2018



Reproductive, Maternal, Neonatal and Child Health Program Overview and Pharmaceuticals Management Training for Pharmacy Professionals

# **Participant Manual**



Ministry of Health, Ethiopia September, 2018

# Reproductive, Maternal, Neonatal and Child Health Program Overview and Pharmaceuticals Management Training for Pharmacy Professionals

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Ministry of Health, Ethiopia September, 2018 Foreword

The Federal Ministry of Health (FMOH) has been coordinating sector wide reforms that aim to

improve equity and quality of maternal and child health services. As part of these efforts, the

ministry is also exerting concerted efforts to improve availability and use of quality RMNCH

pharmaceuticals. Management of RMNCH pharmaceuticals has had significant challenges such

as poor availability of essential pharmaceuticals and wastages of valuable resources as pharmacy

professionals were not demonstrating the required knowledge, skill and attitude towards availing

the pharmaceuticals and ensuring their rational medicine use.

Even though there have been numerous capacity-building activities aimed at improving the

knowledge, skills, and attitude of pharmacy professionals, none of them were aimed towards

RMNCH pharmaceuticals. To alleviate this problem, FMOH has been leading efforts to prepare

a standard training material intended to build the capacity of pharmacy professionals in the

management of RMNCH pharmaceuticals. The Reproductive, Maternal, Neonatal and Child

Health Program Overview and Pharmaceuticals Management Training for Pharmacy

Professionals training program will contribute to the availability and rational use of RMNCH

pharmaceuticals. It will also be used as reference material for professionals working in these

areas and as a teaching aid for colleges.

I would like to take this opportunity to thank all who participated in the development of this

training manual. I would also like to encourage users of the Manual to send their comments

regarding the manual to the Ministry via website: http://www.moh.gov.et or P.O.Box 1234,

Addis Ababa, Ethiopia.

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# Acknowledgement

The Federal Ministry of Health (FMOH) would like to express its gratitude to the United States Agency for International Development (USAID) **USAID Global Health Supply Chain Program-Procurement and Supply Management** (GHSC-PSM) and Clinton Health Access Initiative (CHAI) projects in Ethiopia for their comprehensive support provided on the development of this training curriculum. FMOH would also like to acknowledge UNFPA, CIRHT, R4D, JSI/AIDS Free, JHPIEGO and Transform Primary Health Care (TPHC) projects for their significant technical support throughout the process. The manual was designed and developed by a team of experts drawn from the Pharmaceuticals and Medical Equipment Management Directorate (PMED) at the Federal Ministry of Health (FMOH), and partners working on supply chain management of RMNCH pharmaceuticals.

The Ministry would like to thank the following team of experts for their unreserved efforts to materialize this important training intervention. The material also standardized as per the national in-service training directive of FMOH. The FMOH appreciates their commitment and applauds their achievements.

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# Acronyms

BEmONC Basic Emergency Obstetric and Newborn Care

CBNC Community Based Newborn Care

CEMONC Comprehensive Emergency Obstetric & Newborn Care

CPR Contraceptive Prevalence Rate

EmONC Emergency Obstetric & Newborn Care

FMOH Federal Ministry of Health

HC Health Center

HP Health Post

ICCM Integrated Community Case Management

IMNCI Integrated Management of Neonatal and Childhood Illness

MNH Maternal and Newborn Health

MMR Maternal Mortality Ratio

PFSA Pharmaceuticals Fund and Supply Agency

PHCU Primary Health Care Unit

RMNCH Reproductive, Maternal, Newborn and Child Health

RMU Rational Medicine Use

TT Tetanus Toxoid

WHO World Health Organization

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# Introduction to the training manual

In Ethiopia, Reproductive, Maternal, Neonatal and Child Health (RMNCH) program is given a priority focus and is being implemented in across all levels of health service delivery. However, access to essential reproductive, maternal, newborn, and child health (RMNCH) commodities is often limited in Ethiopia. On top this; there is the problem of inappropriate use of RMNCH medicines resulting in serious consequences of poor health outcomes. This may affect the country's efforts to end preventable child and maternal deaths.

According to the new RH strategy, there is a need to scale up existing high impact interventions whose population coverage lags behind the target, such as skilled birth attendance and antiretroviral prophylaxis for neonates born to HIV infected mothers. The vision of the RH strategy is to consolidate the gains in maternal, newborn, child and adolescent health and attain the long-term vision of the country to end all preventable maternal and child deaths by 2035.

The successful implementation of these programs under the umbrella of RMNCH requires the contribution of all the health professionals. Pharmacy professionals have multiple and critical roles in the provision of quality RMNCH services with the highest possible set of ethics and accountability. They have indispensable roles in promoting rational use of RMNCH medicines and in managing supply chain – including medicines storage, inventory, distribution, and documentation, and in making sure that good quality and affordable RMNCH medicines are available in health facilities at all times.

Despite their critical contributions, they are often overlooked and insufficiently involved in RMNCH decision making process, including in capacity building schemes regarding RMNCH programmatic updates, therapeutic management guidelines and protocols. Because of this, they often fail to establish the links between program priorities and RMNCH life-saving pharmaceuticals – affecting pharmacy practitioners not to play the critical role they are expected to discharge in RMNCH performance improvements.

This training material aims to capacitate pharmacy professionals on the programmatic and operational priorities to pharmacy professionals. Findings indicate that most pharmacy professionals lack understanding on programmatic priorities and targets related to RMNCH

services. They often fail to establish the links between program priorities and RMNCH life-saving pharmaceuticals. On top of that, the collaboration and coordination remain weak between pharmacy professionals and other health professionals.

Hence, this course is intended to achieve pharmacy practitioners' competencies in the areas of key RMNCH tasks that include: RMNCH pharmacotherapy, logistics management, medicine availability and rational use. Accordingly, this training manual focuses on programmatic priorities of RMNCH discussing on the rational use of family planning, maternal health pharmaceuticals, syndromic management of sexually transmitted infections, rational use of neonatal, child health and nutrition pharmaceuticals, the supply chain management of RMNCH pharmaceuticals then at the end ethical and professional standards throughout RMNCH Services will be addressed.

The core competencies that the trainees are expected to attain after going through this course are:

- 1. Provide Compassionate, Respectful and Caring (CRC) healthcare service delivery
- 2. Support the implementation of national RMNCH programs to meet strategic targets
- 3. Promote the rational use of FP pharmaceuticals
- 4. Implement the syndromic management of STIs
- 5. Ensure the rational use of maternal health pharmaceuticals
- 6. Support the implementation of IMNCI and iCCM- CBNC programs
- 7. Ensure functionality of SCM of RMNCH pharmaceuticals
- 8. Apply ethical standards for the provision of RMNCH services

# Course Syllabus

# **Course Description:**

This five days training course is designed for pharmacy professionals to enhance their knowledge, skills, and attitude in the proper management and utilization of RMNCH pharmaceuticals. It is intended to enable pharmacy professionals' play their specific roles on RMNCH spectrum of care in a more effective way.

#### **Course Goal**

To provide target participants with the required knowledge, skills, and attitudes for the effective management and proper use of RMNCH pharmaceuticals at primary health care unit (PHCU) level.

## **Course Objectives**

After completion of this course, the trainees will be able to:

- Describe Compassionate, respectful and Caring (CRC) healthcare service delivery
- Describe RMNCH programs and strategies
- Discuss the rational use of family planning pharmaceuticals.
- Apply the syndromic management of STIs.
- Discuss the rational use of pharmaceuticals in emergency obstetric care
- Discuss the rational use of child health pharmaceuticals used for IMNCI and iCMNCIprograms
- Apply the supply management system to manage RMNCH pharmaceuticals
- Apply ethical standards and effective communication throughout RMNCH continuum of care

#### **Learning Methods & Activities**

- Interactive presentation
- Small group discussion
- Paired exercises
- Think- pair-share
- Role play
- Case study

- Individual reading and reflection
- Written exercises
- Brainstorming
- Jig-saw
- Gallery-walk

# **Learning Materials and Resources**

- Reproductive, Maternal, Neonatal and Child Health Program Overview and Pharmaceuticals
   Management Training for Pharmacy Professionals package:
  - o Participant's manual
  - o Facilitator's guide
  - PPT slides
  - Flipchart
  - LCD Projector
  - Laptop

# Participant selection criteria

Participants for this course shall be pharmacy personnel who are responsible for supply management, pharmaceutical store management, and dispensing health facilities. Additionally, pharmacy services and pharmaceutical supply chain professionals working at FMOH, RHBs/ZHD/WoHO, PFSA, universities, etc. are target audiences of this training.

#### Trainer selection criteria

Trainer of this course shall fulfill the following criteria:

- Trainers who developed this training manual (TWG)
- Trainers who have a TOT certificate on this training course
- Trainers with basic training on this course plus facilitation skill training
- And those with a minimum of bachelor's degree in pharmacy and related fields

# **Methods of Evaluation**

#### **Participant**

- Formative
  - Direct observation with feedback

- Individual exercise
- Group exercises
- o Review of reports

#### Summative

Posttest

#### Course

- Daily feedback filled by the participants
- o End of course evaluation filled by the participants
- o Oral feedback by the participants

## **Certification Criteria:**

Certification for this course bases on the following criteria.

- Full attendance of the course
- Knowledge assessment using posttest 70% for basic training
- For TOT training
  - o Formative assessment 30%
  - o Teach back 20%
  - o Posttest 50%;
  - o Aggregate value of 80% and above
- Note that TOT participants who score less than 80%, shall be given certificate for basic training given that they score 70% and above on the posttest.

# **Duration of the training**

• 5 days.

## Suggested class size and number of trainers

- Suggested training class size shall not be more than 30 participants per classroom for basic training
- For TOT, the maximum class size shall be 20
- Four trainers shall be assigned per one training event.

# **Training Venue**

The training will be conducted at selected national and regional IST centers/CPD providers having appropriate facilities, trainers, and attachment health facilities.

# **Course schedule**

National Training Course on Reproductive, Maternal, Neonatal and Child Health Program Overview and				
Pharmaceuticals Management Training for Pharmacy Professionals				
Organized by in Collaboration with				
Dates:; Venue:				
Time schedule	Activity	Facilitator		
Day One:				
8:30 – 8:45 AM	Registration	Organizers		
8:45 – 9:00 AM	Welcoming and Opening Address			
9:00 -10:00 AM	Introductory Activities			
10:00-10:30 AM	Pre-test			
10:30-10:45 AM	Tea Break	Organizers		
10:45-11:15 AM	Chapter 1: Introduction to CRC			
11:15-11:45	Chapter 1: Healthcare Ethics			
11:45-12:30	Chapter 1: Compassionate care			
12:30 – 2:00 PM	Lunch	Private		
2:00-2:30 PM	Chapter 1: Respectful care			
2:30-3:00 PM	Chapter 1:Compassionate leader			
3:00-3:30	Chapter 2: Overview of strategies and program directions on RMNCH			
	Services			
3:30-3:45 PM	Tea Break	Organizers		
3:45-5:20 PM	Chapter 2: Overview of strategies and program directions, Contd.			
5:20 – 5:30 PM	Daily feedback	Participants		
End of Day one				
Day Two:				
8:30 – 8:45 AM	Recap of Day 1/Introduction to Day 2	Participants		
8:45-9:25 AM	Overview of strategies and program directions			
9:25-10:30 AM	Chapter 3. Rational Use of Family Planning Pharmaceuticals			
10:30-10:45 AM	Tea Break			
10:45- 11:45 AM	Chapter 3. Rational Use of Family Planning Pharmaceuticals, Contd.			

11:45-12:30 PM	Chapter 3. Rational Use of Family Planning Pharmaceuticals, Contd	
12:30 – 2:00 PM	Lunch	Private
2:00-2:35 PM	Chapter 3. Rational Use of Family Planning Pharmaceuticals, Contd	
2:35-3:30 PM	Chapter Three. Syndromic Management of Sexually Transmitted	
	Infections (STIs)	
3:30- 3:45 PM	Tea Break	Organizers
3:45-4:05 PM	Chapter four. Syndromic Management of Sexually Transmitted	
	Infections (STIs)	
4:05-4:50 PM	Chapter Five: Rational use of Maternal health pharmaceuticals	
	Session 5.1: Introduction to Obstetric and Newborn care services	
4:50-5:15 PM	Session 5.2Preventive Use and Safety of Medicines during the Antenatal	
	Care	
5:15-5:30 PM	Daily feedback	Participants
End of day two		
Day Three:		
8:30 – 8:45 A.M.	Recap of Day 2/Introduction to Day 3	Participants
8:45-9:30 AM	Session 5.2 Preventive Use and Safety of Medicines during the Antenatal	
	Care	
9:30-4:30 Am	Session 5.2 Preventive Use and Safety of Medicines during the Antenatal	
	Care	
9:55-10:30 Am	Session: 5.3 Therapeutic use and safety of medicines during antepartum,	
	Contd.	
10:30-10:45 AM	Tea Break	Organizers
10:30 -11:45 AM	Session: 5.3 Therapeutic use and safety of medicines during antepartum,	
	Contd.	
11:45-12:30 PM	Session 5.4: Therapeutic use and safety of medicines during labour and	
	delivery	
12:30 – 2:00 PM	Lunch	Private
2:00-2:30 PM	Session 5.4: Therapeutic use and safety of medicines during labour and	
	delivery	
	l	l .

2:30 – 3:45 PM	Session 5.5: Therapeutic use and safety of medicine during post-partum	
3:45-10:00 PM	Tea Break	Organizers
10.00 – 4:25 PM	Chapter Six: Rational Use of Neonatal and Child Health Medicines	
	6.1. Introduction to rational use of medicine in children,	
4:25 –5:15 AM	6.2 Therapeutic management of essential newborn care and young infant	
	problem medicines	
5:15 – 5:30 PM	Daily feedback	Participants
End of day three		
Day Four:		
8:30 – 8:45 A.M.	Recap of Day 3/Introduction to Day 4	Participants
8:45 – 9:25 AM	6.2 Therapeutic management of essential newborn care and young infant	
	problem medicines	
9:25 – 10:30 AM	Chapter six: Rational Use of Neonatal and Child Health Medicines	
	6.3. Therapeutic use and safety of cough or difficulty breathing	
	medicines	
10:30-10:45 AM	Tea Break	Organizers
10:30-10:45 AM 10:45:11:10	Tea Break Chapter six: Rational Use of Neonatal and Child Health Medicines	Organizers
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	Chapter six: Rational Use of Neonatal and Child Health Medicines 6.3. Therapeutic use and safety of cough or difficulty breathing	Organizers
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10:45:11:10	Chapter six: Rational Use of Neonatal and Child Health Medicines 6.3. Therapeutic use and safety of cough or difficulty breathing medicines Chapter six: Rational Use of Neonatal and Child Health Medicines 6.4 Therapeutic use and safety of medicines for diarrhea and	Organizers  Private
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10:45:11:10 11:10 –12:30 AM 12:30-2:00PM 2:00-3:30PM 3:30-3:45 PM	Chapter six: Rational Use of Neonatal and Child Health Medicines 6.3. Therapeutic use and safety of cough or difficulty breathing medicines  Chapter six: Rational Use of Neonatal and Child Health Medicines 6.4 Therapeutic use and safety of medicines for diarrhea and dysentery  Lunch  Chapter six: Rational Use of Neonatal and Child Health Medicines 6.5 .Common nutritional problems and their management  Tea Break  Chapter six: Rational Use of Neonatal and Child Health Medicines	Private

Day Five:		
8:30 – 8:45 A.M.	Recap of Day 4/Introduction to Day 5	Participants
8:45 -10:30 AM	Chapter seven: RMNCH Pharmaceuticals Supply Chain Management	
10:30-10:45 AM	Tea Break	Organizers
10:45-12:30 PM	Chapter seven: RMNCH Pharmaceuticals Supply Chain Management	
12:30-2:00PM	Lunch	Private
2:00 – 3:30 PM	Chapter eight: Ethical and professional standards throughout RMNCH	
	Services	
3:30-3:45 PM	Tea Break	Organizers
3:45-4:30 PM	Post-test	
	Course evaluation	
	Closing Speech	
End of Program	•	,

# **Chapter 1:** Caring, Respectful and Companionate

# **Healthcare Service**

**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**

- 1.1. Introduction to CRC
- 1.2. Healthcare Ethics
- 1.3. Compassionate care
- 1.4. Respectful care
- **1.5.** Compassionate leader

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



## **Individual reflection**

What is Compassionate, Respect and Caring (CRC)? Time Allowed 15 minutes

#### 1.1.1. Definition of CRC

# Compassion (ሩህሩህ)

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.

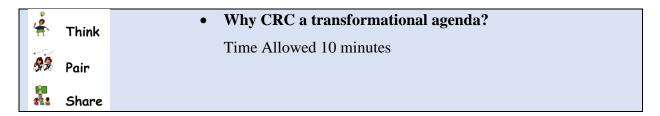
## Respectful (ተገልጋይን የሚያከብር)

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.



# 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: 1 The benefits and beneficiaries of Compassionate and Respectful Care

Beneficiaries	Who	How	
		When health professionals are compassionate, patients are less anxious	
First	Patients	Adherence to medical advice and treatment plans	
		<ul> <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> </ul>	
		Quality of health professionals -patient communication with increased physical functioning, emotional	
		health and decreased physical symptoms of pain in patients	
Second	Health	Health care Professionals satisfaction with their relationships with patients can protect against	
	Professi	professional stress, burnout, substance abuse and even suicide attempts	
	onals	<ul> <li>Burnout is strongly associated with poorer quality of care, patient dissatisfaction, increased medical errors, lawsuits and decreased expressions of compassion</li> </ul>	
		<ul> <li>Participation in a mindful communication associated with short-term and sustained improvement in well-being and attitudes associated with patient care</li> </ul>	
		A major predictor of patient loyalty	
		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	
		Respect from the client/patients	
		Health professionals will find their work more meaningful and gratifying	
Third	Students	Good role modeling is essential for students	
		Increased motivation to be CRC health professionals	
Fourth	Health	Patient satisfaction will rise	
	care	Quality of health care will be improved	
	facilities	Lower malpractice suits	
		Staff will be more loyal to their hospital or health care system	
		Patient adherence to treatment will rise	
		Resources can be conserved	
		Greater employee satisfaction and reduced employee turnover.	

# 1.1.4. National Strategy and Approach of CRC

The development of caring, respectful and compassionate health workers requires a multipronged 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.

