National Clinical Pharmacy Service Implementation Manual in Ethiopia

I

Foreword

The Federal Ministry of Health has been coordinating sector wide reforms that aim to improve equity and quality of health services. It is widely known that the sector is growing in line with the overall growth and transformation plan of the country and it is being guided by the health sector transformation plan. As part of these efforts, the Ethiopian Hospital Services Transformation Guidelines, which is consistent with the national focus on quality improvement in health care, incorporated new national initiatives such as clinical pharmacy service.

Clinical pharmacy is one of the proven strategies for promoting the rational use of medicines. In Ethiopia, various efforts have been made to initiate clinical pharmacy in the Ethiopian health care system and the Federal Ministry of Health has been collaborating in efforts to implement clinical pharmacy service in public health facilities. Hence, the involvement of pharmacists in direct patient care settings is a key intervention to optimize outcomes of drug therapy, thereby improving quality of patient care and reducing overall health care costs. Thus, the development of this document is an important step to standardize the service provided by all health facilities.

It is my belief that pharmacists, clinical pharmacists, CPS providers, and drug information pharmacists who are working in health facilities are the primary users of this document. In addition, program managers and experts involved in designing and conducting trainings, mentoring, supportive supervision, monitoring and evaluation activities of pharmaceutical services at the health facilities will find this manual useful. It is also my strong belief that health system managers, policy makers, academicians, researchers & students will find it valuable.

I would like to take this opportunity to thank all who participated in the development of this implementation manual. I would also like to encourage users of this document to send their comments to the Ministry via website: http://www.moh.gov.et or PO. Box 1234, Addis Ababa, Ethiopia.

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Acronyms/Abbreviations

ACCP	American College of Clinical Pharmacy
CDC	Center for Diseases Prevention and Control
CP	Clinical Pharmacy
CPS	Clinical Pharmacy Service
CRC	Compassionate, Respectful and Caring
ADR/E	Adverse Drug Reactions/Events
DTC	Drug and Therapeutic Committee
DTP	Drug Therapy Problem
FMHACA	Food, Medicine and Healthcare Administration and Control Authority
ESA	Ethiopian Standard Agency
EHRIG	Ethiopian Hospital Reform Implementation Guideline
EHSTG	Ethiopian Hospital Services Transformation Guideline
FMOH	Federal Ministry of Health
GTP	Growth and Transformation Plan
HSTP	Health Sector Transformation Plan
ICU	Intensive Care Unit
KAS	Knowledge, Attitude and Skill
MTM	Medication Therapy Management
MDT	Multidisciplinary Team
OPD	Out-patient Department
PEPFAR	Presidents Emergency Plan for AIDS Relief
PFSA	Pharmaceuticals Fund and Supply Agency
PG	Post-graduate
Pharm D	Doctor of Pharmacy

POM	Pharmacy Only Morning Session
POR	Pharmacy Only Round
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	Standard Operating Procedures
TASH	Tikur Anbesa Specialized Hospital
UG	Undergraduate
UDDS	Unit Dose Dispensing System
UDS	Unit Dose System
USAID	US Agency for International Development
WHO	World Health Organization
FIP	International Pharmaceutical Federation

Operational definitions

Clinical Pharmacy: is a health science discipline where pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention.

Clinical Pharmacy Service: is a patient-centered care developed to promote the rational use of medicines and more specifically, to maximize therapeutic benefits, minimize risk, & reduce cost.

Clinical Pharmacist: is a pharmacist with advanced education (a post graduate degree in clinical pharmacy or pharmacy practice) who provides patient care as a member of the multidisciplinary healthcare team by focusing on pharmacotherapy or comprehensive medication management and assuming responsibility and accountability for optimizing medication-related outcomes.

Clinical Pharmacy Service Provider: is a pharmacist who is assigned by the responsible body to practice and provide clinical pharmacy services in all healthcare settings.

Pharmaceutical care: The International Pharmaceutical Federation (FIP) defines as *'the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life'*.

Monitoring: refers to reviewing, on a continuous basis, the degree to which program activities are completed and targets are being met. Effective, frequent monitoring helps managers to make decisions in a timely manner. This allows corrective action to be taken during service provisions.

Evaluation: refers to periodic assessment of progress toward meeting established objectives and goals. It provides feedback on whether plans had been met and the reasons for success or failure. It should also provide directions for future plans.

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1. Introduction

1.1 Health Care System in Ethiopia

The Ethiopian healthcare system is structured into a three-tier system; primary, secondary, and tertiary level of health care. A comprehensive package of preventive, promotive, curative, palliative and rehabilitative healthcare services are included in the recently revised health policy of Ethiopia. Improving the quality of pharmaceutical services through increasing access to medicine and promoting appropriate use are among priority policy directions. Of the health programs that are given emphasis, patient centered pharmacy services are mentionable.

Considering the global situation and the country's commitment, long-term vision and Growth and Transformation Plan (GTP), a five-year health sector transformation plan (HSTP) is being implemented since 2015. Accordingly, it is stated that the major initiative implemented during the recent period is the launching of clinical pharmacy service (CPS) at hospitals and this effort in providing and strengthening CPS for inpatients and outpatients must be continued as a key means of ensuring rational drug use thereby improving treatment outcome and quality of care.

1.2   Hospital Pharmaceutical Services in Ethiopia

Pharmacy service is an essential component of health care delivery in each country. 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 and prevention of medication errors, adverse drug events and for the prevention and containment of antimicrobial resistance. It also promotes optimal use of limited resources thereby improving quality of care resulting in better health outcomes. Accordingly, pharmacy services should provide assurance that quality and safety of medicines is maintained at all stages of service provision and clients' satisfaction is given of utmost importance. Hospitals should also establish convenient pharmacy work environment that elicits confidence to patients and the staff.

Drugs are an essential component of the health care delivery in a certain health care system. When used rationally, they produce the desired effect of improving patients' illness. Their irrational use on the other hand leads to prolongation of the illness, failure to treatment, development of adverse effects and antimicrobial resistance, and unnecessary expenses to the patient as well as to the health care system. Reports indicated that, inappropriate and economically inefficient use of pharmaceuticals is commonly observed in health care systems

throughout the world, particularly in developing countries. Overall, because of irrational use of medicines, increased morbidity, and mortality due to avoidable treatment failures, waste of resources leading to increased costs and reduced availability of other vital drugs and loss of public thrust towards the system are common.

Pharmacy professionals are expected to play crucial role in the process of promoting rational drug use. Pharmacist helps in achieving the goal of rational use of drugs by following good pharmacy practices. They have the potential to improve therapeutic outcomes and patients' quality of life through managing drug therapy and concurrent non-pharmacologic interventions. To play these roles, however, the role of the pharmacist needs to be redefined and reoriented.

1.3 Clinical Pharmacy Services

1.3.1 The Global Context

Role of pharmacist has been emerging continuously to meet the modulating needs of society. The pharmacist is now not only a supplier of medicines but a provider of care and information with different members of healthcare team and the patients. In the past few decades, there has been a major shift in paradigm of pharmacy practice moving toward clinical pharmacy services. The International Pharmaceutical Federation (FIP) and World Health Organization (WHO) have been promoting the practice, many countries adopting the idea.

Previously hospital pharmaceutical services were almost entirely concerned with the preparation and dispensing of medicines, with little direct patient contact. These technical services are still fundamental to the current service and have become increasingly specialized, but they are now complemented by a wide variety of ward-based, patient-focused activities. These are generally referred to as CPS. There is a handful of evidence indicating the impact of this service in improving patient care. In many countries, where CPS are firmly established, it has been associated with reduced adverse drug events, medication errors, duration of patients' hospital stay, mortality rates, costs of treatment and improved adherence.

Clinical pharmacy service became a unique and separate entity at the University of Kentucky in the late 1960s. During the clinical era (1960–1990) clinical pharmacy has been introduced as a part of hospital pharmacy, pharmacists were expected to dispense drug information, warnings, advice, and suggestions to patients. The American College of Clinical Pharmacy (ACCP) defines *clinical pharmacy* as a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and care. The practice of clinical

pharmacy embraces the philosophy of pharmaceutical care. The FIP defines *pharmaceutical care* as the responsible provision of pharmacotherapy for achieving definite outcomes that improve or maintain a patient's quality of life. CP blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for ensuring optimal patient outcomes.

1.3.2   The National Context

Over the last five decades, globally there has been a trend for pharmacy practice to move away from its original focus on medicine supply to a more inclusive focus on patient care. The role of the pharmacist has evolved from that of a compounder and supplier of pharmaceutical products to that of a provider of services and information, and ultimately, that of a provider of patient care. Increasingly, the pharmacist's task is to ensure that a patient's medicine therapy is appropriately indicated, the most effective available, the safest possible, and convenient for the patient. By taking direct responsibility for individual patient's medicine-related needs, pharmacists can make a unique contribution to the outcome of medicine therapy and to their patients' quality of life.

Recognizing this global change, various efforts have been made in Ethiopia to introduce clinical pharmacy services in the health care system. They include: revision of the undergraduate pharmacy curriculum in public universities in 2008; establishment of drug information center at Tiku Anbessa Specialized Hospital (TASH) in 2009 by Addis Ababa University School of Pharmacy with a technical support from Howard University College of Pharmacy and financial support from PEPFAR/CDC through the American International Health Alliance-Twinning Center; launching of the clinical pharmacy post graduate program at Jimma University in 2009 and pharmacy practice postgraduate program at Addis Ababa University in 2010; inclusion of clinical pharmacy services as one operational standard in the Pharmacy chapter of the Ethiopian Hospital Reform Implementation Guidelines (EHRIG) by the Federal Ministry of Health (FMOH) in 2010 and inclusion of CPS as one standard in the health facilities minimum regulatory standards prepared by the Ethiopian Standards Agency (ESA)/Ethiopian Food, Medicines and Health Care Administration and Control Authority (FMHACA) in 2012.

According to EHRIG, all hospitals are expected to provide CPS as part of their pharmaceutical services. More importantly, the service should be well integrated with all clinical departments. Following the issuance of EHRIG in 2010, Ethiopia has also officially adopted the new service as a critical pharmacy service in healthcare facilities particularly in the hospitals settings throughout the country. According to the 2017 Ethiopian Hospital Services Transformation

Guideline (EHSTG), CPS 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.

Furthermore, to support the smooth implementation of clinical pharmacy services, the Pharmaceuticals Fund and Supply Agency (PFSA), in collaboration with the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Project funded by the US Agency for International Development (USAID) and the Schools of Pharmacy of Jimma, Gondar, and Mekelle Universities, have provided a one-month in-service clinical pharmacy training for 200 hospital pharmacists from 65 selected hospitals throughout the country in 2012/3.

As of 2017, as a result of the concerted effort of all stakeholders and higher teaching institutions, the total number of available pharmacy graduates in Ethiopia reaches around 3000. This number is inclusive of both graduates in the new patient-oriented pharmacy curriculum as well as by the previous curriculum. However, Pharmacists required by 2020 for public health facility is estimated to be 6406, which is higher than 2 times the available number. Moreover, as of 2017 the total MSc graduates in clinical pharmacy and pharmacy practices are about 175 clinical pharmacists. Of these clinical pharmacists, most of them are working in higher institutions as lecturers of clinical pharmacy, some of them are in large hospitals, and the rest are working in different government, non-government, and private organizations. However, there is a huge CP workforce gap at all in health facilities, ministry of health, regional health bureaus, regulatory authorities, government agencies, universities and research institutes.

1.4   Rationale of the Manual

Because of the ministry's commitment to provide CPS to patients in health facilities and the efforts made by governmental and nongovernmental stakeholders, pharmacists working in Ethiopia are expected to integrate with other health professionals and provide a wide range of CPS in health facilities. Hence, they are expected to provide pharmaceutical care to patients. They are required to participate in ward rounds and contribute to the clinical decision making as a team, assess and monitor patients in relation to their drug therapy, provide recommendations on appropriateness and safety of drug therapy, follow patients for treatment outcomes and drug related toxicities, counsel patients on appropriate use of medications and provide drug information services to patients, health care providers and the public.

Despite the efforts made to provide CPS, the hospitals were unable to fully implement the services as expected and make significant progress towards quality pharmaceutical care. Moreover, inconsistent, fragmented, and non-uniform practice of the services was seen among hospitals which already started the service. To address such problems various activities are being conducted by FMOH and stakeholders. In line with this, a national consultative workshop on CPS was conducted to examine its existing status, identify gaps and challenges, and formulate a sound way-forward to improve the service. Studies done in this area were also presented in the workshop, and findings and recommendations were discussed in the workshop. Accordingly, the following 20 key findings were identified from the national consultative discussions.

S. No	Key finding
1.	There is inconsistent and non-uniform implementation of CPS and practice in hospitals.
2.	There is low level and inconsistent documentation and reporting of CPS across hospitals.
3.	Inadequate management and administrative support including lack of resources
4.	There is a huge shortage of pharmacists throughout the country.
5.	There is high attritions rate of CPS providers in hospitals and CP faculties in universities.
6.	Poor collaboration, coordination, and integration of CPS providers with school of pharmacies
7.	There is lack of appropriate staff retention and development mechanisms in hospitals and universities such as incentive mechanisms and risk allowances for CPS providers and faculties.
8.	There is inadequate awareness about the scope, role and importance of CPS from other health professionals, hospital managers, health bureau officials and policy makers side.
9.	There is poor communication skill from the CPS providers side.
10.	There is low professional commitments and motivation by the CPS providers.
11.	There is a KAS gap among CPS providers compared to senior physicians.
12.	Inadequate in-service training programs (onsite & offsite) for CPS providers in different areas.
13.	24-hour CPS is not the standard of care to maintain continuity of pharmaceutical care.
14.	There is lack of supportive supervision, mentoring, follow up and experience sharing practices.
15.	There is no uniform and national job description for CPS providers.
16.	There is poor regulatory support in the implementation of CPS standards and requirements.
17.	There is little recognition and attention given to the service and service providers nationally.
18.	There are limitations on the practical attachment in the UG-Pharmacy and PG curriculums.
19.	There is a gap in the type of UG pharmacy curriculum (there is a need to be Pharm D).
20.	Non-uniform implementation of the national UG pharmacy curriculum across universities.

Therefore, this implementation manual has been developed to address some of the above gaps and challenges identified in the provision of CPS. Hence, this document is developed with the intention of bringing quality and uniformity in CPS of Ethiopia through standardizing the service, providing continuous support, and placing a strong monitoring and evaluation system. Further, this document intends to gather all fragmented national CPS guidelines, SOPs, and standards, and develop a comprehensive guide for easy implementation, support, monitoring and evaluation.

1.5 Goal of the Manual

The goal of this document is to bring quality, uniform, and sustainable clinical pharmacy services in health facilities of Ethiopia through standardizing the services by providing guidance and support and placing a robust monitoring and evaluation system in the area.

1.6 Objectives of the Manual

General Objective

The general objective of this implementation manual is to standardize the provision of CPS through defining the range of CPS and core activities of service providers, putting strategic directions for implementation, and developing a monitoring and evaluation system at all levels.

Specific Objectives

- Identify the national requirements for the provision of CPS.
- Provide a guidance for the provision of the various CPS components.
- Describe the process of creating a model CP site and scale-up.
- Define the roles and responsibilities of key CP stakeholders and providers.
- Serve as a source of guidance for monitoring and evaluation system for CPS.
- Bring ethical and legal practices and professionalism among CPS providers.
- Support rational drug use studies and quality improvement activities.
- Ensure that standardized recording, documentation& reporting of CPS are done in facilities.
- Provide guidance on how to assure the quality of CPS in health facilities.
- Provide guidance on how to establish and/or revitalize CPS in health facilities.

1.7   Scope of the Manual

In general, the document shall be implemented in health facilities of Ethiopia to improve clinical pharmacy practice or service. However, it also touches cross-cutting issues related to CPS such as clinical pharmacy education and research. Even though, this document may not address all the existing problems related to CP practice, education, and research, it can serve as a guidance on the areas of collaboration with key stakeholders to improve the overall CPS. To improve treatment outcome, quality of care and patient safety, private health facilities and community pharmacies are recommended to provide CPS in the necessary areas of patient care by adapting the principles, core activities and processes described in this guideline.

2. Strategies to implement CPS in Ethiopia

Even though there were various efforts made to provide CPS in hospitals, it was unable to implement quality and sustainable CPS in Ethiopia. Moreover, inconsistent, fragmented, and non-uniform service was observed among hospitals where CPS was already started. Hence, CPS implementation strategies would be optimized in a way that can be realized in each health institution of the country to improve the service. Therefore, the following strategic objectives will be used to expand and optimize CPS implementation and service quality in all health facilities of the country. The following strategic objectives implementation plan is attached (annex 2.1).

Strategic Objectives

1. Implement standardized & uniform clinical pharmacy practice model in health facilities.
2. Design and implement clear structure for CPS appropriate to the level of health facility.
3. Set distinctive & integrated roles, responsibilities, and accountabilities for CPS providers.
4. Develop competent, adequate, ethical and compassionate, respectful and caring (CRC) clinical pharmacy professionals.
5. Perform communication, advocacy and promotion activities on CPS.
6. Design and implement a dynamic monitoring and evaluation system for CPS.

Strategic Objective 1: Implement standardized and uniform clinical pharmacy practice model in all health facilities.

- It is essential to implement standardized and uniform nationwide clinical pharmacy practice model that enables service providers' use their knowledge and skill to bring the best treatment outcomes through appropriate, effective, safe, and economical use of medications.
- Globally, there are different clinical pharmacy practice models[1]. Of which, pharmaceutical care is a ground-breaking concept in the practice of pharmacy which emerged in the mid-1970s. The most generally accepted definition of *Pharmaceutical care is given by Hepler and Strand in 1990 and it is defined as 'the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life''*. Then, the

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[1]Pharmaceutical care model, Medication therapy management model, Patient-centered primary care collaborative (PCPCC)MTM in the patient centered medical home (PCMH) model, Society of Hospital Pharmacists of Australia practice model, iMAP program (individualized medication assessment and planning).

International Pharmaceutical Federation (FIP) adopted this definition in 1998 by issuing 'statement of professional standards in pharmaceutical care'.

- Moreover, the concept of the seven-star pharmacist was also introduced by WHO and taken up by FIP in 2000 in its policy statement on 'Good Pharmacy Education and Practice', and sees the pharmacist as *a caregiver, communicator, decision-maker, teacher, life-long learner, leader, manager, and researcher* (added later). Later in 2006, WHO in collaboration with FIP published a document called 'developing pharmacy practice: a focus on patient care' which recognizes pharmaceutical care as a model of pharmacy practice (Annex 2.2).

