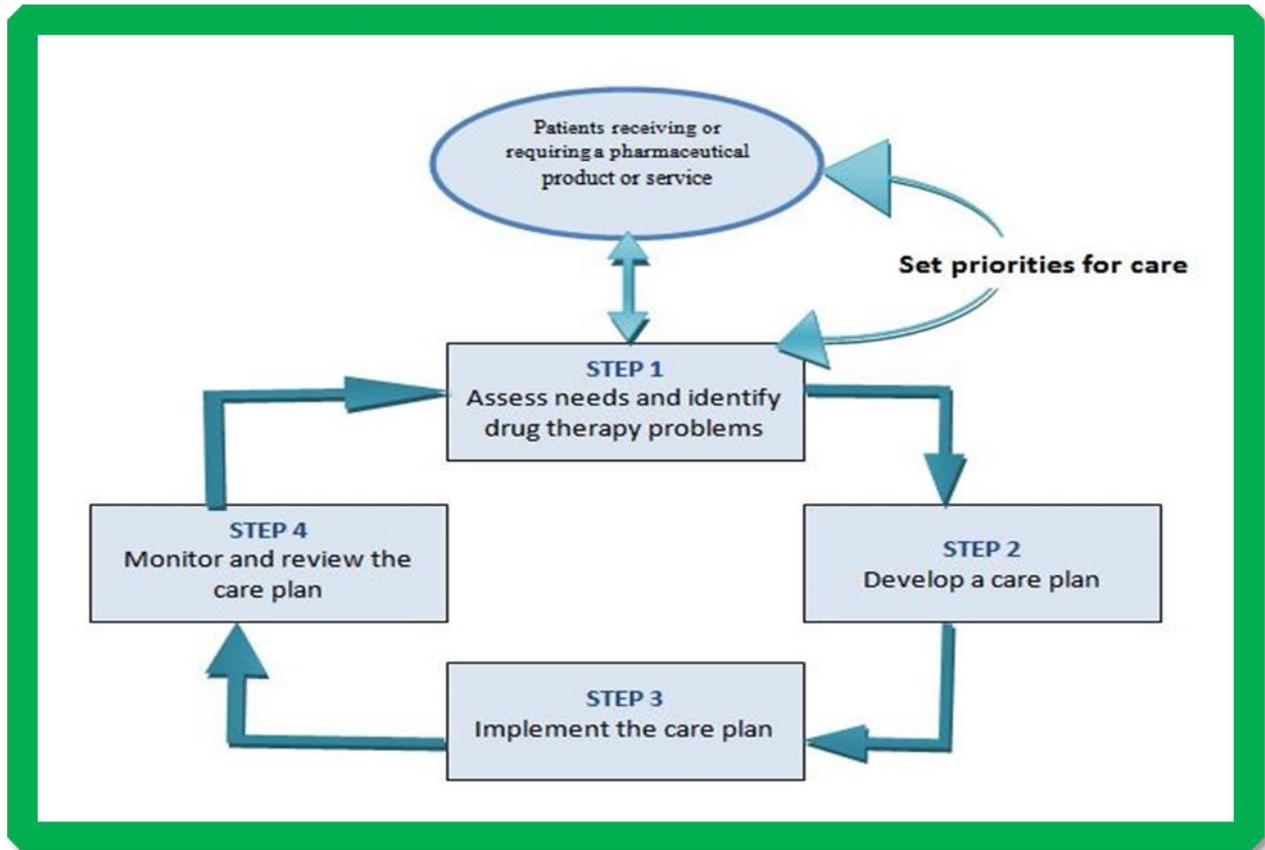


Standard Operating Procedures Manual for the Provision of Clinical Pharmacy Services in Ethiopia



Pharmaceuticals Fund and Supply Agency in collaboration with the US Agency for International Development's Systems for Improved Access to Pharmaceuticals and Services Program

January 2015

Addis Ababa, Ethiopia



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Improved Access. Improved Services.
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FOREWORD

The direct involvement of pharmacists in patient care (clinical pharmacy services) is a key intervention to optimize the outcomes of medicine therapy, thereby improving the quality of patient care. The Pharmaceuticals Fund and Supply Agency (PFSA) has been collaborating in efforts to implement clinical pharmacy services in the Ethiopian health care system. As part of the efforts, the preparation of a guiding document to standardize clinical pharmacy services provided by health facilities was determined to be necessary.

It gives me great pleasure to introduce the first edition of the *Standard Operating Procedures Manual for the Provision of Clinical Pharmacy Services in Ethiopia*. This manual will contribute greatly to the standardization of the provision of clinical pharmacy services in the country.

The manual contains step-by-step procedures for the provision of clinical pharmacy services for inpatients, along with the necessary documentation and reporting. After the draft was developed, the manual was reviewed and enriched by relevant experts from universities and hospitals that are actively involved in pharmacy education and the provision of services, respectively. The draft was also reviewed by senior experts from the US headquarters of Systems for Improved Access to Pharmaceuticals and Services (SIAPS). Health facilities should strive to set up services using the guidelines in this manual. Pharmacists providing clinical pharmacy services are expected to follow the standard operating procedures (SOP) strictly to ensure the provision of quality patient care. They are also expected to document and report services provided. Moreover, health system managers at various levels should provide the necessary support and follow up to ensure the provision of services according to the SOPs.

It is my belief that practicing pharmacists, pharmacy students, health system managers, academicians, researchers and experts involved in education, mentoring, and supportive supervision of pharmaceutical services at the health facility level will find this manual useful. It will undoubtedly be helpful for service provision, management, education, research, and monitoring and evaluation purposes in relation to clinical pharmacy services.

I would like to take this opportunity to thank all members of the team and institutions for their valuable contributions to the development of the manual. I would also like to ask all concerned stakeholders to forward comments on the SOPs to the Agency at the following address:

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Meskele Lera



Director General, Pharmaceuticals Fund and Supply Agency (PFSA)

ACKNOWLEDGMENTS

This SOPs manual was developed with technical and financial support from the SIAPS Project funded by the US Agency for International Development (USAID; cooperative agreement number AID-OAA-A-11-00021). The PFSA would like to acknowledge this technical and financial support. The Agency would also like to extend its appreciation to the following individuals who were actively involved in the development of the SOPs manual:

1. Biyansa Negera–PFSA (Pharmacist)
2. Haileyesus Wossen–PFSA (Pharmacist)
3. Kalkidan Endeshaw–PFSA (Pharmacist)
4. Mahlet Tibebu–PFSA (Pharmacist)
5. Robera Bogale–PFSA (Pharmacist)
6. Seblework T/Haimanot–PFSA(Pharmacist)
7. Siraj Adem–PFSA (Pharmacist)
8. Tayachew Shasho–PFSA (Pharmacist)
9. Tinsae Yigletu–PFSA (Pharmacist)
10. Fikru Worku–SIAPS-PFSA (Pharmacist)
11. Elias Geremew–SIAPS (Pharmacist)

We would also like to acknowledge the following individuals and organizations for actively participating in the workshop that was organized to review the draft SOPs manual.

1. Addisalem Geremew–ALERT Specialized Hospital (Pharmacist)
2. Addisu Getie–Debreworkos Referral Hospital (Pharmacist)
3. Elias Geremew–SIAPS (Pharmacist)
4. Fikru Worku–SIAPS-PFSA (Pharmacist)
5. Haftay Berhane–School of Pharmacy, Mekele University (Clinical Pharmacist)
6. Haileyesus Wossen–PFSA(Pharmacist)
7. Kalkidan Endeshaw–PFSA(Pharmacist)
8. Mahlet Tibebu–PFSA(Pharmacist)
9. Mamo Feyissa–School of Pharmacy, Addis Ababa University (Clinical Pharmacist)
10. Minaleshewa Biruk–School of Pharmacy, Gondar University (Clinical Pharmacist)
11. Seada Abrar–Nigist Elleni Mohammed Memorial Hospital (Pharmacist)
12. Sileshi Tesfaye–Ambo Hospital (Pharmacist)
13. Tesfahun Chanie–School of Pharmacy, Jimma University (Clinical Pharmacist)

Finally, the Agency would like to express its appreciation to Mohan Joshi and Shiou-Chu Wang from SIAPS headquarters for their critical review of the document. We would also like to thank Yared Yigezu from PFSA and Hailu Tadeg, Edmealem Ejigu, and Mark Morris from SIAPS for their coordination role and insight.

Recommended citation

PFSA and SIAPS. *Standard Operating Procedures Manual for the Provision of Clinical Pharmacy Services in Ethiopia*, January 2015, Addis Ababa.

ACRONYMS

| | |
|--------|---|
| ADE | adverse drug event |
| ADR | adverse drug reaction |
| BSA | body surface area |
| CCO | chief clinical officer |
| CEO | chief executive officer |
| DTC | Drug and Therapeutics Committee |
| DTP | drug therapy problem |
| EHRIG | Ethiopian Hospital Reform Implementation Guidelines |
| ESA | Ethiopian Standards Authority |
| FIP | International Pharmaceutical Federation |
| FMHACA | Food, Medicine and Health Care Administration and Control Authority |
| FMOH | Federal Ministry of Health |
| MDT | multidisciplinary team |
| OTC | over-the-counter |
| PCP | pharmaceutical care plan |
| PFSA | Pharmaceuticals Fund and Supply Agency |
| POM | pharmacy only morning session |
| POR | pharmacy only round |
| RHB | Regional Health Bureau |
| SIAPS | Systems for Improved Access to Pharmaceuticals and Services |
| SOP | standard operating procedure |
| USAID | US Agency for International Development |
| ZHD | Zonal Health Department |

1. INTRODUCTION

1.1 Background

The American College of Clinical Pharmacy 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 International Pharmaceutical Federation (FIP) defines *pharmaceutical care* as the responsible provision of pharmacotherapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life. Clinical pharmacy blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes.

