



FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA  
MINISTRY OF HEALTH

**DRUG AND THERAPEUTICS COMMITTEE  
TRAINING COURSE FOR HEALTH  
PROFESSIONALS**

**PARTICIPANT'S MANUAL**

**January, 2019  
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## APPROVAL STATEMENT OF THE MINISTRY

The Federal Ministry of health of Ethiopia has been working towards standardization and institutionalization of In-Service Trainings (IST) at national level. As part of this initiative the ministry developed a national in-service training directive and implementation guide for the health sector. The directive requires all in-service training materials fulfill the standards set in the implementation Guide to ensure the quality of in-service training materials. Accordingly, the ministry reviews and approves existing training materials based on the IST standardization checklist annexed on the IST implementation guide.

As part of the national IST quality control process, this national DRUG AND THERAPEUTICS COMMITTEE training package has been reviewed based on the standardization checklist and approved by the Ministry in January, 2019.



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## Foreword

The Federal Ministry of Health (FMOH) has been coordinating sector wide reforms that aim to improve equity and quality of health services. As part of these efforts, the ministry is also exerting concerted efforts to improve accessibility and quality of pharmaceutical products and services. It is widely known that; the sector is growing in line the overall growth and transformation plan of the country and the sector is being guided by the health sector transformation plan (HSTP).As part of these efforts, establishing and strengthening Drug and Therapeutics Committees (DTC) at health facilities has long been one of the capacity building focus areas so as to improve the supply management and rational use of medicines at health facilities.

Drug and Therapeutics Committee is an essential component of a health facility's effort to improve availability and ensure rational use of medicines. In this regard, efforts have been made by FMHACA, PFSA, and FMOH, in collaboration with development partners. As a result, many health facilities were able to establish DTCs. However, the functionality of the committees varies significantly from hospital to hospital.

Thus, the development of this training manual is an important step to address knowledge, skill and attitude gaps identified to establish and functionalize DTC to improve the supply management and rational use of medicines at health facilities.

I would like to take this opportunity to thank all who participated in the revision and development of this training manual.



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## Acronyms

ADE	Adverse Drug Events
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
AOF	Antimicrobial Order Form
DIS	Drug Information Service
DTC	Drug and Therapeutics Committee
EHRIG	Ethiopian Hospitals Reformation Implementation Guideline
EHCRIG	Ethiopian Health Centre's Reformation Implementation Guideline
EFMHACA	Ethiopian Food Medicine and Healthcare Administration and Control Agency
EML	Essential Medicines List
ESA	Ethiopian Standards Agency
FGD	Focus Group Discussion
FMOH	Federal Ministry of Health
HSDP	Health Sector Development Plan Health Facility
HSTP	Health Sector Transformation Plan
INRUD	International Network for Rational Use of Drugs
INN	International Non-proprietary name
MUE	Medicine Use Evaluation
PFSA	Pharmaceuticals Fund and Supply Agency
QA	Quality Assurance
RHB	Regional Health Bureau
RMU	Rational Medicines Use
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Term of Reference
TOT	Training of Trainers
VEN	Vital, Essential, Non (Less) - Essential
WHO	World Health Organization
WoHO	Woreda Health Office
ZHD	Zonal Health Department

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## Introduction to the manual

The Federal Ministry of Health (FMOH) is leading a sector wide reform to improve accessibility and quality of health services. The country has implemented successive Health Sector Development Plans (HSDPs) since 1997 in four phases each for five years, which have contributed a lot in addressing the priority healthcare needs of the population. The country has now embarked upon its fifth plan, namely, the health sector transformation plan (HSTP) which covers 2015 – 2020, aims to transform the health sector so as to further improve equity, coverage and utilization of essential health services, improve quality of health care, and enhance the implementation capacity of the health sector at all levels of the system.

To have successful health programs, ensuring sustainable availability of medicines, medical supplies, and equipment and strengthened pharmacy service is very crucial. To this end, different pharmacy service initiatives such as Drug and Therapeutics Committee (DTC), Auditable Pharmaceuticals Transaction and Service (APTS), Clinical Pharmacy (CP), Drug Information Service (DIS), Good Dispensing Practice (GDP), prevention and containments of Antimicrobial Resistance (AMR), etc. have been undertaken by the Federal Ministry of Health in collaboration with partner organizations.

Establishing and strengthening at health facilities has long been one of the health system strengthening focus areas so as to improve the supply management and rational use of medicines at health facilities. Federal ministry of health, in collaboration with development partners, conducted national mini assessment survey in June 2018 to assess the performance of DTCs at public health facilities showed that most health facilities have established DTCs.

However, the functionality of the committees varies significantly from facilities to facilities. Functional DTCs were able to develop medicines list for hospitals and health centers, undertake drug use studies, improve rational prescribing, dispensing and patient utilization, develop manual on supply management and use of medicines and establish and strengthen drug information services. Inadequate follow-up and support, lack of performance monitoring and evaluation system, training gaps, and staff turnover were the major challenges identified for DTC performance during the mini assessment. Beside this findings, respondents suggested content revision of the existing DTC training material.

Accordingly, building the capacity of DTC members working at hospitals and health centres was identified as one of the interventions that the Ministry planned to implement to address the challenges. Furthermore, the existing DTC training materials do not fulfill the standards set in the national in-service training directive and implementation guide. Hence, to address these challenges and standardize the training material, it was found necessary and timely to revise the training material that was developed by PFSA in 2016.

The course was revised to enhance health professionals' knowledge, skills, and attitude in critical areas of competencies so that they can meaningfully contribute to establish and functionalize DTC.

The revised training material contains Participant's Manual, Facilitator's Guide and PowerPoint Presentations. The training course considers participants as the focus of the learning process and as such activities in the sessions are designed to be more trainee-focused.

## **Core competency**

At the end of this course, participants will acquire the following core competencies: -

**Required Knowledge:** Rational medicine use, organization and functions of DTC, Developing and maintaining health facility specific medicine and medical device list, identifying medicine supply and use problems, strategies to improve medicine use, medicine safety and quality assurance, antimicrobial resistance prevention & containment and monitoring and evaluation of DTC performance

**Required Skill:** Coordination skill, effective communication skill, problem identifying and designing innovative strategy skills, planning and monitoring skill

**Required Attitude:** CRC, develop sense of DTC ownership, enhance team spirit and accountability

## **Course Syllabus**

### **Course Description**

This 5-days DTC training course is designed for hospital and health center drug and therapeutic committee members to improve the supply management and rational use of medicines at health facilities.

## **Course Goal**

To provide the necessary knowledge, skill and attitude to DTC members to improve the supply management and rational use of medicines at health facilities

## **Participants learning objectives**

At the end of this course participants will be able to:

- Provide CRC health care service delivery
- Promote Rational Medicine Use
- Establish and revitalize DTC
- Develop policies and procedures to manage medicines
- Develop and maintain the health facility's medicine and medical device list
- Identify medicine supply and use problems
- Design intervention strategies to improve medicine related issues
- Promote monitoring and management of ADEs
- Promote prevention and containment of antimicrobial resistance
- Monitor medicine procurement and inventory management
- Communicate, Collaborate and Coordinate DTC related activities
- Monitor and evaluation of DTC performance

## **Training Methods**

- Brainstorming
- Interactive lecture
- Demonstration
- Small group discussion
- Group exercise
- Pair exercise
- Question and answer
- Individual reading

## **Learning Materials and Resources**

- Participant manual
- Facilitator guide

- PowerPoint presentations
- STG and formulary
- LCD Projector
- White board and markers
- Computer
- Flipchart and Markers
- Masking tape
- ADE reporting form
- Prescribing indicator form
- Prescription consolidation form
- Copy of completed/filled prescription
- Copy of TOR and action plan template
- MUE form
- Patient chart

### **Participant Selection Criteria**

The target group for this course is hospital and health center health professionals who are/will be Drug and therapeutic committee members. Additionally, pharmacy services and pharmaceutical supply chain professionals working at FMOH, RHBs/ZHD/WoHO, PFSA, universities, partners, etc. who provide technical support are target audiences of this training.

### **Facilitator / Trainer Selection Criteria**

Facilitators of the first round shall be selected from training material revising technical team. Trainers for this course should be pharmacists, physician, health officer and BSc. Nurse who have DTC TOT training certificate and experiences as a DTC member and technical support provision to the DTC. Trainers of DTC TOT must have experience in adult learning techniques (ALT). Four trainers each staying for the whole duration of the training are needed for each training session. It is strongly recommended to include one clinician among the trainers.

### **Methods of Evaluation**

#### **A. Course Evaluation**

- Daily evaluation

- End of training evaluation
- Participant oral feedback

## **B. Trainees Evaluation**

- ***Formative***
  - Direct observation with feedback
  - Group activities and presentations
  - Individual reflections for questions
- ***Summative***
  - ***For basic training***
    - Review of trainee's work using assignments -20%
    - Written exam (post-test) - 80%
  - ***For TOT training***
    - Teach back:- 50%
    - Posttest:- 50%

## **Certification Criteria**

Certificates will be provided to basic training trainees who have scored 70% and above on summative assessment and attended 100% of the course. For TOT trainees, certificate shall be provided to those who have scored 80% and above on summative assessment and attended 100% of the course.

## **Course Duration**

Five days.

## **Suggested Class size**

Suggested training class size: shall not be more than 25 participants per training venue.

Four trainers each staying for the whole duration of the training are needed for each training session.

## **Training Venue**

The training will be conducted at the nationally recognized IST centers/CPD providers having appropriate facilities, trainers, and attachment health facilities.

## Course Schedule

### Training Course on Drug and Therapeutics Committee for Professionals

Organized by: \_\_\_\_\_

Venue: \_\_\_\_\_

Date: \_\_\_\_\_

#### Day One

Time	Topic	Facilitator/s name
8:30-9:00 am	Registration	
9:00-9:15 am	Welcoming Address/Opening Speech	
9:15-10:00 am	Introductory activities	
10:00-10:30 am	Pre test	
<b>10:30-10:45 am</b>	<b>Tea Break</b>	
10:45-12:30	Introduction to CRC	
<b>12:30-2:00 pm</b>	<b>Lunch Break</b>	
2:00-3:30 pm	Rational use of medicines	
<b>3:30-3:45 pm</b>	<b>Tea Break</b>	
3:45-5:20 pm	Overview of Drug and Therapeutics Committee	
5:20-5:30 pm	Day 1 Evaluation	

#### Day Two

Time	Topic	Facilitator/s name
8:30-8:40 am	Recap of Day One	Participants
8:40-10:30am	Developing policies and procedures to manage medicines	
<b>10:30-10:45 am</b>	<b>Tea Break</b>	
10:45 -12:30pm	Developing and maintaining health facility specific medicine and medical device list	
<b>12:30-2:00 pm</b>	<b>Lunch Break</b>	
2:00-3:30 pm	Developing and maintaining health facility specific medicine and medical device list continued	
<b>3:30-3:45 pm</b>	<b>Tea Break</b>	
3:45-4:50 pm	Developing and maintaining health facility specific medicine and medical device list continued	
4:45-5:20	Identifying Problems with Medicine Use: Introduction and Aggregate Methods	
5:20-5:30 pm	Day 2 Evaluation	

#### Day Three

Time	Topic	Facilitator/s name
8:30-8:40 am	Recap of Day 2	Participants
8:40-10:30 am	Identifying Problems with Medicine Use: Introduction and Aggregate Methods	

<b>10:30-10:45 am</b>	<b>Tea Break</b>	
10:45-12:30 am	Identifying Problems with Medicine Use: Medicine Use Evaluation	
<b>12:30-2:00 pm</b>	<b>Lunch Break</b>	
2:00-3:00 pm	Identifying Problems with Medicine Use: Medicine Use Evaluation cont....	
3:00-3:30 pm	Identifying Problems with Medicine Use: Indicator Methods	
<b>3:30-3:45 pm</b>	<b>Tea Break</b>	
3:45-4:40 pm	Identifying Problems with Medicine Use: Indicator Methods	
4:40-5:20pm	Mid-term Review activity	
5:20-5:30 pm	Day 3 Evaluation	

#### Day Four

Time	Topic	
8:30-8:40 am	Recap of Day 3	Participants
8:40-10:30 am	Strategies to Improve Medicine Use	
<b>10:30-10:45 am</b>	<b>Tea Break</b>	
10:45-12:30 am	Medicine Safety and Quality Assurance	
<b>12:30-2:00 pm</b>	<b>Lunch Break</b>	
2:00-2:30pm	Antimicrobial Resistance Prevention & Containment	
<b>3:40-3:55 pm</b>	<b>Tea Break</b>	
3:30-5:25 pm	Role of DTC in Pharmaceuticals Supply Management	
5:25-5:30 pm	Day 4 Evaluation	

#### Day Five

Time	Topic	
8:30-2:40 am	Recap of Day 4	Participants
8:40-10:30 am	Communicating, Collaborating and Coordinating (CCC) DTC related activities	
<b>10:25-10:40 am</b>	<b>Tea Break</b>	
10:40-11:40 am	Monitoring and evaluation of DTC performance	
<b>12:30-2:00 pm</b>	<b>Lunch Break</b>	
2:00-3:30 pm	Getting Started	
<b>3:30-3:45 pm</b>	<b>Tea Break</b>	
3:45-5:00 pm	Post Test	
5:00-5:30 pm	Closing/Certification and picture program	



# Chapter One: Caring, Respectful and Companionate Healthcare Service

**Allocated Time:** 120 minutes

**Chapter Description:** This chapter is designed to equip healthcare professionals and senior management in health facilities to increase core competencies of compassionate, respectful, holistic, scientifically and culturally acceptable care for patients and their families.

**Chapter Objective:** By the end of this chapter the participants will be able to describe Compassionate, respectful and Caring (CRC) healthcare service delivery


**Enabling Objectives:** By the end of this chapter participants will be able to:

- Describe Compassionate, respectful and caring (CRC)
- List principles of health care Ethics
- Discuss components of compassionate care
- Explain principles of respectful care
- Discuss characteristics of Compassionate leader

## Chapter Outline:

- Introduction to CRC
- Healthcare Ethics
- Compassionate care
- Respectful care
- Compassionate leader
- Summary

# 1. Introduction to Compassionate, Respectful and Caring (CRC)

	<b>Activity 1.1: Individual reflection</b>
	What is Compassionate, Respect and Caring (CRC)?
	<b>Time: 10 minutes</b>

## 1.1.1. Definition of CRC

### Compassion (ፋህፋህ)

Is a feeling of deep sympathy and sorrow for the suffering of others accompanied by a strong desire to alleviate the suffering? Therefore, we can say it is being sensitive to the pain or suffering of others and a deep desire to alleviate the suffering.


### Respectful (ተገልጋይንየሚያከብር)

Is the kind of care, in any setting, which supports and promotes, and does not undermine a person’s self-respect, regardless of any differences?

### Caring (ተንከባካቢ)

**Caring** is an intensification of the affective dimension of empathy in the context of significant suffering. It is coupled with effective interventions to alleviate that suffering.

**Compassionate, respectful and caring (CRC)** - means serving patients, being ethical, living the professional oath, and being a model for young professionals and students. It’s a movement that requires champions who identify with their profession and take pride by helping people.

	<b>Think</b>	<b>Activity 1.2: Pair discussion</b>
	<b>Pair</b>	Why CRC a transformational agenda?
	<b>Share</b>	<b>Time: 10 minutes</b>

## 1.1.2. Why CRC a Transformation agenda?

Helping health professionals’ to become compassionate and respectful practitioners remains a major challenge for the healthcare. Compassionate and respectful care is not only morally and financially essential, but it is required in many countries through national legislation and/or national health policy.

The notion that healthcare services must be expanded beyond the prevention of morbidity or mortality is only one aspect of the agenda. It must encompass respect for patients' basic human rights, including respect for patients' autonomy, dignity, feelings, choices, and preferences. It must include choice of companionship wherever possible.

Taken from the United Nations human rights declaration, 'All human beings are born free and equal in dignity and rights.' The Ethiopian constitution of human rights article 25 and 26 states that the rights to equality and privacy.

In the Ethiopian health system, there are many health professionals who have dedicated their entire career to public service and are respected by the public they serve. However, a significant proportion of health professionals see patients as just 'cases' and do not show compassion. Lack of respect to patients and their families is also a common complaint.

A three-year report of the Ethics Committee and relevant documents in Addis Ababa showed that 39 complaints were related to death of the patient and 15 complaints were about disability. The committee verified that 14 of the 60 claims had an ethical breach and/or negligence and other study also indicated that forwarding bad words, shouting on patients, mistreatment, insulting and hitting of clients are some of unethical practices showed by the health professionals.

#### **Studies showed the need for CRC**

- Lack of role models in many health facilities.
- Measuring the worth of a profession by how much it pays.
- Senior physicians cancel their outpatient clinics without informing their patients.
- Elective surgeries get cancelled.
- Admitted patients are by default getting the care they need from relatives.
- Nurses, for various reasons, have limited their role to providing injections and securing IV lines.
- Proper counseling during dispensing of drugs is also becoming a rarity.
- The quality of lab tests and the quality assurance process that lab professionals have to take before issuing results is not practiced as expected.
- Lack of compassion, respect and care is the common source of grievances in health facilities.

### 1.1.3. The Benefits of CRC

**Table 1: Benefits and beneficiaries of Compassionate and Respectful Care**

Beneficiaries	Who	How
First	Patients	<ul style="list-style-type: none"> <li>• When health professionals are compassionate, patients are less anxious</li> <li>• Adherence to medical advice and treatment plans</li> <li>• Compassionate care correlates positively with both prevention and disease management. Diabetic patients, for example, demonstrate higher self-management skills when they self-report positive relationships with their providers</li> <li>• Hostile emotional states in patients delay the healing processes</li> <li>• Quality of health professionals –patient communication with increased physical functioning, emotional health and decreased physical symptoms of pain in patients</li> </ul>
Second	Health Professionals	<ul style="list-style-type: none"> <li>• Health care Professionals satisfaction with their relationships with patients can protect against professional stress, burnout, substance abuse and even suicide attempts</li> <li>• Burnout is strongly associated with poorer quality of care, patient dissatisfaction, increased medical errors, lawsuits and decreased expressions of compassion</li> <li>• Participation in a mindful communication associated with short-term and sustained improvement in well-being and attitudes associated with patient care</li> <li>• A major predictor of patient loyalty</li> <li>• When health professionals are compassionate, they achieve earlier and more accurate diagnoses because the patient is better able to reveal information when he or she feels emotionally relaxed and safe</li> <li>• Respect from the client/patients</li> <li>• Health professionals will find their work more meaningful and gratifying</li> </ul>
Third	Students	<ul style="list-style-type: none"> <li>• Good role modeling is essential for students</li> <li>• Increased motivation to be CRC health professionals</li> </ul>
Fourth	Health care facilities	<ul style="list-style-type: none"> <li>• Patient satisfaction will rise</li> <li>• Quality of health care will be improved</li> <li>• Lower malpractice suits</li> <li>• Staff will be more loyal to their hospital or health care system</li> <li>• Patient adherence to treatment will rise</li> <li>• Resources can be conserved</li> <li>• Greater employee satisfaction and reduced employee turnover.</li> </ul>

### 1.1.4. National Strategy and Approach of CRC

The development of caring, respectful and compassionate health workers requires a multi-pronged approach in order to make CRC as a culture, self-driven inner motive and a legacy that the current generation of practitioners leaves to their successors.



## **NATIONAL STRATEGY AND APPROACHES FOR CRC**

- *Reforming the recruitment of students for health science and medicine programs.*
- *Improving the curriculum of the various disciplines.*
- *Ownership and engagement of the leadership at all levels of the system.*
- *Inspirational leadership that aims to create an enabling environment.*
- *National, regional and facility level ambassadors.*
- *An advocacy campaign through mass media will also be launched to project positive images of health professionals.*
- *Patients and the general public will also be engaged in this movement.*
- *An annual health professional recognition event will be organized*
- *Putting in place a favorable legislative framework to reinforce CRC which would include regulation on patients' rights and responsibilities (PRR)*
- *Measurement of health care providers on CRC*
- *Comprehensive projects will be designed.*
- *Conducting national assessment related to CRC.*
- *Provision of continuous CRC trainings.*
- *Engagement and ownership of professional associations.*
- *Experience sharing from national and international best practices.*

## **1.1. Healthcare Ethics**

### **1.1.1. Principles of Health Care Ethics**



#### **Activity 1.3: Individual reflection**

- ❖ What is Ethics?
- ❖ What is Health Care Ethics?

**Time: 5 Minutes**

## **Ethics:**

Ethics is derived from the Greek word *ethos*, meaning custom or character. Ethics is the study of morality, which carefully and systematically analyze and reflect moral decisions and behaviors, whether past, present or future. It is a branch of philosophy dealing with standards of conduct and moral judgment.

## **Health Care Ethics:**

It is a set of moral principles, beliefs and values that guide us to make choices about healthcare. The field of health and healthcare raises numerous ethical concerns, including issues of health care delivery, professional integrity, data handling, use of human subjects in research and the application of new techniques.

Ethical principles are the foundations of ethical analysis because they are the viewpoints that guide a decision. There are four fundamental principles of healthcare ethics.

1. Autonomy
2. Beneficence
3. Non-maleficance
4. Justice

### **1. Autonomy**

Autonomy is the promotion of independent choice, self-determination and freedom of action. Autonomy implies independence and ability to be self-directed in one's healthcare. It is the basis of self-determination and entitles the patient to make decisions about what will happen to his or her body.



#### **Case one:**

A 49-year-old client with diabetic finding came with right foot second finger gangrene to a hospital. The surgeon decided that the finger should be removed immediately. But the patient refused the procedure.

**Question:** How should the surgeon handle this case?

**Time: 5 Minutes**

## 2. Beneficence

Beneficence is the ethical principle which morally obliges health workers to do positive and rightful things. It is “doing what is best to the patient”. In the context of professional-patient relationship the professionals are obliged to always and without exception, favor the wellbeing and interest of their patients.



### Case two:

Ms. X was admitted to adult surgical ward with severe excruciating right flank pain with presumptive diagnosis of renal colic. Nurse Y was the duty nurse working that day. The physician who saw her at OPD did not write any order to alleviate the pain.

**Question:** What should the attending nurse do for Ms. X?

**Time: 5 Minutes**

## 3. Non-maleficance

The principle refers to “avoid doing harm”. Patient can be harmed through omitting or committing interventions. When working with clients, healthcare workers must not cause injury or distress to clients. This principle of non-maleficance encourages the avoidance of causing deliberate harm, risk of harm and harm that occurs during the performance of beneficial acts. Non-maleficance also means avoiding harm as consequence of good.



### Case Three:

Mr “X” is admitted to internal medicine ward with cardiac failure. The physician admitted Mr “X” and prescribed some medication which should be given regularly by the ward nurse. A nurse in charge of the ward does not give a patient medication timely and appropriately.

**Question:** What should the ward nurse do for Mr “X”

**Time: 5 Minutes**

## 4. Justice

Justice is fair, equitable and appropriate treatment. Justice refers to fair handling and similar standard of care for similar cases; and fair and equitable resource distribution among citizens. It is the basis for treating all clients in an equal and fair way. A just decision is based on client need

and fair distribution of resources. It would be unjust to make such decision based on how much he or she likes each client.

*Example:*

- Resource scarcity is the common issue in healthcare settings. For example, there may be only one or two neurosurgeons and many patients on the waitlist who need the expertise of these neurosurgeons. In this case we need to serve patients while promoting the principle of justice in transparent way. Example, the rule of first come first serve could be an appropriate rule.
- Justice requires the treatment of all patients equally, irrespective of their sex, education, income or other personal backgrounds.

### **1.1.2. Confidentiality and informed consent.**

#### **Confidentiality**

Confidentiality in healthcare ethics underlines the importance of respecting the privacy of information revealed by a patient to his or her health care provider, as well the limitation of healthcare providers to disclose information to a third party. The healthcare provider must obtain permission from the patient to make such a disclosure.

The information given confidentially, if disclosed to the third party without the consent of the patient, may harm the patient, violating the principle of non-maleficence. Keeping confidentiality promotes autonomy and benefit of the patient.

The high value that is placed on confidentiality has three sources:

- **Autonomy:** personal information should be confidential, and be revealed after getting a consent from the person
- **Respect for others:** human beings deserve respect; one important way of showing respect is by preserving their privacy.
- **Trust:** confidentiality promotes trust between patients and health workers.

#### **The right of patient to confidentiality**

- All identifiable information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death. Exceptionally, family may have a right of access to information that would inform them of their health risks.



- Confidential information can only be disclosed if the patient gives explicit consent or if expressly provided for in the law. Information can be disclosed to other healthcare providers only on a strictly "need to know" basis unless the patient has given explicit consent.
- All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of its storage. Human substances from which identifiable data can be derived must also be protected.

***Exceptions to the requirement to maintain confidentiality***

- Routine breaches of confidentiality occur frequently in many healthcare institutions. Many individuals (physicians, health officers, nurses, laboratory technicians, students, etc) require access to a patient’s health records in order to provide adequate care to that person and, for students, to learn how to practice care provision.
- Care providers routinely inform the family members of a deceased person about the cause of death. These breaches of confidentiality are usually justified, but they should be kept to a minimum and those who gain access to confidential information should be made aware of the need not to spread it any further than is necessary for descendants benefit. Where possible, patients should be informed ahead that such a breach might occur.
- Many countries have laws for the mandatory reporting of patients who suffer from designated diseases, those deemed not fit to drive and those suspected of child abuse. Care providers should be aware of the legal requirements to be able to disclose patient information. However, legal requirements can conflict with the respect for human rights that underlies healthcare ethics. Therefore, care providers should look carefully at the legal requirement to allow such an infringement on a patient’s confidentiality and assure that it is justified.



**Case four:**

An HIV-positive individual is going to continue to have unprotected sexual intercourse with his spouse or other partners.

- Question: 1. How do you manage such an individual?  
2. Discuss situations that breach confidentiality.

**Time: 5 Minutes**

**Ethiopia Council of ministers’ regulation 299/2013, Article 77 Professional Confidentiality**

## **Informed Consent**

Informed consent is legal document whereby a patient signs written information with complete information about the purpose, benefits, risks and other alternatives before he/she receives the care intended. It is a body of shared decision making process, not just an agreement. Patient must obtain and being empowered with adequate information and ensure that he/she participated in their care process.

For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. These terms are explained below:

- A. *Voluntary*:** the decision to either consent or not to consent to treatment must be made by the person him or herself, and must not be influenced by pressure from medical staff, friends or family. This is to promote the autonomy of the patient.
- B. *Informed*:** the person must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments and the consequences of not doing the treatment. This will help to avoid harm—patients may harm themselves if they decide based on unwarranted and incorrect information.
- C. *Capacity*:** the person must be capable of giving consent, which means they understand the information given to them, and they can use it to make an informed decision.

### ***General principle of Informed consent***

Should be given by a patient before any medical treatment is carried out. The ethical and legal rationale behind this is to respect the patient's autonomy and their right to control his or her life. The basic idea of personal autonomy is that everyone's actions and decisions are his or her own.

The principles include:

1. Information for patients
2. Timing of consent process
3. Health Professionals responsibility for seeking consent
4. Decision making for incompetent patients
5. Refusal of treatment

**Ethiopia Council of minister's regulation 299/2013, Article 52. Patient's informed consent**

### 1.1.3. Preventive ethics in the aspect of CRC

#### What is preventive ethics?

Preventive Ethics is a systematic application of ethical principles and values to identify and handle ethical quality gaps, dilemmas, challenges and errors to appropriately and fairly. It could be carried out by an individual or groups in the health care organization to identify prioritize and systematic address quality gaps at the system level.

#### Why is preventive ethics important for CRC healthcare workers?


First and foremost, the CRC health workforce, patients, families and the community at large should have a common understanding that the experience of illness and the practice of medicine lead to situations where important values and principles come to conflict and ethical dilemmas and challenges arise everywhere. Moreover, the CRC health worker should always understand the context in which She/he operates (like the services, the clients, the providers, values, norms, principles, culture, religions, socio-economic-geographic...) as the way in which ethical dilemmas are handled vary from case to case and place to place.

Preventive ethics helps the CRC health workforce to predict, identify, analyze, synthesize and manage ethical dilemmas, challenges and errors to make the appropriate and fair decisions. Hence, preventive ethics enhances honesty and transparency between healthcare workers, patients, families and relevant others to make a deliberated joint decision. Moreover, it inspires mutual understanding and trust amongst the healthcare provider, recipient and the community at large.

Preventive ethics brings all efforts together productively and leads to the satisfaction of clients, providers and the community even if when the decisions are sometimes painful and outcomes are negative.

### 1.1.4. Ethics and law as enablers of CRC

#### The Relation between Ethics and Law

	<b>Activity 1.4: Individual reflection</b>
	What is the relationship between ethics and law? <b>Time: 5 Minutes</b>

**Ethics** as discussed in the previous sessions, is considered as a standard of behavior and a concept of right and wrong beyond what the legal consideration is in any given situation.

**Law** is defined as a rule of conduct or action prescribed or formally recognized as binding or enforced by a controlling authority. Law is composed of a system of rules that govern a society with the intention of maintaining social order, upholding justice and preventing harm to individuals and property. Law systems are often based on ethical principles and are enforced by the police and Criminal justice systems, such as the court system.

Ethics and law support one another to guide individual actions; how to interact with clients and colleagues to work in harmony for optimum outcome; provision of competent and dignified care or benefits of clients/ patients. Ethics serves as fundamental source of law in any legal system; and Healthcare ethics is closely related to law. Though ethics and law are similar, they are not identical.

Often, ethics prescribes higher standards of behavior than prescribed by law; and sometimes what is legal may not be ethical and health professionals will be hard pressed to choose between the two. Moreover, laws differ significantly from one country to another while ethics is applicable across national boundaries.

The responsibilities of healthcare professionals and the rights and responsibilities of the patient is stipulated in legal documents of EFMHACA like regulation 299/2013, directives and health facility standards.

## **1.2. Principles and Standards of Compassionate Care**

### **1.2.1. Qualities of compassionate care**

**Compassion can be defined as:** “sensitivity to the suffering of self and others with a deep wish and commitment to relieve the suffering”.

Developing more compassion can be a way to balance emotions to increase the well-being of patients, healthcare professionals and facilitation of healthcare delivery. For patients, compassion can help prevent health problems and speed-up recovery. Compassion can improve staff efficiency by enhancing cooperation between individuals and teams and between patient and healthcare professionals.



### Activity 1.5: Individual reflection

Can compassion be trained and learned?

**Time:** 2 Minutes

### Qualities of Compassionate Care

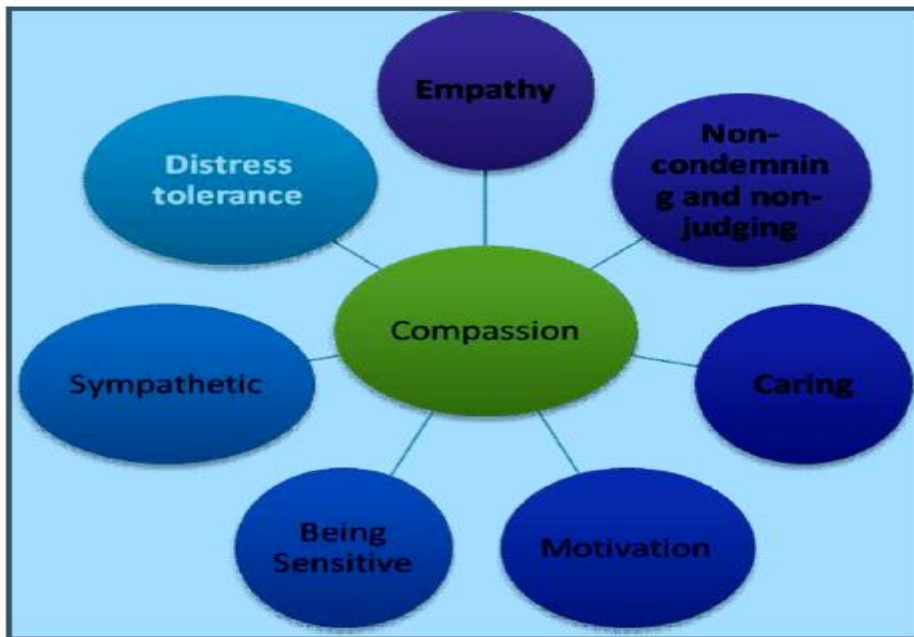


Figure 1: Qualities of compassion



#### Role play on qualities of compassionate care:

##### Instructions:

One participant will take the role of a healthcare provider and another participant will take the role of a mother [with limited mobility] of a sick child with a feeding problem. Other participants should observe and note the discussion.

##### Roles

Healthcare provider

A mother (with limited mobility) of a sick child:

##### Situation:

A mother with limited mobility brings her 3-month-old baby girl with cough and fever to the outpatient clinic. The healthcare provider seemed tired. By the time the mother enters the examination room, he was talking with his subordinate about last night's football game. He had already

noticed her but did not let her to sit. Her child was crying and she was trying to quiet her.

All of a sudden the healthcare provider shouted loudly at the mother to quiet her child or they would have to leave.

While waiting and calming her child, the mother told the healthcare provider that her child is very sick and needs an urgent care. While facing to his friend, the healthcare provider told the mother that he would see her child in five minutes.

After waiting for 10 minutes, the healthcare provider started to examine the child and felt sad about the condition of the child; apologized to her for having let her wait so long. The healthcare provider evaluated the child gently, gave the child a proper treatment, reassured the mother, and the child went home better.

### **Discussion Questions**

Did the health provider demonstrate the characteristics of compassion?

If not, what are the areas /conversation that show poor characteristics of compassion?

If yes, what are the areas /conversation that show good characteristics of compassion?

**Time: 30 minutes**

## **1.2.2. Elements of compassionate care**

According to researches the key elements of compassionate care has categories, each contains theme and subthemes.

- 1. Virtue:** It is described as “good or noble qualities embodied in the character of the health care provider
- 2. Relational space:** is defined as the context and content of a compassionate encounter where the person suffering is aware of and is engaged by, the virtues of the health care provider.