- Considering these, Ethiopia has adopted the pharmaceutical care as a clinical pharmacy practice model. In case of outpatient, ambulatory and community pharmacy services, the modified practice models such as medication therapy management (MTM) (Annex2.3) can be adopted and used as a clinical pharmacy practice model in this country.

- Pharmaceutical care must be understood by all patient care providers making decisions about drug therapy including physicians, nurses, and all other prescribers. However, it is expected that the practitioner who will practice pharmaceutical care as a primary role and full-time career is the pharmacist. The pharmacist is equipped with the necessary academic preparation that focuses on pharmacology, pharmacotherapy, and pharmaceutical care practice.

Strategic Objective 2: Design and implement clear structure for CPS appropriate to the level of health facility.

- As a principle and as stated in the EHSTG, the CPS providers shall be well integrated with the other clinical teams and structures of the health facilities.

- As per the national structure of hospital pharmacy service department or directorate, hospitals should have a clinical pharmacy unit or case team.

- The CPS unit/case team leader should report to the pharmacy services director or head;

- By integrating with the existing other clinical team in health facilities, the CPS unit can further be organized in to teams as inpatient CPS team, outpatient CPS team, and emergency and critical care CPS team, which depends on the level of the hospital and complexity. All these teams will have their own team coordinators.

- The inpatient CPS team will have CPS providers assigned to internal medicine, pediatrics, surgery, and gyne-obs. In addition, for tertiary/teaching hospitals, additional CPS providers can be assigned to other service areas as needed, such as oncology CPS providers. If the hospital has neonatal ICU, it should also be covered by dedicated pharmacists.

- Outpatient CPS team will have CPS providers assigned in chronic care pharmacies and in OPD pharmacies as prescription evaluators and counselors. In addition, for tertiary/teaching hospitals, CPS providers can be assigned to OPD clinics with prescribers, as needed.
- Emergency and critical care CPS team will have CPS providers assigned to emergency departments to work with the resuscitation team, at bedside and in the emergency pharmacy. In addition, CPS providers will be assigned in ICUs (adult, pediatrics, and surgical ICUs).

Strategic Objective 3: Set distinctive and integrated roles, responsibilities and accountabilities for CPS providers.

- A clear and uniform national job description shall be prepared and disseminated to hospitals that consider the professional levels of CPS providers (Annex 2.4).
- Develop a trusting relationship between CPS providers; patients, prescribers, and nurses by recognizing, placing, and utilizing the pharmacist in the delivery of patient care.
- Create a system that pharmacists accept ownership and accountability for the service they provide.
- Set administrative measures against the service providers who do not discharge their duties and responsibilities properly.
- As per the nature of the facility, facility-based CPS SOP can be customized that will guide the general and specialized services being rendered by the CPS providers.
- As resource allows, CPS (pharmaceutical care) should be provided to all patients visiting the facility, be it in the inpatient, outpatient or emergency departments, and the service should be consistent enough to ensure continuity of patient care.
- 24/7 CPS should be provided to deliver adequate hours of operation. By this the clinical pharmacists providing CPS should get appropriate payments for extra time work they provide and there should be a provision of risk allowance and clinical allowance payments
- Ensure that the CPS provider has access to patient chart and information.
- The CPS documents should be provided by the hospital
- Evaluation of patient-specific medication therapy and planning a medicine therapy plan shall be done by the CPS provider together with the patient, prescriber, and nurse.
- Document every CPS given by providers, in the specified section of patient medical record.
- Ensure other health care professionals (prescribers) noticed the recommendations of CPS providers written on the patient medical record.

- There should be active involvement of pharmacists in discharge planning and medication use counseling. Pharmacists should give medication use counseling and patient education at discharge. The pharmacist should make sure that the patient has all drugs, information, and knowledge necessary to carry on the medicine therapy plan.

- As a member of the health care team, the CPS provider should attend and participate at multidisciplinary ward rounds/morning sessions and contribute to patient care.

- If the facility is a teaching hospital, pharmacy interns, pharmacy residents shall be part of the ward round team as appropriate.

- Depending on their area of expertise, specialty and experience, appropriate formal consultation services shall be provided by clinical pharmacists as appropriate.

- Provide a specialized CPS in those hospitals that offer specialty services. For example, dedicated clinical pharmacists can be assigned in, therapeutic drug monitoring, total parenteral nutrition, anticoagulation, dialysis, transplantation, and others, as their career and service area.

Strategic Objective 4: Develop competent, adequate, ethical and compassionate, respectful and caring (CRC) clinical pharmacy professionals.

- In order to effectively improve clinical outcome of patients, minimizes cost of treatment and adverse drug events, it is important to develop adequate, competent, ethical, and professionally disciplined CPS professionals. The staffing for CPS should be scientifically determined based on:
  o Range and complexity of hospital services and clinical pharmacy services required
  o Availability of pharmacy interns and pharmacy residents (for teaching hospitals).
  o Number of patients visiting the facility per year, and
  o Number of beds available in the facility.

- It is important to develop ethical and competent professionals by providing CPD.

- Support the development of ethical and compassionate, respectful and caring (CRC) CPS providers by providing in-service trainings, establishing ethics committee, and taking corrective actions when a practice is found unethical.

- Responsible stakeholders should work in collaboration with the ministry of education for addressing educational issues related to clinical pharmacy including the provision of objective and competency based qualifying exams to pharmacy graduates.

- Qualification exams need to be always requirement to provide clinical pharmacy services.

Strategic Objective 5: Perform communication, advocacy and promotion of CPS

- Developing and contributing to evidence-based guidelines that influence practice.
- Communicating and disseminating the value of CPS and providers in achieving medication optimization.
- Expanding and scaling up practice and research opportunities for CPS providers.
- Organize a series of consultative workshops with different stakeholders of CPS including professional associations.
- Create awareness to health institutions to implement EHSTG and the minimum health facility regulatory standards related to clinical pharmacy service.
- Advocacy of MDT based learning and practice among health science students and practitioners.
- Create ways of experience sharing among health facilities and professionals recognizing best CPS practices.
- Multi-sector collaboration related to the practice and improvement of CPS in the country.
- Assess the health and economic impact of CPS and disseminate the findings to policy makers.

Strategic Objective 6: Design and implement a dynamic monitoring and evaluation system for CPS.

- Perform CPS audit to improve patient outcomes by comparing the existing practice against agreed standards of care, implementing any changes necessary and re-examining the practice.
- All clinical pharmacy services should be documented and reported using standardized formats.
- The CPS recording and documentation formats should be an integral part of the patient chart.
- There should be a periodic supportive supervision, review meetings and clinical mentoring by responsible stakeholders.

3. Clinical pharmacy service: activities and area of practice

3.1 Pharmaceutical care process

The pharmaceutical care process includes assessment, care plan and evaluation.

1. **Assessment**
   - Meet the patient to establish the therapeutic relationship.
   - Obtain relevant information from the patient/care giver/medical record related to reason for the encounter, the patient's demographics, medication experience, and other clinical information.
   - Interpret patient data and evaluate medication therapy:
     - Assessing the appropriateness of current medications based on health conditions, indication, and the therapeutic goals of each medication
     - Evaluating the effectiveness, safety, and affordability of each medication.
     - Assessing medication-taking behaviors and adherence to each medication.
   - Determine whether the patient's drug-related needs are being met (indication, effectiveness, safety, compliance), identify drug therapy problems.
   - Prioritize patient drug therapy problems.
   - Record the pharmacy assessment on the inpatient medication profile form (Annex 3.1).

2. **Care plan**
   - Set goal of therapy.
   - Formulate intervention for resolution, prevention of drug therapy problem/s and achievement of goal of therapy.
   - Consider therapeutic alternatives; select patient-specific pharmacotherapy and nondrug interventions.
   - Communicate the care plan with other healthcare providers.
   - Educate patient/caregivers to ensure understanding of the care plan, to optimize adherence, and to improve therapeutic outcomes.
   - Establish measurable parameters and time frame for monitoring and follow-up
   - Document the care plan on the inpatient medication profile form (Annex 3.1).

3. **Follow-up and evaluation**
   - ➤ Ensure medication appropriateness, effectiveness, safety and patient adherence through clinical finding, laboratory investigation and patient feedback and compare to the goals of therapy.
   - ➤ Assess patient for any new drug therapy problems.
   - ➤ Conduct ongoing assessments and refine the plan of care to optimize medication therapy.
   - ➤ Record patient's current status and key interventions implemented from time to time to achieve the goals of therapy stated for each patient on the pharmaceutical care progress note recording sheet (Annex 3.2).
   - ➤ Schedule the next follow-up evaluation to provide continuous care.

N.B: These important activities shall be performed any time throughout the day including in OPD, emergency, MDT ward rounds, pharmacy only rounds, and chart reviews.

3.2 Clinical Pharmacy Service Areas

Clinical pharmacy service can be provided in a health facility like hospitals, health centers, clinics, community pharmacies, and home care. However, the impact of CPS has been well documented in in-patient settings, and to a lesser extent in ambulatory and community settings. In a hospital setting, CPS shall be provided in the following areas:

- Inpatient departments:
  - o Internal Medicine, Pediatrics, Gynecology & Obstetrics, and Surgery. Depending on their specialty, CPS can be provided in: psychiatry, dermatology, ophthalmology, ENT, TB, burn wards, etc.
  - o Inpatient ward pharmacies in Internal Medicine, Pediatrics, Gynecology & Obstetrics, and Surgery. Depending on convenience, patient load, level and complexity of the hospital the number of inpatient pharmacies can be determined.
- Outpatient departments:
  - o OPD pharmacy as prescription evaluator & counselor, chronic care pharmacy(s), and outpatient clinics (such as ART clinic, TB clinic, diabetic clinic, cardiac clinic, etc).
- Emergency department:
  - o Emergency ward
  - o Emergency pharmacy
- Intensive care unit:
  - o ICUs (Medical ICU, surgical ICU, Pediatrics ICU, Neonatal ICU)
  - o ICU pharmacy

- Oncology department:
  - Oncology pharmacy, oncology clinic and oncology wards.
- Drug information center and poison information center

3.3 Core Clinical Pharmacy Activities

3.3.1. Inpatient Clinical Pharmacy Service

Inpatient CPS should be well integrated with all clinical departments and ward pharmacy services. These services include the following core activities:

A. *Taking admission medication history*

Upon admission, a medication history shall be taken by the CPS provider from each patient and recorded in the patient's medical record. Patient and/or caregiver interview, medication sample observation and previous patient medical chart review can be used as a source of information while taking admission medication history. The CPS provider should follow and complete the information required on the admission medication history section of the inpatient medication profile form. The admission medication history can be taken either together with the admitting physician or separately whichever is convenient for the service and patient. If the patient is already admitted, the information should be collected as soon as possible from the above sources mentioned. Pertinent findings from the admission medication history and any recommendation made shall be communicated to the primary provider and documented in the above form.

B. *Undertaking medication reconciliation*

Medication reconciliation is a standardized process of obtaining a patient's best possible medication history and comparing it to presentation/admission, transfer (between wards and care settings) or discharge medication orders. It is one of the most important safety practices to reduce medication errors during care transitions to avoid errors of transcription, omission, duplication, and drug interactions. Medication reconciliation involves the following steps:

- Determining a current list of medications.
- Identifying a list of medications to be prescribed on admission, transfer, or discharge.
- Comparing the patient's current medication with admission, transfer, or discharge medications list; making clinical decisions based on the two lists.
- Finalizing and communicating the reconciled medication list to the patient and clinicians.
- Recording these activities on the medication reconciliation form (Annex 3.3).

- Once medication reconciliation is conducted, record as *'medications are reconciled at admission, transfer or discharge'* as appropriate.

C. *Provide ward pharmacy service through unit dose dispensing system*

In addition to the pharmaceutical care services, pharmacists coordinate the storage, preparation, and dispensing of all medications in the ward pharmacies. Pharmacists dispense and control the drug distribution in the inpatient settings by implementing unit dose dispensing system (UDDS).

The UDD is a system preferred by the World Health Organization (WHO) from patient care point of view due to the lower possibilities of medication errors associated with this system. In addition, UDD has several potential benefits than other drug distribution methods including:

- Reduces the incidence of medication errors
- Decrease the total cost of medication-related activities
- More efficient use of pharmacy and nursing personnel
- Allow for more direct patient-care involvement by pharmacists and nurses
- Improves overall drug control and drug use monitoring
- More accurate patient billings for medications

Even though the system varies from hospital to hospital, the following distinctive elements are inherent to all UDDS:

- Medications should be contained in single unit packages;
- Medications shall be dispensed in as ready-to-administer form as possible;
- Not more than a 24-hour supply of doses shall be available at patient-care area at any time, and;
- Prescription orders should be transcribed on inpatient prescription registration book (Annex 3.4).

During the operation of UDDS, the pharmacy professionals (mainly technicians) should load unit-dose ward carts for the pharmacists to check. The pharmacists should verify and double check that the correct medication and dosage is filled for the nurse to administer. It is required to package medications that are not commercially available in unit-dose form. Therefore, for an efficient operation of UDDS, the pharmacy professional should:

- Receive a properly identified prescription order or a prescription and a patient chart (preferably) of the physician from nurse, other personnel assigned or care giver.

- Check the order for change, discontinued medication, or other pertinent information and transcribe on the inpatient registration book.

- Register and refill the order after verifying for any therapeutic incompatibilities, drug allergies, interactions, etc.

- Give priority for stat and emergency orders (such list can be prepared) before a medication cart delivery while also giving immediate attention for orders requiring compounding that needs to be handled independently. Then dispatches completed orders of this nature directly to the requestor.

- Check and fill routine orders prior to reaching to the nursing station.

- Conduct a second check by an inpatient pharmacist by comparing available medications ready for patient administration with the patient card requirements.

- Provide a completed medication cart to the nursing station at approximately 30 minutes preceding initiation of a designated cycle of administration.

- Dispense or handle non-routine orders e.g. PRN (as needed) medications in enough quantities to cover all possibilities within each cycle.

- Collaborate with nurses at each prescribed interval so that ordered doses will then be administered as dictated by the medication orders.

Since the overall goal of UDDS is to optimize outcome of patients admitted to wards while also deploying professionals cost-effectively, it would be logical considering some issues differently. Therefore, some supplies (e.g., glove), medication requests that require special attention (e.g., stat medications, emergency medications and medication that need to be compounded and others) can be implemented by customizing to the context of each hospital. Specialty hospitals can also customize the UDDS contextual to their scope/type of service.

D. Making ward rounds

Ward rounds in CPS provision includes pharmacy only round and MDT. A pharmacy only round (POR) is made by a group of pharmacists to hospital inpatients to review and follow up their progress in achieving the goals of therapy. The MDT round is conducted by health care providers to share their contributions to cases and patient-specific issues. MDT facilitates better patient treatment and appropriate medicine use wherein each health professional plays his/her role and responsibility. As a member of the health care team, the pharmacist should be actively involved in MDT rounds. *(for detailed activities of POR and MDT round see clinical pharmacy SOP)*

E. Conducting morning sessions

CPS providers should participate in morning sessions to discuss selected patient cases and to get updated information on patient management. Pharmacist should be actively involved in MDT morning sessions. The MDT morning session is conducted by health care providers to discuss patient-specific issues and decide on actions to be taken to optimize therapy. Pharmacy only morning sessions aim to facilitate better patient care by ensuring appropriate medicine use wherein each pharmacist has a key role and responsibility. The pharmacy team should decide the number of pharmacy-only rounds and morning sessions that should be conducted per week. *(for detailed activities of pharmacy only and MDT morning session see clinical pharmacy SOP)*

F. *Providing discharge medication counseling*

It is a system for providing medication counseling to all patients discharged from health facilities. Pharmacists need to be involved in discharge planning and provide medications counseling to ensure continuity of care after patients are discharged from health facilities. After the patient's discharge medications are reviewed by the CPS provider, the prescriptions should be filled, and the patient is counseled appropriately. In addition to verbal information, the patient shall be provided with supplementary information about the times at which individual medications should be taken, and other required drug information for each drug. Discharge medication counseling includes, but not limited to

- ✓ Informing the name of drugs by showing each drug so that patients/care givers can identify as appropriate.
- ✓ Telling the dose, frequency, specific time of administration, how to administer (if a skill is needed), and how to handle missed doses.
- ✓ Counsel about non-pharmacological treatment approaches and lifestyle modifications.
- ✓ Advice about the benefit and outcome of each drug therapy, expected major side effects from and what to do in their occurrence, pertinent drug-interactions, any warnings, and recommended storage conditions.
- ✓ Provide pertinent printed patient education materials (patient medication information form) as required, to make the patient better understand the use of the medications.
- ✓ Record and document the discharge medications and counseling given on the *discharge medications and counseling section* of the inpatient medication profile form (Annex 3.1).

3.3.2. Outpatient Clinical Pharmacy Service

CPS can be provided in OPD pharmacy as prescription evaluation and counseling (Annex 3. 5). In addition, the services can be provided in chronic care pharmacy(s) and outpatient clinics in the form of medication therapy management (MTM) services. The core process during MTM service includes, collecting patient information like demographic, clinical information (Past medication history, current medications, pertinent laboratory results type of chronic disease etc.), assessing, developing goals and care plans and implementing the care plan in order to achieve the goals. Outpatient clinical pharmacy activities include:

- ✓ Evaluate prescriptions
- ✓ Complete patient medication profile and revise on each encounter
- ✓ Reconcile medication for chronic patients
- ✓ Adjust medication doses as necessary in coordination with the physician
- ✓ Monitor patients according to monitoring parameter
- ✓ Assess, support and ensure patient adherence
- ✓ Double check the prescription and the product before dispensing
- ✓ Educate and counsel patients/ care giver about the medication therapy
- ✓ Document outpatient CP services on the chronic care pharmacy services documentation form (Annex 3.6).
- ✓ Report outpatient clinical pharmacy activities using chronic care pharmacy services reporting form (Annex 3.7).
- ✓ Report adverse drug events

3.3.3. Emergency CPS Activities

In the emergency setting, there is intense pressure, and fast-paced activities, which can lead to medication errors and subsequent adverse drug event. The presence of clinical pharmacist enhances workflow, patient safety and decrease cost of care. In collaboration with emergency physicians and nurses, CPS providers should work to develop and monitor systems that promote safe and effective medication use especially for high-risk patients and procedures. Like inpatient CPS, emergency CPS could be implemented by pharmaceutical care models through timely processes of assessment, care plan and follow up evaluations.