Over the past four decades, 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; launching of the clinical pharmacy postgraduate program at Jimma University and pharmacy practice postgraduate program at Addis Ababa University; inclusion of clinical pharmacy services in the Pharmacy Section of the Ethiopian Hospital Reform Implementation Guidelines (EHRIG) by the Federal Ministry of Health (FMOH) in 2010 and in the health facilities minimum regulatory standards by the Ethiopian Standards Authority (ESA)/Ethiopian Food, Medicines and Health Care Administration and Control Authority (FMHACA) in 2012.

According to the Minimum Standards for Hospitals and EHRIG, all hospitals are expected to provide clinical pharmacy services as part of their pharmaceutical services. The EHRIG states that clinical pharmacy services are patient-oriented services developed to promote the rational use of medicines, and more specifically, to maximize therapeutic benefits (optimize treatment outcomes), minimize risk, reduce cost, and support patient choice and decisions, thereby ensuring the safe, effective, and economic use of medicine treatment in individual patients. EHRIG expects pharmacists to carry out the following functions:

- Provide advice to doctors, nurses, and other health care workers on the clinical use of medicines, economic medicine use, and safety.
- Offer direct patient care services through, for example, medication history-taking, medicines education, and advice.

- Offer hospital managers, including clinical managers, appropriate advice and support to enable them to make informed decisions with respect to medicines policy, procedures, and guidelines designed to ensure safety, effectiveness, and economy in medicine use.

To implement the EHRIG and minimum regulatory standards with regard to 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 been implementing short-term clinical pharmacy training for hospital pharmacists to initiate clinical pharmacy services in the Ethiopian health care system. A total of 200 pharmacists from 66 hospitals have received training to date. It is believed that these trainees have paved the way for the establishment of clinical pharmaceutical services in the country.

Schools of pharmacy in Ethiopia have changed their curricula from being product-focused to being patient-oriented, with the inclusion of a one-year clerkship as well as many clinical courses. The first two batches of students taught under the new curriculum have graduated. Most of the new pharmacists are assigned to public hospitals thereby strengthening the service provision.

As a result of these efforts, many hospitals are currently providing clinical pharmacy services, which is a new development in the practice of health care in the country. However, the services are not being provided in a standardized and uniform manner. Therefore, this standard operating procedures (SOP) manual has been developed to standardize and formalize the provision of clinical pharmacy services in the country. SOPs on how to provide clinical pharmacy services for inpatients, and to document and report the services provided are addressed in this manual. The terms *clinical pharmacy services* and *pharmaceutical care* are used interchangeably in this manual.

1.2. Scope of the Manual

This SOPs manual describes the specific steps pharmacists providing clinical pharmacy services to inpatients in Ethiopia should follow. It contains SOPs for the provision of clinical pharmacy services at the inpatient level, with the necessary documentation and reporting systems.

1.3. Purpose of the Manual

This manual describes specific procedures in pharmaceutical care practice. It should be used as a hands-on reference for pharmacists providing clinical pharmacy services, thereby helping to standardize the practice in all hospitals, with the ultimate goal of optimizing patient care. The manual may also be used as a reference for health system managers, policymakers, health care providers, academicians, researchers, and pharmacy students.

1.4. Objectives of the Manual

General Objective

The general objective of these clinical pharmacy SOPs is to standardize the provision of clinical pharmacy services, thereby optimizing patient outcomes by ensuring the rational use of medicines.

Specific Objectives

- Ensure that standardized clinical pharmacy services are provided in all hospitals and at all times.
- Clarify roles and responsibilities of pharmacists providing pharmaceutical care.
- Provide a detailed description of how to perform clinical pharmacy activities.
- Serve as a source of guidance for new employees.
- Improve the standards for clinical pharmacy services on a continual basis.
- Provide evidence of commitment to improvements in the quality of patient care.

2. THE PHARMACEUTICAL CARE PROCESS

The delivery of effective pharmaceutical care to patients requires pharmacists to practice in a way that uses their time effectively and reflects their responsibility and accountability. The systematic approach to the delivery of pharmaceutical care involves the following four steps, as depicted in figure 1.

- Step 1: Assess the patient's medicine therapy needs and identify actual and potential drug therapy problems (DTP)
- Step 2: Develop a care plan to resolve and/or prevent the DTPs
- Step 3: Implement the care plan
- Step 4: Evaluate and review the care plan

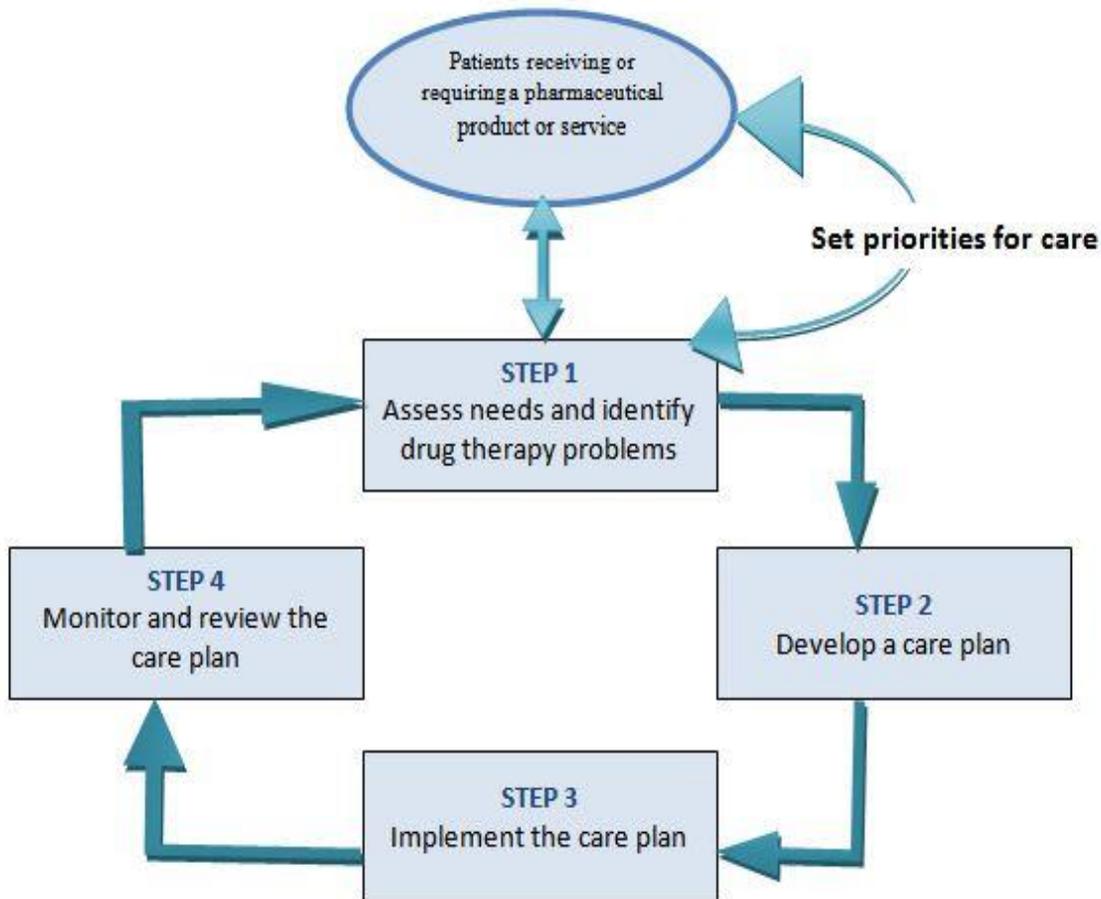


Figure 1. Systematic approach to the delivery of pharmaceutical care

Step 1: Assess the patient’s medicine therapy needs and identify actual and potential drug therapy problems

Good communication needs to be established with the patient, caregiver, and other members of the health care team at the outset in order for pharmacists to collect, synthesize, and interpret relevant information. When pharmacists assess patients, they should take into account all patient and medication factors that may predispose patients to the risk of DTPs. The assessment process involves talking to patients, caregivers, or representatives, and consulting other members of the health care team, as well as reviewing patient medication and clinical records. DTPs are identified by analyzing sociological, pathophysiological, and pharmacological knowledge of the patient, disease, and medicine therapy information collected.

A **DTP** is any undesirable event experienced by a patient, which involves or is suspected to involve, medicine therapy, and which interferes with the achievement of the desired goals of therapy. A DTP is a clinical problem, and it should be identified and resolved in a manner similar to other clinical problems. It should be emphasized here that the most important role of the pharmacist is to *prevent* DTPs from occurring. This is the most valuable service a pharmacist can provide to his/her patient.

All patient problems involving medications may be categorized into one of seven types of DTPs. They include any and all side effects, toxic reactions, treatment failures, or the need for additive, synergistic, or preventive medications, as well as noncompliance. The seven categories of DTPs are described in table 1.