The category of relational space comprised two themes.

- Patient awareness which describes the extent to which patients intuitively knew or initially sensed health care provider capacity for compassion.
- Engaged care giving which refers to tangible indicators of health care provider compassion in the clinical encounter that established and continued to define the health care provider-patient relationship over time.

**3. Virtuous Response:** It is the “Enactment of a virtue toward a person in suffering,” and it is both an individual category and an overarching principle of care that functions as a catalyst to the three core categories of compassionate care giving: “**seeking to understand, relational communicating, and attending to needs**” The category of virtuous response contain three broad themes within it:

- **Knowing the person** refers to the extent to which healthcare providers approached their patients as persons and view their health issues and suffering from this point of view.
- **Seeing the person as priority** involves healthcare providers’ ability to priorities patient needs, setting aside their own assumptions and healthcare system priorities in the process.
- **Beneficence** refers to healthcare providers wanting the best for the patient, informing the three more targeted core categories of compassionate care giving.

**4. Seeking to Understand:** refers to healthcare providers trying to know the patient as a person and his or her unique needs.

The need to understand a person’s desires and tailor his or her care is identified by most patients as a fundamental feature of compassion.

- Seeking to Understand the Person.
- Seeking to Understand the needs of the Person

**5. Relational Communication:** is an important element of compassion identified by patients consisting of verbal and nonverbal displays conveyed by the healthcare provider’s engagement with the person suffering.

There are four specific themes and associated subthemes that convey compassion within clinical communication:


- **Demeanor** (“being”)
- **Affect** (“feeling for”)
- **Behaviors** (“doing for”)
- **Engagement** (“being with”)

### **Attending to Needs**

It refers to “a timely and receptive desire to actively engage in and address a person’s multi-factorial suffering”. Attending to patients’ needs has three interrelated themes:

- **Compassion-Related Needs:** refers to the dimensions of suffering that patient feel compassion: physical, emotional, spiritual, familial and financial.
- **Timely** refers to addressing suffering in a “timely” manner.
- **Action** refers to the initiation and engagement of a dynamic and tangible process aimed at alleviating suffering. Compassion is more action.

### 1.2.3. Principles of compassionate care

	<b>Activity 1.6: Individual reflection</b>
	<b>What are the principles of compassionate care?</b> <b>Time: 5 Minutes</b>

The universal principles of compassion will help us know one another in a more meaningful way where we discover one another respectfully. They create the conditions that allow a person who is suffering to experience the healing power of compassion.

1. **Attention:** is the focus of healthcare provider. Being aware will allow the healthcare provider to focus on what is wrong with a patient; or what matters most to the patient.
  2. **Acknowledgement:** is the principle of what the healthcare professional says. The report of the examination or reflection on the patient’s message. Positive messages of acknowledgment are buoyant; they let someone know that you appreciate them as a unique individual.
  3. **Affection:** is how healthcare providers affect or touch people. Human contact has the ability to touch someone’s life. It is the quality of your connection, mainly through warmth, comfort, kindness and humor. Affection brings joy and healing.
  4. **Acceptance:** is the principle of being with mystery – how you stand at the edge of your understanding or at the beginning of a new experience, and regard what is beyond with equanimity. It is the quality of your presence in the face of the unknown, in the silence. Like the sun in the north at midnight, acceptance welcomes the mysteries of life and is at peace with whom we are and where we are, right now. It is the spirit of Shalom.
- The principle of acceptance is: being at peace with the way things are allows them to change.



#### 1.2.4. Threats to compassionate care

There are factors preventing compassion and compassionate behavior for individual members of staff, teams and units and health facility. Most research discusses compassion at the individual level. In general, the most common threats for compassionate care are:




- **Compassionate fatigue:** Physical, emotional and spiritual fatigue or exhaustion resulting from care giving that causes and a decline in the caregivers' ability to experience joy or feel and care for others.
  - A form of burnout, a kind of “secondary victimization” what is transmitted by clients or patients to care givers through empathetic listening.
- **Unbalanced focus between biomedical model (clinical training) and person:** Effective clinical care is clearly fundamentally important, but human aspects of medicine and care must also be valued in training and in terms of how to be a good healthcare professional.
- **Stress, depression and burnout:**
  - **Self-reported stress** of health service staff is reported greater than that of the general working population.
  - **Burnout** (or **occupation burnout**) is a psychological term referring to general exhaustion and lack of interest or motivation to work.
- **Overall health facility context:** Attention by senior managers and health facility boards to achieve financial balance that affects priorities and behaviors of staff in health facility.

#### *Addressing Threats of compassion*

- Overcoming compassion fatigue
- Developing an inner compassionate self
- Compassion to yourself
- Teaching compassion to professionals through, training and education
- Dealing with staff stress and burnout
- Dealing with wider health facility context

### 1.3. Respectful care

#### 1.3.1. Definition of Concepts of Respectful and Dignified Care

 Think  Pair  Share	<b>Activity 1.7: Pair discussion</b>
	1. Can you share us your experience with regard to respect and dignity in the health care setting? 2. What does respectful care mean to you? <b>Time Allowed: 10 minutes</b>

#### Definition of Dignity (ΔξΔζ)

The word dignity originates from two Latin words: ‘dignitus’ which means merit and ‘dignus’ meaning worth. It is defined from two perspectives:

- Dignity is a quality of the way we treat others.
- Dignity is a quality of a person’s inner self.

#### Types of Dignity

There are four types of dignity: dignity of human being, personal identity, merit and moral status.

##### 1. Dignity of human being

This type of dignity is based on the principle of humanity and the universal worth of human beings their inalienable rights-which can never be taken away.

##### 2. Dignity of personal identity

This form of dignity is related to personal feelings of self-respect and personal identity, which also provides the basis for relationships with other people.

##### 3. Dignity of merit

This is related to a person’s status in a society.

##### 4. Dignity of moral status

This is a variation of dignity of merit, where some people have a personal status because of the way they perceived and respected by others.

#### Attributes of Dignity

There are four attributes of dignity:

1. **Respect:** self-respect, respect for others, respect for people, confidentiality, self-belief and believe in others

2. **Autonomy:** having choice, giving choice, making decisions, competence, rights, needs, and independence
3. **Empowerment:** Feeling of being important and valuable, self-esteem, self-worth, modesty and pride
4. **Communication (may be verbal or non-verbal):** explaining and understanding information, feeling comfort, and giving time to the patients / families

### Definition of Respect (አክብሮት)

- It is a term which is intimately related to dignity
- It is probably the most important action verb used to describe how dignity works in practice.

The action meanings of the word respect are:

- Pay attention to
- Honoring
- Avoiding damage e.g. insulting, injuring
- Not interfering with or interrupting
- Treating with consideration
- Not offending

People can vary by their skills, educational background, gender, age, ethnicity, and experiences. But, as human being, all are entitled to get dignified and respectful care. Every human being must respect others and get respect from others. Therefore, dignity is brought to life by respecting people:

- |                           |                                      |
|---------------------------|--------------------------------------|
| • Rights and freedoms     | • Individuals believes of self-worth |
| • Capabilities and limits | • Personal merits                    |
| • Personal space          | • Reputation                         |
| • Privacy and modesty     | • Habits and values                  |
| • Culture                 |                                      |

## Dignity and respect in the health care setting


Treating clients with dignity implies treating them with courtesy and kindness, but it also means:

- Respecting their rights
- Giving them freedom of choice
- Listening and taking into consideration what they say and
- Respecting their wishes and decisions, even if one disagrees.

Treating clients with dignity implies being sensitive to clients' needs and doing one's best for them, but it also means:

- Involving them in decision making
- Respecting their individuality
- Allowing them to do what they can for themselves and
- Giving them privacy and their own personal space


### 1.3.2. Principles of Respectful Care

	<p><b>Activity 1.8: Individual reflection</b></p> <p>❖ Think of a person who gave you the most respectful care/service.</p> <ul style="list-style-type: none"><li>• Describe the situation?</li><li>• What are the qualities of that person?</li><li>• What did you value most?</li></ul> <p><b>Time: 5 Minutes</b></p>
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The principles of respectful care guide actions and responsibility of care providers in ensuring dignified care for their service users. Dignified care has seven core principles.

- Recognize diversity and uniqueness of individuals
- Uphold responsibility to shape care
- Meaningful conversation
- Recognize the care environment
- Recognize factors affecting dignity
- Value workplace culture
- Challenge dignity barriers


### 1.3.3. Characteristics of Disrespectful Care

	<p><b>Activity 1.9: Pair discussion</b></p> <p>The situation where you received disrespectful care?</p> <ol style="list-style-type: none"> <li>1. Describe the incident?</li> <li>2. What was your reaction?</li> </ol> <p><b>Time: 5 Minutes</b></p>
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#### The Seven categories of Disrespect and abuse

Category	Example
Physical Abuse	Slapping, pinching, kicking, slapping, pushing, beating,
Non-consented care	Absence of informed consent or patient communication, forced
	procedures
Non-confidential care	Lack of privacy (e.g. Laboring in public or disclosure of patient
	information
Non-dignified care	Intentional humiliation, rough treatment shouting, blaming,
	treating to withhold services laughed at patients, provider did not
	introduce themselves, patients not called by their names
	throughout the interaction.
Discrimination based	Discrimination based on ethnicity, age, language, economic
on specific patient	status, education level, etc.
attributes	
Abandonment of care	Women left alone during labor and birth Failure of providers to
	monitor patients and intervene when needed
Detention in facilities	Detention of patients/family in facility after delivery, usually due
	to failure to pay

### 1.3.4. Factors affecting Respectful Care Provision

	<p><b>Activity 1.10: Individual reflection</b></p> <ol style="list-style-type: none"><li>1. What do you think hinders you from providing respectful care in your health facility?</li><li>2. What are the factors that facilitate provision of respectful care in your health facilities?</li></ol> <p><b>Time: 5 Minutes</b></p>
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Different Factors have a significant impact on hindering or facilitating the provision of respectful care service. These factors can be broadly classified in to three major groups; Health care environment, staff attitude & behavior and patient factors

Positive attributes of the physical environment which helped health professional to provide dignified care are related to aspects maintaining physical and informational privacy and dignity, aesthetically pleasing surroundings and single sex accommodation, toilet and washing facilities. Aspect of the environment that maintain physical and informational privacy are listed below

- **Environmental privacy** (for example curtains, doors, screens and adequate separate rooms for intimate procedures or confidential discussions (auditory privacy).
- **Privacy of the body:** covering body, minimizing time exposed, privacy during undressing and clothing are some of the enabling factors to ensure bodily privacy done by health professionals.
- **Aesthetic aspects** of the physical environment (for example space, color, furnishing, décor, managing smells); and the provision of accommodation, toilet and washing facilities
- **Managing peoples in the environment:** such as other patients, family and ward visitors/public contribute positively to maintain dignity in the health
- **Adequate mix and proficient Staffing:** adequately staffed with appropriate number and skill mix, as high workload affects staff interactions, and have strong leaders who are committed to patient dignity.

Physical environment which hinders health professional form providing respectful care are related to the overall health care system, lack of privacy, restricted access to facility /service and

lack of resources. Aspect of the environment that hinders the provision of respectful care are listed below,

- **The healthcare System:** Shortage of staff, unrealistic expectations, poorly educated staff, ‘quick fix’ attitude, low wage, pay ‘lip service’ to dignity, low motivation, lack of respect among professionals, normalization/tolerance of disrespectful care, lack of role model, management bureaucracy and unbalanced staff patient ratio and skill mix.
- **Lack of privacy:** Lack of available single rooms, bath rooms & toilets without nonfunctional locks, use of single rooms only for infectious cases and lack of curtains or screens
- **Restricted access to facility/service:** Badly designed rooms, inadequate facilities (e.g. toilets, bath rooms), Cupboards with drawers that does not open, toilet and bath rooms shared between male and females.
- **Lack of resource:** Run out of hospital, gowns and pyjamas, Lack of medical equipment and supplies

The A, B, C, of respectful health care, is a tool designed to consider the attitudes and behaviors of health care providers

### **A –Attitude**

#### **Ask yourself:**

- How would I be feeling if I was this person?
- Why do I think and feel this way?
- Are my attitudes affecting the care I provide and, if so, how?
- Are my personal beliefs, values, and life experiences influencing my attitude?

### **B- Behavior**

- Introduce yourself. Take time to put the patient at ease and appreciate their circumstances.
- Be completely present. Always include respect and kindness.
- Use language the patient/family can understand

### **Action to be taken**

- Reflect on these questions as part of your everyday practice.
- Discuss provider attitudes and assumptions and how they can influence the care of patients with the care team.
- Challenge and question your attitudes and assumptions as they might affect patient care
- Help to create a culture that questions if and

### **C-Communication**

- Communication revolving around the patient’s needs.
- Patient centered communication with defined boundaries
- Objectivity is an important attribute when assessing the clients’ needs

### Ten Mechanisms to mitigate threats to respectful care -

1. Support clients with same respect you would want for yourself or a member of your family
2. Have a zero tolerance of all forms of disrespect
3. Respect clients' right to privacy
4. Maintain the maximum possible level of independence, choice, and control
5. Treat each client as an individual by offering personalized care
6. Assist clients to maintain confidence and a positive self esteem
7. Act to alleviate clients' loneliness and isolation
8. Listen and support clients to express their needs and wants
9. Ensure client feel able to complain without fear of retribution
10. Engage with family members and care givers as care partners?

## 1.4. Compassionate leader

### 1.4.1. Quality of Compassionate Leadership



#### Activity 1.11: Group exercise

Discuss in a group of 4-5 and share your experience to the larger group.

- What does it mean for you to lead, and manage?
- Can you give an example of a leader whom you know in your professional or personal life? What makes him or her good leader for you?
- Do you know of any individuals in high positions or authority who demonstrate compassionate, respectful and caring practices when they deal with their staff and clients?

**Time: 20 minutes**

### Brief description of leadership theories

Introduces transactional, transformational, and servant leadership theories. It will also provide a better understanding of qualities of CRC leaders, which will enable participants to provide better service and increase awareness of CRC leadership.



- **Transformational leaders:** lead employees by aligning employee goals with their goals. Thus, employees working for transformational leaders start focusing on the company's well-being rather than on what is best for them as individual employees.
- **Transactional leaders:** ensure that employees demonstrate the right behaviors because the leader provides resources in exchange.
- **Servant Leadership:** defines the leader's role as serving the needs of others. According to this approach, the primary mission of the leader is to develop employees and help them reach their goals. Servant leaders put their employees first, understand their personal needs and desires empower them and help them develop their careers.

### **Characteristics of compassionate leaders**

- **'In-tune' feeling:** Their actions abide by their words – and they always have the time to engage with others.
- **Manage their moods:** They know feelings affect others and they use positive emotions to inspire, not infect others with negative feelings.
- **Put people before procedures:** They are willing to set aside or change rules and regulations for the greater good.
- **Show sincere, heartfelt consideration:** They genuinely care for the well-being of others and have a humane side that puts other people's needs before theirs.
- **Are mindful:** They are aware of their own feelings and their impact on others. They are also attentive and sympathetic to the needs of others.
- **Are hopeful:** They move others passionately and purposefully with a shared vision that focuses on positive feeling of hope.
- **Courage to say what they feel:** They communicate their feelings, fears, even doubts which builds trust with their employees.
- **Engage others in frank, open dialogue:** They speak honestly with humility, respect and conviction, and make it safe for others to do the same.
- **Connective and receptive:** They seem to know what other people are thinking and feeling.
- **Take positive and affirming action:** They carry out compassion. They do not just talk about it; they make a promise, act on it and keep it.

## **What does compassionate leadership do for the organization?**

- Positively affects sufferers, clients, employees
- Increases people's capacity for empathy and compassion
- Promotes positive relationships
- Decreases the prevalence of toxic viral negative emotions and behavior
- Increases optimism and hope
- Builds resilience and energy levels
- Counteracts the negative effects of judgment and bias


## **Self-evaluation of compassionate behavior**

Good leaders can evaluate their own behavior using different methodologies. The self-assessment of compassionate leaders should be conducted every six months to enhance self-compassion through mindfulness.

Mindfulness begins with self-awareness: knowing yourself enables you to make choices how you respond to people and situations. Deeper knowledge about yourself enables you to be consistent, to present yourself authentically. You will learn and practice different ways to develop mindfulness and explore how it can contribute to developing compassionate leadership practices through:

- Enhancing attention and concentration
- Increasing creativity and flexibility
- Working efficiently in complex systems and uncertain environments
- Creating meaning and purpose
- Making effective and balanced decisions
- Responding effectively to difference and conflict
- Acting with compassion and kindness
- Enhancing relationships and partnerships
- Enabling genuine and courageous action
- Working ethically and wisely
- Developing cultural intelligence

### 1.4.2. Systems Thinking for CRC

	<p><b>Activity 1.12: Group activity in healthcare system thinking</b></p> <p>Discuss in a group of 4-5 and share your experience to the larger group.</p> <ul style="list-style-type: none"><li>• Discuss concepts of Health System and how it relates with your Health Facility /Hospital and Health Center/ functions.</li><li>• Take your Health Facility/Hospital and Health Center/ and list the various department/core processes/support processes. Using a systems thinking approach, discuss how they interact with each other?</li><li>• Take in to account the CRC concepts and identify gaps you may have experienced in your facilities?</li></ul> <p><b>Time: 20 minutes</b></p>
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**System:** A system is a set of interacting or interdependent components forming an integrated whole.

**Health System:** A health system consists of all the organizations, institutions, resources and people whose primary purpose is to improve health.

**Fully functional health system:** A point which various management systems and subsystems are connected and integrated to provide the best possible health services to all the intended beneficiaries of those services.

**Management systems:** The various components of the overall health system that managers use to plan organize and keep track of resources. Management systems are run by people living in different contexts.

#### **Integrate CRC into Existing System**

Integration of new initiatives into existing system has paramount importance in expediting the process of implementation and ensuring sustainability of CRC in a health system. Integration can be done using “AIDED” model.

**Assess:** Understand the capacity of the unit structure, especially in regards to the availability of resources, as well as human resource; also to assess the level of human capability when integrating and sustaining the CRC by determining the level of support the unit requires before or after carrying out CRC.

**Innovate:** Design and package the CRC to fit with the existing quality of unit structure and their environmental context to spread the CRC throughout the hospital departments.

**Develop:** Build upon existing knowledge of main stakeholders and opinion leaders by encouraging hospital policies, organizational culture, and infrastructure to support the implementation of principles of CRC.

**Engage:** Use existing roles and resources within the hospital units to introduce, translate, and integrate CRC principles into each employee's routine practices.

**Devolve:** Capitalize on existing organizational network of index user groups to release and spread the innovation to new user groups.

### **1.4.3. Organizational culture**

Organizational culture consists of the values and assumptions shared within an organization. Organizational culture directs everyone in the organization toward the “right way” to do things. It frames and shapes the decisions and actions of managers and other employees. As this definition points out, organizational culture consists of two main components: shared values and assumptions.

1. **Shared Values:** are conscious perceptions about what is good or bad, right or wrong. Values tell us what we “ought” to do. They serve as a moral guidance that directs our motivation and potentially our decisions and actions.
2. **Assumptions:** are unconscious perceptions or beliefs that have worked so well in the past that they are considered the correct way to think and act toward problems and opportunities.

Five key systems influence the hospital's effective performance with respect to improving the safety and quality of patient care, as well as sustaining these improvements. The systems are:

1. Using data
2. Planning
3. Communicating
4. Changing performance
5. Staffing

Leaders create and maintain a culture of safety and quality throughout the hospital. Rationale

- CRC thrives in an environment that supports teamwork and respect for other people, regardless of their position in the organization.
- Leaders demonstrate their commitment to CRC and set expectations for those who work in the organization. Leaders evaluate the culture on a regular basis.

- Leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Disruptive behavior that intimidates others and affects morale or staff turnover can be harmful to patient care.
- Leaders must address disruptive behavior of individuals working at all levels of the organization, including management, clinical and administrative staff, licensed independent practitioners, and governing body members.

### **Creating an Organizational culture of empowering employees for CRC**

Having empowered employees is the aim of many leaders. Literature has reported that creating an organizational culture will empower employees to increase customer satisfaction levels, as well as to improve employee morale and productivity.

Employee empowerment encourages communication, participation in shared decision-making and enabling physicians and staff to reach their full potential by creating an optimal healing environment.

There are many different ways to build employee empowerment and engagement, but all share six fundamental actions to promote CRC on the part of leadership:

***Share information and communication:*** Sharing information with employees is important because it not only helps to build trust; it gives employees important information to allow them to make the best possible decisions in critical situations when providing CRC services.

***Create clear goals and objectives:*** Inspire employees to embrace the mission or changes of the organization by appealing to their innate desire to help patients and provide an efficient CRC service. Great leaders share important information in a structured and consistent manner.


***Teach, accept and encourage:*** If you empower employees to make decisions that will help keep customers happy, then you have to be willing to allow them to make mistakes and learn from those mistakes.

***Reward Self-Improvement:*** Create an environment that celebrates both successes and failures. A good leader celebrates successes; and employees who take risks for the benefits of patients/client; also, a good leader will assist employees to develop a plan for growth and reward them as they advance.

**Support a learning environment:** Listen to the voice of physicians, nurses and other staff to understand key barriers, issues, and opportunities to allow them to have a voice in crafting solutions for CRC challenges.

**Create a clear role of autonomy:** Enable frontline workers to execute change by supplying resources (education, funding, access to other skill sets within the health facility, etc.) and removing obstacles themselves.

#### 1.4.4. Leading CRC Health Teams

	<p><b>Activity 1.13: Group activity</b></p> <p>Discuss in a group of 4-5 and share your experience to the larger group.</p> <ul style="list-style-type: none"> <li>• What principles do you think of when implementing CRC?</li> <li>• Do you think there are differences between your current “leading” style and leading based on CRC? If yes, list the differences.</li> </ul> <p><b>Time: 10 minutes</b></p>
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Health facility leaders have intersecting roles as public servants, providers of health care, and managers of both healthcare professionals and other staff.

- **As public servants**, health facility leaders are specifically responsible for maintaining the public trust, placing duty above self-interest and managing resources responsibly
- **As healthcare providers**, health facility leaders have a fiduciary obligation to meet the healthcare needs of individual patients in the context of an equitable, safe, effective, accessible and compassionate health care delivery system.
- **As managers**, leaders are responsible for creating a workplace culture based on integrity, accountability, fairness and respect.

Ethical healthcare leaders apply at least the following six specific behavioral traits:

1. **Ethically conscious:** Have an appreciation for the ethical dimensions and implications of one’s daily actions and decisions or, as described by author John Worthily, the “ethics of the ordinary” (reference?).
2. **Ethically committed:** Be completely devoted to doing the right thing.

3. **Ethically competent:** Demonstrate what Rushworth M. Kidder, president and founder of the Institute for Global Ethics, calls “ethical fitness,” or having the knowledge and understanding required to make ethically sound decisions (reference).
4. **Ethically courageous:** Act upon these competencies even when the action may not be accepted with enthusiasm or endorsement.
5. **Ethically consistent:** Establish and maintain a high ethical standard without making or rationalizing inconvenient exceptions. This means being able to resist pressures to accommodate and justify change inaction or a decision that is ethically flawed.
6. **Ethically candid:** Be open and forthright about the complexity of reconciling conflicting values; be willing to ask uncomfortable questions and be an active, not a passive, advocate of ethical analysis and ethical conduct.

### **Problem-solving in healthcare**

#### Steps of Scientific Problem Solving Skills

1. Define the problem
2. Set the overall objective
3. Conduct a root cause analysis
4. Generate alternative interventions
5. Perform comparative analysis of alternatives
6. Select the best intervention
7. Develop implementation plan and implement plan
8. Develop evaluation plan and evaluate

### **Best Practice Identification**

#### Criteria to select best practices

- **New/Novel idea-** not much practiced in other hospitals in Ethiopia
- **Effectiveness:** has brought empirical change to the implementation of CRC specifically to patient satisfaction and quality of service provision. The practice must work and achieve results that are measurable.
- **Relevant/impact:** improved CRC and quality of patient experience (Explain the relevance of the innovation using a clear baseline and current performance of CRC)
- **Diffusible:** implemented at low cost in other facilities or implemented innovation in other hospitals.

- **Sustainable:** Innovation is easy to understand, easy to communicate and works for long time.
- **Political commitment:** The proposed practice must have support from the relevant national or local authorities.
- **Ethical soundness:** The practice must respect the current rules of ethics for dealing with human populations.

By definition, “Best Practices” should be “new/novel”, “effectiveness” and “relevance”.

### **Monitoring and Evaluation of CRC Health Team**

Potential focus areas where leaders focus to evaluate their CRC staff

- **Quality of work:** Provide accuracy and thorough CRC service
- **Communication and interpersonal skills:** listening, persuasion and empathy to clients/patients and teamwork and cooperation in implementing CRC
- **Planning, administration and organization:** setting objectives, and prioritizing CRC practice
- **CRC knowledge:** knowledge-based training, mentoring, modeling and coaching
- **Attitude:** dedication, loyalty, reliability, flexibility, initiative, and energy towards implementing CRC
- **Ethics:** diversity, sustainability, honesty, integrity, fairness and professionalism
- **Creative thinking:** innovation, receptiveness, problem solving and originality
- **Self-development and growth:** learning, education, advancement, skill-building and career planning

#### **Summary**

- *Dignity of human being is the basis for healthcare delivery*
- *Clients should be treated as human being not as cases*
- *Disrespect and abuse is a problem in Ethiopia.*
- *Zero Tolerance to Disrespectful care shall be a motto for all health workers in the health facilities.*
- *Improving the knowledge of ethics is important to boost the ethical behavior in practice*



## Chapter Two: Rational Medicines Use

**Allocated Time: 120 minutes**

**Chapter Description:** This chapter introduces participants with the concepts of rational use of medicines (RMU). The chapter describes the pillars of medicine use and provides an overview of the causes and consequences of irrational medicine use practices. Participants will also be introduced to the list of possible interventions that can be applied in a health facility setting to sustainably alleviate the problem of irrational use of medicines.

**Chapter Objective:** At the end of this chapter the participants will be able to describe rational use of medicines.


**Enabling Objectives:** At the end of this chapter, participants will be able to:

- Define rational use of medicines
- Describe the pillars of medicine use
- Discuss causes and consequences of irrational use of medicines
- Identify interventions to promote RMU

### Chapter Outline:

- Introduction
- Medicine use process
- Irrational medicine use: Causes and Consequences
- Interventions to promote RMU
- Case study
- Summary

## 2.1. Introduction

	<p><b>Activity 2.1: Medicines and Budget</b></p> <ul style="list-style-type: none"><li>• Can you think of modern healthcare delivery without the availability of medicines and medical devices?</li><li>• How much your health facility budget is spent on medicines?</li><li>• Estimate the amount of resources that can be wasted due to inefficient management and inappropriate use of medicines?</li></ul> <p><b>Time: 5 min</b></p>
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Medicines are an integral part of the healthcare, and modern health care is impossible without the sustainable availability of safe, efficacious, and cost-effective medicines and medical devices. It is estimated that each year, an estimated USD 5.3 trillion is spent worldwide on providing healthcare. Total expenditure on pharmaceuticals valued to be 25% of the healthcare budget. However, more than 50% of this huge resource is lost due to inefficient management and irrational use of medicines at health facilities resulting in significant health and economic losses.

**Rational Medicines Use (RMU)** is the process of *safe, effective, and economic* use of medicines for diagnosis, prevention, and treatment of diseases for the benefit of the patient.

*RMU requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (WHO).*


On the other hand, **Irrational Medicine Use** is the use of medicines in a way that is not compliant with rational use as defined above.

Several studies have been conducted to assess the magnitude of supply problems and irrational medicine use practices in Ethiopia. The recent Pharmaceutical Sector Assessment in Ethiopia conducted by FMHACA in 2016 revealed the following results that call for more attention and action from all concerned to improve availability and promote rational use of medicines.

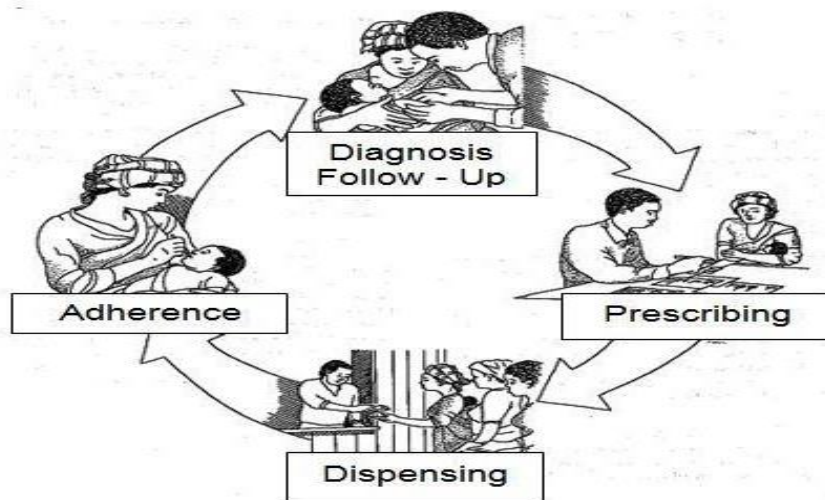
- Median percentage availability of a group of medicines selected in public warehouses was 70.7%

- Median availability of a group of medicines used for chronic illnesses (including hypertension, diabetes, and mental illnesses) was low (54.55%).
- Average number of medicines per-prescription was 2.25 (higher than previous figures)
- 99.67% of prescribed medicines were from the facility specific medicine list and 96.42% were written in generic names.
- Adequacy of labeling practice was 19.9%.
- Antibiotics were prescribed to 73.89% of patients of any age with non-pneumonia ARI in public health facilities.

## 2.2.Medicines Use Process

	<p><b>Activity 2.2: Individual reflection</b></p> <hr/> <p>Who are the major actors in the medicine use process?</p> <p><b>Time:</b> 3 min</p>
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The medicine use process (figure 1) rests on the practices of *prescribing, dispensing, and client use*. To achieve rational use of medicines, all these three practices should be appropriate and follow set standards of practice and use. Accordingly, there are three main actors in the medicines use process: *the prescriber, dispenser, and client*. The prescriber is responsible for prescribing a course of treatment after appropriate diagnosis of patient complaints. The dispenser is responsible for preparing and providing the medications to the patient with adequate counseling. The client is responsible for taking the medicines as per the adherence counseling provided by the prescriber and dispenser.



*Figure 2: The medicine use process*

### **Rational Prescribing:**

Prescribers should follow a standard process of prescribing, which starts with a diagnosis to define the problem that requires treatment. Next, the therapeutic goal should be defined. The prescriber must decide which treatment is required, based on up – to – date information on medicines and therapeutics, to achieve the desired goal for an individual client. When the decision is made to treat the patient with medicines, the best medicine for the patient is selected based on efficacy, safety, suitability, and cost. Then dose, route of administration, and duration of treatment are determined, considering the condition of the patient. When prescribing a medicine, the prescriber should provide proper information to the patient about both the medicine and the patient’s condition. Finally, the prescriber should decide how to monitor the treatment, after considering the probable therapeutic and adverse effects of treatment.

### **Rational dispensing**

The dispenser should correctly validate and interpret the information contained on the prescription. Then, the dispenser should evaluate the appropriateness of the medicines against the specific complaints and conditions of the patients. Evaluating involves identifying whether correct medicine is prescribed at the right dose and duration. It also involves identifying potential interactions of the medicine with other medicines, food, or herbal products. After proper evaluations, the dispenser prepares, labels, and packages the medicines in a suitable container that maintains the quality and potency of the medicines during the duration of use.

Then, the dispenser shall issue medicines to patient with clear instructions and counseling. As a final step, the dispenser records the transactions. Finally, the dispenser should check whether patients have understood the information provided.

### **Rational use by client**

The success of the previous steps of the medicine use process depends on the use of the medicines by the client. Clients should be empowered during prescribing and dispensing steps to participate in major decisions about their health and medications. They should be counseled that outcomes of therapy depends on a good level of adherence to prescribed regimen. The client (and the community) should understand and appreciate the value of using specific medicines.

### **2.3. Irrational medicine use: common forms, causes and consequences**

Various types and causes of irrational use of medicines are prevalent worldwide. The common forms and causes of irrational prescribing, irrational dispensing, and irrational patient use are described below.

#### **Common forms and causes of irrational use of medicines**

Prescribing problems occur during the process of identifying the health problem/s, selecting medicines to treat the problem/s, and determining the amount and duration of drug therapy. The following table summarizes common forms and causes of irrational prescribing practices.

*Table 2: Common forms and causes of irrational prescribing*

<b>Common forms of Irrational Prescribing with examples</b>	<b>Possible Causes</b>
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<p><b>Extravagancy:</b></p> <ul style="list-style-type: none"> <li>• More expensive vs. less expensive drug for comparable efficacy &amp; safety.</li> <li>• An expensive brand drug is used where less expensive equivalents are available</li> <li>• Symptomatic treatment of mild conditions</li> </ul> <p><b>Over prescribing:</b></p> <ul style="list-style-type: none"> <li>• The drug is not needed</li> <li>• The dose is too large</li> <li>• The treatment period is too long</li> <li>• The quantity prescribed is too much for</li> </ul>	<ul style="list-style-type: none"> <li>• Inadequate training in clinical pharmacology</li> <li>• Fear induced prescription</li> <li>• Absence and non-adherence of STG at least for common diseases</li> <li>• Lack of continuing education and supervision</li> <li>• Absence of prescribing privilege by level of training</li> <li>• Assuming “good if many drugs are used”</li> <li>• Promotional influence</li> </ul>
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**the current course of treatment**

**Incorrect prescribing:**

- When the drug is given for an incorrect diagnosis;
- Wrong drug is selected for the indication;
- Prescription is written inappropriately (not legible, information not complete)
- No adjustments are made for co-existing medical, genetic, environmental, or other factors

**Multiple Prescribing:**

- Using two or more medications when one or two would achieve the same effect;
- Several related conditions are treated when treatment of primary condition will improve or cure the related conditions

**Under Prescribing:**

- When needed medications are not prescribed or the dosage is inadequate;
- Length of treatment is too short

- Lack of adequate and unbiased drug information
- Incorrect generalization about a drug from experience
- A belief “a pill for every ill”
- Patient load
- Shortage of essential medicines in the facility
- Pressures from patients

Dispensing problems can occur all the way from the point of receipt of the prescription until the patient leaves the dispensing outlet. These irrational dispensing practices involve misinterpreting what is written on the prescription, poor evaluation of appropriateness of therapy, medicine processing errors, and poor counseling.