Peculiar clinical pharmacy services in the emergency setting include:

- ✓ Participating in resuscitation activities

- ✓ Preparation of drug lists and formulary for the Emergency
- ✓ Refilling medications using Crash Cart
- ✓ Providing consultation on patient-specific drug selection, dosage & dose adjustment
- ✓ Participating in emergency-preparedness efforts and quality-improvement initiatives
- ✓ Assessment of medication allergy and medication-interaction
- ✓ Timely provision of poison information for patients/care givers and healthcare providers
- ✓ Conducting or participating in emergency service related research

3.3.4. Critical care CPS Activities

In the intensive care unit (ICU), critically ill patients are at the extremes of human physiology and receive multiple medication therapies requiring a high degree of monitoring, follow-up, and careful management. The presence of clinical pharmacy service increases patient safety through minimizing drug related problems, reduces unnecessary costs and improves treatment outcomes. Like inpatient CPS, critical care CPS could be implemented by pharmaceutical care models through the processes of assessment, care plan and follow up evaluations.

Peculiar critical care clinical pharmacy activities include:

- Evaluates all drug therapy for appropriate indications, dosage, drug interactions, and drug allergies; monitors drug therapy for effectiveness and ADEs
- Provide pharmacokinetic monitoring when a targeted drug is prescribed.
- Provide drug information, intravenous compatibility and poison information to ICU team
- Actively involved in critical care pharmacotherapy research
- Consult on the administration of drugs through nasogastric (NG) tube

3.3.5. Oncology CPS Activities

- **Provide and distribute Chemotherapeutic Preparation**
  - o Avail all fluid, chemotherapeutic drugs & medical supplies.
  - o Perform checking of every dose of prepared chemotherapy.
  - o During preparation of chemotherapy, receive request from wards and outpatients, verify diluents type and amount, prepare chemotherapy using aseptic technique and performing proper labeling after completing preparation.
  - o Inspects all completed chemotherapy admixtures for particulate matter, signs of incompatibility, degradation or contamination, and proper sealing before dispensing.
  - o Checks the label against the original order for accuracy and completeness.

- o Perform distribution to the respective unit.
- o Provide hands on training for attached pharmacy students in chemotherapy admixture, safe handling and waste disposal.

- **Provide pharmaceutical care for oncology patients**
  - o Ensure that patients receive chemotherapeutic regimen according to protocol
  - o Calculate dose of chemotherapeutic agents based on body surface area
  - o Provide information on safe administration of vesicant and irritant chemotherapeutic agents
  - o Ensure the proper use of antimicrobial agents in the management of infection in oncology patients.
  - o Prevent, identify and monitor the adverse effects of chemotherapeutic agents
  - o Participate in oncology/hematology research activities
  - o Provide counseling on adverse effect of chemotherapeutic agents and its management for patients
  - o Participate in the provision of palliative care mainly on pain management
  - o Document and report the CPS provided

3.3.6 Drug Information Service

Drug information service (DIS) is the process of providing information on the safe and effective use of pharmaceuticals to meet the requirements of health care providers and clients. Nowadays, access to updated, unbiased and well-referenced drug information is fundamental to the rational and effective use of drugs. Since DIS was originated along with the clinical pharmacy concept, it should be considered as one component of the clinical pharmacy service. Therefore, all hospitals should establish their own drug information center (DIC) to provide DIS.

The service generally responds to drug information queries. It also provides education and training to healthcare professionals and/or the public regarding appropriate use of medications. Regular drug information publications such as drug alerts, newsletters, monographs, poison management protocols/algorithm and therapy updates should be prepared and distributed to keep the health care team up-to-date. The DIS notifies the availability of pharmaceuticals to the hospital staff. Moreover, the information that can be provided at clinical wards, ambulatory clinics and in dispensaries can be considered as components of the DIS.

For an effective DIS operation, the DIC should be staffed by appropriately skilled pharmacists who are trained in the provision of drug information, a dedicated room that has sufficient space and equipped with necessary resources.

The pharmacy professional trained to provide DIS should minimally accomplish the following:

- Answering to queries on all aspects of the therapeutic use of drugs
- Documenting the queries asked and the answers provided.
- Provision of proactive information through timely publication of bulletins/newsletters.
- Supporting Drug and Therapeutics Committee (DTC) activities
- Providing/supporting/facilitating patient education on rational medicine use.
- Preceptor ship and educating pharmacy students when applicable.
- Conduct/participate in health service quality improvement and medication use research activities.
- Distribute list of available medication for staff member (provide stock status update)
- Prepare seminars and journal club presentations
- Provide information in the management of poisoning, drug overdose and envenomation.
- Conduct monitoring and evaluation of DIS activities.

3.3.7 Monitoring and Ensuring Medication Safety

3.3.7.1 Monitoring medication safety

There are inherent risks associated with the use of medications. Medication misadventure may be related to professional practice, products, procedures, and systems, including prescribing, transcribing, compounding, packaging, labeling, dispensing, administration, monitoring, and use. The pharmacist has a key role in minimizing medication related adverse effects. They participate in all stages of the medication use process. Every hospital should have a comprehensive program that includes medication safety leader and structure for effective and safe use of medications. This practice shall be implemented in the following medicine management procedures.

A. Drug selection in formulary management

The clinical pharmacist should consider whether the medication being reviewed for deletion or addition to the formulary has potential safety issues, such as similarity in sound or appearance to another medication, admixture or administration handling precautions, specific requirements on

storage or waste, extravasations management, and significant adverse effects that should be monitored. The pharmacist should continue to monitor the literature for new medication safety warnings, in addition to the review and analysis of the institution's medication error data.

B. Patient Admission

Prescribing errors commonly occur during hospital admission as patients take multiple medications which could result a higher risk for ADEs. Therefore, obtaining a medication history and performing reconciliation on admission is crucial. CPS providers should offer continuity of care by transferring patient medicines information as patients move between units of care.

C. Medication Prescribing

Ordering errors include omission, incomplete and unclear orders, wrong drug, wrong time, wrong dose, wrong dosage form, patient allergy and wrong patient. Therefore, the CPS provider should make sure that ordering is made according to the existing recommendation and guidelines of the institution and promote good prescribing practice.

D. Medication Preparation

Common preparation errors include wrong concentration, wrong drug, wrong dose, wrong diluents, wrong volume, wrong patient, or prepared for administration by the wrong route. The CPS provider should ensure that medication preparation is performed under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital.

E. Medication Transcribing, Reviewing and Dispensing

Transcribing errors are defined as any deviation during the transfer of information from an order sheet to documentation forms or medication administration records; and the CPS provider should actively involve through

- Clarifying the order before transcribing with communication to prescriber if necessary
- By not processing incomplete orders (orders must contain the information required in the hospital's medication order policy).
- Completing the transcription process in a quiet, well-lit area, away from distractions.

The following activities should be performed by a pharmacist while reviewing medication order

- All medication orders should be reviewed, interpreted, and validated by a pharmacist prior to dispensing and administration of medication.
- Medications should be available for inpatient use in unit dose.

- Before dispensing pharmacists must make certain that the following are accurate: drug, dose, frequency, quantity, duration, labeling, packaging, and instructions.

F. Medication Administration

The "6 Rights of Medication Administration" -- the right patient, the right drug, the right dose, the right route, the right time, and the right documentation are often discussed in relation to administration errors.

- Pharmacists should ensure that the information resources needed for safe medicines preparation and administration are accessible at the point of care
- Pharmacist should promote safe medication administration through availing information
- Pharmacist should prepare and disseminate a chart for incompatible drugs.

3.3.7.2 Strategies to ensure medication safety

The health institution should prospectively design and implement strategies to reduce certain types of errors to prevent patient harm. Areas which must be addressed are high risk populations (pediatrics, elderly and pregnant), high risk processes, high-alert medications and easily confused drug names, also known as "look-alike/sound-alike" medications.

A. Strategies for handling look-alike/sound-alike medications

Many measurements could be used to avoid errors associated with look-alike and sound-alike medicines such as:

- Develop a list of look-alike and sound-alike medicines in the hospital.
- Place eye-catching labels and warning stickers on storage bins.
- Store medications in nonadjacent areas.
- Using both generic and brand names when appropriate
- Including the indication for use on orders
- Limiting the use of verbal orders
- Avoid abbreviation in drug names

B. Strategies for managing high alert medications

High-alert 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. The following general principles can be used for reducing harm from high-alert medications:

- Preparing list of high-risk medications and availing to all health care providers.

- Develop preprinted order forms and protocols to reflect a standardized approach
- 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 and take action.
- Implement independent double-checks where appropriate.
- Instruct patients on symptoms to monitor and when to contact a health care provider.
- Review and update protocols for proper administration.
- Ensure that antidotes and reversal agents are readily available and have rescue protocols.
- Minimize variability by standardizing strengths

C. Practitioner education

The institution must establish safe medication practice education programs for practitioners. These programs must include proper patient identification, familiarization within the medication ordering, reviewing, preparing, dispensing and monitoring system.

- The pharmacists should serve as a resource regarding all aspects of medicines use and be accessible as a point of contact for health care providers.
- The pharmacists should provide orientation and education to nurses, physicians, and other hospital staff regarding best practices for medicines use.

D. Patient education

- The pharmacists should ensure that all patients are educated on the appropriate use of their medicines.
- The pharmacists should educate the patient on purpose of the prescribed medications, on safe administration, possible side effects, appropriate storage and action(s) to be taken if problems occur.

3.3.7.3 Monitoring and reporting adverse drug event

All suspected reactions to medications, unknown or unexpected reactions, serious adverse reactions, unexpected therapeutic effects, all suspected drug interactions, product quality problems, treatment failures and medication errors should be reported to the regulatory authority immediately. The pharmacy department shall coordinate, in cooperation with medical and nursing staff on ADE program which includes: prevention, identification and reporting of ADR, medication errors and product defects.

Individuals susceptible to an ADR include those:

- With multiple diseases and/or drug therapy

- Geriatric and pediatric patients

- Receiving medicines that are known to be associated with serious adverse effects

- Receiving drugs with a low therapeutic index or potential for multiple interactions

- With organ impairment that may alter drug pharmacokinetics, and

- With a previous ADR

The DTC should appoint an ADR focal person. He/she can 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 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 a drug causing the observed reaction. A literature review may be undertaken to assess the likelihood that a suspected ADR was caused by a drug and/or the advice of other health professionals may be sought. To assess the likelihood,

a standardized causality assessment algorism should be used such as the Naranjo causality assessment algorism (Annex 3.8) or WHO case causality assessment scale (Annex 3.9).

3. **Make recommendations on treatment options**; including possible alternative treatments taking into consideration:

- The likelihood of the suspected drug(s) causing the reaction
- The clinical significance of the reaction
- The status 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 ADR

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 through the national reporting mechanism;**

The Hospital Pharmacy department should avail reporting form, retain the necessary documentation. A standardized form should be used to record and report ADRs (Annex 3.10) or the online reporting mechanism can be used through their website (www.fmhaca.gov.et/#).

3.3.7.4 Monitoring and reporting allergic reactions

Drug allergies are a subset of adverse drug reactions that are usually mediated by the immune system. Allergic or hypersensitivity reactions account for about one-third of all adverse drug reactions. Care must be exercised in defining an allergic reaction. Even with such care, exact definition often remains difficult, because re-challenge with the suspected agent is usually unethical. Allergic reaction to drugs should be documented and kept with the patient chart for future references. Furthermore, the hospital should establish drug allergy reporting system which generates useful data on the safety and management of the allergic reaction. In addition, patient should be provided allergy card (Annex 3.11).

3.3.7.5 Monitoring drug interactions

Identification, resolution, and prevention of drug-interactions are important determinants for patient management. As a rule of thumb, the following activities should be used to monitor drug interactions:

- Document all drugs including POM, herbal preparations, OTC, recreational drug that the patient is taking.
- Understand the pharmacokinetics and pharmacodynamics of the drugs given, keeping in mind the important mechanisms of drug interaction.
- Minimize the number of drugs given to any patient and try to ensure that the benefits outweigh the risks for each.
- Be particularly vigilant with patients taking low therapeutic index drugs.
- Be cautious in high risk clinical settings.

3.3.8 Co-led and Participate in Antimicrobial Stewardship Programs

Antimicrobial stewardship program (ASP) involves the appropriate selection, dosing, route of administration, and duration of antimicrobial therapy. Use of ASP in combination with infection prevention and control efforts limits the emergence and transmission of antimicrobial-resistant pathogens.

The primary goal of ASP is to optimize clinical outcomes while minimizing the unintended consequences of antimicrobial use (e.g., toxicity, emergence of resistance). Reducing health care costs without adversely affecting the quality of care is a secondary goal of ASP. ASP should be led by infectious diseases (ID) experts and co-led by clinical pharmacists.

Two proactive core strategies form the foundation of an ASP with various supplemental elements depending on local practice patterns and resource availability.

- **Core Strategies**
  - ✓ Prospective audit with direct intervention and feedback
  - ✓ Formulary restriction and preauthorization requirements
- **Supplemental Elements**
  - ✓ Education and training
  - ✓ Facility specific evidence-based guidelines and clinical pathways
  - ✓ Antimicrobial cycling
  - ✓ Antimicrobial order forms

- ✓ Combination therapy
- ✓ Streamlining or de-escalation of therapy
- ✓ Dose optimization
- ✓ Parenteral-to-oral (IV to PO) conversion
- ✓ Communication

CPS provider activities include:

- Provides direct pharmaceutical care services by promoting the safe and effective use of antimicrobials.
- Coordinates and maintains the ASP.
- Conduct daily ASP activities including prospective patient review and feedback
- Generate and analyze process, and measures for ASP related patient outcomes
- Report on applicable ASP metrics, including antimicrobial utilization and identify opportunities to optimize antimicrobial use and patient care
- Participate in ASP quality improvement projects in collaboration with pharmacy, infectious diseases, clinical microbiology, and infection prevention.
- Participate in developing and maintaining the anti-infective formulary, guidelines, clinical pathways, and order sets.
- Serves as a secretary of the ASP and active member of infection prevention committee.
- Serves as a liaison between the department of Pharmacy and Infectious Diseases unit.
- Evaluate trends in antimicrobial resistance patterns, advice prescribers if microbial resistance is suspected

(For further details, see the national guideline on antimicrobial stewardship program in hospitals in Ethiopia)

3.3.9 Committee related activities

All committees that make decisions concerning medication management and use shall have at least one pharmacist as a member. This includes the drug and therapeutics, infection-control, medication-use evaluation, medication safety, the institutional review board, etc. Pharmacists shall be involved in the development, implementation and assessment of care plans, protocols, guidelines, formularies, etc.

3.3.10 Research and quality improvement activities

In collaboration with the DTC the CPS providers should undertake the following rational drug uses studies and quality improvement activities:

- Prescription monitoring
- Indicator studies
- Drug use evaluation

(*for the detail, see FMOH EHSTG 2017*)

3.3.11 Other clinical pharmacy services

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

4. Requirements for Implementation of Clinical Pharmacy Services

Availability of resources (e.g. personnel, space, materials) and support (e.g. organization, administration) can influence the scope, type, quality and continuity of CPS offered. Hospital administrators and pharmacy managers must address several resource related issues to fully implement CPS. The requirements for provision of CPS should address the 4Ps i.e. Professional, Practice, Product and Premises.

4.1 Professional

The provision of CPS requires adequate number of competent service providers with required skill, knowledge and attitude.

4.1.1 Required knowledge, skill and attitude

CPS providers are required to have the following knowledge: pharmacology, pharmacotherapy and pharmaceutical care practice. The pharmaceutical care providers includes knowledge about:

- Patient: personal, social and physiological information.
- Disease: characteristics of the disease, intent of treatment and goal of therapy.
- Drug therapy: characteristics of the drug, its actions and outcome of therapy.
- Knowledge and skill on laboratory result and procedures interpretations.
- Drug information resources

CPS providers are also required to have the following skills:
- Obtaining clinical information from the patient: observation, interview, and physical assessment skill
- Communication skill
  - o The ability to communicate clearly and effectively with patients, family members, physicians, nurses, pharmacists, and other health care professionals is an important skill.
- Documentation skill, and
- Self-improvement skill
- Medical literature retrieval, evaluation, problem-solving skills, expertise in information technology, verbal and written drug information communication.

CPS providers should the following attitudes: maintain confidentiality of patient and/or site-specific information, demonstrates respect for patients, colleagues, and other personnel at the site, and accepts responsibility and accountability for his/her work and actions.

4.1.2 Staffing and competency

Plan for professional staffing should consider the scope and type of services, scope of professional practice (e.g. B.Pharm, MSc/M.Pharm, PharmD, PhD) and service operation hours. The service requires a pharmacist who completed at least the patient oriented Bachelor of Pharmacy degree and/or had a one month in-service training on clinical pharmacy. The pharmacist should also be registered by the appropriate body before he/she assigned to practice.

Staffing structure and level/ratios required to deliver clinical pharmacy services should be determined by the level and type of facility, patient case mix, and range of services. As described in EHSTG, the number of CPS providers for ward-based practice is based on the number of beds. However, variations may exist at the facility level and are subject to change based on discussions with the facility management and director/head of pharmacy services. In general, staffing must be sufficient to ensure that all patients receive appropriate and desired pharmaceutical care for 24 hours service.

The current recommended staffing level for inpatient clinical pharmacy service is:

a) For non-acute general wards (e.g. internal medicine, pediatrics, surgery, gyne-obs, etc)
   • One (1) CPS provider per 35 beds for primary hospitals and health centers. This means to provide 24/7 service 3 CPS providers are needed per 35 beds in primary hospitals and health centers.
   • One (1) CPS provider per 30 beds for general hospitals. This means to provide 24/7 service 3 CPS providers are needed per 30 beds in general hospitals.
   • One (1) CPS provider per 25 beds for tertiary- teaching/referral hospitals. This means to provide 24/7 service 3 CPS providers are needed per 25 beds in tertiary-teaching/referral hospitals.

b) For Emergency and critical care units
   • One (1) CPS provider per 5 beds for ICU, PICU & NICU units
   • One (1) CPS provider per 10 beds for emergency clinic, dialysis center, transplants center, oncology and hematology units.

In ambulatory care clinic and chronic care pharmacy, the number of CPS provider required may vary based on the level of the hospital (primary, secondary, tertiary) and number of patients served on daily basis. The recommended number of practitioners will be one (1) CPS provider per 30 prescriptions per day.