#### 1.2. Healthcare Ethics

# 1.2.1. Principles of health care ethics



## **Individual reflection**

- $\square$  What is ethics?
- $\square$  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-maleficence

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** 

6

#### 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-maleficence

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-maleficence encourages the avoidance of causing deliberate harm, risk of harm and harm that occurs during the performance of beneficial acts. Non-maleficence 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.

#### 1.2.2. 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.

#### **Ouestion:**

- 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 a 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

1.2.3. 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.

**1.2.4.** Ethics and law as enablers of CRC

The Relation between Ethics and Law

Individual reflection

☐ What is the relationship between ethics and law?

**Time:** 5 Minutes

11

**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.

# 1.3. Principles and Standards of Compassionate Care

# **1.3.1.** 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.



## **Individual reflection**

# ☐ Can compassion be trained and learned?

Time Allowed: 5 Minutes

## Qualities of Compassionate Care

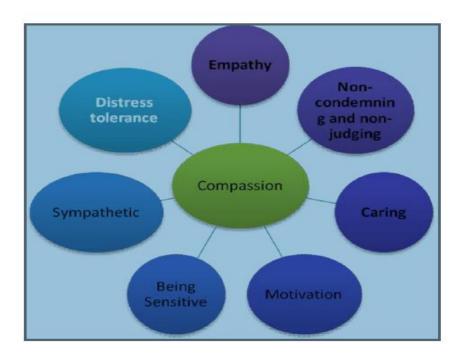


Figure 1:1 Qualities of compassion



# 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 allowed: 30 minutes

#### 1.3.2. 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:

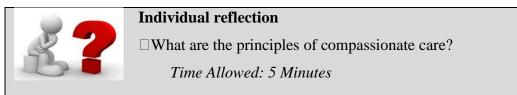
- Demeanor ("being")
- Affect ("feeling for")
- Behaviors ("doing for")
- Engagement ("being with")

## **Attending to Needs**

It refers to "a timely and receptive desire to actively engage in and address a person's multifactorial 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.

# 1.3.3. Principles of compassionate care



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.

#### **1.3.4.** 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

## 1.4. Respectful care

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

Time Allowed: 10 minutes



- 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?

### Definition of Dignity (ልእልና)

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. (**N.B.** Refer to Hand-out 3.1 for details.)

#### **Attributes of Dignity**

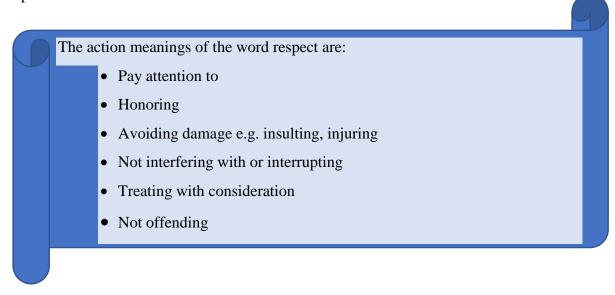
There are four attributes of dignity:

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.



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
- Capabilities and limits
- Personal space
- Privacy and modesty
- Culture

- Individuals believes of self-worth
- Personal merits
- Reputation
- Habits and values

## 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

## 1.4.2. Principles of Respectful Care



#### Individual reflection

- ☐ Think of a person who gave you the most respectful care/service.
  - Describe the situation?
  - What are the qualities of that person?
  - What did you value most?

**Time: 5 Minutes** 

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

# 1.4.3. Characteristics of Disrespectful Care



The situation where you received disrespectful care?

- 1. Describe the incident?
- 2. What was your reaction?

**Time: 5 Minutes** 

## 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 on specific patient attributes	Discrimination based on ethnicity, age, language, economic status, education level, etc.
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

# 1.4.4. Factors affecting Respectful Care Provision



## **Individual reflection**

- 1. What do you think hinders you from providing respectful care in your health facility?
- 2. What are the factors that facilitates provision of respectful care in your health facilities?

**Time: 5 Minutes** 

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 and 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?

## 1.5. Compassionate leader

## 1.5.1. Quality of Compassionate Leadership



#### **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?

Duration: 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

## 1.5.2. Systems Thinking for CRC



## Group activity in healthcare system thinking

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

- Discuss concepts of Health System and how it relates with your Health Facility /Hospital and Health Center/ functions.
- 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?
- Take in to account the CRC concepts and identify gaps you may have experienced in your facilities?

Duration: 20 minutes

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.

#### 1.5.3. 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.

- 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 and 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.

## 1.5.4. Leading CRC Health Teams



#### **Group activity**

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

- What principles do you think of when implementing CRC?
- Do you think there are differences between your current "leading" style and leading based on CRC? If yes, list the differences.

**Duration: 10 minutes** 

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 Rush worth 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-base 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

#### 1.6. Summary

#### **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 2: Overview of strategies and program directions on RMNCH Services

**Allocated Time**: 85 minutes

**Chapter Description**: This chapter is prepared to enhance participants' understanding on RMNCH programs and strategies including targets, components of the service, and interventions. The chapter also describes the expected roles of pharmacy professionals in the provision of RMNCH services.

**Primary Objective:** By the end of this chapter, participants will be able to:

Describe RMNCH programs and strategies

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

- Identify RMNCH related programs, strategies, targets, and interventions
- Recognize the essential RMNCH service packages at each tier system
- Classify RMNCH priority pharmaceuticals
- Discuss the role of pharmacy professionals in RMNCH services

## **Chapter outline**

- 2.1. RMNCH programs, strategies, targets, and interventions
- 2.2. Essential RMNCH service packages
- 2.3. RMNCH priority pharmaceuticals
- 2.4. Role of pharmacy professionals in RMNCH services

# 2.1. RMNCH programs, strategies, targets, and interventions



## **Brainstorming for 5 minutes:**

- What do you know about the current RMNCH programs and strategies being implemented in Ethiopia?
- Do you think Ethiopia has a national strategic plan for RMNCH related activities?

RMNCH covers the health concerns and interventions across the life course involving women before and during pregnancy; newborns, that is, the first 28 days of life; and children to their fifth birthday. In its essence, Reproductive Health covers a wide range of intervention areas and all stages of life. Due to special importance to women particularly during the reproductive years, the focus of RMNCH goes to family planning or birth spacing methods, maternal health related conditions which addresses the health of women pre-pregnancy, during pregnancy, childbirth and postpartum.

According to the policy document of World Health Organization (WHO), it is emphasized that having policies are essential for ensuring all women and children have the opportunity to achieve the highest standard of health, by supporting the development of and sustaining effective health systems and by creating environments that promote health more broadly. Improving maternal and child health not only helps to secure the right to health, but reduces poverty and stimulates economic growth.

The National Health Policy, 1993, states, "Special attention shall be given to health needs of the family, particularly women and children." Recognizing the importance of RMNCH interventions, Ethiopia has devised different programs, developed strategies and interventional tools for the RMNCH service provision. As an integral part of the five-year Health Sector Transformation Plan (HSTP), Reproductive, Maternal, Neonatal, Child, Adolescent and Youth Health has been explicitly discussed with a set targets and intervention modalities. Previously a national strategic document on reproductive health has been designed in line with the broader strategic framework and context of the Health Sector Development Program (HSDP) and aligned with the lifespan of the third and fourth plans of the HSDP that has been used from 2000-2015 G.C.

The HSDP is changed to accommodate national and global changes which had happened in the past 10 years. This has necessitated preparing a comprehensive and up-to-date strategy that incorporates these developments to be used as one of the policy tools to potentiate transformation in the health sector and accelerate national progress towards ending preventable maternal and child death. The development of the national RH strategy 2016-2020 is imperative to consolidate the encouraging gains in maternal, newborn, child and adolescent survival and the long-term vision of the country to end all preventable maternal and child deaths by 2035.

The new RH strategy contextualizes and incorporates selected high impact reproductive health interventions and service delivery models that have gained global acceptance, keeping the primary healthcare unit at the core. The service delivery model will be based on life cycle approach and ensuring continuum of promotive, preventive and curative care across time: prepregnancy, pregnancy, childbirth, postpartum and neonatal period and through reproductive age. This approach is based on the sound premise that the health of an individual across the life stages and levels of delivery are interlinked.

This RH strategy encompasses 12 strategic objectives under core thematic areas of: improving maternal and newborn health (MNH), improving family planning, improving adolescent and youth reproductive health, prevention and management of reproductive organ cancers, addressing the social determinants of reproductive health, and prevention and treatment of pelvic organ prolapse.

## 2.1.1 RMNCH Components

In RMNCH scope an integrated care is required as there is an obvious linkage between reproductive, maternal, newborn and child health. They share a number of similar and interrelated causes for their morbidities and mortalities. In the past, safe motherhood and child survival programs often operated separately, leaving disconnections in care that affected both mothers and newborns. It is now recognized that delivering specific interventions at pivotal points in the continuum has multiple benefits. Linking interventions in packages can also increase their efficiency and cost-effectiveness.

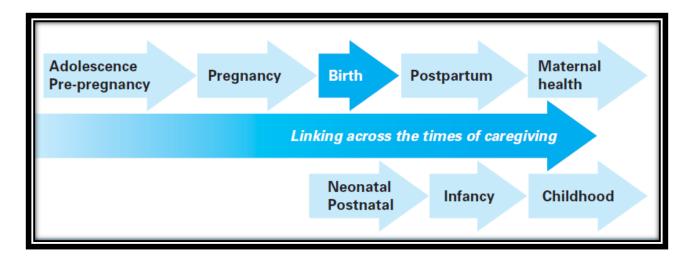


Figure 2: 1 Continuum of care model for maternal, newborn and child health Reproductive Health/Family Planning

FMOH integrated family planning with the national maternal and child health (MCH) program in the early 1980s in public health facilities. Since then, the family planning service coverage increased largely as a result of a significant increase in access to health facilities.

The contraceptive prevalence rate (CPR) has showed progressive growth over the years as showed below.

 Year
 1991(CSA)
 2000 ()
 2005 (EDHS)
 2011 (EDHS)
 2016(EDHS)

 CPR
 3%
 8.2%
 14.7%
 29%
 35%

Table 2:1 Contraceptive prevalence rates

An enormous effort is being made to increase CPR by FMOH through programmatic interventions. FMOH is working to increase the CPR and reduce the unmet need with particular focus on long acting and permanent contraceptive methods. Among others, the utilization of long-acting reversible and permanent methods is extremely low. As the country continues its efforts to increase FP uptake through a rights-based approach, efforts are being made to improve the utilization of long acting reversible and permanent methods.

According to the RH strategy the plan is to reach contraceptive prevalence rate of 55% and increase the long acting reversible and permanent contraceptive methods use to 48% by the year 2020.

#### A. Maternal Health

Maternal health refers to the health of women during pregnancy, childbirth, and the postpartum period. Despite several decades of global health initiatives focused on maternal health, an unacceptable level of preventable maternal mortality remains an unfinished agenda and one of the world's most critical challenges.

Maternal health program in Ethiopia focuses on implementation of evidence based high impact Maternal Neonatal Health (MNH) interventions through availing effective health services that include essential and emergency obstetrics care in a continuum of care approach. It works to address the internationally agreed optimal strategy to reduce maternal mortality by ensuring that all pregnancies are wanted, all births are attended by skilled personnel operating in teams in health facilities, and all women with complications have access to emergency obstetric care.

Proper care during pregnancy and delivery is important for the health of both the mother and the baby. It includes antenatal care, delivery care and postnatal care. Accordingly, a number of interventional tools are there for maternal health service provision.

- Emergency obstetric care
- Quality maternal and newborn health care
- Emergency obstetrics referral network
- Maternal death surveillance and response
- Elimination of obstetric fistula
- Safe abortion service
- Home delivery free Kebeles

The maternal health program has set targets to be achieved through the above mentioned interventional mechanisms. FMOH targeted to provide BEmONC and CEmONC services in 100% of health centers and hospitals. Moreover, Iron folate supplementation, PMTCT & ART treatment for HIV+ pregnant women are included in addition to the management of complications that happen during delivery like pre-eclampsia and eclampsia.

#### B. Newborn and Child Health

In Ethiopia, under-five mortality rate has declined by two thirds from the 1990 figure of 204/1,000 live births to 68/1,000 live births in 2012, thus meeting the target for Millennium Development Goal 4 (MDG 4) on child survival three years ahead of time. Disaggregation of the

mortality data by age reveals that the decline in neonatal mortality is not as impressive as the infant and child mortality figures. It has fallen only by 42% during the same period; from 54/1000 live births in 1990 to 28/1000 live births in 2013. About 44% of the childhood deaths occur within the first 28 days of life, thus increasingly accounting for a larger proportion of the under five deaths.

Over two-thirds of childhood deaths in Ethiopia are caused by a few and easily preventable conditions; mainly infections, neonatal conditions and malnutrition. The major direct causes of under-five mortality, based on the 2014 WHO/CHERG estimates are:

Table 2: 2 Major Direct causes of under-five mortality

Pneumonia (18%)	Measles (2%)
Diarrhoea (9%)	Malaria (3%)
Prematurity (11%)	Congenital anomalies (4%)
New-born infection (9%)	HIV (2%), and others(21%)
Asphyxia (14%)	Measles (2%)
Injury (6%)	

The aforementioned disease condition also affect children aged above 5 years. As the age of the child increases beyond 5 years, non-communicable health problems are also more prevalent.

Taking into consideration the situations key newborn & child survival interventions are being implemented in two major initiatives which are community and facility based initiatives. Ethiopia's flagship Health Extension Program (HEP) is the platform for delivery of community based basic promotive, preventive, and curative newborn & child health services.

Integrated Community Case Management (ICCM) and Community Based Newborn Care (CBNC), which addresses:

- Pneumonia
- Diarrhea
- Malaria
- Malnutrition
- New-born conditions

Whereas the health facility level initiatives are delivered through:

- Integrated Management of Neonatal and Childhood Illness (IMNCI),
- New-born Corner Initiative and Neonatal Intensive Care Unit (NICU)

The national newborn and child survival strategy is designed to consolidate the encouraging gains in child survival and the long-term vision of the country to end all preventable child deaths by 2035.

#### C. Nutrition

Maternal, infant and child under nutrition are still national problems with important consequences for survival and for incidence of acute and chronic diseases, healthy development, and economic productivity, at both individual and societal levels. Over the past decade, since the National Nutrition Strategy was developed, the government, implementers and nutrition development partners have strived to create appropriate channels, capacity and resources through which the intergenerational cycle of malnutrition could be halted and through which policy landscapes and government commitment could be improved.

The last four national level Demographic and Health Surveys (EDHS) show a decreasing trend in the proportion of children who are stunted and underweight. The current prevalence of stunting among children under the age of five remains unacceptably high, with 38%, 24% underweight, and 9.9 % identified with severe acute malnutrition, mainly wasting, according to 2016 DHS report. Anemia prevalence among under-five children remains high at44%, even though it declined by 19% over the last 6 years (EDHS, 2011).

The level of chronic under nutrition among women (15–49 years old) in Ethiopia is relatively high, with 27% having a body mass index (BMI) of less than 18.5 kg/m, with no significant progress over the last decade. Similarly, the prevalence of anemia among women in their productive age group (15–49) was found to be 17% (EDHS 2011). The proportion of non-pregnant adolescents aged 15–19 years with chronic malnutrition (BMI <18.5) was 36%

Nutrition is a cross-cutting programmatic area that aims to address nutrition intervention in the health sphere and also other organizations following the multi-sectoral approach for nutrition. In this, we have nutrition specific and sensitive interventions modalities. The nutrition specific activities directly address inadequate dietary intake or disease—the immediate causes of malnutrition like maternal and child under nutrition including micronutrient supplementation,

deworming, treatment of severe acute malnutrition and breastfeeding promotion, which directly address dietary intake and disease for infants. On the other hand, nutrition sensitive interventions focuses on improving the underlying determinants of nutrition (adequate food access, healthy environments, adequate health services, and care practices), or aim at least to avoid harm to the underlying or immediate causes, especially among the most nutritionally vulnerable populations and individuals.

Boldly, the nutrition-specific interventions being provided in the health sector include the community and facility level interventions

#### **Micronutrient interventions**

- Provide school and facility based biannual de-worming for adolescents
- Provide IFA and de-worming for Pregnant & lactating Mothers
- Bi annual Vitamin A supplementation (VAS) and Deworming for under five children. The
  modality of VAS and deworming is different is different part of the country. All agrarian
  regions and city administrations implement the VAS & deworming on a routine basis
  whereas the rest of regions implement it through Community Health Days/CHD/ every
  quarter.

Community management of acute malnutrition (CMAM): there are four main components of CMAM;

- Community outreach/mobilization: Health Extension workers and Community health workers(CHWs) conduct community screening for early case finding; give basic nutritional advice to mothers; and provide patient follow up for defaulters and encourage return to the program. Community mobilization also includes sensitization of the population to promote understanding of program objectives and methods.
- **Inpatient Treatment/ care**: Children who are acutely malnourished with associated medical complications and/or poor appetite; and infants less than 6 months with SAM need to be treated in inpatient care facility until they are well enough to continue nutritional rehabilitation in OTP.
- Outpatient Treatment Program (OTP): Outpatient care is intended for children of SAM without medical complications and for children who have recovered in inpatient care with improved appetite. They receive ready-to-use therapeutic food (RUTF) and

routine medicines, which will be taken at home, and the child would visit outpatient care site every week. Most children with SAM have no medical complications and can be treated in outpatient care.

• Targeted supplementary feeding program (TSFP): Individuals with moderate acute malnutrition and no medical complications are supported and provided with dry takehome rations (or in some cases on-site feeding) and simple medicines. All the above interventions in the nutrition services are being provided in communities at health posts and the health centers.

## 2.2. Essential RMNCH service package at each tier system



#### **Brainstorming for 5 minutes:**

- What does the current Ethiopia health service tier look like?
- How does the RMNCH implementation align with the tier?

The Ethiopian health service is restructured into a three-tier system; primary, secondary, and tertiary level of care. The primary level of care includes primary hospital, health center and health post.

