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Working Manual for the Establishment and Operation of Drug and Therapeutics Committee (DTC) at Health Facilities in Ethiopia

(First *Edition)*

Pharmaceuticals Fund and Supply Agency (PFSA)

September 2015

Addis Ababa, Ethiopia

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Pharmaceuticals Fund and Supply Agency (PFSA) in Collaboration with World Health Organization (WHO)

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Acknowledgments/Disclaimer

This document is produced with the financial support of the European Community through the World Health organization. The views expressed herein are those of the authors and can therefore in no way be taken to reflect the official opinion of the European Community or the World Health Organization.

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Foreword

Establishing Drug and Therapeutics Committees (DTCs) at health facilities is one of the most effective strategies to improve the supply management and use of medicines. DTC provides a forum to bring together all the relevant professionals to work jointly to improve healthcare delivery through the proper management and rational use of medicines. There has been effort to establish and operationalize DTCs at health facilities in Ethiopia since the 1980s. The National DTC Guideline was issued by the then Drug Administration and Control Authority (DACA) in 2004. Many hospitals and health centers are able to establish and operationalize DTCs as a result of the effort made by the Agency so far, in collaboration with concerned government bodies and development partners, so far in the form of training and supportive supervision.

Though policy documents support the importance of having functional DTCs at health facilities and set as a requirement, still DTCs are not appropriately institutionalized and get the expected support and follow-up throughout the healthcare system of the country. As a result, the healthcare system is not benefiting from the technical support of DTCs to the expected level to ensure the availability and rational use of medicines at health service delivery points.

Findings of the 2013 national assessment on DTC performance has indicated the need for a national working manual so as to guide the establishment and routine operations of health facility DTCs, and to establish a system for DTC follow-up and support at all levels of the healthcare system. This National Working Manual is, therefore, developed to provide practical guidance on how to establish and operate DTC at health facilities, and on how to provide the necessary follow-up and support to health facility DTCs by Federal and Regional bodies, and health facility management with the ultimate goal of providing quality and cost-effective health services. Concerned professionals at all levels of the healthcare system will get this Manual useful in undertaking and supporting DTC-related activities. It will also be useful for academic institutions to train health science students regarding DTC and its roles as part of their undergraduate training.

I would like to take this opportunity to thank all members of the PFSA-WHO-USAID/SIAPS Joint Team for producing this Working Manual. I would also like to encourage users of the Manual to send their comments regarding the Manual to the Agency via mail (Pharmaceuticals Fund and Supply Agency (PFSA), P. O. Box 21904, Addis Ababa, Ethiopia)

Meskele Lera

Director General, Pharmaceuticals Fund and Supply Agency (PFSA)

Acknowledgments

This Working Manual was developed with technical and financial support from the World Health Organization (WHO). PFSA would like to acknowledge technical and financial support of WHO. The Agency is also grateful to the technical support provided by United States Agency for International Development/Systems for Improved Access to Pharmaceuticals and Services (USAID/SIAPS) Program. We would also like to extend our appreciation to the following individuals who were actively involved in the development Manual as a member of the PFSA-WHO-USAID/SIAPS Joint Team:

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6. Mr. Fikru Worku – USAID/SAIPS - PFSA
7. Mr. WorknehGetahun – USAID/SIAPS

We would like to acknowledge the individuals and their organizations *(Annex I)* who participated in the workshop organized to review the Working Manual for their feedbacks. Last, but not least, the Agency would like to thank Mr. Yared Yiegezu (PFSA) and Mr. Abraham G/Giorgis (WHO) for coordinating the development process.

Recommended citation

PFSA. National Working Manual for the Establishment and Operation of Drug and Therapeutics Committee (DTC) at Health Facilities in Ethiopia, September 2015, Addis Ababa.

ACRONYMS

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
APTS	Auditable Pharmaceutical Transactions and Services
BPR	Business Process Reengineering
CCO	Chief Clinical Officer
CEO	Chief Executive Officer
DACA	Drug Administration and Control Authority
DTC	Drug and Therapeutics Committee
DUE	Drug Use Evaluation
EHCRIG	Ethiopian Health Centers Reform Implementation Guidelines
EHRIG	Ethiopian Hospital Reform Implementation Guidelines
ESA	Ethiopian Standards Agency
EFMHACA	Ethiopian Food, Medicine and Healthcare Administration and Control Authority
FMOH	Federal Ministry of Health
IPLS	Integrated Pharmaceutical Logistics System
ME	Medication Error
PFSA	Pharmaceuticals Fund and Supply Agency
PLMP	Pharmaceutical Logistics Master Plan
RHB	Regional Health Bureau
RMU	Rational Medicine Use
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	Standard Operating Procedure
STG	Standard Treatment Guidelines
TOR	Terms of Reference
USAID	United States Agency for International Development
VEN	Vital, Essential, Non(Less) Essential
WHO	World Health Organization
ZHD	Zonal Health Department
USD	United States Dollar

1. Introduction

1.1. Background

The availability of safe, effective, quality and affordable pharmaceuticals accompanied by their rational use is a prerequisite for the delivery of quality health services. . In most developing countries, medicines represent 20 to 40% of total public and private health expenditure. Unfortunately, and for a variety of reasons, a significant proportion of this resource is lost. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards. Establishing Drug and Therapeutics Committees (DTCs) in health facilities is one of the key strategies to improve the supply management, promote rational medicines use (RMU) and optimize patient care.DTC provides a forum to bring together all the relevant professionals to work jointly to improve healthcare delivery through the proper management and rational medicines use. A well-functioning DTC has been shown to be one of the most effective strategies to improve the supply management and use of medicines at health facilities in many countries.

Ethiopia has experience in establishing and operating DTC since the 1980s. The National DTC Guideline currently in use was issued by the former Drug Administration and Control Authority (DACA) in 2004. Efforts were made to establish and strengthen DTCs at hospitals and health centers throughout the country. Federal Ministry of Health (FMOH), Pharmaceuticals Fund and Supply Agency (PFSA), and Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA, the former DACA), in collaboration with partners, have worked a lot in this regard. As a result of the efforts, many hospitals and health centers are able to establish and operate DTCs, improve the management and promote the rational use of medicinesthrough their DTCs as a result of the effort made as revealed by the national DTC assessment conducted at public hospitals in 2013. The assessment has also indicated the gap in institutional ownership, and lack of integrated follow-up and support for DTCs,and the need for a working manual to guide activities of the DTCs for them to function to their full potential.

The presences of functional DTCs are indicated as one of the requirements for hospitals and health centers in the Ethiopian Hospital Reform Implementation Guidelines (EHRIG) and Ethiopian Health Centers Reform Implementation Guidelines (EHCRIG) respectively. The

health facility minimum regulatory standards issued by Ethiopian Standards Agency (ESA) have also set the presence of functional DTCs as one of the requirements of hospitals and health centers. It is believed that health facility DTCs can significantly improve the supply management, promote the rational use of medicines and optimize patient care at health facilities and hence at most effort should be made at all levels to establish and functionalize them.

Developing a working manual which augments the practicability of the existing DTC guideline becomes important to fully realize the benefits of DTC. Thus, this manual is prepared to provide practical guidance on how to establish and operate DTC at health facilities, through providing the necessary follow-up and support to health facility DTCs by Federal, Regional, Zonal and Woreda administrative bodies with the ultimate goal of providing quality and cost-effective healthcare to patients.

1.2. Scope

This Working Manual describes the structure, roles and responsibilities of Health Facility DTCs and the follow-up and support that should be provided by Federal and Regional bodies to health facility DTCs.

The manual is meant for use by health facility DTCs to guide their operations. Healthcare managers and professionals at federal, region, zone, woreda and health facility levels also will get this working manual useful to establish and strengthen DTCs and provide the necessary support. The working manual as well be useful for faculty and students in the health science stream to equip them with the necessary know-how on establishing and operating DTC to improve the management and use of medicines.

1.3 Purpose

The purposes of this Working Manual are to:

1. Provide general framework on how to establish and operate DTCs at health facilities;
2. Describe the objectives and functions of health facility DTC;
3. Describe the roles and responsibilities of Federal and Regional bodies in establishing and strengthening DTCs at health facilities.
4. Support the standardization of DTCs functions across the health facilities.

2. Goal and Objectives of DTC

Goal

The goal of a DTC is to ensure that patients are provided with the best possible safe, effective, affordable and quality therapeutic care.