*Table 3: Common Forms and Cause of Irrational Dispensing Practices*

<b>Common forms of Dispensing Errors</b>	<b>Possible Causes</b>
<b>Misreading the prescription</b>	<ul style="list-style-type: none"> <li>• Maybe due to many prescriptions at the same time</li> <li>• Illegible handwriting,</li> <li>• Careless attitude of dispensing staff,</li> <li>• Inappropriate dispensing environment.</li> </ul>
<b>Prescription evaluation error</b>	<ul style="list-style-type: none"> <li>• Poor therapeutics knowledge</li> <li>• Inattention and distractions</li> <li>• Inadequate environment</li> </ul>
<b>Errors during verbal communication</b>	<ul style="list-style-type: none"> <li>• Due to sound-alike names</li> </ul>
<b>Picking error, i.e., picking the next medicine</b>	<ul style="list-style-type: none"> <li>• Due to similar packing (color and shape)</li> <li>• Lack of attention due to distractions</li> <li>• Negligence while dispensing,</li> </ul>

- Inadequate shelving

<b>Counting error, i.e., dispensing the wrong quantity of medicines</b>	<ul style="list-style-type: none"> <li>• Due to interruptions during counting</li> <li>• Distractions</li> <li>• Work overload/rush hours</li> <li>• Poor arithmetic skills</li> </ul>
<b>Billing error, i.e., entering details on the bill incorrectly.</b>	<ul style="list-style-type: none"> <li>• Due to distraction or inattention while billing</li> <li>• Having the bill prepared by a newly appointed staff member who is not familiar with the billing system.</li> </ul>
<b>Packing error, i.e., mix up of parcels, or putting somebody else's medicine in the parcel</b>	<ul style="list-style-type: none"> <li>• Carelessness or distractions during packing.</li> <li>• Inadequate workspace</li> </ul>
<b>Delivery error, i.e., delivering the parcel to the wrong person</b>	<ul style="list-style-type: none"> <li>• Due to similar patient names</li> <li>• Due to same total on the bill</li> <li>• Due to distractions while handing over the parcel.</li> </ul>
<b>Expiry error, i.e., dispensing expired medicines</b>	<ul style="list-style-type: none"> <li>• Bin management is not applied</li> <li>• Regular shelf checking for expiry is not done.</li> <li>• Each strip/bottle is not checked for date of expiry while dispensing.</li> </ul>
<b>Counseling error, i.e., failure to provide adequate information and not checking whether the client has understood the information provided or not.</b>	<ul style="list-style-type: none"> <li>• Lack of knowledge, carelessness, patient load, inconvenient dispensing environment.</li> </ul>

Clients play critical role for the positive outcome of the medicine use process by adhering to agreed treatment regimen. Irrational use of medicine by clients can take various forms which are summarized in the table below.

*Table 4: Common forms of Irrational Patient Use and their Causes*

<b>Common forms of Irrational Patient Use</b>	<b>Possible Causes</b>
<ul style="list-style-type: none"> <li>• Medicines are not used according to the information provided by the prescriber and dispenser</li> <li>• Self-medication with prescription medicines and wrong use of antibiotics.</li> <li>• Using two or more medicines simultaneously and unnecessarily</li> </ul>	<ul style="list-style-type: none"> <li>• Complicated dosage schedule</li> <li>• Social or physical problems to go to drug outlets</li> <li>• The medicines not perceived as effective</li> <li>• Occurrence of side effects</li> <li>• Unable to pay prescription charges</li> <li>• Pill burden</li> </ul>

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following the principle “a pill for every ill”. Overconsumption of medicines concerns mostly painkillers and cough and cold preparations.

- Unsafe traditional medicines.
  - Overuse of injections, mainly in developing countries with the widespread belief that injections are more effective than orally administered medicines.
  - Use of needlessly expensive medicines. Due to the lack of knowledge, branded medications are preferred, containing the same active substance as their cheaper equivalents generic medicines.
  - Inconvenience of taking drugs everyday
  - Inadequate information/poor understanding of delivered information
  - Due to illness like schizophrenia
  - Health care system (long waiting times, uncaring staff, uncomfortable environment, exhausted drug supply, inaccessibility of the health institution), etc.
  - Forgetfulness about taking the medication
  - Unable to finish because of feeling better because of disappearance of symptoms
  - Fear of dependence
- 

### **Other factors that contribute to irrational use**

The health system is one contributor to irrational medicine use. Factors affecting the health system include unreliable supply, medicine shortages, expired medicines, and availability of substandard and counterfeit medicines. Such inefficiencies in the system lead to a lack of confidence in the system by healthcare providers and clients.

In addition, health systems that fail to implement policies on standard treatment guidelines, essential medicine list, and medicine formularies are missing well proven methods to increase the rational use of medicines.

Unavailability of suitable infrastructure like diagnostic facilities, appropriate dispensing rooms, within a health facility will have a negative impact on the rational use of medicines. Low numbers of skilled health professionals with higher burden of clients do have impact on rational medicine use practices.

### **Consequences of irrational medicines use**

Irrational use of medicines has significant adverse effects on healthcare costs and the quality of medicine therapy and medical care, as well as being a primary contributor to the spread of antimicrobial resistance. Other negative effects are the increased likelihood of adverse drug events and encouraging patients' inappropriate reliance on medicines. Generally, irrational use of



medicines may lead to ineffective & unsafe treatment, exacerbation or prolongation of illness, distress & harm to patient, increase the cost of treatment, antimicrobial resistance, and adverse drug events.

#### **2.4. Interventions to Promote Rational Medicines Use**

Health systems in general and health facilities in particular can work to reduce irrational use and minimize its consequences using different proven interventions. The WHO has identified 12 core strategies to improve medicines use and these are:

1. A mandated multi-disciplinary national body to coordinate medicine use policies
2. Clinical guidelines.
3. Essential medicines list based on treatments of choice
4. **Drugs and Therapeutics Committees in health facilities**
5. Problem-based pharmacotherapy training in undergraduate curricula
6. Continuing in-service medical education as a licensure requirement
7. Supervision, audit, and feedback
8. Independent information on medicines
9. Public education about medicines
10. Avoidance of perverse/corruption financial incentives
11. Appropriate and enforced regulation
12. Sufficient government expenditure to ensure availability of medicines and staff.

Moreover, the WHO has also identified five of these strategies listed below to be effective in developing countries.

1. Implement Standard treatment guidelines
2. Develop Essential drug lists (National, HF)
3. **Establish Drug and Therapeutics Committees in health facilities**
4. Provide Problem-based basic training in pharmacotherapy

## 5. Provide Targeted Continuing Education for health professionals

Establishing DTC is important in order to facilitate and implement the core strategies recommended by WHO. These strategies will be discussed in more detail in the coming sessions.

### 2.5. Case studies

Identify the irrational practices in the following medicine use practices:

1. W/ro Senait went to a pharmacy and made verbal request for Amoxicillin and cough syrup for her 8 years old daughter with complaints of cough and poor appetite. As she did not have enough amount of money, she wanted to purchase only ten capsules of Amoxicillin and one bottle of cough syrup suspension. The dispenser fulfilled her request.
2. Abraham complains of mild, intermittent crampy abdominal pain associated with diarrhea. Stool Examination showed Giardia Lambia Trophozoites. He is an educated and well known engineer and he asked his physician to prescribe him just Levamisole, 150 mg tablet p.o. to be taken as a single dose which he think it to be the best treatment option. Accordingly the physician prescribed him Levamisole, 150 mg tablet.
3. W/ro Betelhem is a 35 years old woman who is treated for TB and on her anti –TB medicine currently. After she had taken her medicines for the first week correctly, her friends advised her to visit a well known traditional healer of the town. Then she visited the traditional healer and received some traditional medicines which demand the ultimate cease of anti – TB medications. W/ro Betelhem decided to stop the anti – TB medicines without consulting her physician and start taking the traditional one, after a week she returned to her doctor with a very exacerbated health condition.

#### *Summary*

- Irrational use of medicines is a global and national problem
- Irrational medicines use causes huge negative impacts on health and economy.
- The prescriber, dispenser and clients have major roles in ensuring rational medicines use.
- Healthcare professionals should be able to identify specific problems and their causes in order to properly tackle them

- WHO has devised effective strategies meant to improve medicines use and promote rational use
- Establishing and having functional DTC is a major strategy for promoting rational medicine use

## Chapter Three: Overview of Drug and Therapeutics Committee

**Allocated Time:** 80 minutes

**Chapter Description:** This chapter provides an overview of drug and therapeutics committee (DTC). It starts by emphasizing the role of DTC in promoting the rational management and use of medicines and medical devices. Then, the major functions of DTC are explained. Also, the guiding principles of a viable DTC are discussed. The final portion of the chapter is dedicated to explaining the organization of DTC in health facilities.

**Chapter Objective:** At the end of this chapter, the participants will be able to discuss the role and functions of DTC in promoting rational management and use of medicines.

**Enabling Objectives:** At the end of this chapter, participants will be able to:


- Discuss the functions of DTC
- Describe the guiding principles of DTC
- Explain the organization of DTC

### Chapter Outline:

- Introduction
- Functions of DTC
- Guiding principles for DTC
- Organization of DTC
- Summary

### 3.1. Introduction

DTC is one of the most effective strategies to promote the rational use of medicines and medical devices. The medicine use process in health facilities is a multifaceted process that requires the active involvement of various departments including clinical, pharmacy, administrative. A single entity cannot adequately address all issues regarding medicines. It requires a concerted effort to avail most needed, safe, efficacious, and cost-effective medicines. It also requires even more collaboration and coordination to ensure available medicines are appropriately used for the intended purpose.

	<p><b>Activity 3.1: Think, Pair, Share</b></p> <ul style="list-style-type: none"><li>• List important local policy documents that support the establishment of DTC?</li><li>• What are the inefficiencies in medicine management and use that require the establishment of DTCs in health facilities?</li></ul> <p><b>Time:</b>5 min</p>
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Recognizing its benefits, the Ethiopian Ministry of Health has made efforts to include DTC in its health transformation plans (HSTP)<sup>1</sup> and reform guidelines (EHSTG<sup>2</sup> and EHCRIG<sup>3</sup>) which necessitate health facilities to establish a functional DTC. Moreover, the Ethiopian Standard Agency (ESA) has set establishment of DTC in its minimum regulatory standards health facility.

**DTC** is the committee composed of medical, pharmacy and administrative departments. DTC evaluates the clinical use of medicines, develops policies for managing pharmaceutical use and administration, and manages the formulary system. DTC is an essential component of a health facility's effort to improve availability and ensure rational use of medicines.

Particular areas of inefficiency and medicine use problems that necessitate the establishment of DTC include:

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<sup>1</sup> Health Sector Transformation Plan (HSTP)


<sup>2</sup>Ethiopian Hospital Service Transformation Guidelines (EHSTG)

<sup>3</sup> Ethiopian Health Center Reform Implementation Guidelines (EHCRIG)

- Poor selection of medicines, without consideration for relative efficacy, cost-effectiveness, or local availability
- Inefficient procurement practices, resulting in non-availability, inadequate quality, wastage, or use of unnecessarily expensive medicines
- Prescribing not in accordance with standard treatment guidelines
- Poor dispensing practices resulting in medication errors, and patients' lack of knowledge about dosing schedules
- Patients not adhering to dosing schedules and treatment advice.

In Ethiopia, since the issuing of Pharmacy and Therapeutics Committee (PTC) establishment guideline by MOH in 1986, a lot of efforts have been exerted to establish and strengthen DTCs. In-service trainings were conducted in all corners of the country to capacitate medical and pharmacy professionals. A national study coordinated by PFSA in 2014 showed that 97.8% of 111 hospitals had established DTC. Another study conducted in 2018 indicated that all of the 40 health centers included in the study have established DTCs. However, the functionality of DTC varies from facility to facility.

### 3.2. Functions of DTC

	<b>Activity 3.2: DTC Function</b>
	<p>What are the major functions of DTC?</p> <p><b>Time:</b> 2 min</p>

The role of the committee is to evaluate the clinical use of medicines, develop policies for managing medicine use and administration, and manage the formulary system. The DTC has various key responsibilities in determining what medicines will be available, at what cost, how they will be used, and disposed. It is to be recalled that there are many possible functions of a DTC, and the committee must decide which to undertake as a priority; this decision may depend on local context and capacity. Furthermore, certain functions will require liaison with other committees or teams, for example the infection control committee or the procurement team. The most important

The primary functions of DTC are summarized below.

### **Advising Medical, Pharmacy, and Administrative departments on medicine related issues:**

The DTC is a valuable resource that can provide advice to medical staff, nurses, administration, pharmacy and other departments and groups within the hospital. The DTC can advise on all issues, policies and guidelines concerning the selection, distribution and use of medicines. Usually a DTC will provide advice and an executive body, usually the clinical departments, the pharmacy or hospital management, will implement it.

### **Developing policies and procedures to manage medicines**

Lack of policies will adversely affect medicine selection, procurement, distribution, and use. The DTC has the most expertise to develop policies on: New, non-formulary, restricted, investigational medicines, Monitoring and evaluation of medicine use, Interventions to promote rational use of medicines, Pharmaceutical management issues in the hospital, and Pharmaceutical promotion.

### **Developing and maintaining the health facility's medicine and medical device list**

DTC should set explicit evaluation criteria such as efficacy, relative efficacy, effectiveness, safety, quality, and cost to select medicines for use in the health facility. The DTC should follow consistent decision-making that is transparent, evidence-based, and time sensitive to local context.

### **Identifying medicine supply and use problems**

The DTC should monitor the rational use of medicines by conducting medicine use studies to identify problems. The DTC can use a number of qualitative and quantitative methods to investigate problems with medicine use and supply.

### **Promoting the monitoring and management of ADEs**

The DTC should have a plan to monitor, assess, report, correct identified problems, and prevent ADEs. This is a very critical function of DTC to assure medicines are efficacious, safe, and are of high quality.

### **Promoting prevention and containment of antimicrobial resistance (AMR)**

The DTC has a responsibility to coordinate efforts to prevent and contain AMR by instituting policies and implementing various strategies such as infection prevention, antimicrobial medicines prescribing privileges, and surveillance.

### **Monitoring medicine procurement and inventory management**

The DTC should develop policies to facilitate supply management of medicines and medical devices in the health facility. The DTC should also identify problems and recommend interventions to streamline the management of pharmaceuticals.

### **Designing intervention strategies to improve medicine related issues**

After problems are identified through various investigation methods, the DTC is expected to address these problems by designing strategies. Strategies to improve medicine use problems include educations, managerial, and regulatory strategies.

### **Communicating, Collaborating and Coordinating**

The DTC should play a coordinating and collaborating role within the facility and beyond to be able to carry out its activities effectively. The DTC should actively communicate decisions and findings to all concerned. The DTC should record, document, and report all DTC related activities

These functions of DTC will be discussed in more detail in the coming chapters.

## **3.3. Guiding principles for DTC**

Success of DTC largely depends on commitment of members, having strong and visible support from the senior hospital management, and abiding by the guiding principles listed below.

### **A multidisciplinary approach sensitive to local context**

DTC activities will involve different cadres of health professional, who will have different experiences, beliefs, skills, practices, motivations, and status. Often a DTC must manage conflict arising between clinicians and the pharmacy or administration concerning prescribing restrictions that result from the implementation of agreed guidelines. Such conflicts can be reduced if staffs are convinced of the need for, and benefits of, change and there is strong institutional commitment with the support of people in authority. Wide representation on the DTC and



documenting and disseminating decisions taken to correct problems in the use of medicines helps to convince health-care workers. Everyone who contributes should be acknowledged.

### **Transparency and commitment to good service**

The success of a DTC will depend upon its being active, working regularly in a consistent direction and making sound decisions in a transparent way. This is especially important in medicine selection and procurement policies. The people involved should not be influenced by inappropriate medicine advertisements, promotional activities, or personal financial interests.

### **Technical competency**

A DTC must have the appropriate technical competence. Members will have different competencies and the DTC process of discussion and appraisal of medicine use issues is a good way to educate members in areas outside their expertise. Good science and evidence (if possible) must be the basis of all DTC decisions.

### **Administrative support**

Administrative support is very important. Otherwise a DTC may not be able to implement its decisions. Administrative support can provide the executive authority needed to gain the cooperation of senior medical staff. The administration can also provide the funds needed to undertake many of the DTC's activities.

### **Ethical conduct**

For the committee to maintain objectivity and credibility, a strict ethics policy must be developed and rigorously enforced at all times. The committee should have no relationship with pharmaceutical companies other than a purely professional one that encourages the acquisition of quality medicines and the flow of unbiased information about their products.

Other important principles for a successful DTC include:

- DTCs should have clear terms of reference (TOR) that articulate its position within a health facility.
- DTCs should consider the local environment when defining their functions.
- DTCs need to have formalized reporting line to the health facility's management.

- Standardized procedures for decision-making and documentation should be implemented by the DTC.
- DTCs should support in identifying, prioritizing, and implementing systems improvement initiatives in the area of medicines supply management and use.
- DTCs should have a system that ensures timely, effective, and appropriate communication of information for the intended audience.
- DTCs should have monitoring & evaluation systems in place to evaluate their effectiveness

### 3.4. Organization of DTC

DTC should be composed of health care professionals from the medical staff (with representatives of the major specialties), pharmacists, nursing personnel, and representatives from administration and finance. Although this mix of personnel would provide the most input from diverse segments of the health care organization, there is no single recommendation that dictates who should be in this committee.

*Table 5: Composition of DTC*

<b>DTC Committee members</b>	
<b>Hospital<sup>4</sup></b>	<b>Health Center</b>
Chief Clinical Officer/ Equivalent – Chairperson	Head of Health center – Chairperson
Head/Director of Pharmacy Services –Secretary	Head of Pharmacy Services - Secretary
One relevant representative from Pharmacy Department	Head of Nursing Service – Member
Heads / Representatives of major <sup>5</sup> Clinical Departments – Members	Outpatient Case Team Coordinator Member
Matron – Member	Head of Laboratory Service – Member
Head of Laboratory Service - Member	Head of finance - Member
Head biomedical team	
Chairman of hospital quality improvement team	
Head of Finance Section- Member	

<sup>4</sup> CEOs of hospitals should consider participation on DTC meetings on on-call basis.

<sup>5</sup> This depends on the specialty service provided by the facility. For example, a facility that provides psychiatry service should have a representative from that department.

The members shall be appointed by the health facility management and the committee must maintain a line of authority and support to the management. If deemed necessary, other clinical and diagnostic departments can be represented in the Committee. It 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.

DTCs can establish standing subcommittees to carry out specific tasks such as Antimicrobial subcommittee, ADE subcommittee, etc. If the DTC finds some task which demands a group of people to stay together temporarily, it may organize also relevant ad hoc committees.

DTC of the health facility should have Clear Terms of Reference (TOR) and action plan approved by the management of health facility. Terms of reference, policies, decisions, and other actions of the DTC should be documented, and the records should be kept appropriately (TOR, **Annex 13**)

#### **Duties and Responsibilities of the Chairperson**

- Ensures that the aims and objectives of the DTC are applied
- Ensures that decisions of the committee are based on scientific evidence
- 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.
- Communicates relevant decisions and information made by management to DTC
- Coordinates and collaborates with relevant internal units and external stakeholders

### **Duties and Responsibilities of the Secretariat**

- In consultation with the chairperson, prepares the agenda for meetings and notifies all members of the DTC at least three days before the meeting.
- Collects and circulates all pertinent material for meetings to all members at least three days before the meeting.
- Prepares the minutes of meetings and disseminates 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.
- Participates in other activities of the committee
- In collaboration with the chairperson, communicates relevant decisions and information made by management to DTC
- Ensures that health facility staff are communicated about relevant decisions and recommendations

### **Duties and Responsibilities of Members**

- Demonstrate professional competence through active participation in the meetings.
- Propose issues/agenda that need to be discussed
- Participate in activities of the committee
- Give prior notification if he/she will not be attending the next meeting, and make sure relevant representative is assigned.
- Communicate and enforce decisions of the committee to the department/case team they represent
- Perform other activities that is assigned to them by the DTC

## Duties and Responsibilities of the Health facility

The health facility has also a great deal of responsibility in the establishment and functionality of the DTC. Some of the major responsibilities include:

- Establish the DTC officially as per the standard requirements
- Assign the members by official letter
- Incorporate the activities of the DTC in the annual plan of the health facility
- Allocate the necessary resources for DTC activities
- Provide sufficient time for DTC members to perform their responsibility in the DTC
- Request reports from the DTC regularly and give timely feedback
- Closely monitor, evaluate, and support the DTC

## DTC Meetings

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

## Summary

- *Ethiopia has national guidelines, plans, standards to establish a functional DTC*
- *DTC is the committee composed of medical, pharmacy and administrative departments*
- *The DTC has priority roles and functions to improve medicine supply and promote rational use of medicines*
- *Major roles and functions of the committee includes advisory role, developing policies and procedures, medicines list developing, identifying medicine use problems and designing strategies for improving the identified medicines use problems*
- *DTC is made up of multi-disciplinary teams in the health facilities*

## Chapter Four: Developing Policies and Procedures to Manage Medicines and Medical Devices

**Allocated Time:** 150 minutes

**Chapter Description:** This chapter explains why policies and procedures are required at health facilities and describes what policies and procedures are expected at facility levels which are currently available at some of the health facilities. It also discusses the basic principles and steps in the development of facility specific policies and procedures and how to formulate these documents.

**Chapter Objective:** By the end of this chapter, participants will be able to formulate facility level policies and procedures.

**Enabling Objectives:** By the end of this chapter, participants will be able to:-

- Explain why policies and procedures are required at health facilities
- Describe the existing policies and procedures related to management of medicines and medical devices at health facilities
- Determine what they are lacking for efficient management of medicines and medical devices.
- Formulate facility specific policies and procedures for the management of medicines and medical devices.

### Chapter Outline:

- Introduction
- Facility level Policies and procedures
- Guiding principles and steps in developing policies and procedures
- Sample policy and procedure document development
- Summary

## 4.1 Introduction

Medicines form an increasingly important part of modern healthcare and their management is underpinned by principles of safe practice by staff involved in the storage, dispensing and administration of medicines. The medicines themselves and the legislation surrounding their use are becoming increasingly complex.

To ensure that all aspects of proper management of medicines are in place, appropriate policies and procedures, that outline a legal framework that health facilities should implement and adhere to, is a necessity.

Policies and procedures are an essential part of any organization. Together, policies and procedures provide a roadmap for day-to-day operations. They ensure compliance with laws and regulations, give guidance for decision-making, and streamline internal processes. They also ensure that there is supportive system and environment to appropriately manage medicines.

### Activity 4.1: Policy and Procedures



- What is policy?
- What is procedure?
- What are the differences between the two?
- Which 'wh' questions they answer?




**Time: 5 min**

A policy is a deliberate system of principles to guide decisions and achieve rational outcomes. An effective policy should outline what employees must do or not do directions, limits, principles, and guidance for decision making. Policies answer questions like: What? Why?

A procedure is the counterpart to a policy; it is the instruction on how a policy is followed. A policy defines a rule, and the procedure defines who is expected to do it and how they are expected to do it. Procedures answer questions like: How? When? Where?

When policies and procedures are well thought out and, most importantly, implemented they provide common understanding and agreement on why and how things should be done. Procedures provide clear instructions and guidelines on what should/must be done in a particular set of circumstances or with regard to a particular issue.

## Why policies and procedures are important?

Activity 4.2: Think -pair and share – Why policies and procedures are important?	
 <b>Think</b>	What are the main reasons why having policies and procedures is important?
 <b>Pair</b>	
 <b>Share</b>	
<b>Time:</b> 5 min	

### Set expectations

Policies and procedures set expected standards of behaviour, conduct and performance for staff ensuring consistency in the performance of activities. They provide persons working in the organization with a framework as to the manner in which actions are to be executed.

### Create accountable system

The set standards provide guidance and transparency for staffs to lay grounds on what is expected of whom in clear terms. This will promote efficiency within the organization in that ideas do not continually have to be deliberated.

### Ensure compliance

Policies and procedures that are regularly reviewed and updated will assist an organization in meeting its legal obligations. By establishing a consistent approach to ensure safe and secure practices, it also serves as a tool for quality improvement within the organization.

### Establish internal control system

Policies and procedures help create an internal control framework within an organization. Management uses this internal control framework to rely upon and ensure that the organization's objectives are being met.

## 4.2 Facility level Policies and Procedures

Health facilities are expected to develop policies and procedures to set directions on how medicines and medical devices should be managed. These documents could be issued in areas such as:-

- Medicine and medical devices procurement
- Stock transfer



- Ward medications and supplies stock management
- Medicine use by different departments and levels of professionals
- Inventory management and storage
- Information and knowledge sharing and task handing over
- Recording, documentation and reporting (including prescriptions)
- Management and control of special medicines
- Medicines management during emergencies and outbreaks
- Medical representatives and other pharmaceuticals promotion activities control

Currently, the main documents that were developed/adopted by health facility DTCs in Ethiopia include, but are not limited to:

- Medicines and medical devices procurement policy
- Stock transfer policy
- Poison and antidote management policy
- Medicine use policy
- AMR prevention and containment policy
- Formulary system management policy

**Activity 4.3: Discuss on available policies and procedures & the gaps**



- What policies and procedures were developed or adopted by the health facility for medicines and medical devices management?
- What policies or procedures that the health facility is lacking?

**Time: 5 min**


### 4.3 Guiding principles and steps in developing policies and procedures

#### 4.3.1 Guiding Principles in developing policies and procedures

Some of the guiding principles that should be considered in formulating policies and procedures include, but not limited to, that they:

- Shouldn't **contradict or conflict** with national, regional or other superior policies and procedures
- Should be **aligned** with the organization's vision, mission, values and organizational priorities
- Should be structured, drafted and presented in a way that makes the policy **understandable** and easy to read and interpret.
- Should be **concise, to the point; action-orientated** and should have a logical and coherent structure.
- Should **promote effective communication** among the stakeholders.
- Must be made clear whether any matter or action prescribed in the policy is **mandatory or discretionary** by using the words "must/should" or "may".
- Should take into account what is both **practical and reasonable**.
- Should be developed by through **involvement** of all relevant staff members.

#### 4.3.2 Steps in developing policies and procedures

<b>Activity 4.4: Group exercise - Matching quiz on steps in policies and procedures</b>	
	You are required to list the logical steps of policies and procedures development <b>Time: 15 minutes</b>
Instruction: First, try to match the steps with their definitions. Then, try to list the steps down in a logical flow.	

The following steps summarize the key stages involved in developing policies:

**Identify need** - The process of policy development begins with recognizing the need for written policy. The organization needs to know and understand the purpose of policies and to recognize that the issue or problem can be effectively dealt with by developing of a policy.

**Identify who will take lead responsibility** - The policy development process may take place over a certain period of time. There needs to be someone or perhaps a committee who is "driving" the process.

**Gather information**-Sufficient information should be collected through reviewing policy documents from other health facilities, doing researches on the issue, organizing meetings with stakeholders, reviewing documents (e.g. minutes, reports) on the issue, etc.

**Draft policy** - The development of policy is a collaborative and iterative activity. Drafting of policies and procedures should be done by subject matter experts and relevant professionals.

**Consult with appropriate stakeholders** - When the draft policy is completed, it should be circulated to key stakeholders, discussed in further meetings and forums. At this stage, it is necessary to seek help from stakeholders to fine tune the wording and clarify meanings.

**Finalize / approve policy** - The final policy document must be submitted in writing for approval and it needs to be formally endorsed by the management of the organization.

**Consider whether procedures are required**-After a policy is finalized, there might be a need to develop procedures with clear guidance on how it should be implemented and by whom.

**Implement** - Following formal endorsement, the policy should be communicated throughout the organization and to all stakeholders and should be implemented. Training sessions might be required for the staff. If the policy is not well communicated, it may fail.

**Monitor, review and revise** - The implementation of policies and procedures should be monitored. Policies and procedures may still require further adjustments and, furthermore, the reasons for their existence may change. A general practice is to set a date for the policy to be reviewed.

#### 4.4 Sample policy and procedure document development(practical exercise)

Policies and procedures can be simple or complex depending on the issues to be addressed and on the level in which the policies and procedures are to be developed.

Facility level policies need to be simple and straight forward, as much as possible. Using the sample policy document annexed (*Sample Storage Policy*) as a guide, the DTC can develop all sorts of facility level policies and procedures.

##### Activity 4.5: Group Activity - Develop a sample policy



- In group of 4 or 5, select one topic that you think a policy & procedure should be developed for.
- Draft a simple policy for the topic you have selected.

Note: the draft policy shouldn't be a completed one; but, it should address the issues addressed in this chapter.

**Time:** 45 min

##### Summary

- *Policies and procedures are an essential part of any organization and, together, they provide a roadmap for day-to-day operations*
- *Health facilities are expected to develop different policies and procedures to set directions on how medicines and medical devices should be managed*
- *Currently, only few facility specific policies and procedures were developed and being in use*
- *There are clear steps in developing policies and procedures which health facilities need to exercise in formulating these legal documents*

## Chapter Five: Developing and Maintaining Health Facility Specific Medicines and Medical Devices List

**Allocated Time:** 260 minutes

**Chapter Description:** This chapter introduces participants the basic concepts and principles of the formulary system. Benefits arising from the appropriate selection, development, implementation and maintenance of health facility specific medicines and medical devices list will be discussed.

**Chapter Objective:** At the end of this chapter, participants will be able to implement the formulary management system.

**Enabling Objectives:** At the end of this chapter, participants will be able to:

- Discuss the formulary management principles and benefits
- Develop list of medicines and medical devices for the health facility
- Discuss the management of non-formulary and restricted medicines
- Describe the maintenance of formulary system
- Monitor implementation of formulary system.

### Chapter Outline:

- Introduction
- Developing facility specific medicines and medical devices list
- Non-formulary and restricted medicines
- Maintaining a medicines and medical devices list
- Monitoring implementation of Formulary system
- Summary

## 5.1. Introduction

As many as 70 percent of all medicines on the market today are either duplicative or of questionable value, many are minor variations of a proto-type drug product and offer no therapeutic advantage over the other. With so many different pharmaceutical products available, prescribers often find it difficult to keep their knowledge up-to-date and compare alternatives. In addition, the variety of available products may contribute to inconsistent prescribing practices within the same healthcare system.


The formulary system that selection and maintenance of most efficacious, safe, and cost-effective medicines and medical devices using explicit selection criteria, satisfies the priority healthcare needs of the population. In the health facility settings, DTC is responsible in developing and maintaining facility specific medicines and medical devices list.

### Definitions of key terms


<b>Medicine and medical devices list:</b>	Is a list of medicines and medical devices approved for use in a specific health care setting. The list contains all medicines with strength and dosage forms, and medical devices (medical supplies, laboratory supplies/reagents and medical equipment). Some countries refer it as “ <i>Formulary List</i> ”.
<b>Formulary:</b>	The document that describes medicines which are available for use in a country or health facility. It provides information on indications, dosage, duration of treatment, interactions, precautions, and contraindications of the medicines included in the Medicines and medical devices list. Some countries refer it as “ <i>Formulary Manual</i> ”.
<b>Formulary System:</b>	The system of periodically evaluating and selecting medicines and medical devices for the medicines and medical devices list and maintaining the list.
<b>Standard Treatment Guidelines (STGs):</b>	Is also known as “ <i>treatment protocols/clinical guidelines</i> ” is systematically developed collection of statements designed to assist practitioners in making decisions about appropriate healthcare for specific clinical circumstances.

<b>VEN System:</b>	Is a method to set up priorities for medicines according to their health impact into Vital (V), Essential (E) and Non-essential (N) categories
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Medicines and medical devices are selected with due regard to disease prevalence and evidence of efficacy, safety, and comparative cost-effectiveness. The selected medicines and medical devices are always intended to be available in the health facility. Healthcare provider’s involvement in the development and updating process, a user-friendly format, adequate distribution and adherence follow-up are critical for successful use of the list.

<b>Activity 5.1: Facility specific medicines and medical devices list</b>	
	<p>Did your facility developed facility specific medicines and medical devices list?</p> <ul style="list-style-type: none"> <li>• If Yes, who developed the list? And when was it first developed?</li> <li>• If No, what are the reasons?</li> </ul> <p><b>Time: 3 min</b></p>

Benefits of an effective Facility Specific medicines and medical devices list

<b>Activity 5.2: Think and share on facility specific medicines and medical devices list</b>	
	<p>What do you think about the benefits of developing facility specific medicines and medical devices list?</p> <p><b>Time: 3 min</b></p>

The rationale for the selection and uses of limited number of medicines is that it leads to improved supply of medicines, promotes rational prescribing and lowers cost. A comprehensive medicine and medical devices list and active formulary system provide numerous benefits to health facilities. Some of the benefits include;

- **Improved quality of care:** only effective and safest products that have been evaluated in a systematic manner will be available to treat the disease states of the local area.
- **Drug therapy at a lower overall cost:** availability of most effective medicines to treat common health problems resulting in improved outcomes, and reduced inventory costs.
- **Consistent supply of medicines;** improved the procurement and inventory management

Every step in the formulary system will result in a more efficient system that will better utilize scarce health care resources. Besides the benefits, development and maintenance of facility

specific medicines and medical devices list is one of the requirements of EHSTG and EHCRI; as discussed in chapter 2 (DTC overview).