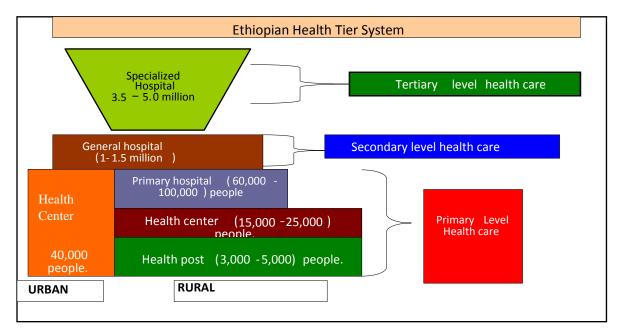


Figure 2: 2 Ethiopian Health tier

Table 2: 3 RMNCH service package across the tier system

	Family	Maternal	Neonatal and	Nutrition
	planning	Health	Child Health	
PHCU	short& long acting FP	ANC PNC Delivery BEMONC	CBNC &ICCM/ (ICMNCI)  IMNCI	CINS
Secondary level Health Care	short& long acting FP Permanent FP service	ANC PNC Delivery BEmONC	NBC NICU	CINS
Tertiary level Health care	short& long acting FP Permanent FP service	ANC PNC Delivery CEmONC	NBC  NICU and other specialized clinical care	CINS

The primary health care unit (PHCU) which is composed of a health center (HC) and five satellite health posts (HP) provide services to approximately 25,000 people altogether.

This tier system embraces all the health care services provided at all levels. As a part of the health care package, RMNCH services are provided at these levels in comprehensive manner.

In maternal Health the in addition of the ANC,PNC and delivery service there are BEmONC and CEmONC services which are provided based on the signal signs. BEmONC embraces service

package of Parenteral antibiotics ,Parenteral oxytocics drugs , Parenteral anticonvulsivants, Manual removal of placenta, Removal of retained products of conception, Assisted vaginal delivery (vacuum extraction) and Newborn care. The CEmONC service includes Surgery (caesarean section) and Blood transfusion in addition f the services indicated in BEmONC.

Nutrition program operates in the principle of Comprehensive Integrated Nutrition Service at all level (CINS). Although the complexity may vary based on the level, the focus is provision of comprehensive care at all level.

## 2.3. RMNCH priority pharmaceuticals



Brainstorming for 5 minutes:

Why Reproductive, Maternal, Newborn and Child health commodities are priority items?

Ensuring that every women and child can survive and thrive is a priority for Ethiopia health system, and central to the goal of saving women's lives and improving child health. Access to safe, quality, and affordable RMNCH pharmaceuticals is the key to achieve these national and global priorities.

Globally in 2010, the UN commission identified 13 pharmaceuticals as a priority for the RMNCH services. These 13 overlooked life-saving pharmaceuticals across, if more widely accessed and properly used, could save the lives of more than 6 million women and children.

Table 2:4 UN commission 13 life-saving pharmaceutics for women and children

	Reproductive	Maternal	Child Health	Newborn Health
	Health	Health		
UN commission	Female	• Oxytocin	Amoxicillin	Injectable
identified 13	Condom	• Misoprostol	• Oral	Antibiotics
pharmaceuticals	Contraceptive	• Magnesium	Rehydration	Antenatal
	Implant	sulfate	Salt	Corticosteroids
	• Emergency		• Zinc	Chlorhexidine
	Contraception			Resuscitation

# 2.1.2 Family Planning products

The health conditions/interventions and products for Family planning include:

Table 2:5 family planning pharmaceuticals

Conditions	Medicines
Prevent unplanned pregnancy	• Condom
Protect from STI transmission	
Prevent unplanned pregnancy	• Pills
	Emergency pill
	• Injectables
	• IUCD
	• Implant

## 2.1.3 Maternal Health Essential Pharmaceuticals

The health conditions/interventions and medicines for maternal health include:

Table 2:6 Maternal health essential pharmaceuticals

Condition	Medicines
Caesarian Section	• Lidocaine HCL 5% (in dextrose 7.5%)ampule,
	2ml w/o Epinephrine
	Bupivacaine ampule
	Epinephrine 1mg/ml ampule
	Ketamine 10ml Vial
	Atropine Sulphate 1mg Injection
	Halothane 250ml
	<ul> <li>Suxamethonium 100mg/2ml injection</li> </ul>
	Ceftriaxone powder for Injection, 1gm vial
Active management of	Oxytocin 10 IU
third stage labour	Ergometrine Maleate 0.2mg

Post-Partum Sepsis	Metronidazole injection, 500mg in 100ml vial
	<ul> <li>Gentamycin of 40mg/ml, 2ml ampule</li> </ul>
	<ul> <li>Ceftriaxone powder for injection ,1gm vial</li> </ul>
	<ul> <li>Amoxicillin,500mg capsule</li> </ul>
	• Metronidazole ,250mg capsule
Labour	Oxytocin 10IU,1ml ampule
Induction/Augmentation	<ul> <li>Misoprostol 25 micrograms tablet</li> </ul>
Management of Severe	Magnesium Sulphate Injection
Pre-Eclampsia&	Diazepam ampule
Eclampsia	Calcium Gluconate
	Hydralazine Injection
	Methyldopa Tablets
	<ul> <li>Nifedipine10mg Tablet</li> </ul>
	<ul> <li>Ceftriaxone 1gm Vial</li> </ul>
	<ul> <li>Metronidazole 500mg Inj</li> </ul>
Post-PartumHemorrhage	Misoprostol 200mg Tablet
	Oxytocin 10 IU
	Ergometrine Maleate 0.2mg
Comprehensive abortion	Mifepristone+ MisoprostolCombi pack Tablet
care /CAC	<ul> <li>Misoprostol 200mg Tablet</li> </ul>
	<ul> <li>Ibuprofen 400mg Tablet</li> </ul>
	• Diclofenac 75ml inj
	<ul> <li>Metronidazole 250mg cap</li> </ul>
	<ul> <li>Doxycycline 100mg capsule</li> </ul>
	MVA kit

# 2.1.4 Neonatal and Child Health Essential Pharmaceuticals

The health conditions/interventions and products Neonatal and Child Health include:

Table 2.7 Neonatal and child health essential pharmaceuticals

Condition	Medicines
Pneumonia	Amoxicillin oral formulation includes,
	dispersible tablets and suspension
Diarrhea	Oral Rehydration Salt, low osmolality sachet
	Zinc Sulphate Dispersible Tablets 20mg
Newborn Care	
Cord care	Chlorhexidine Gel 4% - 21 gm
Conjunctive	Tetracycline Eye Ointment 1% - 4gm
Neonatal Sepsis & Local	Amoxicillin Dispersible Tablets, 125mg
Bacterial Infection	Gentamicin Injection, 20mg/2ml
	Ampicillin 250mg powder of injection

2.1.5 Nutrition essential pharmaceuticals

The health conditions/interventions and products for Nutrition include

Table 2-8 Nutrition essential pharmaceuticals

Condition	Medicines
I. Uncomplicated severe acute	Amoxicillin DT
malnutrition	RUTF (Plumpy nut or BP-100)
	De-worming (Mebendazole 500 mg
	tablet, Albendazole 400mg tablet)
	Vitamin A
	Folic acid
	Measles Vaccine
II. Complicated severe acute	
malnutrition child with	
	F-75
Hypoglycemia	10% glucose or 10% sucrose

SAM plus watery diarrhea and/or	ReSoMal
vomiting and Dehydration	
	Oxygen
SAM with shock	Glucose 5 ml/kg by IV
	IV fluids
	Blood transfusion
SAM with Severe Anemia (hemoglobin	Blood transfusion
concentration of < 4 g/dl or hematocrit	
<12%).	
SAM with corneal clouding and	Vitamin A
ulceration	Chloramphenicol or tetracycline
	Atropine 1%
SAM with Heart failure	Furosemide 1 mg/kg
SAM with Infections	
No Medical Complications	Amoxicillin
Failed Appetite Test: Medical	Gentamycin IV or IM
Complications	Ampicillin IV
( Unable to feed , Vomiting everything	Amoxicillin
shock, Convulsions, lethargic/very weak,	
pneumonia/severe pneumonia,	
hypoglycemia, hypothermia, dermatosis	
with raw skin/fissures, jaundice, bleeding	
tendencies, complicated measles,)	
If the child has medical complications	Oral Amoxicillin
other than mentioned above,	IM Gentamicin
(dehydration, dysentery, persistent	IV Ampicillin
diarrhea, fever other than malaria,	
measles without complication)	
If child fails to improve within 48 hours	Chloramphenicol IV or IM
	Ceftriaxone 100 mg/kg IV or IM +

	Gentamicin
If a specific infection requires an	Specific antibiotic as indicated Plus
additional antibiotic, ALSO GIVE:	F75
	F100
Children with MAM	Cereal plus (CSB+)
	Super Cereal plus or (Corn Soy Blend
	(CSB++)) or
	RUSF such as plumpy Sup

## 2.4. Role of Pharmacy Professionals in RMNCH



- What do you think the major professional responsibility of a pharmacist as a health care team
- As a pharmacist, how do you think you could contribute for the quality RMNCH service provision?

Pharmacists are responsible for the management of medicines to ensure the availability of medicines at an affordable price, while maintaining the quality of the medicines throughout the supply chain. It is the responsibility of the pharmacist to oversee the complete medicine distribution cycle, starting from the prescription according to the diagnosis, choice of medicine, dispensing, preparation, counselling/provision of information and administration of the medicines.

Good Dispensing Practices: A good dispensing practice ensures that the correct medicine is delivered to the right client, in the required dosage and quantities, with clear information, and in package that maintains the quality of the medicine. As dispensing is the final checkpoint before the client leaves the health facility, due emphasis should be given to ensure that the patient is given the right medicine, understands how to take and adhere to prescribed medicines, how to manage side effects, and how to avoid interactions. It should be borne in mind that any error in the dispensing process can seriously affect the care of the client mainly with adverse health and economic consequences.

Counseling of Patients: Take time to explain to the client (and care takers in case of infants and children) the rationale and the potential adverse effects of treatment. The pharmacy professional should reinforce and elaborate the prescriber's instructions. For example, for contraceptive user, a provider should explain to the woman about the advantages and disadvantages, the benefits and risks, effectiveness, importance of adherence, relevant medicine interactions, common and serious side effects, management of side effects and when to seek immediate medical attention.

Counseling of women before a planned pregnancy should be carried out, including discussion of risks associated with specific therapeutic agents, traditional medicines, and abuse of substances such as nicotine and alcohol. For women with chronic diseases and on drug therapy, preconception counselling and medication review is good practice. (E.g. women with chronic hypertension and a previous pregnancy complicated by preeclampsia, preconception counselling on how to prevent preeclampsia or reduce its severity is important). Furthermore, preconception use of folic acid to reduce neural tube defects is advisable. During pregnancy women should be advised to avoid self-medication. Parents or caregivers must be warned to keep all medicines out of reach of children.

The following are the key role of a pharmacy professional on RMNCH pharmaceuticals

- Obtain, store, dispense and dispose RMNCH Pharmaceuticals
  - The pharmacist should obtain, store and secure RMNCH pharmaceuticals to fulfill demand at health facility level.
  - o Pharmacists are responsible for dispensing RMNCH pharmaceuticals.
  - The Pharmacist should lead disposal of expired and damaged medicines at health facility level
- Management of drug interaction
  - The pharmacist, along with the prescriber has a duty to ensure that patients are aware of the risk of side effects and their management. With their detailed knowledge of medicine, pharmacists have the ability to relate unexpected symptoms experienced by patients to possible adverse effects of their drug therapy. Their practice also ensures that ADRs are minimized by avoiding drugs with potential side effects in susceptible patients. Thus, pharmacist has a major role to play in relation to prevention, detection, and reporting ADRs.

- Contribute to health care system improvements and public health initiatives
  - Pharmacist plays a big role on disseminate evaluated information about RMNCH pharmaceuticals and various aspects of self-care.
  - Engage in preventive care activities and services
  - o Comply with national professional obligations, guidelines, and legislations
  - o Support national policies that promote improved maternal health outcomes
- Ensure the integration of RMNCH Pharmaceuticals in to Integrated Pharmaceuticals Management System (IPLS)
  - Identify list of RMNCH Pharmaceuticals
  - Report and request RMNCH pharmaceuticals using Report and Requisition Form
     (RRF) to Pharmaceuticals Fund and Supply Agency (PFSA)
  - o Strength HC and HP linkage

# 2.5. Summary

- RMNCH is one of the major national focus areas in the Ethiopian healthcare system and different programs, strategies, targets, and interventions are being implemented.
- Ethiopia has a three-tier health system, and at each tier system different RMNCH service packages are being delivered to the public.
- A priority list of pharmaceuticals that are used in RMNCH continuum of care should be continuously available in the health system to properly implement RMNCH programs.
- Pharmacists have important roles to contribute in the proper implementation of RMNCH services.

Chapter 3: **Chapter Three: Rational Use of Family** 

planning pharmaceuticals

**Allocated time**: 205 minutes

**Chapter description:** 

This chapter describes the rational use of pharmaceuticals used for family planning purpose. The

chapter specifically discusses the types, eligibility criteria, drug interactions, side effect and its

managements of family planning pharmaceuticals.

**Primary Objective:** By the end of this chapter participants will be able to:

Discuss the rational use of family planning pharmaceuticals.

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

Identify the types of family planning pharmaceuticals

Describe the eligibility, characteristics, effectiveness, and side effect management of short

acting family planning pharmaceuticals

Describe the eligibility, characteristics, effectiveness and side effect management of long

acting reversible family planning pharmaceuticals

**Chapter Outline** 

3.1. Introduction

3.2. Types of family planning pharmaceuticals

3.3. Short acting family planning pharmaceuticals

3.4. Long acting family planning pharmaceuticals

3.5. Chapter Summary

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#### 2.6. Introduction



## **Brainstorming for 5 minutes:**

What types of contraceptives do you know?

The scope of reproductive health is vast, and in this course, we concentrate primarily on family planning methods. Contraceptive use in Ethiopia is showing a significant improvement over the past decade. However, unmet need and discontinuation rate among women of reproductive age is still higher, for a variety of reasons. Lack of information about the available contraceptives choice and their characteristics, incorrect perception about contraceptives, fear of side effect and poor side effect management, and frequent stock outs are some of the factors contributing to the method discontinuation and to the high unmet need. In this session, participants will thus, get lessons on basic issues of popular contraceptives, aiming at addressing critical gaps on family planning medicines and services. Specifically, the chapter will highlight the key characteristics of contraceptives, side effects, and interaction and their managements.

# 2.7. Types of family planning products



Think-pair-share for 5 minutes

• How can you classify FP methods?

There are different types of birth control methods available today than ever. They can be divided into a few groups based on the duration of protection on the mechanism how they work, on the bases of duration, they can be classified as **short acting** and **long acting reversible** family planning methods. While Depo Provera, oral contraceptives and condom are short acting; IUCD and implants are on the other hand classified as long acting reversible family planning methods, since they protect for more than two years once the service are provided.

There are also **permanent methods** of contraception. These are among the most effective FP methods available for men & women who desire to have no more children. They are also one of the safest methods. These are currently the world's most popular & most widely used FP method (projected to remain so over the next 20 decades) and account for nearly half of all contraceptive use. However, permanent methods are the least utilized in Ethiopia.

The two permanent methods include:

- Female sterilization
  - Also called tubal sterilization, tubal ligation, voluntary surgical contraception, tubectomy, bi-tubal ligation, tying the tubes, minilap, and "the operation."
  - It works because the fallopian tubes are blocked or cut. Eggs released from the ovaries cannot move down the tubes, and so they do not meet sperm.
- Male Sterilization/Vasectomy/:
  - Also called male surgical contraception.
  - It works by closing off each vas deferens, keeping sperm out of semen. Semen is ejaculated, but it cannot cause pregnancy

Depending on the mechanisms how they work, they are grouped as follows:

- Hormonal methods—These use medications (hormones) to prevent ovulation. Hormonal
  methods include birth control pills (oral contraceptives), Depo Provera injections, and
  implants.
- Barrier methods—These methods work by preventing the sperm from getting to and fertilizing the egg. Barrier methods include the condom, diaphragm, and cervical cap.
   The condom is the only form of birth control that also protects against sexually transmitted diseases, including HIV (the virus that causes AIDS).
- Intrauterine devices—Intrauterine contraceptive devices (IUCDs) are inserted into the uterus, where they stay from one to 10 years.

# 2.8. Short Acting Contraceptives



# **Interactive discussion 5 minutes**

Tell at least 3 short acting FP pharmaceuticals

#### i. Combined Oral Contraceptives

Combined Oral Contraceptives are pills that contain low doses of 2 hormones—a progestin and an estrogen—like the natural hormones progesterone and estrogen in a woman's body. They work primarily by suppressing hormones responsible for ovulation. They also thicken cervical mucous to black sperm. Combined oral contraceptives (COCs) are also called "the Pill," low-

dose combined pills, and OCPs. Combined Oral Contraceptives are safe for nearly all women, including women who:

- Have or have not had children, are not married, are of any age, including adolescents and women over 40 years old
- Have just had an abortion or miscarriage, anemia now or had in the past, varicose veins, and are infected with HIV, whether on antiretroviral therapy or not
- Smoke cigarettes—if under 35 years old



Oral contraceptive pills

Figure 3:1 oral contraceptive pills

A woman with any of the conditions listed below should not use COCs

- Not breastfeeding and less than 3 weeks since giving birth
- Not breastfeeding and between 3 and 6 weeks postpartum with additional risk of developing a blood clot in a deep vein (VTE)
- Primarily breastfeeding between 6 weeks and 6 months since giving birth
- Age 35 or older and smoke 15 cigarettes a day
- History of high blood pressure, gall bladder disease, jaundice while using COCs, migraine headaches without aura that while using COCs
- History of breast cancer more than 5 years ago, and it has not returned
- Diabetes for more than 20 years or multiple risk factors for arterial cardiovascular disease such as older age, smoking, diabetes, and high blood pressure

#### **Characteristics of Combined pills-**

- They do not build up in a woman's body or collect in the stomach;
- Do not make infertile;
- Do not cause birth defects or multiple births;

- Do not change sexual behavior and
- Do not disrupt an existing pregnancy
- Do not provide protection from STIs, HIV, or HBV
- Safe and effective if used correctly
- Can be stopped at any time
- Has the following health benefits:
  - COC help in protecting against risks of pregnancy, cancer of the lining of the uterus (endometrial cancer), Cancer of the ovary and Symptomatic pelvic inflammatory disease
  - o It may help protect against Ovarian cysts and Iron-deficiency anemia
  - It reduces menstrual cramps, menstrual bleeding problems, ovulation pain, excess hair on face or body, symptoms of polycystic ovarian, syndrome (irregular bleeding, acne, excess hair on face or body), symptoms of endometriosis and pelvic pain, irregular bleeding)

#### **Effectiveness of COCs**



# **Interactive discussion for 5 minutes**

• What are the effectiveness of COC?