Objectives

The objectives of DTC are to:

- Ensure availability of safe, effective, affordable and good quality medicines in the facility;
- Ensure the implementation of initiatives designed to improve the supply management, promote rational medicines use and optimize patient care in the facility;
- Maximize drug safety through facilitation of preventing, detecting, monitoring, managing, evaluating and reporting Adverse Drug Events (ADEs);
- Conduct studies to identify problems in the supply management and use of medicines;
- Develop and implement interventions to improve medicines supply management and use.

3. The Guiding Principles for the roles and responsibilities of DTCs

3.1. DTCs should have oversight of the total medicines management system within a Health facility.

DTCs are able to provide a strategic lead for a health facility across all steps of the medicines supply management cycle (Medicines selection, quantification, procurement, storage, distribution and use). DTCs can assist in delivering consistent decisions and messages across the facility regarding the supply management, rational medicines use and patient care. Accordingly, all health services of the facility should have access to the advice and services of a DTC. However, it may be impractical for a health Post to have its own DTC. In such cases, it may be represented at and function under the governance of a DTC from a nearby health center. So that the health center's DTC should provide guidance to the health post to ensure standardization and consistency of DTC activities. It is the responsibility of the health post to have a mechanism in place to implement the decisions, procedures or guideline provided by the respective health center DTC.

3.2. DTCs should have clear Terms of Reference (TOR).

Health facilities need to be aware of where and how the DTC fits into their governance structures. This should be indicated in the TOR of the DTC. Health facility DTCs should develop their own TOR and be approved by the facility top management. The content of the terms of reference (TOR) for a DTC is annexed *(Annex II)*.The TOR could be revised if required.

3.3. DTCs should consider the local context when defining their functions.

DTCs have a key role in the management of medicines in the health facility and need to assist the management by ensuring that their functions are being undertaken within the health facility. The functions outlined in the manual demonstrate some of the responsibilities of DTCs and it is essential to prioritize the DTCs' activities according to the local context and level of risk.

3.4. DTCs should be both proactive and responsive.

DTCs should set and manage the agenda of medicines management within the health facility and develop an annual work plan. DTCs should undertake horizon scanning, when setting their annual work plan. This work plan should be proactive as well as be responsive to issues arising throughout the year that have not been included when the work plan was devised and agreed. The work plan should define the purpose and expected outcomes of the included initiatives.

3.5. DTCs should have formalized reporting structures.

DTCs need to have appropriate place in the organizational structure of the health facility and accordingly should have formalized reporting lines to the health facility's management that are articulated in the organizational structure or the facility's governance framework. An organizational structure should be included in the terms of reference to highlight direct reporting lines from the DTC to clinical governance and/or the management. DTCs are able to advise and assist, as well as be accountable to, the health facility's management. The DTC report should include the agenda items discussed, the number of meetings conducted, main decisions and activities made, and challenges encountered during the reporting period.

3.6. Membership of the DTC should be multidisciplinary.

DTC membership should reflect the functions of the DTC and its accountability within the health facility. DTC members should have the appropriate skill mix and expertise to facilitate

competent review and evaluation of all the steps in the medicines management cycle relevant to particular issues. Core membership should include clinicians, pharmacy professionals, Nurses, Laboratory professionals and executive (representing the health facility administration and/or finance) with expertise in therapeutics and the ability to understand and balance financial and clinical pressures. Assignment of DTC members should go in line with official procedures. For some meetings and tasks it may be appropriate to invite specialists/experts relevant to the topic under consideration to assist in this process.

New members of the DTC should have an orientation that includes the principles involved in DTC decision making review of the TOR, annual work plan and an understanding of their role and responsibilities.

3.7. DTCs may establish subcommittees or assign focal person to manage specific tasks.

DTCs may establish a subcommittee or assign focal person to manage specific projects or tasks, when appropriate. When establishing subcommittees or assigning focal person, the governance and reporting arrangements need to be determined and included in the DTC TOR. Such subcommittee (or focal person) may include Medication safety / ADE, Drug use studies, Antimicrobial Resistance, Medicine list Management Subcommittee, etc. These subcommittees should report directly to the DTC.

3.8. Standardized procedures for decision-making regarding development of facility specific medicines list and formulary management need to be defined and applied.

Each health facility should develop and maintain its own list of medicines. Facility specific medicine list should be developed based on morbidity data and national list of medicines. The purpose of maintaining a formulary is to ensure safe, clinically appropriate and cost effective use of medicines. Standard criteria for decision-making should be defined and implemented consistently across all formulary decisions. Standard criteria for decision-making may include:

- Indication and patient population/ Epidemiology
- Clinical effectiveness of the medicine
- Evidence from the literature relating to the safety of the medicine, including the inherent risk associated with the use of the medicine, e.g. need for additional medicines to manage side effects

- Place in therapy and alternate treatments
- Patient safety
- Any potential implications for the management of patients who receive the medicine
- Cost effectiveness, including changes to cost of care, e.g. monitoring
- Access considerations, e.g. equity of access
- Financial implications for the Health Facility.

The DTC also should take into account decisions made nationally unless there are compelling local circumstances or important new information has become available since the national decision was made.

Approval of a medicine for inclusion to the health facility medicines list should include the active ingredient/generic name, strength(s), dosage form(s), indication(s) and any restrictions (e.g. by prescriber, by indication or duration of therapy).

Approval should also include monitoring usage of new additions to a formulary, such as audits, outcome evaluation, monitoring adverse events or medication incidents. Decisions should be made in a defined time period without compromising the quality of information and evaluation required.

3.9. Standardized processes and documentation should be implemented by the DTC. DTCs should have standardized processes and documentation to assist in and provide transparency on its decision-making and communication pathways. Clear agendas should be set prior to each meeting.

Items for action and follow-up from previous meetings should be documented and reviewed at each meeting. All decisions should be clearly documented and include the process and rationale for the decision and any action required.

DTCs should specify how and where the minutes are kept requirements for length of time to archive minutes and processes for communication of decisions. There should be a mechanism to record any activities that may occur between meetings.

Any potential conflicts of interest should be declared, recorded and a report made available, if required along with a resolution

3.10. DTCs should undertake assessments within the health facility with respect to medicines use and recommend strategies to mitigate problems identified.

DTCs should address medication use issues and recommend strategies for implementation to promote RMU.

Before attempting to change medicine use, the scale of the problem should be assessed and quantified. The underlying reason for the problem behavior then need to be investigated using both quantitative and qualitative methods. It is a mistake to intervene before understanding the reasons for a problem behavior.

After identifying the reasons for the existing medicine use problems, we can choose from the existing several choices of interventions to change medicine use practices. The major approaches of interventions can be categorized as educational, managerial and regulatory. Whichever approach is used, interventions should focus and target on specific problems depending on the reasons of the problems the assessment already revealed. DTCs should also identify key performance indicators that the health facility should monitor in order to ensure that strategies or actions employed to address the medicine use problems are effective.

3.11. DTCs should identify and prioritize a systems improvement plan and assign responsibilities and timeframes for completion.

DTCs are responsible for ensuring the RMU within the health facility. All therapeutic interventions require ongoing monitoring with regard to use, outcomes and adverse events. The type of outcome evaluation, level of monitoring and review processes may vary. Requirements for ongoing monitoring and audit of decisions can be included as part of the approval process and should occur within a defined time period. This may involve monitoring of new medicines, reviewing the use of high-cost medicines or identifying when medication incidents or adverse events occur. Quality improvement areas should be prioritized; plans should be developed and implemented, monitored and evaluated. This process should include a cycle of audit, intervention followed by re-audit and ongoing monitoring.

3.12. DTCs should have monitoring systems in place to evaluate their effectiveness.

DTCs of the health facility are expected to monitor and evaluate their performance against their annual working plan.

DTCs should review their annual working plan quarterly. DTCs should use a meaningful tool to evaluate their current practice and progress. *(Annex III)*

3.13. DTCs should develop a communication system that ensures timely, effective and appropriate information for the intended audience.

It is the responsibility of the DTC to ensure that its advices and decisions related to medicines management and use are communicated to relevant health professionals and patients and implemented. DTCs are responsible for the process to ensure appropriate and relevant education is provided about all areas of medicines management and use.

DTCs should establish an overall framework for the timely and effective dissemination of its decisions and implement an effective communication strategy. Decisions should be communicated in a timely manner for the management and relevant professionals. This communication should be undertaken by an appropriate person (Preferably DTC Chair or Secretary), who can competently explain the complexities of the information in terms the recipients can understand. Major DTC decisions should be approved by the facility management prior to implementation.