### **Principles of management of formulary system**

The formulary system utilizes the medical and pharmacy staffs to evaluate, appraise, and select those products that are efficacious, safe, quality, and available at a reasonable price. Development and maintenance of the list should conform to the following principles:

- Select Medicines according to the needs of population to treat the locally identified diseases and conditions.
- Use explicit selection criteria, based on proven efficacy, safety, quality and cost
- Use evidence-based information to select and evaluate medicines for the list
- Select “medicines of choice” in accordance with updated clinical treatment guidelines.
- Avoid duplications, both therapeutic and pharmaceutical (dosage forms)
- Be consistent with the national medicines list or standard treatment guidelines
- International nonproprietary names (INN) (i.e., generic names) should be used.
- Medicines should be restricted to appropriate practitioners.
- Consider requests for the addition of new drugs only when made by health-care staff, not by the pharmaceutical industry
- Carry out annual systematic reviews of all therapeutic classes and update the list
- Apply transparency throughout the list development and maintenance process
- Avail the list to all units and monitor its utilization.


## **5.2. Developing facility specific medicines and medical devices list**

Appropriate selection of medicines can achieve the results of cost containment and enhanced equity in access to essential medicines and improve quality of care. The DTC should consider many factors while developing facility specific medicines and medical devices list. Besides the DTC should utilize objective, up to date and evidence-based information sources during selection and evaluation of medicines and medical devices for the list.

### **5.2.1. Selection criteria for medicines and medical devices**



The process of selecting medicines which is multi factorial ultimately brings the best medicines to the health care system. The process should follow carefully considered policies and procedures for determining the most useful medicine search time when an evaluation is done.

<b>Activity 5.3: Probing question on Selecting medicines for the list</b>	
	What criteria should we consider while selecting medicines and medical devices for the list? <b>Time: 3 min</b>

The following represent major criteria to be considered when evaluating all new requests for addition to the facility specific medicines and medical devices list:

- ***Disease Patterns of the area:*** The morbidity of the area needs to be assessed carefully before developing the list. Standard treatment guidelines prepared for different levels of health facilities must be reviewed to determine appropriate medicines for the disease patterns identified.
- ***Health system diagnostic facility and personnel expertise available:*** Availability of health care professionals who have training, experience and credentials necessary to use the selected medicines and medical devices is important. Consequently, availability of support facilities (laboratory and diagnostics imaging etc.) and services for each level of the healthcare system determine which individual medicine and medical device will be made available.
- ***Efficacy, Safety and Quality:*** Careful evaluation of all sources of information must be done to ensure that evidence of efficacy, safety and quality is supported by the literature and is unbiased and accurate. While selecting it is necessary to include those with well-known safety profiles through careful risk-benefit assessment.
- ***Cost and Cost-Effectiveness:*** The cost of a medicine in relation to its benefits is an important consideration. A medicine with questionable efficacy or benefits at a high cost would have an unfavorable cost-effectiveness ratio. When a new medicine with equal efficacy and possibly fewer adverse side effects at a higher cost is requested for inclusion, the decision may require consideration of cost of treatment over the cost of individual medicine.

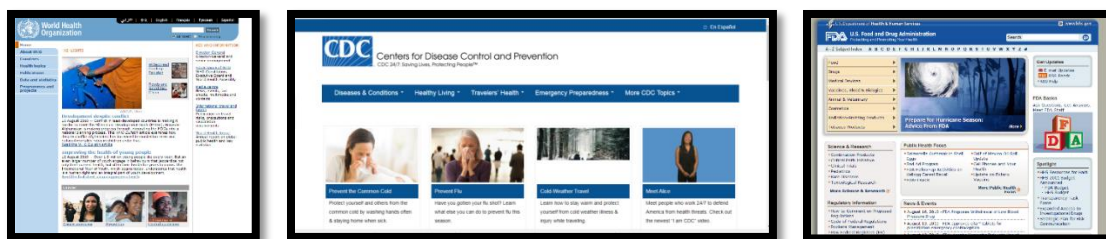
- **Availability of Financial Resources:** The health care system must have enough budgets to purchase and have the medicines. A thorough cost analysis is therefore, necessary before the medicine is accepted for the list. If the resources are not available for the consistent procurement of a medicine, then it should not be accepted for inclusion to the list.
- **Medicines That Are Well Known:** Ideally, medicines that are selected for the list are ones that are well known, have been on the market for years, and have clinical experience to support their pharmacological profiles. This idea may not be attainable for all medicines, but it should be one of the basic parameters to consider when selecting a medicine.

### 5.2.2. Information sources

Adequate resources to obtain information and to evaluate the efficacy, safety, quality, and cost of a medicine are essential. Unbiased sources of information such as journals, newsletters, STGs, formularies, textbooks, etc. are required in evaluating medicines' characteristics. A comprehensive review of journal articles, especially of randomized controlled trials and meta-analysis will provide unbiased information. Medical information sources fall under three categories as primary, secondary and tertiary as presented below.

<b>Table 6: Sources of information</b>	
<b>Primary sources:</b>	Articles and unpublished studies/research thesis that may be obtained from journals and services that provide the entire article
<b>Examples</b>	<ul style="list-style-type: none"> <li>• <i>Ethiopian Medical Journal,</i></li> <li>• <i>Ethiopian Pharmaceutical Journal,</i></li> <li>• <i>British Medical Journal (BMJ),</i></li> <li>• <i>American Journal of Health-System Pharmacy (AJHP)</i></li> </ul>
<b>Secondary sources:</b>	Indexing and abstracting services that provide abbreviated reviews of articles; review journals, meta-analysis; usually published in newsletters, CD-ROM databases, and online services.
<b>Examples</b>	<ul style="list-style-type: none"> <li>• <i>MEDLINE/PUBMED abstracts,</i></li> <li>• <i>Drug Bulletins</i></li> <li>• <i>Pharmaceutical Abstracts</i></li> </ul>
<b>Tertiary sources:</b>	Published textbooks, which can be an excellent source of information if reputable and current sources are used
<b>Examples</b>	<ul style="list-style-type: none"> <li>• <i>Martindale: The Extra Pharmacopoeia,</i></li> <li>• <i>British National Formulary,</i></li> <li>• <i>Ethiopian National formulary,</i></li> <li>• <i>Standard Treatment Guidelines for hospitals</i></li> </ul>

At times, even well-designed searches of standard medical literature may not yield enough information to make clinical decisions or recommendations. In these cases, alternative resources may need to be employed. Such source of information might be a general internet search or consumer health information (WHO, CDC, FDA etc.) sources. Common examples of sources are presented below).



**Figure 3: Common consumer health information sources**

**Table 7: Online Consumer Information Sources**

Web Site URL	Maintained By	Contains Information About
<a href="http://www.nlm.nih.gov/medlineplus/">http://www.nlm.nih.gov/medlineplus/</a>	National Library of Medicine	Various medications as well as disease states and conditions.
<a href="http://www.fda.gov/cder/">http://www.fda.gov/cder/</a>	Food and Drug Administration	New drugs, dietary supplements and recalls of drug or food.
<a href="http://www.healthfinder.gov/">http://www.healthfinder.gov/</a>	Department of Health and Human Services	Variety of common medical conditions and diseases.
<a href="http://www.cdc.gov/">http://www.cdc.gov/</a>	Center for Disease Control and Prevention	Treatment and prevention of infectious diseases and listing of public health issues.
<a href="http://ods.od.nih.gov/">http://ods.od.nih.gov/</a>	National Institute of Health	Compiles scientific information available about the efficacy and safety of dietary supplements.
<a href="http://www.who.int/en/">http://www.who.int/en/</a>	United Nations	Information on outbreak, communicable and non-communicable diseases, etc.


When we are looking for programs, performance reports, and other information specific to local context, we can also look for local websites. There are organizations that provide health and pharmaceutical related information in Ethiopia which some of them are listed below.

**Table 8: Local Health Information Sources**

Web Site URL	Maintained By	Contains Information About
<a href="http://www.moh.gov.et/cs/home">http://www.moh.gov.et/cs/home</a>	FMoH	Health care services, programs, documents & initiatives in the country.
<a href="http://www.fmhaca.gov.">http://www.fmhaca.gov.</a>	FMHACA	Food, medicine and health care services regulatory

<a href="#">et/index.html</a>		standards, inspection and licensing, product quality assessment and product registration requirements/ documents.
<a href="http://www.pfsa.gov.et/">http://www.pfsa.gov.et/</a>	PFSA	National procurement, tender, forecasting and quantification and distribution of program and revolving drug fund pharmaceuticals.
<a href="https://www.ephi.gov.et/index.php">https://www.ephi.gov.et/index.php</a>	EPHI	National disease prevalence and surveillance, public health nutrition, laboratory services and public health researches.

Ideally, the health facility will have access to pharmaceutical information service to handle requests concerning the selection and addition/deletion of medicines and medical devices to/from the list. If not, a pharmacist or a physician can provide the necessary evaluations using resources listed above. However, in many settings, National STGs and formulary manuals, registered medicines list, PFSA procurement and pricelist, essential medicines list and FMOH master lists are local information sources commonly used during the selection and maintenance of facility specific medicines and medical devices list.

<b>Activity 5.4: Probing question on Formularies and STGs</b>	
	What are the similarities and differences between Formulary manual and STG? <b>Time: 5 Minutes</b>

### Formulary Manual

A formulary manual contains summary of medicine information. The formulary manual is the publication that brings all of the relevant data concerning medicines together in a manual or booklet. It is a handy reference that contains selected information that is relevant to the healthcare provider. There is no set standard on how it is arranged or what it includes. But commonly includes the *generic name of a medicine, indications for use, dosage schedules, contraindications, side effects, medicine interactions and important information* that should be given to the patient. A formulary manual is drug centred- i.e. it is based on monographs for individual drugs or therapeutic groups. An example of Medicine description in a formulary manual is presented below:

**Magnesium Hydroxide:** *Suspension, 375 mg/5ml, 7.75 % Tablet (chewable), 300 mg, 311 mg*

- **Indications:** ulcer and non-ulcer dyspepsia; GERD.

- **Cautions:** renal impairment, hypermagnesemia, hepatic impairment, notes above.
- **Drug interactions:** as for Aluminum hydroxide, also see notes above.
- **Contraindications:** see notes above, hypersensitivity to any component of the formulation, severe renal impairment.
- **Side effects:** diarrhea, abdominal cramps, muscle weakness, respiratory depression, hypermagnesemia and hypotension.
- **Dose and Administration:** Tablet, **Adult:** Chew 2 - 4 tablets repeated according to patients needs with maximum daily dose of 16 tablets. **Child** (7-14 years): one tablet with maximum of 4 tablets per day. Mixture, **Adult:** 5 -15 ml repeated according to patient's needs with maximum daily dose of 60 ml. **Child:** 2.55ml as needed up to 4 times/day.
- **Storage:** at room temperature, avoid freezing.

### Standard Treatment Guidelines

Standard Treatment guidelines (STGs) are another aspect of formulary management system. It is a systematically developed statement designed to assist practitioner and patient in making decisions about appropriate healthcare for specific clinical circumstances. STGs are prepared with special focus on management of diseases. They briefly describe disease conditions; their management (both Pharmaco-therapeutic & Non-Pharmacotherapeutic management). It provides first line Pharmaco-therapeutic treatment approaches and alternatives. An example how STGs are organized is shown below using amebic liver abscess.

#### ***Example: AMEBIC LIVER ABSCESS***

**Amebic liver abscess** is the most common extra-intestinal manifestations of amebiasis. It is 7 to 10 times more common in adult men. In symptomatic patients, fever and right upper quadrant pain are the usual manifestations. Point tenderness over the liver with or without right side pleural effusion is also common.

#### **Treatment:**

Non-Drug treatment: Aspiration of the abscess can be done whenever necessary.

Drug treatment

*First line*

Metronidazole:

Adults: 500-750 mg, P.O. TID or 500 mg IV QID for 10 days.

For children: 7.5 mg/kg, P.O. TID for 5 days.

(For, S/Es, C/Is and dosage forms see page 14)

*Alternative*

Adults: 2g P.O. QD for 3 consecutive days. For Children: 50-60mg/kg daily for 3 days.

(For S/Es, C/Is and dosage forms see above)

Formulary manual and STGs require a meticulous approach to developing and publishing the document. They must be prepared carefully using only evidenced-based information; they must be written by experts and reviewed frequently to maintain up-to-date information.

### 5.2.3. VEN system of classification of Medicines and medical devices

The other concept to consider while developing List of Medicines is to categorize each medicine as Vital (V), Essential (E) and Non-essential (N). The VEN system, in which medicines are sorted according to their health impact into vital, essential, and non-essential categories, is a well-known method to help set priorities for purchasing medicines and keeping stock.

#### Activity 5.5: Probing question on VEN system



What do you think when you hear the terms Vital, Essential, Non-essential medicines?

**Time: 3 min**

#### **Vital (V)**

- **Potentially lifesaving:** required saving patient's life in certain conditions; patient may die or may be harmed or disabled because of lack of this medicine
- Crucial to provide basic health services, without which it is impossible to deliver the basic services in the specific catchment area (in its absence, service may be discontinued).
- Must always be available

#### **Essential (E)**

- Effective against less severe but significant illness, not vital; it is between vital and less essential
- It is lifesaving; without which patient may be in difficulty/ problem /may be somehow substituted

- Essential to the service without which it is difficult to give the health service
- It is mandatory at least once a day, or at least once a week, or at least once in a month or once in a quarter of the year, but not as highly mandatory as vitals

- Non-essentials (N)**
- Effective for minor illnesses and low therapeutic advantage
  - Important to patients; however, patients will not die because the absence of these medicines
  - Necessary to give the health service; however, health service delivery will not be discontinued in the absence of these medicines
  - Last priority medicines (when budgets are limited, these categories are the first to be adjusted in reconciling requirements with the budget/fund)


Health facilities can use a number of ways to decide how to focus their efforts to improve their medicine supply. The VEN system provides a valuable service to the health care system. The main objective is to give priority to **essential lifesaving** medicines as opposed to expensive, non-essential items. The DTC should be involved in the application of this system to the facility's list by identifying the VEN class for all medicines approved for the list.

In terms of medicine procurement and inventory management, one way to identify priorities is by applying the VEN system during selecting medicines for a certain setup. Regardless of how well a supply system works, there will always be more opportunities to improve the system that a DTC has time and resources to address. Therefore, the DTC and managers of pharmaceutical supply must narrow down the scope of what is manageable and what will provide the best return for their efforts.

**N.B.** Classifying a medicine to the non-essential category does not mean that the medicine is no longer required/available to the health facility. It indicates that the medicine may be considered a lower priority than other medicines in the list.

#### **5.2.4. SOP for developing facility specific medicines and medical devices list**

**Activity 5.6: Facility specific medicines and medical devices list**

	<p>What steps would you follow while developing facility specific medicines and medical devices list?  <b>Time: 5 min</b></p>
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Development of facility specific medicines and medical devices list should be done in a systematic way. The most logical approach is selecting medicines based on disease prevalence and recommended treatment measures mentioned in the STG specific to the level of the health facility. One of the most important roles of DTC is to guide and maintain the development of facility specific medicines and medical devices list.

**Purpose:** To guide step-by-step activities in developing a facility specific medicine list.

**Responsibility:** Health facility Drug and Therapeutics Committee (DTC) or assigned formulary sub-committee.

**Procedure:**

<b>Steps</b>		<b>Remark</b>
1	Introduce the concept; create the demand and obtain support from the facility management and staff	Successful implementation of the list requires support from both the medical staff and administrators
2	Establish a sub-committee to coordinate the development process	A subcommittee of the DTC having 3-5 members representing key departments/units
3	Prepare and introduce the role and responsibilities of the sub-committee	<b>Refer annex IV</b>
4	Set criteria for selection of medicines	<b>Refer 5.2.1</b> <i>(Disease patterns of the area, diagnostic facility and personnel expertise etc.)</i>
5	List identified diseases affecting the community	Information can be obtained from morbidity and mortality reports
6	Select medicine/s for all identified health problems adhering to the recent STG.	Considering the selection criteria listed under section 5.2.1. <i>(Medicine/s of choices, alternatives and other and supplementary pharmaceuticals needed to manage the case using generic name).</i>
	List down all medical devices (diagnostics, medical supplies and equipment required to diagnose, mitigate and treat the disease).	While listing, consider specifying full details of each item selected <b>Example.</b> <i>X ray Films 18x24, X ray Films, 30x40  Gloves, surgical Latex, disposable, sterile, pre-</i>



		<i>powdered, individually wrapped in pairs, size 7.5, Cotton wool absorbent 100gm</i>
7	Specify the required strengths and dosage forms of the selected medicine/s.	Use the “List of (Essential) Medicines for Ethiopia” to identify all available forms and strengths. <b>Example.</b> ( <i>Frusemide Injection, 10mg/ml in 2ml ampoule Frusemide Tablet, 40mg</i> ),
8	Categorize each item into VEN by the level of their importance to treat each of the disease	Consider each of the strengths and dosage forms of a medicine. <b>Example.</b> <i>Hydrochlorothiazide tablet, 25mg, - E Mannitol Injection, 20% in 500 -V Cotton wool absorbent 100gm -E</i>
9	Classify medicines and medical devices pharmacotherapeutically, Sort the list alphabetically, code and align with existing coding system	1. <b>MEDICINES</b> <i>GI.000 GASTROINTESTINAL MEDICINES CV.000 CARDIOVASCULAR MEDICINES</i> 2. <b>MEDICAL SUPPLIES</b> 3. <b>LABORATORY REAGENTS AND CHEMICALS</b> 4. <b>MEDICAL EQUIPMENTS Etc</b> Note also that a Medicine may have more than one Therapeutic Category <b>Draft medicines and medical devices prepared</b>
10	Circulate the draft list to different HF units for comment	Practitioners have different experiences and will use their expertise to review the list and comment on draft list
11	Evaluate comments and edit the list accordingly ( <i>incorporate accepted ones and remove un-accepted ones</i> )	You can use literature reviews or other appropriate information resources for unbiased decision making
12	Submit the draft facility medicines list to DTC meeting for final review.	The DTC members should review the draft according to their department
13	Include comments from DTC and finalize the medicines list	

This task is completed when:

- The document is:
  - Prepared with preface, acknowledgement, List of Contributors and DTC members on separate pages prior to list of medicines, Table of contents acronyms and indexes
  - Printed and distributed to all departments;
- The facility management in charge has issued an order of compliance with the facility specific medicines list;
- The facility uses the list to procure products and implement procedures on the use of non-formulary medicines;
- The list is updated annually

#### **Activity 5.7: Exercise on development of facility specific medicines and medical devices list**



Assume you are a member of DTC/formulary sub-committee. You are assigned to develop list of medicines and medical devices for the facility. Before developing the entire list, DTC requires your team to demonstrate a sample list of medicines and medical devices for a specific health problem.

**Instruction/question:** Develop a sample medicines and medical devices list for the health problem.

**Time:** 45 Minutes

### **5.3. Non-Formulary and Restricted Medicines**

#### **5.3.1. Non-formulary Medicines**

It would be very difficult for the DTC to review and update the list when new health problem arises, or healthcare service expansion occurs. Furthermore, there are situations where patients who require specialized treatments or patients who have been stabilized on medicines from practitioners outside of the healthcare system. In such circumstances, the DTC will develop a non-formulary list to keep medicines and medical supplies until the entire list is reviewed and updated.

Most formulary systems are designed as “*open*” systems. The open system allows for the introduction of non-formulary medicines on a limited basis, usually for a single patient use. A “*closed*” system reflects the DTC’s choice to exclude all non-formulary medicines from being available in any form.

Control of non-formulary medicines is important because an open system will invariably become problematic and impede the system of formulary management. Since, non-formulary medicines

may not pass through the complete evaluation process, DTC should be cautious in managing non-formulary medicines. Hence:

- Limiting the number of non-formulary medicines
- Keeping DTC approval as a requirement for the purchase of non-formulary medicines
- Limiting access to appropriate prescribers
- Keeping a register of all requests for non-formulary medicines
- Reviewing frequently and discussing at DTC meetings

Policies and procedures on how these medicines will be purchased are necessary, and close follow-up of all non-formulary medicines by the DTC is warranted to limit their use.

### **5.3.2. Restricted Medicines**

Any medicine, no matter how effective and safe, must be measured against the personnel who will be handling it. For example, certain antiretroviral medicines should be limited to facilities where trained physicians are available to prescribe and monitor them. Restricted medicines need to be defined by the DTC to limit their use. Some examples of restricted medicines and their applicability include:

- Use of vancomycin, restricted only to senior physicians and not allowed for mid-level providers;
- Antineoplastic medicines should be limited to facilities that have oncology expertise.
- Antipsychotic medicines for use by mental health professionals (e.g., use of risperidone can be restricted to psychiatrists)

The use of restricted medicines requires close monitoring and evaluation. These include determining that appropriate patients are receiving the medicines and that authorized medical staff are prescribing and providing follow-up for patients on these medications.

Like non-formulary list, development and implementation of policies and procedures on how restricted medicines would be purchased and utilized are necessary. Besides, DTC should closely follow-up use of all restricted medicines to warrant their limited use.

## 5.4. Maintaining a formulary system

The formulary maintenance process has two key components: (a) Additions and deletions of medicines, and (b) Regular revision of the list.

### A. Additions and deletions of medicines

Additions and deletions should be handled following specific policies and procedures developed by the DTC. A transparent methodology must be developed for these important decisions concerning addition or deletion of a medicine. See the previous section (“Process for Selecting New Medicines”) for recommended criteria for adding medicines to the medicine list.

#### 5.4.1. SOP for addition and deletion of medicine

After the facility specific medicines and medical supplies list is prepared, based on the request from practitioners there may be a necessity to add a new medicine or delete of existing one. This should be done after thorough evaluation of a proposed medicine.

**Purpose:** To add a new medicine or delete an existing one from facility specific medicine list.

**Responsibility:** The DTC Secretary, Formulary sub-Committee and DTC.

#### Procedures:

Steps		Remark
1	Receive request for Addition/ deletion	DTC Secretary/Formulary sub-Committee receives a written request for addition of new medicine or deletion of the existing one will be submitted to DTC secretary by practitioner.
2	Conduct evaluation	The DTC secretary/Formulary sub-committee conducts literature evaluation based on criteria using appropriate sources of information
3	Prepare written report to the DTC	The DTC secretary/Formulary sub-committee submits written report to DTC for decision.
4	Organize a DTC meeting	The DTC conducts meeting and discusses to pass approval or rejection
5	Communicate	The decision will be disseminated to all departments through official letter.

**This task is completed when:**

- The decision (on addition or deletion) made is incorporated in the next revised facility specific medicines list
- The facility management in charge has issued an order of compliance with the medicines list.

**B. Revising facility specific medicine and medical supplies list**

Routine review is important to maintain formulary system. The review involves the evaluation of a complete section of medicines. This review would evaluate current medicines in the list in a systematic manner so that the entire medicine list is reviewed over a one-year period. This task is difficult, but it will provide the necessary review and analysis of medicines in the list as a medical discipline is changing rapidly. Any new medicine that would offer an advantage over the current selections would be evaluated and considered for the List. Medicines that are no longer used or lack enough evidence of efficacy, safety, and quality and cost- effectiveness should be evaluated and deleted when an acceptable alternative is identified.

**5.5. Monitoring adherence to facility specific medicine and medical devices list**

The existence of a well-maintained formulary does not mean that prescribers will adhere to it. Methods to promote formulary adherence include the following:

- Reviewing and taking action on all non-formulary medicine use; action may include adding the medicine to the formulary, educating the prescriber about the non-formulary status of the medicines or banning use of the medicine.
- Prohibiting the use of non-formulary drug samples in the hospital
- Establishing procedures and approved medicine lists for therapeutic interchange or substitution
- Facilitating access to the formulary list, with copies at each units of the health facility
- Involving all medical staff in all formulary decisions
- Advertising and promoting all formulary changes
- Establishing agreed procedures for the management of non-formulary and restricted medicines

A register of all non-listed medicine requests should be kept by the pharmacy. The compiled record can tell the DTC about prescribers' adherence to the formulary list and can also help in deciding the prospects of the medicine/s.

### *Summary*

- *Development of facility specific medicines list is the main function of DTCs*
- *There are principles that govern and criteria we need to comply during facility specific medicines list development process*
- *The VEN system of medicines classification helps to prioritize medicines availability*
- *Maintaining facility specific list of medicines is beneficial in many aspects*
- *A non-formulary list keeps medicines and medical supplies until the entire list is reviewed and updated*
- *Restricted medicines need to be defined by the DTC to limit their use*
- *Adherence to utilization of Facility specific medicines and medical devices should be monitored*

## Chapter Six: Identifying Problems with Medicine Use

**Allocated Time:** 430 minutes

**Chapter Description:** This chapter describes the stepwise approach to perform Quantitative and Qualitative methods of identifying medicine supply and use problems. It will illustrate aggregate method, indicator method and medicine use evaluation methods of identifying medicine use problems in detail.

**Chapter Objective:** At the end of this chapter the participants will be able to perform Quantitative and Qualitative methods of identifying medicine supply and use problems properly.

**Enabling Objectives:** At the end of this chapter, participants will be able to:-


- Describe stepwise approach to investigate problems in the supply and use of medicines
- Perform aggregate method (ABC analysis) to identify medicine supply and use problems
- Identify medicine use problems using indicator methods
- Practice medicine use evaluations to identify medicine use problems
- Describe Qualitative methods to investigate medicine use and healthcare provider behavior

### Chapter Outline:

- Introduction
- Stepwise approach to investigate problems in the supply and use of medicines
- Quantitative and Qualitative methods
- Summary

## 6.1. Introduction

Essential medicines are one of the vital tools needed to improve and maintain health. However, for too many people throughout the world medicines are still unaffordable, unavailable, unsafe and improperly used. Inappropriate medicine use results in poor patient outcomes and wastes significant amounts of money and other resources. This problem is worldwide, especially in developing countries like Ethiopia.

	<b>Activity 6.1: Methods to identify medicine supply and use problems</b>
	What methods do you know to identify medicine supply and use problems? <b>Time: 3 min</b>

Data from health facilities may be used to evaluate specific aspects of health provision and drug use and to generate indicators that provide information on prescribing habits, dispensing practice and aspects of patient care. These indicators can be used to determine where drug use problems exist, provide a mechanism for monitoring and supervision and motivate health care providers to adhere to established health care standards. DTC should engage in coordinating collection of data, describe patterns of medicine use, to address medicine use problems and monitor medicine use over time.

DTC can use two basic methods:

- Quantitative methods (to measure what is being done). Commonly used methods are Aggregate methods, Indicator Study methods and Medicine Use Evaluation
- Qualitative methods (to provide information on why it is being done). Commonly used methods are In-depth interview, Focus group discussions and Structured Questionnaires

These methods are used to better understand the magnitude and causes of problems before intervening to correct them. Depending on the findings of the studies appropriate interventions will be designed and implemented.

## 6.2. Stepwise approach to investigating the supply and 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 improving



drug use is to investigate what kinds of problems there are and the extent to which they occur. Unless drug use is investigated, measured and documented, it is impossible to evaluate the effectiveness of interventions to promote rational use. This chapter describes a number of methods or tools to investigate medicine use. It is important to choose the combination of methods most suited to the type of problem to be investigated and the type of data available.

### ***STEP 1: General investigation to identify problem areas***

Initial investigation should identify broad areas of inappropriate use and supply 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 medicine 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.

### ***STEP 2: In-depth investigations of specific problems***

Once an area of inappropriate medicine use or supply 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 may include, for example:

- Prescription audit to see if the treatment of a specific disease is in accordance with guidelines (the percentage of prescribing encounters in accordance with standard treatment guidelines).
- Qualitative methods to determine the causes of a medicine supply and 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.
- Medicine utilization review to see if the use of a specific medicine is in accordance with previously agreed criteria.


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

Strategies to promote more rational use of medicines are described in chapter 7.

**6.3. Quantitative Methods**

**6.3.1. Aggregate methods**

Aggregate data on medicine use can be obtained from many sources in the health care system. Procurement records, warehouse medicine records, pharmacy stock, and dispensing records are some of the data sources that can be used to obtain a variety of information. Careful review of these records will provide the DTC with insight concerning medicine use, cost of medicines and other data. The DTC must promptly analyze any identified problems in reviewing these data and institute a strategy to remedy each problem.

	<b>Activity 6.2: ABC analysis</b>
	<ul style="list-style-type: none"><li>• What do you know about ABC analysis?</li><li>• How can it help to identify medicine use problems?</li></ul> <p><b>Time: 5 min</b></p>

The commonly used aggregate methods are ABC and VEN analysis. Though ABC analysis and VEN analysis are the main aggregate methods of identifying medicines use problems, ABC/VEN reconciliation should be done to identify the real problem.

**ABC Analysis**

The 80/20 rule, also known as the Pareto Principle, is based on observations made by an Italian economist, Vilfredo Pareto. It is also known as “separating the vital few from the trivial many” because for any group of things that contribute to a common effect, a relatively few contributors account for a majority of the effect.

In terms of pharmaceutical supply, it is known that only a few inventory items account for the greatest expense or consumption. Based on the same thinking as the 80/20 rule, ABC analysis categorizes medicines into three classes based on their budget expenditure.

- **Class A items** are the few items that account for the highest cost (70-80%), lower in items (10-20%).

- **Class B items** comprise the next group of that take 15–20% of expenditure, 10-20% of items.
- **Class C items** include low-cost (5-10%) that account for highest items (60-80%).

**Note:** Conducting analysis on items to be procured (prospective) is more useful as it can help avail most needed medicines when reconciled with VEN analysis thereby preventing wastage of resources.

**SOP for performing ABC analysis**

ABC analysis is a method for determining and comparing medicine cost within the formulary system. DTC members are expected to conduct ABC analysis to identify drug use problem. The following SOP will help on how to conduct the analysis.

<b>Task</b>	Performing ABC analysis
<b>Completed by</b>	Assigned Pharmacy staffs under the close supervision of DTC
<b>Purpose</b>	To analyze particular period medicine consumption/purchased in order to determine which items account for the greatest proportion of the budget.
<b>When to perform</b>	Every year at the beginning of the budget year and when the need arises
<b>How to perform</b>	By collecting procurement/consumption data of the specific period using spreadsheet/Excel sheet.
<b>Note</b>	<ul style="list-style-type: none"> <li>• Before performing the ABC analysis the DTC should define the scope of the analysis i.e. the type of eligible items (Donation or purchased) and period to be review. ABC analysis can be conducted separately for medicines supplied by donation.</li> <li>• It is very important to conduct ABC-VEN reconciliation analysis prior to every procurement</li> </ul>

**ABC analysis involves the following steps:**

**Step 1:** List all items purchased/received during the year and their respective units, total quantity and unit cost, receiving voucher no., expiry date using excel sheet as shown at the template under Step 2.

**Step 2:** Calculate the total cost of each item purchased or received by multiplying the total quantity by the unit cost.

F4      fx      =D4\*E4

A	B	C	D	E	F	G	H	I
S/N	Description (Drug name in generic, strength, dosage form, pack size)	Unit	Quantity	Unit Cost	Total Cost	Receiving Date (E.C.)	Receiving Voucher Serial Number	Expiry Date
1	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20	17/02 /2002	296416	Sep-14
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00	19/12/2003	181216	Oct-14
3	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00	29/06/2004	130794	Jan. 2015
4	Norfloxacin 400 mg of 100	Pack	8	45	360.00	22/06/2004	130828	Mar-15
5	Surgical glove 7.5 of 50	Box	20	225	4,500.00	06/04/2004	130818	Apr-15

**Step 3:** Sort the list alphabetically

S/N	Description (Drug name in generic, strength, dosage form, pack size and brand)	Unit	Quantity	Unit Cost	Total Cost,
1	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20
2	Ceftriaxone injection 1 gm	Vial	20000	4.48	89600.00
3	Ceftriaxone injection 1gm	Vial	3000	5	15000
4	Norfloxacin 400 mg of 100	Pack	8	45	360.00
5	Norfloxacin 400 mg of 10	Pack	20	50	1000
6	Surgical glove 7.5 of 50	Box	20	225	4500.00

**Step 4:** Aggregate same medicines and add their total costs under the total cost column.

**Same medicines** are those with the same generic name, strength and dosage form but may have different brands, pack sizes, period of purchases, sources and unit prices.

**Step 5:** Sort the list based on the total cost in a descending order so that the largest cost or value item will be on the top and the lowest at the bottom.

S/N	Description (Drug name in generic, strength, dosage form, pack size and brand)	Unit	Quantity	Unit Cost	Total Cost,
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4	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00
1	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20
5	Surgical glove 7.5 of 50	Box	20	225	4500.00
3	Norfloxacin 400 mg of 100	Pack	8	45	360.00

**Step 6:** Calculate the overall cost of all items purchased or received by adding the total cost of all items.

S/N	Description (Drug name in generic, strength, dosage form, pack size)	Unit	Quantity	Unit Cost	Total Cost
3	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00
1	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20
5	Surgical glove 7.5 of 50	Box	20	225	4,500.00
4	Norfloxacin 400 mg of 100	Pack	8	45	360.00
<b>Total</b>					<b>229,131.20</b>

**Step 7:** Calculate percent total cost of each item by dividing the total cost of each item by the overall cost of all items and multiplying the result by 100.

G4							fx	=F4/\$F\$9*100
A	B	C	D	E	F	G		
S/N	Description (Drug name in generic, strength, dosage form, pack size)	Unit	Quantity	Unit Cost	Total Cost	% Total Cost		
3	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00	54.7		
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00	39.1		
1	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20	4.1		
5	Surgical glove 7.5 of 50	Box	20	225	4,500.00	2.0		
4	Norfloxacin 400 mg of 100	Pack	8	45	360.00	0.2		
Total					229,131.20			

**Step 8:** Calculate the cumulative percent total cost of each medicine, Cumulative percent total cost for the first item is its percent total cost, for the rest of the items in list ,add cumulative percentage of the previous item to that of the item below it till you did for all items.