Note that the first two categories of DTPs are associated with the INDICATION. The third and fourth categories of DTPs are associated with EFFECTIVENESS. The fifth and sixth categories of DTPs are associated with SAFETY. The seventh category deals with patient COMPLIANCE. As with most clinical problems, DTPs cannot be resolved or prevented unless the cause of the problem is clearly understood. It is necessary to identify and categorize not only the DTP, but also its most likely cause. Only then can the pharmacist proceed with confidence to its resolution or prevention.

Table 1. Categories and Common Causes of Drug Therapy Problems

| Assessment | Drug Therapy Problem | Causes |
|------------|-----------------------------------|---|
| Indication | Unnecessary medicine therapy | No valid medication indication for the medicine at this time |
| | | Multiple medicine products are used when only a single medicine therapy is required |
| | | The condition is better treated with non-medicine therapy |
| | | Medicine therapy is used to treat an avoidable adverse drug reaction (ADR) associated with another medication |
| | Needs additional medicine therapy | The medical problem is caused by drug abuse, alcohol use, or smoking |
| | | A medical condition exists that requires the initiation of new medicine therapy |
| | | Preventive therapy is needed to reduce the risk of developing a new condition |

| Assessment | Drug Therapy Problem | Causes |
|-----------------------------|------------------------------|---|
| Effectiveness | Ineffective medicine | A medical condition requires combination therapy to achieve synergism or additive effects |
| | | The medicine is not the most effective one for treating the medical condition |
| | | The medication is not effective for the medical condition |
| | | The condition is refractory to the medication being used |
| | | The dosage form is inappropriate |
| | | The dose is too low to give the desired outcome |
| | | The dosage interval is too infrequent |
| | | The duration of therapy is too short |
| | | A medicine interaction reduces the amount of active drug available |
| | | The medication causes an undesirable reaction that is not dose-related |
| Safety | Adverse drug reaction | A safer medicine is needed because of patient risk factors |
| | | A medicine interaction causes an undesirable reaction |
| | | The regimen was administered or changed too rapidly |
| | | The product causes an allergic reaction |
| | | The medicine is contraindicated because of patient risk factors |
| | Dosage too high | The dose is too high for the patient |
| | | The dosing frequency is too short |
| | | The duration of therapy is too long |
| | | A medicine interaction causes a toxic reaction to the medication |
| | | The dose was administered too rapidly |
| Compliance/adherence | Noncompliance | The patient does not understand the instructions |
| | | The patient prefers not to take the medication |
| | | The patient forgets to take the medication |
| | | The medication is too expensive |
| | | The patient cannot swallow or self-administer the medication properly |
| | | The medication is not available to the patient |

Although the focus is on DTPs, the process allows for the identification of disease-related problems as the therapeutic approach is verified and validated. In addition, opportunities for health promotion and preventive health care are identified.

Step 2: Develop a care plan to resolve and/or prevent drug therapy problems

Prioritize Drug Therapy Problems

Once identified (Step 1), DTPs should be prioritized within the context of the overall clinical management of the patient.

Identify Desired Therapeutic Objectives and Proposed Actions

A statement should be made of what the pharmacist intends to achieve for a patient in relation to each DTP. The statement should be agreed upon with the patient and the health care team. The therapeutic objectives should be expressed as measurable outcomes to be achieved within a

defined time frame. In deciding on the most appropriate actions, it is vital that the pharmacist confirms the acceptability of the actions with the patient. If a number of options exist, the patient should be given sufficient information to select the most appropriate option.

Develop a Monitoring Strategy

A monitoring strategy should be developed to measure progress in the achievement of the therapeutic objectives. The strategy should be agreed upon with the patient and other members of the health care team, and should be undertaken at specified intervals and for a defined period of time prior to further review.

Document the Care Plan

The pharmacist's record of DTPs and therapeutic objectives, together with the proposed actions, form a documented pharmaceutical care plan. Good documentation facilitates continuity of care and clinical audit.

Step 3: Implement the Care Plan

The pharmaceutical care plan is implemented with the agreement of the patient and within the context of the overall care of the patient, in cooperation with other members of the health care team.

Step 4: Evaluate and Review the Care Plan

Actual outcomes are evaluated in relation to the therapeutic objectives to determine whether the DTPs have been resolved. If the expected outcomes have not been achieved, the care plan should be reviewed. The actual outcomes may then be accepted as being the best achievable for the patient, or an alternative plan may be necessary. The plan should be modified as the original DTPs resolve and if any new DTPs requiring resolution appear.

Pharmacists should follow the aforementioned step-by-step process to provide pharmaceutical care to patients.

3. STANDARD OPERATING PROCEDURES

These SOPs cover the procedures to be followed when providing clinical pharmacy services to inpatients. They include: assessment; development and implementation of a pharmaceutical care plan; follow up, monitoring and evaluation; discharge planning and counseling; multidisciplinary team activities; and pharmacy-led care planning sessions.

The pharmacist providing clinical pharmacy services for inpatients should start providing the services as soon as the patient is admitted so that he/she can support the prescriber in the selection of medicines for individual patients.

3.1 Assessment

Introduction

The purpose of assessment is to determine if the patient's medicine-related needs are being met and if any actual or potential DTPs are present. This includes collecting, analyzing, and interpreting information about the patient, the patient's medical condition, and the patient's medicine therapies.

Objective

The objective of assessment is to determine the patient's medication needs by obtaining information on the patient's conditions and medications.

3.1.1. Collection of Patient-Specific Information

Introduction

Collecting, organizing, and integrating pertinent patient, medicine, and disease information are important to identify the patient's medicine-related needs and medicine-related problems, which is the first step in the assessment of the patient.

Objective

To obtain relevant patient-specific information that may assist in overall decision making regarding medicine therapy and patient care.

Procedures

- 1) Establish the identity of the patient by ward/bed number, name, gender, and age.
- 2) Review the patient's medical chart before visiting the patient.

- 3) Have the *Inpatient Medication Profile Form (Form 1)* and *Medication Reconciliation Form (Form 3)* ready, and record all relevant information on the appropriate form according to the instructions provided in this manual on how to complete each form.
- 4) Introduce yourself.
- 5) Establish rapport with (or greet) the patient/caregiver.
- 6) Determine the ability of the patient to communicate appropriately (cognition, alertness, mental acuity, age, frailty, psychological state, social circumstances); if the patient is unable to communicate, contact the caregiver.
- 7) Explain the purpose of the interview.
- 8) Respect the patient's right to decline an interview.
- 9) If the patient or caregiver accepts the interview, make the environment suitable for the interview to allow for privacy and confidentiality for the patient and minimize the risk of interruption and distraction.
- 10) Adopt a physical position that allows the interview to take place comfortably and effectively.
- 11) In the event that the patient is not involved in the administration and management of his/her medicine, the interview should be continued with the relevant person(s), e.g., relative or caregiver, after obtaining consent from the patient, if possible.
- 12) Employ an appropriate interview manner, e.g., avoid appearing rushed, be polite, attentive, maintain eye contact, avoid interrupting the patient, be non-judgmental, and communicate clearly and effectively.
- 13) Collect patient-specific data. The following information should be obtained and reviewed:
 - a) Patient demographic data
 - b) Past medical history
 - c) Past medication history, including prescribed medicines, over-the-counter (OTC) medicines, and herbal medicines history. Assess the medication experience of the patient. Note whether the data collected needs attention during the development of the care plan (medication taking behavior, understanding, concern, belief, etc.).
 - d) Immunization status
 - e) History of ADRs, including medication allergy histories and history of past ADRs
 - f) Family history, social and illicit drug use, alcohol and smoking history, and food or diet preference or habit
 - g) Transfer/referral letter from other institutions or any document that shows the patient's past medication history, such as the *Medication Information Record (Form 4)*, if available
 - h) Current diagnosis

- i) Relevant diagnostic parameters (laboratory tests, X-ray, ultrasound, etc.)
- j) Current medication use, including prescribed medicines, OTC medicines, and herbal medicines
- k) Any other relevant information and the patient's special needs

14) After collecting patient-specific data:

- a) Summarize the important patient information
- b) Ask the patient if he/she has any questions concerning his/her medicines
- c) Encourage the patient to provide further information, which may be remembered following the interview
- d) Inform the patient that a pharmaceutical care plan will be developed and when the next discussion with a pharmacist will be

3.1.2 Identification of drug therapy problems

Introduction

A DTP is any undesirable event experienced, or with a potential to be experienced, by a patient that involves, or is suspected to involve, medicine therapy, and that interferes with the achievement of the desired goals of therapy and requires professional judgment to resolve. The identification of a DTP is the focus of the assessment made in this step of the patient care process. Although DTP identification is technically part of the assessment process, it represents the truly unique contribution made by pharmacists providing pharmaceutical care.

Objective

To identify actual and potential DTPs.

Procedure

- 1) Analyze the data that have been collected to assess whether the medicine-related needs of the patient have been met or not.
 - a) Evaluate whether all of the patient's medications are: appropriately indicated; the most effective available; the safest possible; and if the patient is able and willing to take the medication as intended to rule out some medication problems.
 - b) With other members of the health care team, assess the appropriateness of the current medications on the basis of health conditions, indications, and the therapeutic goals of each medication.
 - c) Evaluate the effectiveness, safety, and affordability of each medication.
 - d) Evaluate medication-taking behaviors and adherence to each medication.
- 2) Check whether the medicine order is comprehensive and unambiguous, that appropriate terminology is used, and that medicine names are not abbreviated.