Examples of methods of communication:

- Letters and feedback
- Pharmacy or therapeutic drugs bulletin, fact sheets, high-risk medicine alerts
- Inter-and Intra-departmental meetings
- Intranet or internet website
- Alerts in electronic medicines management systems (e.g. dispensing, prescribing and administration software)

3.14. DTCs should engage with internal and external stakeholders

Networking with internal and external stakeholders and partners is an important aspect of communication, enabling advocacy and involvement in the broader context of medicines management, medicine safety or RMU policy decision-making. So DTCs should collaborate

with the relevant internal and external stakeholders in order to enhance its performance on the promotion of the safe and quality use of medicines.

The manner in which DTCs engage will vary, according to the local environment. However, suggested engagement includes formalized reporting and communications

3.15. DTCs should be adequately resourced by the health facility to enable them undertake their functions and responsibilities.

It is essential that health facility appropriately fund and support DTCs to enable them to fulfill their roles and responsibilities. This support depends on the defined scope and function of the DTC and the size of the health facility(s) it serves and may include:

- Allocating time for the DTC member to attend meetings, review meeting papers and supporting documents and attend to out of session issues.
- Funding and allocating adequate time for administrative support to assist the DTC with correspondence, communication (agenda and minutes)and stationary materials as agreed by management
- Providing resources such as personnel, budget and other relevant resources as per demand to support the DTC to undertake its functions and activities, including those identified within the annual work plan.
- Providing additional resources, when needed, to support subcommittees to undertake their activities

3.16. DTCs should get the necessary follow-up and support

It is clear that DTCs decisions should be approved by the management of the health facility, so that the management is expected to actively engage and support activities of DTCs. Employment of Scheduled and integrated follow up mechanism by the management enhances the performance of DTCs.

The health facility management should monitor and evaluate DTC activities. Besides this, there should be a system at each level of the health care that provides follow up and support to strengthen and evaluate health facility DTCs.

4. Organization of Drug and Therapeutics Committee at health facilities

DTCs of hospitals and health centers should be multi-disciplinary. A functional DTC should have a multidisciplinary, transparent approach, technical competence and an official mandate.

4.1. Organization of Hospital DTC

DTCs established at Hospital level should have the following members:

- Chief Clinical Officer/Equivalent-Chairperson
- Head/Director of Pharmacy Services–Secretary
- Drug Supply Management Officer- Member
- Heads/representatives of major Clinical Departments- Members
- Head of Nursing Service - Member
- Head of Laboratory Service - Member
- Clinical Pharmacy Service Coordinator – Member
- Drug Information Service Focal Person - Member
- Head of Finance Section- Member

If deemed necessary, other clinical and diagnostic departments can be represented in the Committee. The DTC can utilize the expertise of all specialists found in the health facility through consultation as it is not possible to represent all departments in the committee.

4.2 Organization of Health Center DTC

DTCs established at Health Center should have the following members:

- Head of Health center-Chairperson
- Head of Pharmacy Services-Secretary
- Head of Nursing Service -Member
- Outpatient Case Team Coordinator – Member
- Head of Laboratory Service - Member
- Head of Finance–Member

If deemed necessary, it is possible to include focal from such areas as MCH Service, ART Clinic, TB Clinic, Chronic care, DIS, etc.

5. Duties and Responsibilities

5.1 Duties and Responsibilities of DTC

There are many possible functions of a DTC, and the committee must decide which to undertake as a priority depending on capacities and needs. Certain functions may require liaison with existing hospital committees or teams in the health facility e.g. the infection control committee or the procurement team. The major duties and responsibilities of DTC are briefly described as follows.

5.1.1. Advisory Functions:

The DTC should provide practical advice to medical staff, nurses, administration, pharmacy and other departments on all issues, procedures and guidelines concerning the selection, quantification, procurement, distribution, storage and use of medicines and patient care in the health facility. It should also play advisory role regarding pharmaceuticals waste management. Usually, the DTC will provide the advice to an executive body such as the hospital/health center management for decision making.

5.1.2. Developing/Adopting guidelines and procedures on the management and use of medicines:

DTC is the most appropriate body to develop drug guidelines and procedures pertaining to the selection, quantification, inventory management, storage and distribution, and use of medicines to be implemented within the health facility. DTCs should adopt and facilitate the implementation of drug management and use guidelines and procedures developed at federal and region levels like Clinical Pharmacy Service SOPs, Integrated Pharmaceutical Logistics System (IPLS) SOPs, Auditable Pharmaceutical Transactions and Services (APTS) directives, and Good Prescribing and Dispensing Practice Manuals.

Health facilities should adopt National Formulary of Medicines for Ethiopia. It should not be expected that all health facilities develop their own individual formularies. However, specialized hospitals can develop their own STGs and Formularies of the medicines for their specialty

services.

5.1.3. Developing and updating the facility's medicine list:

Health facilities should develop medicine list through their DTCs and update the list regularly. Medicines for the facility's medicine list should be selected for prevalent health problems of the area on the basis of a recent standard treatment guidelines (STG) nationally developed for that level of the health facility. Cost of the full course of treatment should be taken into account when comparing medicines with the same safety and efficacy profiles. The medicine list should be comprehensive in that it should contain medical supplies, and laboratory reagents and chemicals, in addition to drugs. The DTC should make sure that the procurement of medicines and the prescribing is guided by the list through continuous follow-up. The list should be reviewed annually so as to update it in line with local and national changes in treatment protocol and/or disease pattern. *(Annex IV)*

5.1.4. Promoting Adherence to STG and use of Standard Prescription Paper

Experience has shown that even when pharmaceutical supply is based on an approved formulary or essential medicines list, ample opportunity exists for ineffective, unsafe, or wasteful prescribing. The Drug and Therapeutics Committee (DTC) is responsible for numerous important pharmaceutical management functions including the development and implementation of STGs. When implemented effectively, an STG offers advantages to providers, supply managers and health policy makers.

Ensuring the availability and use of STGs provides the very essence of the DTC's efforts to promote rational pharmaceutical therapy. Every effort should be made to readily avail for all practitioners, educate practitioners in the use and importance of the guidelines and update them regularly to ensure accuracy of the information provided change the prescribing patterns. Using drug use evaluations (DUEs) can be helpful in monitoring and ensuring compliance with the STGs.

The DTC should encourage prescribers to use Standard Prescription Paper (Annex V) and completely fill all the necessary information.

5.1.5. Prevention & Containment of Antimicrobial Resistance (AMR)

DTCs are important to monitor and improve medicines use in institutional settings and help contain AMR. The World Health Organization (WHO) Global Strategy for Containment of Antimicrobial Resistance stated that DTCs are a key means of intervention to contain AMR in institutional settings. In hospital settings, the DTC is a key body to help preserve effectiveness of existing antimicrobials. This goal can be accomplished by various methods—

- Updating and managing antimicrobial formulary
- Developing policies on antimicrobial procurement and quality
- Developing and updating antibiotic guidelines
- Developing policies to improve compliance with guidelines
    - reserve antibiotics, levels of prescribing, automatic stop orders, antimicrobial order forms
- Providing pre-service and in-service education on rational use of AMs
- Contributing to collection and management of antimicrobial surveillance and resistance information for coordinated action with the Infection Control Committee
- Providing education to patients on the use and abuse of antimicrobials and encouraging adherence
- Supporting pharmacovigilance activities for antimicrobials
- DTC can create AMR subcommittee to help

5.1.6. NPS Proper handling

DTCs are also expected to oversee the proper handling and administration of narcotic drugs and psychotropic substances. It is very important that DTCs should update healthcare providers on the list of controlled narcotic drugs and psychotropic substances, and the regulations regarding their storage, prescribing, dispensing, and documentation and reporting requirements as per the national guidelines.

5.1.7 Infection Control

The spread of infectious diseases in hospitals between patients and staff is a serious problem. These hospital-acquired infections (called *nosocomial infections*) contribute to morbidity and

mortality in hospitals and health care facilities and significantly compromises quality of service The goal of IC programs is to decrease and minimize the spread of infections between patients and providers in health care facilities

Although an Infection Control Committee (ICC), is responsible for infection control the entire health care community is responsible for developing and following procedures to prevent infections. Because it can play a pivotal role in assisting the ICC and in leading the hospital in IC activities, the DTC bears much of the responsibility. Some authorities believe that effective ICCs and DTCs will provide the basis for developing more comprehensive quality assurance programs throughout the health care organization.