H5								fx	=H4+G5
A	B	C	D	E	F	G	H		
S/N	Description (Drug name in generic, strength, dosage form, pack size)	Unit	Quantity	Unit Cost	Total Cost	% Total Cost	% Total cost		
3	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00	54.7	54.7		
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00	39.1	93.8		
1	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20	4.1	97.9		
5	Surgical glove 7.5 of 50	Box	20	225	4,500.00	2.0	99.8		
4	Norfloxacin 400 mg of 100	Pack	8	45	360.00	0.2	100.0		
Total					229,131.20				

**Step 9:** Adjust the serial no. column starting from 1.

Calculate cumulative percent order by dividing the number of items for each row by the total number of items multiplied by 100.

B	C	D	E	F	G	H	I	J
	fx =B4/\$B\$8*100							
S/N	Description (Drug name in generic, strength, dosage form, pack size)	Unit	Quantity	Unit Cost	Total Cost	% Total Cost	Cumulative % Total cost	% order
1	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00	54.7	54.7	20
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00	39.1	93.8	40
3	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20	4.1	97.9	60
4	Surgical glove 7.5 of 50	Box	20	225	4,500.00	2.0	99.8	80
5	Norfloxacin 400 mg of 100	Pack	8	45	360.00	0.2	100.0	100
Total					229,131.20			

**Step 10:** Determine cut-off points for A, B and C classes and categorize the list of items according to the definition given earlier in this section.

B	C	D	E	F	G	H	I	J	K
	fx A								
S/N	Description (Drug name in generic, strength, dosage form, pack size)	Unit	Quantity	Unit Cost	Total Cost	% Total Cost	Cumulative % Total cost	% order	ABC Category
1	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00	54.7	54.7	20	A
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00	39.1	93.8	40	B
3	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20	4.1	97.9	60	C
4	Surgical glove 7.5 of 50	Box	20	225	4,500.00	2.0	99.8	80	C
5	Norfloxacin 400 mg of 100	Pack	8	45	360.00	0.2	100.0	100	C
Total					229,131.20				

**Step 11:** Insert the VEN category of each item as prepared in the medicine list and reconcile the results (refer the section on ABC/VEN reconciliation below).

B	C	D	E	F	G	H	I	J	K	L
S/N	Description (Drug name in generic, strength, dosage form, pack size)	Unit	Quantity	Unit Cost	Total Cost	% Total Cost	Cumulative % Total cost	% order	ABC Category	VEN Category
1	Prednisolone 5 mg of 1000	Box	1000	125.34	125,340.00	54.7	54.7	20	A	N
2	Ceftriaxone injection 1 gm	vial	20000	4.48	89,600.00	39.1	93.8	40	B	V
3	Acyclovir 400mg of 25*10	Pack	960	9.72	9,331.20	4.1	97.9	60	C	E
4	Surgical glove 7.5 of 50	Box	20	225	4,500.00	2.0	99.8	80	C	V
5	Norfloxacin 400 mg of 100	Pack	8	45	360.00	0.2	100.0	100	C	E
Total					229,131.20					

**Step 12:** ABC/VEN reconciliation

After performing ABC and VEN analysis; reconciliation is important to indicate the drug use problem. Utilizing VEN category in interpreting ABC analysis data will help to show whether there is correct or incorrect practice of pharmaceuticals procurement and use. The DTC should thoroughly discuss on the items that lie in each category. For example the presence of N items in A category can be an indicator of irrational practice. But some V items may lie in the C category due to low consumption pattern or low cost.


**Applications of ABC Analysis**

A DTC can use the ABC analysis to:

- Measure the degree to which actual consumption reflects public health needs and morbidity. Reduce inventory levels and costs by arranging for more frequent purchase or delivery of smaller quantities of class A items
- Seek major cost reductions by finding lower prices on class A items and reduce inventory of items that have limited use, but cost the system large amounts of money
- Provide information for choosing the most cost-effective alternatives and finding opportunities for therapeutic substitution



- Gather information for pharmaco-economic analysis. ABC analysis will provide basic information for performing a cost-minimization and cost-effectiveness analysis.

	<p><b>Activity 6.3: ABC analysis group exercise</b></p> <p><b>ABC analysis group exercise:</b> Do the ABC analysis exercise and share your result to the larger group</p> <ul style="list-style-type: none"> <li>• Form a group with 5 members</li> </ul> <p>In this activity, you will be provided with raw excel procurement/consumption data to conduct an ABC analysis using a stepwise approach. After finalizing the ABC analysis in the excel sheet, you are expected to do reconciliation using given VEN category. Summarize the results obtained based on the following questions</p> <ul style="list-style-type: none"> <li>• What percentages of items do represent A, B, C category in terms of budget and item no.?</li> <li>• Analyze items as V , E, N medicines in A,B,C category <ul style="list-style-type: none"> <li>○ Any N item in A category?</li> <li>○ Any V item in C category?</li> </ul> </li> <li>• Your recommendations concerning the medicine list from this ABC/VEN analysis?</li> <li>• What particular product(s) may need to be reviewed more closely by the DTC because of their value?</li> </ul> <p><b>Time: 30 min</b></p>
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### 6.3.2. Indicator methods

Drug use indicators are intended to measure specific aspects of healthcare provider behaviour and medicine use in a hospital, health center and pharmaceutical retail outlets. Indicators will provide information to healthcare managers concerning drug use, prescribing habits, dispensing practice and important aspects of patient care. They can also reflect the status of an important characteristic of the given health care service.

This part describes objective measures that can describe the drug use situation in individual health facility. Such measures, or indicators, will allow making basic comparisons between situations in different areas or at different times. In addition, when an intervention is undertaken to improve aspects of drug use, the indicators can be used to measure impact. Indicators can also serve as simple supervisory tools to detect problems in performance by individual providers or health facilities.

Studies to measure drug use will vary from setting to setting. The nature and design of such studies will depend on many factors, which include the specific information needs of health

managers; the types of record-keeping systems available in health facilities; the types of providers whose behaviour is to be characterized; and the resources available to carry out the work. Indicators selected to assess a health care service should be relevant, easily generated and measured, valid, consistent, reliable, representative, sensitive to change, understandable, and action-oriented.

### **Types of Medicine Use Indicators study methods**

Medicine use indicators have been developed by WHO and International Network for Rational Use of Drugs (INRUD) for assessing healthcare and drug use for primary health care in hospitals, health center and pharmaceutical retail outlets. These indicators are classified as Core medicine use indicators and Complementary indicators.

The medicine use indicators can be collected at one time in a cross-sectional survey, or they can be measured at different points in time to assess change in performance. One feature to note is that the indicators can be done based on either *retrospective and/or prospective* data. Retrospective data describe drug use during patient visits that took place in the past, preferably over a one-year period to control for seasonal variations. These data are extracted from medical records/prescriptions kept at the health facilities. Prospective data, on the other hand, describe drug use during patient visits that take place on the day of the survey.

### **I. Core Medicine Use Indicators**

Core medicine use indicators; include prescribing indicators, patient care indicators and health facility indicators. Results of these indicators should point to particular medicine use problems that need further examination in more detail and ultimately a plan to resolve the problem by the DTC. The specific indicators under each of these classes of indicators are listed below.

#### **A. Prescribing indicators**

- Average number of medicines per encounter
- Percentage of medicines prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of drugs prescribed from the facility's medicines list
- Completeness of Prescription information

### ***B. Patient care indicators***

- Average consultation time
- Average dispensing time
- Average dispensing counseling time
- Percentage of drugs actually dispensed
- Percentage of drugs adequately labeled
- Percentage of patients who know how to take their medicines

### ***C. Health facility indicators***

- Availability of facility-specific medicine list
- Availability of key medicines
- Availability of standard treatment guidelines
- Availability of national formulary

## **A. Prescribing indicators**

The indicators of prescribing practices measure the performance of health care providers in several key dimensions related to the appropriate use of drugs. The indicators are based on the practices observed in a sample of clinical encounters taking place at outpatient health facilities for the treatment of acute or chronic illness. These encounters can be observed retrospectively, from data recorded in historical medical records, or they can be observed prospectively, from a group of patients attending the clinic on the day the data are collected.

The core prescribing indicators measure general prescribing tendencies within a given setting, independent of specific diagnoses. The data to measure the prescribing indicators can be recorded on **Prescribing Indicator Form** (Annex 6.1) and **Prescription Consolidation Form** (Annex 6.2). The prescribing indicator form requires that each indicator be entered directly by data collectors in the field. Its main advantage is that it allows immediate summaries of the indicators to be produced and discussed with staff from the health facility.

In order to record data in a consistent and reproducible way, DTC of the health facility is expected to agree on the following points before performing prescribing indicators.

***Define medicines to be regarded as antibiotics:*** Antimicrobial agents are not always classified in an identical way. Sometimes drugs such as antiprotozoals, antihelminthics or antituberculosis

agents are placed in a separate category from antibiotics, while other systems may classify all these products in a single category of anti-infective or antimicrobials.

**Define Medicines to be classified as generic:** To calculate the percentage of drugs prescribed by generic name, DTC/investigators need to have a list of drug names that are to be counted as generics to classify them as generic or brand.

**Define Medicines to be regarded as an injection:** To calculate the percentage of drugs prescribed as injection, DTC need to have a list of injections that are not to be counted as injection. E.g. immunization medicines and injectable contraceptives are excluded.

**Agree on Combination medicine:** Known combination medicines should be counted as a single medicine.

Descriptions of each of the prescribing indicators are presented below:

**1. Average number of drugs per encounter**

<b>Target</b>	< 2 per encounter
<b>Purpose</b>	To measure the degree of poly pharmacy
<b>Prerequisites</b>	Known combination drugs are counted as one. Guidelines are needed on how to count certain ambiguous prescribing practices (e.g. some standardized sequential therapies).
<b>Process</b>	Request all available records for the past 12 months before beginning sampling. Consider only encounters for a single disease, complaint, or symptom. List the number of medicines given per encounter. Combination products are counted as one medicine. The same product prescribed consecutively in different forms (i.e. injection and tablet) should be counted as one medicine, however if the same product is prescribed simultaneously in different forms, each form should be counted separately
<b>Calculation</b>	Average, calculated by dividing the total number of different medicines prescribed, by the number of encounters surveyed. It is not relevant whether the patient actually received the medicines.  Average number of medicines = Total number of medicines prescribed/number of prescriptions

Follow up questions to understand the problem could be:

- How do you interpret if the result is high number or low number?

- What are the follow-up questions that should follow to understand the problem clearly? (see Annex 6.6)

## **2. Percentage of medicine prescribed by generic name**

<i>Target</i>	100%
<i>Purpose</i>	To measure the tendency to prescribe by generic name
<i>Prerequisites</i>	Investigators must be able to observe the actual names used in the prescription rather than only having access to the names of the products dispensed, since these may be different; a list must be available of specific product names to be counted as generic medicines.
<i>Process</i>	Request all available records for the past 12 months before beginning sampling. Determine the encounters where a generic medicine has been prescribed.
<i>Calculation</i>	Percentage, calculated by dividing the number of medicines prescribed by generic name by the total number of medicines prescribed, multiplied by 100. Percentage, number of medicines prescribed by generic name/total number of medicines prescribed *100

What are the factors that affect prescribing by generic name? (See Annex 6.6)

## **3. Percentage of encounters with an antibiotic prescribed**

<i>Target</i>	20-30 %
<i>Purpose</i>	To measure the overall level of use antibiotics
<i>Prerequisites</i>	Investigators should identify medicines such as antiprotozoal, antihelmintics or antituberculosis, agents are placed in separate category or as antibiotics.
<i>Process</i>	Request all available records for the past 12 months before beginning sampling. Determine encounters where at least one antibiotic has been prescribed.
<i>Calculation</i>	Total number of encounters with one or more antibiotics/total number of encounters x100

Follow up questions could be: What types of antibiotics and which modes of delivery (injection, tablets and syrups) are most commonly prescribed? (See Annex 6.6)

## **4. Percentage of encounters with an injection prescribed**

<i>Target</i>	<25%
<i>Purpose</i>	To measure the overall level of use of injections.
<i>Prerequisites</i>	A list of all the medicines which are to be counted as injections must be available; investigators must be instructed on medicines which are not considered as an injection like, immunizations, injectable family planning.
<i>Process</i>	Request all available records for the past 12 months before beginning sampling. Determine encounters where an injection has been prescribed. Do not count immunizations and injectable contraceptives.
<i>Calculation</i>	Total number of prescriptions with one or more injection/total number of prescriptions x100

What are the beliefs about the relative efficacy of injections versus oral medications? (Annex 6.6)

### 5. *Percentage of Medicines Prescribed from health facility medicine list*

<i>Target</i>	100%
<i>Purpose</i>	To measure the degree to which practices conform to a national drug policy, as indicated by prescribing from the health facility's medicine' list
<i>Prerequisites</i>	Copies of a published health facility's medicine list to which data on prescribed drugs can be compared; procedures are needed for determining whether or not brand name products are equivalent to ones appearing in generic form on the drug list
<i>Process</i>	Request all available records for the past 12 months before beginning sampling. Determine how many of the prescribed medicines are included on the health facility's medicine list, even if they are not prescribed under an internationally recognized name
<i>Calculation</i>	Percentage, calculated by dividing the number of medicines prescribed which are listed on the essential medicines list by the total number of medicines prescribed, multiplied by 100 Percentage = total number of medicines prescribed from the drug list/total number of medicine prescribed *100

### 6. *Completeness of prescriptions*

<i>Target</i>	100%
<i>Purpose</i>	To measure the degree to which practices conform to a national drug policy, as indicated on the completeness of prescription information for the type of facility surveyed.
<i>Prerequisites</i>	Standard prescription is needed. All prescriptions to be evaluated should be collected
<i>Process</i>	On the sample prescriptions, check completeness of patient information (Name, sex, age, weight, card no. and diagnosis), medication information (Name dose, frequency, route and duration), and prescriber (name, qualification, signature and date) and dispenser (name, qualification, signature and date) information on each of the prescriptions
<i>Calculation</i>	Percentage, calculated by dividing the number of prescriptions with complete information (as per indicated in the process) by the total number of prescriptions, multiplied by 100

## **B. Patient care indicators**

In order to understand the way medicines are used it is important to consider what takes place at health facilities from both the provider's and the patient's perspectives. Patients who enter in the facilities with a set of symptoms and complaints, and with expectations about the care they will receive; they typically leave with a package of medicines or with a prescription to obtain them in

the private market. The patient care indicators address key aspects of what patients experience at health facilities, and how well they have been prepared to deal with the medicines that have been prescribed and dispensed.

The time that prescribers and dispensers spend with each patient sets important limits on the potential quality of diagnosis and treatment. Patients for whom medicines are prescribed should, at a minimum, receive well-labeled medications, and should understand how to take each drug. In a drug use indicator study, the adequacy of patient care is measured by observing a sample of patient encounters as they normally occur, and by interviewing patients as they leave the facilities. All the data needed to measure the patient care indicators for each facility can be recorded and summarized on the **Patient Care Indicator form (Annex 6.3)**. The following tasks are required to measure the patient care indicators.

***Design a procedure for collecting prospective data:***

Because patient care encounters are always conducted prospectively, it is necessary to arrange for patient observations and interviews. Attention should be given to the methods of data collection before the study begins as patient flow can be organized in different ways. The methods should be reasonably consistent in all facilities and should not overly influence the routine process of patient care. To reduce the variations in time that occur with different patients it is recommended that the patient care process be timed for at least 30 individual encounters.

***Specify how consultation and dispensing times will be measured:***

It is necessary to develop a consistent method for observing the beginning and end of consultation and dispensing encounters.

***Identify the sources of data to compare prescribed and dispensed medicines:***

Not all prescribed medicines are actually dispensed at the health facility. This may happen because medicines which are usually available are out of stock, or when medicines are intentionally prescribed to be purchased in the private sector due to business motive. Measuring the degree to which medicines must be obtained in the facility provides some indication about the reliability of medicines supply as well as how prescribing choices match the range of pharmaceuticals available in the system.

***Adequacy of labelling***

It is very important that dispensed medicines be labelled with the necessary information. At a minimum, dispensed medicines should be labelled with patient name, name of the medicine, dose, frequency and duration of use/quantity dispensed, and expiry date. This information is obtained by observing packages of the medicines dispensed to the sampled number of encounters during the exit interview.

***Define criteria for adequate patients' knowledge about medications:***

At some point during the examination or dispensing process, details about the medication prescribed should be explained to the patient. Ideally, this explanation includes the reasons why the medication is being given, how each drug should be used, as well as information about precautions and possible side effects. Because most of these factors are difficult to measure patients should only be evaluated on their knowledge of when and in what quantity each drug should be taken. This should be evaluated for each medication actually dispensed to the patient.

Patients' knowledge can be evaluated when the prescribed dosage has been recorded on the drug package. If the necessary data (dose, dose, frequency and duration) are available in the label, the knowledge of the patient can be evaluated against this record.

Detailed descriptions of each of the patient care indicators are presented below.

***1. Average consultation time***

<i>Purpose</i>	To measure the time that medical personnel spend with patients in the process of consultation and prescribing
<i>Prerequisites</i>	Procedures for accurately recording the time spent during the consultation, that is, the time between entering and leaving the consultation room. Waiting time is not included
<i>Process</i>	For a series of encounters, observe and record the time the prescriber takes to examine the patient
<i>Calculation</i>	Calculation Average, calculated by dividing the total time for a series of consultations, by the number of consultations. Average consultation time = total time for a serious of consultation/number of consultations

***2. Average dispensing counselling time***

<i>Purpose</i>	To measure the average time that pharmacy personnel dispensing medicines spend while counselling patients
<i>Prerequisites</i>	Procedures for accurately recording the average time patients spent with pharmacy personnel to get information on how to use the medicines dispensed to them should be in place



*Process* For a series of encounters, observe and record the time the dispenser takes to counsel the patient

*Calculation* Average, calculated by dividing the total time for counselling series of encounters, by the number of encounters observed.  
Average dispensing counselling time = total time for a series of counselling/number of counselling

### **3. Percentage of medicines actually dispensed**

*Target* 100%

*Purpose* To measure the degree to which health facilities are able to provide the medicines which were prescribed to patients

*Prerequisites* Information on which drugs were prescribed, and whether these drugs were actually dispensed at the health facility

*Process* Interview patients leaving the dispensing area or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient. Count how many chemical entities were prescribed and dispensed.

*Calculation* Percentage, calculated by dividing the number of drugs actually dispensed at the health facility by the total number of drugs prescribed, multiplied by 100.  
Percentage of medicines actually dispensed = No. of medicines dispensed/total number of medicines prescribed \*100

### **4. Percentage of medicines adequately labelled**

*Target* 100 %

*Purpose* To measure the degree to which dispenser record essential information on the medicines packages they dispense

*Prerequisites* Investigators must be able to examine the medicines packages as they are actually dispensed at the health facility

*Process* Interview patients leaving the dispensing area or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient.

Check if each medicine label conforms to all requirements for adequate labelling. Count a medicine as adequately labelled only if all requirements are met

*Calculation* Calculation Percentage calculated by dividing the number of drug packages containing at least name of the medicine, dose, frequency and duration/total quantity of the medicine dispensed.  
Percentage of medicines adequately labelled = Number of medicines with adequate label/total number of medicines dispensed\*100

### **5. % of patients knowing how to take medicines**

*Target* 100%

*Purpose* To measure the effectiveness of the information given to patients on the dosage schedule of the medicines dispensed to them.

*Prerequisites* Access to a written prescription or to a patient card against which patients' knowledge on the dosage schedule can be checked, or access to standards for

how each common drug is supposed to be used is the most reliable source of information for this indicator. If it is difficult to access such sources, the patients' knowledge can also be compared against the label on the medicine packages dispensed to them

*Process* Interview patients leaving the dispensing area or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient.

Check if the patient knows both the appropriate dosage and duration of each medicine (i.e., how much, how often and for how long he or she should take each medicine). Count the patient as having adequate knowledge only if both criteria are met for all medicines dispensed to the patient.

*Calculation* Percentage, calculated by dividing the number of patients who can adequately report the dosage schedule (dose, frequency and duration/total quantity dispensed) for all medicines, by the total number of patients interviewed, multiplied by 100.

$\% \text{ of patients knowing how to take medicines} = \text{number of patients who can adequately report dosage of all medicines dispensed to them} / \text{total number of patients} * 100$

Follow up questions to understand the problem clearly could be: (Annex 6.6)

- What is the typical content of communication about pharmaceuticals: what medicines do, how they should be taken, possible side effects and precautions, relative importance of different products?
- What do patients actually understand about the medicines they have received: what medicines do, how they should be taken, side effects?

### **C. Health facility indicators**

The ability to prescribe dispense medicines rationally is influenced by many features of the working environment. Two particularly important components are an adequate supply of essential medicines and access to unbiased information about these medicines.

#### ***1. Availability of copy of the health facility's medicines list***

*Purpose* To indicate the extent to which copies of the facility's medicine list, is available at health facilities

*Prerequisites* The health facility should have its own up-to-date medicines list prepared by DTC; if not, the indicator would always be scored "no"

*Process* Ask to see a copy of the current applicable medicine list of the facility. Only count a facility as having medicine list if the facility is able to produce the current version. If the current version of the document is not physically available or if it has been more than three years since the list was last updated, mark "no".

*Calculation* Yes or no, per facility

## 2. Percentage availability of key essential medicines

<i>Purpose</i>	To measure the availability of key medicines recommended for the treatment of some common health problems at health facilities
<i>Prerequisites</i>	A short list of key essential medicines (15 - 20) must be compiled that should always be available in the facility
<i>Process</i>	Go through the shelves and identify which of the listed essential medicines are available at the facility at the time of the survey. Only count in stock medicines in the facility at the time of the visit regardless of whether or not they are available at an offsite storage facility.
<i>Calculation</i>	Percentage, calculated by dividing the number of specified key medicines actually in stock by the total number of medicines on the checklist, multiplied by 100. Percentage availability of key medicines = number of key medicines available in stock/total number of key medicines identified as key *100

*What is the system for informing prescribers about medicines stock-outs (Annex 6.6).*

## 3. Availability of Standard Treatment Guidelines

<i>Purpose</i>	To indicate the extent to which copies of STG nationally developed for the level of health facility is available in the health facility
<i>Prerequisites</i>	There should be STG national developed for the level of health facility
<i>Process</i>	Ask to see a copy of the relevant STGs national developed for the level of the health facility. Only count a facility as having each STG if the facility is able to produce the current version. If the current version of the document is not physically available, mark “no”
<i>Calculation</i>	Yes or no, per facility

### *Recommended sample size for conducting indicator study*

In order to conduct prescribing indicators the size of samples drawn within each facility must be at least 100 encounters. The sample should be taken from outpatient dispensary from a year record. For patient care indicators at least 30 encounters are recommended. These samples can be chosen based on random Sampling or systematic random sampling methods.


### **Follow-up Questions for specific indicators**

For each of the indicators discussed above, there should be follow-up questions so as to understand the problem clearly (Annex 6.6).

## **II. Complementary Medicine Use Indicator**

Health facilities can use the following complementary indicators to complement findings of the core drug use indicators.

- Percentage of patients treated without medicines
- Average medicines cost per encounter
- Percentage of medicine cost spent on antibiotics or 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 medicines information

	<p><b>Activity 6.4: Group exercise on Indicator methods</b></p>
	<p>Do the indicator method exercise and share your result to the larger group</p> <ul style="list-style-type: none"> <li>• Make groups with 5 members</li> <li>• Sample 10 prescriptions</li> <li>• Ensure you are provided with, Facility-specific medicine list, Data collection formats and 30 filled prescriptions from a health facility</li> <li>• Prior to data collection, agree on generics, medicines to be considered as antibiotics, injections, and combination products.</li> <li>• Collect the data using the format provided to your group</li> <li>• Assess the completeness of prescribing and dispensing information on the sampled prescriptions</li> </ul>
	<ul style="list-style-type: none"> <li>• Summarize your data by calculating the following indicators: <ul style="list-style-type: none"> <li>○ Average number of medicines per encounter</li> <li>○ Percentage of medicines prescribed by generic name</li> <li>○ Percentage of encounters with an antibiotic prescribed</li> <li>○ Percentage of encounters with an injection prescribed</li> <li>○ Percentage of medicines prescribed which are from the facilities medicines list</li> </ul> </li> </ul>
	<ul style="list-style-type: none"> <li>• Interpret your findings in relation to the recommended targets for each indicator, draw conclusion and forward recommendations for the health facility.</li> </ul> <p><b>Time: 60 minutes</b></p>

### 6.3.3. Medicine Use Evaluation (MUE)

Medicine use evaluation is an ongoing, systematic, criteria-based program of medicine evaluations that will help to ensure appropriate medicine use. It is ongoing review of prescribing, dispensing and use of medication.

Identifying medicine use problems and implementing strategies to alleviate these problems are the main activities in which DTC should be highly engaged. All DTCs should be actively involved in the evaluation and selection of new medicines for the medicine list and ensuring the availability of these medicines. It must also ensure that these medicines are used appropriately so that patients receive the maximum benefit from their pharmaceutical therapy.

Medicine use studies using aggregate data or health facility indicators may indicate that there is over- or under-consumption of medicines, and qualitative studies may indicate why certain health staff and patients behave the way they do. However, such studies do not provide detail about the exact nature of the irrational use. Such details may concern incorrect medicine choices, incorrect dose, prescribing medicines that cause ADEs or drug interactions, and the use of expensive drugs when cheaper ones would do.

A MUE will:

- *Define* appropriate medicine use (by establishing approved criteria)
- *Audit* criteria against what is being prescribed
- *Provide* feedback to prescribers on all identified problems
- *Monitor* to see if criteria are followed and prescribing is improved

MUE involves a comprehensive review of patients' prescription and medication data before, during and after dispensing to ensure appropriate medication decision-making and positive patient outcomes. It encompasses a drug review against predetermined criteria that results in changes to drug therapy when these criteria are not met. If therapy is determined to be inappropriate, interventions with providers or patients will be necessary to optimize pharmaceutical therapy. As a quality assurance measure, MUE programs provide corrective action, prescriber feedback and further evaluations. This terminology can be used interchangeably with that of drug use review (DUR) and medication use review (MUR).

A MUE can be structured so that it will assess the actual process of administering or dispensing a medicine (i.e., appropriate indications, dose, and medicine interactions) or assess the outcomes (i.e., cured infections, decreased lipid levels).

**SOP for conducting MUE (Mandatory for Hospitals)**

Conducting MUE is mandatory for hospitals; Health centers can also perform MUE.

This SOP will describe on how to conduct MUE.

<b>Task</b>	Performing medicine use evaluation
<b>Completed by</b>	Hospital DTC members
<b>Purpose</b>	<ul style="list-style-type: none"> <li>• To promote optimal medication therapy and ensure that drug therapy meets current standards of care.</li> <li>• To Establish criteria for appropriate drug utilization</li> <li>• To evaluate the effectiveness of medication therapy</li> <li>• To enhance responsibility/accountability in the medicine use process</li> <li>• To control medicine cost</li> <li>• To prevent medication related problems</li> <li>• To identify areas in which further information and education may be needed by health-care providers</li> </ul>
<b>When to perform</b>	Performing MUE is recommended when <ul style="list-style-type: none"> <li>• Problems indicated from indicator studies</li> <li>• High number of ADEs</li> <li>• Signs of treatment failures</li> <li>• Excessive number of non-formulary medications used</li> <li>• Use of high-cost medicines where less expensive alternatives exist</li> <li>• Excessive number of medicines within a therapeutic category etc</li> </ul>

**Note:** The problems to be addressed by medicine use evaluation may be identified from any of the data including prescription indicators, dispensing data and aggregate data. The main source of data for medicine use evaluation is the patient records. Medicine use evaluation may be based on data collected prospectively and retrospectively.

The following eight steps are used for conducting MUE.

***Step 1: Establish Responsibility***

The DTC or a responsible subcommittee of DTC should be established to conduct MUEs in the facility. The committee will develop procedures and plan to conduct the study.

### ***Step 2: Develop Scope of Activities***

This step involves identifying the specific areas where the evaluation should focus on. These areas may be extensive or focuses on a single aspect of the pharmaceutical therapy. Results from ABC, VEN analysis, ADE reports antibiotic sensitivity results, procurement studies, indicator studies, patient complaints or feedback, and staff feedback can be used as a starting point for MUE. Because of the large number of medicines available at a facility, the DTC must concentrate on the most important medicines, those with the highest potential for problems, to get the most return from the study.

### ***Step 3: Establish Criteria***

Criteria are statements that define correct medicine use. Establishing criteria is the most important procedure in MUE. Criteria for the use of any medicine should be established by the DTC using reliable up-to-date literature sources and recognized international and local experts. The criteria for any MUE should reflect what is in the country's STGs and any medicine-use protocols that exist. Credibility of the MUE relies on criteria that are based on evidence-based medicine. Criteria must be developed with and accepted by the respective health care providers for the process to be credible.

Criteria should be developed for three to five of the most important process indicators (indication, dose, quantity dispensed, laboratory result, contraindication, drug interaction etc), outcome related and Pharmacy administration indicators. Reviewing larger numbers of indicators will make the MUE process more difficult and may significantly impair the outcomes of the review.

### ***Step 4: Define and Establish Thresholds***

After developing criteria, the DTC must establish a threshold or standard (benchmark) against which the criteria will be judged. A threshold refers to the percentage of charts or records that will meet or exceed the established criteria for the medicine. Ideally, this threshold should be 100 %, but realistically, a bit smaller percentage will be more appropriate to account for exceptions to routine medicine use practices. A threshold of 90 and above is commonly used for many criteria, but each instance must be carefully analyzed before reaching a conclusion.

**Table 9: Sample of selected indicators, criteria and thresholds for conducting MUE on Ciprofloxacin**

<b>Indicator</b>	<b>Criteria</b>	<b>Threshold, %</b>
Indication	Complicated, chronic, or relapsing urinary tract infection (UTI) Gonorrhoea Resistant respiratory tract infections Bone and joint infections Prostatitis Gastrointestinal (GI) infections	90
Dose	Complicated or recurrent infections: 500–750 mg bid GI infections: 500 mg bid Gonorrhoea: 250 mg in 1 dose Dose in renal disease decrease as follows: Creatinine clearance (CrCl) 30–50 ml/min – 250–500 q 12 h; 5–29 ml/min – 250–500 q 18 h; Hemodialysis—500 mg q 24 h	95
Duration	Complicated UTI: 10–21 days Respiratory: 7–14 days Osteomyelitis: 4–6 weeks GI infection: 5 days	95
Contraindications	Pregnancy and lactation, allergy	100
Medicine interactions	Medicines—theophylline, antacids, iron, sucralfate, probenecid Food: decreased absorption with milk	90
Outcome	Negative cultures, Improved symptomatology, No treatment failures	90

**Step 5: Collect Data and Organize Results**

MUEs can be accomplished retrospectively or prospectively by reviewing a sample of patient charts or prescriptions (50 to 75) with the medicine under evaluation. Random or systematic random sampling method can be used to draw the samples for evaluation from the total patient charts or prescriptions with the medicine prescribed during a specific period of time. Use the attached **MUE Criteria Form (Annex 6.4)** to collect the necessary data from each chart or prescription.

**Step 6: Analyze Data**

Data analysis is one of the major steps in MUE. The following important procedures should be completed when analyzing data:

- Calculate the percentage for each criterion on the format.



- Tabulate results for each indicator.
- Analyze results to see if the criteria and thresholds are met or not. If a threshold is not met, it may indicate a medicine use problem that requires the attention of the DTC.

***Step 7: Develop Recommendations and Intervention Plan***

After completing the data analysis, appropriate recommendations should be forwarded by the DTC based on the findings. Findings of the study along with the recommendation should be presented to the staff and the findings should be reported to the health facility management. The DTC should appropriately document finding of the study for future reference. Further investigation must be conducted on all medicines that do not meet the thresholds and appropriate interventions must be designed and implemented to improve the use of the medicines.

***Step 8: Conduct MUE Follow-up***

Follow-up in every MUE is critical to ensure resolution of any unresolved medicine use problems. The DTC should follow-up implementation of the interventions designed to resolve the problems identified. After implementing the recommended interventions, the DTC should periodically re-evaluate the practice using the same criteria.

**When do MUEs Go Wrong?**


Some problems in the MUE procedure will serve to make this process ineffective. Because it is a complicated and multifactorial process, it may easily get delayed and become an ineffective evaluation. Some of the difficulties which may cause MUE failures are:

- Lack of DTC/subcommittee authorized to conduct the MUE
- Poor problem prioritization, communication and documentation
- Lack of committee members' involvement.
- Inadequate follow-up by DTC and management
- Overly intrusive data collection and evaluation
- Failure to obtain “buy in” from medical staff

The performance of a MUE must be kept in perspective at all times. If a MUE becomes very time-consuming with only minimal results, then the methodology must be changed and the MUE

restructured (in terms of criteria, data collection, and interventions) to provide meaningful results.

**Note:** Though the commonly used MUE is medicine-focused, MUE can also be diseases-focused where sample of patient charts or prescriptions for a specific disease is used as a source of data. In this case, how the disease is diagnosed and therapeutically managed is evaluated based on established criteria.

	<p><b>Activity 6.5: Group exercise</b></p> <p><b>Medicine Use Evaluation:</b> Do medicine use evaluation and share your result to the larger group</p> <ul style="list-style-type: none"><li>• Make groups with 5 members</li><li>• Ensure you have the STG, Formulary, Patient Chart and the Format</li><li>• Conduct medicine use evaluation following the steps using the patient chart and MUE Criteria form (Annex 6.4) provided</li><li>• Summarize your findings and analyze using the following questions:<ul style="list-style-type: none"><li>○ Are the thresholds met for each indicator?</li><li>○ What recommendations do you forward to the health facility?</li></ul></li></ul> <p><b>Time: 80 min</b></p>
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## 6.4. Qualitative Methods

Quantitative methods identify the presence of medicine use problems and their magnitude, but not necessarily answer *why* the medicine use problems are occurring. The qualitative methods provide ways to target health providers, patients, provider-patient interactions, and the complex of cultural, social, economic, and structural factors that can influence behavior. Thus answers the *why* of medicine use problems. The commonly used methods include:

- Focus Group Discussion (FGDs)
- In-depth Interview
- Structured Questionnaire
- Structured Observation

Before establishing a procedure to correct an identified medicine use problem, the DTC should determine why prescribers, dispensers and patients act as they do, thus giving insight into how their inappropriate medicine use behaviour can be changed. The Qualitative methods provide a mechanism for the DTC to quickly assess the causes of a medicine use problem. The following are a few examples of ways the qualitative methods can be used in a health system.