Its effectiveness depends on the user. When no pill-taking mistakes are made, less than 1 pregnancy per 100 women using COCs over the first year (3 per 1,000 women). At common levels of adherence, about 8 pregnancies per 100 women using COCs over the first year. This means that 92 of every 100 women using COCs will not become pregnant.

The factors that determine pill effectiveness include:

- Correct and consistent use
  - o COCs should be taken within the 1<sup>st</sup> seven days of the menstrual cycle (days 1-7).
  - o COCs must be taken daily, preferably at the same time of the day or night.
  - If client missed pills or started late, clients are advised to follow the recommended practice for managing missed pills.
- Proper storage, observance of shelf life and expiration date.

- o Pills should be stored at room temperature with proper ventilation.
- Too much heat may harden the pills and reduce the bio availability of the hormone content of the pills.

#### Vomiting or Diarrhea

- o If the client vomits within two hours after taking a pill, she should take another pill from another pack as soon as possible, then keep taking pills as usual.
- o If with vomiting or diarrhea for more than two days, follow these instructions:
  - o Take a hormonal pill as soon as possible.
  - o If on the third week, finish all hormonal pills in the pack. Throw away the 7 nonhormonal pills in a 28-pill pack and start a new pack the next day.
  - Use a backup method for the next 7 days.
  - o Also, if she had sex in the past 5 days, can consider ECPs

## • Drug Interaction

 Effectiveness may be lowered when taken with certain medicines such as rifampicin and most anticonvulsants.

#### Side effects and its management

Some users report the following side effects:

- Changes in bleeding patterns including lighter bleeding and fewer days of bleeding, irregular, infrequent and no monthly bleeding
- Headaches, dizziness, nausea, breast tenderness, slight weight changes (loss or gain),
   mood changes and acne (can improve or worsen, but usually improves)
- Other possible changes: blood pressure increases a few points (mm Hg). When increase is due to COCs, blood pressure declines quickly after use of COCs stops.

Manage the side effects as below:

- Headache, breast tenderness
  - O Suggest aspirin, ibuprofen, paracetamol, or other pain reliever.
  - Regardless of her age, a woman who develops migraine headaches, with or without aura, or whose migraine headaches become worse while using COCs should stop using COCs.
- Irregular bleeding

 For modest short-term relief, she can try 800 mg ibuprofen 3 times daily after meals for 5 days or other nonsteroidal anti-inflammatory drug (NSAID), beginning when irregular bleeding starts

**Note**: Many side effects will subside after a few months of use. For a woman whose side effects persist, a different COC formulation is given, if available, for at least 3 months.

#### **Drug interaction**

- Barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate, rifampicin, rifabutin, and ritonavir may make COCs less effective.
- Combined Oral pills, may make lamotrigine less effective

#### Pill pack

Two types of pill packets are available. One type has 28 pills in a packet, with 21 "active" pills containing hormones and seven "inactive or reminder" pills of a different color. The reminder pills do not contain hormones. This one is the widely available pills in Ethiopia. Another type of pills contains only the 21 "active/hormone containing" tablets.

These pills are further divided into:

- Monophasic pills provide the same amount of estrogen and progesterone in every hormonal pill.
- **Biphasic pills** have the first 10 pills with one dosage and the next 11 pills having another level of estrogen and progestin.
- **Triphasic pills** have the first seven pills or so with one dosage, the next seven pills have another dosage and the last seven pills with yet another dosage.

All prevent pregnancy in the same way.

# **Counseling points for COCs**

- Explain how to use COCs
  - Explain pill pack: Show which kind of pack 21 pills or 28 pills. With 28-pill packs, point out that the last 7 pills are a different color and do not contain hormones.
  - Show how to take the first pill from the pack and then how to follow the directions or arrows on the pack to take the rest of the pills.

## • Give key instruction:

- o Take one pill each day until the pack is empty.
- Discuss cues for taking a pill every day. Linking pill-taking to a daily activity may help her remember.
- Taking pills at the same time each day helps to remember them. It also may help reduce some side effects.

# • Explain starting next pack

- 28-pill packs: When she finishes one pack, she should take the first pill from the next pack on the very next day.
- 21-pill packs: After she takes the last pill from one pack, she should wait 7 days and then take the first pill from the next pack.
- It is very important to start the next pack on time. Starting a pack late risks pregnancy.
- Provide backup method and explain use
  - o Sometimes she may need to use a backup method, such as when she misses pills.
  - Backup methods include abstinence, male or female condoms, spermicides, and withdrawal. Tell her that spermicides and withdrawal are the least effective contraceptive methods. Give her condoms, if possible.
- Describe the most common side effects and how to manage the side effects
- Explain how to avoid missing doses and how to handle missed doses
- Explain about benefits of extended and continuous use
- ii. Progestin-Only Injectables



# Think-pair-share for 5 minutes

• What are the advantages of injectable contraceptives?

The injectable contraceptives depot medroxy progesterone acetate (DMPA) contains a progestin like the natural hormone progesterone in a woman's body.

• DMPA, the most widely used progestin-only injectable, is also known as the shot, "the jab," the injection, Depo, Depo-Provera, Megestrone, and Petogen.

- It is given by injection into the muscle (intramuscular injection). The hormone is then released slowly into the bloodstream. A different formulation of DMPA can be injected just under the skin (subcutaneous injection).
- DMPA works by inhibition of ovulation: After a 150-mg injection of DMPA, ovulation
  does not occur for at least 14 weeks. Levels of Follicle Stimulating Hormones (FSH) and
  Luteinizing Hormone (LH) are lowered and an LH surge does not occur. It also thickens
  the cervical mucus

In addition to eligibility criteria indicated for POPs, women with any of the following conditions should not use DMPA:

- Severe high blood pressure (systolic 160 mm Hg or higher or diastolic 100 mm Hg or higher)
- History of heart disease or current heart disease due to blocked or narrowed arteries (ischemic heart disease)
- History of stroke, multiple risk factors for arterial cardiovascular disease such as diabetes and high blood pressure
- Unexplained vaginal bleeding before evaluation for possible serious underlying condition
- Diabetes for more than 20 years or damage to arteries, vision, kidneys, or nervous system caused by diabetes



Figure 3: 2 Progestin-Only Injectables

#### **Characteristics of DMPA**

- Convenient and easy to use (does not require a daily routine or supplies).
- Once injected, it is not user dependent,

- Can be provided by lower level health professionals
- Suitable for breastfeeding women (after 6 weeks postpartum)
- Provides immediate postpartum (in non-breastfeeding women) or post-abortion contraception.
- May be used by women at any age or parity (for women of reproductive age)
- DMPA does not provide protection against STIs/HIV.



## Group reading, discussion and reflection for 15 minutes

What are the advantage and disadvantage of injectable (DMPA).

Table 3:1 Advantages and Disadvantages of DMPA

There may be a decrease in bone density

discontinuation and that bone density loss

However,

reversible

this

after

long-term users.

is

condition

#### **Advantages Disadvantages** Return to fertility is delayed - average is Progestin-only injectable is a very safe contraceptive. about 4 months from the last injection Reversible after the duration of action. Requires injection every three months to No need for daily intake continue its effects Does not interfere with sexual intercourse Does not protect against STI/HIV/AIDS Private since it is not coitally dependent. Menstrual irregularity during the first few Has no estrogen-related side effects such months of use nausea, dizziness, serious Amenorrhea; some women get anxious if as nor complications such they do not have menses as thrombophlebitis(inflammation of the wall Not possible to discontinue immediately, until DMPA is cleared from the woman's of a vein with associated thrombosis, often occurring in the legs during body

pregnancy) or pulmonary embolism (the

sudden blockage of a major blood vessel

(artery) in the lung, usually by a blood

*clot*)

• Has beneficial non-contraceptive effects:

- Helps prevent iron-deficiency anemia because of the scanty menses and the consequent amenorrhea
- May make seizures less frequent in women with epilepsy
- Reduces the risk of ectopic pregnancies
- o Prevents endometrial cancer
- DMPA presents no overall risks for cancer, congenital malformations, or infertility.

is greater during pregnancy.

#### **Effectiveness of DMPAs**

- Effectiveness depends on getting injections regularly: Risk of pregnancy is greatest when a woman misses an injection.
- As commonly used, about 3 pregnancies per 100 women using progestin-only injectables over the first year.
- When women have injections on time, less than 1 pregnancy per 100 women using progestin-only injectables over the first year (3 per 1,000 women).

#### **Side effects and their management:**

- Progestin-only injectables can stop monthly bleeding, but this is not harmful. It is like not
  having monthly bleeding during pregnancy. Blood is not building up inside the woman,
  do not disrupt an existing pregnancy, do not make women infertile.
- Increased appetite causing weight gain for some women (0.5 kg, on the average, in the first year).
- There are menstrual changes for almost all women.
  - o First 3 months: irregular bleeding or prolonged bleeding
  - o At one year: no monthly bleeding or infrequent bleeding
- Headaches, dizziness, abdominal bloating and discomfort, mood changes, less sex drive

• Other possible physical changes: loss of bone density

Manage the side effects as below:

- For modest short-term relief she can try (one at a time), beginning when heavy bleeding starts: 50 μg of ethinyl estradiol daily for 21 days,
- Head ache: suggest aspirin (325–650 mg), ibuprofen (200–400 mg), paracetamol (325–1000 mg), or other pain reliever

# iii. Progestin-Only Pills



*Group discussion:* Use the participant manual to read, discuss, and summarize the information under each of following in 15-20 minutes, then share to the larger group.

- Mechanism of action
- Eligibility criteria
- Characteristics
- Effectiveness
- Side effects and its management
- Group 1: POPs
- Group 2: ECPs
- Group 3: Condoms (male and female)

Are pills that contain very low doses of a progestin like the natural hormone progesterone in a woman's body. POPs work primarily by: thickening cervical mucus (this blocks sperm from meeting an egg) and disrupting the menstrual cycle, including preventing the release of eggs from the ovaries (ovulation)

#### Progestin-Only Pills:

- Do not contain estrogen, and so can be used throughout breastfeeding and by women who cannot use methods with estrogen.
- Progestin-only pills (POPs) are also called "minipills" and progestin-only oral contraceptives.

- Nearly all women can use POPs safely and effectively, including women who are breast feeding, and cigarettes smoking regardless of age.
- POPs contain 0.025 mg 0.030 mg progesterone of different chemical composition.
- Women can safely use POPs even if they have HIV/AIDS, or are on ritonavir-free ART.

Woman with conditions any of the following should not use POPS.

- Breastfeeding and less than 6 weeks since giving birth
- Acute blood clot in deep veins of legs or lungs
- Had breast cancer more than 5 years ago, and it has not returned
- Severe liver disease, infection, or tumor
- Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies

#### **Characteristics of POPs:**

In addition to the characteristics listed under COCs, the following also apply for POPs:

- Progestin-only pills do not cause a breastfeeding woman's milk to dry up,
- They do not cause diarrhea in breastfeeding babies
- They can reduce the risk of ectopic pregnancy
- Cigarette smokers can take POPs
- Patients with anemia (now in in the past), varicose veins, goiter can take POPs

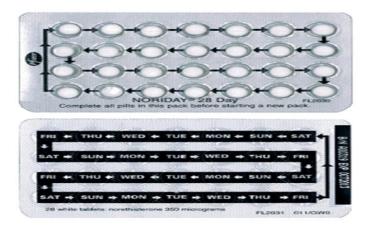


Figure 3:1 Progestin-only pills

#### **Effectiveness of POPs**

- Effectiveness depends on the user: For women who have regular periods, risk of pregnancy is greatest if pills are taken late or missed completely.
- Breastfeeding women:
  - With usual level of adherence, about 1 pregnancy per 100 women using POPs over the first year.
  - When pills are taken every day, less than 1 pregnancy per 100 women using POPs over the first year (3 per 1,000 women).
- Less effective for women not breastfeeding:
  - At usual levels of adherence, about 3 to 10 pregnancies per 100women using POPs over the first year. This means that 90 to 97 of every 100 women will not become pregnant.
  - When pills are taken every day at the same time, less than 1 pregnancy per 100 women using POPs over the first year (9 per 1,000 women).

## Side Effects and their management

The common side effects are:

- Frequent/irregular/infrequent/prolonged bleeding: for breastfeeding women, longer delay in return of monthly bleeding after childbirth (lengthened postpartum amenorrhea)
- Headaches, dizziness, mood changes, breast tenderness, abdominal pain, and nausea
- Other possible physical changes: for women not breastfeeding, enlarged ovarian follicles

#### Manage the side effects as below:

- For reducing irregular or heavy bleeding
  - For modest short-term relief she can try 800 mg ibuprofen 3 times daily after meals for 5 days or other nonsteroidal anti-inflammatory drug (NSAID), beginning when irregular bleeding starts.
  - Suggest iron tablet for preventing Anemia
- For head ache or breast tenderness
  - Suggest aspirin (325–650 mg), ibuprofen (200–400 mg), paracetamol (325–1000 mg), or other pain reliever.

## **Drug interaction**

- Taking barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate, rifampicin, rifabutin. or ritonavir or ritonavir boosted protease inhibitors.
- A backup contraceptive method should also be used because these medications reduce the
  effectiveness of POPs.

# Pill pack

- The pill pack usually contains either 28 pills. Sometimes, packs with 35 pills may be available.
- All pills in POP packs are the same color and all are active pills, containing a hormone that prevents pregnancy.

**Note**: Patients should be shown how to take the first pill from the pack and then how to follow the directions or arrows on the pack to take the rest of the pills.

#### **Counseling points**

In addition to the general counseling points for pills (shown under COCs), use the following specific points when counseling about POPs.

- Explain pill pack:
  - o Show which kind of pack—28 pills or 35 pills.
  - Explain that all pills in POP packs are the same color and all are active pills,
     containing a hormone that prevents pregnancy.
  - Show how to take the first pill from the pack and then how to follow the directions or arrows on the pack to take the rest of the pills.
- Explain that effectiveness decreases when breastfeeding stops:
  - Without the additional protection of breastfeeding itself, POPs are not as effective as most other hormonal methods.
  - When she stops breastfeeding, she can continue taking POPs if she is satisfied with the method, or she is welcome to come back for another method.

#### iv. Emergency Contraceptive Pills (ECPs)

Emergency Contraceptive Pills (ECPs) contain a progestin alone, or a progestin and an estrogen together. These are hormones like the natural hormones progesterone and estrogen in a woman's body. ECPs are sometimes called "morning after" pills or post coital contraceptives. They work primarily by preventing or delaying the release of eggs from the ovaries (ovulation).

The pills should be taken as soon as possible after unprotected sex. The sooner ECPs are taken after unprotected sex, the better they prevent pregnancy. Taking ECPs prevents pregnancy only from acts of sex that took place in the 5 days before. ECPs do not protect a woman from pregnancy if the sex is performed after she takes ECPs—not even on the next day.



Figure 3: 2 Emergency contraception

Exactly how ECP works is not known. However, levonorgestrel ECPs may (1) temporarily block eggs from being released from ovary or prevent or delay ovulation; (2) alter transport or binding of sperm or egg to prevent fertilization; (3) prevent implantation should fertilization occur depending on the phase of the menstrual cycle.

#### **Effectiveness of ECPs:**

- If 100 women each had sex once during the second or third week of the menstrual cycle without using contraception, 8 would likely become pregnant.
- If all 100 women used progestin-only ECPs, one would likely become pregnant.
- If all 100 women used estrogen and progestin ECPs, 2 would likely become pregnant.
- All ECPs work best when taken as soon as possible after unprotected sex but may be effective up to 5 days (120 hours).

#### Side Effects and their management

ECPs do not cause abortion or birth defects if pregnancy occurs; and are not dangerous to a woman's health and do not make women infertile. ECPs can be safely used by all women, including women who cannot use ongoing hormonal contraceptive methods.

The common side effects are:

- Changes in bleeding patterns including:
   Slight irregular bleeding for 1-2 days after taking ECPS
   Monthly bleeding that starts earlier or late than expected
- In the week after taking ECPs: nausea, abdominal pain, fatigue, headaches, breast tenderness, dizziness, vomiting.

These side effects do not require major medical interventions, they resolve by themselves.

# **Drug interaction**

- There are no specific data about the interaction of ECPs with other drugs that the client may be taking.
- Efficacy of ECPs could possibly be affected by rifampicin, griseofulvin, certain anticonvulsant drugs and ritonavir.
- If the client is taking any of these drugs, advise her that the ECPs may be less effective for her, but will not cause her harm.

Note:

ECPs are safe, even when used repeatedly. Compared with the potential health risks of pregnancy, taking ECPs to prevent unintended pregnancy is much safer. Women should be able to access and use ECPs as many times as they need. However, ongoing methods of contraception are more effective than ECPs. Only barrier methods, such as condoms, protect against HIV and sexually transmitted infections (STIs).

#### v. Condoms

There are two types of condoms: the male condom which is made of latex and the female condom which is made of plastic. 'Dual protection' (also known as 'dual use') implies use of condoms (male or female condoms) in addition to other contraceptive methods (also called "dual method use"). Dual protection can also mean the use of condoms for protection from HIV/STIs as well as pregnancy.

#### **Male Condoms**

Male Condoms are sheaths, or coverings, that fit over a man's erect penis. Most are made of thin latex rubber. Condom works by forming a barrier that keeps sperm out of the vagina- preventing pregnancy. Also keep infections in semen, on the penis, or in the vagina from infecting the other partner.

All men and women can safely use male condoms except those with severe allergic reaction to latex rubber. Condoms can be used any time the client wants.



Figure 3: 3 Male condoms

#### **Characteristics**

- Have no hormonal side effects.
- Can be used as a temporary or backup method.
- Can be used without seeing a health care provider.
- Available in health facilities, over the counter and in shops, kiosk, supermarkets, etc.
- Return of fertility after use of condom is stopped is immediate.

#### **Effectiveness**

- Effectiveness depends on the user: Risk of pregnancy or sexually transmitted infection (STI) is greatest when condoms are not used with every act of sex. Very few pregnancies or infections occur due to incorrect use, slips, or breaks.
- Protection against pregnancy:
  - As commonly used, about 15 pregnancies per 100 women whose partners use male condoms over the first year.
  - When used correctly with every act of sex, about 2 pregnancies per 100 women whose partners use male condoms over the first year.
- Protection against HIV and other STIs:

- Male condoms significantly reduce the risk of becoming infected with HIV when used correctly with every act of sex.
- When used consistently and correctly, condom use prevents 80% to 95% of HIV transmission that would have occurred without condoms.
- Condoms reduce the risk of becoming infected with many STIs when used consistently and correctly.
  - Protect best against STIs spread by discharge, such as HIV, gonorrhea, and Chlamydia.
  - Also protect against STIs spread by skin-to-skin contact, such as herpes simplex virus and human papilloma virus.
- Effectiveness of condoms depends on proper use. Clients should be counseled on the following points:
  - Use a new condom for each act of sex
  - Before any physical contact place, the condom on the tip of the erect penis with the rolled side out
  - o Unroll the condom all the way to the base of the erect penis
  - Immediately after ejaculation, hold the rim of the condom in place and withdraw the penis while it is still erect.
  - o Dispose of the used condom safely.