4.2 Practice

The CPS provider should start providing the services as soon as the patient is arrived /admitted, so that he/she can support the prescriber in the selection of medicines for individual patients. Always in practice there should be a consideration of therapy individualization. Some of the activities in CPS provision include;

- Admission medication history taking
- Providing medication reconciliation services
- Participating in ward round and morning sessions (MDT & Pharmacy only)
- Monitoring patient outcomes
- Drug information provision
- Medication Therapy Management Services (MTMS)
- Implementing unit dose dispensing system in the inpatient pharmacy
- Prescription evaluation and interpretation at pharmacy
- Patient counseling and education
- Providing discharge medication counseling
- Conducting research
- Participation and contributing in hospital committees (ASP, DTC, IPC, etc)
- ADE monitoring and reporting
- Documentation and reporting

NB: In all clinical pharmacy activities, CPS standard operating procedures should be followed.

4.3 Product (equipment and facility)

For the provision of clinical pharmacy service, there shall be adequate space, equipment, and supplies that facilitate service provision.

- There're should be adequate space, equipment and furniture [desks, chairs, telephone, computer with internet access and printer], in an amount and type sufficient for clinical pharmacy activities.

- Updated medication information resources must be available. These should include appropriate pharmacy and medical journals, text books, data bases, and hospital specific resources (medication list, formularies, guideline, and protocol).

- clinical pharmacy working, and documenting forms should be duplicated and continuously available (e.g. inpatient medication profile form, pharmaceutical care progress note recording sheet, medication reconciliation form, medication information record (annex 4.1), clinical pharmacy interventions daily summary and monthly summary and reporting form.). These documents should be incorporated with the patient medical card. *These clinical pharmacy working documents shall be duplicated by/at hospital/facility level.*

- As per the regulatory standard there shall be adequate, suitable dispensing equipment in the dispensary. Each item must be clean, in good repair and of suitable material. Equipment shall be specific for each service which may be provided in the pharmacy.

4.4 Premises

Selecting the space required to provide clinical pharmacy services need due consideration for patient privacy, confidentiality and convenience. Provision of clinical pharmacy service should be uninterrupted 24/7. Therefore, there should be dedicated duty room(s) around/closer to each service area. Working stations should be assigned for clinical pharmacists in each ward which have up-to-date drug information sources and internet access. The clinical pharmacy coordinator should have an office with supplies.

At OPD pharmacy level, there should be a private area for pharmacist-patient consultations in dispensing units. There should be a dedicated room (separate or with physician) for clinical pharmacist/service provider for full time clinical pharmacy service provision at ambulatory care clinics.

Emergency clinical pharmacy service shall be provided for 24/7. Therefore, there should be dedicated duty room(s) and office(s) for uninterrupted services.

To ensure optimal operational performance and quality provision of DIS, dedicated room with adequate space shall be allocated. These resources must be located in areas that facilitate the provision of services to other healthcare providers and patients.

5. Ethical and Legal Aspects of Clinical Pharmacy Services

Clinical pharmacy service providers during their patient focused practice have a covenantal relationship with their patients. This relationship relies on the trust placed in the clinical pharmacist/CPS provider by the patient and the commitment to act in the best interest of individual patient, patient population and public, in the context of legal and ethical parameters.

Clinical pharmacy service providers exhibit the traits of professionalism; responsibility and commitment to excellence, respect for others, honesty and integrity, duty of care, and compassion. They subscribe to the pharmacy professional's code of ethics and adhere to all pharmacist-related legal and ethical standards.

Ethical Considerations in Pharmaceutical Care Practice

1. Pharmaceutical care involves applied ethics in that it consists of the practical application of moral standards to specific ends.

2. Pharmaceutical care practitioners should not only be clinically competent, but must also adhere to the law, professional codes of conduct, and ethical standards.

3. Pharmaceutical care practitioner should have professional behaviors: Do the very best you can for every patient. In all cases, do no harm. Tell the patient the truth. Be fair. Be loyal. Recognize that the patient is the ultimate decision maker. Always protect your patient's privacy.

4. Pharmaceutical care practitioner should have the following respective ethical principles: Beneficence, non-malfeasance, veracity, justice, fidelity, autonomy/paternalism and confidentiality.

5. The pharmaceutical care practitioner must learn to recognize when his/her personal values (political views, religious beliefs, or social expectations) interfere with professional responsibilities and mandated behaviors.

6. The pharmaceutical care practitioner should know actual ethical problems that are routinely experienced in the practice. The most common situations that involved ethical issues could be grouped into two different types:

   (1) Those which consist of privacy and confidentiality, conflict of interest, respect for patient autonomy, duty to warn, and value conflicts and which occur daily during the patient/practitioner interaction and

   (2) Those which involve the allocation of resources, rationing, justice, and competency, are more episodic and patient-specific, and occur in the institutional context.

7. As a rule, clinical problems should be identified and resolved first, followed by legal issues, and if an ethical dilemma remains it can then be resolved systematically and comprehensively.

8. The process for resolving ethical issues in practice is to:

(a) Recognize when a patient encounter raises an important ethical problem, and gather the relevant facts involved;

(b) Work with the patient to describe the problem that has to be resolved;

(c) Determine what each of you considers to be an acceptable resolution to the case;

(d) Generate reasonable alternatives to resolve the ethical dilemma, and consider each option in relation to the fundamental ethical principles and the patient's position;

(e) Select the resolution that you and the patient will implement;

(f) Critically examine the decision that has been made, and justify it;

(g) Do the right thing—implement it.

9. Pharmaceutical care providers are accountable for what they do during service provision. As a result, any negligence and malpractice of CPS will make accountable by medico legal aspects within institutional rules and regulations, professional code of ethics and/or national health professional's proclamation, as appropriate.

Clinical pharmacists/clinical pharmacy service providers:

- Have the obligations to act in the best interest of the individual patient.
- Have the responsibilities to provide professional care to patients in attaining optimal therapeutic/health outcomes.
- Shall promote the safe, and appropriate use of medicines and ensure timely access to medicines for the patients.
- Should always strive to provide information to patients and the public regarding professional services truthfully, accurately, and clearly.
- Shall treat patients without prejudice of age, gender, sexual orientation, ethnicity, religion, disability or socio-economic status; and not allow personal beliefs to influence the practice.
- Shall hold the details of patient information confidential by taking all reasonable steps to prevent accidental disclosure or unauthorized access to confidential information and should not disclose such information to anyone without proper patient authorization/consent except where the best interest of the patient requires or required by law.
- Shall ensure and adhere CPS standard operating procedures are adhered for the care and safety of the patient.

- Shall refrain from misleading the public by promoting or criticizing any health product or services, through advertisements or other endorsements.
- Shall make sure that their professional judgment is not impaired by personal or commercial interests, incentives, targets or similar measures.
- Shall seek to maintain professional boundaries in the relationships with colleagues, other members of the health care team and stakeholders to achieve the highest standard of care for the best interest of the patient.
- Should behave in a way that justifies trust and maintains the reputation of profession, including acting in accordance to the policies and regulations of workplace.
- Should always strive to develop and increase professional knowledge and competency.
- Shall be receptive; respond promptly and politely to shortcomings, complaints and criticism pertaining to practices.
- Shall honor commitments, agreements and arrangements for the provision of pharmaceutical care.
- Shall be liable to provide accurate information that do not mislead others or make claims that cannot be justified.
- Shall keep abreast with the most current professional knowledge and skills up-to-date to maintain a high standard of competency in clinical pharmacy services.
- Shall refrain from publicly criticizing their colleagues and other healthcare professionals.
- Shall always contribute to the best of their abilities for the betterment of the profession of clinical pharmacy and uphold their profession in a positive manner.
- Should participate, support, and promote health services research involving CPS.
- Should work with their local facilities to develop research and quality improvement projects that accurately reflect the importance of CPS and role of providers in the health care.
- Shall contribute to the development, education and training of colleagues and students, sharing relevant knowledge, skills and expertise to meet competency standards.

(For the detail of code of ethics of pharmacist in Ethiopia, see annex 5.1).

6. Model Clinical Pharmacy Service Site Creation and Scale up

6.1 The concept of model CPS sites

Model CPS sites are those sites that can serve as a show case in providing quality pharmaceutical care and share best experiences to other facilities. The concept of creating model CPS site is establishing a CPS that can serve as center of excellence in terms of service quality, coverage, client satisfaction and continuity. Model CPS sites improve quality of care, advance CP practice, and elevate professional accountability and transparency. It can also be used as a reference site for those designing and assessing CP training programs, pre-service and in-service CPS training sites and evaluating service components by policy makers.

Model CPS sites can be established by selecting and upgrading some of the existing CPS sites. These candidates shall be selected using a baseline assessment tool. Then after, a continuous technical and material support shall be provided until they become model CPS sites. Using the lessons learnt and benchmarking best practices, the number of model CPS sites shall be expanded and scaled up every year through the same process.

6.2 Process towards creating model CPS sites

I. **Baseline Assessment:** Baseline assessment should be performed using a predefined checklist (annex 6.1) prior to selecting healthcare facilities as a candidate to model CPS site.

II. **Candidate model site selection:** Model site should be selected among facilities based on their initial CPS level, coverage (professional and CPS), continuity of service, and documentation. Geographic distribution and level of facilities shall be taken in to consideration.

III. **Provide continuous Support:** FMOH, RHB, hospital mangers and other stakeholders of CPS should provide continuous support through training, supportive supervision, advocacy and promotion, experience sharing, networking, partnership, review meetings and workshops. The support shall also include required materials for service expansion and initiation of new services.

IV. **Expansion of best practice:** Health facilities should share their experiences to other sites and develop more advanced CPS.

V. **Clustering model sites:** Model CPS sites will have clusters of health facilities in their proximity and they will provide the necessary technical support to enable others become model.

VI. **Monitoring and evaluation:** A continuous monitoring and periodic evaluation should be undertaken for the model or candidate sites to evaluate their performances and to ensure whether they are in track.

VII. **Recognition and award/graduation:** The FMOH should assess the clinical pharmacy sites every year. To be recognized as the 'Best Clinical Pharmacy Practice Model Site' within a specified year, the site should score the highest performance among the model sites. The best clinical pharmacy practitioner should be recognized in the annual professional conferences and review meetings. The best CPS practice should be scaled up to other practice sites within the country.
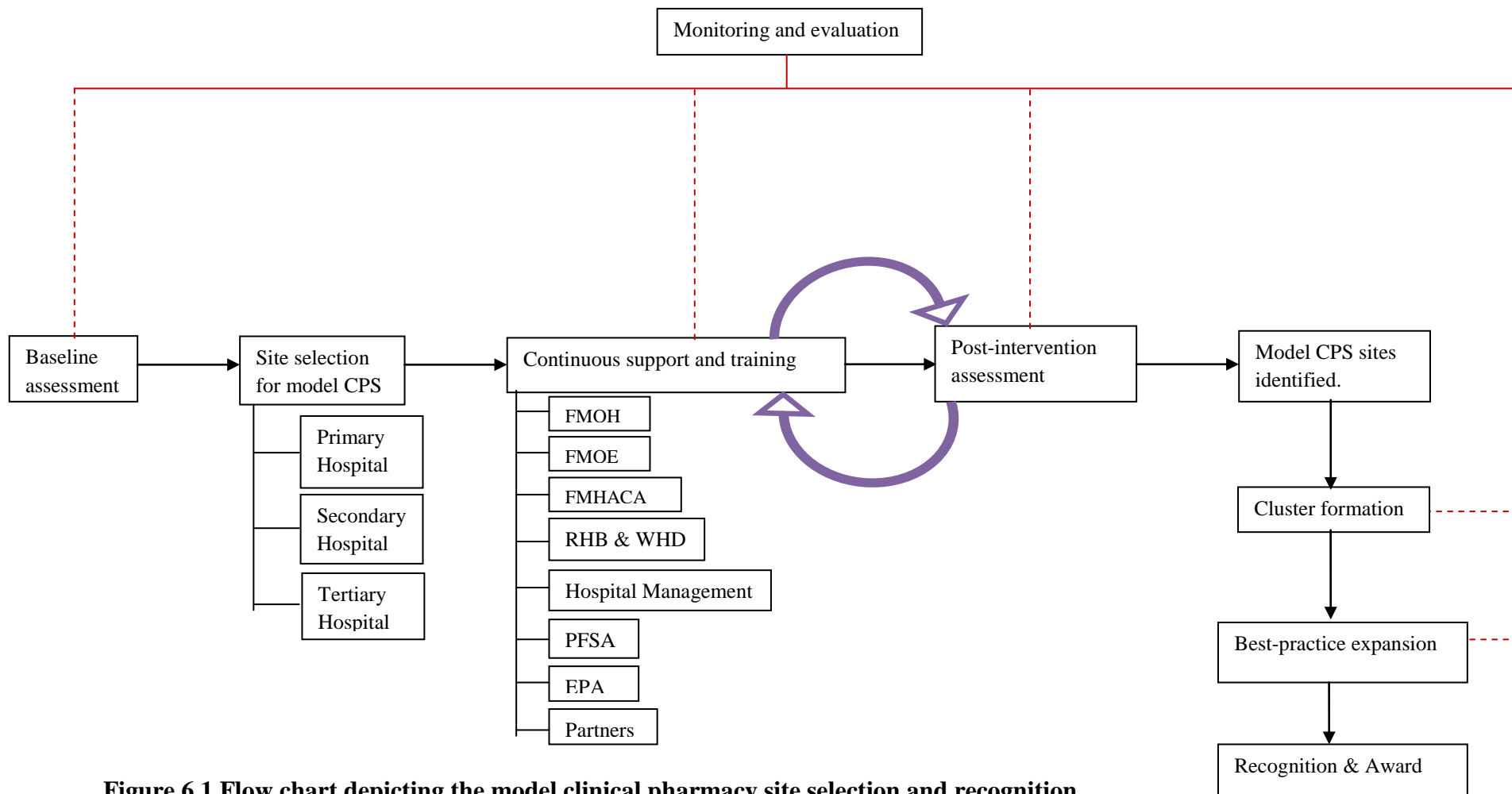
Figure 6.1 Flow chart depicting the model clinical pharmacy site selection and recognition

Abbreviations: CPS=Clinical Pharmacy Service; EPA=Ethiopian Pharmaceutical Association; FMHACA=Food, Medicine, and Healthcare Administration and Control Authority; FMOE=Federal Ministry of Education; FMOH=Federal Ministry of Health; PFSA=Pharmaceutical Fund and Supply Agency; RHB=Regional Health Bureau; WHD=Woreda Health Department

6.3 Standards for model clinical pharmacy service sites

The following standards should be considered for facilities to be a model CPS sites. For the detailed monitoring and evaluation of model CPS sites, see annex 6.2.

6.3.1 Professional qualifications and number

Clinical pharmacy practitioners should be competent and qualified graduates and be practitioners who provide comprehensive medication management and care for patients in all service units. The number of CPS providers in model sites should be adequate considering the level of hospital, service complexity, patient flow, bed number and coverage of service units.

6.3.2 Process of care (service availability and quality)

Clinical pharmacy practitioners should work at inpatient, outpatient, and emergency service units in collaboration with other providers to deliver comprehensive pharmaceutical care. The practitioner strives to ensure if the patient's drug related needs are met, medications are appropriately indicated, the most effective available, the safest possible medications are being used and the patient is able and willing to take the medication as intended. Generally, the clinical pharmacy process of care should comprise the following components:

- Assessment of the patient
- Evaluation of medication therapy
- Development and implementation of a care plan; and
- Follow-up evaluation and medication monitoring, and discharge counseling.

6.3.3 Documentation of CPS

Any activity undertaken by a Clinical pharmacy practitioner that affects patient care should be documented making a permanent record of the pharmacist's services, actions and recommendations. Documentation can be used to provide evidence of the effect of clinical pharmacy services on patient care. It can also be used to obtain adequate resources for continuity of service and research. Documentation should be conducted in a continuous, complete and accurate manner by ensuring patient confidentiality.

6.3.4 Collaborative and Team-Based Practice

Clinical pharmacy practitioners work with other health professionals as members of the healthcare team to provide high-quality, coordinated, patient-centered care. Good collaboration among health care providers will improve service delivery, reduce errors and is a two-way educational process. The components of collaborative and team-based practices are:

- Recognize the value and structure of the pharmacy and multi-disciplinary team
- Communicate in a professional and ethical manner
- Treat colleagues with respect
- Collaborate with other healthcare professionals to manage patient care
- Ensure effective handover between team members or to another healthcare professional to ensure continuity of patient care.
- Participates, collaborates, and advises on therapeutic decision-making and use appropriate referral in a multi-professional team.
- Participating in preparations, presentation, discussion of seminars and patient cases in pharmacy only rounds and morning sessions.
- Demonstrates a broad understanding of the services delivered by other healthcare professionals and disciplines.
- Understand and use medical terms and clinical knowledge
- Take a deep sense of responsibility with respect to medical care

6.3.5 Professional Development and Maintenance of Competence

Patient care provision requires knowledge, character and behavioral development. When individuals choose to become pharmaceutical care practitioner, he/she make a commitment to meet the patient's drug-related needs whenever and wherever they might arise. Clinical pharmacy practitioners maintain competence in clinical problem-solving, judgment, and decision-making; communication and education; medical information evaluation and management; management of patient populations; and a broad range of therapeutic knowledge.

- Understands and accepts the importance of life-long learning for pharmacists
- Consistent participation in continuing professional development (CPD) activities enhances direct patient care practice abilities

- Maintenance of active licensure, including required continuing pharmacy education activities.

- Professional and career development by participating in formal and informal activities that enhance practice, research, teaching, leadership, and/or management.

- Demonstrates the ability to critically reflect on their own practice and skills, to identify learning and development needs.

6.3. 6 Professionalism and Ethics

Pharmaceutical care practitioners should not only be clinically competent, but must also adhere to the law, professional codes of conduct, and ethical standards. The practitioner must learn to recognize when his/her personal values (political views, religious beliefs, or social expectations) interfere with professional responsibilities and mandated behaviors. Clinical pharmacy practitioners exhibit the traits of professionalism: responsibility, commitment to excellence, honesty, integrity and care, respect and compassion. They subscribe to the pharmacy professions code of ethics and adhere to all pharmacist-related legal and ethical standards.

- Uphold the highest standards of integrity and honesty

- Always working in patients' best interests

- Make fair allocation and use of resources

- Respect patient Autonomy

- Keep Patient Confidentiality and Privacy

- Serve as a credible role model/leader for students, trainees, and colleagues by exhibiting the values and behaviors of a professional

- Advance clinical pharmacy through professional stewardship, training of future clinical pharmacy practitioners, and active engagement in professional societies

- Accepts responsibility for his/her actions and decisions

- Recognizes their scope of practice and the extent of their current competency and expertise and works accordingly

- Recognizes ethical dilemmas in practice scenarios and reasons through dilemmas in a structured manner

- Understands and adheres to laws, regulations and policies set by regulatory bodies

6.3. 7 Research

Clinical pharmacy practitioners should conduct and participate in research activities to advance practice and healthcare outcome.

