety and privacy			
		Implementation of coding to uniquely identify medicines			
		Bin ownership is implemented			
		Presence of monthly reports for products, finance and services			
		Presence of audit report (internal)			
		Wastage rate in monetary value is <2%			
		Presence of annual report on ABC and VEN analyses			
		Presence of survey report on patient satisfaction of overall pharmacy services			

SN	Standard	Method of evaluation	Met	Unmet	Remark
6	The hospital provides clinical pharmacy services at inpatient, outpatient and emergency departments	Clinical pharmacy service is implemented in the hospital			
		Completed patient medication profile form, pharmaceutical care progress recording form and medication reconciliation forms are part of the patient chart (hint: see randomly selected 10 patient charts at an inpatient ward)			
		Ward pharmacy available in each major ward and functions for 24 hrs.			
		Unit dose dispensing is implemented at ward pharmacies (medicines are dispensed only for 24hrs.)			
		Presence of completed chronic patient's medication profile form (in chronic care pharmacies).			
		Regular participation of pharmacists in ward rounds, morning sessions and seminars (ask a physician and a nurses in major wards)			
		Participation of pharmacists in admission medication history taking and discharge medication counseling (ask a physician and a nurse in major wards)			

SN	Standard	Method of evaluation	Met	Unmet	Remark
7	The hospital provides drug information services to health care providers, patients and the public.	Presence of properly filled query receiving and answering forms (see the previous month records)			
		Presence of recently prepared sample drug alert/newsletter, therapy update, drug monograph			
		Presence of updates on stock availability to the hospital community (ask health care team or see records)			
		Presence medicine use education for patients (ask the appropriate unit)			
		Has started providing poison information			
		Presence of yearly and weekly plans (see the plan)			
8	The hospital has a functional compounding service	Separate premises for compounding service			
		Availability of equipment, materials and chemicals			
		Availability of SOP for all compounding procedures			
		Recorded documents for all compounded items			

SN	Standard	Method of evaluation	Met	Unmet	Remark
9	The hospital selects, quantifies, procures, stores and distributes safe, effective and quality pharmaceuticals to ensure uninterrupted supply.	Presence of procurement policy			
		Presence of annual pharmaceutical quantification and supply plan			
		Report that shows percentage of procured items from the hospital list.			
		Presence of updated bin card (check randomly selected 10 bin cards)			
		Availability of paper based or electronic inventory management tool			
		Presence of physical inventory report for dispensaries for stores			
		Presence of stock status analysis report			
		Good storage practice is being followed			
10	The hospital regularly monitors medication use and safety.	Presence of semi-annual prescription monitoring report			
		Presence of annual DUE Report			
		Presence of ADE report			
		Presence of WHO drug use indicator study report			
		Presence of update on (high alert medications, error prone abbreviations, look-alike and sound alike medication list …)			

SN	Standard	Method of evaluation	Met	Unmet	Remark
11	The hospital conducts continuous segregation, documentation and safe disposal of pharmaceutical wastes	Presence of SOP for disposal for the hospital			
		Presence of list of disposed products with description			
		Expired medicines are separately segregated			
		Presence of certificate for disposed medicines (minutes during disposal)			
12	The hospital pharmacy monitors and evaluates its performance	Presence of quarterly minutes/proceedings on performance review meeting			
		Presence of monthly minutes on pharmacy discussion forum in each service unit			
		Presence of copies of regular reports to relevant government bodies on selected indicators			

4.2 Indicators

In addition to the Operational Standard Assessment Checklist, pharmacy services will be monitored based on the following indicators on a regular basis. The indicators assess the effectiveness/outcomes of implementation of the recommendations provided in this chapter.

Table 7:Pharmacy Chapter Indicators

SN	Indicators	Formula	Frequency	Remark
1	Percentage availability of key medicines at the hospital	$\frac{\sum \text{Number of months key medicine were available}}{(\text{Review period in month} * \text{number of key medicine})} \times 100$		
2	Percentage availability of pharmaceuticals selected for top 10 diseases at the hospital	$\frac{\sum \text{Number of months pharmaceuticals were available}}{(\text{Review period in month} * \text{number of pharmaceuticals})} \times 100$		
3	Pharmaceutical wastage rate	$\frac{\text{Total value of pharmaceutical wasted during the period}}{\text{Total stock available for sale in the period}} \times 100$		
4	Consumption to Stock Ratio	$\frac{\text{Cost of despensed medicines during the month}}{\text{Stock avaialble for sale at cost during the month}} \times 100$		
5	Months of stock	Stock on hand divided by Average monthly consumption (AMC)		