#### Side effects and its management

- If mild irritation in or around the vagina or penis or mild allergic reaction to condoms, manage as:
  - Suggest trying another brand of condoms. A person may be more sensitive to one brand of condoms than to others.
  - Suggest putting lubricant or water on the condom to reduce rubbing that may cause irritation.
  - If symptoms persist, assess, or refer for possible vaginal infection or STI as appropriate.
    - If there is no infection and irritation continues or recurs, the client may have an allergy to latex.

- If not at risk of STIs, including HIV, help the client choose another method.
- If the client or partner is at risk for STIs, suggest using female condoms or plastic male condoms, if available. If not available, urge continued use of latex condoms. Tell the client to stop using latex condoms if symptoms become severe (see Severe allergic reaction to condom, below).
- If neither partner has an infection, a mutually faithful sexual relationship provides STI protection without requiring condom use but does not protect against pregnancy.
- If severe allergic reaction to condom (rash over much of the body, difficulty breathing, dizziness or loss of consciousness during or after use of condom), manage as the following:
  - Tell the client to stop using latex condoms.
  - Refer for care, if necessary. Severe allergic reaction to latex could lead to life-threatening anaphylactic shock. Help the client choose another method.
  - If the client or partner cannot avoid risk of STIs, suggest they use female condoms or plastic male condoms, if available. If neither partner has an infection, a mutually faithful sexual relationship provides STI protection without requiring condom use but does not protect against pregnancy.

#### **Female condoms**

A female condom enables a woman to control its use to prevent pregnancy and STIs including HIV. Female condoms are sheaths, or linings, that fit loosely inside a woman's vagina, made of thin, transparent, soft plastic film. Female condoms work by forming a barrier that keeps sperm out of the vagina, preventing pregnancy. Also keep infections in semen, on the penis, or in the vagina from infecting the other partner. All women can use plastic female condoms. No medical conditions prevent the use of this method.

#### Female condoms have:

- Flexible rings at both ends,
- One ring at the closed end helps to insert the condom
- The ring at the open end holds part of the condom outside the vagina

• Lubricated with a silicone-based lubricant on the inside and outside.



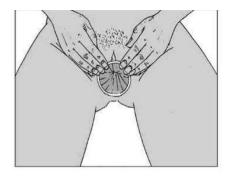


Figure 3: 4 Female Condom

#### **Characteristics**

- Return of fertility after use of female condom is stopped is immediate.
- Some women like female condoms:
  - o Women can initiate use of female condom
  - Have a soft, moist texture that feels more natural than male latex condoms during sex
  - o Help protect against both pregnancy and STIs, including HIV
  - Outer ring provides added sexual stimulation for some women
  - o Can be used without seeing a health care provider
- Some men like female condoms:
  - o Can be inserted ahead of time so do not interrupt sex
  - o Are not tight or constricting like male condoms
  - o Do not dull the sensation of sex like male condoms
  - o Do not have to be removed immediately after ejaculation

#### **Effectiveness**

- Effectiveness depends on the user: Risk of pregnancy or sexually transmitted infection (STI) is greatest when female condoms are not used with every act of sex. Few pregnancies or infections occur due to incorrect use, slips, or breaks.
- Protection against pregnancy:

- As commonly used, about 21 pregnancies per 100 women using female condoms over the first year. This means that 79 of every 100 women using female condoms will not become pregnant.
- When used correctly with every act of sex, about 5 pregnancies per 100 women using female condoms over the first year.
- Protection against HIV and other STIs:
  - Female condoms reduce the risk of infection with STIs, including HIV, when used correctly with every act of sex.
- Effectiveness of female condoms depends on proper use. Clients should be counseled on the following points:
  - O Use a new female condom for each act of sex
  - o Before any physical contact, insert the condom into the vagina
  - o Ensure that the penis enters the condom and stays inside the condom
  - After the man withdraws his penis, hold the outer ring of the condom, twist to seal in fluids, and gently pull it out of the vagina
  - Dispose of the used condom safely

#### Side effects and their management:

- If mild irritation in or around the vagina or penis
  - Usually goes away on its own without treatment.
  - Suggest adding lubricant to the inside of the condom or onto the penis to reduce rubbing that may cause irritation.
  - If symptoms persist, assess and treat for possible vaginal infection or STI, as appropriate.
  - If there is no infection, help the client choose another method unless the client is at risk for STIs, including HIV
  - For clients at risk of STIs, including HIV, suggest using male condoms. If using male condoms is not possible, urge continued use of female condoms despite discomfort.

 If neither partner has an infection, a mutually faithful sexual relationship provides STI protection without requiring condom use but does not protect against pregnancy.

# 2.9. Long Acting Contraceptives



# **Brainstorming for 5 minutes**

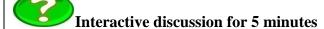
- What do you know about long acting reversible family planning pharmaceuticals?
- What do know about implants, IUCDs?
- What are the benefit of implants and IUCDs?

## i. Contraceptive Implants

Contraceptive implants are small plastic rods or capsules, each about the size of a matchstick, that release a progestin like the natural hormone progesterone in a woman's body. They are inserted under the skin in a woman's upper arm. Implants work by thickening cervical mucus and partially preventing ovulation (in about half of menstrual cycles).

The following forms of implants are available:

- Jadelle is a two-rod system designed to deliver a steady daily dose of levonorgestrel over a period of five years.
- Sino-implant (II) is identical to Jadelle but is approved for use over a period of four years.
- Implanon—a single-rod system—continually releases a low, steady dose of the progestin etonogestrel for a period of up to three years. Currently, the available single rod implant is Implanon NXT.
  - Implanon NXT contain 68 mg of ETG, are prequalified by the WHO, and are more than 99% effective at preventing pregnancy.
  - o Implanon NXT contains 3% barium sulphate, therefore, the rod in Implanon NXT can be detected by x-ray, and it uses an improved insertion device. This makes Implanon NXT as an improved generation as compared to the previous Implanon classic, which is now completely replaced by Implanon NXT



- What are **eligibility criteria** for implants?
- Mention some of the conditions where implants cannot be used by women

Implants are safe and suitable for nearly all women including women who:

- Have or have not had children or not married
- Are of any age, including adolescents and women over 40 years old
- Have just had an abortion, miscarriage, or ectopic pregnancy
- Smoke cigarettes, regardless of woman's age or number of cigarettes smoked
- Have anemia now or in the past, have varicose veins and are infected with HIV, whether or not on antiretroviral therapy

Usually, a woman with any of the conditions listed under POPs should not use implants including women with unexplained vaginal bleeding before evaluation for possible serious underlying condition



Figure 3: 5 Implanon

# **Characteristics of progestin-only implants**

- Highly effective, easy to use, long-acting pregnancy protection but easily reversible, do
  not interfere with intercourse, have no effect on quality or quantity of breast milk
- Have non-contraceptive health benefits (help prevent ectopic pregnancy and irondeficiency anemia)

- Insertion involves minor surgical procedure and some discomfort for a day or two;
   Cannot be initiated or discontinued without a provider
- Provide no protection from sexually transmitted infections including HIV

#### **Effectiveness**

One of the most effective and long-lasting methods:

- Less than 1 pregnancy per 100 women using implants over the first year (5 per 10,000 women).
- Implants start to lose effectiveness sooner for heavier women.

# **Side Effects and their Management**



#### Paired, discuss and reflection for 15 minutes

How to manage the side effects of implant?

#### The common side effects are:

- Changes in bleeding patterns: It may occur during the first several months and after about one year. Lighter bleeding, irregular bleeding, infrequent bleeding, and/or no monthly bleeding may be observed.
- Other side-effects include: headaches, abdominal pain, acne (can improve or worsen), weight change, breast tenderness, dizziness, mood changes, nausea
- Other possible physical changes: Enlarged ovarian follicles

#### The bleeding is managed as:

- Many women using implants experience irregular bleeding (at unexpected times that bothers the client). It is not harmful and usually becomes less or stops after the first year of use.
- For modest short-term relief: 800 mg ibuprofen 3 times daily after meals for 5 days, beginning when irregular bleeding starts.

• If these drugs do not produce improvement, a woman can take combined oral contraceptives with the progestin levonorgestrel one pill daily for 21 days beginning when irregular bleeding starts

For ordinary headaches, mild abdominal pain and breast fullness or tenderness:

• Suggest aspirin (325–650 mg), ibuprofen (200–400 mg), paracetamol (325–1000 mg), or other pain reliever.

#### For acne:

• If client wants to stop using implants because of acne, suggest switching to COCs. Many women's acne improves with COC use.

**Note:** If the side effects persist after appropriate management, switching to other methods is an important suggestion.

## **Drug Interaction with Implant contraceptives**

The following categories of drugs may reduce effectiveness of implants as they are known to be liver enzyme inducers which break down the hormones in implants.

- Anti-epilepsy: Anti-epilepsy (seizure disorder) drugs such as barbiturates (phenobarbital), phenytoin, and carbamazepine, but not valproic acid.
- Anti-TBs (rifampicin)
- ARVs non-nucleoside reverse transcriptase inhibitors (NNRTIs) and Ritonavir-boosted protease inhibitors.

#### ii. Copper-Bearing Intrauterine Device (TCu-380A intrauterine device)

The intrauterine contraceptive device (IUD or IUCD) is a small plastic device inserted into a woman's uterus to prevent pregnancy. The most commonly inserted IUDs are shaped like a T and have copper wires or bands on the plastic stem and arms. The TCu-380A, or "Copper T," is the most widely used copper IUD in the world. It is effective for up to 12 years. They work by impairing viability of sperm and interfering with sperm movement which prevent fertilization.

IUD is safe and suitable for nearly all women. Most women can use IUDs, including women who:

- Are breastfeeding;
- Have or have not had children;

- Are not married, are of any age, including adolescents and women over 40 years old;
- Have just had an abortion or miscarriage (if no evidence of infection);
- Have history of ectopic pregnancy, pelvic inflammatory disease (PID);
- Have vaginal infections;
- Have anemia:
- Are infected with HIV or are on antiretroviral therapy and doing well. A woman who develops AIDS while using an IUD can continue to use the device.

Women with any of the following conditions should not use IUD:

- Pregnancy;
- Septic infection following childbirth or abortion (if insertion is immediately postpartum or post abortion);
- Unexplained vaginal bleeding (before evaluation);
- Cervical, endometrial, or ovarian cancer;
- Current pelvic inflammatory disease, current purulent cervicitis (gonorrhea or chlamydia);
- Malignant gestational trophoblastic disease;
- Known pelvic tuberculosis;
- Uterine fibroid or other anatomical abnormalities resulting in distortion of the uterine cavity, which is incompatible with IUD insertion
- Generally, should not be initiated in a woman with AIDS who is not taking antiretroviral drugs (ARVs).

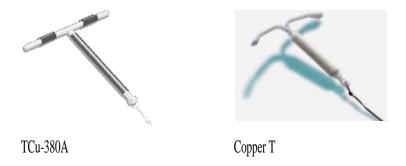


Figure 3: 6 IUD

#### **Characteristics of copper IUDs**

- Highly effective, do not interfere with intercourse
- Long-acting pregnancy protection but easily reversible (rapid return to fertility)
- Have beneficial non-contraceptive effects (protection from endometrial cancer and ectopic pregnancy)
- Provider needed to initiate and discontinue use
- May cause minor pain or discomfort during insertion and removal procedures
- Complications are rare (i.e., pelvic inflammatory disease and uterine perforation)
- Small risk of expulsion (a woman should check for IUD strings after menses)
- Provide no protection from sexually transmitted infections including HIV

#### **Effectiveness**

• One of the most effective and long-lasting methods: Less than 1 pregnancy per 100 women using an IUD over the first year (6 to 8 per 1,000 women).

#### Side Effects and their management

Side effects (generally not signs of a health problem; may diminish or change over time)

- Pain or cramping during menses
- Prolonged and heavy menstrual bleeding,
- Bleeding, or spotting between monthly periods

The following complications may rarely happen.

- Puncturing (perforation) of the wall of the uterus by the IUD or an instrument used for insertion. Usually heals without treatment.
- Miscarriage, preterm birth, or infection in the rare case that the woman becomes pregnant with the IUD in place.

The heavy or prolonged bleeding is managed as:

 NSAIDs such as ibuprofen (400 mg) or indomethacin (25 mg) 2 times daily after meals for 5 days, beginning when heavy bleeding starts

The cramping and pain is managed as:

- Suggest aspirin (325–650 mg), ibuprofen (200–400 mg), paracetamol (325–1000 mg), or other pain reliever.
- Note that if there is heavy or prolonged bleeding, aspirin should not be used because it
  may increase bleeding.

#### **Case studies**



# Case study 1

**Instructions:** Read the case study 1 and there are questions following the case that needs answer. Discuss in group and provide the answers for each of the question based on the case history.

Sr. Hanna is a nurse working in the FP clinic at your facility. She wants to consult you about the cases she faces every time. She presented one of the cases as follows.

Mrs Y is a 37-year-old married woman whose last child is a 9-months-old baby. She does not breastfeed. She was successfully treated for breast cancer three years back. She wants to delay pregnancy for some time. She and her husband both feel healthy. They decided to get tested for sexually transmitted infections (STIs), including HIV, and to begin using contraception. But Mrs Y smokes 15 cigarettes every day. She wants a contraceptive suitable for her condition. She thinks that she would like to use progestin-only implants so as to protect pregnancies for three years.

#### **Question**

Sr. Hann wants to know more about the suitable Family planning pharmaceuticals for her client and asks the following questions:

- 1. Which Family planning pharmaceuticals are contraindicated for client Y?
- 2. What kind of Family planning pharmaceuticals recommend for client Y.
- 3. Which Family planning pharmaceuticals are contraindicated for Mrs. Y?
- 4. What kind of Family planning pharmaceuticals recommend for Mrs.Y.

# CASE STUDY Inst

#### Case study 2

**Instructions:** Read the case study 2 and there are questions following the case that needs answer. Discuss in group and provide the answers for each of the question based on the case history

Sr. Meselu is a nurse in your health facility she wants a consultation with you about a family planning case she faced recently. One of her client, 35 years old woman, who was taking combined pills for the last 1 year, came with a complaint of irregular, spotty menstrual bleeding, head ache without aura and dizziness. Because of this, the client wants to have a shift into implant insertion. When taking the history Meselu learns that her client's mother has suffered from breast cancer and is currently successfully treated. Meselu found undiagnosed lump on breast physical examination, the client has undergone a further clinical examination for the lump and is diagnosed with benign breast disease. Meselu asked you the following questions for clarifications. What do you advise her?

- **1.** How do I manage the side-effects?
- **2.** Can I proceed with providing the client with the implant contraceptive?
  - a. If yes, why?
  - b. If no, why?
- **3.** In general, what are the conditions for which a woman is not indicated for implant insertion?
- **4.** The following medical conditions warrant stopping use or switching of contraceptive implants. (Indicate or tick True or False.)

a.	Unexplained vaginal bleeding	True False
b.	Migraine without aura	True False
c.	Spotting within the first three months	True False
d.	Migraine with aura	True False

# Frequently asked questions (FAQs) about contraceptive pharmaceuticals



# Home take assignment

On Frequently asked Questions (FAQs) and submit the assignment in the morning the next day.

Answer yes or no and put explanation for your answers

Table 3:2 frequently asked questions about COCs

SN	Questions
1	Should a woman take a "rest" from COCs after taking them for a time?
2	If a woman has been taking COCs for a long time, will she still be protected from
	pregnancy after she stops taking COCs?
3	How long does it take to become pregnant after stopping COCs?
4	Do COCs cause abortion?
5	Do COCs cause birth defects? Will the fetus be harmed if a woman accidentally takes
	COCs while she is pregnant?
6	Do COCs cause women to gain or lose a lot of weight?
7	Do COCs change women's mood or sex drive?
8	What can a provider say to a client asking about COCs and breast cancer?
9	Can women with varicose veins use COCs?
10	Can COCs be used as emergency contraceptive pills (ECPs) after unprotected sex?
11	Can a woman safely take COCs throughout her life?
	bleeding (menarche) to menopause

*Table 3:3 Frequently asked questions about POPs* 

SN	Questions
1	Can a woman who is breastfeeding safely use POPs?
2	What should a woman do when she stops breastfeeding her baby? can she continue
	taking POPs?
3	Do POPs cause birth defects? Will the fetus be harmed if a woman accidentally takes

	POPs while she is pregnant?
4	How long does it take to become pregnant after stopping POPs?
5	If a woman does not have monthly bleeding while taking POPs, does this mean that she
	is pregnant?

Table 3:4 Frequently asked questions on ECs

SN	Questions
1	Do ECPs disrupt an existing pregnancy?
2	Do ECPs cause birth defects? Will the fetus be harmed if a woman accidentally takes
	ECPs while she is pregnant?
3	How long do ECPs protect a woman from pregnancy?
4	What oral contraceptive pills can be used as ECPs?
5	Is it safe to take 40 or 50 progestin-only pills as ECPs?
6	Are ECPs safe for women with HIV or AIDS? can women on antiretroviral therapy
	safely use ECPs?

Table 3:5 Frequently asked questions about Injectable

SN	Questions
1	Can women who could get sexually transmitted infections
	(STIs) use progestin-only injectables?
2	If a woman does not have monthly bleeding while using progestin-only injectables, does
	this mean that she is pregnant?
3	Can a woman who is breastfeeding safely use progestin-only injectables?
4	How much weight do women gain when they use progestin-only injectables?
5	Do progestin-only injectables make a woman infertile?
6	How long does it take to become pregnant after stopping DMPA?

Table 3:6 Frequently asked question about Implants

SN	Questions
1	Do users of implants require follow-up visits?
2	Can implants be left permanently in a woman's arm?
3	Do implants cause cancer?
4	How long does is take to become pregnant after the implants are removed?
5	Can implants move around within a woman's body or come out of her arm?
6	Can a woman work soon after having implants inserted?
7	Must a woman have a pelvic examination before she can have implants inserted?