- They complement a quantitative study
- They collect data to explore a topic about which little is known
- They provide background data before developing the training materials for a planned educational intervention and for developing managerial and regulatory interventions

### *Summary*

- The first step to addressing problems of irrational use of medicines is to measure the problem, analyze it and understand the causes underlying it. There are four main methods, all of which should be regularly used by DTCs.
- **Aggregate data methods** (ABC analysis and VEN analysis) involve data that do not relate to individual patients and can be collected relatively easily.
- **Drug use indicator studies** (Prescribing, Patient care and Health care facility indicators) involve collecting data at the level of the individual patient.
- **Medicine use evaluation** is a system of ongoing criteria-based evaluation of medicine use that will help to ensure appropriate use at the individual patient level.
- **Qualitative methods** (FGD, in-depth interview, structured observation and structured questionnaires) are useful for identifying why medicine use problems occur.

## Chapter Seven: Strategies to Improve Medicine

**Allocated Time:** 100 minutes

**Chapter Description:** This chapter describes the three common strategies to improve the use of medicines (educational, managerial and regulatory intervention). Within each strategy, the mostly used intervention methods will be discussed in detail. Finally, how to choose an appropriate strategy and evaluate their intervention will be dealt.

**Chapter Objective:** By the end of this chapter, participants will be able to identify educational, managerial and regulatory interventions used in improving the use of medicines

**Enabling Objectives:** By the end of this chapter, participants will be able to:

- Identify effective strategies to improve medicine supply and use
- Choose an appropriate strategy for improving medicine use
- Evaluate strategies using established criteria

### Chapter Outline:

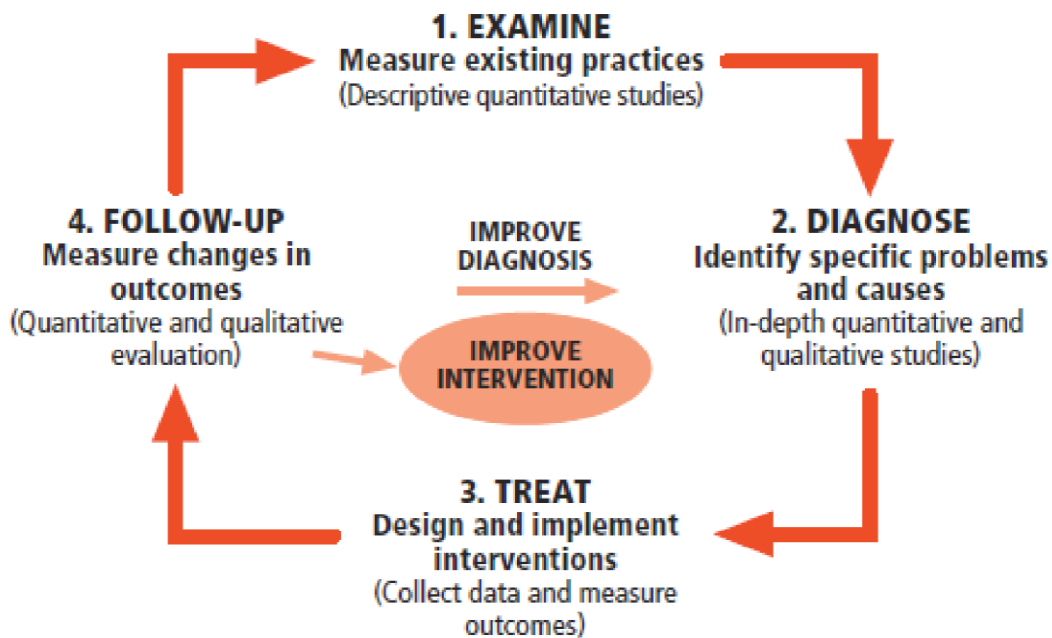
- Introduction
- Strategies to Improve Medicine Use
- Choosing an intervention
- Evaluating an intervention
- Summary

## 7.1 Introduction

Once medicines list have been developed to the formulary and all of the evaluation criteria have been satisfied, then serious consideration must be given to ensure that the medicines are used appropriately by the health care system. To assess professional's adherence to the developed medicine list, medicine supply and use problems identification should be undertaken and then appropriate strategies should be designed.

As described in previous sessions, DTC is responsible for numerous important pharmaceutical management functions. Implementing appropriate strategies to improve medicine use is considered to be one of the most important functions of a DTC which will improve health outcomes and decrease health related cost.

A comprehensive approach, involving several interventions rather than just one, and the participation of professionals in health facility while developing and implementing interventions is more likely to be effective. Figure 4, summarizes the process of changing a medicine use problem.



Source: INRUD materials from the WHO/INRUD Promoting Rational Drug Use Course.

*Figure 4: Changing a medicine use problem: an overview of the process*


## 7.2. Strategies to Improve Medicine Use

Strategies or interventions that can be used to promote rational medicine use may be categorized into three main types:

- **Educational strategies**-which aim to inform and persuade healthcare providers and users
- **Managerial strategies**-which aim to structure and guide decisions made by healthcare providers.
- **Regulatory strategies**-which aim to restrict or limit the decisions of healthcare providers.

### 7.2.1. Educational Strategies

Physicians, nurses, pharmacists and indeed, all professionals need constant updating of their skills and knowledge. It is difficult for health care providers to keep up with the constant changes in the pharmaceutical literature without intensive efforts by the individual and the health care system. Hence, the DTC must be involved in educational programs for health care professionals. Educational methods are intended to inform and persuade practitioners and include the following:

Activity 7.1: Question on educational strategies	
	List any techniques that are intended to inform and persuade practitioners? <b>Time:</b> 3 min

#### I) Printed materials

##### Pharmaceutical Bulletins and Newsletters

Pharmaceutical newsletters can be a valuable instrument for the DTC in providing medicine information. These newsletters, which can be published monthly, quarterly, or at longer intervals, should provide interested staff with accurate and unbiased information that will improve use of medicine.

Newsletters and bulletins have an advantage over formal group presentations because busy practitioners can read the information on their own schedules.

Pharmaceutical newsletters are more likely to be effective in improving use of medicines if appropriate principles are followed.

## **Formulary and STGs**

The use of a formulary manual has been shown to be a valuable asset in providing information about drugs to health professionals (see chapter 5).

Like all printed materials they will be more effective if they are pocket-sized, regularly updated and easily available, and accompanied by other more interactive educational strategies. The role of the DTC lies on ensuring the availability, implementation and proper use of regularly updated formulary manuals and standard treatment guidelines (STGs).

## **II) Face-to-Face Communications**

The effectiveness of face-to-face educational program is affected by certain factors. Key points concerning face-to-face communications include the following:

- Focuses on information of local relevance
- Is kept brief (a few clear messages and instructions on what to do)
- Supplies the repetitive information needed for individuals to learn
- Is run by a presenter who has in-depth knowledge and interest in the subject and the materials presented and who has an effective teaching style

## **In-service Educational Programs, Workshops, and Seminars**

The information database on medicines and pharmacological therapy is constantly changing. To provide optimized patient care, the professionals require up-to-date information thus, in-service education and other educational programs are necessary. The DTC should have a plan to provide these programs at times when as many of the professional staff as possible can attend. This type of educational programs have varying degrees of success, depending largely on the materials being presented, the style of presentation and the educational level and experience of the instructor.

## **Educational Outreach (Person-to-Person or Academic Detailing)**

Person-to-person education, within the health facilities, is the most effective educational method of changing prescribing behaviour. The beneficial effects can be striking because people will be more attentive and absorb more information with this type of education. The world's pharmaceutical companies have shown this technique to be extremely useful; they have hired

thousands of representatives to meet face-to-face with prescribers to provide information and market their products. Academic detailing can accomplish the same result but brings a more balanced, objective message.

Principles of this type of education include the following:-

- Focusing on specific problems and targeting the prescribers
- Addressing the underlying causes of prescribing problems such as inadequate knowledge
- Allowing an interactive discussion that involves the targeted audience
- Using concise and authoritative materials to augment presentations
- Giving sufficient attention to solving practical problems encountered by prescribers in real settings

### **Influencing Opinion Leaders**

The identification of health care leaders and other influential persons involved in prescribing medicines and then providing education, guidance and policies to them can have important benefits. These leaders of the health care system may well be in a position to teach or direct other health care providers and students on the appropriate standards of care.

### **Patient Education**

Providing regular patient education by physicians, health officers, nurses and pharmacy professionals will enable patients to contribute their best for appropriate therapy and improve health outcomes.

### **III) Drug Information Services**

Drug Information Service (DIS) is the process of providing information on the safe and effective use of therapeutic and diagnostic pharmaceuticals. The purpose of DIS is to ensure that appropriate information is available continuously to meet the requirements of health care professionals.

Neither training nor other educational activities of the DTC can be successful and sustainable without a reliable source of unbiased information. There should be small DIS at least two or three current authoritative reference books, and, if possible, peer-reviewed journals. DTC should



secure a small budget from the hospital to cover the purchase of books, journals and bulletins. Drug information units may produce local bulletins that can give updated and practical medicines prescribing information.

Establishing DIS at health facilities is a very important requirement to make such services accessible and improving medicine uses.

### 7.2.2 Managerial Strategies

The DTC, through its role of promoting rational pharmacological therapy, should have a number of managerial methods in place to help ensure that medicines are used correctly. These methods include the following:

#### A. Implementation of Standard Treatment Guidelines

STGs bring another important dimension improving pharmacological therapy. When developed and implemented correctly, it brings significant advantages to health care programs.

#### Activity 7.2: Probing question on educational strategies



How implementing STGs could improve medicine use?

**Time:** 2 min

STGs are used at different points of the therapeutic process. Ethiopia has experience in developing and using STGs. But, there are challenges in availing updated STG and healthcare providers' adherence. Promoting the guideline is crucial. The role of the DTC lies on availing as well monitoring the implementation and use of national STGs at their own respective facilities.

The process of implementing evidence-based STGs can significantly be associated with improved use of medicines. Effective implementation of STG should be accompanied by training and supervision. The monitoring system and supervisory efforts should focus on the priority health problems and standard treatments for these problems. Using Medicine use evaluations (MUEs) can be helpful in monitoring and ensuring compliance with the STGs.

#### B. Audit and Feedback

Monitoring medicine use and then giving feedback to prescribers on the data collected is a very powerful way to change prescribing behavior. Audit and feedback may take several forms and range from the general to the specific, as follows:

- **Monitoring and supervision of medicine management** including adherence to the formulary, procurement, storage, distribution, etc., often using aggregate data. Information is fed back to the DTC and relevant departments.
- **Monitoring and supervising prescribing** habits in health facilities before and after an intervention (for example training and supervision) using drug use indicators (chapter 6). Information is fed back to all prescribers.
- **Medicine use evaluation** is focused on the use of one drug or the treatment of one disease, usually in a hospital. It is an ongoing, systematic, criteria-based program of medicine use.

MUE should be an ongoing process during which medicine-related problems are regularly addressed.

### C. Clinical Pharmacy Program

Clinical pharmacy blends a caring orientation with specialized therapeutic knowledge, experience and judgment for the purpose of ensuring optimal patient outcomes. Clinical Pharmacy Service can

- Help to ensure that indications for medicine use are appropriate, correct doses are prescribed, drug interactions and adverse drug reactions are avoided and patient counselling/education is provided
- Provide prescribers with up-to-date, unbiased drug information

#### Activity 7.3: Drill on role of DTC in Clinical Pharmacy




What are the role of DTC in strengthen the Clinical Pharmacy Service?

**Time:** 3 min

DTC of the health facility is expected to strengthen the Clinical Pharmacy Service, by creating awareness for the staff and management, fulfilling reference materials for clinical oriented pharmacists, conduct experience sharing events with best performing hospitals on clinical pharmacy services and other related activities which can strengthen the service.

## D. Medicine Restrictions

Many medicines, especially antibiotics, are misused, creating the need to apply restrictions on availability and use. Some common types of restrictions and controls are discussed below.

<b>Activity 7.4: Pair Reading</b>	
	Read lists of medication restriction types and their definition <b>Time:</b> 5 min

### Facility specific medicine list and Procurement Lists

The most common method to restrict medicine availability is by use of an approved medicine list or by use of a restricted procurement list. These lists are especially useful for limiting the number of antibiotics, which can become excessive if many providers and prescribers choose many different antibiotics and have many different brand preferences. Medicines list can also restrict the use of medicines by limiting the number and types of medicine that will be made available at each level of health care. Formulary management and medicine selection are discussed in detail in chapter 5, “Developing and maintaining facility specific medicines list.” The DTC should follow the implementation of national restricted use of medicines within their facilities.

### Structured Order Forms

Another method of medicine restriction is the use of a structured order form that requires certain antibiotics to be prescribed for certain indications only. These forms may also have preprinted doses and dose intervals. This method has been successful for controlling medicine use in some hospitals.

### Automatic Stop Orders

Automatic stop orders are useful for hospitalized patients and enforce restrictions on the duration of medicine use. This method has been found to provide valuable controls on the extended use of medicines, especially antibiotics and narcotics. It is a common problem for patients to be left on antibiotics for a long period because physicians have neglected to discontinue the medicine.

### Control of Medical Representatives and Other Pharmaceutical Promotion Activities

Within the administrative area of the committee, the DTC must play a role in the management of pharmaceutical company representatives and promotion of medicines. Medical representatives may promote their products with biased or inaccurate information. All promotional claims

should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation, and in good taste. The DTC should develop a guideline on control of medical representatives and pharmaceutical promotion activities that can be used in the health facility.

### **E. Avoiding Perverse Financial Incentives on Medicine**

Perverse financial incentives must always be avoided. The way health facilities charge for medicines, particularly for outpatients and pharmacies, may affect the way they are used.

Such examples of adverse promotion include:

- The overuse of medicines including the use of expensive medicines where cheaper one would be just as good and prescribers earn part of their income from the sales of medicines.
- The promotion of Polypharmacy where the patient must pay the same fee or fixed charge regardless of the number and quantity of medicines they receive (e.g., a registration fee covering all medicines).

The DTC has a role in advising the health facility management or other health authority concerning these issues.

### **7.2.3. Regulatory Strategies**

Improving appropriate medicine use through regulatory requirements is an important factor. Regulatory activities that the DTC can enforce in the facility includes restriction of management of special medicines by some professionals, controlling narcotic and psychotropic medicines by pharmacy professionals, Restricting of professionals who are engaged in unethical practice etc. The DTC should also ensure implementation of national regulatory policies (registration, professional licensing, licensing of pharmaceutical outlets, regulating pharmaceutical promotion activities etc.).

### **7.3. Choosing an Intervention**

Choosing an intervention depends on the type of medicine use problem and the reasons for the problem.

### Activity 7.5: MUE techniques



Enumerate some of quantitative and qualitative techniques in medicine use problem identification?

**Time:** 3 min

Once the medicine use problem and its underlying causes are identified, several choices of interventions exist to change medicine use practices. Whichever approach is used, interventions should focus on specific problem behaviors and should target prescribers, dispensers, facilities, or the public, depending on where the problem lies according to the findings from the assessment.

A single intervention rarely results in suitable changes, so a combined strategy is preferred.

There are six commonly used steps in developing strategy to improve medicine use.

1. **Identify the problem and recognize the need for action:** Within the facility, a consensus must exist about the most important problems in medicine use. Recognition of the primary problems may come from the results of medicine use problem identification methods (discussed in chapter 6).
2. **Identify underlying causes and motivating factors:** Many factors can contribute to the irrational use of medicines. Thus, these factors must be investigated and understood. Carry out different kinds of qualitative methods (chapter 6) to identify the underlining causes.
3. **List possible interventions:** Educational, managerial, and regulatory interventions can be used to address medicine use problems. Whenever possible, a combination or sequence of interventions should be used, and there should be evidence that the interventions are effective in similar settings.
4. **Assess resources available for action:** When deciding which intervention or combination of interventions to test, it is important to take stock of what resources are available.
5. **Choose an intervention or interventions to test:** Factors to consider when choosing an intervention include the effectiveness with which it addresses the underlying cause of the problem; its previous success rate in similar situations, areas, or countries, its cost, and whether it can be sustained with available resources.

6. **Monitor the impact and restructure the intervention:** During testing interventions, it is important to monitor related medicine use in order to evaluate the interventions efficacy or unexpected negative effect.

The most effective interventions often combine different aspects of educational, managerial and regulatory strategies to achieve maximum impact at a single point in time, or in sequence to reinforce effects.

#### **7.4. Evaluating Interventions**

The changes that different strategies have resulted should be measured and evaluated using established criteria. The change should be measured by comparing the situation before and after implementation of a specific strategy. If, for example, the problem associated with outpatient antibiotics prescribing was 60% before enforcing STGs, it should again be measured and compared after implementing STG or training is given to prescribers.

##### ***Summary***

- *Strategies to improve medicine use—one of the DTC's many functions. These programs are needed because irrational use of medicines will reverse any advantages gained in providing other DTC functions.*
- *Important strategies to improve medicine use include—Education, Managerial and Regulatory programs.*
- *A single intervention rarely results in suitable changes, so a combined strategy is preferred*
- *Each of these areas should be addressed carefully for a successful DTC and pharmaceutical management program*

## Chapter Eight: Medicine Safety and Quality Assurance

**Allocated Time:** 105 minutes

**Chapter Description:** This chapter describes causes, consequences and magnitude of ADEs. It will also equip trainees with the required knowledge and skills to monitor and address ADEs and ensure medicine quality.

**Chapter Objective:** By the end of this chapter, participants will be able to describe the role of DTC in monitoring ADEs and assuring quality of medicine.

**Enabling Objectives:** By the end of this chapter, participants will be able to:

- Recognize causes, consequences & magnitudes of ADEs
- Discuss the process of monitoring, evaluating and preventing ADEs.
- Identify how medicine quality is assessed and ensured

### Chapter Outline:

- Introduction
- Prevention and Reporting of ADEs
- Medicines quality assurance
- Summary

## Key Definitions

### Activity 8.1: Probing Question



Define Adverse Drug Events?  
**Time: 2 min**

**Adverse Drug Reaction (ADR):** Any response to a drug which is noxious and unintended, and which occurs at doses normally used in human for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” In other words, an ADR is harm directly caused by the medicine at normal doses, during normal use.

**Side Effect:** Any unintended effect of a pharmaceutical product occurring at doses normally used in humans which is related to the pharmacological properties of the medicine. Such effects may be well-known and even expected and may require little or no change in patient management.

**Medication Errors:** A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.

**Adverse Drug Events (ADE):** Any untoward medical occurrence that may be present during treatment with a medicine but does not necessarily have a causal relationship with this treatment, that is, an adverse outcome that occurs while the patient is taking the medicine but is not, or not necessarily, attributable to it. ADEs include side effects, ADR and medication error.

**Pharmaceutical Quality Assurance:** Pharmaceutical quality assurance may be defined as the sum of all activities and responsibilities required to ensure that the medicine that reaches the patient is safe, effective, and acceptable to the patient.

**Visual Inspection:** is the process of examining products and their packaging to look for problems and product quality.



## **8.1. Introduction**

Medicine safety problems are commonly caused by medication errors, poor quality medicines and certain medicines that are inherently unsafe (cytotoxic drugs, for example). Such safety problems are manifested through ADEs, which may result in serious patient harm, extended hospital stay and large consumption of resources.

ADEs can be divided into non-preventable ADEs (related to the nature of drug) and preventable ADEs (caused by medication errors). Medication errors can cause serious injuries to patients, but most medication errors do not result in ADEs. Generally, ADEs can occur at any phase of the medication management process, and they can be as a result of an action taken, that is, an error of commission, or as a result of an action not taken, that is, an error of omission.

Studies of ADEs and errors in medication prescribing and administration have been conducted in developed countries where resources for such studies are available. These studies have shown a substantial problem in terms of patient injury and increased cost of health care. The risk of an ADE has been about 1 to 5 percent in U.S. hospitals, and about one third of the events were preventable. Preventable ADEs added more than four days to the length of stay and more than USD 4,000 to the cost of the hospital admission. Most errors that result in ADEs occur at the stage of physician ordering or medicine administration.

It was not until the disaster caused by thalidomide in 1961 that the first systematic international efforts were initiated to address drug safety issues. At that time many thousands of congenitally deformed infants were born as the result of exposure in utero to an unsafe medicine promoted for use by pregnant mothers.



Unfortunately, there are often shortcomings in prescribing and taking medicines. One important concern is that of safety. Medicines are produced synthetically or from natural substances, and most will exhibit some form of side effect or adverse reaction. These side effects or adverse reactions may range from relatively mild to, in rare cases, serious and life threatening.

## **8.2. Prevention and Reporting of ADEs**

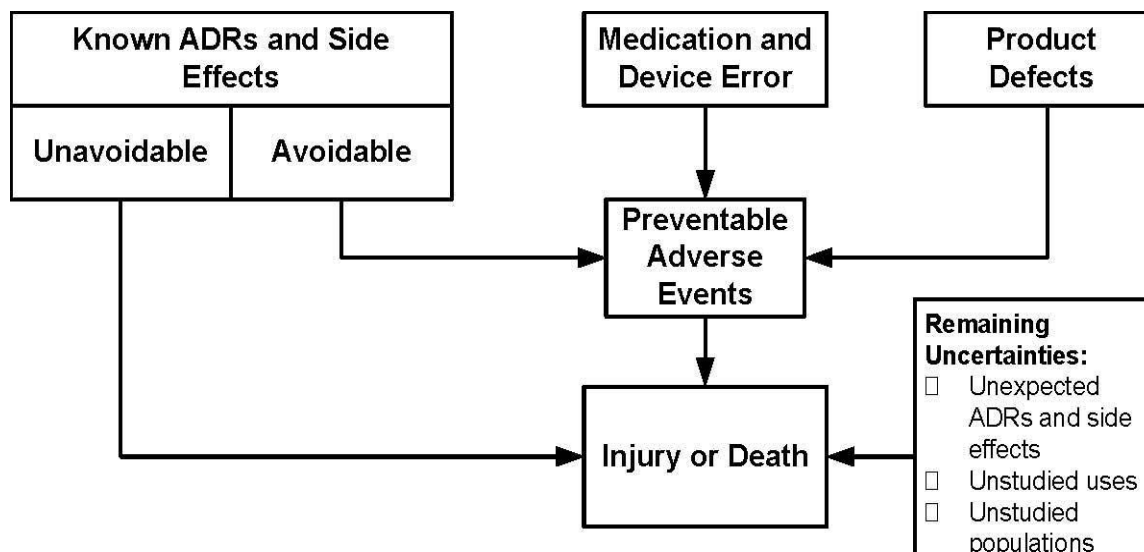
The DTC should be involved in the processing and analysis of spontaneous case reports arising from patients and medical providers.

## Prevention of Adverse Drug Events

Prevention of many serious ADEs is possible and a necessary function of the DTC. Without a prevention program, many ADEs will occur needlessly, producing an increase in morbidity and associated health care cost. Many authorities agree that over 50 percent of ADEs may be preventable. There is a general lack of knowledge concerning ADEs, including the incidence, severity and impact on health care.

<b>Activity 8.2: Pair Study</b>	
 <b>Think</b>	Study the following schematic presentation of preventable and unavoidable adverse events <b>Time: 3 min</b>
 <b>Pair</b>	

Many ADEs are related to the prescribing of an incorrect dose and to administration of a medicine to a patient with a known allergy. Figure 5 below illustrates the factors that contribute to preventable adverse reactions.




**Figure 5: Schematic Representation of preventable and unavoidable adverse events**

Preventing an ADE can be enhanced by the practitioner by evaluating the following before prescribing, dispensing and administering of medicine:-

- Is this medicine the correct one for the patient’s clinical condition?
- Are the dose, route and interval correct?

- Does the patient have any medical or physical conditions that would affect the pharmacokinetic aspects of the medicine?
- Does the patient have an allergy to this medication or a chemically similar medicine?
- Is the patient on another medicine (or herbal product) that would cause a significant medicine interaction?
- What is the patient's compliance with the medication?
- Is the medicine being prescribed a medicine that is at high risk for producing ADRs (e.g., aminoglycosides, digoxin, warfarin, heparin, and antineoplastic)? Special precautions are necessary when using these high-risk medicines.
- Is the medicine being prescribed of high quality (i.e., reputable manufacturer, not expired, no deterioration)?
- Is the medicine being administered correctly (e.g., sterile needle or syringe for injectable medicines or with food for gastrointestinal irritants)?

### Role of DTC in preventing ADEs




<b>Activity 8.3: Role of DTC in preventing ADEs</b>	
	<p>What DTC should perform to limit the occurrence of ADEs?</p> <p><b>Time: 3 min</b></p>

DTC should perform the following activities in order to limit the occurrence of ADEs:


- Educate staff, especially providers, concerning ADEs.
- Educate clients on ADE issues.
- Identify medicines on the formulary that are high risk and should be monitored closely by physicians and pharmacists. For examples: Aminoglycosides, Digoxin, Heparin, Warfarin
- Ensure identification of high-risk patient populations, including pregnant women, breast-feeding women, the elderly, children, and patients with renal or liver dysfunction; close monitoring of these patient populations by physicians and pharmacists will help prevent serious adverse reactions.

- Review medication errors and product quality complaints to ensure they are not contributing to the incidence of ADEs at health facility.
- Review ADE reports regularly, and inform the professional staff of the incidence and impact of ADEs in the region.
- Discuss changes in the formulary or standard treatment guidelines for significant or recurring problems with ADRs.

### Reporting of ADEs

<b>Activity 8.4: Experience Sharing</b>	
 <b>Think</b>  <b>Pair</b>  <b>Share</b>	<p>Have you ever reported ADE in your respective health facility?</p> <p><b>Time: 2 min</b></p>

DTC is expected to facilitate the reporting of ADEs occurring in the health facilities. The following SOP describes the procedures and activities when reporting ADEs. This SOP helps to improve quality of patient care and health outcome.

<b>Case Study: Reporting ADE</b>	
	<p>Ato Ahmed Tasew is 48 years old known hypertensive patient (card number 23076) went for a follow up to <b>AB</b> hospital found in Addis Ababa, woreda 09 kebele 14 on 14/6/2008E.C. While the healthcare provider (S/r Zewde) was measuring his BP it is found 185/120 mmHg. Ato Ahmed smokes half a pack of Nyala Cigarettes a day. Ato Ahmed was admitted to emergency room for 12 hours and prescribed ABC brand of Hydralazine 20mg/ml injection to be given 5mg every 20 minutes until BP drops and XYZ brand of Furosemide 10mg/ml in 2ml injection; 20mg dose daily for three days. The nurse gives the two medications as prescribed. Ato Ahmed gets improvement and discharged after 12 hours of stay in emergency room. On the next day, Ato Ahmed comes to the hospital with complains of red, swollen skin on his legs and becomes very sick and was admitted to medical ward in AB Hospital. Hydralazine 20 mg/ml injection was produced by Parma lab firm <b>Q</b> with batch number of ABA612CXF and expiry</p>

	<p>date of 29/2/2018 and XYZ which produced by pharma firm <b>Z</b> with batch number of AA1012AXA and expiry date of 31/7/2018. Next morning when the duty healthcare provider was about to give Furosemide she found out it was cloudy. The nurse decided to stop the Furosemide medication temporarily and the swelling subsides after five days and he become stable of discontinuation of medication.</p>
<p>Question: Assume you were the healthcare provider, how would you report Ato Ahmed`s case?</p>	

### SOP for completing Adverse Drug Event formats

<b>Task</b>	<b>Completion of ADEs reporting</b>
<b>Completed by</b>	All health care providers who encountered ADEs and ADE focal person
<b>Purpose</b>	To report Adverse Drug Events
<b>When to perform</b>	As soon as Adverse Drug Events identified.
<b>What to report</b>	All suspected reaction to the drug: Unexpected reactions, unknown or serious ADRs, unexpected therapeutic effects, all suspected drug interactions, product quality problems, treatment failure, and medication error.
<p><b>Note:</b> Drugs include conventional drugs, herbal drugs, traditional medicines, biological, medical supplies, medicated cosmetics</p> <p>DTC will follow and support professionals on how to report and assign focal person.</p>	

<b>Steps</b>	<b>Activity</b>	<b>Note</b>
1	<p><b>Patient background information-</b> write the patient background information starting from Patient name; Card no, Age Sex, Weight, Height, Ethnic group and Substance abuse.</p>	<p>It's not necessary to write the full name of patient's, write initials only.</p> <p>Substance abuse: refers to the harmful or hazardous use of psychoactive substances, including alcohol, chat, cigarettes and illicit drugs.</p>
2	<p><b>Drug name:</b> Write all information including brand name and manufacturer</p>	<p>Avoid Non – Standard Abbreviations</p>

3	<b>S/C:</b> Fill all Suspected and concomitantly used drugs	Write 'S' for suspected drugs and 'C' for concomitantly used drugs
4	<b>Product Dosage and Frequency:</b> write dose/dosage form, route and frequency of the drug	
5	<b>Date:</b> write the date of drug taking started, reaction started and taking stopped	In European calendar (dd/mm/yy)  If the medicine hasn't been discontinued at the time of reporting, write 'continuing'
6	<b>Indication:</b> write reason for drug use	
7	<b>Adverse Drug Event Description</b>	Clear description about the nature of adverse event, the date of onset, duration, time course and laboratory test results including '-ve' and normal results of any relevant test performed should be reported.  The severity of the reaction i.e whether it has necessitated prolonged hospitalization or not, discontinuation of the medicine or not, etc has to be reported.
8	<b>Reaction necessitated:</b>  <b>Discontinuation of drugs:</b> tick yes or no  <b>Hospitalization:</b> tick yes or no	
9	<b>Reaction subsides after discontinuation of suspected drug:</b> tick yes or no  <b>Reaction reappear after restart of suspected drug :</b> tick yes or no	
10	<b>Treatment Reaction:</b> write any treatment given at the facility for the identified ADE (Reaction).	
11	<b>Outcome:</b> tick the outcome of the ADE	<b>Example:</b> died, not recovered with or with out


12	<b>Sequela:</b> write any sequela condition that result due to the ADEs	<b>Sequela:</b> is a pathological condition resulting from a prior disease, injury or attack.
13	<b>Relevant medical conditions:</b> write any relevant medical conditions if occurred	<b>Examples:</b> Allergies, renal disease etc
14	<b>Reported by:</b> write the name, the profession, email address, telephone, name of the individual reporting the ADE and their institution and date of reporting	
15	<b>Product Quality problem</b> write drug trade name, batch no, dosage form, strength, the size/type of package of the suspected drug	<b>Example:</b> color change, separating of components, powdering, molding etc
16	<b>For office use:</b> leave empty	This section of the form is to be used by the regulatory body to which the ADE is reported
17	<b>From:</b> write your postal address at the end of postage	Put the postal address (B. O. Box) of the health facility
18	<b>Provide the completed format to the ADE focal person</b>	

**The ADEs report is completed when:**

1. ADE focal person send the completed ADE reporting format to FMHACA and summary report to the facility DTC
2. When the focal person routinely follows and communicates to the responsible body.
3. When the focal person receive confirmation from the nearest FMHACA or regulatory authority.
4. When the DTC takes measures on the reported ADE until FMHACA takes the appropriate measures and gives feedback and the feedback is implemented.

**Note: the ADE reporting format is annexed**

### 8.3. Medicines quality assurance

<b>Activity 8.5 Plenary discussion</b>	
	<ul style="list-style-type: none"> <li>• What do you understand by “Quality of Medicines”? And why do we care about quality of medicines?</li> <li>• Who do you think are responsible for ensuring quality of medicines?</li> <li>• What roles does the DTC at the health facility can play to ensure access to quality medicines?</li> </ul> <p><b>Time: 5 min</b></p>

The purpose of a QA for health facilities is to ensure that every medicine reaching a patient is safe, effective and meets quality standards. 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 pharmacy, medical and nursing departments, as well as the DTC.

### **How is quality of Medicines assessed and Assured?**

Product selection should be guided by an effective DTC that has thoroughly evaluated the evidence-based information. Preferably, only the dosage forms that have a long shelf-life and are of acceptable stability and bioavailability should be selected.

All medicines should be inspected thoroughly during procurement, transportation, receiving and storing and in dispensing units. Inspection should include visual inspection and a review of product specifications (including expiration dates) to ensure that the medicine meets specifications. Thus DTC is responsible for monitoring visual inspection upon receiving the medicines procured and stock transfer from store to dispensing units.

The health care system needs a program to monitor the quality of medicines and medical supplies.




All quality defects must be reported using ADEs reporting formats and the pharmacy or procurement department should keep files of these reports. Procurement, pharmacy and the DTC should periodically evaluate these reports.

The FMHACA are the national focal points responsible to take appropriate measures upon receipt of reports on product problems.

Quality of products received in the health care system is the responsibility of many individuals and organizations. The national medicine regulatory authority takes the prime responsibility of ensuring the quality of medicines during market authorization and post marketing surveillance.



## Responsibilities of different actors in ensuring quality of Medicines

Activity 8.6 Brainstorming and Pair Reading	
 <b>Think</b>	Mention some of the responsibilities of DTC in ensuring quality of medicines?  <b>Time: 3 min</b>
 <b>Pair</b>	
 <b>Share</b>	

### A. DTC is responsible in

- Selecting medicines for the medicines list and procurement
- Advising on appropriate storage and transportation of medicines
- Coordinating medicine quality monitoring
- Ensuring quality defect report communicated to appropriate body

The DTC should work closely with the departments of the respective health institution, including pharmacy (DSM), nursing and medical to ensure that pharmaceutical quality assurance procedures are practiced throughout the system.

The DTC should work with 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. Complaints about quality should be analyzed and recommendations developed to deal with quality defects.