SN	Indicators	Formula	Frequency	Remark
6	Inventory accuracy rate	Total number of items where stock record equals physical count / (Total number of items counted) x 100		
7	Affordability of dispensed medicines	Average price of medicines dispensed per patients on cash (P) X 30 days. Smallest salary of unskilled government worker (961). (DW)= (Px30)/961; If DW <1 = affordable; if DW >1 to DW < 3 = some-how affordable and if DW> 3= un-affordable		
8	Average monthly level of effort (LOE)	Total # ofPatients served in all dispensaries / (Total number of dispensers)		
9	Proportion of charts that are reviewed by a pharmacist within 24 hours of admission	Number of charts reviewed by clinical pharmacist / (Total number of admission during the review period)		
10	Proportion of charts with completed inpatient medication profile forms	# of patient charts with completed inpatient profile form / (Total number of admission during the review period)		
11	Average number of drugs per prescription	Total number of drugs on reviewed prescriptions / (Total number of prescriptions reviewed)		

SN	Indicators	Formula	Frequency	Remark
12	Percentage of drugs actually dispensed	Total number of drugs actualy dispensed / (Total number of drugs on reviewed prescriptions) × 100		
13	Percentage of prescriptions with antibiotics	Number of prescriptions with antibiotics / (Total number of prescriptions reviewed) ×100		
14	Percentage of dispensed medicines adequately labeled	Total number of dispensed medicines adequately labeled / (Total number of medicines dispensed) ×100		
15	Absolute deviation percentage	| Forcasted quantity-actual consumption|*100 / (Actual consumption)		
16	Order fill rate	# of orders filled with more than 80% of its line items / (Total orders)		
17	Order Turn-around Time	∑# of days taken by hospital to process each order from Supplier / (Total number of orders reviewed)		
18	Proportion of drug budget out of the total recurrent budget	Proportion of budget allocated to drugs/total recurrent budget * 100		

SN	Indicators	Formula	Frequency	Remark
19	Percentage of prescriptions compounded per month	Total number of compounded preparations per month / total number of compounding preparations requested per month		
20	Number of drug information queries filled	Total number of drug information queries filled per month		
21	Percentage of patient satisfied with pharmacy services	Survey		
22	Percentage of Patient's with correct knowledge on dosage	Survey		

Section 5 Source Document and Appendices

5.1. Source Documents

1. Federal Democratic Republic of Ethiopia: Ministry of Health, HSDP IV. Addis Ababa, Ethiopia: Annual Performance Report EFY 2004 (2011/2012); 2013.
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4. Windau-Melmer, Tamara. 2013. A Guide for Advocating for Respectful Maternity Care. Washington, DC: Futures Group, Health Policy Project.
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6. Federal Democratic Republic of Ethiopia: Ministry of Health, Management Protocol on Selected Obstetrics Topics, January, 2010
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8. Federal Democratic Republic of Ethiopia: Ministry of Health, National Guideline for Family Planning Services in Ethiopia, February – 2011
9. WHO recommendations on postnatal care of the mother and newborn. Geneva (Switzerland): World Health Organization (WHO); 2013 Oct. 62 (p. 120)
10. Federal Ministry of Health, National Mother and Baby Friendly Service Guideline, 2016
11. Integrated Management of Pregnancy and Childbirth, Standards for Maternal and Neonatal Care, WHO, 2007.
12. Pocket book of hospital care for children, second edition: WHO, 2013
13. Global Initiatives for Improving Hospital Care for children: State of the Art and Future Prospects PEDIATRICS Volume 121, Number 4, April 2008
14. Assessment Tool for Hospital Care for Children, Second Edition: WHO 2015

5.2. Appendices

Annex 1: A Sample List of Emergency Medicines

SN	Name of the Drug	Dosage Form and Strength
1	Acetylcystene	Powder
2	Activated Charcoal	Powder 25G, 50G, Suspension
3	Adrenaline (Epinephrine)	Injection, 1mg/ml, 1:1000 solution
4	Acetazolamide	Tablet, 250mg
5	Aminophylline	Injection, 25mg/ml in 10-ml ampoule
6	Atenolol	Injection, 5mg /ml
7	Atropine Sulphate	Injection, 0.6mg in 1-ml ampoule
8	Adenosine	Injection, 3mg/ml
9	BAL (Dimercaprol)	Injection, 50mg/ml
10	Calcium Gluconate	Injection, 10%
11	Chlorpromazine	Injection, 25mg/ml in 2-ml vial
12	Dexamethasone	Injection, 4mg/ml in 2ml ampoule
13	Digoxin	Injection, 0.25mg/ml in 2ml ampoule
14	Diazepam	Injection, 5mg/ml in 2ml vial
15	Dobutamine	Injection, 12.5mg/ml in 20ml ampoule
16	Dopamine	Injection, 40mg/ml in 5ml ampoule
17	Frusemide	Injection, 10mg/ml in 2ml ampoule
18	Glyceryl Trinitrate	Sublingual tablet, 0.5mg
19	Heparin	Injection, 5000 Units/vial
20	Haloperidol	Injection, 5mg/ml in 1ml ampoule
21	Hysocine n-butylbromide	Injection, 20mg/ml in 1ml ampoule
22	Hydrocortisone	Powder for Injection, 100mg
23	Insulin (Soluble)	Injection,40IU/ml in 10ml vial
24	Ipecauanha	Syrup