Table 3:7 Frequently asked questions for IUCD

SN	Questions
1	Does the IUCD cause pelvic inflammatory disease (PID)?
2	Can young women and older women use IUCD?
3	Does the IUCD make a woman infertile?
4	Can a woman who has never had a baby use an IUCD?
5	Can the IUCD travel from the woman's uterus to other parts of her body, such as her
	heart or her brain?
6	Must an IUCD be inserted only during a woman's monthly bleeding?

# 2.10. Summary

- Contraceptives help families to plan the number of children they want to have.

  Contraceptives have important benefit for the health of women
- FP methods can be classified by their mechanism (hormonal, barrier, intrauterine devices) and by duration of action (short acting, long acting reversible, and permanent methods).
- OCPs, Progestin-Only Injectables, POPs, ECPs, Condoms are short acting FP methods that have their own specific characteristics, level of effectiveness, and side effect profiles.
- Implants and IUCDs are long acting reversible FP methods that have their own specific characteristics, level of effectiveness, and side effect profiles.

# **Chapter 4:** Syndromic Management of Sexually

# **Transmitted Infections**

Allocated time: 75 minutes

# **Chapter description:**

This chapter is designed for participants to provide an overview of the syndromic approach of STI treatment with the agents used in each case.

**Primary Objective:** At the end of this chapter participants will be able to:

• Apply the syndromic management of STIs.

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

- Identify STI management approaches
- Discuss common STI syndromes
- Describe STI kits available in the country

# **Chapter Outline**

- 4.1. Introduction
- 4.2. STI management approaches
- 4.3. STI Syndromes
- 4.4. STI kits
- 4.5. Chapter Summary

#### 4.1. Introduction



# **Brainstorming for 5 minutes**

- What STIs do you know and explain in brief
- Indicate how prevalent are STIs.

Sexually transmitted infections (STIs) are among the most common causes of illness in the world and have far reaching health, social and economic consequences. STIs have public health importance because of their magnitude, potential complications, and their interaction with HIV/AIDS. They affect the health and social well-being of women disproportionately by producing significant impact on their reproductive potential.

As their name implies, the main mode of transmission of STI is through unprotected sexual intercourse. Other modes of transmission include: mother-to-child, blood transfusions, or other contact with blood or blood products.

One means of reducing the impact of STIs is through effective case identification and management. This obviously entails improving the quality of care and treatment of patients with STIs.

## 4.2. Management approaches of STIs



# Think-pair-share for 15 minutes

• Read, discuss in pairs, and reflect management approaches of STIs

Globally, health providers manage STIs using one of the following three diagnostic approaches: etiologic, clinical, and syndromic approach. Traditionally, a presumed sexually transmitted infection has been diagnosed by either clinical appearance alone (which is often inaccurate) or a laboratory-based test, which can be complicated and expensive and commonly delays in treatment.

In Ethiopia, syndromic approach is the public health approach used to manage STI cases. Syndromic management is based on the identification of a group of symptoms and easily recognized signs associated with infection with well-defined pathogens. Treatment for each syndrome is directed against the main organisms within that geographical setting responsible for

the syndrome. The syndromic approach has been shown to be highly effective for the management of majority of the STI. Prompt and efficient case detection and treatment, results in immediate health benefits for individual patients.

#### Diagnostic approaches:

• Identification of clinical syndrome and giving treatment targeting all the locally known pathogens which can cause the syndrome

#### Advantages:

- Complete STI care offered at first visit
- Simple, rapid and inexpensive
- Patients treated for possible mixed infections
- Accessible to a broad range of health workers
- Curtails unnecessary referral to hospitals

# Challenges

- Risk of over-treatment
- Requires prior research to determine the common causes of particular syndromes
- Asymptomatic infections are missed
- Has low specificity and positive predictive value for detecting cervical infections in women presenting with vaginal discharge.

# 4.3. STI Syndromes



# **Group Activity for 30 minutes**

Discuss in groups the characteristics, causative agents, treatment algorithm, and the medicines used to treat the STIs.

# Commonly encountered STI syndromes are:

- I. Urethral discharge in men
- II. Recurrent/Persistent Urethral Discharge Syndrome
- III. Genital ulcer

- IV. Vaginal discharge
- V. Lower abdominal pain in women
- VI. Inguinal bubo
- VII. Scrotal swelling
- VIII. Neonatal conjunctivitis.

# I. Urethral discharge in men

Urethral discharge is one of the commonest STIs among men in Ethiopia. Urethral discharge is the presence of abnormal secretions from the distal part of the urethra and it is the characteristic manifestation of urethritis. It can be accompanied by burning sensations (dysuria) during urination and urgency of urination. The appearance of the discharge can be purulent or mucoid, clear, white, or yellowish-green according to the causative agents and other factors like prior treatments with antibiotics. The two most common causative agents of the syndrome are Neisseria gonorrhea and Chlamydia trachomatis, 81% and 36.8% respectively.

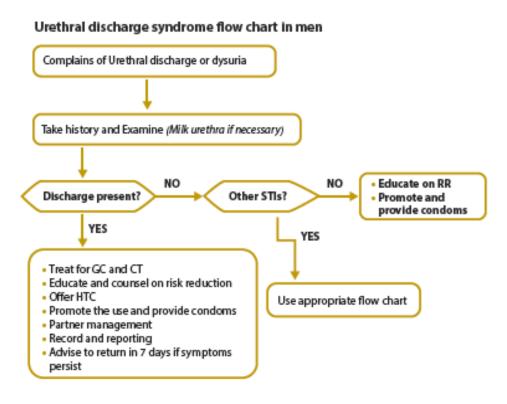


Figure 4.1 The algorithm of syndromic case management of urethral discharge syndrome

Table 4.1 Treatment of urethral discharge in men

Ceftriaxone 250mg IM stat/Spectinomycin 2 gm IM stat

#### Plus

Azithromycin 1gm po stat/Doxycycline 100 mg po bid for 7 days/Tetracycline 500 mg po qid for 7 days/Erythromycin 500 mg po qid for 7 days in cases of contraindications for Tetracycline (children and pregnancy)

Note: The preferred regimen is Ceftriaxone 250mg IM stat plus Azithromycin 1gm po stat

# II. Recurrent/Persistent Urethral Discharge Syndrome

Some patients may complain of persistent or recurrent burning sensation on urination, with or without discharge, due to various reasons:

- Inadequate treatment or poor compliance and/or
- Re-infection (partner/s not managed)
- Persistent urethritis after Doxycycline based treatment might be caused by doxycycline-resistant M. genitalium.
- T. vaginalis is also known to cause urethritis in men
- Infection by drug-resistant organisms (N. gonorrhea)

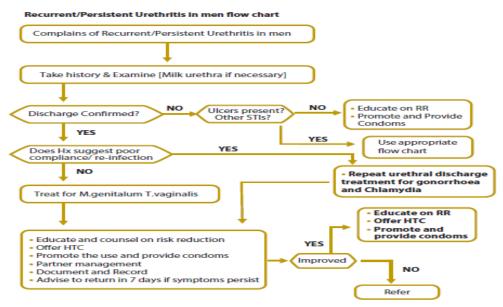


Figure 4.2 The algorithm of syndromic case management of recurrent or persistent urethral discharge syndrome

Table 4.2 Treatment of Persistent/Recurrent Urethritis Syndrome

#### Re-treat with initial regimen

• If non-compliant or re-exposure occurs, re-treat with the initial regimen with due emphasis on drug compliance and/or partner management.

### Cover M. genitalium and T. vaginalis

- If compliant with the initial regimen and re-exposure can be excluded, the recommended drug for persistent or recurrent urethral discharge syndrome in Ethiopia is:
- Metronidazole 2 gm po. stat/Tinidazole 1gm po once for 3 days (Avoid Alcohol!)

#### **PLUS**

• Azithromycin 1 g orally in a single dose (only if not used during the initial episode to address doxycycline resistant M.genitalium)

#### Referral

• If men require treatment with a new antibiotic regimen and a sexually transmitted agent is the suspected cause, all partners in the past 3 months before the initial diagnosis and any interim partners should be referred for evaluation and appropriate treatment of treatment failure.

### **III. Genital Ulcer Syndrome**

Genital ulcer is an open sore or a break in the continuity of the skin or mucous membrane of the genitalia because of sexually acquired infections. Genital ulcer facilitates transmission of HIV more than other sexually transmitted infections. Different kinds of bacteria and viruses cause genital ulcer. HSV2 alone was the leading cause of genital ulcer syndrome in both males and females constituting 44% and 76% of the cases respectively. Moreover dual infection with other genital ulcer pathogens was found in 52% of males and 78% of females. (Validation study, 2001).

Common clinical manifestations of genital ulcer are:

- Constitutional symptoms such as fever, headache, malaise, and muscular pain
- Recurrent painful vesicles and irritations
- Shallow and non-indurated tender ulcers

- Common sites in male are glance penis, prepuce and penile shaft
- Common sites in women are vulva, perineum, vagina and cervix and can cause occasionally severe vulvo- vaginitis and necrotizing cervicitis
- Painless indurated ulcer (Chancre)
- Regional lymph adenopathy

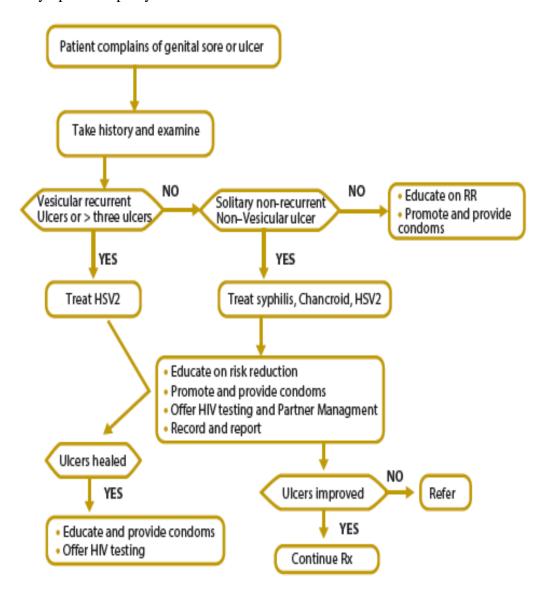


Figure 4.3 The Algorithm of Syndromic Case Management of Genital Ulcer Syndrome

Table 4.3 Treatment of Genital Ulcer

#### 1. Treatment for Non- Vesicular Genital Ulcer

• Benzathine penicillin 2.4 million units IM stat /Doxycycline(in penicillin allergy)100mg bid for 14 days

plus

 Ciprofloxacin 500mg bid orally for 3 days /Erythromycin 500mg tab qid for 7 days

plus

• Acyclovir 400mg tid orally for 10 days (or 200mg five times per day of 10 day)

### 2. Treatment for Vesicular, multiple or recurrent genital ulcer

• Acyclovir 200 mg five times per day for 10 days

Or

• Acyclovir 400 mg tid for 7 days

### 3. Treatment for recurrent infection:

• Acyclovir 400 mg tid for 7 days

### IV. Vaginal Discharge Syndrome

Abnormal vaginal discharge occurs when a woman notices a change in color, odor and amount of vaginal discharge accompanied by pruritus. Bacterial vaginosis (Gardnerella vaginalis) is the leading cause of vaginal discharge in Ethiopia followed by candidiasis, trichomoniasis, gonococcal and chlamydia cervicitis in that order.

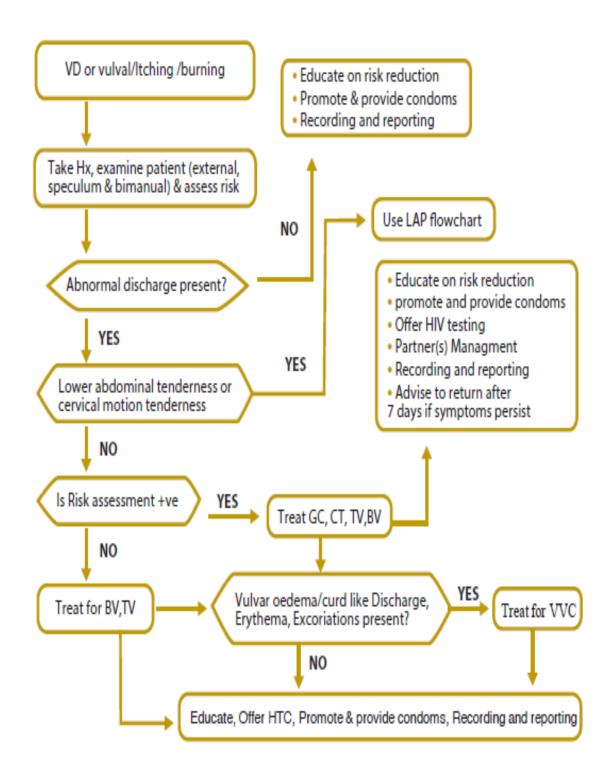


Figure 4.4: The Algorithm of Syndromic Case Management of Vaginal Discharge Syndrome

Table 4.4 Treatment of Vaginal Discharge Syndrome

Risk Assessment Positive	Risk Assessment Negative
Ceftriaxone 250mg IM stat/Spectinomycin 2 gm IM stat	Metronidazole 500 mg bid for 7 days
Plus	If discharge is white or curd-like add
Azithromycin 1gm po stat/Doxycycline 100 mg po bid for	Clotrimazole vaginal pessary 200 mg at bed
7 days Plus	time for 3 days
Metronidazole 500 mg bid for 7 days	
If discharge is white or curd-like add Clotrimazole vaginal	
pessary 200 mg at bed time for 3 days	
Note: The preferred regimen is Ceftriaxone 250mg IM stat	
plus	
Azithromycin 1gm po stat plus Metronidazole 500 mg bid	
for 7days	

### V. Lower Abdominal Pain/Pelvic Inflammatory Disease

Pelvic inflammatory disease (PID) refers to a clinical syndrome resulting from ascending infection from the cervix and/or vagina. PID comprises a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tubo-ovarian abscess and pelvic peritonitis. The inflammation may also spread to the liver, spleen or appendix.

PID improves with antibiotics alone and the fever usually subsides in less than 72 hours. However, failure to improve within 72 hours after antibiotic treatment indicates failure of medical treatment and the patient should be referred for surgical evaluation and treatment. The commonest pathogens associated with PID, which are transmitted sexually, are C. trachomatis and N. gonorrhea.

The commonest manifestations of pelvic inflammatory diseases include: lower abdominal pain, abnormal vaginal discharge, inter-menstrual or post coital bleeding, dysuria, backache, fever, nausea and vomiting, cervical excitation tenderness, etc.

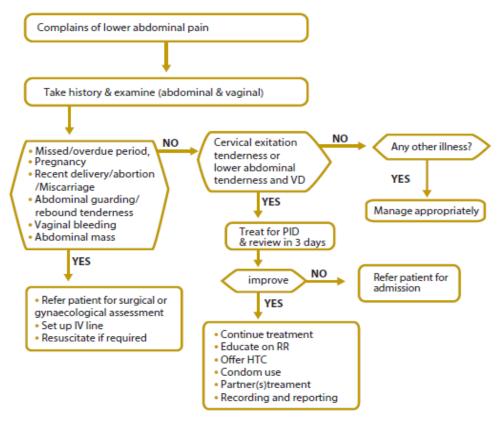


Figure 4.5The Algorithm of Syndromic Case Management of Lower Abdominal Pain Syndrome

Table 4.5 Treatment of Lower Abdominal Pain Syndrome

For outpatient	For inpatient
Ceftriaxone 250 mg IM stat /Spectinomycin 2gm	Ceftriaxone 250 mg i.m/i.v /Spectinomycin 2
i.m stat	gm i.m bid
Plus	Plus
Azithromycin 1gm po stat/Doxycycline 100 mg	Azithromycin 1gm po daily /Doxycycline 100
po b.i.d for 14 days <b>Plus</b>	mg po b.i.d for 14 days
Metronidazole 500 mg po b.i.d for 14 days	Plus
Admit if there is no improvement within 72 hours	Metronidazole 500 mg po b.i.d for 14 days
Note: The preferred regimen is Ceftriaxone	

250mg IM stat

plus

Azithromycin 1gm po stat

plus

Metronidazole 500 mg bid for 14 days

### VI. Scrotal Swelling Syndrome

Trauma, tumor, or torsion of the testis or inflammation of the epididymis can cause scrotal swelling. Mostly the inflammation of the epididymis is caused by sexually transmitted diseases. Among patients who are younger than 35 years, the swelling is likely to be caused by sexually transmitted infections due to N. gonorrhea, C. trachomatis, T. pallidum, and others. Some of the signs and symptoms of scrotal swelling are: pain and swelling of the scrotum, tender and hot scrotum on palpation, edema and erythema of the scrotum, dysuria, and sometimes, frequency and urethral discharge can be there.

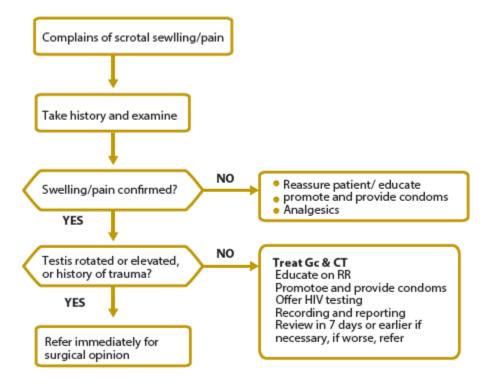


Figure 4.6The Algorithm of Syndromic Case Management of Scrotal Swelling Syndrome

Table 4.6 Treatment of Scrotal Swelling Syndrome

Ceftriaxone 250mg i.m stat/ Spectinomycin 2gms i.m stat.

#### **Plus**

Azithromycin 1gm po stat/ Doxycycline 100mg po bid for 7 days/ Tetracycline 500mg qid for 7 days

Note: The preferred regimen is Ceftriaxone 250mg IM stat plus Azithromycin 1gm po stat

### VII. Inguinal Bubo Syndrome (Swollen Glands)

Inguinal bubo is defined as swelling of inguinal lymph nodes because of STIs. The common causes of inguinal and femoral bubo are: Chlamydia trachomatis (L1, L2 and L3), Klebsiella granulomatis (donovanosis), Treponema pallidum, and Haemophilius ducreyia.