- 3) Look for any non-formulary medicine orders.
- 4) Detect actual and potential DTPs.
- 5) Record and document any identified DTPs on the *Inpatient Medication Profile Form (Form 1)* and report the identified adverse drug event (ADE) to the ADR focal person using the FMHACA “yellow form” (Adverse Drug Event Reporting Form in annex A).

3.2 Development and Implementation of a Pharmaceutical Care Plan

Introduction

The care plan contains specific actions to achieve the pharmacotherapy needs and address problems of a specific patient.

Objective

To set goals according to the patient’s medical condition and to intervene at the right time, if necessary.

3.2.1 Goals of Therapy

Introduction

The goals of therapy are the ultimate result expected at the end of the therapeutic period.

Objective

To optimize a patient’s medical condition within a given time frame.

Procedures

- 1) Identify the overall goals of therapy for an individual patient.
- 2) Establish the goals of therapy for each indication of medicine therapy based on clinical and laboratory parameters.
- 3) Discuss the goals of therapy with both the patient and the health care team.
- 4) Make realistic goals of therapy appropriate to the patient’s present and potential capabilities, available resources, and within an achievable time frame.
- 5) Based on the agreed goals of therapy, prepare a pharmaceutical care plan (PCP) that addresses the medicine therapy needs and prioritized DTPs, according to the patient’s disease condition, age, co-morbidity, renal and liver functions, pregnancy status, etc., in

collaboration with other health care professionals to optimize the patient's health outcomes. The PCP should include follow up, monitoring, and evaluation components.

3.2.2 Intervention/Implementation

Introduction

Interventions are specific actions that are taken in accordance with the PCP to resolve DTPs, to optimize the patient's medication needs, and to prevent potential DTPs.

Objective

To implement measures to resolve or prevent identified DTPs to achieve the goals of therapy for the patient's medical condition.

Procedures

- 1) Share the patient's PCP with the health care team.
- 2) Reconcile the medications the patient has been taking with the ones about to be ordered.
- 3) Make the intervention individualized to each patient, as stated in the goals of therapy:
 - a) Interventions to resolve DTPs.
 - b) Interventions to achieve the goals of therapy.
 - c) Interventions to prevent potential DTPs.
- 4) With the prescriber, discuss the selection of appropriate and cost-effective medicines for each patient based on updated Standard Treatment Protocols.
- 5) Check whether the medicine order is written in accordance with legal prescribing requirements and restrictions, and provide advice to the prescriber on corrections, if necessary.
- 6) Discuss patient-specific recommendations with the physician.
- 7) Perform calculations for dosage adjustments, aid in the reconstitution for parenteral preparations, and follow-up on the stability after reconstitution.
- 8) Provide key medication care information to the nurses taking care of the patient, and encourage the nurses to report any ADEs identified.
- 9) Provide patient education and counseling.
- 10) Document the interventions made on the *Inpatient Medication Profile Form (Form 1)* and *Medication Reconciliation Form (Form 3)*.

3.3 Follow Up, Monitoring, and Evaluation

Introduction

In this step, the actual results and outcomes from medicine therapies are observed, continually monitored, evaluated, and documented.

Objective

To continually re-evaluate and modify therapeutic goals with changing patient conditions and responses to therapy.

Procedures

- 1) Ask the patient/caregiver about the patient's health status or progress.
- 2) Acknowledge the patient and the caregiver if improvements are reported or observed.
- 3) Review the patient's medical record in conjunction with the patient's clinical progress note.
- 4) Evaluate the patient's outcomes, determine the patient's progress toward the achievement of the goals of therapy, determine whether any safety or adherence issues are present, and assess whether any new DTPs have developed.
- 5) Take into account recent consultations, pathology results and investigations, treatment plans, and daily progress when determining the appropriateness of current medicine orders and when planning patient care.
- 6) Check that the medicine order is written in accordance with legal and local prescribing requirements and restrictions.
- 7) Review all recent medicine orders and medication administration records. The medicine orders may include routine medicine orders, variable dose medicines, intravenous therapy, single dose medicines, anesthetic and operative records, epidural medicine or other analgesics (i.e., all records of medicines, fluids, or procedures affecting the patient, such as diet/feeding orders).
- 8) After going through the checklist below, document the interventions, treatment progress, and patient status on the patient progress note using Form 2.

Checklist for follow up:

- 1) Check whether all necessary medicines are ordered and available.
- 2) Ensure the patient's access to the medications ordered.

- 3) Check whether the medicine order is in accordance with patient's previous medicines, patient-specific considerations, e.g., disease state, pregnancy, medicine dosage and dosage schedule, especially with respect to age, renal function, liver function, dosage form and method of administration, and medication duplications.
- 4) Check the medication administration record to ensure that all doses ordered have been administered.
- 5) Check whether administration times are appropriate, e.g., with respect to food, other medicines, and procedures.
- 6) Review whether infusion solution is used with regard to concentrations, compatibilities, rate, and clinical targets, e.g., blood sugar levels, and blood pressure.
- 7) Make sure that the medicine administration order clearly indicates the date and time at which medicine administration is to commence.
- 8) Make sure that the duration of administration of medicine is appropriate. Specific consideration should be given to medications commonly used in short courses, e.g., antibiotics, and analgesics.
- 9) Ensure that the detected actual or potential DTPs are resolved.
- 10) Check that the order is cancelled in all sections of the medication administration record when medicine therapy is intended to cease.
- 11) Evaluate the adherence of the patient to the treatment being given.
- 12) Monitor and evaluate whether the overall medication therapy management is being implemented as planned.

3.4 Discharge Planning and Counseling

Introduction

Discharge planning is the process by which the patient is assisted to develop a plan of care for ongoing maintenance and improvement of health care, even after he or she is discharged from the hospital. Discharge planning usually involves notifying patients of their next physician's appointment and explaining medication schedules. Pharmacists should be actively involved in discharge planning and provide the necessary medication information (verbal and written) to the patient.

Objective

To ensure continuity of care through pharmacist involvement in decision making about a patient's discharge medication and provision of medication information counseling.

Procedure

- 1) Review the patient's medical chart and medication forms used throughout the care process.
- 2) Be actively involved with the health care team during discharge decisions.
- 3) Reconcile the medications the patient has been taking with the ones to be ordered for discharge and record them on the *Medication Reconciliation Form (Form 3)*.
- 4) Work with the attending physician in the selection of discharge medications.
- 5) Check for any signs of patient non-adherence and take corrective actions.
- 6) Complete the *Medication Information Record (Form 4)* and provide it to the patient or caregiver. Inform the patient or caregiver that he/she should present the form when visiting health care providers in the future.
- 7) Verbal information should be given to patients (and/or caregivers) about their medicines.
 - a) Provide verbal information to the patient or caregiver on the appropriate use of the discharge medications.
 - b) Give information about the medicines in a way that the patient/caregiver can understand and before the patient is discharged.
 - c) Check whether the patient has understood the information given and provide answers/explanations if he/she has questions.
- 8) Encourage the patient or caregiver to seek information from the facility if he/she encounters medicine-related problems, and advise who to contact if he/she needs more information about the medicines, who will prescribe continuing treatment, and how to access further supplies.
- 9) Document the discharge medications and counseling provided to the patient on the *Inpatient Medication Profile Form (Form 1)* and update the *Pharmaceutical Care Progress Note Recording Sheet (Form 2)*.

3.5 Pharmacy Only Rounds and Morning Sessions

Introduction

A pharmacy only ward round is a visit made by a group of pharmacists to hospital inpatients to review and follow up their progress in achieving the goals of therapy. Pharmacy only morning sessions (POMS) are organized to discuss selected patient cases and to get updated information on patient management. Pharmacy only rounds (POR) and 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 rounds and morning sessions that should be conducted per week.

Objectives

- To exchange information on pharmacology, pharmacokinetics, and other aspects of medicine therapy.
- To optimize therapeutic management by influencing medicine therapy selection, implementation, monitoring, and follow up.

Procedures

3.5.1 Pharmacy Only Morning Session Activity

- 1) Conduct POMS in a scheduled manner.
- 2) Select a case suitable for discussion in pharmacy only meetings.
- 3) The POM should be conducted in a way that assures the sharing of knowledge and experience.
- 4) Prepare a comprehensive presentation that includes the patient history, assessment, pharmacotherapy, DTP identified, and intervention.
- 5) Focus the discussion on the current case intervention.
- 6) Discuss the appropriateness of the current or alternate medication/ doses and nutritional changes.
- 7) Interface with pharmacy staff regarding unusual medication orders, patient issues, and non-formulary needs.

3.5.2 Pharmacy Only Round Activities

- 1) Review medication history and assess the current medication management of all patients prior to the POR.
- 2) Identify patients and cases to be discussed in the POR.
- 3) The responsible pharmacist should document the patient's pharmaceutical care issues to be discussed with the pharmacy team.
- 4) Present each case in the ward and discuss:
 - a) List patient problems, medicine therapy, monitoring parameters, therapeutic end-points, dosage, potential ADRs, and interactions.
 - b) Discuss the appropriateness of the current or alternate medication/doses and nutritional changes.