SN	Name of the Drug	Dosage Form and Strength
25	Isoprenaline	Injection, 20mcg/ml
26	Isosorbide dinitrate	Subligual tablet, 5mg
27	Intravenous fluid (IV fluids)	5%Dextrose, 540ml
		10%Dextrose, 540ml
		5%Dextrose with sodium chloride, 540ml
		Ringer lactate, 540ml
		0.9% Sodium Chloride, 540ml
31	Lignocaine (Xylocard)	Injection, 21.3mg/ml in 50ml vial
32	Mannitol	Injection, 20% in 300ml vial
33	Magnesium Sulphate	Injection, 50%, 10ml (5gm ampoule)
34	Methyl-ergometrine	Injection 0.2mg/ml in 1 ml ampoule
35	Metoclopramide	Injection, 5mg/ml in 2ml ampoule
36	Morphine	Injection, 10mg/ml in 2-ml ampoule
37	Naloxone	Injection, 0.4mg/ml in 1 ml ampoule
38	Noradernaline (norepi-nephrine)	Injection,1mg/ml in 1 ml ampoule
39	Nitroprusside	Injection - 50mg
40	Nifedipine	Capsule, 5mg
41	Oxygen	
42	Oxytocin	Injection, 5units /ml in 1ml ampoule
43	Paracetamol	Injection, 150mg/ml in 2ml ampoule
45	Pheniramine maleate	Injection, 22.75 mg/ml in 2ml ampoule
46	Phenobarbitone	Injection, 200mg/ml in 1ml ampoule
47	Phenytoin sodium	Injection, 50mg/ml in 5 ml ampoule
48	Pilocarpine	Eye drop, 2%, 4%
49	Polygeline with Elec-trolytes	IV solution, 3.5%

SN	Name of the Drug	Dosage Form and Strength
50	Polyvenum Antisnake venom	Injection
51	Propanolol	Injection, 1 mg / ml
52	Phytomenadione (Vit K)	Injection 10mg/ml
53	Potassium Chloride	Injection,150mg/ml in 10ml ampoule
54	Pralidoxime (PAM)	Injection,25mg/ml in 20ml ampoule
55	Protamine Sulphate	Injection, 10mg/ml in 10ml ampoule
56	Quinine Sulphate	Tablet, 200mg
57	Ranitidine	Injection, 25mg/ml in 2ml ampoule
58	Salbutamol	Respiratory solution, 5mg/ml in 15ml vial
59	Silver sulphadiazine	cream 1%
60	Sodium bi-carbonate	Injection, 75mg/ml in 10ml ampoule
61	Sodium Stibogluconate	Injection, 100mg/ml
62	Streptokinase	Injection,1.5million IU
63	Tetanus Toxoide	Injection, 0.5ml
64	Thiopentone	Injection,0.5gm 1gm per ampoule
65	Verapamil (Isoptin)	Injection, 2.5mg/ml in 2ml ampoule
66	Suxamethonium (Succinylcholine chloride)	Injection 50mg/ml - 2ml ampoule or 10ml vial
67	Ephidrine	Injection 30mg/ml - 1ml ampoule
68	Hydrallazine	Injection, 20mg/ml – vial
69	Paraldehyde	injection, 5ml
70	25% Dextrose	Injection
71	Amiodarone	Injection 50mg/ml, tablet 100mg
72	Ipratopium Bromide (Respiratory Solution)	Nebulizer

Annex 2: Standard Prescription Paper

PRESCRIPTION PAPER **Ser No**_____

Name of Hospital: _____

Tel: _____

Patient's full Name: _____

Sex: _ Age: _____Weight: _____ Card No._____

Region: ___ Town _____ Woreda ____ Kebele _____

House No. _____ Tel. No: _____ ☐ Inpatient ☐ Outpatient

Specific Diagnosis, if not ICD _____

Drug Name, Strength, Dosage Form, Dose, Frequency, Duration, Quantity, Route of Administration & other information	Price (dispensers use only)
℞	
Total Price	

Reconciliation: (Cash sales Ticket's SR No and Sig of cashier) _____

Or (Register Code, SR No and Sig of dispenser for credit/free)

_____

	Prescriber's	Evaluator's	Counselor's
Full name	_____	_____	_____
Qualification	_____	_____	_____
Registration #	_____	_____	_____
Signature	_____	_____	_____
Date:	_____	_____	_____

See overleaf

PRESCRIPTION PAPER **Ser No**_____

Name of Hospital: _____

Tel: _____

Patient's full Name: _____

Sex: _ Age: __ Weight: __ Card No. _____

Region: ___ Town _____ Woreda ____ Kebele _____

House No. _____ Tel. No: _____ ☐ Inpatient ☐ Outpatient

Specific Diagnosis, if not ICD _____

Drug Name, Strength, Dosage Form, Dose, Frequency, Duration, Quantity, Route of Administration & other information	Price (dispensers use only)
℞	
Total Price	

Reconciliation: (Cash sales Ticket's SR No and Sig of cashier) _____

Or (Register code, SR No and Sig of dispenser for credit/free)