Clinical manifestations include:

- Constitutional symptoms of fever, headache and pain
- Tender unilateral or bilateral lymphadenopathy forms a classical "groove sign" in the inguinal area
- Fluctuant abscess formation which forma coalesce mass (bubo)
- Sometime concomitantly occur with genital ulcer

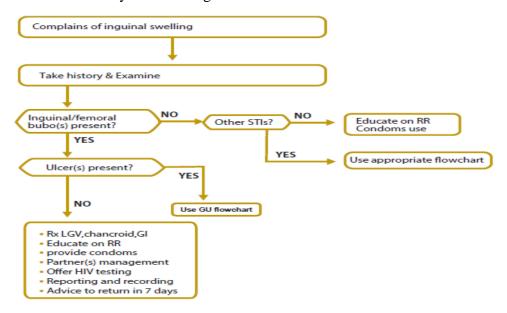


Figure 4.7. The Algorithm of Syndromic Case Management of Inguinal Bubo Syndrome

Table 4.7 Treatment of Inguinal Bubo

Ciprofloxacin 500mg bid orally for 3 days

### Plus

Doxycycline 100 mg bid orally for 14 days /Erythromycin 500mg po qid for 14 days.

If patient have genital ulcer, **add** Acyclovir 400mg tid orally for 10 days (or 200mg five times per day for 10 days)

**Note:** surgical incisions are contraindicated; aspirate pus with hypodermic needle through the health skin

### VIII. Neonatal Conjunctivitis

Neonatal conjunctivitis (ophthalmia neonatorum) is an ocular redness, swelling and drainage which can be sometimes purulent due to pathogenic agents occurring in infants less than 4 weeks of age. The neonates get the infections from their infected mothers. Neonatal conjunctivitis can cause loss of sight if it is not managed properly and promptly. Some of the common etiologic causes of neonatal conjunctivitis are: N. gonorrhea, C. trachomatis, S. pneumoniae, and others. Neonatal conjunctivitis can also occur due to irritant chemicals such as silver nitrate solution, which is applied to the eye of the neonate for prophylactic purposes.

Neonatal conjunctivitis can be prevented by:

- Wiping the baby's both eyes with dry and clean cotton cloth as soon as the baby is born.
- Apply 1% tetracycline eye ointment into the eyes of the newborn infant.
- Properly open the eye of the infant and place the ointment on the lower conjunctival sacs and avoid placing on the eye leads.

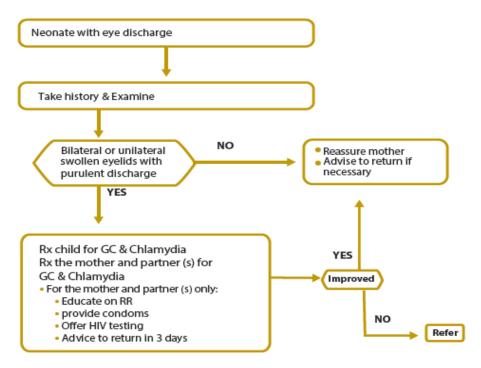


Figure 4.8 The Algorithm of Syndromic Case Management of Neonatal Conjunctivitis Syndrome

*Table 4.8 Treatment of Neonatal Conjunctivitis (Ophthalmia Neonatorum)* 

Ceftriaxone 50mg/kg IM stat maximum dose 125/ Spectinomycin 25 mg/kg IM stat maximum dose 75mg

#### Plus

Erythromycin 50mg/kg orally in four divided doses for 14 days

**Note**: TTC is used as prophylaxis for neonatal conjunctivitis but note for treatment

### 4.4. STI Kits

STI management through pre-packed treatment kits has been an approach to strengthen the syndromic approach of STI treatment. In addition to the recommended drugs for the specific syndrome, the package comprises condoms, partner referral card, information sheet on adherence and illustrative pictures. Currently, three types of Pre-Packed STI treatment kits namely: Addis Cure, Addis Cure Plus and Ul-cure are in use in Ethiopia for the treatment of urethral discharge, vaginal discharge and genital ulcer syndromes respectively.

Table 4.9. Types of STI kits and their components

Types of STI Kit	STI syndrome	% of STI	Components of the Kit
		burden	
Addis Cure	Urethral	31.6%	Ceftriaxone 250mg
	Discharge		Azithromycin 1gm
			Water for injection 10ml
			Syringe 5ml
Addis Cure+	Vaginal Discharge	43.9%	Ceftriaxone250mg
			Azithromycin 1gm
			Water for injection 10ml
			Syringe 5ml
			Metronidazole 250mg (28)
Ulcure	Genital Ulcer	9.2%	Benzathine Penicillin 2.4 MIU
			Syringe 5ml (2)
			Ciprofloxacin 500mg (6)
			Acyclovir 400mg PO (30)
			Water for injection 10ml

### 4.5. Summary

- STIs can be managed using one of the following three diagnostic approaches: etiologic, clinical, and syndromic approach. In Ethiopia, STIs are managed by the syndromic approach
- The common symptoms include: Urethral discharge in men, Genital ulcer, Vaginal discharge, Lower abdominal pain in women, Inguinal bubo, Scrotal swelling, Neonatal conjunctivitis.
- Addis cure, Addis cure+ and Ulcure are the three pre-packed kits used for the treatment of STI syndrome.

# **Chapter 5:** Rational use of Maternal Health

### **Pharmaceuticals**

### **Chapter Description:**

This chapter is designed for participants to enable them to contribute towards the promotion of the rational use of maternal medicines. The chapter describes the medicines' therapeutic use, safety, and related considerations for rendering quality maternal health care services.

### **Primary Objective:** At the end of this chapter participants will be able to:

• Discuss the rational use of pharmaceuticals in emergency obstetric care

### **Enabling objectives:**

- Identify the intervention packages in Emergency Obstetric care
- Describe the preventive use and safety of medicines during the antenatal care
- Describe the therapeutic use and safety of medicines during antepartum
- Identify the therapeutic use and safety of medicines during labor and delivery
- Discuss the therapeutic use and safety of medicine during post-partum

### **Chapter outline**

- 4.1. Introduction to Obstetric care services
- 4.2. Preventive use and safety of medicines during the antenatal care
- 4.3. Therapeutic use and safety of medicines during antepartum
- 4.4. Therapeutic use and safety of medicines during labor and delivery
- 4.5. Therapeutic use and safety of medicine during post-partum
- 4.6. Summary

### 5.1 Introduction to Obstetric care services

#### **5.1.1 Introduction**



## **Brainstorming (4 minutes):**

What are the most common causes of maternal death?

Maternal and child health is intimately bound up with economic development, education, gender issues and rights. Most pregnancies and births are uneventful with good maternal and perinatal outcome. However, approximately 15% of all pregnant women develop potentially life-threatening complications that call for skilled care and some will require major obstetrical interventions to survive.

Ethiopia has achieved impressive results in terms of reducing maternal deaths. Despite the improvement, significant number of mothers are still dying from easily preventable maternal conditions. Hemorrhage, eclampsia, obstructed labor, maternal sepsis, and abortion are the leading cause of maternal deaths. Multiple factors — mainly through delaying appropriate interventions — are responsible for the high maternal and perinatal mortality/morbidity in Ethiopia. Some obstetric complications, particularly hemorrhage, require fast interventions in less than 2 hours from the onset of bleeding, otherwise deaths may occur even more quickly.

### 5.1.2 The three-delay model



### **Brainstorming (3 minutes):**

What do you know about the three-delay model?

Any delay in receiving the appropriate obstetric interventions may have fatal consequences. The various factors that create the delays are collectively known as "the three delays model". As shown in figure 4.1., the three delays include: delays in recognizing problems and deciding to seek care; delays in transportation to reach appropriate care; and delays in receiving appropriate care at the health facility.

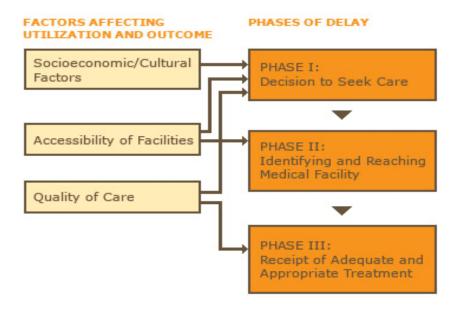


Figure 5.1 The three delays and factors affecting utilization and outcome

The first two delays reveal the factors that affect health care seeking at the family and community level – not recognizing complication, cultural and spiritual beliefs, lack of transport and long distance and time taken to reach health facility are some of the factors that belong to the first two delays. The third delay is particularly related to health care providers, access to appropriate medicine, and the health system. Thus, lack of access to essential medicine, supplies and equipment is among the most important factors contributing to the delays.

# **5.1.3 Functional components of BEmONC and CEmONC services**



## Think-Pair-share (3 minutes):

What are the functional components of emergency obstetric care?

One way of reducing maternal mortality is by improving the availability, accessibility, quality and use of services for the treatment of complications that arise during pregnancy and childbirth. Emergency Obstetric and Newborn Care (EmONC) is a package of high impact interventions designed for managing most of the direct cause of obstetric complications. As shown in table 4.1, the interventions are classified as Basic and Comprehensive EmONC services depending on the scope of services.

Table 4.1 Functional components of BEmONC and CEmONC services

Basic EmONC	Comprehensive EmONC
(In Primary Health Care Facility)	(In District Hospital and above)
Parenteral antibiotics	All Basic EmONC plus,
Parenteral oxytocic drugs	• Surgery (caesarean section)
Parenteral anticonvulsants	<ul> <li>Blood transfusion</li> </ul>
Manual removal of placenta	
Removal of retained products of conception	
Assisted vaginal delivery (vacuum extraction)	
Newborn care	

As shown in the above table; parenteral antibiotics, parenteral oxytocic drugs and anticonvulsants are among the basic components of the service packages in BEmONC and CEmONC services. Thus, the proper function and success of interventions rely on reliable availability, accessibility, and rational use of quality medicines.

Table 4.2. Review questions on obstetric care services

Questions	Answers
What are the leading causes of	
maternal deaths	
Mention the functional	
components of BEmONC and	
CEmONC?	
How do you define oxytocic	
drugs?	
What are your roles in EmONC	
interventions	

# 5.2 Preventive use and safety of medicines during the antenatal care

## **5.2.1** Antenatal Care Service Package



#### **Individual reflection for 5 minutes**

- What is antenatal care? Why is it important?
- What contribution do you think a pharmacist will have in antenatal care?
   Group work (tree approach game): 15 minutes



## **Instruction:**

- O **Discuss** in group of 3 or 4 and the purpose is to assemble various issues of ANC in the form of Tree
- Read the Antenatal care topic and determine a sentence or a phrase that the group assumes as a central point for explaining ANC
- o Write this main point as the **main trunk** and basic issues as **root** of the tree
- Identify further points that seem to be the branches for the central point you identified.
   Try to limit the assumed branches to a maximum of five.
- Further Examine each branches and extract and summaries the details related to that branch. These are the leaves.
- Assemble the diagram of tree showing the basic issues (root) main theme (trunk), the sub-themes (branches) and the detail of each sub-theme (leaves).

Antenatal care (ANC) is defined as the complex of interventions that a pregnant woman receives from organized health care services with the objective of assuring every pregnancy to culminate in the delivery of a healthy child without impairing the health of the mother.

According to the 2016 EDHS, it has been estimated that 25% female deaths in Ethiopia is due to pregnancy-related causes. The major causes of these deaths are hemorrhage, hypertension in pregnancy, obstructed labor, and sepsis. Furthermore malaria, HIV/AIDS, anemia, and malnutrition are associated with an increased risk of maternal and newborn complications and deaths which could easily be prevented through simple and cost-effective interventions.

The major goal of focused antenatal care is, therefore, to help women maintain normal pregnancies through:

- o Early detection and treatment of problems and complications
- o Prevention of complications and disease
- Birth preparedness and complication readiness
- Health promotion

Every pregnant woman must receive at least 4 checkups during pregnancy (Registration and 1st check-up within 12 weeks, 14-26 weeks, 28-32 weeks and 36-40 weeks). At ANC visit, the following activities are performed:-

### 1. History recording, and general physical examinations

2. **Laboratory investigations**: Urine analysis, syphilis (rapid test - RPR or VDRL), Blood-group typing (ABO and rhesus), Hemoglobin (Hb) or hematocrit count, HIV test, CD4 count for all HIV positive pregnant women, ultrasound, if available, Hepatitis surface Antigen (HBsAg). While all of these tests are performed in the first visit, hemoglobin and urine examination are repeated in all of the subsequent 3 visits.

### 3. Implementing essential ANC interventions:

- 3.1. **Health promotion and disease prevention**: In this intervention, for instance, health education and counseling, iron and folate supplements, Tetanus Toxoid (TT) vaccination, deworming and PMTCT interventions for HIV positive mother are among the essential interventions implemented for prevention purpose in ANC visits.
- 3.2. Early detection and treatment of complications: In this intervention, detection of danger signs and treatment of complications are important interventions. The danger signs in pregnancy which demands prompt management include: vaginal bleeding, sudden leaking of fluid from vagina, severe headache which will not be relieved by simple analgesics, dizziness and blurring of vision, sustained vomiting, swelling (hands, face, etc.), loss of fetal movements, convulsions, premature onset of contractions (before 37 weeks), severe or unusual abdominal pain and high fever.

#### **Medicines used in Antenatal Care**

The standard guidelines for ANC in Ethiopia emphasize that every pregnant mother should receive tetanus toxoid injections, iron and folate supplements, and deworming medications from a skilled provider. The priority medicines used for preventive purpose in ANC are indicated in the box below.

Medicines used for preventive purpose

- 1. Ferrous Salt + Folic Acid Tablet, 60 mg Iron + 400 micrograms Folic Acid
- 2. Tetanus Toxoid vaccination
- 3. Albendazole, 400 mg; Mebendazole, 100 mg,

# I. Iron and Folic Acid supplementation

Iron requirements increase during pregnancy because of maternal blood volume expansion, fetal needs, placenta and cord needs and blood loss at the time of delivery. Maternal iron deficiency can cause anemia during pregnancy, spontaneous abortion, premature delivery, and delivery of a low-birth-weight baby.

Folic acid is essential in the synthesis of DNA and RNA. Pregnant women, who take 0.4 to 0.8 mg of folic acid daily during the first trimester of pregnancy, are significantly less likely to have a child with Neural Tube Defects such as spina bifida<sup>1</sup>. Folic acid supplementation after the first month of pregnancy will not prevent neural tube defects. However, it will contribute to other aspects of maternal and fetal health. To prevent anemia during pregnancy, daily oral iron and folic acid supplementation is recommended as part of the antenatal care services.

Table 5:1 Dose, administration, and significant interaction of iron and folic acid supplement

Supplement composition	1 ferrous sulfate tablet: 60 mg Iron + 400 micrograms Folic Acid
Dose and Administration	One ferrous sulfate tablet, orally, once daily
Duration	Starting from the first ANC visit throughout the pregnancy and
	until 3 months after delivery or abortion.
Drug and Food Interactions	Magnesium Trisilicate, Tetracycline, eggs and milk can inhibit the absorption of iron.

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<sup>&</sup>lt;sup>1</sup>uncommon congenital defect in which a vertebra is malformed.

## **Common Side effects**

Nausea, vomiting, abdominal pain or discomfort, blackening of stools, diarrhea and constipation. Gastric irritation may occur when taken on an empty stomach

### **Important counseling point:**

- To enhance absorption and reduce gastric irritation: It is better to take oral iron between meals, particularly; meat or vitamin-rich foods (fruits and vegetables).
- To reduce drug and food interaction: Oral iron preparations should not be taken within one hour before or within two hours after ingestion of antacids, egg or milk. Tetracycline and iron supplement has antagonistic effect to each other. If both medicines prescribed together, tetracycline should be administered three hours after or two hours before oral iron supplements
- For preventing Neural Tube Defect: Folic acid must be taken in the first month of pregnancy.
- For safe storage: Advice to store in a place where children cannot get it; and, in a dry place.
   Note that iron has a poisoning effect for children

#### II. Tetanus Toxoid vaccination

Tetanus is a preventable disease through primary prophylaxis of Tetanus Toxoid (TT). Tetanus can develop in women who have not been immunized or who have not received a booster dose within the past 10 years. Tetanus toxoid vaccination is provided for pregnant women according to the following administration schedule.

Table 5.2 Schedule for Tetanus Toxoid administration

Dose	Time for	<b>Duration of</b>	Notes
Dose	administration	protection	Notes
TT1	During the first ANC	No protection	First TT dose initiated if the woman has  not previously been vaccinated, or
TT2	4 weeks after TT1	3 years	vaccination status is not known
TT3	At least 6 months after TT2	5 years	If the woman has proof of vaccination in  - childhood or adolescence with tetanus -
TT4	At least one year after TT3	10 years	containing vaccine, 1 dose of TT is given during the first ANC and a second dose is given a year later.
TT5	At least one year after TT4	45 years	If the woman has had 1–4 doses of tetanus toxoid vaccine in the past, she will be given one dose of TT before delivery

# III. Anthelminthic drugs for deworming:

Worm infestation during pregnancy is an important health issue as they can cause anaemia, malnutrition, growth faltering, and impaired cognitive development. The worm infestations lead to nutritional deficiencies by causing either protein and nutrient loss or malabsorption. Anemia in pregnant women is mainly attributed to hookworm infestation. Hence, anthelminthic deworming has the potential to address the problem of maternal anemia and to improve maternal well-being, birth weights and infant mortality.

The Common available anthelminthic drugs used to treat worm infestations are Mebendazole and Albendazole.

Table 5.3 Dose, administration, and adverse effect of deworming Medication

Drug	Dosage	Significant Side effect	Drug interaction	
	Mebendazole 500 mg once in	Diarrhea,	Both have serious	
Mebendazole	second or third trimester to	abdominal pain	reaction with alcohol.	
Wichenduzoie	every woman in hookworm		Hence, alcohol should	
(drug of	endemic areas		be avoided before or	
choice)			after taking these	
Albendazole	A single dose of 400 mg of oral	Nausea and	medicines.	
( Alternative)	Albendazole	headache		

### **5.2.2** Prevention of Mother to Child Transmission of HIV

Provider initiated routine HIV testing and counseling (HTC) using the option approach is the recommended approach for all clients seen within the context of maternal care (i.e. at ANC, labor, immediate postpartum). HIV-positive women need focused antenatal care, with extra care to reduce the risk of adverse pregnancy outcomes and the likelihood of HIV transmission from mother-to-child.

All HIV positive pregnant women should start ART as soon as possible irrespective of their gestational age, clinical stage and CD4 counts. Highly Active Anti Retro Viral Therapy (HAART) for HIV positive pregnant mothers is indicated based on recommendations of Option B+ regimen (test-and-treat principle). Once started, a woman should continue taking ART for her entire life.