5.1.8 Drug information services (DIS)

Rational use of drugs requires access to objective drug information. The ever-growing number of pharmaceuticals, the increased amount and complexity of literature, and the critical need for unbiased assessment of clinical data underscore the importance of well-developed DI skills. Drug information Service (DIS) is a unit designed for receiving, collecting, analyzing, and providing unbiased, accurate and up-to-date information about drugs and their use. DIS requires clinically trained staff with access references, internet and databases, computers, appropriate budget source, staff training facilities and service quality assurance mechanisms. A DTC can significantly overlooks provision of reliable and updated information to health care professionals and hence facilitates the establishment of Drug information unit and assess its impact in the promotion of rational drug use.

5.1.9 Quality assurance

The purpose of quality assurance (QA) in public pharmaceutical supply systems is to make certain that each medicine reaching a patient is safe, effective, and of standard quality. QA activities in a hospital or clinic should be comprehensive, spanning the entire supply process from medicine selection to patient use. A comprehensive quality assurance program includes both technical and managerial activities from selection to patient use. Many areas within a health care system may be involved with quality assurance, including procurement, pharmacy, medical, and nursing departments, as well as the DTC.

Ensuring quality of a product is twofold;-*Obtaining* quality products that are safe and effective through structured selection and procurement methods and *maintaining* quality products through the appropriate storage, distribution, monitoring, and prescribing methods

The DTC is an important component of the hospital's or health center's QA program. The DTC should have an active advisory role on all components of the QA program to ensure that medicines are of the highest quality.

The DTC should work in defining product specifications, providing technical advice to the health care organization on Procurement of Pharmaceuticals, and analyzing quality complaints. *It should also* work with drug regulatory agencies, the procurement department, suppliers, pharmacies, physicians, and patients to analyze, evaluate, and take action on quality complaints of products. This function of the DTC is vital to ensure that medicines of good quality are available.

5.1.10 Pharmaceutical care

The use of clinically oriented pharmacy personnel to help achieve rational use of medicines is an important intervention, one that is frequently overlooked in many countries. A well-trained pharmacist will have the skills to monitor, evaluate, and make recommendations on the use of medicines. These skills should be used as much as possible to improve pharmaceutical therapy. Pharmacists have been shown to contribute to improved care when they are involved on medical ward rounds. Studies have shown this practice to be a valuable addition to improving the use of medications in a hospital.

These individuals can be expected to ensure that indications for use are appropriate; that correct doses are prescribed, medicine interactions, and adverse drug reactions are avoided or minimized; and that patient counseling and education is provided. Pharmacy personnel can supply medical providers with up-to-date, unbiased information to help with difficult pharmaceutical therapy decisions. Pharmacists with medicine information skills should be members of the DTC. Where skills may not be available to provide some of these services, it is advisable to provide training because availability of these skills has been shown to be cost-effective in improving pharmaceutical therapy and in decreasing adverse events.

An important part of a pharmacy program is to control the use of certain medications by providing generic substitution and therapeutic substitution (interchange). In these programs, pharmacists are authorized to substitute a medicine that has been prescribed by a physician with a medicine that is considered to be equivalent. The DTC and medical staff must approve of any medicine that is a part of a therapeutic substitution scheme.

5.1.11 ART/TB/Malaria, and Maternal and Child health

Activities aimed at strengthening pharmaceutical systems, services, and supply chains for ARV/TB/Malaria medicines and commodities. DTC provides technical and thought leadership through active participation in ARV/TB/Malaria initiatives. DTC develops mechanisms for technical assistance and capacity building to ensure an uninterrupted supply of ARV/TB/Malaria medicines, and the utilization of reliable pharmaceutical information for improved decision making and planning.

DTC should also work on increasing access to essential medicines, medical devices, and health supplies that effectively address leading avoidable causes of death during pregnancy, childbirth, and childhood. An active, DTC can help to maintain a focus on the full set of RMNCH commodities and long-term product availability issues, strengthen coordination between stakeholders, and reduce duplication and inefficiencies. DTC can also provide a consultative forum that can effectively coordinate reproductive health commodities security activities among partners and develop, implement and monitor the implementation of the national Reproductive Health Commodity Security Strategy.

5.1.12 Assessing medicine use to identify problems:

It is important for the DTC to identify and prioritize problems in the management and use of medicines and make appropriate recommendations. Methods DTCs can use to identify drug use problems include:

- Aggregate methods that includes ABC/VEN analyses and Defined Daily Dose methodology*(Annex VI)*
- Indicator Methods – Prescribing indicators, patient care indicators, health facility indicators *(Annex VII)*

- Drug use evaluation (DUE)*(Annex VIII)*
- Monitoring adverse drug reactions and medication errors
- Antimicrobials use pattern
- Qualitative medicine use studies
- Hospitals with the necessary infrastructure may conduct Antimicrobial resistance surveillance. The studies are not a one time activities and should be conducted regularly.

5.1.13 Designing and implementing effective interventions to improve medicine management and use:

The data collected by the DTC should be used to correct any drug use problems that are identified by different methods of drug use studies. The DTC should conduct interventions to promote rational drug use. Such interventions may include:

- *Educational strategies* such as establishing drug information service, patient education, providing continuing education to prescribers and dispensers, etc.
- *Managerial strategies* such as implementing STGs, implementing clinical pharmacy service, medicine use evaluation and feedback, developing/adopting and implementing procedures and procedures to improve the management and use of medicines, etc.
- *Regulatory Strategies* such as adherence to facility specific list of medicines, use of standard prescription paper, prescribing and dispensing restrictions, regulation of pharmaceutical promotional activities, etc.

5.1.14 Managing Adverse Drug Events (ADE):

The DTC should implement programs to track Adverse Drug Reaction (ADRs), Medication Errors (ME) and product quality defects and use the information to improve healthcare.

The DTC should be involved in the processing and analysis of spontaneous reports arising from patients and healthcare professionals. The DTC should also perform analysis of ADRs, ME and product quality problems to study the prevalence, severity, and trends at their facility.

The DTC should initiate discussions on analyzed medicine-related problems on a regular schedule. The result of these discussions and analysis should then be used to design interventions, methods, procedures that will prevent similar errors to re-occur in the future at the facility. With the information obtained through this process, a definitive decision can be made

upon the facts as presented. Determine if the reaction is an ADR, medication error, or a quality defect. The actions taken should be followed-up to determine further improvement in their facility. Healthcare providers should be familiar with the pharmacovigilance (PV) system of the country and encouraged to report ADE cases when they encounter through a PV system that should be established in the facility. Patients with medication related allergy should be provided with Allergy card (Annex IX). ADEs collected in the healthcare facility should be reported to the national PV center at FMHACA. A focal person should be assigned to coordinate all ADE monitoring activities in the facility and serve as a link between the facility activities and the national PV center. *(Annex X)*

5.1.15 Information dissemination and transparency: The DTC must disseminate information about its activities, decisions and recommendations to all the staff who should implement the decisions. Inadequate dissemination of information leads to a loss of credibility. It is also very important that the DTC operates in such a way so as to ensure transparency of all its decisions and to avoid conflict of interest.

5.1.16 Managing drug supply: The main aim of Drug supply management is to ensure availability, affordability and rational use of *essential drugs. This involves proper selection, Quantification, Procurement, Inventory management and distribution of pharmaceuticals*. Under each cycle proper Quality monitoring is mandatory. The drug management cycle illustrates the necessity for coordination of managerial and technical support with appropriate drug policies and guidelines in order for the system to run smoothly. The DTC should oversee the proper implementation of the policies and procedures developed/adopted to improve the management of medicines the DTC should also manage the appropriate waste management measures in the facility and recommend corrective actions timely.