_____

	Prescriber's	Evaluator's	Counselor's
Full name	_____	_____	_____
Qualification	_____	_____	_____
Registration #	_____	_____	_____
Signature	_____	_____	_____
Date:	_____	_____	_____

See overleaf

Please Note the Following Information

1. **Prescriptions:**
   - 1.1. Are valid only if it has the seal of the health institution
   - 1.2. Filled and blank are legal documents, treat them as fixed assets
   - 1.3. Written and verbal information to the client complement one another
2. **The prescriber:**
   - 2.1. Never allow others to use Rx issued under your custody
   - 2.2. Drug treatment is only one of the treatment options
   - 2.3. Write the prescription correctly and legibly
   - 2.4. Diagnosis and other parts of the prescription should be completed
   - 2.5. Abbreviations are NOT recommended
   - 2.6. Please accept prescription verification call from the dispenser
   - 2.7. If dosage must be repeated by the same Rx, describe so and sign
3. **The Rx Evaluator -Pharmacy Professional should check for:**
   - 3.1. Legality of the Rx; (Standard Rx, authorized signature, title & date)
   - 3.2. Legibility (must be clear-never do guess work)
   - 3.3. Completeness of Rx (make sure all parts of RX are filled)
   - 3.4. Medication history using open ended questions
   - 3.5. Correctness of indication, dose, duration, contraindications, safety, interactions and others using recent STG, formulary and resources in DIS etc.
   - 3.6. Verification with the prescriber-If in doubt
   - 3.7. Drug therapy problems (DTPs) and document using relevant format
   - 3.8. Price of medicines Rx, announce to the patient and confirm payment
4. **The Counselor-Pharmacy Professional:**
   - 4.1. Dispenses the medicines to patients
   - 4.2. Check for whom the medicine is being dispensed: Patient or care taker
   - 4.3. Arrange appropriate container and packaging for the product
   - 4.4. Labels of medicines should be clear, legible and indelible
   - 4.5. Dispense with appropriate information and counseling
   - 4.6. Record Rx in special recording if refilling is prescribed
   - 4.7. keep filled prescriptions at least for 2 years
5. **Minimum drug label information**:
   - 5.1. Patient name
   - 5.2. Generic name, strength and dosage-form of the medicine, dose, frequency and duration of use of the medicines
   - 5.3. Route of administration and storage condition and quantity

Please Note the Following Information

1. **Prescriptions:**
   - 1.1. Are valid only if it has the seal of the health institution
   - 1.2. Filled and blank are legal documents, treat them as fixed assets
   - 1.3. Written and verbal information to the client complement one another
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   - 2.1. Never allow others to use Rx issued under your custody
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   - 2.7. If dosage must be repeated by the same Rx, describe so and sign
3. **The Rx Evaluator -Pharmacy Professional should check for:**
   - 3.1. Legality of the Rx; (Standard Rx, authorized signature, title & date)
   - 3.2. Legibility (must be clear-never do guess work)
   - 3.3. Completeness of Rx (make sure all parts of RX are filled)
   - 3.4. Medication history using open ended questions
   - 3.5. Correctness of indication, dose, duration, contraindications, safety, interactions and others using STG, formulary & information of DIS.
   - 3.6. Verification with the prescriber-If in doubt
   - 3.7. Drug therapy problems (DTPs) and document using relevant format
   - 3.8. Price of medicines Rx, announce to the patient and confirm payment
4. **The Counselor-Pharmacy Professional:**
   - 4.1. Dispenses the medicines to patients
   - 4.2. Check for whom the medicine is being dispensed: Patient or care taker
   - 4.3. Arrange appropriate container and packaging for the product
   - 4.4. Labels of medicines should be clear, legible and indelible
   - 4.5. Dispense with appropriate information and counseling
   - 4.6. Record Rx in special recording if refilling is prescribed
   - 4.7. keep filled prescriptions at least for 2 years
5. **Minimum drug label information**:
   - 5.1. Patient name
   - 5.2. Generic name, strength and dosage-form of the medicine, dose, Frequency and duration of use of the medicines
   - 5.3. Route of administration and storage condition and quantity

Annex 3: In-patient Medication Profile Form

(Follow the instructions Clinical pharmacy SOP when completing this form)
Name of Hospital: _____
Region: _____
1. Patient Information
Name: _____
Card #: _____ Sex: _____ Age: _____
Wt.: _____ Height: _____ BSA: _____
Pregnancy status: _____
Date of admission: _____
Ward: _____ Bed No: _____
Diagnosis: _____

2. Past Medical and Medication History
Medical history: _____
Medication history and adherence: _____
ADRs and/or Allergies: _____
Immunization Status: _____

3. Current Medications

Indication	Drug & Dosage Regimen (Name, Dosage Form, Dose, Frequency)	Start Date	Stop Date