- c) Interface with pharmacy staff regarding unusual medication orders, patient issues, and non-formulary needs.
- d) Perform medication dosage form conversion on medications that are typically converted from intravenous to oral dosing, whenever possible, or prior to patient discharge.
- e) Identify conditions that need renal/ hepatic dosing optimization for medications commonly used in inpatient care, depending on pertinent laboratory results.

3.5.3 After POM and POR

The responsible pharmacist should:

- 1) Communicate the recommendations to the health care team and implement the decisions made by the team.
- 2) The case owner should consider all the outcomes of the round and morning sessions to optimize the medicine therapy.
- 3) Take important comments or suggestions from the participants to improve subsequent sessions.
- 4) Document and report all the results of the session on the *Clinical Pharmacy Interventions Daily Summary Form (Form 5)*.

3.6 Multidisciplinary Team Activities

3.6.1 Multidisciplinary Team Round

Introduction

The multidisciplinary team (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 activities.

Objectives

- To provide patient-specific medicine information to health care professionals at the time of medicine therapy decisions.
- To optimize medicine treatment by influencing medicine therapy selection, implementation, and monitoring by involvement in medicine therapy decisions.
- To participate in discharge planning or other follow up.

Procedure

- 1) Attend routine MDT ward rounds.
- 2) Be proactively involved in the medicine therapy decision.
 - a) Give suggestions for the selection and monitoring of medicines in accordance with the patient's condition.
 - b) Contribute information about the patient's medication and medicine management.
- 3) Immediately review all medicine orders and correct incomplete and invalid prescriptions.
- 4) Respond to any medicine information inquiries.
- 5) Detect ADRs and medicine interactions for all prescribed medications.
- 6) Participate in discharge planning or planning for ongoing care.
- 7) Complete the necessary part of the *Clinical Pharmacy Interventions Daily Summary Form (Form 5)*.

3.6.2 Multidisciplinary Team Morning Session

Introduction

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. The pharmacist should be actively involved in MDT morning sessions.

Objectives

- To provide the team with detailed information on the medicines prescribed for selected cases.
- To optimize case-specific treatment by identifying DTPs in the case, medicine selection, and provide medicine information.
- To participate in discharge planning or other follow up on the selected case.

Procedures

- 1) Routinely attend the MDT morning session.
- 2) Be actively involved in the case selection and presentation in the MDT morning session.

- 3) Actively discuss the case with the team and provide the pharmacy service contribution for the team.
- 4) Identify any DTP observed for the presented case and resolve it by providing rational information, especially for the prescriber.
- 5) Be involved in the correct medicine selection for the case in the event of a DTP and provide medicine information for the team on the prescribed medication.
- 6) Be involved in the discussion of patient follow up for the case presented and discussed by the MDT and provide the medication information necessary for patient follow up.
- 7) Regularly update the team about the issues of medicine availability, shortage, and expiry, and act as the pharmacist in charge as regards the communication of hospital pharmacy service issues.
- 8) Respond to any medicine information inquiries.
- 9) Be involved in the discussion of discharge planning for the patient whose case is presented and discussed by the MDT, and provide information necessary for patient discharge.
- 10) At the end of participation in MDT ward rounds and morning session, the pharmacist in charge will perform follow up:
 - a) Respond to medicine information inquiries.
 - b) Discuss changes to medicine therapy with the patient and provide counseling, where appropriate.
 - c) Communicate changes in medicine therapy to other relevant staff.
 - d) Make monitoring adjustments, as per the medicine therapy change.
 - e) Complete the necessary documentation on the *Clinical Pharmacy Interventions Daily Summary Form (Form 5)*.

4. SOPS FOR DOCUMENTING AND REPORTING CLINICAL PHARMACY SERVICES

Introduction

Documentation is central to the provision of clinical pharmacy services. As an integral member of the health care team, the pharmacist must document the care provided. Each step in the patient care process should be documented. Documentation is vital to a patient's continuity of care. It demonstrates both the accountability of the pharmacist and gives value to the pharmacist's services. Failure to document clinical pharmacy activities and patient outcomes can directly affect the quality of care provided to the patient. If pharmacists are not communicating data/information routinely with other providers, they may not be considered an essential and integral part of the health care team. *If you are not documenting the care you provide in a comprehensive manner, then you do not have a practice.*

This part of the manual has been developed to guide the documentation of clinical pharmacy services at health facilities. The chapter contains documentation and reporting formats and instructions on how to complete each of the forms.

- Inpatient Medication Profile Form (*Form 1*)
- Pharmaceutical Care Progress Recording Sheet (*Form 2*)
- Medication Reconciliation Form (*Form 3*)
- Medication Information Record (*Form 4*)
- Clinical Pharmacy Intervention Daily Summary Form (*Form 5*)
- Clinical Pharmacy Intervention Monthly Summary and Reporting Form (*Form 6*)

Pharmacists who are providing clinical pharmacy services are advised to follow the instructions provided here closely when completing each documentation and reporting form to ensure data quality. Other members of the health care team (physicians, health officers, and nurses) should be encouraged to review and use the information recorded on the forms. Reports will be collected from health facilities by the respective PFSA Hubs and the Regional Health Bureau (RHB)/ Zonal Health Department (ZHD) on a monthly basis. PFSA Hubs will aggregate the monthly reports and send the compiled report to the PFSA headquarters quarterly. The PFSA headquarters will aggregate the reports of all Hubs.

Other stakeholders will access the reports from the PFSA headquarters or Hubs on request. The reports will provide valuable information for decision makers at every level to identify challenges, and to design and implement appropriate strategies so as to further strengthen clinical pharmacy services.

Objectives

- To standardize the provision of clinical pharmacy services.
- To ensure the availability of data about the service provided as evidence.

General Instructions

- When entering information on all forms, write neatly and legibly.
- Deleting, erasing, or whitening out entries is not allowed. If an incorrect entry is made, cross out the word or phrase with one line, write the correct word or phrase, and put your initials or signature by the correction.
- When entering data, follow the rows strictly to avoid mix-ups of information.
- All information required on a form should be provided. Do not leave blank any space allocated for you to record data.
- After recording all of the necessary data on a form, file it properly as described in the SOPs manual.
- Make sure that all forms are available in adequate quantities at your facility at all times.
- Write in a size that fits the space provided.
- Write all entries in English (not in Amharic).
- Dates must be uniform and similar to the one commonly used on the Patient's Medical Chart. Use the Ethiopian calendar with the date/month/year format (dd/mm/yy) and always use the calendar as a reference to avoid error.
- All forms are expected to be completed by the pharmacist providing clinical pharmacy services/pharmaceutical care.

4.1. Inpatient Medication Profile Form (Form 1)

Introduction

The Inpatient Medication Profile Form is used to record basic patient, medical, and medication information for admitted patients. The form should be printed or duplicated on one page, front and back, and should be part of the Patient Medical Chart for each patient. Print the hospital's name on the form prior to duplication. Access other patient information that is necessary to provide the service, such as vital signs, laboratory results, and the like from the Patient Medical Chart, diagnostic examination order sheets, and the Prescription Paper. Write the date on which you started documenting the patient's medication profile and record the necessary information under each section of the form following the instructions provided below.

Purpose

The purpose of the Inpatient Medication Profile Form is to be a source of medicine-related information for the provision of care to admitted patients on a continuous basis, from admission to discharge. The form contains socio-demographic, clinical, medication, DTPs, care plan, and related information pertinent to the provision of pharmaceutical care. Therefore:

- It should be used by the health care team as a source of medicine-related information.
- It will be helpful for follow up and prevention/resolution of medicine-related problems, such as ADRs, drug-drug, and medication-disease interactions, over- and under-dosing, and adherence problems.

When to Complete the Form

The Inpatient Medication Profile Form should be completed starting from admission of the patient until his/her discharge.

How to Complete the Form

The Inpatient Medication Profile Form has six major sections, each of which is used to record patient and medication-related information necessary for the provision of care for individual patients. The sections are:

- Patient Information
- Past Medical and Medication History
- Current Medications
- Drug Therapy Problems (Pharmacist's Assessment)
- Recommendation/Intervention
- Discharge Medication and Counseling

4.1.1. Patient Information

Fill in the following patient information in the spaces provided:

- The *patient's name* and *card number* should be recorded because it is essential to identify the patient to whom the record belongs.
- Demographic information, such as *age, sex, weight, height, and body surface area (BSA)*, especially for pediatric patients, and *pregnancy status* (in weeks), should be recorded for the purpose of individualizing medicine therapy (to determine the appropriate medication and dosage regimens for treatment).
- The *ward* in which the patient is admitted, *date of admission*, and *bed number* should be recorded.
- *Diagnosis* must be recorded to offer a general overview of the patient's medical problems.

Past Medical and Medication History

- Record the past medical history (information about past serious illnesses, hospitalizations, surgical procedures, deliveries, accidents, or injuries) in the space provided.
- The *patient's medication history* should be assessed and recorded in a very organized manner. It should include a summary of all the events a patient has had in his/her lifetime that involve medicine therapy, including immunization status, social drug use, and history of relevant medication use, along with his/her medication taking behavior (*adherence*) since it

is shaped by the patient's attitudes, beliefs, and preferences about medicine therapy and determines a patient's medication taking behavior.