- The pharmacist should initiate, participate in, and support clinical and practice-related research including prescription review, drug use evaluation, indicator study methods etc.
- The pharmacist shall ensure that policies and procedures for the safe and proper use of medications are established and followed
- A pharmacist shall be a member of the hospital's research and evidence generation team.

7. Roles and responsibilities of key stakeholders for CPS provision

Stakeholders for clinical pharmacy service implementation are individuals or groups who have a pledge in supporting the implementation of clinical pharmacy services. In addition to this, it includes those who can affect, and are affected by the clinical pharmacy services. These includes; FMOH, FMOE, RHB, EPA, EFMHACA, board and hospital management, ZHD, partners, Woreda health office, PFSA, other health professionals, patients and academic institutions.

Stakeholders can greatly influence the intended outcome and success of clinical pharmacy service. Their involvement can take place during any stage of the implementation of clinical pharmacy services. Thus, performing a stakeholder analysis during the planning stage can greatly influence the development of an effective implementation strategy. Stakeholders can help to make a clinical pharmacy services implementation successful through:

- Providing valuable information regarding needs, resources, realistic objectives, and practical considerations
- Recognizing hidden items that might not be obvious in the planning stage
- Identifying points of opposition and prevent problems during implementation
- Encouraging a sense of ownership in the services
- Ensuring the proper functioning of the service.

A multi-track communications strategy that targets key stakeholders helps to attain objectives of the clinical pharmacy services through:

- Consensus building
- Participatory planning and management
- Evidence-based decision making
- Stakeholder/customer awareness and informed choice
- Experience sharing
- Advocacy and policy promotion

Table 7.1: Key stakeholders for implementation of clinical pharmacy services

Key stakeholders	Roles	Responsibilities
FMOH	Policy support, budget, staffing, incentive and recognition package, supervision	Decentralization, Auditing the services, supportive supervision, promote professional code of conduct, set clinical standards and guidelines, set qualification exam, recognition and awarding.
FMOE	Quality education, Curriculum revision, graduating required number of pharmacists.	Provide Exit and entrance exams for students, curriculum standardization and harmonization.
RHB	Resource allocation, professional and administrative roles, organize training, periodic monitoring and evaluation, and facilitate continuing professional development of clinical pharmacy service.	Promote professional code of conduct, close follow up of implementation, Supportive supervision and continuous follow-up, recognition and awarding.
EPA	Initiate and promote CPD, facilitating inter-professional collaboration, curriculum revision, to improve quality of services and education, promote professional ethics and professional rights, and provide in-service training.	Set professional direction, develop code of conduct and medico-legal related documents. Accreditation of CPD, develop guidelines, influence revising and harmonizing the pharmacy training curriculum, formulating health policy, develop code of ethics and advocate clinical pharmacy service.
EFMHACA	Determine scope of practice, Directive and guideline development, registration and licensing of clinical pharmacists, accredit CPD.	Ensuring quality of service, develop code of conduct and medico-legal related documents, setting policies, standards, directives and guidelines.
Board and hospital management	Set strategy and priorities, allocate resources, recruit and organize clinical pharmacy staffs, allocate incentives, provide on the job training, promote inter-professional experience sharing.	Monitors interventions, supervise disease management and risk management, continuous follow-up
Zonal health department	Resource allocation, professional and administrative roles, Organizing training, periodic monitoring and evaluation, CPD	Promote professional code of conduct, close follow up of implementation, supportive supervision and continuous follow-up
Woreda health office	Resource allocation, professional and administrative roles, facilitate	Promote professional code of conduct, follow up implementation, supportive supervision.

	training.	
PFSA	Availing medications, provide technical support	Ensure the availability of pharmaceuticals, provide continuous supply, improve access to pharmaceuticals
Partners	Harmonization & alignment, participation, provision of support, adopt reforms, involvement in planning, implementation & support M&E.	Transparency, advocacy, capacity building, provide technical and financial support, supportive supervision.
Other health professionals	Collaboration and engagement, ownership, participate in the establishment of goal of therapy, evaluation of patient outcome	Involvement in the implementation of pharmaceutical care, feedback on the clinical pharmacy service.
Patients	Involve in the ultimate decision of his/her health care, participate in the establishment of goal of therapy, Ask questions whenever they arise.	Provide accurate and complete information, contribute to the care plan as agreed upon (act on the education and instructions they received, collect important outcome parameters, keep appointments), Maintain a diary of medication use, signs, and symptoms, and test results if needed to evaluate effectiveness, safety, and compliance and notify any changes and/or problems with their drug therapy in order to act on them before the occurrence of harms.
Academic institutions	Providing quality education, organizing pre-service and in-service training, developing training modules, collaborating with hospital pharmacy staff, mentoring.	Curriculum revision based on the need of the country. Producing qualified, competent and ethically disciplined clinical pharmacist.

8. Quality Assurance of Clinical Pharmacy Services

Quality assurance (QA) is defined as "all activities that contribute to defining, designing, assessing, monitoring, and improving the quality of healthcare" (Quality Assurance Project, 1993). These activities can be performed as part of the accreditation of pharmacies, supervision of CPS provider, or other efforts to improve the performance and the quality of clinical pharmacy services particularly and healthcare at large. Therefore, the main goals of a quality management system for CPS are to:

- Ensure the provision of an appropriate clinical pharmacy services to patients
- Ensure patients' medicine expectations and needs are addressed
- Identify and minimize risks associated with clinical pharmacy service delivery
- Identify areas for quality improvement, including staff development programs
- Provide a mechanism in order to implement and sustain quality improvement.
- Ensure improvement of patients' treatment outcomes
- Help the clinical pharmacists prepare for the transition to value-based payment models
- Give opportunity for CPS provider to participate in the hospital quality improvement programs and reporting of pharmacy quality data
- Monitor and evaluate the CPS, including the standard of services provided

The QA approach to address the quality of clinical pharmacy services under three core quality assurance functions: defining quality, measuring quality, and improving quality. The QA triangle effectively illustrates the synergy between these three QA functions (Figure 8.1).
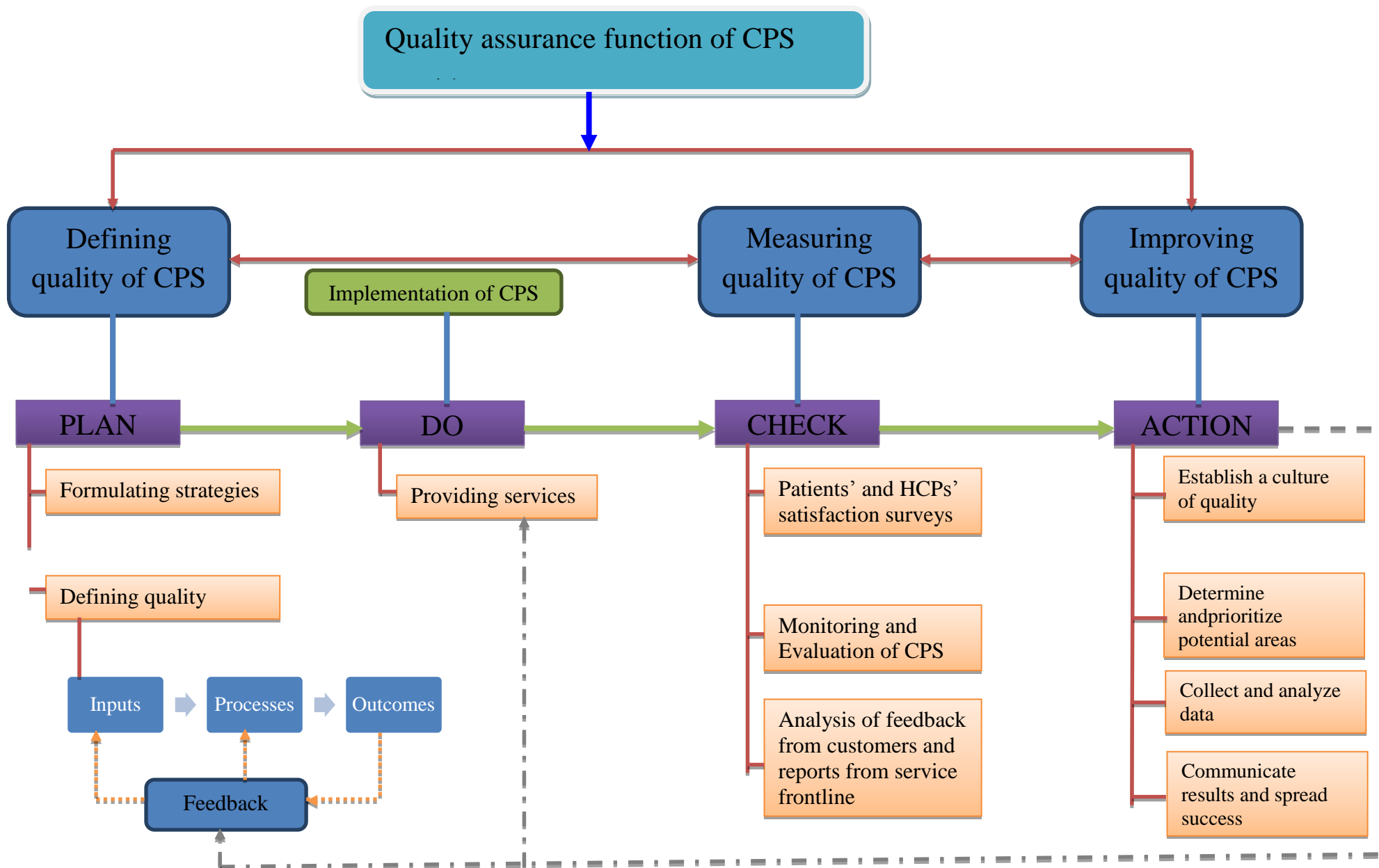
Figure 8.1: Quality assurance framework and service quality management in CPS

8.1 Defining Quality of Clinical Pharmacy Services

Quality of clinical pharmacy services can be divided into three major areas namely: inputs, processes and outcomes. Thus, quality improvement must address the inputs and activities carried out (processes) to ensure or improve the quality of pharmaceutical care (outcomes).

I. **Inputs***:* These are characteristics of CPS provider, the tools and resources, technology, rules and regulations, and the physical or organizational settings used for CPS provision.

II. **Process**: These are set of activities that occur between the patient, CPS provider and, other health care provider encompassing the services and products that are provided to patients and the manner in which the services are provided. These includes clinical pharmacy and patient interaction, inter-personal relationship, techniques and procedures, and total quality management. Process assessment reviews the activities involved in the delivery of clinical pharmacy service: Some of them includes:

   a) Multidisciplinary team & pharmacy only based activities (morning sessions, rounds, seminars, journal club, etc.).
   b) Provision of drug information for the patients, health care professionals, and the public at large based on the standards.
   c) Activities within provision of CPS, including advanced services for inpatient, outpatient, and emergency units.
   d) Documenting and reporting CPS data as per the recommended format, etc.

III. **Outcome:** These are changes in a patient's current and future health status that can be attributed to antecedent pharmaceutical care. Outcome assessment reviews the results of CPS provision and focuses on the economic, clinical, and humanistic consequences of pharmaceutical care processes.

   a. **Clinical impact**
      - **Quality of care:** prevention of infections, reduction in morbidity and mortality, containment of antimicrobial resistance, improvement of patient care and overall healthcare system, avoidance of healthcare associated errors
      - **Quantity of care:** Clinical endpoints improved from the services [e.g. Controlled blood pressure, controlled blood sugar (glycated haemoglobin A1C ((HbA1C)),

etc.]; drug therapy problem identified, prevented, and resolved; health-related quality of life improved by clinical pharmacy services.

b. **Economic impact:** Costs of care (direct & indirect) reduced due to clinical pharmacy services provision and improved use of recourses.

c. **Humanistic impact**: Satisfaction of patients, health care professionals, hospital managers, healthcare system and community with clinical pharmacy services.

8.2 Measuring Quality of Clinical Pharmacy Services

Measuring quality of CPS includes development, implementation and monitoring of standards and guidance. Clinical pharmacists perform clinical interventions or provide CPS that involves pharmaceutical assessment, development of pharmaceutical care plan and follow-up including the identification of actual or potential drug-related problems, the provision of recommendations to resolve or prevent them, and subsequently document the clinical intervention, to improve health outcomes for consumers. CPS providers should follow sated professional practice, competency standards and guidance.

Measuring quality of CPS consists of quantifying the current level of performance or compliance with expected standards. This process requires identifying indicators of performance, collecting data, and analyzing information. Measuring quality is inextricably linked with defining quality of CPS, because the indicators for measuring quality are related to the specific definition or standard of quality CPS. When standards define quality, measuring quality of clinical pharmacy services requires assessing the level of compliance with standards, helps to identify areas for improvement or enhancement.

The following are dimensions of quality of CPS that need to be continually measured.

1. Time and timelines: How long must a patient waits for getting CPS and completed on time?
2. Completeness: Is everything the patient needed and expected for clinical pharmacy services provided? Are the pharmaceutical assessments, care-plans, and follow-ups complete, accurate and of quality?
3. Courtesy: How are the patients treated by the clinical pharmacist?
4. Consistency: Is same level of clinical pharmacy services provided to each patient each time across space?
5. Accessibility and convenience: How easy and quick is it to obtain clinical pharmacy services?
6. Accuracy: Are clinical pharmacy services performed right and correct every time?
7. Responsiveness: How well does the hospital and clinical pharmacists react to unusual situations of clinical pharmacy services? How willing are the clinical pharmacists are to offer a speedy service?
8. Assurance: How the knowledge and skill level and politeness of the clinical pharmacists and to what extent they create trust and confidence?

For more detailed measurement of quality of CPS, see model clinical pharmacy site and monitoring and evaluation (annex 8.1).

8.3 Improving Quality of Clinical Pharmacy Services

Quality improvement (QI) is a systematic, formal approach to the analysis of practice performance and efforts to improve performance. Understanding and properly implementing QI is essential to a well-functioning clinical pharmacy practice and is necessary for clinical pharmacy providers in improving efficiency, patient safety, or clinical outcomes. The QI program provides a formal process to objectively and systematically monitor and evaluate the quality, appropriateness, efficiency, safety, and effectiveness of care and service utilizing a multidimensional approach.

Besides maintaining sated standards, QA activities should also focus on improving the current standards set for provision of clinical pharmacy services. It should always start from identifying the problem and their root cause. The identified problems should be documented and reported. Routine quality activities may highlight areas of concern that require further investigation. A QI

program should be implemented by all centres to ensure that practice standards are met and regularly evaluated.

The following are some of QI packages, which will be expected to improve CPS.

1. **Trainings:** Trainings and staff development programs (pre-service and in service) should be established to support the development of clinical pharmacists' knowledge, skills and attitude to increase the performance of clinical pharmacy services, and the subsequent documentation of drug-related problems and clinical interventions.

2. **Continuous professional development:** Clinical pharmacists need to take a continual professional development as per the standards set in the country.

3. **Clinical pharmacy services audit and feedback:** Hospital managers, pharmacy heads and clinical pharmacists should regularly review and make internal and external audit for the types and numbers of services provided and interventions performed for quality assurance purposes. Common issues involved in clinical pharmacy services and interventions could be identified, and measures could be taken to help prevent those from recurring.

4. **Research:** Outcome researches (focusing on clinical, economic and humanistic areas), Pharmacoeconomics, drug utilization reviews/evaluation, health system researches and other relevant problem-identifying and problem-solving studies have a direct benefit by showcasing the relevance of clinical pharmacy services. Therefore, hospitals and/or stakeholders should support related research, which will enhance continuity of pharmaceutical services.

5. **Management/leadership support:** In general, health facilities, RHB, FMOH in collaboration with stakeholders, should focus on the QI program elements of quality assurance (i.e. inputs, processes and outcomes) for the pharmaceutical care and should provide a continual effort for improving the quality of clinical pharmacy services.

9. Monitoring and Evaluation of Clinical Pharmacy Services

9.1 Introduction

Good quality data delivered on time to users (as information) is an important aspect of healthcare planning, management and decision making. Data must be collected, processed and used to ensure quality health service provision in general and CPS in particular. Routine monitoring and evaluation of CPS using quality data enables to measure and improve performance and to make decisions in a timely manner. Therefore, recording and documentation of CPS is critical accountability of pharmacists providing pharmaceutical care. The CPS providers are responsible to record and document their services using the inpatient medication profile form, pharmaceutical care progress sheet and medication reconciliation form.

These forms should be an integral part of the patient medical chart by placing just after the nursing care plan sheet. CPS delivered by the clinical pharmacist should be recorded, documented and reported according to the *'SOP manual for the provision of CPS in Ethiopia'* to ensure data quality. Reports will be collected from health facilities by the respective Regional Health Bureaus (RHB)/Zonal Health Department (ZHD)/Woreda Health Office (WoHO) on a monthly basis. RHB/ZHD will aggregate the monthly reports and send the compiled report to FMOH as per national reporting period. FMOH will aggregate the reports of all regions and university hospitals regularly for decision making.

9.2 Clinical Pharmacy Services Supportive Supervision

Supportive supervision is a process that individuals or groups of people from relevant stakeholders' conduct site visit to specific facility to promotes quality at all levels of the health system by strengthening relationships within the system, focusing on the identification and resolution of problems and helping to optimize the allocation of resources, promotion of high standards, team work and facilitation of two-way communications.

Supportive supervision at all levels should be conducted based on a predefined checklist developed to assess the progress of key aspects of CPS implementation. FMOH/RHB including lower level health administration offices and health facility management, should have clearly defined objective and timeline to provide regular supportive supervision. The onsite supportive supervision for CPS can be carried out independently or jointly.