4. Pharmacist's Assessment and Care Plan:

5. Recommendations/Interventions:

6. Discharge Medication and Counseling:

Annex 4: Pharmaceutical Care Progress Note Recording Form

Pharmaceutical Care Progress Note Recording Sheet
(Follow the instructions Clinical pharmacy SOP when completing this form)
Patient Name: _____
Card No. _____

Annex 5: Medication Reconciliation Form

Follow the instructions from Clinical pharmacy SOP when completing this form)

Hospital _____Region _____
Patient name: _____ Age _____
Sex _____ Weight _____
Source(s) of medication list _____
Allergic: _____

Medication information source	Regimen (Drug name, Dose, Frequency, Duration)	Reconciliation						Adjustments/ Changes made
		Plan on admission		Plan on transfer		Plan On Discharge		
		C	DC	C	DC	C	DC	
Pre-admission Medication								
Current Medication								

C – Continue, DC - Discontinue
Recorded by: Name _____
Signature _____ Date _____

Annex 6: List of Equipment and Materials for Compounding

SN	Equipment/material	Description
1	Working bench	Level, smooth, impervious, free of cracks and crevices and non-shedding; covered with protector sheets of plastic, rubber or absorbable paper when appropriate
2	Mortar and pestle	250 ml capacity or more; glass type and porcelain type
3	Water distiller	Stainless steel of 20 litter capacity or more
4	Water bath	Stainless steel of 4 openings or more
5	Electrical hotplate	Various Sizes and Features
6	Evaporating dish	Stainless steel (glazed inside) and porcelain type; with/without handling
7	Spatula	Stainless steel and plastic type, flexible and non-flexible, different blade lengths.
8	Gloves	disposable, non-sterile
9	Glass rod	Different length and thicknesses
10	Wash bottle	250ml capacity, polyethylene
11	Funnel	Glass type and plastic type (polyethylene)
12	Beakers	Glass type; different capacity
13	Volumetric flask	Glass type; different capacity
14	Balances	Prescription, torsion, triple beam, electronic; capacities of not less than 300 gm; sensitivity of not less than 0.1 mg.
15	Ointment tile	Glass type
16	Micropipettes	Glass type; different capacities (less than 1ml); with pipette bulb
17	Pipettes	Glass type; different capacities (1ml-100ml); with pipette bulb
18	Cylindrical graduate	Glass and plastic type; different capacity
19	Conical graduate	Glass and plastic type; different capacity
20	Weighing dishes	Plastic, aluminum, stainless steel type
21	Weighing paper	Normal paper; grease-proof for semisolids
22	Thermometers	Fridge and wall thermometer
23	Scientific calculator	

Annex 7: Compounding Process Description

A. General Procedures for Compounding

1. Receive, validate and interpret the prescription as per the Standard Operating Procedures (SOP) for dispensing
2. Ensure that the compounding area, equipment and containers are ready for the process and don't compromise the quality of the final product
3. Calculate the quantity of each ingredient accurately
4. Weigh and measure the ingredients necessary for compounding of the product as per the procedures for weighing and measuring, respectively
5. Compound the preparation following the appropriate procedure
6. Transfer to the final container, if it is not prepared in the final container, and make up to volume, if necessary
7. Close the container and shake well as appropriate
8. Assign beyond-use date for the preparation
9. Prepare and attach a proper label on the product container
10. Clean all the equipment used for the compounding process and return to their original place
11. Clean the working table
12. Record the compounding process on the Compounding Sheet
13. Dispense the product to the patient with proper counselling
14. Record the prescription on the Compounding Prescription Registration Book

B. Procedures for Weighing

1. Select a balance with appropriate capacity and sensitivity.
2. If weighing a solid material which requires being size reduced (ground) or sieved, always ensure that this is carried out before weighing.
3. Ensure that the balance is clean, dry and working properly
4. Put the balance on a level, non-vibrating and clean table

5. Adjust the balance, put the container for the material to be weighed and weigh it (to deduct from the final total weight) or use auto-zero to cancel its weight. Grease-proof papers should be used for weighing of semisolids.
6. Read carefully the label of the material to be weighed (check name, strength, expiry date)
7. Check the appearance and any sign of stability problems.
8. Add the material to be weighed on to the container using spatula until the correct weight is obtained, close the container and return to the original place
9. Carefully remove the weighed material and transfer to the suitable container
10. Clean the balance and its accessories.
11. Return the balance and its accessories to the original place
12. Clean the working table

C. Procedures for Measuring Liquids

1. Make sure the availability of appropriate graduated measure (cylindrical graduate, conical graduate, pipette, syringe, and dropper) depending on the viscosity and quantity of the liquid to be weighed.
2. Select a clean and dry graduated measure of appropriate size.
3. Read the label of the liquid carefully (check name, strength, expiry date)
4. Check the appearance and any sign of stability problems.
5. Pour the liquid into the measure until the desired volume is obtained.
6. In case of measuring more than one liquid, hold the cap of the container in your hand, preferably between the fourth finger and the palm of the hand, so that the possibility of exchange of closures ending up with cross-contamination is minimized.
7. Transfer the liquid from the measure.
8. Allow to drain for sufficient time. Viscous liquids need more time as compared to aqueous, alcoholic and hydrochloric liquids which can drain within 30 seconds.
9. Clean the measure and replace to its original place.
10. Clean the working table.