### B. Health facilities Pharmacy units are responsible for

- Inspecting products
- Reporting and taking action on quality defects
- Ensuring appropriate storage in the warehouse, pharmacy and departments.
- Using appropriate containers for dispensing
- Instructing patients on appropriate use of medicines

### C. Health care providers

- Monitoring and promoting quality assurance in their facilities
- Reporting quality defects

#### **D. Patients**

- Storing medicines correctly
- Taking medicines correctly
- Reporting quality defects to health facility/ health care provider

#### ***Summary***

- *Medicine safety and quality issues are critical to a health care system*
- *ADEs can occur at any phase of the medication management process*
- *The DTC is in a position to have a significant impact on monitoring and addressing ADEs*
- *Mandatory reporting of ADEs by all health care practitioners could be an important step in improving medicine use.*

## Chapter Nine: Antimicrobial Resistance Prevention & Containment

**Allocated Time:** 70 minutes

**Chapter Description:** This chapter provides a review of global and national status of AMR, factors contributing to the emerging of AMR, consequences, Antimicrobial Resistance prevention and containment strategies in Ethiopia.

**Chapter Objective:** By the end of this chapter the participants will be able to discuss the impact of Antimicrobial Resistance and ways of preventing AMR.

**Enabling Objectives:** By the end of this chapter participants will be able to:

- Describe antimicrobial resistance and the factors contributing to its emergence and spread
- Discuss the global and national magnitude of Antimicrobial resistance
- Describe the consequences of antimicrobial resistance
- Discuss AMR prevention and containment strategy in Ethiopia.
- Describe the role of DTC in combating AMR.

### Chapter Outline:

- Introduction
- Global and national magnitude, Factors and Consequence of AMR
- AMR prevention and Containment Strategy in Ethiopia
- Role of DTC in combating AMR
- Summary

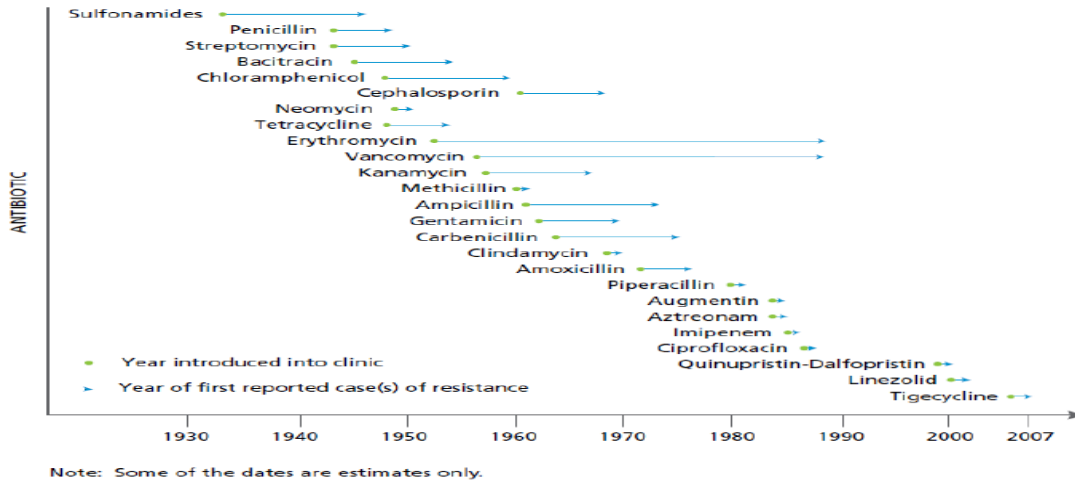
## 9.1. Introduction

The use of antimicrobial medicines has greatly contributed to the decline in morbidity and mortality by infectious diseases over the past half-century. This achievement, however, is being undermined by the rapidly growing problem of antimicrobial resistance (AMR). Since the first use of antibiotics in the 1930s and 1940s, microbes have quickly adapted and developed mechanisms to escape their effects.

*Antimicrobial resistance (AMR) is the ability of microbes to grow in the presence of a class of drugs known as antimicrobials that would normally kill microbes or limit microbial growth. It occurs when microorganisms such as bacteria, viruses, fungi and parasites change in ways that render the medications used to cure the infections they cause ineffective. Some microbes are resistant to almost all types of antimicrobials. When the microorganisms become resistant to most antimicrobials they are often referred to as “superbugs.”*

Unnecessary and inappropriate uses of antibiotics have greatly favored the emergence and spread of resistant bacteria. Therefore, it is important to identify the underlying causes of AMR and tackle its spread. With the declining trend of new antimicrobial options developmental activities today, worldwide stronger action needs to be taken to avert a situation that entails an ever increasing health and economic burden.

Over several decades, to varying degrees, bacteria causing common infections have developed resistance to each new antibiotic, usually immediately following their use at clinical settings (See Figure below), and AMR has evolved to become a worldwide health threat.



*Figure 6: Drug Resistance immediately after clinical applications*

## 9.2. Global and National Magnitude of AMR

### Activity 9.1: Probing Question

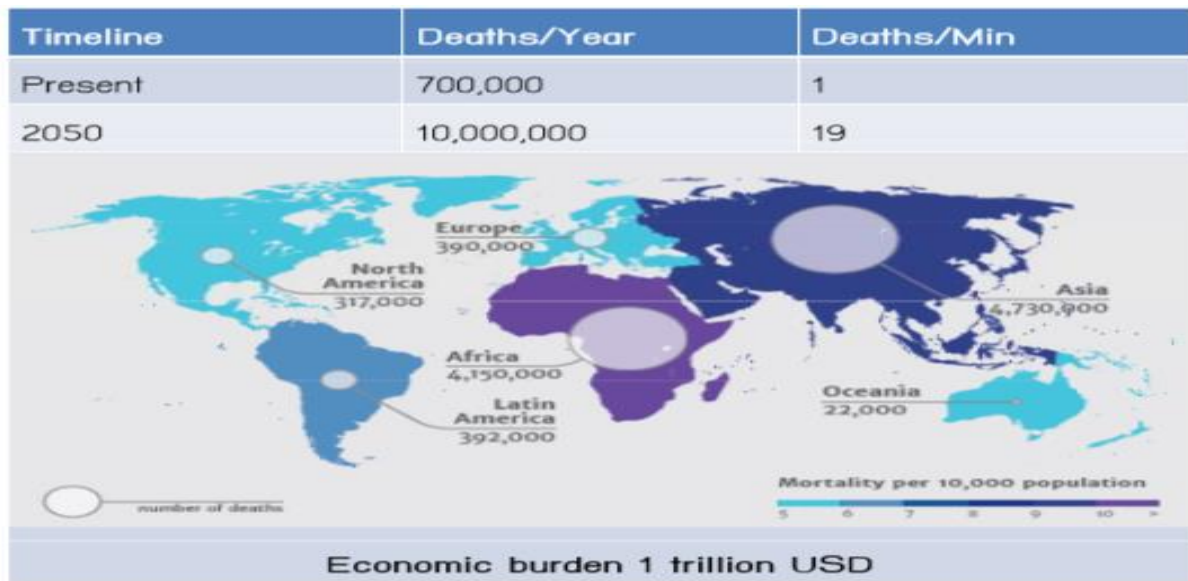


What makes AMR become a global phenomenon?

**Time: 3 min**

The crisis of AMR has been building up over decades throughout the world, so that today many common and life-threatening infections are becoming difficult or even impossible to treat, sometimes turning a common infection into a life-threatening one. Infectious diseases, such as tuberculosis (TB), sexually transmitted infections, acute respiratory infections, malaria, dysentery, HIV/AIDS, streptococcal, staphylococcal spp. and many others are becoming increasingly difficult and expensive to treat, and the burden is greatest in developing countries where resources are limited and infection rates are high.

The status of AMR is also at an alarming level in Ethiopia. According to 2009 antimicrobial use, resistance and containment baseline survey, high levels of AMR to first line antimicrobials were identified. Staphylococcus, Streptococcus pneumoniae, salmonella species, and Staphylococcus aureus were particularly the most common bacteria that have shown increased resistance.



*Figure 7: Global economic burden of AMR (WHO)*

## Factors Contributing to AMR

Antimicrobial resistance is the result of many factors with biological, behavioral, technical, economic, regulatory, and educational roots. But among all these factors, irrational use of antimicrobials is the greatest driver of resistance.

The irrational use of antimicrobials practices which contribute to the development of AMR include, but not limited to the following:

- Unnecessary prescription of antibiotics, such as for viral infections (colds) or for prolonged prophylaxis
- Using broad-spectrum antibiotics (such as third generation cephalosporin's, carbapenems) when narrow-spectrum antibiotics are effective
- Prescribing too low doses
- Not prescribing according to microbiology results/absence of diagnostic facilities
- Prescribing intravenous therapy when oral therapy is known to be effective and clinically safe
- Omitting or delaying administration of doses and not taking antibiotics as prescribed by patients.
- Limited access to health care

- Antimicrobials available without prescription and irrational self-administration
- Accessible but poor quality, sub-standard or counterfeit antimicrobials
- Weak monitoring and regulatory systems
- Poor infection control systems in health facilities,
- Economic incentives for prescribers and dispensers (unethical promotions)
- Poverty and economic hardships that lead to early termination of treatments or sharing of medicines within the family
- Insufficient level of training among health professionals, etc.

### **Consequences of AMR**

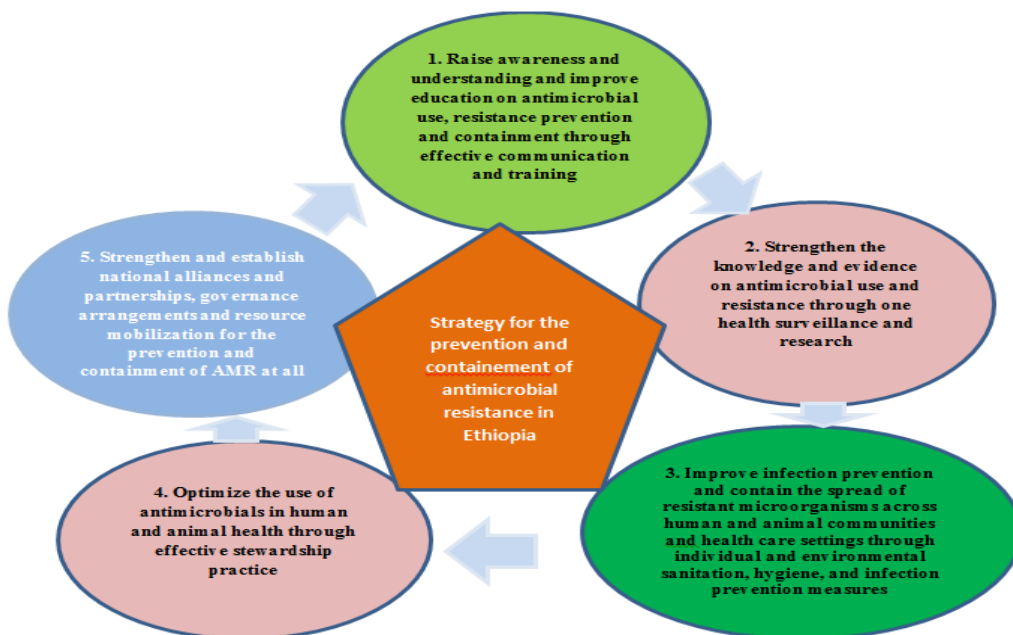
Antimicrobial resistance is responsible for countless human deaths and billions of dollars in healthcare expenses. Many patients around the world suffer harm due to AMR because infections (caused by viruses, bacteria, fungi, protozoa, or helminthes) are no longer susceptible to the common medicines used to treat them. The following points summarize the consequences of AMR.

- Increased morbidity & mortality
- Longer duration of illness:
- Longer treatment
  - Excess length of stay 6.4 – 12.7 days/patient
- Treatment with expensive drugs
- Increased burden on health system
- Negates technological advances in medical sector
  - Complex surgeries
  - Transplantations and other interventions
- Patient acts as reservoir of resistant organisms which are passed to community and health-care workers
- Huge economic impact (both direct & indirect)

### **9.3. AMR prevention and Containment Strategy in Ethiopia**


Recognizing the public health crisis due to AMR, several nations, international agencies, and many other organizations worldwide have acted to counteract it through strategies applied in the

relevant sectors. Ethiopia has its own national strategy 2015 to 2020 to prevent and contain AMR. This national strategy addresses the following five key strategic issues:



*Figure 8: Strategy for the prevention and containment of AMR for Ethiopia*

#### 9.4. Roles of Drug and Therapeutics Committee to combat AMR

	<b>Activity 9.2: Brainstorming</b>
	<p>What are the roles of DTC to combat AMR in institutional settings?</p> <p><b>Time: 2 min</b></p>

DTCs are important to monitor and improve medicines use in institutional settings and help to 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. This goal can be accomplished by various methods: -

- Updating and managing antimicrobials in their formulary list
- Lead and ensure the implementation of national and updating antibiotic guidelines
- Ensure implementation of policies to improve compliance with guidelines



- Reserve antibiotics, levels of prescribing, automatic stop orders, antimicrobial order forms
- Providing in-service education on rational use of Antimicrobials
- 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

### **DTC Collaboration with Departments and Committees**

DTCs can collaborate with other hospital units and departments resulting in synergistic action to contain the threat of AMR with the following:

- Different departments - for education of medical students, physicians, pharmacists, nurses, and patients
- The Infection Control Committee - to reduce spread of resistant pathogens
- The microbiology department - for collection and management of information on pathogens and resistant patterns
- Health facility management - to develop and implement policies on antibiotic use
- Pharmacy - to improve antimicrobial procurement and quality

### ***Summary***

- *AMR forms nowadays one of the world's most public health threats. It is increasing across the world while approaches in the area of new drug delivery system are declining.*
- *AMR has serious public health consequences. It increases mortality and morbidity from infectious diseases. It also increases treatment costs, illness duration and has many negative economic consequences.*
- *DTC have many roles in monitoring and improving medicines use in institutional settings to contain AMR.*

## Chapter Ten: Role of DTC in Pharmaceuticals Supply Management

**Allocated Time:** 60 minutes

**Chapter Description:** In this chapter the participants will be introduced to the overview basic functions of pharmaceutical supply management and role of DTC in managing pharmaceutical supply. Finally the concept and role of DTC in efficient management of medicines & medical devices will be dealt.

**Chapter Objective:** By the end of this session, participants will be able identify the role of DTC in pharmaceutical supply management and efficient management of medicine and medical devices.


**Enabling Objectives:** By the end of this chapter, participants will be able to:

- Identify the role of DTC in pharmaceutical supply management.
- Explain efficient management of medicines & medical devices

### Chapter Outline:

- Introduction
- Basic pharmaceutical supply management functions and the role of DTC
- Efficient management of medicines & medical devices
- Summary

## 10.1. Introduction


	<p><b>Activity 10.1: Pharmaceutical Supply Management</b></p> <ul style="list-style-type: none"><li>• What is pharmaceutical supply management and list its basic functions?</li><li>• Do DTC have a role in managing pharmaceutical in health facilities?</li></ul> <p><b>Time: 5 min</b></p>
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Mortality figures across developing regions reflect a huge burden of illness that can be substantially reduced if carefully selected, low-cost pharmaceuticals are available and appropriately used. Pharmaceutical supply management is the set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines, health products, and services in any health care setting.

Activities in the pharmaceutical management system are organized according to functional components of a cycle and related to the selection, quantification, procurement, distribution, store, and use of products. It operates within and is affected by a political, legal, and regulatory framework. The components of pharmaceutical supply management are the same for all sectors although procedures and activities within each component may differ.

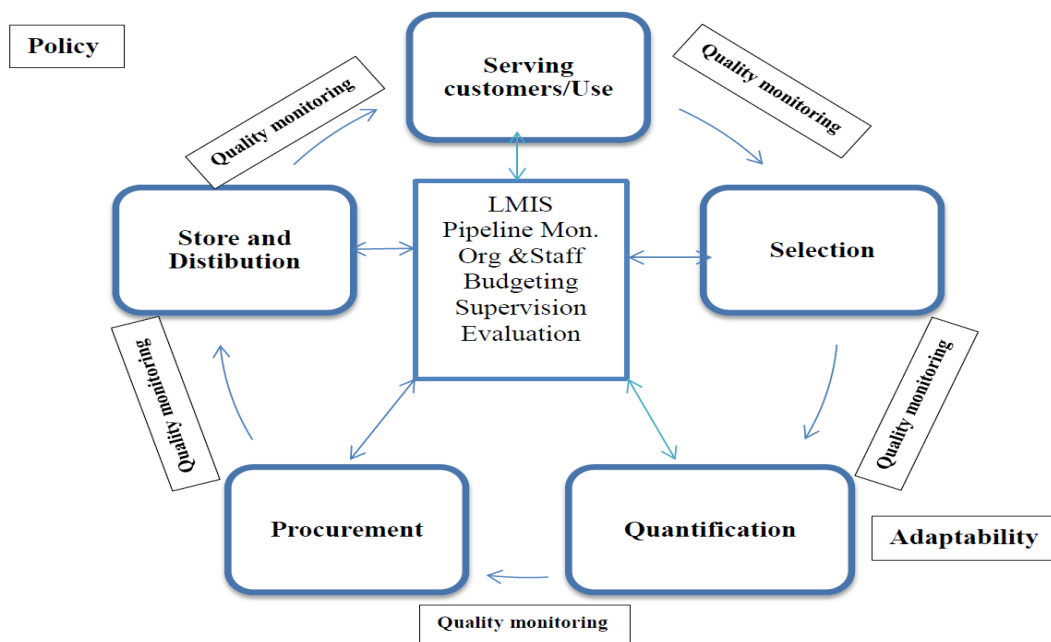
Pharmaceutical management in the health sector should follow well-established principles but must be flexible and responsive to the varied settings and services offered to ensure effective health service delivery. DTC have inevitable role in managing pharmaceutical supply and ensuring efficient utilization of pharmaceuticals and medical devices.

## 10.2. Basic pharmaceutical supply management functions and the role of DTC

	<p><b>Activity 10.2: Group exercise</b></p> <p>Group discussion on role of DTC in PSM</p> <ul style="list-style-type: none"> <li>➤ Discuss the role of DTC in each in each functions of PSM (selection, quantification, procurement, inventory management/distribution/storage and LMIS)</li> </ul> <p><i>Note: group the participants in to 5 teams and read, discuss and present.</i></p> <p><b>Time: 25 minutes</b></p>
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A useful way to understand the complex field of pharmaceutical management is to think of it as a cycle. Each component of the cycle builds on the previous one and leads to the next. In this chapter basic pharmaceutical supply management functions and the role DTC in each function will be discussed.

The pharmaceutical supply management cycle in Ethiopia includes five basic functions as indicated in figure below.



**Figure 9: Pharmaceutical Supply Management Cycle**

### **10.2.1. Pharmaceutical Selection**

No public or private health care facility in the world can afford to procure all drugs circulating in the market within its given budget. Limiting list of medicines and medical devices is one of the most effective ways to control drug expenditure. This process begins with defining a list of common diseases for each level of health care. The treatment of first choice, the national formulary system and the treatment guidelines for each health problem is the basis for facility specific essential medicines. Reducing the number of items leads to larger quantities to procure which in turn encourages competitive drug prices and simplifies other supply management activities and reduces inventory-carrying.

#### **Role of DTC in Pharmaceutical Selection**

DTC has got a critical role in selection of facility specific medicines. This includes:

- Performing step-by-step activities discussed in chapter 5 to develop a facility specific medicine list.
- Periodically revising list of medicines and medical devices to reflect the current judgment of the medical staff.
  - Developing policies and procedures for additions and deletions of medicines and medical devices.
  - Adding a new medicine or deleting an existing one from facility specific medicine list after evaluating the proposed medicines and medical devices for deletion and addition using appropriate sources of information
- Managing non-formulary medicines and medical devices.

### **10.2.2. Pharmaceutical Quantification**

Quantification is the process of estimating the quantity and cost of the products required for a specific health program (or service) during a specific period and determining when the products should be procured and distributed to ensure an uninterrupted supply. It is not a one-time that ends when the final quantities and costs of the pharmaceuticals have been determined. It is an iterative process with reviews and updates required year-round. Quantification links information on medicines demand from the health facility level with program policies and plans at the

national level to estimate the quantities and costs of the medicines required for a health program.

It has two parts:

**i. Forecasting**

- Estimating quantity of each product required to meet demand for the forecast period.

**ii. Supply planning**

- Adjusting quantities forecasted to determine quantities to procure and time of delivery of the products

At facility level quantification should be performed annually by team members composed of pharmacy professionals (pharmacy head/drug supply manager), clinicians, laboratory, nursing, warehouse managers, and other relevant departments. Once quantification team built consensus on the forecasting assumption, the quantity for each product is forecasted using the following methods. These are:

- Consumption method
- Morbidity method
- Adjusted-consumption method
- Service-level projection

Consumption and morbidity methods are most commonly used.

**Consumption Method:**

In this method, a list of all health commodities to be procured is prepared, and the most accurate inventory records of past consumption are used to calculate the quantities needed for each product. Consumption at different outlets of the facility should be recorded, compiled and analyzed for the appropriate supply and use of pharmaceuticals. Consumption method is the most reliable predictor of future pharmaceutical need. This method is applicable when:

- Accurate consumption data are available or easily obtainable
- Medicines supply at health facility has been consistent (not out of stock for more than 3 months)
- Inventory management is reasonably good

- Wastage and loss through expiry, damage and theft are not excessive

**Morbidity method:**

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

- Consumption data are incomplete or not available
- Budget is unlikely to be sufficient to meet estimated requirements
- Health facilities or services are new.

Ideally, multiple types of data and method of forecast should be used to calculate forecasts. Then these results should be compared and reconciled to arrive at the best forecast consumption figures. To make rational reduction of the forecasted products, different prioritizing mechanisms such as ABC and VEN analysis can be used.

**Supply planning:**

Supply planning is adjusting quantities forecasted to determine quantities to procure and time of delivery of the products. Based on the above forecast, pharmaceutical supply management unit estimates the total pharmaceuticals required for the specified period. The planning also estimates the overall cost by considering updated information on the price of pharmaceuticals, transportation, loading/unloading, and telephone cost and other expenses as needed.

## **Role of DTC in the Quantification Process**

DTC have enormous role in health facilities quantification process. Some of this includes:

- Develop and approve a quantification plan.
- Review quantification list in relation to the existing facility list and take appropriate action
- Review if the estimated total value of the forecast is in line with the health facilities budget.
- Take appropriate measure if the forecast is beyond the budget
- Follow timely completion of the quantification process and document the whole process.
- Submit verified version of final forecast to the health facility management for approval.
- Follow the timely submission of the approved forecast to PFSA.

### **10.2.3. Pharmaceutical procurement**

An effective procurement process seeks to ensure the availability of the right medicine in right quantities, at reasonable prices, and recognized standards of quality.

The major procurement methods used by health system are open tender, restricted tender, competitive negotiation and direct procurement. In Ethiopia, public health facilities should procure preferentially through PFSA, products which are not found at PFSA can be procured from private suppliers using stock out certificate.

### **Role of DTC in Procurement**

The role of DTC in pharmaceutical procurement is:

- Developing procurement policy and procedures
- Ensuring its implementation of this policy

### **10.2.4. Inventory Management, Storage and Distribution**

The purpose of an inventory management is to inform when and how much of a pharmaceuticals to order and to maintain an appropriate stock level to meet the needs of patients. A well designed and well operated inventory control system helps to prevent shortages, oversupply, and expiry of pharmaceuticals.



Within hospitals and health centers, products will be managed centrally in the Pharmacy Store. All products will be received into the pharmacy store and most of the products will be stored there, until they are needed in the various dispensing units within the facility.

Storing is the safe keeping of pharmaceuticals to avoid damage, expiry, and theft. Proper storage procedures help to ensure that storage facilities protect the shelf life of products, that only high-quality products are issued, and that there is little or no waste due to damaged or expired products. If proper storage procedures are followed, customers can be assured that they have received a high quality product.

### **Role of DTC in inventory management, storage and distribution of pharmaceuticals**

The role of DTC in inventory management, storage and distribution of pharmaceuticals within health facility includes:

- Monitoring the resupply of dispensing units is according established schedule.
- Approve medicines list of each dispensing units and monitor the resupply is as per the list
- Monitor the application of storage guideline in the pharmacy store and dispensing units.
- Make sure that system is in place to monitor stock status at main pharmacy store and dispensing units, and disposal of unfit for use medicines is working.


### **10.2.5. Logistics Management Information System (LMIS)**

The LMIS is the means through which we collect, organize, and report information to other levels in the system in order to make decisions that govern the logistics system and ensure that all six rights are fulfilled for each client.

#### **The role of DTC in strengthening LMIS**

- Monitoring if transaction and stock keeping records are used as per the standard
- Monitoring quality of data generated by LMIS report.
- Following regularity and timeliness of reports of logistics information to relevant body.

### 10.3. Role DTC in Efficient management of medicines & medical devices

	<p><b>Activity 10.3: Efficient management of medicines and medical devices</b></p> <ul style="list-style-type: none"><li>• What are the commonly used tool/methods to efficiently manage pharmaceuticals in your facility?</li><li>• Mention the role DTC in efficient management of medicines and medical devices</li></ul> <p><b>Time: 2 Minutes</b></p>
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In developing countries; essential medicine list, STG, generic substitution and tax minimization are effective instruments for improving pharmaceutical purchasing and improving affordability. In addition to these tools in our country pharmaceutical service delivery arrangement called Auditable Pharmaceutical Transaction and Service (APTS) that enables public health facilities to efficiently utilize their pharmaceutical budget was introduced in the past few years. To efficiently manage medicines and medical supply budget the following methodologies should be used by health facilities:

- a. **VEN/ABC reconciliation:** This method identifies the most needed medicines used to treat common diseases in relation to budget consumption to address priority health problems by the limited budget and minimize irrelevant medicines which are vulnerable to expiry.
- b. **Establishing effective medicines sales management system:** This includes taking physical inventory, establishing beginning stock and recording received stocks, estimating cost, price setting, summarizing the daily sales medicines as cash, credit and free and auditing by reconciling the calculated value with the physical count. This contributes to efficient utilizations of medicines budget.
- c. **Bin management:** In all dispensaries to ensure accountability of each dispenser, accessibility of medicines, identifying of the slow moving items and increase work efficiency it requires proper bin management.
- d. **Stock status analysis**

#### The roles of DTC in efficient management medicine and medical devices

- Monitoring periodically if ABC/VEN is done.

- Monitoring the application of storage guideline in the pharmacy store and dispensing units.
- Making sure that system is in place to monitor stock status at main pharmacy store and dispensing units, and disposal of unfit for use medicines is working.
- Making sure that the stock status analysis was undertaken
  - To identify the usable stocks from obsolete stocks.
  - To get reliable financial and product information.
  - To use the stock effectively and increase sales.
- Following APTS monthly report generation and advising the administrators to facilitate regular audit

### ***Summary***

- *The main aim of pharmaceutical supply management is to ensure availability, affordability and rational use of all medicines.*
- *This involves proper selection, quantification, procurement, inventory management and distribution of medicines.*
- *DTC plays different in each component of PSM and efficiently managing pharmaceuticals and medical supplies.*

## Chapter Eleven: Collaborating, Coordinating and Communicating DTC related activities

**Allocated Time:** 60 minutes

**Chapter Description:** This chapter describes the concepts of Communicating, Collaborating and Coordinating (CCC) of DTC activities in the health facility. Discussion will be made how to systematically coordinate and collaborate relevant stakeholders to perform DTC functions and thereby promote rational medicines supply and use. It will also provide trainees with the required knowledge and attitude of communication of DTC activities.

**Chapter Objective:** By the end of this chapter, participants will be able to establish a mechanism to systematically coordinate, collaborate, and communicate DTC activities.

**Enabling Objectives:** By the end of this chapter, participants will be able to:


- Describe the concepts of coordination, collaboration and communication
- Discuss appropriate areas of coordination, collaboration and communicate DTC activities

This chapter has the following outlines:

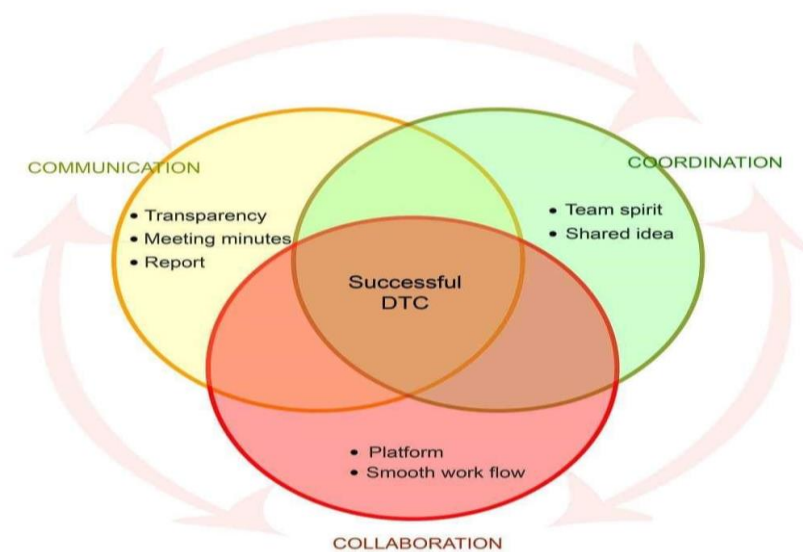
### Chapter Outline:

- Introduction
- Coordination, Collaboration and Communication of DTC activities
- Summary

## 11. 1. Introduction

Activity 11: Brainstorming on CCC	
	What are coordination, collaboration & communication mean in DTC? <b>Time:</b> 3 min

A healthcare system that supports effective teamwork can improve the quality of patient care and enhance patient safety. Teams can work to their best when they have a clear purpose; protocols and procedures, and effective coordination, collaboration & communication.



**Figure 10: Mechanisms of coordination, collaboration and communication**

Collaboration is working together to accomplish a task and discussing with each other to solve difficult problems. Coordination is the harmonious adjustment or interaction of different people or groups to achieve a goal or effect. Communication is imparting or interchanging thoughts, opinions, or information by speech, writing, or signs.

The health sector comprises diverse stakeholders with varying interests. Aligning plans and synergy in the implementation of DTC's action plan will be advocated taking into account the need for ensuring access to quality, safe and efficacious medicines in the health facility. Hence this could be achieved through applying mechanisms of collaboration, coordination and communication (CCC) by:

- Mapping potential stakeholders

- Advocating, awareness creation and communicating with relevant stakeholders
- Mobilizing resources for effective implementation of the policies/guides and DTC action plan
- Establishing a platform (e.g. meetings, discussion forums, seminars and workshops) to enhance collaboration, coordination, and communication.

CCC could be attained through formal as well as informal interactions within and outside of the health facility.

## **11.2 Coordination, Collaboration and Communication of DTC activities**

### **I. Collaboration**

Collaboration is a process where two or more people or organizations work together in an intersection of common goals by sharing knowledge, learning and building consensus. It requires an understanding of the goal, clearly defined rules of engagement, an understanding of available resources, a means to manage resources, a means to keep track of progress towards the goal and voluntary participation.

Creating Collaboration needs a more purposeful starting point. It requires a problem or a potential and a desire to deal with it. In brief, key steps in forging and completing collaborations include:

1. **Define the challenge:** If collaborations are to be set in a result framework, they need some kind of achievement point or target.
2. **Define the collaborators:** Arrange teams and units are defined in terms of building to differences rather than similarities.
3. **Create the space and time commitment:** Getting ideas and input or agreement and buy-in to collaboration and step to action.
4. **Harness the result:** disseminate collaborative results.

### **II. Coordination**

Coordination is a decomposition of a problem into smaller problems (tasks), the distribution of these tasks to workers, the completion of the tasks, the integration of results, and the confirmation of desired results. DTC cannot undertake all tasks required by it-self.

Consequently, it has to organize relevant people/ groups to share tasks. This can be done by giving assignment to individuals, forming sub-committees from different units/departments.

Areas of coordination includes

- Engagement of relevant departments either as member of DTC or available for consultation to assist decision making.
- Mobilize relevant stakeholders to review significant preventable ADEs (chapter8)
- Facilitation of regular educational program for staff and patients
- Organize on the job trainings with other stakeholders
- Organize impact and outcome indicators assessments on quality of care and adherence to documented policies.
- Organize meetings with DTC members of other facilities, so as to promote experience sharing

### **III. Communication**

Communication is a means of or the act of exchanging information how persons understand each other and how information (policies, prospects, findings, reports and all other human experiences) is transferred in organizations. The information that DTC is expected to communicate includes

- Introducing medicine DTC guidelines, list, formulary, manual
- Disseminating endorsed policies and procedures related to selection, prescribing, procurement, storage, distribution, administration, safety procedures, monitoring and use.
- Familiarizing findings of drug utilization reviews, drug administration, investigational drug studies,
- Educational materials for provision of objective information on drug use
- Cases of poor treatment outcome due to suspected antibiotic resistant microorganisms
- DTC performance reports to the applicable offices regularly and consistently
- Any DTC information that is appropriate for clinical and economic decision.

Proper recording and documentation are integral activities in the process communicating DTC related information that is needed in any form. In order to come up with the right, unbiased

decision, any DTC related information, minutes, studies and assessments, etc. should be kept in a way that they are complete so as to serve as a base to take further action.

Regular Reporting DTC activities via standard formats, to the applicable stakeholders, can be input to augment the health system courses of action as a whole. Well-functioning reporting systems enable to:

- Collect and analyze important information about the services provided,
- Improve readiness to challenges and limitations encountered,
- Improve quality of service being provided,
- Share the lessons learned with others health facilities
- Decide future support.

#### ***Summary***

- *Effective coordination, collaboration and communication are the main contributing factors for the success of DTC.*
- *Standardized and consistent way of reporting DTC activities is mandatory to make the data more valuable for the facility and the overall health system at large.*



## Chapter Twelve: Monitoring and Evaluation of DTC Performance

**Allocated Time:** 90 minutes

**Chapter Description:** This chapter discusses on monitoring and evaluation of DTC activities.

**Primary Objective:** At the end of this chapter participants will be able to monitor and evaluate DTC activities at health facilities.