5.2Duties and Responsibilities of the Chairperson

Chairperson of the DTC will have the following duties and responsibilities:

- Ensures that the aims and objectives of the DTC are applied
- Ensures that decisions of the committee are based on scientific evidence, where such evidence is available.
- Establishes good relationship between the committee and health facility management
- Appoints an acting chairperson from the members if he/she is to be absent.
- Presents performance report to health facility management
- Represents the committee in the management meetings and other relevant events
- Calls regular and extraordinary meetings
- Chairs the meetings.
- Communicate relevant decisions and information made by management to DTC

5.3 Duties and Responsibilities of the Secretariat

The DTC secretary will have the following during and responsibilities:

- In consultation with the chairperson, prepares the agenda for meetings and notify to all members of the DTC at least three days before the meeting.
- Collect and circulates all pertinent material for meetings to all members at least three days before the meeting.
- Prepares the minutes of meetings and disseminate to all members within three days after the meeting.
- Follows up the action plans of the committee.
- Ensures that the decisions taken by the committee are submitted to the health facility management.
- Participate in other activities of the committee
- In collaboration with the chair person communicate relevant decisions and information made by management to DTC

5.4 Duties and Responsibilities of a Member

A DTC member will have the following duties and responsibilities:

- Demonstrates professional competence through active participation in the meetings.
- Proposes issues that need to be discussed
- Participates in activities of the committee
- Give prior notification if he/she will not be attending the next meeting.
- Communicate decisions of the Committee to the department/case team they represent
- Perform other activities that is assigned for them by the DTC

6. Meetings of the DTC

- DTCs should meet regularly, at least six times a year
- DTCs can call extraordinary meetings when necessary
- If the chair person is not available for various reasons his/her delegate should chair the meeting
- The committee may invite persons within or outside the health facility to DTC meetings who can contribute from their specialized knowledge or experience.
- Issues to be discussed should be determined jointly by the chairperson and the secretary.
- An agenda is desirable and should be prepared and submitted to members three days before the meeting.
- Minutes should be kept by the secretary and should be maintained in the permanent records of the health facility. *(Annex XI)*
- Recommendations of the DTC should be presented to management committee for adoption of recommendations.
- Two-third of the membership of the committee will constitute a quorum for any meeting.
- Decisions made if 50% + of the members agree
- Correspondence should be addressed to the secretariat of the DTC

7. DTC Follow-up and Support

Health facility DTCs should get coordinated regular follow-up and support from health facility management and quality team, Woreda Health Office, Zonal Health Department (ZHD), Regional Health Bureaus (RHBs), PFSA, FMOH, EFMHACA and development partners as per the level of the health facility. This requires establishing a joint DTC Follow-up and support Fora /forum at respective levels following PFSA's organizational structure.

At Federal level, there should be joint forums between FMOH, PFSA and EFMHACA to oversight and guide the overall DTC activities. PFSA Hubs and EFMHACA which are located at capital cities of Regional states should have a forum with RHB and Regional Regulatory Body, and PFSA Hubs that are located at Zones should have a forum with ZHDs to provide the necessary follow-up and support to DTCs of health facilities under their catchment area. PFSA Hubs serving facilities from two or more regions/zones should establish a forum with members from each of the regions/zones.

The Joint Forum is responsible for providing joint support to health facility DTCs under their catchment based on a joint action plan approved by the respective offices.

Among the vast roles the following can be mentioned as major support activities that the joint forum can perform:

- Providing continuous and close follow up and technical support to DTCs.
- Assessing the gap of trainings and provide capacity building in terms of training as a continuous effort to counteract gap created as a result of staff turnover.
- Monitoring and evaluating the functional status of DTC's in order to improve the performance of the DTC.
- Enforce the DTC guidelines.
- Organizing regional or national forums where best practices and challenges of DTCs could be discussed and best practices are acknowledged.
- Designing and Implementing Strategies to motivate DTCs
- Conduct assessment and detailed investigations to identify the actual outcomes and impacts of hospital DTCs.

There should be a mechanism in place to quarterly review implementation status of the agreed upon joint plan. Identifying best DTC practices through routine report or assessment, providing the necessary recognition, and scaling up best practices to other health facilities should be part of the Joint Fora's role. Health Center DTCs should support Health Posts under the health center in the management and use of medicines.

DTC-related activities should be appropriately documented at all levels using appropriate formats and be reported to the next higher level on quarterly basis as part of the health facilities' performance report.

There should be a monitoring and Evaluation system at each level of the health care. *(Annex III).*

8. Starting and Revitalizing DTC

8.1 Starting a DTC

For health facilities to establish DTC, at least the Medical director or head of pharmacy should get the Training or orientation on DTC. Thus, those trained/oriented professionals, supported by the health facility management, should play the leadership role in initiating DTC in the facility. Starting a DTC will requires to undertake a lot of advocacy. The medical director and pharmacy head need to explain the results from the training to the management, senior medical staffs and other relevant stakeholders. They also should have gathered evidences about the medicine use problems and drug management in their respective health facility. Prior to meeting the management, senior staffs and stakeholders, it will be good if they can conduct some studies like VEN/ABC reconciliation, prescribing indicator studies. This helps to show how much high the problem is and which problems are the most serious and how this might negatively affects patient outcome and the health facility budget.

During the presentation they should show how much time does these studies took and the possibility of having many other drug related problems that need to be identified and resolved to improve patient care. They should also emphasize that these detailed investigations needs resources and collaborative efforts of different professionals. The directions of the meeting have to be shifted to implementing the intervention and evaluate it by measuring the drug use problem before and after implementation. Interventions may be educational, managerial or regulatory and should be implemented with the full cooperation and participation of the senior prescribers and

stakeholders. Measure also the cost of the intervention and the savings in terms of less drugs used as health facility administrators are likely to be more supportive in the future if they see that your measures have saved money. The type of interventions used will depend on the nature of drug use problem identified and investigated.

If the above process has been followed, it is very likely that you will already have started planning a DTC. By now, the senior medical and administrative officials that are kept fully involved in the process should be sufficiently motivated to help in the establishment of a DTC. Terms of reference, membership and methods of working need to be agreed by the senior physicians and management. A successful DTC is an active one. Therefore, the cycle of changing drug use problems should be continued, addressing one drug problem at a time.

8.2 Revitalizing non-functioning DTCs

In some cases DTCs may be established but cease to function. The way to address this issue is similar to starting up a DTC from scratch. Often DTCs do not function because there is:

- lack of awareness of drug use problems or interest to address these problems
- lack of awareness of what a DTC could do to address drug use problems
- lack of time or reward for members to undertake any DTC activities
- lack of support from health facility's management.
- Lack of members commitment

Just as with changing medicine use problems, the first step in revitalizing DTC is to identify and quantify the problem and understand why it exists. Only after this, can solutions be found. Therefore, if staffs are unaware of medicine use problems, demonstrate the problems and their underlying causes. If DTC members are not active, find out the reasons. If a DTC has ceased to function because a specific issue that failed to be resolved, investigate that specific issue and tackle the problem again following an agreed set of steps. Resolve the simpler problems before tackling the more complex ones.

It is not the role of the DTC to take over the function of any department. The membership of the DTC should be drawn from the various departments and their expertise used to ensure that all aspects of drug management and use are performed to a high level in a coordinated manner.

There is nearly always something we can do to get started. Patients deserve all efforts to ensure that they receive drugs appropriate to their clinical needs in doses that meet their individual requirements.

Source Documents:

1. DACA. Guideline for the Establishment and Operation of Drug and Therapeutics Committee in Ethiopia, 2004, Addis Ababa.
2. PFSA (2014). National Assessment on Functional Status and Perceived Effectiveness of Drug and Therapeutics Committees at Public Hospitals in Ethiopia, Addis Ababa.
3. FMoH. Ethiopian Hospital Reform Implementation Guideline, Vol. 1, Chapter4: Pharmacy service. Addis Ababa; 2010.
4. Ethiopian Standards Authority. Comprehensive Specialized Hospital Requirements, Ethiopian Standard ES 3618, Addis Ababa, 2012.
5. WHO (2003). Drug and Therapeutics Committee. A practical guide. WHO/EDM/PAR/2004.1, Geneva, Switzerland
6. WHO and MSH (2013). Managing Access to Medicines and Health Technologies, Kumarian Press, USA
7. Council of Australian Therapeutic Advisory Group (CATAG). Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals, 2013, Australia.
8. EFMHACA. Directives to Control and Promote Proper Use of Narcotic Drugs and Psychotropic Substances, Addis Ababa; 2013.
9. EFMHACA. Directives to Control Narcotic Drugs and Psychotropic Substances Prescription Papers, Addis Ababa; 2013.
10. EFMHACA. Guideline for Adverse Drug Events monitoring (Pharmacovigilance). 3rd Edition. Addis Ababa; 2013.