9.3 Clinical Pharmacy Services Review Meeting

CPS implementation status and performance of stakeholders can be reviewed at different level of the health sector as follows:

- At facility level as facility performance review meeting quarterly
- At regional level, as regional performance review meeting bi-annually
- At national level as national performance review meeting annually

Table 9.1: Summary table for organizing CPS review meetings at different levels

9.4 Clinical Pharmacy Services Audit

Meeting name/tool	Facility review meeting	Regional review meeting	National program evaluation meeting
Frequency of meeting	Quarterly	Biannually	Annually
Length of meeting	Half day	1-2 days	2 days
Participant of meeting	Hospital CEO, medical director, pharmacy head, nursing head, CPS coordinator, CPS providers, ward case team coordinators, HR and finance officer	Hospital CEO, Hospital Pharmacy head, CPS coordinator, Regional Curative unit, Regional pharmacy unit, partners and PMED staff if necessary	Regional Curative unit, RHB core process owner, Pharmacy service/CPS officer, PMED, MSD and partners
Venue for the meeting	At facility	Town selected by the host RHB	Town selected by FMOH
Who chairs the meeting	Pharmacy head/CPS coordinator	RHB pharmacy core process owner	PMED

CPS audit aims to improve patient outcomes by examining how current clinical practice compares to agreed standards of care, implementing any changes necessary and then re-examining practice to ensure that real improvements have been made. CPS providers can be involved in many different types of audit. These may range from topics including audit of clinical services themselves (for example, clinical pharmacy interventions) or may examine which and how treatments are used within the framework of drug use evaluations.

9.5 Clinical Pharmacy Service Indicators

S. No	Indicators
1.	Proportion of patients whose admission medication history is taken within 24 hours
2.	Proportion of charts with completed inpatient medication profile forms
3.	Proportion of patients whose medications are reconciled up on admission
4.	Number of drug therapy problems identified
5.	Acceptance rate of DTPs identified
6.	Percentage of multidisciplinary team (MDT) ward rounds conducted by CPS provider
7.	Proportion of patients whose medications are reconciled during discharge
8.	Proportion of patients who received discharge medication counseling
9.	Functional unit dose dispensing system in inpatient pharmacies
10.	Pharmaceutical care provided to chronic patients
11.	Proportion of facilities that send clinical pharmacy report monthly

Indicator 1: Proportion of patients whose admission medication history is taken within 24 hours						
Definition	It is the proportion of patients whose admission medication history is taken within 24 hours out of all admitted patients in a facility.					
Formula	$\dfrac{Number\,of\,patients\;whose\;admission\;medication\;history\;is\;taken\;\;by\;CPS\;provider}{Total\,number\,of\,admission\;during\;the\;review\;period}$					
Interpretation	This indicator measures proportion of patients whose medication history is taken within 24 hrs of admission to the health facility in the review period.					
Disaggregation	By health facility, by region, by ward					
Source	Patient medical recording card (inpatient medication profile form)					
Method of data collection	Survey					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Biannually

Indicator 2: Proportion of charts with completed inpatient medication profile forms						
Definition	It is the proportion of completeness of the inpatient medication profile form on admission at the reviewing period.					
Formula	$\dfrac{\#\;of\,patient\;charts\;with\;completed\;inpatient\;medication\;profile\,form}{Total\;number\,of\,admission\;durig\;the\;review\;period}$					
Interpretation	This indicator measures proportion of charts with completed inpatient medication profile forms in the health facility in the review period.					
Disaggregation	By health facility, by region, by ward					
Source	Patient medical recording card					
Method of data collection	Survey					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Quarterly

Indicator 3	**Proportion of patients whose medications are reconciled up on admission**					
Definition	Percentage of patients who received documented medication reconciliation on admission, with resolution of identified discrepancies					
Formula	*Number of patients who received documented medication reconciliation on admission X100* *Total Number of patients admitted in the review period*					
Interpretation	This indicator measures percentage of patients whose medication is reconciled, and discrepancies are resolved up on admission to the health facility in the review period.					
Disaggregation	By level of health facilities, region, ward					
Source	Patient medical recording card					
Method of data collection	Survey					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Biannually

Indicator 4: Number of drug therapy problems identified					
Definition	Numbers of drug therapy problems (DTPs) are those that are identified during the pharmaceutical care provision and communicated to the physician or nurse in charge.				
Formula	*Total number of DTPs identified and communicated*				
Interpretation	This indicator shows the quality of inpatient service by measuring prevalence of drug therapy problems. A DTP is considered as identified when it is communicated to the prescriber or nurse in charge. DTPs are classified as: - Unnecessary drug therapy - Need additional drug therapy - Ineffective drug - Dose too low - Dose too high - Adverse reaction - Noncompliance				
Disaggregation	By inpatient and outpatient, by type of DTP, by facility, by ward,				
Sources	Clinical pharmacy interventions daily summary and monthly summary form				
Method of data collection	Routine aggregation of health facility DTP report				
Frequency of Reporting	HC	Hospital	WoHO	ZHD/ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Quarterly

Indicator 5	**Acceptance rate of DTPs identified and communicated**					
Definition	It is the percentage of DTPs identified and communicated by CPS provider which is accepted by the prescribers during their communication so that issues can be resolved or prevented within a reporting period.					
Formula	*Total number of DTPs accepted by other healthcare professionals* x 100 *Total number of DTPs identified* and communicated					
Interpretation	This indicator measures acceptance rate of DTPs identified and communicated. Ideally all DTPs identified and communicated to prescribers shall be accepted by prescribers. But because many reasons, the target for this indicator is 80%.					
Disaggregation	By health facility, type of DTP, ward					
Sources	Clinical pharmacy interventions daily summary and monthly summary form					
Method of data collection	Routine aggregation of health facility DTP report					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Quarterly

Indicator 6	**Percentage of multidisciplinary team ward rounds conducted by CPS provider**					
Definition	Percentage of multidisciplinary team (MDT) ward round conducted by CPS provider to provide pharmaceutical care for inpatients.					
Formula	*Number of MDT ward rounds conducted by CPS providers x 100* *Total number of MDT ward rounds conducted* in the ward in the review period					
Interpretation	This indicator measures percentage of MDT ward round conducted by CPS provider to provide pharmaceutical care for inpatients admitted in their respective wards in a certain period.					
Disaggregation	By health facility, ward					
Source	Daily clinical pharmacy activity report form					
Method of data collection	Routine aggregation of health facility DTP report					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Quarterly

Indicator 7	**Percentage of patients whose medications are reconciled during discharge**					
Definition	Percentage of patients who received documented medication reconciliation at discharge, with resolution of identified discrepancies.					
Formula	*Number of patients who received documented medication reconciliation at discharge x 100* *Number of patient discharged*					
Interpretation	This indicator measures percentage of patients whose medication is reconciled, and discrepancies are resolved at discharge from the health facility.					
Disaggregation	By level of health facilities, by ward					
Source	Patient medical reconciliation form from patient chart					
Method of data collection	Survey					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Biannually

Indicator 8	**Proportion of patients who received discharge medication counseling**					
Definition	Proportion of patients who received documented medication counseling upon discharge by the CPS provider in the review period.					
Formula	*Number of patients who received discharge medication counseling x 100* *Number of patients discharged*					
Interpretation	This indicator measures percentage of patients who get counseling about their medications up on discharge from the health facility in the review period.					
Disaggregation	By health facility, ward					
Source	Patient medical record					
Method of data collection	Survey					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Biannually

Indicator 9	**Percentage of facilities with functional unit dose dispensing system in their inpatient pharmacies**					
Definition	Percentage of hospitals that provide UDDS and fulfill functionality criteria.					
Formula	*Number of hospitals with functional Unit dose system X100* *Total number of hospitals*					
Interpretation	This indicator shows the functionality of UDDS in the inpatient ward pharmacy of the hospital. The presence of functional UDDS is expressed in terms of 1. Availability of dedicated ward pharmacy(s) 2. Dispensing of medicines in a single dose package 3. Dispensing of medicines in a ready to administer form and 4. Dispensing of medicines only for 24 hours 5. Dispensing of medicines with a pharmacy specific documentation. A health facility UDS is considered functional when a minimum of 80% score (4 out of 5) is achieved using the above checklist.					
Disaggregation	By health facility					
Source	Observation of inpatient pharmacy, inpatient medication registration form, interview of ward nurses					
Method of data collection	Survey					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Biannually

Indicator 10	**Percentage of facilities with functional chronic care pharmacy service**					
Definition	Percentage of facilities with functional chronic care pharmacy service that provide comprehensive pharmaceutical care to patients with chronic illness.					
Formula	*Number of facilities with functional chronic care pharmacy x 100* *Total number of facilities in the review period*					
Interpretation	This indicator measures the percentage of facilities with functional chronic care pharmacy service that provide comprehensive pharmaceutical care to patients with chronic illness in their chronic care pharmacy. In a comprehensive pharmaceutical care, obtain pertinent demographic information; document the chronic illness; interpret laboratory values; identify drug allergies, ADEs, maintain a comprehensive list of prescription and nonprescription medications and update during subsequent patient encounters. For a chronic care pharmacy service to be functional there should be at least one dedicated chronic care pharmacy and CPS provider with proper documentation and follow-up of patients.					
Disaggregation	By health facility					
Source	chronic care pharmacy service documentation forms					
Method of data collection	survey					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Biannually

Indicator 11	**Proportion of facilities that send clinical pharmacy report monthly**					
Definition	Proportion of facilities that send clinical pharmacy report monthly.					
Formula	*Number of facilities that send CPS report monthly X100* *Total Number of facilities in the review period*					
Interpretation	This indicator measures proportion of facilities that send clinical pharmacy report monthly to FMOH in the review period.					
Disaggregation	By level of health facilities, region					
Source	Monthly pharmacy service activity report (monthly CPS report)					
Method of data collection	Routine data from facility					
Frequency of Reporting	HC	Hospitals	WoHO	ZHD/ ScHO	RHB	FMOH
		Monthly	Monthly	Monthly	Monthly	Biannually

10. Clinical Pharmacy program and its implementation in Ethiopia

10.1 Initiating Clinical Pharmacy Service in a Facility

Pharmaceutical care practice is relatively new that there are few practices that have been established long enough from which to learn. Therefore, it is necessary to learn from other patient care practitioners who have built successful practices. The way to get started will depend on the various circumstances and context of the health facilities. Many hospitals and health centers do not have pharmaceutical care practice yet and others may not function properly. In order to implement pharmaceutical care, practice the following guidelines should be considered.

1. Become a competent practitioner
2. Understand and describe your service
3. Identify or create a supportive practice environment
4. Accommodate the organization
5. Develop techniques to recruit patients
6. Be realistic about your expectations

At national level, CPS program and its implementation requires set strategic objectives, detailed activity plans, performance measure, time line, responsible body and estimated cost (annex 10.1). The following stepwise approach should be used to start CPS provision.

10.1.1. Stepwise approach to start Provision of Clinical pharmacy service

Step 1: Organizing Evidences and requirements

Starting clinical pharmacy service will require undertaking a lot of advocacy. It is better to prepare gathered evidence to show the needs for clinical pharmacy services, and the existing situation in the health facility. Furthermore, use the guidelines and standards as mandatory requirement for implementing the service program.

Step 2: Discussion with health facility management

Discuss the importance of provision of clinical pharmacy service with the health facility management; presenting the benefits, functions and roles of CPS. The input that is obtained in this discussion will serve as an input for future plan.

Step 3: Present the draft plan and establish consensus

Present the draft plan and establish consensus with the health facility management and health providers to initiate provision of CPS (see sample action plan format below-table 10.1). The required resources shall be clearly discussed with the management.

Step 4: Launching and Orienting Health Facility Staff

As soon as all required facilities and materials are secured, officially launch the provision of CPS at the health facility. During launching; orient health facility staff and department heads. Explain briefly the importance, role and structure of clinical pharmacy. The clinical pharmacy implementation manual and SOP can be used as a main reference for the orientation.

Step 5: Follow the progress and revise the action plan

While providing clinical pharmacy service using available resources, seek for potential sources to fulfill the required materials for smooth functioning of the program.

Step 6: Record, report and document all activities performed at all steps

10.2 Revitalizing Clinical Pharmacy Service in a Facility

When the established clinical pharmacy service doesn't function properly or become non-functioning, revitalizing the service provision is the main remedy as soon as possible. For the clinical pharmacy service said to be functional, it should at least fulfill the following minimum requirements:

1. CPS focal person assigned with official letter
2. Has SOP approved by the health facility DTC/management
3. Has current action plan with primary clinical pharmacy services
4. Undertake activities based on current action plan
   - Conduct admission medication history taking
   - Participate in ward rounds, morning sessions and seminars
   - Perform medication reconciliation
   - Conduct patient monitoring and follow-up
   - Provide drug information
   - Record, document and report CPS activities properly
5. Regularly record, report and document the CP activities

If the service failed to fulfill the above-mentioned requirements, we can say the clinical pharmacy is poorly functioning. Therefore, revitalizing the services should be initiated. Steps to be followed in the process are listed below.

10.2.1. Stepwise approach in revitalizing non-functioning/poorly functioning CP Service

Step 1: Problem Identification

Discuss with responsible bodies why the clinical pharmacy services are interrupted and determine root cause. Identify possible causes: Possible causes might be lack of:

- Commitment from professionals
- Adequate number of clinical pharmacy professionals and high work load
- Proper recognition and incentive mechanism
- Awareness and support among health facility staff and management
- Resource

Step 2: Understand and Prioritize the Problem

Prioritize the identified problems and understand the root causes. This is a crucial step in the process of revitalizing the service since it can help to know the root causes which will lead to the solution.

Step 3: Prepare and Present the Revitalizing Plan

The draft plan of revitalization should be prepared based on the problems identified and prioritized problems. The prepared draft plan should be presented to the management to revitalize CPS (see sample action plan format below-table 10.1).

Step 4: Revitalization of CPS

Finally, motivate the clinical pharmacy staff and start the process of implementation.

Table 10.1 Sample plan of action template

Objective	Activity	Responsible person	Timeline	Resources	Remark

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Annexes

Annex A: List of participants during manual development

S. No.	Name	Organization
1.	Maru Legesse	FMoH-PMED
2.	Mariamawit Teshome	FMoH-PMED
3.	Regasa Bayisa	FMoH-PMED
4.	Sufyan Abdulber	FMoH-PMED
5.	Yidnekachew Degefaw	FMoH-PMED
6.	Belete Ayalneh	GHSC- PSM
7.	Tsegaye Melaku	Jimma University
8.	AsebMegbiyaneh	Yekatit 12 Hospital
9.	KirubelMinsamo	Haramaya University
10.	Misrak Feleke	St. Paul's Hospital MMC
11.	Bethelehem Lemma	TikurAnbessa Specialized Hospital
12.	Tarekegn Dagnaw	St. Peter Hospital
13.	Tadele Mekuriya	Ambo University
14.	Assefa Mulu	Addis Ababa University
15.	Teshager Aklilu	Wollo University
16.	Tesfay Mehari	Mekelle University
17.	Lydia Yohannes	EkaKotebe (Amanuel)
18.	Mohammed Assen Seid	University of Gondar
19.	Habib Ahmed	ALERT Hospital
20.	Alemseged Beyene	Addis Ababa University
21.	Yosef Wakwoya	GHSC-PSM
22.	Elias Geremew	GHSC-PSM
23.	Mequanint Kassa	University of Gondar
24.	Dumessa Edessa	Haramaya University
25.	Abraham Sisay	St. Paul's Hospital MMC
26.	Bodena Bayisa	Jimma University

27.	HaftomNiguse	Mekelle University
28.	Asaminew Goa	WolaytaSoddo University
29.	YohannesAyele	Haramaya University
30.	Mohammed Hassen	University of Gondar
31.	Asrat Agalu	Ethiopian Pharmaceutical Association (EPA)
32.	Fikreselam Habte	Amanuel MSH
33.	Tigestu Alemu	Addis Ababa University

Annex B: List of participants during consultative workshop

Full name	Occupation title	Organization work place and location
1. Marelign Demeke	C/ Pharmacist	D/Tabor G. Hospital
2. Beneyis Shishge	C/ Pharmacist	D/Tabor G. Hospital
3. T/ Haimanot Fentie	C/ Pharmacist	Wollo University
4. Getinet Nibret	C/ Pharmacist	D/Markos R. Hospital
5. Getachew Ayal	C/ Pharmacist	D/Markos R. Hospital
6. Abebe Bimerew	C/ Pharmacist	AA FMOH
7. Ahemed Mohammed	C/ Pharmacist	Dupti Hospital
8. Debela Gemeda	C/ Pharmacist	AA St Paulos
9. Dawit Hankara	C/ Pharmacist	Adare Hospital
10. Mihret Asseged	C/ Pharmacist	Adare Hospital
11. Esliman Abdela	C/ Pharmacist	UOG
12. Gorfineh Teshome	C/ Pharmacist	Jimma University
13. Semahal Hailay	C/ Pharmacist	Ayder University
14. Edosa Terefe	C/ Pharmacist	AA University
15. Getnet Gashaw	C/ Pharmacist	AA University
16. Misrak Feleke	C/ Pharmacist	SPHMMC
17. Ephrem Kibrom	C/ Pharmacist	Dissie R Hospital
18. Dagemawit Ahemed	H/Pharmacist	Dessie R Hospital
19. Abera Alemu	Pharmacist	DD RHB
20. Abdulazize Temam	Pharmacist	DCH
21. Tefera Kasahun	Pharmacist	DCH
22. Gobazie Temesgen	Pharmacist	AAU

23. Seife Demissie	Pharmacist	AMSH
24. Fikreselam Habte	Pharmacist	AMSH
25. Firehiwot Amare	Pharmacist	Haram University
26. Zigbey Brhane	Pharmacist	Ayder Hospital
27. Marimawet Teshome	Pharmacist	FMOH
28. Wondemagegn Ahmed	Pharmacist	Jugal Hospital
29. Hana Sintayhu	Pharmacist	Jugal Hospital
30. Olika Legessa	Pharmacist	Shas R Hospital
31. Abduhakim Dema	Pharmacist	Shas R Hospital
32. Wodessen Shewarega	Pharmacist	FMOH
33. Emebet Nigussie	Pharmacist	Sabia Hospital
34. Tsegaye Melaku	C/Pharmacist	JU SOP
35. Yenus Mohammed	Pharmacist	Afar RHB
36. Awolachaw Tesfaye	Pharmacist	AAHB
37. Mohammed Yimar	C/Pharmacist	Dupti Hospital
38. Dargaze Chemer	C/Pharmacist	Butajira Hospital
39. Ehetemariam Shambel	C/Pharmacist	FMOH
40. Endalelig Sileshie	Pharmacist	SNNP HB
41. Birtukan Zewde	Pharmacist	H.U.C.S.H
42. Derese Challa	C/Pharmacist	H.U.C.S.H
43. Mhammed Mawi	MD	Jugol Hosp
44. Birtukan Zewde	MPH	HURH
45. Milkeso Beleke	CEO	Shas R Hosp
46. Edao Fejo	CEO	AMSH
47. Muhedin Redi	CEO	DCH
48. Wubetu Yihunie	CEO	DMRH
49. Hassen Mohammed	CEO	Dupti Hosp
50. Wubaye Marew	D/CEO	D/T G Hosp
51. Regasa Bayisa	Director	FMOH