D. Stability and Beyond-use Dating

1. Compounding pharmacists should avoid ingredients and conditions that could result in excessive physical deterioration or chemical decomposition of drug preparations, especially when compounding.
2. The beyond-use date is the date after which a compounded preparation is not to be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates is assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.
3. Compounders should consult and apply drug-specific and general stability documentation and literature when available, and should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy when assigning a beyond-use date.
4. At all steps in the compounding, dispensing, and storage process, the compounder should observe the compounded drug preparation for signs of instability. However, excessive chemical degradation and other drug concentration loss due to reactions may be invisible more often than they are visible.
5. In the absence of stability information that is applicable to a specific drug and preparation, the following maximum beyond-use dates are recommended for non-sterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated.

E. Non-Aqueous Liquids and Solid Formulations

Where the Manufactured Drug Product is the Source of Active Ingredient— The beyond-use date is not later than 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier. Where a USP or BP Substance is the Source of Active Ingredient— The beyond-use date is not later than 6 months.

For Water-Containing Formulations (prepared from ingredients in solid form): The beyond-use date is not later than 14days for liquid preparations when stored at cold temperatures between 2 and 8 (36 and 46 F).

For All Other Formulations:
The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier. These beyond-use date limits may be exceeded when there is supporting valid scientific stability information that is directly applicable to the specific preparation (i.e., the same drug concentration range, pH, recipients, vehicle, water content, etc.).

F. Labelling

Compounded products must be labelled according to regulatory requirements. In addition, labels of these products should also include names of any preservatives used. This information may be useful for avoiding sensitivity reactions in susceptible individuals and for explaining differences in flavour where the preservatives vary.
When non-pharmacopoeia products are prepared, the labels should document the complete list of ingredients and their amounts/proportions for future reference by other pharmacists and health professionals.
The pharmacist should examine the product for correct labelling after completion of the compounding process. Labels on compounded products for individual patient should have a minimum of the following information:

- Patient's name
- Name of the compounder
- Name and address of the compounding institution

- A complete list of ingredients and preparation name
- Strength
- Quantity of each ingredients
- Directions for use
- Date of preparation
- Beyond-use date
- Storage condition
- Batch number

G. Packaging

Compounded preparations should be packaged in containers meeting standard requirements. The container used depends on the physical and chemical properties of the compounded preparation. Container–drug interaction should be considered with substances such as phenolic compounds and sorptive materials (e.g., polypeptides and proteins). The containers and container closures should also be made of clean materials that are neither reactive, additive, nor absorptive. The containers and closures shall be of suitable material so as not to alter the quality, strength, or purity of the compounded drug.

Annex 8: Compounding Process Recoding Form (Compounding sheet)

Name of the dispensary/health institution _____

Date _____Batch number/control umber_____ Batch quantity _____

Description of ingredients				**Name or initials of the person in charge**
Name	**Source**	**Batch number**	**Quantity**	
Description of the steps of the preparation				
Beyond use Date: _____				
Yield: _____ **Loss:** _____ **Reason for loss:** _____				
Prepared by: Name _____ **Signature** _____ **date** _____				
End control before release of the product				
Parameters	**Comment**			
Approved by: Name _____ **Signature** _____ **Date** _____				

Annex 9: Compounding Prescription Register Form

S N	Patient identifiers					Diagnosis (ICD) Code No.	Description of the preparation				Name or Initials of the dispenser
	Name of the Patient	Sex	Age	Wt.(kg)	Card No		Ingredients		Qty dispensed	Control number	
							Name & strength	Quantity			

Annex 10: Pharmaceutical storage guideline

Activities		Justification
1.	Store pharmaceuticals in a dry, well-lit, well- ventilated storeroom - away from direct sunlight. Temperatures in the storeroom should not exceed 25oC.	Extreme heat and exposure to direct sunlight can degrade pharmaceuticals and dramatically shorten shelf life. Direct sunlight raises the temperature of the product and can reduce its shelf life or may damage the product by other mechanisms.
2.	Clean and disinfect the storeroom regularly. Keep food and drink out of the storeroom.	Pests are less attracted to the storeroom if it is regularly cleaned and disinfected. The outside of the store should also be kept clean, and any garbage should be stored in covered containers. Water should not be allowed to stagnate near the building. Would should be varnished or painted to discourage pests. If possible, a regular schedule for extermination will also help eliminate pests.
3.	Protect storeroom from water and moisture.	Moisture can destroy both supplies and their packaging. If the packaging is damaged, the product is still unacceptable to the patient even when the pharmaceutical is not damaged.