Annexes:

Annex I: List of Workshop Participants

Workineh Getahun	**USAID/SIAPS**
Betelehem Gulelat	**ALERT**
Regassa Bayissa	**FMOH**
Fikru Worku	**USAID/SIAPS-PFSA**
Admassu Teketel	**PFSA**
Mahlet Tibebu	**PFSA**
Siraj Adem	**PFSA**
Bahiru Zewde	**EFMHACA**
Tilahun Birhane	**PFSA(Addis Ababa)**
Fitsum Girma	**PFSA (Adama)**
Hyleyesus Wossen	**PFSA**
Robera Bogale	**PFSA**
Alemthehay Adam	**Meshuwalkiya**
Tibeb Zeleke	**Addis Ababa Regional Health Bureau**
Seife Demissie	**Amanuel hospital**
Teshome Tafese	**Oomia Regional Health Bureau**
Mulugeta Teshome	**Kolfe HC**
Manayeh Wubalem	**Tirunsh beijing hospital**

Annex II: Contents of a DTC Terms of Reference (TOR)

- A mission statement
- Objectives and strategic priorities
- Scope and what is outside the scope
- Reporting structure/organizational chart or governance structure within the health Facility
- Delegated authority to make decisions (e.g. financial or policy) vs advisory role
- Outline of the function
- Relationship with other organizational committees
- Membership and length of appointment (or appointment review process)
- Appointment process (including length of term) for DTC Chair and DTC Secretary
- Attendance expectation of committee members and use of alternates or delegates
- Statement addressing conflicts of interest
- Information pertaining to frequency of meeting
- Quorum requirements
- Establishment and governance of subcommittees
- Process for approval and endorsement of TOR
- Review timeframe for TOR

Annex-III Drug and Therapeutics Committees Performance Evaluation Check list

S/N	Items	Yes	No	Remark
1	**Is the DTC Functional?**			
	• Are DTC members assigned with formal letter?			
	• Are the members DTC multi disciplinary?			
	• Does the DTC have Terms of Reference (TOR)?			
	• Does the DTC have Annual Action Plan for the current budget year?			
	• Is the DTC Plan part of the health facility's overall plan?			
	• Does DTC conducts regular meeting? (at least every 2 months)			
	• Does minutes of all DTC meetings recorded and filed?			
	• Does health facility management support the DTC?			
2	**General activities**			
	• Has the DTC developed and implemented interventions to improve the supply management and use of medicines in the facility?			
	• Has the DTC developed/revised medicine list of the health facility?			
	• Has the DTC Conducted indicator based drug use study periodically?			
	• Does the DTC Conduct drug use evaluation, DUE) periodically?			
	• Has the DTC designed and implemented interventions to improve the supply management and use of medicines?			
	• Has the DTC Developed/adopted drug supply management guide?			
	• Has the DTC developed and implemented procedures for identifying problems prescribing and use of Antimicrobial drugs?			
	• Does the DTC report its performance to the health facility management quarterly?			
	• Does the DTC evaluate its performance at least annually?			
	• Does the health facility's management evaluate performance of the DTC and provide feedback quarterly?			
	• Are the activities of DTC part of the regular report of the hospital?			

Annex IV: Template for Pharmaceuticals List Preparation

These are the major contents of the template for pharmaceutical list preparation.

Title: List of Pharmaceuticals for _____ Hospital/Health Center (_____ Edition)

List of DTC members: *List the names and professions of DTC members and their position in the DTC*

List of editors: *List the name, profession and position of the DTC members who were assigned in the editorial subcommittee of the DTC*

Table of Contents

Acknowledgments: *In this part, acknowledge individuals and institutions (including the DTC members) who in one or another way contributed to the preparation of the list*

List of acronyms and abbreviations: List down acronyms and abbreviations used in the list alphabetically

Foreword : *In this part, write brief description about the importance of the list preparation, how it will be used and revised, and acknowledge groups and institutions who contributed for the preparation of the list in the name of the highest management official of the health facility (CEO of a hospital, Head/Director of a Health Center). Include the name and position of the official who foreword the message.*

Introduction: *Under this part, include the following briefly: Background information about the health facility, background information about the health facility's DTC and the list development process.*

Pharmaceuticals list management principles: *In this part describe the major Pharmaceuticals List management Principles*

General guide for prescribers and dispensers: *Since all the efforts made to avail the medicines will be nullified if medicines are used irrationally at the level of prescribing, dispensing and patient use. It could be relevant to consider describing guides for prescribers and dispensers in order to effectively manage the formulary system.*

List of pharmaceuticals

Medicines: *Follow the FMHACA categorization for the medicines (generic name of the medicine, strength (s), and dosage form(s) should be indicated for each medicine). Include Program medicines (ARVs, TB and Leprosy, Malaria.) Use the following format for describing the medicines under each sub-category*

S/N	Generic name of the medicine	Dosage form (s) and Strength (s)	Unit	VEN Category
GI.000 Gastrointestinal Medicines				
GI. 100 Antacids				
1				
2				

Medical supplies: *You may sub-classify medical supplies into the following: Dressing supplies, Tubes and Drains, Injectable supplies, Sutures, X-ray supplies and Other Supplies*

S/N	Full description of the medical supply	Unit	VEN Category
1			
2			

Laboratory reagents and chemicals: *List alphabetically using the format indicated under medical supplies*

Medical equipments: *List alphabetically using the format indicated under medical supplies*

For all classes of pharmaceuticals, include program pharmaceuticals classify each of the pharmaceuticals in the list into Vital (V), Essential (E) or Less-Essential (N).

Annex V: Standard prescription

PRESCRIPTION PAPER Code_____

Institution Name: _____Tel. No… ……
Patient's full Name: _____
Sex: ___ Age:___ Weight: _____ Card No. _____
Region: _____Town _____ Woreda_____Kebele _____
House No. ____ Tel. No: _____☐ Inpatient ☐ Outpatient
Diagnosis, if not ICD _____

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

Prescriber's Dispenser's

Full name _____ _____
Qualification _____ _____
Registration #_____ _____
Signature _____ _____
Date: _____ _____

See overleaf

Please Note the Following Information

1. **Prescriptions:**
   - are valid only if it has the seal of the health institution
   - filled and blank are legal documents, treat them as fixed assets
   - written and verbal information to the client complement one another
2. **The prescriber:**
   - drug treatment is only one of the treatment options
   - write the prescription correctly and legibly
   - diagnosis and other parts of the prescription have to be complete
   - abbreviations are NOT recommended
   - please accept prescription verification call from the dispenser
3. **The Dispenser:**
   - check legality of the prescription
   - check completeness and accuracies before dispensing
   - check for whom the medicine is being dispensed: actual client o care taker
   - if in doubt about the contents of the prescription; verify with the prescriber
   - containers used for packaging must be appropriate for the product
   - labels of drugs should be clear, legible and indelible
   - drugs should be dispensed with appropriate information and counseling
   - keep filled prescriptions at least for 2 years
4. **Minimum drug label information** should include the following:
   - Patient name
   - Generic name, strength and dosage form of the medicine
   - Dose, Frequency and Duration of use of the medicines
   - Quantity of the medicine dispensed
   - How to take or administer the medicine?
   - Storage condition

Annex VI. Methods to Investigate Medicine use problems

Stepwise approach to investigating the use of medicines

Medicines have been used irrationally for as long as they have been available; this reduces quality of care, wastes resources and may cause harm to patients. The first step to addressing problems of irrational use of medicines is to measure the problem, analyze it and understand the causes underlying it. Unless medicine use is investigated, measured and documented, it is impossible to evaluate the effectiveness of interventions to promote rational use. There are four main methods, all of which should be regularly used by DTCs.

- ***Aggregate data methods*** involve data that do not relate to individual patients and can be collected relatively easily. Methods such as VEN analysis ABC analysis, Therapeutic Category Analysis, and Defined Daily Dose (DDD) methodology are used to identify broad problem areas in drug use.
- ***Drug indicators studies*** involve collecting data at the level of the individual patient but do not usually include sufficient information to make judgments about drug appropriateness for diagnosis. Such data can be used to identify problem areas in medicine use and patient care, and evaluate interventions designed to correct the problems identified.
- ***Drug use evaluation***s a system of ongoing criteria-based evaluation of drug use that will help to ensure appropriate use at the individual patient level. This method involves the detailed analysis of individual patient data.
- ***Qualitative methods*** such as focus group discussion, in-depth interview, structured observation and structured questionnaires are useful for identifying why drug use problems occur.

STEP 1: General investigation to identify problem areas

Initial investigation should identify broad areas of inappropriate use of medicines. There are two main ways of doing this:

- **Aggregate data methods** use data that are not collected at the individual patient level; such data are often routinely available for purposes other than investigating drug use, for example stock records. Aggregate data give an overview of drug use, which is useful in managing the formulary list.

- **Indicator study methods** use data which are collected at the individual patient level, for example prescriptions or patient–provider interactions. Indicator study data are collected specifically to investigate medicine use, but do not include sufficient information to make individual judgments concerning the appropriateness of a drug prescription for an individual diagnosis. Such data can therefore be collected by trained personnel who are not doctors, pharmacists or nurses.