Annex 2.1 Pharmaceutical care model

Model	Description	Key elements	Steps
Pharmaceutical care	The pharmaceutical care model is now defined as a patient-centered way to deliver medication management services. The model stresses a pharmacist's responsibility for a patient's drug-related needs and being held accountable for the commitment. The purpose is to achieve positive patient outcomes. The pharmacist ensures that all of a patient's drug therapy is indicated, effective, and safe and that the patient is able and willing to adhere to instructions. It is a generalist practice, consistent with the concepts of primary care and the medical home.	The pharmaceutical care model has three key components: 1) Identify a patient's actual and potential drug therapy problems (DTPs). 2) Resolve actual DTPs. 3) Prevent potential DTPs from becoming actual DTPs. The pharmaceutical care process has three key steps: 1) ASSESS 2) CARE PLAN 3) EVALUATION **In the standards of care for pharmaceutical care, the practitioner:** 1) Collects patient-specific information to use in decision-making regarding all drug therapies 2) Analyzes assessment data to determine that drug-related needs are being met; that all medications are indicated, effective, and safe; and that the patient is able and willing to take the medication as intended. 3) Analyzes assessment data to determine whether any DTPs are present 4) Identifies goals of therapy that are patient-centered 5) Develops a care plan including interventions to resolve DTPs, achieve goals of therapy, and prevent DTPs 6) Develops a schedule to follow up and evaluate the effectiveness of drug therapies and any adverse events experienced by the patient 7) Evaluates the patient's outcomes and determines progress toward achieving goals of therapy, identifies safety and adherence issues, and assesses whether new DTPs have developed	**1) ASSESSMENT of patient's drug-related needs** Includes a pharmacotherapy workup and a full review of systems to identify DTPs. All DTPs are categorized and must fall under one of four categories, composed of seven types of DTPs: a. Indication i. Unnecessary drug therapy ii. Needs additional drug therapy b. Effectiveness i. Ineffective drug ii. Dosage too low c. Safety i. Adverse drug reaction ii. Dosage too high d. Adherence i. Patient not able or willing to take medication **CARE PLAN development to meet patient's needs** Four categories of interventions are selected to establish goals of therapy: a. Resolve DTPs. b. Achieve goals of therapy. c. Prevent future DTPs. d. Schedule follow-up. Types of interventions that can occur: a. Initiate new drug therapy. b. Change dosage regimen. c. Change the drug product. d. Discontinue drug therapy. e. Institute a monitoring plan. f. Patient-specific instructions g. Removal of barriers to obtain medication h. Drug administration device provided i. Refer patient. **Follow-up EVALUATION** Each condition is categorized into eight predetermined outcomes: a. Resolved b. Stable c. Improved d. Partly improved e. Unimproved f. Worsened g. Failure h. Expired (patient died)

Annex 2.2 Medication Therapy Management (MTM) Model

Clinical Pharmacy Practice Model	Description of Model	Key Elements	Steps

Medication therapy management (MTM)	MTM is defined as a distinct service or group of services that optimize therapeutic outcomes for individual patients. In this model, the patient is empowered to take an active role in managing his or her medications.	All MTM services should include:
		(1) Establishing a pharmacist-patient relationship in which the pharmacist provides individualized services specific to the patient (or caregiver) to whom services are provided
		(2) The interaction between the patient (or caregiver) and pharmacist preferably occurs through face-to-face communication.
		(3) Opportunities for pharmacists and other qualified health care providers to identify patients who should receive MTM services
		(4) Payment for MTM services consistent with contemporary provider payment rates
		(5) Processes to improve continuity of care, outcomes, and outcome measures
			The MTM service model has five core elements:
			1) Medication therapy review (MTR)
			A systematic process of collecting patient-specific information
			  a. Assessing medications to identify medication-related problems (MRPs) by reviewing indication, effectiveness, safety, and adherence
			  b. Developing a prioritized list of MRPs
			  c. Creating a plan to resolve MRPs
			Two main types of MTR:
			  a. Comprehensive: annual and after transitions of care
			  b. Targeted: addresses specific MRP
			2) Personal medication record (PMR)
			  a. A comprehensive record of all medications (prescription, over-the-counter, herbal, and other dietary supplements), which is intended for patients to use in medication self-management
			  b. Can be created as part of discharge process in the institutional setting or as part of patient care in the ambulatory care setting
			  c. Patients are responsible for documenting any changes to their therapeutic regimens to ensure a current and accurate record.
			3) Medication-related action plan (MAP)
			  a. Intended for patient use; contains a list of actions for self-management
			    The pharmacist-created MAP includes items the patient can act on that are within the pharmacist's scope of practice or agreed on by other members of the health care team.
			4) Intervention and/or referral
			Recommendations on selection of medications; options to address MRPs, recommended monitoring parameters, and follow-up care
			5) Documentation and follow-up
			  a. MTM services should be documented in a consistent manner, and follow-up MTM visits are scheduled on the basis of the individual patient's medication-related needs.
			  b. Documentation for patients may include the PMR, MAP, and educational materials.
			  c. Documentation to physicians may include a cover letter, the patient's PMR, the SOAP note, and the care plan.

Annex 2.3 Recommended Job Descriptions for CPS Providers

Key Tasks/Responsibilities

1. **Provide comprehensive pharmaceutical care to patients during their hospital stay**

   - Take and document admission medication history using in-patient medication profile form.

   - Review all medication orders and validate prescription

   - Identify patients' drug related needs (indication, efficacy, safety and adherence)

   - Detect existing or potential adverse reactions and treatment failures

   - Identify drug incompatibilities and interactions and assess their clinical significance

   - Develop a pharmaceutical care plan that can address the patients' drug related needs

   - Participating in resuscitation activities in emergency wards

   - Using crash board cart refilling the medications every time in the emergency ward

   - Document the pharmaceutical care plan by using in-patient medication profile form

   - Undertake dose calculations and adjustment by apply pharmacokinetic dosing principles

   - Propose for modification of the therapeutic plan in case of adverse effects, patient noncompliance, evidence-based efficacy problem and as appropriate, in consultation with other health care team members.

   - Monitor and document daily progress of the patient's disease state(s) and outcome of treatment by using pharmaceutical care progress note recoding form

   - Monitor and document the patient medication adherence and communicate with the nursing staff.

2. **Provide drug information services:**

   - During prescription writing, provide information related to its availability and approximate costs of the medications.

   - Provide drug information services to the health care team proactively and communicate information verbally and/or in written

   - Timely provision of poison   information for patients/care givers and healthcare providers

   - Act as a bridge between the DIC and the other health care team to disseminate information coming from the center and to bring questions to the center

   - Organize and provide continuing medical education to the health care team on current and important topics by considering as a regular duty when the need arises.

3. **Attend ward rounds, morning sessions and meetings**

   - Regularly attend major ward rounds in the respective wards assigned and actively contribute to the medical decision pertaining drug therapy

- Take responsibilities in presenting seminars and case presentations when necessary.
- Organize and conduct pharmacy morning sessions, case presentations, pharmacotherapy updates, staff audits to improve pharmaceutical care and pharmacy services

4. **Provide discharge medication counseling**

- Plan discharge medication counseling ahead of time
- Provide organized and structured discharge medication counseling to patients about their diseases and drugs prescribed using medication information form to improve outcome of drug therapy
- Record the discharge medication counseling and document in a patient chart.

5. **Dispense drugs and medical supplies in chronic care pharmacies, ward and OPD pharmacies**

- Evaluate prescription, counsel patients and dispense drug and medical supplies at OPD and chronic care pharmacies
- Provide a 24-hr ward pharmacy services by implementing unit dose drug dispensing system (UDDDS) in each ward pharmacy
- Dispense drugs in ward pharmacies and sign on the dispenser column of patient medication sheet found in patient charts.
- Assist patients to get available and affordable medications in a timely manner
- Provide an intravenous preparation and simple mixing of injectable drugs to promote patient safety
- Improve drug availability and accessibility in each specific ward
- Reduce drug wastage by implementing UDDDs at each specific ward
- Conduct regular inventory at each pharmacy (maintain proper storage, recording, reporting system)
- Quantify the drug and medical supplies need for each pharmacy by maintaining consumption data
- Preparation of drug lists for the emergency

6. **Monitor drug use problems in the hospital wards**

- Monitor and report adverse drug reactions in wards using ADR reporting forms to ADR focal person in the hospital
- Monitor prescriptions in wards and assist prescription monitoring system to generate data that will be used for decision making by hospital officials and community
- Monitor drug utilization in wards and assist drug utilization assessments to generate data that will be used for intervention and action by the hospital administrators

Annex 3.1 Inpatient medication profile form

<table>
<tr>
<td colspan="5" align="center">Inpatient Medication Profile Form

Patient name: _____Sex: ____Age: _____Weight: _____ Height: _____ BMI: _____ BSA_____ Card No.: _____</td>
<td rowspan="9"></td>
</tr>
<tr>
<td>Date of Admission:</td>
<td colspan="4" align="center">Admission Medication History</td>
</tr>
<tr>
<td rowspan="5">Diagnosis:</td>
<td rowspan="5">Medical history</td>
<td colspan="2">Medication History (name, dose, frequency, duration)</td>
<td>Allergies:</td>
</tr>
<tr>
<td colspan="2" rowspan="2"></td>
<td>Adverse Drug Reactions:</td>
</tr>
<tr>
<td rowspan="2">Substance use history:</td>
</tr>
<tr>
<td colspan="2">Adherence statues:</td>
<td>Pregnancy status:</td>
</tr>
<tr>
<td colspan="2"></td>
<td>Immunization status:</td>
</tr>
<tr>
<td colspan="5" align="center">Current Medications</td>
</tr>
<tr>
<td>Indication</td>
<td>Drug <i>(Name, Strength, Dosage form, Dose, Route and frequency)</i></td>
<td>Start Date & Time</td>
<td>Stop Date and Time (Optional)</td>
<td>Response

Effectiveness/Safety</td>
<td>Initials & Sign.</td>
</tr>
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Pharmacist's assessment and care plan:

Recommendations/interventions:

Discharge medication and counseling:

Annex 3.2 Pharmaceutical care progress note recording sheet

Form 2: Pharmaceutical Care Progress Note
(Follow the instructions when completing this form)

Patient Name: _____Card No. _____

Annex 3.3 Medication Reconciliation Form

(Follow the instructions when completing this form)

Patient name: _____ Age _____ Sex _____Weight _____

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

Completed by: Name _____ Signature _____ Date _____

Annex 3.4 Inpatient Medication Consumption Registration Book

Patient Name _____ **Age**_____ **Sex/**_____ **Card No**_____ **Bed No**_____
diagnosis_____ **Sponsor/Organization** _____ **others if any**_____

S/N	Date	Drug/Service code	Description: (Medicines Name Strength, Dosage Form) brand if any and Services	Total QTY	Retail price	Total Retail Price	Patient /care giver Sig
					Total		

Dispensers/Lab Tech, X-ray tech, Nurse, Name and Signature _____

Function: This sheet is used to record medicines, supplies and reagents with their financial values consumed by admitted patients.

Location: This registration book will be placed in inpatient pharmacy or in wards

Work process: The nurse or ward pharmacist will record medicines, supplies and reagents with their financial values consumed by the patient during admission. During discharge, the record will be reconciled with actual consumption and approved by the personnel in charge and payment will be effected if the patient must pay at last on cash or will be documented for sponsors if sponsors will pay for Note: This system is very easy when software or excel sheet is used for recording.

Annex 3.5 Prescription Evaluation Checklist				
Prescription evaluation checklist				
Prescription evaluation parameters	**Availability of required information on the prescription**			**Remark**
1. Check for legality	• Standard prescription of the hospital?			
	• Signed by an authorized prescriber?			
	• Name of an authorized prescriber present or titer?			
	• Date of the Prescription written?			
	• Right medicine on right prescription is written (Standard, NPS and ART)?			
2. Check for legibility	• Legibly written that do not encourage guess work?			
	• Nonstandard abbreviation present on the PRESCRIPTION			
3. Check for completeness	• All parts of the Prescription have been written completely?			
	• If not complete, at least these present?	• Card #	• age	
		• Patient name	• weight	
		• Sex	• Specific diagnosis	
	• Are these drug parameters present?	• Drug Name	• Route of administration	
		• Strength	• Frequency	
		• Dosage Form	• Duration	
		• Dose	• Quantity as appropriate.	
4. Medication history?	• Asked for allergy or any ADR or complaint?			
	• Asked liver disease and /or renal disease?			
	• Asked for pregnancy or breast feeding?			
	• Asked current medications including COC, OTCs, drugs for chronic illness?			
	• Asked for use of alcohol, chat or other substances			
	• Asked for any adherence problems identified?			
5. Check for correctness	• Any drug-drug, drug-food, drug-disease interaction?			
	• Indication correct?	• Is there unnecessary drug therapy?		
		• Is there a need for additional drug therapy?		
	• Effectiveness problem present?	• Ineffective drug?		
		• Dosage too low?		
	• Safety problem present?	• Adverse drug reaction?		
		• Dosage too high?		
		• Any contraindication/s?		
6. Asked for ability to pay for the medication?				
7. Have you communicated possible drug therapy problems to the prescriber?				
8. Have you documented any DTPs and/ or issues on the prescription on appropriate format?				
9. Have you signed on part of prescription corresponding to name of the dispenser/evaluator?				

Annex 3.6: Chronic Care Pharmacy Services Documentation Form (Follow the Instructional Guides while completing this form)

Name of Hospital: _____; Region: _____

Patient Information	Clinical Information
Card No.: _____ Name: _____ Sex: _____; Age: _____; Wt._____Ht._____ Date started: _____	**Type/s of chronic disease**: _____ **Current Status**: Improved: ☐ Stable: ☐ Partially improved: ☐ Un improved: ☐ Worsened: ☐ Failure ☐ **History of**: 1. Allergy/ADR: Yes ☐ No ☐ If yes, specify the drug/s: _____ 2. Alcohol/substance abuse: Yes ☐ No ☐ If yes, specify: _____ 3. Traditional medicine use: Yes ☐ No ☐ If yes, specify: _____

Address				
Patient's telephone: _____	Pertinent past medication history	Concomitant diseases	Date	Monitoring parameters

For women/mothers
Pregnant: ☐ Breast feeding: ☐ On oral contraceptives: ☐

Drug therapy problems (ADRs, drug interactions, non-adherence, etc.)

Date	DTP identified	Therapeutic goal/s (TG)	Recommendations/Intervention (R/I)	Outcomes of intervention	Accepted (Y/N/C)

Medicine Dispensing Information

Date	Reason for visit	Weight	TG achieved (Y/N)	Prescriber's Initials	Medication name, strength, dosage form, dose, frequency	Quantity	Other drugs (for concomitant diseases)	Date of Next Visit	Dispenser's sig.

Annex 3.7: Chronic Care Pharmacy Services Reporting Form

Name of Hospital _____**Reporting Month** _____**Year**_____

1° diagnosis of the NCD	Sex		Category of DTP Identified*							Interventions made							Remark
	M	F	1	2	3	4	5	6	7	A	B	C	D	E	F	G	
Total																	

Reported by _____**Signature**_____**Date**_____

*Drug therapy problem category: 1-Unnecessary drug therapy; 2-Needs additional therapy; 3-Ineffective drug; 4-Dosage too low;5-Adverse drug reaction; 6-Dosage too high; 7-Adherence
**Interventions made: A-Discontinued unnecessary drug therapy; B-Initiated additional drug therapy; C-Changed ineffective drug; D-Increased dosage; E-Adverse drug reactions managed; F-Decreased dosage; G-Improved compliance

Annex 3.8: Naranjo Algorithm* for assessing probability of an ADR

Question	Yes	No	Do Not Know	Score
Are there previous conclusive reports on this reaction?	+1	0	0	
Did the adverse reaction appear when the drug was administered?	+2	-1	0	
Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was administered?	+1	0	0	
Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0	
Are there alternate causes (other than the drug) that could solely have caused reaction?	-1	+2	0	
Did the reaction reappear when a placebo was given?	-1	+1	0	
Was the drug detected in the blood (or other fluids) in a concentration known to be toxic?	+1	0	0	
Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
Was the adverse event confirmed by objective evidence?	+1	0	0	
				Total Score
Score: **0-1 Doubtful** **2-4 Possible** **5-8 Probable** **>9 Definite**				

* Adapted from Naranjo CA, Busto U, Sellars EM, et al, Clin Pharmacol Ther. 1981; 30:239-245

Annex 3.9 WHO-UMC causality Criteria

Causality term	Assessment criteria
Certain	• Event or lab test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e.. an objective and specific medical disorder or a recognized pharmacologic phenomenon) • Re-challenge satisfactory, if necessary
Probable/likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Re-challenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanation
Conditional/unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

Annex 3.10: 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 subside after D/C of suspected drug □ YES □ No □ Information not available Reaction reappear 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 sequelae   □ Unknown

Sequelae

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

መጅመሪ ያ እ ዚህ ላ ይ እ ጠፍ

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 the financial support from USAID

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Food, Medicine and Health Care Administration and Control Authority
Regulatory Information Development and Dissemination Team
P.O.Box 5681-Tel.0115-52314 , Addis Ababa, Ethiopia

Annex 3.11: Allergy Card

መመሪያ

ለማንኛውም ጤና ባለሙያ

- እባክዎ ሕክምና በሚሰጡ ወይም መድኃኒት በሚያድሉበት ወቅት ታካሚው ለየትኛው መድኃኒት አለርጂ እንዳለባቸው ይጠይቁ ፡፡
- ከዚያም በዚህ መታወቂያ ካርድ ላይ ይመዝግቡላቸው፡፡

- ታካሚው ከዚህ በፊት ያጋጠማቸውን አለርጂ አስመዝግበውም ከሆነ ካርዳቸውን እንዲያሳዩዎት ይጠይቁ ፡፡ ለአለርጂው ምክንያት የሆነው መድኃኒት በድጋሚ እንዳይታዘዝ ወይም እንዳይሰጥ ጥረት ያድርጉ፡፡

ለማንኛውም ታካሚ

- እባክዎ ወደ የትኛውም የሕክምና መገልገያ ተቋም ማለትም ሆስፒታል ፣ ጤና ኬላ ፣ ክሊኒክ ለመታከም ወይም መድኃኒት ለመግዛት ሲሄዱ አለርጂ ካጋጠመዎት አለርጂውን ያስከተለው መድኃኒት ስም በዚህ መታወቂያ ካርድ ላይ እንዲመዘገብልዎት ይጠይቁ ፡፡
- በሌላ ጊዜም ለመታከም ወይም መድኃኒት ለመግዛት ሲሄዱ ለጤና ባለሙያ ካርዱን ማሳየትን አይርሱ ፡፡ ይህም ለአለርጂው ምክንያት የሆነው መድኃኒት በድጋሚ እንዳይታዘዝልዎት ወይም እንዳይሰጥዎት

የመድኃኒት አለርጂ መታወቂያ ካርድ

የባለ መታወቂያው ስም_____ ያታ_____

እድሜ/ የተወለዱበት ቀን_____

አድራሻ: ክልል_____ወረዳ_____ቀበሌ_____ቤ.ቁ_____

ካርዱ የተሰጠበት ቀን_____

አለርጂውን ያስከተለው መድኃኒት ስም

1_____

2_____

3_____

በአለርጂው ምክንያት የደረሰው ችግር ዝርዝር

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እባክዎ ከካርዱ ጀርባ ያለውን መመሪያ ይመልከቱ

Drug Administration and Control Authority of Ethiopia — USAID FROM THE AMERICAN PEOPLE — msh Management Sciences for Health — SPS Strengthening Pharmaceutical Systems

Annex 4.1: Medication Information Sheet

Name of the medication & dosage form	Strength	Amount to be taken	Reason for taking the med	Time to take your medication				Common side effect	Special instruction
				Morning	Lunch	Dinner	Bed time		

ANNEX 5.1: Code of ethics for pharmacists practicing in Ethiopia

The Code of Ethics for Pharmacists was adopted by the membership of the American Pharmacist Association (the then American Pharmaceutical Association) October 27, 1994.