**Enabling Objectives:** By the end of this chapter, participants will be able to:

- Describe monitoring and evaluation as applied to DTC performance
- Identify indicators for monitoring and evaluating the performance of DTC
- Identify tools to assess DTC performances

This chapter has the following outlines:

### Chapter Outline:

- Introduction
- Criteria for functional DTC
- Checklists to assess DTC performances
- Summary

## 12.1. Introduction

### Activity 12: Probing Questions



- What is Monitoring?
- What is Evaluation?
- What is the difference between monitoring and evaluation?
- What is the importance of monitoring and evaluation?

**Monitoring:** The routine process of data collection (monthly, quarterly, annually) intended to measure whether the DTC is doing what is set out to do.

**Evaluation:** The systematic investigations carried out periodically to check whether the activities implemented are having the desired effect.

The key distinction between the two is that evaluations are done independently to provide managers and staff with an objective assessment of whether or not they are on track. They are also more rigorous in their procedures, design and methodology, and generally involve more extensive analysis.

Monitoring and evaluation help improve performance and achieve results. The overall purpose of monitoring and evaluation is the measurement and assessment of performance in order to more effectively manage the outcomes and outputs. Many health facilities have DTC, but most of them are not effective in improving the use of medicines. Therefore, monitoring and evaluation is critical for the success of DTC activities. Monitoring and evaluation helps to:

- Monitor progress in the implementation of DTC plans;
- Identify the strengths and weaknesses of the DTC
- Identify problems hindering DTC activities you had not anticipated
- Identify and implement solutions to those problems as quickly as possible
- Evaluate performance objectively; and
- Revise strategies and plans based on evidence

DTC performance should be monitored and evaluated by the DTC itself as well as by the health facility management and higher levels as part of the national/regional health system M & E. It is

the joint responsibility of the health facility management and the DTC to apply the feedbacks provided when external monitoring and evaluations are undertaken. The performance evaluation should be based on the agreed upon goals, objectives and action plans of the DTC.

## 12.2. Criteria for DTC functionality

DTC functionality at health facilities serves as a proxy indicator of the ability of a health facility to engage mix of health care providers and departments to meet the health facility needs with a full range of products and services and their rational utilization.

*Table 10: Criteria for functional DTC*

DTC functionality criteria				
S.N	Criteria (weight in %)	Availability		
		Yes (1)	No (0)	Weight (%)
1	Assigned DTC members by official letter (10)			
2	Has approved TOR (10)			
3	Meets regularly at least every months with documented minute (10)			
4	Has developed action plan (10)			
5	Has updated health facility specific medicine and medical devices list (15)			
6	Has medicine use policy and procedures (at least two policies (10)			
7	Conduct supply and medicine use problem studies (10)			
8	Take actions based on the supply and medicine use study findings (15)			
9	Report its performance activities to the management (10)			
DTC functionality (%)				
Functionality of DTC ( $\geq 75\%$ ) (If yes 1, If no 0)				

A health facility is considered as having functional DTC if it scores 80%

### 12.3. DTC Monitoring and Evaluation Checklist

The purpose of these checks lists for DTCs is to monitor and evaluate the functionality of DTCs in the health facilities. This will provide DTCs support in achieving effective medicines management governance and promote rational medicine uses. Improvements in the values of the indicators are expected in subsequent assessments in health facilities with functioning DTC.

This monitoring and evaluation check list will be used by health facility's DTC and higher organizations like WoHO/ Zone/RHB/MOH to monitor and evaluate DTC activities. The monitoring and evaluation can be taken at a specified period of time (monthly, quarterly or annually). In the case of health facility, members of the DTC or an adhoc committee established by DTC can undertake monitoring and evaluation. For the higher organizations like WoHO, Zone, RHB or MOH, the monitoring and evaluation can be done as part of their routine work plan accomplishment. Detailed checklist are presented on the attached annex

#### *Summary*

- *Monitoring and Evaluation of DTC activities are require to measure whether the DTC is doing what is set out to do and to check whether the DTC activities implemented are having the desired effect*
- *Facility themselves or higher organizations like WoHO/ Zone/RHB/MOH can take monitoring and evaluation on DTC activities*
- *Indicators and check lists are used to monitor and evaluate DTC activities*

## Chapter Thirteen: Getting Started

**Allocated Time:** 85 minutes

**Chapter Description:** This chapter discusses on steps to establish, revitalize and action plan preparation of DTC.

**Primary Objective:** By the end of this chapter, the health facility will be able to establish, revitalize DTC and prepare action plan at health facilities.

**Enabling Objectives:** By the end of this chapter, participants will be able to:

- Discuss the steps of starting a DTC where none exists
- Discuss the steps of revitalizing DTC
- Prepare draft action plan to establish or revitalized DTC

### Chapter Outline:


- Introduction
- Stepwise approach to establish DTC
- Planning to establish/revitalize DTC
- Summary

### 13.1. Introduction

The Ethiopian hospitals service and transformation guidelines (EHSTG), health centers reform implementation guidelines (EHCRIG) and the minimum regulatory standard considers DTC as compulsory requirement. However, health facilities either do not established DTC or where exist they are not functional .The way to get started will depend on context in the health care facilities. This could be a good beginning to initiate the establishment of DTC at health facilities.

### 13.2. Stepwise approach to establish DTC

#### 13.1.1. A stepwise approach to establish a new DTC

Activity 13.1: Reflection points on steps in establishing DTC	
	What steps will you follow to establish DTC at your health facility? <b>Time: 3 min</b>

Steps stated below are formulated in such a way the initiative in establishing DTC.


*Table 11: Stepwise approach to establishing drug and therapeutic committee*

Steps	Activity	Approach
<b>Step 1:</b>	Identify the existing problem.	<ul style="list-style-type: none"> <li>• Collect information to show the needs for DTC, and the existing situation in the health facility.</li> <li>• Using the guidelines and standards as reference for the establishment of DTC.</li> </ul>
<b>Steps2:</b>	Organize management meeting	<ul style="list-style-type: none"> <li>• This can be done by personnel trained on DTC or any other individual who took the responsibility to support DTC activities.</li> </ul>
<b>Step 3:</b>	Relevant staffs orientation	<ul style="list-style-type: none"> <li>• Organize orientation for department heads and other relevant staff.</li> <li>• The DTC SOP manual and the materials collected from this training can be used as a main reference for the orientation.</li> </ul>
<b>Step 4:</b>	Assign DTC chair person, secretary and members	<ul style="list-style-type: none"> <li>• The management will assign with official letter</li> </ul>

<b>Step 5:</b>	Conduct first DTC meeting	The first meeting agendas include : <ul style="list-style-type: none"> <li>• TOR approval and action plan development.</li> <li>• Present and discuss on the draft action plan and TOR (See Annex 13 Sample TOR).</li> <li>• Meetings should continue at least every one month and there may be additional meetings if it is found necessary (there should be at least 12 meetings in year). Minutes for every meeting should be recorded and documented</li> </ul>
<b>Step 6:</b>	Orient staff	<ul style="list-style-type: none"> <li>• Sensitize all staffs on established DTC, approved TOR and action plan.</li> </ul>

### 13.1.2. A Stepwise approach in revitalizing DTC

When the established Drug and therapeutic committee don't function properly revitalizing the service provision is the main remedy as soon as possible. Steps to be followed in the process of revitalizing poorly functioning DTC are listed below.

<b>Activity 13.2: Reflection points on steps is revitalizing non- functioning DTC</b>	
	<p>What steps will you follow to revitalize non-function DTC at your health facility</p> <p><b>Time: 3 min</b></p>


*Table 12: Stepwise approach in revitalizing Drug and Therapeutic Committee*

<b>Step</b>	<b>Activates</b>	<b>Approach</b>
<b>Step 1:</b>	Identify possible causes	<ul style="list-style-type: none"> <li>• Lack of awareness of medicine use problems and what a DTC could do to address medicine use problems.</li> <li>• Lack of time for members to undertake any DTC activities.</li> <li>• Lack of commitment of DTC members.</li> <li>• Lack of support from health facility management.</li> <li>• High work burden among staff.</li> </ul>
<b>Step2:</b>	Prioritization	<ul style="list-style-type: none"> <li>• Using appropriate technique to Identified problems and understand the root causes: it can help to know the root causes which will lead to the solution.</li> </ul>
<b>Step3:</b>	Prepare the draft plan	<ul style="list-style-type: none"> <li>• The draft plan of revitalization should be based on the problems identified and prioritized</li> </ul>

		(Annex 14 planning template)
<b>Step 4:</b>	Communicate and discussion	<ul style="list-style-type: none"> <li>Communicated and discussed with the health facilities management to approve the plan of revitalization and support the process.</li> </ul>
<b>Step5:</b>	Revitalization	<ul style="list-style-type: none"> <li>Based on the approved plan of revitalization: Start the revitalization by providing orientation to the DTC members.</li> </ul>

### 13.3. Plan to establish/revitalizing Drug and therapeutic committee

The action plan should be guide to establishment and revitalization of DTC should be depending on context in the health care facilities (See annex14).

<b>Activity 13.3: Group Exercise on Planning</b>	
	<p>Prepare draft plan of action to establish or revitalize DTC at your facility. Use the planning template annexed.</p> <p><b>Time: 30 min</b></p>

### *Summary*

- Preparing action plan to establish or revitalize DTC should include: measuring the problem quantitatively, investigating the problem qualitatively to understand underlying reasons for the problem, developing and implementing an intervention to correct the problem, measuring the drug use problem again in order to evaluate the intervention.*
- Getting a DTC started or making it functional will require a strategy based on: Political and administrative support, local conditions, local data, starting small and then scaling up, handling a problem that can easily be addressed.*



# **ANNEXES**

## **Annex 4: Proper Medicines Storage Policy and Procedures, Sample**

### **Policy**

For patients get the full benefits of medicines and to ensure that each medicine that are intended to be used are of acceptable safety, quality and efficacy; medicines should be stored in the highest possible storage condition by the facility. Furthermore, the medicines are to be stored in a secure and orderly manner and are to be accessible only to licensed pharmacy personnel and other professionals.

### **Procedures**

To ensure all usable medicines are of appropriate safety, quality and efficacy; the following procedures should be followed by the pharmacy store at all times:

1. Each health professional, working in a pharmacy store, should have a procedure in place to assure that all usable medications have not expired and are in a good condition to be dispensed.
  - The expiration date of all medications should be checked, monthly. To assure this process has been followed, supervisor's initials and date will be indicated in bin cards.
  - Visual inspections should be done, monthly.
2. All medicines that are stored in pharmacy store should have proper labeling and should be stored according to the manufacturer's recommendation.
  - The labeling will include the following:
    - Name of drug,
    - Strength,
    - Expiration date
    - Quantity per package
    - Storage information such as the temperature and light requirements
3. Medicines should be stored in such a way that they should facilitate FEFO procedures and stock management.
4. Drugs are accessible only to authorized personnel and are to be maintained in a secure manner.

5. Usable medicines, non-usable medicines and other non-medical items should be stored separately.
6. All controlled drugs are to be stored in a securely locked cabinet. Current inventory is to be maintained on each controlled substance.
7. Storeroom should be kept Clean at all times
8. Fire safety equipment should be available, accessible, and functional at all times and employees should be trained on to use it.
9. Cartons should be stacked at least 10 cm off the floor, 30 cm away from the wall and no more than 2.5m high with arrows pointing up.
10. Flammable products should be stored separately from other products.

**Annex 6.1: Prescribing Indicator Form**

S/ N	# of Medicines	# of Generics	Antibiotics 0/1*	Injections 0/1*	# on Facility List	Diagnosis (Opt)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						
36						
37						
38						
Tot al						
Avg						
%						

**Remember:** 0 = No; 1 = Yes

**Annex 6.2: Prescriptions consolidation form (validity of prescriptions)**

Rx code	Prescription	Responses on review of validity of Prescriptions																			
		Patient related information								Medicine related information				Prescriber's related information			Dispenser's related information				
	Std	Date of Rx	Card no	Name of pt	Age	Sex	Ad	Wt	Dx	Name of medicine	Dose	Frequency	Route of adm	Duration/qty	Name	Profession	Signature	Name	Profession	Signature	
1																					
2																					
3																					
4																					
5																					
6																					
7																					
8																					
9																					
10																					
11																					
12																					
13																					
14																					
15																					
16																					
30																					
Total																					
Average																					
%																					

**Annex 6.3 Patient Care Indicators Forms**

**A. Adequate labelling and patient Knowledge**

Patient identifier (code/#) \_\_\_\_\_; No of drugs prescribed \_\_\_\_\_; No. of drugs dispensed \_\_\_\_\_

Age \_\_\_\_\_; Sex \_\_\_\_\_; Educational status \_\_\_\_\_

Name of Health Facility: \_\_\_\_\_

<b>Adequate labelling</b>							<b>Patient knowledge</b>			
Indicate response as ✓(yes) or x(No)							Indicate response as ✓(yes) or x(No)			
S/N	Name of dispensed drug	Strength	Dose	Freq.	Amount of drug/Duration	Overall result	Dose	Freq.	Duration/R eason for prescription	Overall result
1										
2										
3										

.....

Patient identifier (code/#) \_\_\_\_\_; No of drugs prescribed \_\_\_\_\_; No. of drugs dispensed \_\_\_\_\_

Age \_\_\_\_\_; Sex \_\_\_\_\_; Educational status \_\_\_\_\_

Name of Health Facility: \_\_\_\_\_

<b>Adequate labelling</b>							<b>Patient knowledge</b>			
Indicate response as ✓(yes) or x(No)							Indicate response as ✓(yes) or x(No)			
S/N	Name of dispensed drug	Strength	Dose	Freq.	Amount of drug/Duration	Overall result	Dose	Freq.	Duration/Reason for prescription	Overall result
1										
2										
3										

**B. Dispensing time and dispensing counselling time**

Name of Health Facility: \_\_\_\_\_

S/N	Dispensing time* (Minutes)	Dispensing counselling time ** (Seconds)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
<b>Total</b>		
<b>Average</b>		

\*Dispensing time is the time between presenting of prescriptions to the pharmacy personnel and collecting of drugs

\*\* Dispensing counselling time is the time the pharmacy personnel spends in counselling the patient about the dispensed medicines

**Annex 6.4: MUE Criteria Form For:** \_\_\_\_\_

Patient number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21		
Data collector's initials																							
Patient chart number																							
Diagnosis																							
Age																							
Sex																							
Weight																							
Date treated																							
<b>Criteria (indicators)</b>																							
<b>Indications</b>	Threshold	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Average	
1.																							
2.																							
3.																							
4.																							
5.																							
6.																							
<b>Doses</b>	Threshold	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Average	
1.																							
2.																							
3.																							
4.																							
5.																							
6.																							



<b>Duration</b>	Threshold	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Average	
1.																								
2.																								
3.																								
4.																								
5.																								
6.																								
<b>Drug Interactions</b>	Threshold	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Average
1.																								
2.																								
3.																								
4.																								
5.																								
6.																								
<b>Contraindications</b>	Threshold	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Average
1.																								
2.																								
3.																								
4.																								
5.																								
6.																								
Y/N = yes/no																								

**Annex 6.5: Standard Prescription Paper**

\_\_\_\_\_ Hospital: Tel +251 -----

**PRESCRIPTION PAPER**

Patient's full Name: \_\_\_\_\_

Sex: \_\_\_\_\_ Age: \_\_\_\_\_ Weight: \_\_\_\_\_ Card No. \_\_\_\_\_

Region: \_\_\_\_\_ Town \_\_\_\_\_ Woreda \_\_\_\_\_ Kebele \_\_\_\_\_

House No. \_\_\_\_\_ Tel. No: \_\_\_\_\_  Inpatient  Outpatient

Diagnosis, if not ICD \_\_\_\_\_

**Rx**

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 \_\_\_\_\_

\_\_\_\_\_

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:**

- Medicine 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 or 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
- Medicines should be dispensed with appropriate information and counselling
- Keep filled prescriptions at least for 2 years

### **4. Minimum medicine 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 6.6: Follow up questions on specific indicators

### 1. Average number of medicines per encounter

<p><b>High number of medicines per encounter:</b></p> <p>Are there shortages of therapeutically correct drugs? Do prescribers lack therapeutic training or appropriate diagnostic equipment? How secure are prescribers in their ability to diagnose and treat the common illnesses? How strongly do prescribers feel that patient demand influences their practice, and do observations of clinical encounters support this? Are there financial incentives to encourage polypharmacy?</p>	<p><b>Low number of medicines per encounter:</b></p> <p>Are there absolute constraints in the drug supply system such that very few drugs tend to be available? Are there administrative regulations that limit the number of drugs that can be prescribed?</p> <p>Do prescribers have appropriate training in therapeutics? Is there significant drug “leakage” from the system?</p>
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### 2. Percentage of medicines prescribed by generic name

<p><b>Supply factors:</b></p> <p>Are predominantly generic or branded forms of drugs available in health facilities? How closely have brand names of products been chosen to model their generic name? Are drugs supplied in bulk containers and labelled at the facility, and how are the names written on the labels? Are branded products being prescribed which are not available in health facilities?</p>	<p><b>Prescriber factors:</b></p> <p>Do prescribers know the correct generic names for most drugs? How often are prescribers visited by pharmaceutical representatives, and what kind of promotional material is left for them to use? Does the training of the prescribers affect their willingness to prescribe generically?</p>	<p><b>Health problem factors:</b></p> <p>Which classes of drugs seem to be particularly problematic? Are there certain common health problems for which a generic form of treatment is not supplied in the system?</p>
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### 3. Percentage of encounters with an antibiotic prescribed

<p><b>Specifics of antibiotic prescribing:</b></p> <p>What types of antibiotics and which modes of delivery (injections, tablets, syrups) are most commonly prescribed? What is the relative use of narrow vs. broad spectrum antibiotics? What proportion of antibiotic</p>	<p><b>Possible influences on antibiotic prescribing:</b></p> <p>What are the cultural beliefs in the community about antibiotics, and are patient expectations of receiving certain types of antibiotic very high? How strongly are particular antibiotics marketed? Are some antibiotics distributed in the system more than would be indicated by local morbidity patterns? How effective is the drug quality assurance system, and do prescribers have</p>	<p><b>Impact of antibiotic use:</b></p> <p>What are the local resistance patterns to commonly-used antibiotics? How often are particular organisms treated with drugs to which they are</p>
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<p>prescribing is represented by dermatological products, by ophthalmologic products? How much do antibiotics cost, as a percentage of all prescribing or for particularly expensive forms of antibiotic?</p>	<p>faith that the drugs they are prescribing contain the appropriate therapeutic amounts? Are laboratory facilities necessary for differential diagnosis available and used by prescribers?</p>	<p>likely to be resistant, for example, in specific sexually-transmitted diseases?</p>
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#### 4. Percentage injections

<p><i>Specifics of injection use:</i> What are the specific health problems for which injections are given? Are injections given more often to adults or children treated for these conditions? What is the availability of syrups and mixtures as alternative modes of therapy for small children?</p>	<p><i>Possible influences on injection use:</i> What are the beliefs and attitudes of patients and health providers about the relative efficacy of injections versus oral medications? Do prescribers report patient demand as an important factor in determining injection use, and do observations of clinical encounters support this? What is the availability of injections outside the public health facility, and is competition with the private injectionists for patient loyalty an important factor? Do patients bring their own needles or syringes? Is there a financial incentive for a health worker to give an injected rather than an oral form of medication?</p>	<p><i>Impact of overuse of injections:</i> Are appropriate sterilizing units available in health facilities, and are they being used appropriately? What is the local prevalence of HIV and hepatitis-B infections, and is there evidence that lack of sterile technique is a possible source of these blood-borne infections? What are the cost implications of injection use, comparing oral and injected alternatives for the same health problem?</p>
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#### 5. Percentage of medicines prescribed from health facility specific drugs list

<p><i>Specifics of prescribing:</i> What are the most common drugs being prescribed that are not on the list or formulary? Which health problems are these drugs intended to treat? Are the drugs being prescribed from outside the list generic products or branded products? What is the value of non-EDL drugs compared to EDL drugs?</p>	<p><i>Supply factors:</i> Is there an adequate supply of the drugs on the essential drugs list or formulary? Who makes decisions about which drugs are ordered for the health facility? Are the forms used for drug orders based on the essential drugs list or formulary, or are they developed from lists of previously-consumed drugs?</p>	<p><i>Characteristics of the list:</i> How does the essential drugs list or formulary compare to other standard lists of this type, in terms of organization and number of products listed? Do prescribers know about the existence of the list, and which drugs are contained on the list? What efforts have been made to disseminate appropriate unbiased drug information linked to the list or formulary? What is the attitude of prescribers towards the essential drugs list or formulary and its role in the health system?</p>
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6. Average consultation time

<p><i>Health facility aspects:</i> What is the physical organization of the clinic, and is there appropriate allowance for privacy and confidentiality? What is the average workload of health staff, and does the volume of clinic visits allow time for appropriate interactions with patients? What is the volume of patient attendances at different times, during the course of the work day and by week? Could chronic disease patients be scheduled at times when the workload is less?</p>	<p><i>Prescriber factors:</i> Do the training programmes for various categories of health workers include training in effective communication? Do health workers see communication as an important aspect of their work role? Are there important socioeconomic, ethnic, or status differences between health workers and their patients?</p>	<p><i>Characteristics of patient-provider interactions:</i> What actually takes place during the clinical encounter between a patient and a health worker? What is the quality of this interaction in terms of effective communication about illness, explanation about illnesses and drugs, and nonverbal expressions of empathy? Are patients and health workers satisfied with what takes place during clinical encounters? Do their expectations about what should take place differ, for example, do patients expect to be more thoroughly examined than providers feel is necessary?</p>
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7. Average dispensing time

<p><i>Health facility aspects:</i> What is the layout of the dispensary, and does it allow for private pharmacist-patient interactions? What is the workload of dispensers, and do they have sufficient time to explain medications to patients? Are dispensing supplies available? What impact does drug supply have on the dispensing process, in terms of the availability of products, how efficiently they are stored, and whether appropriate hygienic techniques are followed? How is decision-making organized within the dispensary, in regard to product substitution, the number of days' supply dispensed, and so forth? What is the impact of patient fees for drugs on the type and quantity of drugs that are dispensed?</p>	<p><i>Dispenser's background:</i> What is the average level of training of personnel working in the dispensary? Have they been appropriately trained in educating patients about drugs? What is the understanding of dispensary personnel about their responsibilities, and do they feel it includes patient education? Do dispensers ask patients to repeat how they will take the drugs?</p>	<p><i>Characteristics of patient-dispenser interactions:</i> What is the quality of the interaction between dispensers and patients? Is there communication about the purpose for individual drugs, how they should be taken, and possible side effects? Are dispensers and patients satisfied with their interaction? What is the patient's understanding of the dispenser's role? Do patients expect to learn more from dispensers about drugs?</p>
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8. *Percentage of medicines actually dispensed*

<p><i>Differences between prescribed and dispensed medicines:</i> Are there certain types of medicines that are routinely prescribed, yet not dispensed? Is the problem more common for specific therapeutic classes or medicines to treat particular illnesses? Are medicines not being dispensed even when they are available in health facility stores? Are medicines which are not dispensed available in the local community? What are the reasons why pharmacists did not dispense the medicines as they were prescribed? Are there rules laid down for what they will dispense?</p>	<p><i>Patient attitudes:</i> Do patients plan to purchase the medicines that were not dispensed at the health facility? If they do not plan to purchase them, is it because they cannot afford to pay for them, or because they do not think the medicines are important? If they plan to purchase only a proportion of the drugs prescribed, how do they prioritize? What do patients understand are the reasons for products not being given in the amounts they were prescribed, or are they even aware that this was the case?</p>
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9. *Percentage of drugs adequately labelled*

<p><i>Specify inadequate labeling:</i> What element of appropriate labeling is missing: the name of the patient, the correct generic name of the drug, or the drug strength? Is the information written legibly? Is information on how the drug is to be taken also written on the label, using terminology that patients are likely to understand? Is the information on dosage correct according to the standard for this drug?</p>	<p><i>Reasons for inadequate labeling:</i> Are dispensers adequately trained in how drugs are to be packaged and labeled? Are there adequate packaging materials available at health facilities? Do dispensers have time, given their typical workload, to package and label drugs appropriately? Are procedures adequately supervised by pharmacy and medical personnel?</p>
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10. *Patients' knowledge of correct dosage*

<p><i>Patient-provider communication:</i> Is the physical layout of the clinic (examination and dispensing areas) conducive to communication about health problems and drugs? How do different health workers (physicians, nurses, pharmacy attendants) describe their role in communicating about drugs, and how often do they perform the functions they describe? What is the typical content of communication about pharmaceuticals: what drugs do, how they should be taken, possible side effects and precautions, relative importance of different products, and so forth? Is information about drugs offered voluntarily by health workers, or do they depend on patients to ask specific questions? Do patients ask questions?</p>	<p><i>Patient understanding and compliance:</i> What do patients actually understand about the drugs they have received: what drugs do, how they should be taken, side effects, and so forth? How does patient understanding compare with the information communicated during clinical and dispensing encounters? What are the sources of misunderstanding about drugs: lack of correct information, cultural or language differences between patients and providers, lack of patient interest, or other factors? Do patients leaving health facilities intend to comply with recommendations about drugs? What are the reasons for expected or actual noncompliance with recommended drug therapies?</p>
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*11. Availability of copy of essential drugs list or formulary*

<p><i>Characteristics of the list or formulary:</i> Which products are included on the drugs list or formulary? How does the list compare with WHO recommendations? Does the same list apply to different levels of care, or are only subsets of drugs recommended at lower levels? Does the list or formulary contain descriptive information about drugs or therapeutic guidelines? What efforts have been made to disseminate the essential drugs list or formulary to individual prescribers? Is the formulary or EDL clean with unbroken binding, or dirty indicating that it has been used?</p>	<p><i>Prescriber attitudes:</i> How do prescribers describe the purpose of the essential drugs list? Are they generally aware of which drugs are on the list? Do health personnel responsible for drug procurement at individual facilities consult the list when making purchase decisions? Do prescribers recommend similar types of therapy in both their public sector and private sector practices? Do prescribers think they could affect the next list?</p>
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*12. Availability of key medicines*

<p><i>Supply system:</i> Are there particular classes of medicines or particular dose forms (for example, pediatric syrups) which are more likely to be out of stock? Does the incidence of the stock-outs tend to vary seasonally with the drug procurement cycle? Once products go out of stock, how long do they tend to remain out of stock? What is the system for informing prescribers about pharmacy stock-outs, and are there procedures for therapeutic substitution by pharmacists or dispensers?</p>	<p><i>Focus on key drugs:</i> Are there particular health problems for which drugs tend to go out of stock on a regular basis, for example, malaria or tuberculosis? Are there therapeutic alternatives in stock for the drugs which are found to be out of stock? Do prescribers respond to the absence of a drug by continuing to prescribe it and expecting patients to purchase the product in the private sector, or by switching to a therapeutic alternative?</p>
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### **Annex 8.1: Monitoring Medicine Safety and Quality: Case for ADE reporting**

Ato Ahmed Tasew is 48 years old known hypertensive patient (card number 23076) went for a follow up to **AB** hospital found in Addis Ababa, woreda 09 kebele 14 on 14/6/2008E.C. While the healthcare provider (S/r Zewde) was measuring his BP it is found 185/120 mmHg. Ato Ahmed smokes half a pack of Nyala Cigarettes a day. Ato Ahmed was admitted to emergency room for 12 hours and prescribed ABC brand of Hydralazine 20mg/ml injection to be given 5mg every 20 minutes until BP drops and XYZ brand of Furosemide 10mg/ml in 2ml injection; 20mg dose daily for three days. The nurse gives the two medications as prescribed. Ato Ahmed gets improvement and discharged after 12 hours of stay in emergency room. On the next day, Ato Ahmed comes to the hospital with complains of red, swollen skin on his legs and becomes very sick and was admitted to medical ward in AB Hospital. Hydralazine 20 mg/ml injection was produced by Parma lab firm **Q** with batch number of ABA612CXF and expiry date of 29/2/2018 and XYZ which produced by pharma firm **Z** with batch number of AA1012AXA and expiry date of 31/7/2018. Next morning when the duty healthcare provider was about to give Furosemide she found out it was cloudy. The nurse decided to stop the Furosemide medication temporarily and the swelling subsides after five days and he become stable of discontinuation of medication. Assume you were the healthcare provider, how would you report Ato Ahmed`s case?

**Annex 8.2: 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-----				
<b>Information on suspected drug/vaccine      S=suspected drug      C=concomitantly used drugs</b>						
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)
<b>Adverse drug event description(include all available laboratory test results)</b>						
Reaction necessitated			Reaction subside after D/C of suspected drug			
Discontinuation of drug/s <input type="checkbox"/> YES <input type="checkbox"/> No			<input type="checkbox"/> YES <input type="checkbox"/> No <input type="checkbox"/> Information not available			
Hospitalization prolonged <input type="checkbox"/> YES <input type="checkbox"/> No			Reaction reappear after restart of suspected drug			
			<input type="checkbox"/> YES <input type="checkbox"/> No <input type="checkbox"/> Information not available			
Treatment of reaction						
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 Sequelae						

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

Reported by: Name		Profession:		Email address:		Telephone	
-----		-----		-----		-----	
Name of health institution						Date	
<b>Product quality problem:</b> 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

□□□□□ □□□ □□ □□□

**what to report**

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

**NB. Drugs includes**

- Conventional drugs
- Herbal drugs
- Traditional medicines
- Biologicals
- Medical supplies
- Medicated cosmetics

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

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Reply Service License No HQ2 -----  
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Postage prepaid

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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 12: DTC Monitoring and Evaluation Checklist

SCOPE and FUNCTIONS		Yes	No	Comment
General	Has the DTC assigned chairman, secretary and members with official letter?			
	Is the membership of the DTC multidisciplinary? (include representatives across a range of disciplines, which have expertise and skills to reflect the functions of the DTC? e.g. medical, nursing and pharmacy...etc)			
	Does the DTC have approved TOR			
	Is the authority and accountability for decision-making clearly defined in the TOR?			
	Are the terms of reference and membership regularly reviewed to reflect organizational or functional changes?			
	Is there mechanism to hand over DTC activities when chairman, secretary or members leave membership?			
	Does the DTC develop plan of action for the current year			
	Is there regular DTC meeting with a minimum frequency of every months			
	Is there minutes recorded and documented for each meetings undertaken			
Developing policies and procedures to manage medicines	Has the DTC developed procurement policy			
	If yes, has the procurement policy approved by the management?			
	Does the facility procure as per the developed procurement policy			
	Has the DTC developed AMR prevention and containment Policy			
	Has the DTC developed policy to monitor medicines promotion within the health facility?			
Developing	Has the DTC developed facility specific drug list?			

and maintaining the health facility's medicine and medical device list	If yes, is the list	Classified by VEN?			
		Coded with APTS code?			
		Update within two year's period?			
		Include medical supplies			
	Does the list distributed to relevant departments (all prescribing units, pharmacy, laboratory etc.)				
	Does the list in use during quantification and procurement?				
	If yes, are all the drugs purchased within one year's period from the list only?				
Identifying medicine supply and use problems	Does the DTC undertake assessments with respect to medicines use?	Aggregate methods of study (ABC/VEN)			
		Indicator studies			
		MUE			
	Does the DTC assess availability of tracer medicines in the facility				
	Others _____				
Designing intervention strategies to improve medicine related issues	When problems are identified, are -----	strategies identified			
		If yes, mention:			
		Recommendations made to mitigate that problem?			
		Implantations followed or applied?			
	Does the facility use standard prescription paper?				
	Does the DTC support DIS provision?				
Promoting the monitoring and management of ADEs	Does the DTC have strategy to promote monitoring and management of ADEs?				
	Does the DTC monitor reporting of ADEs to FMHACA?				
	Number of ADE report to FDA _____ and Reported to DTC _____ during the last one year				
Promoting prevention	Has the DTC established antimicrobial stewardship program (ASP) in the facility?				

and containment of AMR	If yes, does DTC take report from ASP?					
	Does DTC discuss on strategies to mitigate the problem					
Monitoring medicine procurement and inventory management	Does the DTC involve in annual budget allocation for medicines?					
	Does the DTC reviewed quantification done for medicines and supplies?					
	Does the DTC endorsed procurement lists prepared and get feedback?					
	Does the DTC monitor inventory management?					
	If yes,	Is there stock transfer procedures agreed by DTC?				
		Does the DTC discuss on stock status?				
		percentage of wastage for the recent three years year1 _____ year2 _____ year3 _____				
	Is there a mechanism to manage specific tasks and projects, as required? I.e. have any task forces been established and managed specific tasks?					
	Does the DTC report its activities to the management at least quarterly?					
	Does the DTC conduct forum with the health facility management and/or staff to discuss on medicine use related issues at least annually?					
Monitoring and evaluation	Has the DTC follow the implementation of STGs in the facility?					
	Has the health facility management evaluated the performance of the DTC during the last one year?					
	Does the DTC evaluate their current practice and progresses using the check list?					

### **Annex 13: Contents of a DTC Term of Reference (TOR)**

- A mission statement
- Objectives
- Scope and what is outside the scope
- Reporting structure/organizational chart/governance structure within the health facility
- 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 and Ad hoc committees
- Process for approval and endorsement of TOR
- Review timeframe for TOR



**Annex 14: Planning and Reporting Template for Establishing/Revitalizing DTCs**

**Name of Hospital:**-----**Region:**-----**Zone:**-----

**Telephone:**----- **Fax:**-----**Email address:**-----

**EFY:**-----

S.N	Process Indicator or Milestones	Objective	Implementation Time												Responsible person	Collaborators	Resource Needed	Implementation status • Fully achieved • Partially achieved • on progress • not started • cancelled	Brief description of Results achieved	Brief description of challenges faced	Way forward/recommendations
			J	F	M	A	M	J	J	A	S	N	O	D							
Activity 1:	Establishing DTC																				
Activity 2:	Develop specific drug list																				
	Revitalize DTC																				