- Document *allergies* and/or *ADRs*, with a specific description of the reactions that occurred. Check whether the patient has a Medicine Allergy Identification card. If the patient has an allergy history and does not have the card, complete one, and give him/her the Medicine Allergy Identification Card (*Annex B*).
- Record the *immunization status* of the patient. Check his/her immunization card, if possible.

Current Medications

- Write the active medical condition, illness, disease, signs, and/or symptoms being treated or being prevented by the use of medications under the *indication* column.
- Under the *drug and dosage regimen* column, record the *drug product name, dosage form, dose, and frequency of administration* of each medication for each indication that the patient is actually taking.
- The *date* at which the patient *started* and *stopped* each medication should be recorded.

Pharmacist's Assessment (Drug Therapy Problem Identification) and Care Plan

- This section is used to record the DTPs associated with each medical diagnosis. Each medical diagnosis may have one or more DTPs associated with it. A DTP can be resolved or prevented only when the cause of the problem is clearly understood. Therefore, it is necessary to identify and categorize both the DTP and its *cause* using the classification below as a reference. If the medicine therapy is not in these categories, record it with an explanation. Make sure to also clearly indicate important laboratory results and other examination results as evidence of the DTP identified.
- Briefly state the care plan based on your assessment.
- For each identified DTP, indicate the *date* and *time* when it was identified and write your *signature* and *initials*.

Recommendations/Interventions

Recommendations/interventions that are to be implemented should be recorded appropriately and clearly. Interventions are designed to resolve DTPs, achieve the stated goals of therapy, and prevent new DTPs from developing.

- *Recommendations/interventions* include initiating new medicine therapy, discontinuing medicine therapy, or changing the product and/or dosage regimen. Additional interventions to achieve the goals of therapy may include patient education, medication

compliance reminders/devices, referrals to other health care providers, or monitoring equipment to measure outcome parameters.

- The status of the recommendations/interventions made should be documented as accepted or not. The practitioner's initials and signature that made the recommendations should be noted. If the intervention/recommendation made was not accepted, mention clearly the reason why it failed to be accepted.

Discharge Medication and Counseling

- By being directly involved in discharge planning, record the: *date and time of discharge; medication, including the name, dosage form, and dosage of all discharge medications; and counseling and education* provided to the patient or caregiver.
- Write your name and signature after you provide the discharge medication and counseling to the patient.
- It is very important to complete and provide the *Medication Information Record (Form 4)* to the patient to ensure continuity of care.

4. Pharmacist's Assessment and Care Plan:

5. Recommendations/Interventions:

6. Discharge Medication and Counseling:

4.2. Pharmaceutical Care Progress Note Recording Sheet (Form 2)

Introduction

The Pharmaceutical Care Progress Note Recording Sheet is used to record the patient's *current status* and key interventions implemented from time to time to achieve the goals of therapy stated for each patient. The progress note should be written clearly and kept together with the *Patient Medication Profile Form* for each patient.

Purpose

The purpose of the Pharmaceutical Care Progress Note Recording Sheet is to serve as an easy reference on the status of the patient and key interventions implemented by the health care team at every visit.

When to Complete the Form

The Pharmaceutical Care Progress Note Recording Sheet should be completed during each patient visit.

How to Complete the Form

- 1) Write the *name* of the patient and *card number*.
- 2) Write the *date* and *time* each time you visit the patient.
- 3) Use the explanation (N.B.) and table 2 below to record the *Current Status*.
- 4) The effectiveness and safety of the medications used should be documented during every patient visit.
- 5) Record the key interventions implemented.
- 6) As soon as ADEs are identified, they should be reported using the ADE Reporting Form (“yellow form”) of the FMHACA and should be mentioned on the Patient Medication Profile Form, whether they are reported or not.
- 7) The pharmacist responsible for the care of the patient should write his/her name and place his/her signature after preparing each and every progress note.

N.B. *Current Status* indicates the patient's actual status at each visit. The evaluation involves comparing the goals of therapy with the patient's current status. The terminologies describe the patient's status, the medical conditions, and the comparative evaluation of that status with the previously determined therapeutic goals. The terms also describe the actions taken as a result of the follow-up evaluation.

Table 2. Patient Status Category

| Status | Definitions |
|---------------------|---|
| Resolved | Therapeutic goals achieved for the acute condition, discontinue therapy |
| Stable | Therapeutic goals achieved, continue the same therapy for chronic disease management |
| Improved | Progress is being made in achieving goals, continue the same therapy because more time is required to assess the full benefit of therapy |
| Partial improvement | Progress is being made, but minor adjustments in therapy are required to fully achieve the therapeutic goals before the next assessment |
| Unimproved | Little or no progress has been made, but continue the same therapy to allow additional time for benefit to be observed |
| Worsened | A decline in health is observed despite an adequate duration using the optimal medication; modify medicine therapy (e.g., increase the dose of the current medication, add a second agent with additive or synergistic effects) |
| Failure | Therapeutic goals have not been achieved despite an adequate dose and duration of therapy; discontinue current medication(s) and start new therapy |
| Expired | The patient died while receiving medicine therapy; document possible contributing factors, if they may be medicine-related |

Form 2: Pharmaceutical Care Progress Note Recording Sheet

(Follow the instructions when completing this form)

Patient Name: _____ Card No. _____

4.3. Medication Reconciliation Form (Form 3)

Introduction

Medication reconciliation is the standardized process of obtaining a patient's best possible history and comparing it to presentation, transfer, or discharge medication orders in the context of the patient's medication management plan. Medication reconciliation is a formal process intended to prevent medication errors and medicine-related problems at transition points in patient care. It is an essential element of medication management and should occur at all points of transition between episodes of care. Medication reconciliation also involves documenting discrepancies identified between the medication history and current medication orders and how these discrepancies were resolved.

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

Purpose

The purpose of medication reconciliation is to ensure that patients receive all intended medicines and to avoid errors of transcription, omission, duplication of therapy, and drug-drug, and medication-disease interactions.

When to Complete the Form

The medication reconciliation process and completing the form should commence as soon as possible on presentation or admission of a patient. A documented, confirmed medicines list must be available before medicines are prescribed. The Medication Reconciliation Form should be completed during:

- Presentation or admission to a health facility
- Transfer between wards and care settings within the health facility
- Discharge or transfer from the health facility to the community or other health facilities
- The Medication Reconciliation Form is completed for each patient at each service unit twice during his/her stay in the hospital, i.e., during admission, and at transfer or discharge.

How to Complete the Form

- 1) Write *name of the hospital*.
- 2) Write the *name, age, sex and weight* of the patient.
- 3) Indicate the *source (s)* from where you obtained information about the medication.

- 4) Record the medicine(s) to which the patient is known to be *allergic* (if any), with a brief description of the reaction.
- 5) For *Pre-admission Medication*, record the *name, dose, frequency, and duration of administration of the medication(s)* the patient has been taking prior to admission. Get such information from the Medication Information Record and/or the Medication Reconciliation Form, if the patient had been discharged, transferred, or referred in the past. If such a record is not available, get the information by asking the patient or caregiver.
- 6) Under the *Reconciliation* column, place a tick mark (√) under the appropriate sub-column regarding the decision on pre-admission medications made during admission, i.e., whether to *Continue (C)* or *Discontinue (DC)* for each medication. Record minor adjustments/changes made on pre-admission medications that are continued under the *adjustments/changes made* column.
- 7) Write the date, and put your signature and initials after entering the information regarding the pre-admission medications.
- 8) The list of medicines the patient is taking at discharge or transfer along with the *dose, frequency, and duration* of use should be recorded under the *Current Medication* rows.
- 9) The plan for transfer or discharge regarding each of the medications the patient is taking should be noted by ticking under the *Continue (C)* or *Discontinue (DC)* column. Minor adjustments/changes made on current medications at transfer or discharge should be recorded under the *adjustments/changes made* column.
- 10) Finally, write your name, put your signature, and record the date of discharge or transfer.

Form 3: Medication Reconciliation Form
(Follow the instructions when completing this form)

Hospital

Patient name: _____ Age _____ Sex _____ Weight _____

Source(s) of medication list _____

Allergic: _____

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

Recorded by: Name _____ Signature _____ Date _____

4.4 Medication Information Record (Form 4)

Introduction

The Medication Information Record is used to provide written medication information for patients leaving the facility in the case of referral, transfer, or discharge. The Record is designed such that one sheet may be used to provide medication information for two patients. The sheet should therefore be printed/copied and cut into two pieces. It is very important that the responsible pharmacist be part of the team during referral, transfer, or discharge planning so that he/she is involved in the team's decisions and may provide the necessary medication-related information and advice for the patient.

Purpose

The purpose of the Medication Information Record is to provide written medication information for patients leaving the facility in the case of referral, transfer, or discharge to ensure continuity of care. The completed form is used as a source of patient-specific medication-related information for the patient and health care providers.

When to Complete the Form

The Medication Information Record should be completed at the time of referral, transfer, or discharge of inpatients.

How to Complete the Form

When completing the Medication Information Record, the pharmacist should:

- 1) Write the *name* of the hospital and the *date* when the information was provided.
- 2) Write the *name of the patient* and the *diagnosis (Dx)*.
- 3) List the medicine(s) to which the patient is *allergic*.
- 4) Write all the medications the patient has been taking during his/her stay in the facility and those the patient will be using following referral, transfer, or discharge, along with the *start* and *stop date* of each medication.
- 5) Write the necessary information regarding the appropriate use of the medications that the patient is taking (how to take, interactions, side effects, ADRs, cautions) in the space provided under the table.
- 6) Write the *name* and *address* of the hospital/caregiver to whom the patient can communicate in case of any problems relating to his/her medications.