4.	Keep fire safety equipment available, accessible, and functional, and train employees to use it.	Stopping a fire before it spreads can save expensive supplies and the storage facility. The right equipment should be available; water is able to put out paper fires, but is ineffective on electrical and chemical fires. Place well-maintained fire extinguishers at suitable positions in the storeroom. If a fire extinguisher is not available, keep sand or soil in a bucket nearby.
5.	Store latex products away from electric motors and fluorescent lights.	Latex products can be damaged if they are directly exposed to fluorescent lights and electric motors. Electric motors and fluorescent lights create the chemical ozone which can rapidly deteriorate latex products. Keep latex products in paper boxes and cartons.
6.	Maintain cold storage, including a cold chain, as required.	Cold storage (2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit) is essential for maintaining the shelf life of certain pharmaceuticals. These items are irrevocably damaged if the cold chain is broken. If electricity is unreliable, the use of cylindered gas or kerosene-powered refrigeration is recommended. Many drugs require storage below 25 oC. There may also be products that should be stored at a temperature below 0oC and hence the required storage condition should be maintained for these products.

7.	Limit storage area access to authorized personnel. Drugs which need an access-controlled environment such as narcotics, psychotropic, etc. should be stored under lock and key separate from the rest of stock preferably a locked wire cage within the storage facility or a lockable cabinet.	To prevent theft and pilferage, lock the storeroom and/or limit access to personnel other than authorized staff, and track the movement of pharmaceuticals.
8.	Stack cartons at least 10 cm off the floor, 30 cm away from the wall and other stacks, and no more than 2.5m high.	Pallets keep the products off the floor so they are less susceptible to pests, water and dirt damage. Stack pallets 30 cm away from the walls and each other to promote air circulation and to ease movement of stock, cleaning and inspection. Do not stack cartons more than 2.5m as the weight of the products may crush the cartons at the bottom. This will reduce potential injury to warehouse personnel. If cartons are particularly heavy, stack cartons less than 2.5m. Where feasible, strong well-organized shelving is preferred.
9.	Store medical supplies away from insecticides, chemicals, old files, office supplies and other materials.	Exposure to insecticides and other chemicals may affect the shelf life of pharmaceuticals. Old files and office supplies may get in the way and reduce space for medical supplies or make them less accessible. "De-junking" the storeroom regularly makes more space for storage.

10.	Store flammable products separately from other products. Take appropriate safety precautions. Storage areas and cabinets should be clearly marked to indicate that they contain highly flammable liquids and should display the international hazard symbol. Corrosive or oxidant products, laboratory chemicals and reagents should be stored away from flammables, ideally in a separate steel cabinet to prevent leakage.	Some medical procedures use flammable products, such as alcohol, cylindered gas, or mineral spirits. Such products should be stored in the coolest possible place, away from electrical appliances and other products and near a fire extinguisher.
11.	Store pharmaceuticals to facilitate FEFO procedures and stock management.	FEFO (First Expiry, First Out) is a method of managing drugs in a storage facility where the drugs are managed by their expiry date. Drugs that will expire first are issued first, regardless of when they were received at the health facility.

12.	Store drugs in their original shipping cartons. Arrange cartons with arrows pointing up, and with identification labels, expiry dates, and manufacturing dates clearly visible.	Drugs should not be opened to repackage them. Store supplies in their original shipping cartons. Items should be stored according to manufacturer's instructions on the cartons; this includes paying attention to the direction of the arrows. Identification labels make it easier to follow FEFO, and make it easier to select the right product.
13.	Separate unusable pharmaceuticals from usable pharmaceuticals and dispose of damaged or expired products without delay.	Do not dispense expired drugs to the patients. Designate a separate part of the storeroom for damaged and expired goods.

Pharmaceuticals Requiring Cold Storage:
Thermo-labile medicines must be kept in a refrigerator.
The refrigerator should only be used for storing pharmaceuticals.
The refrigerator should not be overloaded and stock should be kept in an orderly manner.
The door of the refrigerator should close tightly.
Uninterrupted power supply must be ensured.
The temperature of the refrigerator should be maintained between 2oC and 8oC.
The temperature of the refrigerator must be monitored and charted twice daily. A WHO approved dial thermometer or alcohol or mercury thermometer should be used. The thermometer must be hung from the middle shelf of the refrigerator.
If the power is off for any length of time, the refrigerator should not be opened until the power supply is restored.
The cold chain must be maintained when the refrigerator is cleaned. Cooler boxes should be used to maintain the cold chain.
The following procedures should be followed when the refrigerator is cleaned:

The inside of the refrigerator should be cleaned with an appropriate cleansing solution and wiped dry
The door gasket should be cleaned, especially along the bottom edge on upright units.
The freezing compartment should be defrosted if there is more than 10 mm of ice on the evaporator.
The condenser coil on the back of the refrigerator should be cleaned and dust removed from the compressor.