Preamble

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

I. A pharmacist respects the covenant relationship between the patient and pharmacist.

Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.

II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.

A pharmacist places concern for the well-being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.

III. A pharmacist respects the autonomy and dignity of each patient.

A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.

IV. A pharmacist acts with honesty and integrity in professional relationships.

A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.

V. A pharmacist maintains professional competence.

A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

VI. A pharmacist respects the values and abilities of colleagues and other health professionals.

When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.

VII. A pharmacist serves individual, community, and societal needs.

The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.

VIII. A pharmacist seeks justice in the distribution of health resources.

When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.

(Adopted October 27, 1994)

Annex 6.1 Baseline assessment check list for model clinical pharmacy service site selection

Part I: General Information

1. What is the TOTAL number of pharmacy professionals currently available at your Hospital? #: _____	
1.1 Clinically trained pharmacists with 5-year curriculum	#: _____
1.2 Pharmacists who took 1-month in-service training	#: _____
1.3 Clinical pharmacists with MSc degree	#: _____
1.4 Druggists with Diploma in pharmacy	#: _____
2. Total number of beds in the hospital (approximate)	#: _____

Part II: Clinical Pharmacy Services Information

3. Do your facility started providing clinical pharmacy services? 1. Yes ☐ 2. No ☐
4. If yes to Q 3, when was it?
    a. More than 5 years
    b. 3-5 years
    c. 1-2 years
    d. Less than 1 year
5. If yes to Q 3, in which areas is the service being provided currently?
    a. inpatient (wards)
    b. outpatient (chronic care pharmacies)
    c. emergency
6. If yes to Q 2, is the service being provided 24/7 (a continuum clinical pharmacy service)?1. Yes ☐ 2. No ☐
7. If yes to Q 2, did the hospital/pharmacy unit officially familiarized the service to create awareness among the staff?
   1. Yes ☐ 2. No ☐
8. If clinical pharmacy service is started in the hospital in patient, which areas are **currently** covered, and specify the number of pharmacists working in each ward below?
    a. Medical Ward ☐; #: _____; No of pharmacists who are working full time#:
    b. Pediatric Ward ☐, #: _____
    c. Surgical Ward ☐, #: _____
    d. Gyne-Obs Ward ☐, #: _____
    e. Emergency and ICU ☐, #: _____
    f. Chronic care pharmacy(s) ☐, #: _____
    g. Others, specify
       _____
    h. The service was started but currently stopped at all ☐, #: _____,
9. If yes to Q 2, does the hospital officially assigned a coordinator or case team leader for CPS? 1. Yes ☐ 2. No ☐
   (if yes to this question, please attach copy of letter of assignment)
10. If yes to Q 2, do the pharmacists have working station/area, including reading and gown changing area? 1. Yes ☐ 2. No ☐

11. Do clinical pharmacy service providers have job-description approved by the hospital management?
    1. Yes ☐   2. No ☐
    (if Yes to Q 4, please make a copy of the Job- description and document)

12. Are charts of patients reviewed within 24 hours of admission in the assigned wards? 1. Yes ☐
    2. No ☐
    - a. 100% ☐
    - b. >75% ☐
    - c. 50-75% ☐
    - d. 25-50% ☐
    - e. <25% ☐

13. Do you think the no. of pharmacists is enough to provide clinical pharmacy services in this hospital?
    1. Yes ☐   2. No ☐

14. Which specific clinical pharmacy activities are the pharmacists in this hospital are performing?
    - a. Take admission medication history ☐
    - b. Attend morning sessions: with MDT ☐
    - c. Attend morning sessions: pharmacist-only ☐
    - d. Conduct chart reviews, at least once/day ☐
    - e. Involve in ward rounds: with MDT ☐
    - f. Make ward rounds: pharmacist-only ☐
    - g. Work at chronic care pharmacy ☐
    - h. Provide drug information services in DIC/DIS ☐
    - i. Provide discharge medication counseling ☐
    - j. Working in ward pharmacies using unit dose system ☐
    - k. Conduct drug use evaluations ☐
    - l. Others, specify:
      _____

15. Is there a system of regularly reporting the clinical pharmacy services to the pharmacy department head or hospital management? 1. Yes ☐   2. No ☐ (if yes, please attach copy of the recent report)

16. Which inpatient wards in the hospital get their medications and supplies from respective/nearby ward pharmacies?
    - a. Medical wards ☐
    - b. Pediatrics ☐
    - c. Surgical ☐
    - d. Gyne-Obs ☐
    - e. Others ☐   Please specify_____

17. If yes to Q 17, does the ward pharmacy functions using unit dose drug dispensing system (UDS)? 1. Yes ☐   2. No ☐
    (if needed, please explain UDS as follows: Medications are contained in single unit packages; they are dispensed as ready-to-administer form as possible; for most medications, not more than a 24-hour supply of doses is dispensed, and a pharmacy-based medication record is maintained).

18. How do you rate the support from the hospital management (CEO or medical director) towards pharmacy service in general and CPS in particular?
    - a. Excellent
    - b. Very good
    - c. Good
    - d. Fair

      e.   Poor

      f.   Very poor

19. What reference materials do you have to provide clinical pharmacy service? (Including internet, CDs, books, journals)? Specify,

_____
_

20. Does your facility have functional DIC/DIS (dedicated pharmacist, dedicated room & adequate resources)?1. Yes ☐ 2. No ☐

(If yes, please go and see the DIC/DIS and check any recent query response or drug alert/newsletter, or other evidence)

21. If yes to Q 22, do you use the DIC/DIS as a source of information for your clinical pharmacy activities? 1. Yes ☐ 2. No ☐

22. Are patient medical charts accessible to the pharmacists in your hospital? 1. Yes ☐ 2. No ☐

23. Are clinical pharmacy service recording and documentation tools available at your hospital?

      a.   Patient medication profile form   1. Yes ☐   2. No ☐

      b.   Clinical pharmacy progress note form   1. Yes ☐   2. No ☐

      c.   Medication reconciliation form   1. Yes ☐   2. No ☐

      d.   Others, if any, specify:

               _____

24. For how many patients does patient medication profile form filled for those getting clinical pharmacy service (services from admission to discharge)?

      a.   100%   ☐

      b.   >75%   ☐

      c.   50-75%   ☐

      d.   25-50%   ☐

      e.   <25%   ☐

25. Are all the above clinical pharmacy service recording and documentation tools part of the patient medical chart?

1. Yes ☐ 2. No ☐ (if yes, please see 3 sample medical charts and check patient medication profile form randomly)

26. Who prints and avails the clinical pharmacy services documentation tools in your facility?

      a.   By the facility system like other tools   ☐

      b.   By the pharmacy department   ☐

      c.   By the clinical pharmacy providers   ☐

      d.   Others,   ☐, Please specify _____

27. How do you rate the level of acceptance/satisfaction of the clinical pharmacy service by managers and other health care professionals?

	Acceptance Rate					
	Excellent	Very good	Good	Fair	Poor	Very poor
Management						
Healthcare providers						
Your level of satisfaction by the service you provide						

28. What is your hospital's strength in relation to clinical pharmacy services which is attributable to?
      a. Professionals (Pharmacists)_____
      b. Existing CP practice and performance _____
      c. Management support and system_____
      d. Premise, facility, and equipment _____
29. What are your hospital's weaknesses in relation to clinical pharmacy services which is attributable to?
      a. Professionals (Pharmacists)_____
      b. Existing CP practice and performance _____
      c. Management support and system_____
      d. Premise, facility, and equipment _____
30. Do you think, your hospital can be a 'model clinical pharmacy service site' which can share best experiences for others?
      a. As it is?   1. Yes ☐   2. No ☐
      b. With minimal support   1. Yes ☐   2. No ☐
      c. Never   1. Yes ☐   2. No ☐

To be filled by the data collectors' team!

What is your recommendation on this hospital to be 'a candidate model clinical pharmacy site' in relation to:

- Existing CP practice and performance   1. Yes ☐2. No ☐

- Physical infrastructure   1. Yes ☐2. No ☐

- Pharmacists professionalism and motivation   1. Yes ☐2. No ☐

- Management support   1. Yes ☐2. No ☐

- **Overall**   1. Yes ☐2. No ☐

Scoring and result
Base on the above qualitative and quantitative findings the result will be reviewed with a team of experts at FMOH then the result will be announced directly to the health facilities via official letter.

Annex 6.2 Monitoring and Evaluation Checklist for Model CPS sites				
Performance and Outcome Indicators	**Checklist**			**Resources**
1. Maintenance of relevant level of competence necessary to perform clinical pharmacy services				
1.1. The presence of relevant drug information **databases, text books and references** pertaining to clinical pharmacy profession: Lexi-comp® or MicroMedex®, MedScape®, Up-to-Date®, Dipiro, Koda-Kimble or other relevant resources	☐ FA	☐ PA	☐ NA	
1.2. The presence of up-to-date national and international guidelines and standard operating procedures including SOP for CPS, SOP for DIS, STGs, Formulary, different guidelines ….	☐ FA	☐ PA	☐ NA	
1.3. Presentation and participation of clinical pharmacy service providers in seminars, case presentations, journal club presentations regularly per month	☐ ≥ 2	☐ 1	☐ No or sparingly	
1.4. Number of in-service trainings given by the facility to clinical pharmacy service providers	☐ ≥ 2	☐ 1	☐ No	
1.5. Local, national or international participations in workshops, conferences or other relevant activities pertaining to clinical pharmacy per annum	☐ ≥ 2	☐ 1	☐ No	
2. Documentation of detailed activities of the clinical pharmacy services				
2.1. The presence of records of pharmaceutical care and clinical intervention formats in all patients' medical charts.	☐ FA	☐ PA	☐ NA	
2.2. Presence of admission medication history practice up on medication (patients with completed medication history by pharmacists within 24 hours of admission or presentation)	☐ >90%	☐ 50–90%	☐ ≤50%	
2.3. Presence of medication reconciliation practice (patients with competed medication reconciliation by a pharmacist on presentation, transfer or discharge)	☐ > 90%	☐ 50–90%	☐ ≤ 50%	
2.4. patients that received appropriate verbal counseling and/or written information about their medicines during discharge (discharge medication counseling)	☐ > 90%	☐ 50–90%	☐ ≤ 50%	
2.4.1. Percentage of patients receiving discharge medicines who also receive medicines information	☐ > 90%	☐ 50–90%	☐ ≤ 50%	
2.5. The presence of a clear, complete and quality follow-up plan in all patients' medical charts	☐ > 90%	☐ 50–90%	☐ ≤ 50%	
2.5.1. Percentage of discharge summaries that document an accurate medicines list and the reasons for all medication therapy changes from medications taken prior to admission	☐ >90%	☐ 50–90%	☐ ≤ 50%	
2.5.2. Satisfaction of key stakeholders	☐ >90%	☐ 50–90%	☐ ≤ 50%	
3. Criterion 3: Intra and inter-collaboration work with patients and other healthcare providers				
3.1. Percentage of clinical pharmacists regularly participating in MDT rounds	☐ > 90%	☐ 50–90%	☐ ≤ 50%	

3.1.1. Communication with prescribers about actual or potential drug-related problems when appropriate				
3.1.2. Prompt communication with the appropriate healthcare provider according to the severity of the drug-related problem				
3.2. Percentage of clinical pharmacists regularly participating in morning sessions	☐ >90%	☐ 50–90%	☐ ≤ 50%	
3.3. Percentage of clinical pharmacists regularly participating in pharmacy only rounds (at least two per weeks)	☐ >90%	☐ 50–90%	☐ ≤ 50%	
3.4. Percentage of clinical pharmacists regularly participating case presentations	☐ >90%	☐ 50–90%	☐ ≤ 50%	
4. Criterion 4: Participation in problem-identifying and problem-solving researches				
4.1. Number of ongoing study, research papers or published articles (operational, outcome based) related to **drug use evaluation studies, prescription monitoring, patient satisfaction,** in the hospital setting per clinical pharmacy department/unit per annum	☐ ≥ 2	☐ 1	☐ No	
5. Criterion 5: Professionals and premises				
5.1. The presence of full-time competent and adequate professionals as per the standard	☐ FA	☐ PA	☐ NA	
5.2. The presence of a continuum clinical pharmacy service (24/7)	☐ FA	☐ PA	☐ NA	
5.3. The presence of functional and well-equipped drug information center as per SOP	☐ FA	☐ PA	☐ NA	
5.4. The presence of adequate offices and resources for clinical pharmacy staff as per this manual.	☐ FA	☐ PA	☐ NA	
5.5. The presence of adequate recognition mechanism[2] for clinical pharmacy staff	☐ FA	☐ PA	☐ NA	
6. Criterion 6: Maintenance of a system to monitor and evaluate the CPS performed to enable continuous quality improvement				
6.1. The presence of a system to evaluate clinical pharmacy service at regular intervals for quality assurance purposes	☐ FA	☐ PA	☐ NA	
6.2. The presence of a system to identify trends and takes action to minimize potential drug-related problems	☐ FA	☐ PA	☐ NA	
6.3. The presence of a support from all concerned management officials	☐ FA	☐ PA	☐ NA	
6.4. The presence of a system for utilizing benchmark and peer review measures and patient feedback, where available, to evaluate performance	☐ FA	☐ PA	☐ NA	

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[2]Recognition: Acknowledgment, compensation, duty, scholarships, trainings

Annex 10.1: Implementation plan of clinical pharmacy services in Ethiopia

Implementation plan of clinical pharmacy service in Ethiopia						
Strategic Objective	**Activities**	**Performance measures**	**Timeline**	**Responsible body**	**Resources**	**Remark**
Implement standardized and uniform clinical pharmacy practice model in health facilities	• Development of a pharmaceutical care model • Development of CPS Implementation manual • Implementation of a standardized and uniform clinical pharmacy practice	• Standardize CPS model and implementation manual implemented • Implementation of CPS in all hospital of the country	By the end of 2018 (for the model and the manual) and 2020 (for the practice)	• FMOH • RHB • EPA • Partners • FMHACA • Hospital management	USD 100,000	
Design and implement structure for CPS providers appropriate to the level of facility	• Integrate clinical pharmacy with the other clinical teams and structures of the health facilities • Strengthen a clinical pharmacy unit • Establish a clear chain of leadership for clinical pharmacists	• Presence of a clear and uniform structure, line of communication and leadership at primary, secondary and tertiary hospitals • CPS is integrated with another clinical team • CPS is visible in facility	By the end of 2020	• FMOH • RHB • EPA • Partners • FMHACA • Hospital management	USD 20,000	
Set distinctive and integrated roles for CPS providers to effectively give responsibility as well as accountability for the CPS	• Establish a clear and uniform national job description for clinical pharmacists • Develop a trusting relationship between CPS providers with patients and other healthcare professionals • Create a system of ownership and accountability • Provide and document CPS to all patients 24/7 • Provision of risk allowance and clinical allowance payments	• Presence of 24/7 CPS • Presence of a clear, complete and quality pharmaceutical care plan and records of clinical interventions in all patients' medical charts • Percentage of clinical pharmacists regularly participating in ward rounds and morning, seminar, etc. • economic, clinical and humanistic outcome of CPS	By the end of 2020 and then every year afterwards	• FMOH • RHB • EPA • FMHACA • Hospital management	USD 40,000	

		• risk and clinical allowance for CPS providers			
Develop competent, adequate, and ethical clinical pharmacy professionals	• Development of adequate, competent, professionally disciplined, and accountable clinical pharmacy professionals thorough supporting pre-service education providing in service training and properly implementing code of ethics.	• Presence of adequate, competent, professionally disciplined, and accountable clinical pharmacy professionals for all hospitals of the country	By the end of 2020	• FMOE • FMOH • EPA • HERQA • RHB • Partners	USD 2,000,000
Perform communication, Advocacy and Promotion of CPS	• Development of evidence-based guideline • Communication and dissemination of the value of clinical pharmacists • Expansion and scale up of clinical pharmacy practice • Disseminate the result of health and economic impact assessment of CPS • Organize consultative meeting with higher officials and stakeholder	• Results of the economic, clinical and humanistic outcome of CPS disseminated • clinical pharmacy forum is organized regionally and nationally with different stakeholders • different evidence-based guidelines/protocols prepared	By the end of 2020 and then every year afterwards	• EPA • Clinical pharmacists • FMOH • FMHACA • Hospital management • RHB • Partners	USD 40,000
Design and Implement a dynamic Monitoring and Evaluation System for CPS	• Recording, reporting and documenting all clinical pharmacy activities • Audit clinical pharmacy activities • Conduct mentoring and supportive supervision.	• Presence of a clear, complete and quality pharmaceutical care plan and records of clinical interventions in all patients' medical charts • mentoring and supportive supervision conducted • regular CPS report generated	By the end of 2020 and then every year afterwards	• FMOH • RHB • Hospital management • Partners	USD 80,000