- 7) Provide the Medication Information Form to the patient, along with verbal advice about handling it safely, using it appropriately, and to show this information record whenever he/she visits a health facility so that health care professionals can easily access the past medical/medication history of the patient.

Remember: *This form **does not** replace the verbal medication counseling that should be provided to each patient.*

Form 4
MEDICATION INFORMATION RECORD

Name of Hospital _____ Date _____
 Patient Name: _____
 Dx: _____
 Allergic to _____

| Drug & Dosage Regimen (Name, Strength, Dosage Form, Dose, Frequency) | Start Date | Stop Date |
|--|------------|-----------|
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Form 4
MEDICATION INFORMATION RECORD

Name of Hospital _____ Date _____
 Patient Name: _____
 Dx: _____
 Allergic to _____

| Drug & Dosage Regimen (Name, Strength, Dosage Form, Dose, Frequency) | Start Date | Stop Date |
|--|------------|-----------|
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4.5. Clinical Pharmacy Interventions Daily Summary Form (Form 5)

Introduction

The Clinical Pharmacy Interventions Daily Summary Form is used to summarize clinical pharmacy services activities carried out by a pharmacist on daily basis. The form is used to record summarized information from inpatient care units. Each pharmacist providing clinical pharmacy services should complete the form on a daily basis. The Clinical Pharmacy Interventions Daily Summary Form should be printed on one sheet, front and back, made available in the office of the head of pharmacy, and filed in a separate clinical pharmacy services documentation cabinet.

Purpose

The purpose of the Clinical Pharmacy Interventions Daily Summary Form is to record summarized information on the clinical pharmacy activities that assigned pharmacists are providing to patients on a daily basis in inpatient care units. This record is also the basis for compiling information for regular reporting and research purpose.

When to Complete the Form

Each clinical pharmacy activity should be recorded on the day it is performed. The information related to ward rounds and morning sessions should be filled in on the summary form on the last work day of the week, adding up all sessions attended and presentations made during that specific week.

How to Complete the Form

The form has two sections: daily direct patient care intervention summary, and weekly morning session and round summary. Record the necessary information on the form using the instructions below. Use Form 1 as a source of data when completing this daily clinical activity summary form. One form may be used for more than a day.

4.5.1. Daily Direct Patient Care Interventions Summary

- 1) Record the *name of the hospital* and the *ward* on the top of the form.
- 2) Record the *date* in the space provided, in case the form is used for more than one day.
- 3) The *card numbers* should be noted (if the card numbers are coded for privacy purposes, then use the coded card numbers).
- 4) Record the patient's *diagnosis* in the diagnosis column.
- 5) Clearly write the *DTP identified* and its specific *cause* using the categories listed in *Table 1*. Write a single DTP in each row; use another row for additional DTPs, if any. You can record

a description of the DTP and its cause if you encounter a DTP that does not fit any of the categories given.

- 6) Clearly and briefly record the *interventions proposed* to resolve the identified DTP, achieve the goals of therapy, or prevent potential DTPs. Write each intervention in each row; use another row for additional interventions, if any.
- 7) Tick (✓) one of the three choices to indicate the *status of acceptance* of each intervention proposed, whether it is fully accepted, partially accepted, or rejected.

Fully accepted: If all the recommendation(s) you made is/are accepted.

Partially accepted: If some of the recommendation(s) you made is/are accepted.

Rejected: If the recommendation(s) is/are not accepted at all.

- 8) Put Y (Yes) if follow up has been made or N (No) if no follow up was done for the patient in the *Follow-up Made* column.
- 9) Put Y (Yes) if pharmaceutical care provided is *documented* using relevant documentation formats or N (No) if pharmaceutical care provided is not documented at all.
- 10) The *initials* and *signature* of the clinical pharmacy service provider should be made in the last column of each row, and for each case.

4.5.2. Weekly MDT Rounds and POMS Morning Sessions Summary

- For the MDT and POMS activities listed in the column *Description of Activities*, write the number of activities *planned* and those *achieved* on a weekly basis.
- Write the *title/topic* of the cases actually presented for the MDT and POMS morning sessions in the last column.
- The *name* and *signature* of the person who compiled the data should be placed in the space provided.

Form 5: Clinical Pharmacy Interventions Daily Summary Form

(Follow the instructions when completing this form)

Name of Hospital: _____

Ward: _____

1) Daily direct patient care intervention summary

| Date | Card No | Diagnosis | Drug Therapy Problem Identified and the Cause | Intervention Proposed | Intervention Accepted | | | Follow-up made (Y-Yes, N-No) | Intervention documented (Y-Yes, N-No) | Initial & Sign |
|------|---------|-----------|---|-----------------------|-----------------------|-----------|----------|------------------------------|---------------------------------------|----------------|
| | | | | | Fully | Partially | Rejected | | | |
| | | | | | | | | | | |
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2) Weekly MDT Rounds and POMS Morning Sessions Summary

| Description of Activity | | Number of Sessions per Week | | Specific Topics Presented |
|-------------------------|--------------------------------------|-----------------------------|----------|---------------------------|
| | | Planned | Achieved | |
| MDT | Morning Session | | | |
| | Seminar | | | |
| | Ward Round | | | |
| Pharmacy only | Morning Session/Case Presentation | | | |
| | Ward Round | | | |

Reported by: Name _____ Signature _____

4.6. Clinical Pharmacy Interventions Monthly Summary and Reporting Form (Form 6)

Introduction

The Clinical Pharmacy Interventions Monthly Summary and Reporting Form is used to document and report the clinical pharmacy activities of a specific ward or hospital on a monthly basis. The source of information for the monthly summary is the data collected on a daily basis using the Clinical Pharmacy Interventions Daily Summary Form (Form 5). The data should be compiled on a monthly and quarterly basis by the specific ward and health facility that uses the daily summarized information. The summary data should be reported to the PFSA Branches and to the RHB/ZHD on a monthly basis. The PFSA head office and its Hubs and the RHB/ZHD aggregate, analyze, and generate information for decision making on clinical pharmacy services. The form should be printed on one page and kept in the office of the pharmacy head in a separate cabinet for the documentation of clinical pharmacy services.

Purpose

The Clinical Pharmacy Interventions Monthly Summary and Reporting Form is a source of information on the clinical pharmacy activities being undertaken in specific wards and health facilities, including the number of patients who have received pharmaceutical care services, the DTPs identified, and the interventions proposed and implemented, in collaboration with other members of the health care team. The information is useful for assessing the clinical and economic impacts of clinical pharmacy services and mobilizing more resources to further expand and strengthen services. The form is also used by the PFSA (head office and Hubs) to aggregate and produce quarterly reports.

Who Completes the Form

The Clinical Pharmacy Interventions Monthly Summary and Reporting Form should be completed by the pharmacists responsible for coordinating clinical pharmacy and inpatient pharmacy activities in each ward, and the head of pharmacy services in the hospital. Each ward's monthly forms should be prepared separately and then aggregated and reported. Pharmacists preparing quarterly reports at PFSA Hubs and the head office will also use this form.

When to Complete the Form

The form should be completed at the end of each month so that data are captured from the inpatient units where pharmaceutical care is provided.

How to Complete the Form

Follow the instructions provided below when completing the Clinical Pharmacy Interventions Monthly Summary and Reporting Form.

- 1) Use the *Clinical Pharmacy Interventions Daily Summary Form (Form 5)* and, if necessary, use the clinical pharmacy intervention documentation forms (*Forms 1 and 2*) as references to complete this form.
- 2) Use the *Remarks* column to note any relevant additional information related to the data entered.
- 3) Write the reporting *month* and *year*.
- 4) Accurately record the total *number of patients* to whom clinical pharmacy services were provided in the hospital.
- 5) Write the total *number of patients* for whom the Medication Profile Form was completed.
- 6) Under *Type and Number of DTPs identified*, write the number of each DTP identified according to the standard classification of DTPs. Use the *Others (Specify)* row to record any DTPs that might not fit any of the DTPs listed, and specify the DTP and its cause in the space provided. Add up the DTPs and write the total number of DTPs identified in the *Total* row. For ADRs managed, indicate the number of ADRs reported to FMHACA during the month in the *Remarks* column.
- 7) Write the *type and number of interventions* made to address the DTPs identified, achieve the goals of therapy, and prevent potential DTPs. Add them up and put the result in the *Total Interventions Made* space. Use the *Others (Specify)* row to record interventions that might not fit the categories given.
- 8) Under *Acceptance of Interventions*, record the number of fully accepted, partially accepted, and rejected interventions in the respective row for each category.
- 9) Under *Activities of the MDT*, record the number of *MDT morning sessions* and *ward rounds* attended by pharmacists, and the *number of cases/topics presented* by pharmacists in the MDT morning sessions. Reports of pharmacists working in the same ward on MDT morning sessions and ward rounds should not be totaled as they will be attending the same sessions together.
- 10) Under *Pharmacy Only Activities*, record the number of Pharmacy Only Morning Sessions and Ward Rounds conducted, and the *number of cases/topics presented* in the POMS.
- 11) In the space provided, note any challenges encountered when using the clinical pharmacy services documentation, summary, and reporting forms, and possible solutions.
- 12) Write the number of pharmacists who were involved in the provision of clinical pharmacy services during the reporting period by classifying them into *trained* (pharmacists trained in the one-month clinical pharmacy training program) or *graduated* (pharmacists who are trained according to the new patient-oriented undergraduate pharmacy curriculum).