Annex 11: Bin Card

Hospital Name: _____
Product Name, Strength and Dosage Form: _____
Unit of Issue: _____

Date	Doc. No. (Receiving or Issuing)	Received from or Issued t	Quantity				Batch No.	Expiry Date	Remark
			Received	Issued	Loss/Adj.	Balance			

Annex 12: Stock Record Card

Hospital Name: _____
Product Name, Strength and Dosage Form: _____
Unit of Issue: _____ Maximum Stock Level: _____ Emergency Order Point: _____

Date	Doc. No. (Receiving or Issuing)	Received from or Issued t	Quantity				Batch No.	Expiry Date	Remark
			Received	Issued	Loss/Adj.	Balance			

Annex 13: Internal Facility Report and Resupply Form (IFRR)

Name of Dispensing Unit: _____ Reporting Period From: _____ To: _____ Maximum Level: _____

Ser. No.	Item	UNIT OF ISSUE	COMPLETED BY UNIT				COMPLETED BY STORE			
			Beginning Balance	Quantity Received	Loss/ Adjustment	Ending Balance	Calculated Consumption E = A + B +/- C - D	Maximum Quantity F =E * 2	Quantity Needed to Reach Max. G = F – C	Quantity to be Supplied
			A	B	C	D	E	F	G	H
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
	Remarks:									
	Completed by (Name, Date and Signature):						Completed by (Name, Date and Signature):			
	Approved by (Name, Date and Signature):									

Annex 14: Report and Requisition Form (RRF)

Health Facility: _____ Region: _____ Zone: _____ Woreda: _____

Reporting Period **From**: month/day/year **To** month/day/year **Maximum Stock Level**: 4 months **Emergency Order Point**: 0.5 months

No	Product Code	Product Description	Unit of Issue	Report Part							Requisition Part		
				Beginning Balance	Quantity Received	Losses/ Adjustments	Ending Balance		Calculated Consumption	Days Out of Stock	Maximum Stock Quantity	Quantity needed to reach Max	Quantity Ordered
							In DU	In store					
				A	B	C	D	E	F = A + B +/- C - D - E	G	$H = \frac{120 \times F}{(60 - G)}$	I = G - D - E	
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
	Products with shelf life ≤ 6 months (S/No, Quantity and Expiry date):								Remarks:				

Completed by: _____ Signature: _____ Date: _____

Verified by: _____ Signature: _____ Date: _____

Approved by: _____ Signature: _____ Date: _____

Annex 15: Record for Returning Unusable Commodities (RRUC)

Date: _____

To: _____

(Name of Health Centre or PFSA Hub)

Facility returning commodities:

Region:_____ Zone: _____ Woreda: _____ Kebele: _____

Item Description	Unit	Quantity Returned	Reason for Return/Non-Use

Sending Certification:

Completed by: _____ Signature: _____ Date: _____

Remarks:

Carrier Certification:

Carried by: _____ Signature: _____ Date: _____

Remarks:

Receiving Facility Certification:

Received by: _____ Signature: _____ Date: _____

Remarks:

Annex 16: ADR reporting Form

Food Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA)
Adverse Drug Event reporting form

Patient Name (abbreviation)	Card No	Age, Date of birth	Sex	Weight	Height

Ethnic group	Substance of abuse

Information on suspected drug/vaccine **S=suspected drug** **C=concomitantly used drugs**

Drug name(write all information including brand name batch no and manufacturer	S/C	Dose/dosage form, route, frequency	Date drug taking was started (D/M/Y)	Date drug reaction started (D/M/Y)	Date drug taking was stopped (D/M/Y)	Indication (Reason for drug use)

Adverse drug event description(include all available laboratory test results)

Reaction necessitated:
Discontinuation of drug/s ☐ YES ☐ No
Hospitalization prolonged ☐ YES ☐ No

Reaction subsided after D/C of suspected drug?
☐ YES ☐ No ☐ Information not available
Reaction reappeared after restart of suspected drug?
☐ YES ☐ No ☐ Information not available

Treatment of reaction:

Outcome: ☐ Died due to the adverse event ☐ Died, drug may be contributory ☐ Not yet recovered
☐ Recovered without sequelae ☐ Recovered with squelae ☐ Unknown

Squelae:

Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc

Reported by: Name	Profession:	Email address:	Telephone

Name of health institution: Date

Product quality problem: Color change, separating of components, powdering, crumbling, caking, molding, change of odor, incomplete pack, suspected contamination, poor packaging/poor labeling, etc (Write if anything different than given above)

Drug trade name	Batch No	Registration no	Dosage form and strength	Size /type of package

For office use only	
Received on:	Registration no:
Key: D/M/Y ; Date /Month/Year D/C: Discontinue treatment Y:YES N:NO	

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what to report

All suspected reactions to drugs
Unknown or unexpected reactions
Serious adverse drug reactions
Unexpected therapeutic effects
All suspected drug interactions
Product quality problems
Treatment failures
Medication errors

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

This ADE reporting form was prepared by FMHACA in collaboration with MSH/SPS and financial support from USAID

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From ----------

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Food, Medicine and Health care Administration
And Control Authority of Ethiopia

Food, Medicine and Health Care Administration and Control Authority
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IN PARTNERSHIP TO FIGHT HIVAIDS
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U.S. President's Malaria Initiative