STEP 2: In-depth investigation of specific problems

Once an area of inappropriate medicine use is identified, it should be examined in-depth in order to determine the size and nature of the problem and the reasons underlying the problem. Such investigation includes:

- **Qualitative methods** to determine the causes of a drug use problem.
  There may be many rational reasons why people use medicines inappropriately; unless these reasons are understood it is impossible to devise an effective strategy to change behavior.
- **Drug use evaluation** to see if the use of a specific medicine is in accordance with previously agreed criteria/guidelines.

STEP 3: Develop, implement and evaluate strategies to correct the problem

Strategies to promote more rational use of medicines should be designed and implemented by the DTC to reduce inappropriate use.

Analysis of aggregate medicine use data

Aggregate data can be used to conduct VEN analysis, ABC analysis, therapeutic category analysis, and defined daily dose (DDD) analyses. All these methods are very powerful tools that a DTC can and should use to manage medicines and identify medicine use problems. Aggregate data on drug use can be obtained from many sources within the health-care system, including procurement records, warehouse drug records, pharmacy stock and dispensing records, medication error records and adverse drug reaction (ADR) records. Aggregate data sources can be used to obtain a variety of information, for example:

- Cost of drugs used – individual drugs and drug categories
  - Which are the most expensive drugs?

- On which drugs is most money spent?
- What are the most expensive therapeutic categories?
- What is the percentage of the budget spent on certain drugs or drug classes?

- Quantities (in units, for example tablets) of drugs used
  - Which are the most frequently and infrequently used drugs?
  - Does actual drug consumption match expected consumption according to morbidity records?
  - Per capita use of specific products
- Relative use of therapeutically substitutable products
- Incidence of adverse drug reactions and medication errors.

All of this data may be broken down (disaggregated) by area of the hospital – surgical wards, medical wards, pediatrics wards, etc. Any identified problems discovered in reviewing this data should be promptly analyzed by the DTC, and a strategy to remedy the problem instituted.

a) VEN Analysis

VEN is a system of categorization medicines based on their degree of importance to provide services at health facilities. It is a method of classifying medicines by their clinical importance into Vital (V), essential (E) or nonessential/less essential (N).The criteria for prioritization of medicines into VEN are as follows:

- **Vital medicines (V)**: potentially life-saving or crucial to providing basic health services. These products should be always available in adequate amounts.
- **Essential medicines (E)**: effective against less severe but significant forms of disease, butnot absolutely vital to providing basic health care.
- **Non-essential medicines (N)**: used for minor or self-limited illnesses; these may or maynot be included in the medicines list, but they are the least important items stocked.

b) ABC analysis

ABC analysis most pharmacists and managers know that only a few drug items account for the greatest drug expenditure. Often 70–80% of the budget is spent on 10–20% of the medicines.

ABC analysis is the analysis of annual medicine consumption and cost in order to determine which items account for the greatest proportion of the budget. ABC analysis can:

• Reveal high usage items for which there are lower-cost alternatives on the list or available in the market. This information can be used to: — choose more cost-effective alternative medicines — identify opportunities for therapeutic substitution — negotiate lower prices with suppliers.

• Measure the degree to which actual drug consumption reflects public health needs and so identify irrational drug use, through comparing drug consumption to morbidity patterns.

• Identify purchases for items not on the hospital essential medicines list i.e. the use of non-formulary medicines. ABC analysis can be applied to drug consumption data over a one-year period or shorter. It can also be applied to a particular tender or set of tenders. A summary of the steps is shown in box 6.1. After an ABC analysis has been completed, individual drugs, particularly from category A, should be examined to identify duplication, use of non-formulary drugs and expensive drugs for which there are cheaper therapeutic equivalents. In some cases the ABC analysis may need to take into account varying price levels, brand products and medical devices, such as syringes. ABC analysis can also be used to analyze one therapeutic class, where all the medicines have equal or similar efficacy. In summary, the major advantage of ABC analysis is that it identifies those medicines on which most of the budget is spent; a major disadvantage is that it cannot provide information to compare medicines of differing efficacy. Using a spreadsheet computer programme such as Microsoft Excel or Lotus 1-2-3 makes ABC analysis much easier.

SUMMARY OF *STEPS OF ABC ANALYSIS*

• *List all the items consumed or purchased.*

• *For each item consumed or*

purchased, write down

— the unit cost of each item (using the prices for a fixed date if prices have varied over time)

— the quantity of each item consumed or purchased.

• Calculate the monetary value of consumption by multiplying the unit cost by the number of units consumed for each item. The total value of consumption is the sum of all items.

• Calculate the percentage of the total consumption value represented by each item by dividing the value of each item by the total consumption value.

• Rearrange the list by ranking the items, in descending order, by percentage value of total consumption.

• Calculate the cumulative percentage value of the total value for each item; beginning with the first (top) item, add its percentage to that of the item below it in the list.

• Categorize your items into:

— A, those few items accounting for 75–80% of total value

— B, those items which take up the next 15–20%

— C, the bulk of items which only account for the remaining 5–10% of value.

Typically, class A items constitute 10–20% of all items, with class B items constituting another 10–20% and the remaining 60–80% being in category C.

The results may be presented graphically by plotting the percentage of total cumulative value on the vertical or y axis and the number of items (accounting for this cumulative value) on the horizontal or x axis

c) ABC/VEN Reconciliation

- ABC/VEN reconciliation builds on ABC analysis. It involves sorting the list of medicines in the ABC analysis by VEN so as to identify whether there is relatively high expenditure on low priority medicines (N category items in "A"). Take appropriate measure on those medicines which fall in 'A' class in ABC analysis while they are N in the VEN analysis.

Undertake drug use evaluation (DUE) on the medicines suspected to be overused that fall under class "A".

d) Therapeutic category analysis

Building on the ABC analysis, therapeutic category analysis can:

- identify therapeutic categories that account for the highest consumption and greatest expenditures
- indicate potential inappropriate use if taken together with information on the morbidity pattern
- identify medicines that are overused or whose consumption is not accounted for by the number of cases of a particular disease, for example chloroquine and malaria
- help the DTC choose the most cost-effective drugs within a therapeutic class and to choose alternative medicines for therapeutic substitution.

The procedure is similar to ABC analysis, and the steps are shown below. As in ABC analysis, a small number of high-cost therapeutic categories account for most of the expenditure. More detailed analysis can be performed within each high-cost category to identify the higher cost drugs and more cost-effective therapeutic alternatives. The steps are:

- Do the first three steps of ABC analysis to produce a list of all items by volume and value of consumption.
- Assign a therapeutic category to each drug using the Pharmacologic-Therapeutic Classification system used on the List of Medicines in Ethiopia.
- Rearrange the list into therapeutic categories and sum the percentage value of items in each category, in order to identify the categories accounting for greatest expenditure.

e) Defined daily dose (DDD)

The defined daily dose (DDD) methodology converts and standardizes readily available product quantity data, such as packages, tablets, injection vials, bottles, into crude estimates of clinical exposure to medicines, such as the number of daily doses. The DDD is the assumed average daily maintenance dose for the medication's main indication.

The units in the recommended dose of a medicine may be milligrams for solid oral formulations like tablets and capsules or milliliters for liquid oral or injection formulations. Converting aggregate quantities available from pharmacy inventory records or sales statistics in to DDDs

roughly indicates how many potential treatment days of a medicine have been procured, distributed or consumed. The medicines can then be compared, using units such as:

- Number of DDD per 1000 inhabitants per day, for total drug consumption
- Number of no. of DDD per 100 beds per day (100 bed-days), for hospital use.

For instance, if the calculations for amoxicillin show that there were 4 DDDs per 1000inhabitants per day in 2002, this suggests that on any given day, for every 1000 persons, 4 adults received a daily dose of 1 g of amoxicillin. If calculations of gentamicin use are expressed as 2 DDD per 100 bed-days, this tells us that, for every 100 beds in the hospital, every day 2 patients received 240 mg of gentamicin. The assigned DDD for amoxicillin is1 g and for gentamicin is 240 mg. These interpretations assume that the prescribed daily dose (the quantity actually prescribed to a patient) is the same as the defined daily dose, although this may not, in fact, be the case.