- 13) The report should be compiled by the head of the pharmacy section/representative and sent to the hospital chief executive officer/chief clinical officer (CEO/CCO), hospital Drug and Therapeutics Committee (DTC), and PFSA Hubs on a monthly basis by the fifth day of the following month (Ethiopian calendar). Using a tick mark (√), indicate to whom the report was sent.

- 14) The pharmacists who compiled and approved the report should write their *names* and *signatures* in the spaces provided and include the reporting date.

Form 6: Clinical Pharmacy Interventions Monthly Summary and Reporting Form
(Follow the instructions when completing this form)

Name of Hospital: _____ Month/Year: _____

| S/N | Description | Number | Remarks |
|-----|--|--------|---------|
| 1 | Total number of patients who received pharmaceutical care | | |
| 2 | Total number of patients with <i>Inpatient Medication Profile forms</i> prepared | | |
| 3 | Type and number of drug therapy problems identified | | |
| | Unnecessary drug therapy | | |
| | Needs additional drug therapy | | |
| | Ineffective drug | | |
| | Dosage too low | | |
| | Adverse drug reaction | | |
| | Dosage too high | | |
| | Noncompliance | | |
| | Others (Specify) | | |
| | Total | | |
| 4 | Type and number of interventions made | | |
| | Discontinued unnecessary drug therapy | | |
| | Initiated additional drug therapy | | |
| | Changed ineffective drug | | |
| | Increased dosage | | |
| | Adverse drug reactions managed | | |
| | Decreased dosage | | |
| | Improved compliance | | |
| | Others (specify) | | |
| | Total | | |
| 5 | Acceptance of interventions | | |
| | Accepted fully | | |
| | Accepted partially | | |
| | Rejected | | |
| 6 | Activities of the Multidisciplinary Team (MDT) | | |
| | Number of MDT morning sessions attended | | |
| | Number of cases presented by a pharmacist in the MDT morning sessions | | |
| | Number of MDT ward rounds attended | | |
| 7 | Pharmacy Only Activities | | |
| | Number of pharmacy only morning sessions conducted | | |
| | Number of cases presented at pharmacy only morning sessions conducted | | |
| | Number of pharmacy only ward rounds conducted | | |

Challenges in using the documentation and reporting forms (please indicate possible solutions):

Number of pharmacists that provided clinical pharmacy services during this month:

Trained _____ Graduated _____

Report sent to: Hospital CEO/CCO Hospital DTC PFSA Hub RHB/ZHD

Report compiled by: Name _____ Signature _____

Report approved by: Name _____ Signature _____ Date _____

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ANNEX A. FMHACA ADVERSE DRUG EVENT REPORTING FORM

Instructions for Completing the Form

1. General

The ADR reporting form collects basic information about the patient, the medicine, the adverse reaction, the action taken, and the outcome.

- The *age, sex, description of the adverse reaction, information on suspected medicine, and outcome* are all considered essential and the information should be filled in.
- The form should be completed by health professionals, such as physicians, pharmacists, nurses, health officers, dentists, etc.
- Complete the form to the best of your ability.
- Avoid non-standard abbreviations.
- Use a separate form for each patient.
- Write legibly.

2. Specific

Reaction information

The patient's identity

Information about the patient's identity, nutritional status, and habits should be provided. It is not necessary to write the patient's full name. Use the patient's initials only, e.g., ASZ for Addis Solomon Zerga. The card number needs to also be provided as the card number and patient's identity are useful to obtain additional information, if needed, as well as for retrospective and prospective studies of adverse drug reactions.

Description of the adverse drug reaction

Clearly and briefly describe the nature of the adverse drug reaction, the diagnosis, the date of onset, duration, period of time, and laboratory test results, including negative and normal results of any relevant tests performed. The severity of the reaction, i.e., whether it necessitated a prolonged hospitalization or discontinuation of the medication should be reported.

Information on the suspected medicine

This information includes the *name and source* of the medicine, the *dose, route of administration*, and the impact of the withdrawal and re-administration of the suspected medicine on the adverse reaction.

Medicine name

Use the brand name of suspected medicine(s). If the generic name is used, specify the manufacturer of the medicine. Avoid non-standard abbreviations, such as PPF, CAF, MTC, TTC, etc.

Dosage form and strength

The dosage form, such as tablet, capsule, syrup, suspension, elixir, emulsion, injection, eye drop/ointment, topical cream/ointment, otic drop, nasal drop, rectal/vaginal suppository, etc., should be noted. The strength should also be expressed using the metric system, e.g., 500 mg tab, 250mg/5ml syrup, 1gm rectal suppository. Sometimes the strength may be expressed in %, e.g., 2% hydrocortisone ointment.

Frequency

Frequency of the administration of the medicine should be clearly written using standard abbreviations, for example:

3 times a day as tid or 8 hrly
2 times a day as bid or 12 hrly
4 times a day as qid or 6 hrly

Route

Route of administration should be expressed using a standard abbreviation, e.g., Peros as PO, Intramuscular as IM, Intravenous as IV, Per rectal as PR, Topical as TO.

It is also useful to indicate whether the medication was taken before or after a meal using Latin abbreviations, such as ac, pc, etc.

Date

The dates the medicine was *started* and *discontinued* are important data to assess the cause and effect relationship of the medicine and the adverse reaction. The dates should therefore be clearly written on the form as date/month/year in the Ethiopian calendar. If the medicine has not been discontinued at the time of reporting, write “continuing.”

Dechallenge and rechallenge

If the reaction subsides after discontinuation of the suspected medicine (dechallenge), check Y (Yes), and if not, check N (No). If the reaction reappears after the suspected medicine is restarted (rechallenge), check Y (Yes), and if not, check N (No). If there is no dechallenge and rechallenge, check NA (not available).

Medicines used concurrently

List any other prescription or non-prescription medicines used concurrently with the suspected medication, with all descriptors noted, i.e., brand name, route, dosage form, strength, frequency, indication, date started, and date stopped. This information is useful for the evaluation of possible medicine interactions.

Indication

Write the reason why the medicine was used or the diagnosis for which the medication was prescribed for both the suspected medicine and other medications used concurrently.

Treatment

The treatment for the reaction, the final outcome of the reaction, and sequelae should be noted.

Product quality information

Product quality information, such as color or odor change, caking, poor packaging/labeling, etc., should be recorded.

The professional who completed the form should write the name of the institution at which he/she is working and his/her name, profession, telephone number, and e-mail address; write the date, sign and submit the completed form to the ADR focal person of the hospital.

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

| | | | |
|---|--|----------------|-----------|
| Reaction necessitated: Discontinuation of drug/s <input type="checkbox"/> YES <input type="checkbox"/> No Hospitalization prolonged <input type="checkbox"/> YES <input type="checkbox"/> No | Reaction subsided after D/C of suspected drug? <input type="checkbox"/> YES <input type="checkbox"/> No <input type="checkbox"/> Information not available Reaction reappeared after restart of suspected drug? <input type="checkbox"/> YES <input type="checkbox"/> No <input type="checkbox"/> Information not available | | |
| Treatment of reaction: <hr/> <hr/> | | | |
| Outcome: <input type="checkbox"/> Died due to the adverse event <input type="checkbox"/> Died, drug may be contributory <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Recovered without sequelae <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown | | | |
| Squelae: Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc <hr/> | | | |
| Reported by: Name | Profession: | Email address: | Telephone |
| Name of health institution: | Date | | |

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

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

For office use only

| | |
|--|------------------|
| Received on: | Registration no: |
| Key: D/M/Y ; Date /Month/Year D/C: Discontinue treatment Y:YES N:NO | |

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

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From _____

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

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 And Control Authority of Ethiopia

Food, Medicine and Health Care Administration and Control Authority
Regulatory Information Development and Dissemination Team
 P.O.Box 5681 Tel.0115-523142
 Addis Ababa, Ethiopia

ANNEX B. DRUG ALLERGY IDENTIFICATION CARD, FMHACA

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ለማንኛውም ጤና ባለሙያ

- እባክዎ ሕክምና በሚሰጡ ወይም መድኃኒት በሚያድሉበት ወቅት ታካሚዎ ለየትኛው መድኃኒት አለርጂ እንዳለባቸው ይጠይቁ ።
- ከዚያም በዚህ መታወቂያ ካርድ ላይ ይመዘገቡላቸው።
- ታካሚው ከዚህ በፊት ያጋጠማቸውን አለርጂ አስመዘገቡዎ ከሆነ ካርዳቸውን እንዲያላዩዎት ይጠይቁ ። ለአለርጂው ምክንያት የሆነው መድኃኒት በድጋሚ እንዳይታዘዝ ወይም እንዳይሰጥ ጥረት ያድርጉ።

ለማንኛውም ታካሚ

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

የመድኃኒት አለርጂ መታወቂያ ካርድ

የባለ መታወቂያው ስም _____ የታ _____

እድሜ/ የተወለዱበት ቀን _____

አድራሻ: ክልል _____ ወረዳ _____ ቀበሌ _____ ቤቁ _____

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