Summary steps of DDD Calculation

Steps	**Example**
1. Find out the total amount of medicines used or procured in one year in terms of the number of units (tablets, capsules, injections) and the strength (mg, g (gm), IU)	Yearly amounts of methyldopa used by a provincial hospital and surrounding clinics, covering a population of 2 million: 25,000 tablets of methyldopa 250 mg, and 3,000 tablets of methyldopa 500 mg
2. Calculate the total quantity consumed in one year in terms of mg/g/I.U. by multiplying the number of units (tabs, caps, inj.) by the strength of dose	Total yearly consumption of methyldopa = (25,000 x 250 mg) + (3000 x 500 mg) = 7,750 000 mg (7750 g)
3. Divide the total quantity by the assigned DDD for that medicine	Assigned DDD = 1 g for Methyldopa. Thus, number of DDDs of methyldopa consumed = 7750 g/1 g = 7750 DDD
4. Divide the total quantity by the number of patients (if known) or by the population (as shown)	Annual consumption of methyldopa = 7750 DDD per 2, 000, 000 inhabitants per year = 3.875 DDD per 1000 inhabitants per year

Qualitative Methods

Qualitative Methods are used to understand why drug use problem is happening? (to understand causes of a medicine use problem). Qualitative methods to understand the causes of drug use problems include focus group discussion (FGD), in-depth interview, structured observation, and structured questionnaire.

Annex VII: Drug Use Indicators

The WHO/INRUD drug use indicators are intended to measure aspects of health provider behavior in primary health-care facilities in a reliable way, irrespective of who collects the data. The indicators provide information to health-care managers concerning medicine use, prescribing habits and important aspects of patient care. All the indicators have been extensively field-tested in many countries and found to be relevant, easily generated and measured, valid, consistent, reliable, representative, sensitive to change, understandable, and action oriented. DTCs can use indicator studies to:

- describe current treatment practices to determine whether there are problems in medicine use, and which facilities or prescribers have problems. When an indicator study shows unacceptable results, the DTC can investigate the problem in more depth and then take action to improve these results.
- trends over time show through the repeated measurement of the indicators so providing a monitoring mechanism. Prescribers and facilities whose performance falls below a specific standard of quality can be targeted for more intensive supervision.
- motivate health-care providers and DTC members to improve and follow established health-care standards.
- evaluate the impact of interventions designed to change prescribing behavior by measuring indicators in control and intervention facilities before and after the intervention

DRUG USE INDICATORS

A. WHO/INRUD drug use indicators for all health-care facilities

Prescribing indicators:

- *Average number of drugs per encounter*
- *Percentage of drugs prescribed by generic name*
- *Percentage of encounters with an antibiotic prescribed*
- *Percentage of encounters with an injection prescribed*
- *Percentage of drugs prescribed from essential medicines list or formulary*

Patient care indicators:

- *Average consultation time*
- *Average dispensing time*
- *Percentage of drugs actually dispensed*
- *Percentage of drugs adequately labeled*
- *Patients' knowledge of correct doses*

Health Facility indicators:

- *Availability of essential medicines list or formulary to practitioners*
- *Availability of standard treatment guidelines*
- *Availability of key drugs*

Complementary drug use indicators:

- *Percentage of patients treated without drugs*
- *Average drug cost per encounter*
- *Percentage of drug cost spent on antibiotics*
- *Percentage of drug cost spent on injections*
- *Percentage of prescriptions in accordance with treatment guidelines*
- *Percentage of patients satisfied with the care they receive*
- *Percentage of health facilities with access to impartial drug information*

B. ***Selected indicators used in hospitals:***

- *Average number of days per hospital admission*
- *Percentage of drugs prescribed that are consistent with the hospital formulary list*
- *Average number of drugs per inpatient-day*
- *Average number of antibiotics per inpatient-day*
- *Average number of injections per inpatient-day*
- *Average drug cost per inpatient-day*
- *Percentage of surgical patients who receive appropriate surgical prophylaxis*
- *Number of antimicrobial sensitivity tests reported per hospital admission*
- *Percentage of inpatients who experience morbidity as a result of a preventable ADR*
- *Percentage of inpatients deaths as a result of a preventable ADR*
- *Percentage of patients who report adequate post-operative pain control*

Annex VIII: Drug use evaluation (drug utilization review)

Drug use evaluation (DUE) is a system of ongoing, systematic, criteria-based evaluation of drug use that will help ensure that medicines are used appropriately (at the individual patient level). If therapy is deemed to be inappropriate, interventions with providers or patients will be necessary to optimize drug therapy. A DUE is drug- or disease-specific and can be structured so that it will assess the actual process of prescribing, dispensing or administering a drug (indications, dose, drug interactions, etc.). DUE is the same as drug utilization review (DUR) and terms are used synonymously.

Medication use evaluation (MUE) is similar to DUE but emphasizes improving patient outcomes and individual quality of life; it is, therefore, highly dependent on a multidisciplinary approach involving all professionals dealing with drug therapy. An MUE will assess clinical outcomes (cured infections, decreased lipid levels, etc.).

The goal of a DUE or MUE is to promote optimal medication therapy and ensure that drug therapy meets current standards of care. Additional objectives may include:

- creating guidelines (criteria) for appropriate drug utilization
- evaluating the effectiveness of medication therapy
- enhancing responsibility/accountability in the medicine use process
- controlling medicine cost
- preventing medication related problems, for example adverse drug reactions, treatment failures, over-use, under-use, incorrect doses and non-formulary medicine use
- identifying areas in which further information and education may be needed by healthcare providers, etc.

Once the main problem areas are identified, a DUE system can be established relatively quickly.

The steps of a DUE

1. Establish responsibility: Identifying and assigning individuals and groups is the first step in the process of undertaking
2. Develop scope of activities.
3. Establish criteria.

4. Define and establish thresholds.
5. Collect data and organize results.
6. Analyze data.
7. Develop recommendations and plan of action.
8. Conduct MUE follow-up.

Annex IX: Allergy card

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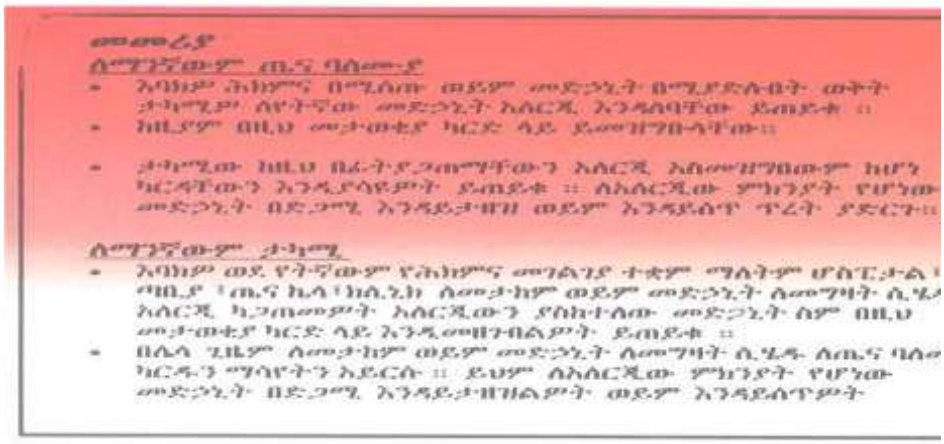
USAID msh SPS



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- ታካሚው ከዚህ በፊት ያጋጠማቸውን አለርጂ አስመዝግበውም ከሆነ ካርዳቸውን አንዲያሳዩዎት ይጠይቁ ። ለአለርጂው ምክንያት የሆነው መድኃኒት በድጋሚ አንዳይታዘዝ ወይም አንዳይሰጥ ጥረት ያድርጉ።

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Annex X: ADE reporting format

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

Patient Name (abbreviation)	Card No	Age, Date of birth	Sex	Weight	Height
Ethnic group		Substance of abuse			

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

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

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

Reaction necessitated: Discontinuation of drug/s □ YES □ No Hospitalization prolonged □ YES □ No	Reaction subsided after D/C of suspected drug? □ YES □ No □ Information not available Reaction reappeared after restart of suspected drug? □ YES □ No □ Information not available
Treatment of reaction:	
Outcome: □ Died due to the adverse event □ Died, drug may be contributory □ Not yet recovered □ Recovered without sequelae □ Recovered with squelae □ Unknown	
Squelae:	
Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc	

Reported by: Name	Profession:	Email address:	Telephone
Name of health institution:			Date

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

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

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

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what to report

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

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

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

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From ----------

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Postage prepaid

Food, Medicine and Health care Administration
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 XI: Template for Recording DTC Meeting Minutes

Minutes of _____Hospital/Health Center DTC Meeting

Date, time and place of Meeting: _____

Meeting Participants

Name	Position in DTC	Signature
1.xxx xxx___	Chairperson	_____
2. _____	_____	_____
3. _____	_____	_____

List of Absentees *(and the reasons why they are absent)*

1.

2.

Agenda

(List down the agenda items to be discussed)

Proceedings

(For each agenda item, record the major issues raised, assignments given and decisions made)

(At the end, record date, time and place of the next meeting, and the time at which the meeting was completed)