### **Anti-Retroviral Medicines for pregnant women**



### Pair Reading and reflection – 10 minutes:

What are the major classes of ARV?

How do they act in inhabiting viral further progression?

There are three major classes of Anti-Retro-Viral (ARV) medicines available for use in Ethiopia: Nucleoside reverse transcriptase inhibitors, non-Nucleoside reverse transcriptase inhibitors and Protease inhibitors.

The nucleoside and non-nucleoside reverse transcriptase inhibitors both have the same "target." They prevent HIV from entering the infected cell's center, so HIV can't start making new copies. Protease inhibitors are used when the central part of the body cell makes parts of the HIV virus after infection; these parts have to be cut and put together in the right way before the new HIV copies can leave the cell. Protease inhibitors prevent this "cutting and putting together" from happening correctly, so the newly produced virus parts cannot leave the infected cell and infect other cells.

Table 5.4 Recommended ARV First line drug regimen in PMTCT

Diagnosis of HIV and	Type of regimen	Dose and administration
initiation of ART at:		
ANC (newly identified)	TDF+3TC+EFV	TDF - 300 mg, once daily
Intra-partum (L&D), newly identified	TDF+3TC+EFV	3TC- 150 mg, twice daily
Postpartum period (newly identified)	TDF+3TC+EFV	or 300 mg once daily
Pregnant mother on Pre-ART follow up	TDF+3TC+EFV	– EFV- 600 mg once daily
Already on HAART before pregnancy	Continue with the regimen th	e woman has started
Alternative regimen:	AZT +3TC +EFV	AZT 300mg twice daily

# Justification for preferring Tenofovir (TDF), Lamivudine (3TC) and Efavirenz (EFV):

- TDF is more suitable for HIV+ pregnant women than AZT because it does not cause anemia
  which is common during pregnancy; and is less likely to cause toxicity and long-term side
  effects.
- TDF and 3TC are rarely discontinued due to side effects or toxicity, compared to the other ARVs.

- EFV is alternative to NVP and is found to be safe in 1st trimester and dosed once daily. NVP which may cause severe liver and skin toxicity especially women with high CD4 count.
- Efavirenz has been suspected to cause birth defects; however recent findings confirm the safety of Efavirenz. Therefore, Efavirenz can be used at any time during pregnancy

### **Common adverse effects**

Side effects to the TDF/3TC/EFV regimen are generally mild, usually most noticed during the first few weeks of treatment and tend to disappear by the end of the first month. The most common side effects of TDF/3TC/EFV are summarized in the table below.

Table 5.5 The most likely side effects of TDF/3TC/EFV

ARV Drug	Very Common side effects	Potentially Serious
		side effects
Zidovudine (AZT)	Nausea, Diarrhea, Headache, Fatigue	Pallor
	Muscle pain	
Tenofovir (TDF)		Renal insufficiency, Effect
		on fetal bone
Lamivudine (3TC)	Nausea; Diarrhea;	
Nevirapine (NVP)	Nausea, Diarrhea	Yellow eyes, Skin rash
		Fatigue AND shortness of
		breath, Fever
Efavirenz(EVF)	Nausea, Diarrhea, Strange Dreams,	Seek care urgently, Yellow
	Difficulty Sleeping, Memory problems,	Eyes, Psychosis or
	Headache; Dizziness	confusion, Skin Rash



# Paired Exercise ( 5 Minutes)

**Instructions:** Fill in the blanks in the table, by answering OK if right or No if it is wrong to each question asked about the ART regimen.

Table 5.6. Exercise on ART Regimens during Pregnancy

ART regimens	OK in first trimester	OK if hemoglobin less than 7	Preferred regimen in pregnancy	OK during breastfeeding	OK with High CD4 count
TDF-3TC-EFV					
AZT-3TC-NVP					
TDF-3TC-NVP					
AZT-3TC-EFV					

### Prophylaxis for HIV exposed infants

For all HIV exposed infants/newborns, provide NVP syrup for prophylaxis as per the infant dosing guide according to the national PMTCT guideline as per the below table.

Table 5.7. NVP prophylaxis for HIV exposed newborn/infant

G		New born ARV prophylaxis regimen		
Scenarios	Mother	Breastfeeding	Non-breastfeeding	
HIV positive mothers on ART during pregnancy and labor	Continue ART	NVP daily until 6 weeks	NVP daily until 6 weeks	
HIV positive mother not on treatment in postnatal period	Initiate ART	NVP daily for 12 weeks	Initiate NVP daily in baby is less than 72 hours of age	
Women on ART during pregnancy for less than four weeks or Start ART during labor	Continue ART	NVP daily for 12 weeks	NVP until 6 weeks	

HIV positive mother interrupts moderate ART while breastfeeding (after relating infant is 6 weeks of age) and	ssess the other for lated issues d manage cordingly	Re-initiate the exposed infant with NVP and continue until 6 weeks after maternal ART is re-initiated. OR Until one week after breastfeeding has ended
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Table 5.8. NVP daily dose for HIV exposed infants

Infant age	Birth weight	NVP daily dosing	Dose in ml
Birth to 6 weeks	2000 g - 2499 g	10mg once daily	1ml
	Birth weight ≥2500	15 mg once daily	1.5ml
Age 6 weeks to 6 n	nonths	20 mg once daily	2ml
Age 6 months to 9 months		30 mg once daily	3ml
Age > 9 months		40 mg once daily	4ml

# 5.3Therapeutic use and safety of medicines during antepartum

### 5.3.1 Introduction



### Think-pair-share for 5 minutes

Have you ever seen any case of complications in your facility during the antepartum period? If Any, what was the case? How was the case managed therapeutically?

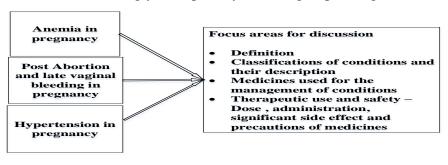
Antepartum period refers to the period from the time of conception up to the onset of labor. Complication may develop any time during this period. The most common complications that may occur in this period are anemia, hyperemesis, abortion, bleeding, and hypertension, among others. There are also problems associated with the use of medicines in pregnancy endangering the lives of both the mother and the fetus. These complications and their therapeutic managements are described in this session.

### Major complications during antepartum



Jig-saw exercise major complications (60 minutes)

- **Be** in to **three groups** as indicated below.
  - o Group A: Anemia in pregnancy
  - Group B: Post abortion care and late vaginal bleeding in pregnancy
  - o Group C: Hypertension in pregnancy
- Discuss on each topic on the focus areas indicated below and be ready for teaching your topic to your new group arrengment in a regroup sessions.



### 5.3.2 Anaemia in pregnancy

Anaemia in pregnancy is defined as when the Haemoglobin (Hgb) level is below 11gm/dl in the first and third trimesters and below 10.5gm/dl in the second trimester of gestation.

Anemia is one of the major indirect causes of maternal death. It is estimated that 41.8% of pregnant women globally are anemic; where almost half of the anemia cases globally are caused by due to iron deficiency. Other causes of anaemia include malaria, hookworm and other helminthes, chronic infections, and genetic conditions.

The 2016 EDHS shows that 24% percent of women in Ethiopia are anaemic. Eighteen percent of these women are classified as mildly anemic, while 5% of them are moderately anaemic, and 1% severely anaemic. Low haemoglobin concentrations, indicative of moderate or severe anaemia during pregnancy, have been associated with an increased risk of premature delivery, maternal and child mortality, and infectious diseases. Thus, providing appropriate treatment for pregnant women with moderate or severe anemia is one of the most important interventions in the efforts of reducing maternal deaths secondary to anemia.

### **Medicines used for treatment of Anemia in Pregnancy**

(Any Ferrous Salt containing elemental form of Iron of accepted therapeutic value)

- Ferrous Sulphate 300mg tablet (32% elemental Iron)
- Ferrous Fumarate 325mg tablet (33% elemental Iron)
- Ferous Gluconate 300mg tablet (12% elemental Iron)

#### **Classifications of Anaemia**

Anaemia is classified into severe and moderate. The management protocol is defined based on the the classification and the level of health facilities. The classification of anemia and their management is summarized in the table below.

Table 5.9 Classification and medical management of anemia in pregnancy

Classification	Sign	Management protocol
	Haemoglobin <7 g/dl AND/OR	Severe Anemia is managed at
	Severe palmar and conjunctival pallor OR	Referral hospital level with possible blood transfusion. Therefore, at
Severe Anemia	Pallor with any of:	Health Center levels, this case
	• 30 breaths per minute	should immediately be referred to
	• If the pregnant mother tires easily, and	hospital with blood transfusion set
	• There is breathlessness at rest	up
		Should be treated with daily dose of
		120 mg of elemental Iron and 400
		μg or 0.4 mg Folic Acid (1 tablet of
		60 mg of elemental iron twice daily
Moderate	Haemoglobin 7-11 g/dl OR	for 3 months)
Anemia	Palmar or conjunctival pallor.	• If hemoglobin returns to normal,
		she can then switch to the
		standard antenatal dose to
		prevent recurrence of anemia.
		• <b>IF No progress</b> , she should be
		referred to hospital
No clinical	• Haemoglobin >11g/dl.	1 tablet of 60 mg of elemental iron
Anemia	• No pallor	once daily for 3 months

### **5.3.3** Post-Abortion care

Abortion is defined as the termination of pregnancy before the 28<sup>th</sup> weeks of gestation. When vaginal bleeding is occurring at gestational age less than 28 weeks, it is called early vaginal bleeding in pregnancy. The causes of early vaginal bleeding include: abortion, ectopic pregnancy, molar pregnancy, and other local lacerations. Of these causes, abortion is the leading

cause of bleeding and maternal death in early pregnancy – calling for significant attention in its

management. Therefore, the focus of discussion will be on safe post abortion care.

Post abortion care is a comprehensive service to treat women that present to a health care facility

after abortion has occurred spontaneously or after an attempted termination of pregnancy.

Definitive management of abortion depends on several factors, which include: the type and

classification of abortion; the stage of abortion; and the size of the uterus as identified by a pelvic

exam.

**Classification and stage of Abortion** 

Threatened abortion: a condition in which vaginal bleeding is less than that of in inevitable

abortion and the cervix is closed.

When a pregnancy is complicated by bleeding from the vagina, but the cervix is closed, this may

signal for a threatened abortion. There is a chance that the pregnancy may continue normally,

provided the fetus is showing signs of life. This type of abortion does not usually require medical

treatment.

**Inevitable abortion:** An inevitable abortion is when the fetus is entirely in the uterus, but the

pregnancy will definitely end in the expulsion of the fetus. This is a condition in which

1. vaginal bleeding has been profuse,

2. membranes usually show gross rupturing,

3. the cervix has become dilated, and

4. abortion is almost certain.

**Incomplete abortion**: An incomplete abortion is when

1. part of the fetal tissue or placenta is still in the uterus and

2. the cervix is open.

If you leave an incomplete abortion without treatment for some time there is an increased risk

that it will be complicated with infection and this could be life-threatening for the woman.

Complete abortion: A complete abortion means that all parts of the fetus and placenta have

been expelled through the vagina; nothing is left behind in the uterus and the cervix has closed.

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**Missed abortion**: This refers to fetal death in-utero before 28 weeks gestation which does not show any sign of expulsion and the cervix is completely closed. The dead fetus is likely to be retained in the uterus for some time unless there is an intervention in a specialized health facility.

**Septic abortion**: abortion associated with serious infection of the products of conception and endometrial lining of the uterus, leading to generalized infection. Pathogenic organisms of the bowel or vagina usually causes it.

### **Management of Post Abortion Care**

### **Medicines used in the management of Post Abortion Care**

For management of incomplete and missed abortion

- Misoprostol 200mc(μ)g, tablet
- Oxytocin 10 units/ml, 1ml injection
- Methyl ergometrine 2mg injection

For management of infections in septic abortion

- Ampicillin 500 mg PLUS
- Gentamicin 80mg/2ml PLUS
- Metronidazole 500mg injection

*Table 5.10 Medical management of complications in post abortion care* 

Type of abortion	Gestational age of pregnancy	Medical management protocol
THREATENED ABORTION	Less than 28 Weeks	Medical treatment is not usually necessary
INEVITABLE ABORTION	Less than 12 weeks	It should be managed Ergometrine 0.2 mg IM (repeated after 15 minutes if necessary)  OR Misoprostol 400 mcg by mouth (repeated once after 4 hours, if necessary)

Type of abortion	Gestational age of pregnancy	Medical management protocol
	More than 12 weeks:	If products of conceptus tissue is not expelled:  Infuse Oxytocin 40 units in 1 L IV fluids (normal saline or Ringer's lactate) at 40 drops per minute to help achieve expulsion of products of conception.
	Less than 12 weeks	If evacuation is not immediately possible: Give Ergometrine 0.2 mg IM (repeated after 15 minutes, if necessary) OR Misoprostol 400 mcg orally (repeated once after 4 hours, if necessary).
INCOMPLETE ABORTION	More than 12 weeks	Infuse Oxytocin 40 units in 1L IV fluids (Normal saline or Ringer's lactate) at 40 drops per minute until expulsion of products of conception occurs;  - If necessary, give Misoprostol 200 mcg vaginally every 4 hours until expulsion, but do not administer more than 800 mcg.
Complete Abortion	n	If the abortion is complete and when there is no sign of infection, medical treatment is not indicated
Missed abortion	12-24 week	Misoprostol 200 micrograms, vaginal, 12 hourly until expulsion or 400 micrograms, oral, 4 hourly until expulsion
	4-12 week	Misoprostol 800 micrograms, vaginal or sublingual, every 24 hours for two days
Missed Abortion and 13-17 were Intrauterine fetal death with previous caesarean 18-26 were		200 microgram 6hourly 100 microgram 6hourly
section	27-42 weeks	25-50 microgram 4hourly

Type of abortion	Gestational age of pregnancy	Medical management protocol
Septic abortion	Less than 28 Weeks	Give ampicillin 2 g IV every 6 hours  PLUS gentamicin 5 mg/kg body weight IV every 24 hours
		PLUS metronidazole 500 mg IV every 8 hours until the woman is fever-free for 48 hours.

### Vaginal bleeding in late pregnancy

Vaginal bleeding that occurs after 28 weeks of pregnancy and in labor but before the occurrence of delivery is known as vaginal bleeding in late pregnancy. However, when the pregnancy is in full term, a small amount of blood mixed with mucus is discharged from vagina - this phenomenon is not a problem – rather, it is a sign of start for labor and is known as "bloody show".

Vaginal bleeding that occur after 28 weeks is often termed as Antepartum Hemorrhage (APH). The most common causes of antepartum hemorrhage are placenta abruption<sup>2</sup> and placenta Previa<sup>3</sup>. When the severe bleeding occurs in labor, it may be a sign of uterine rupture. Vaginal or rectal examination should not be done in APH as it can aggravate bleeding. All cases of antepartum hemorrhage should be managed in a facility with set up for cesarean delivery; therefore, the patient should be **referred urgently** while continuing resuscitation and supportive care.

<sup>&</sup>lt;sup>2</sup> The sudden detachment of placenta from the uterine wall before labor, which often cause pain and light bleeding <sup>3</sup>Pregnancy in which the placenta is implanted in the lower part of the uterus (instead of the upper part); can cause bleeding late in pregnancy.

# Medicines and supplies used for resuscitation and supportive care

#### 1. Fluid

Should be started an IV infusion

### 2. Loading dose of Triple antibiotics

- If the diagnosis is ruptured uterus, in addition to the IV fluid, loading dose of triple antibiotic should be given as indicated below.
- Ampicillin 2gm iv stat,
- Metronidazole 500mg iv (Chloramphenicol 2gm iv) stat, Gentamycin 80mg iv stat

## **5.3.4** Hypertension in pregnancy

Hypertension in pregnancy is defined as a systolic blood pressure of more than 140 mm Hg or diastolic blood pressure of more than 90 mm Hg measured on two occasions at least 4 hours apart and within one-week period; or a single blood pressure recording of more than 160/110 mm Hg in a woman who had normal blood pressure prior to or during early pregnancy. The diagnosis of a hypertensive disorder in a pregnant woman depends, in part, upon the gestational age at presentation. They are classified as follows.

- Preeclampsia refers to a syndrome of new onset of hypertension (diastolic blood pressure 90–110 mm Hg) and proteinuria<sup>4</sup> after 20 weeks of gestation in a woman previously having normal blood pressure. If the diastolic blood pressure ≥ 110 mm Hg and the proteinuria is 3+ more, it is known as sever pre-eclampsia.
- **Superimposed preeclampsia** is worsening hypertension and/or new onset proteinuria in a woman with preexisting hypertension.
- **Eclampsia** refers to the occurrence of one or more generalized convulsions and/or coma in the setting of preeclampsia and in the absence of other neurologic conditions.
- **Preexisting (chronic) hypertension** is defined as systolic pressure ≥140 mmHg and/or diastolic pressure ≥90 mmHg that antedates pregnancy, is present before the 20th week of pregnancy, or persists longer than 6 weeks of postpartum.
- **Gestational hypertension** refers to elevated blood pressure detected after 20 weeks of gestation in the absence of proteinuria.

<sup>&</sup>lt;sup>4</sup> The presence of excessive protein (chiefly albumin but also globulin) in the urine; usually a symptom of kidney disorder

### Medicines used for managing Sever pre-eclampsia and eclampsia

#### **Anticonvulsant:**

- Magnesium Sulphate Injection, 20 %, 50 % in 20ml/10ml or
- Diazepam...

### Antihypertensive drugs: diastolic pressure is $\geq 110$ mm Hg

- Hydralazine Injection, 20 mg/ml in 1 ml ampoule.(first choice)
- Labetalol or Nifedipine Immediate release capsule 10 mg (if Hydralazine is not available)

### Non-severe hypertension: diastolic pressure between 90 -110 mm Hg

- Methyldopa Tablet, 250 mg, 500mg or
- Nifedipine, Capsule, 5 mg, 10 mg; Tablet, 10 mg

## Treatment protocol for managing Hypertension disorder in pregnancy in Pregnancy

**a. Magnesium Sulphate**: is the drug of choice for prevention and treatment of severe pre-eclampsia and eclampsia. When severe pre-eclampsia and eclampsia is suspected in a health center, loading dose of Magnesium Sulfate should be given immediately and refer the mother to higher health facilities where they can complete the treatment.

#### **Dose and Administration**

#### **Loading dose**

- 4 gm Magnesium Sulfate (MgSO<sub>4</sub>) as 20% solution IV given over 5 minutes (Mix 8 ml of 50% MgSO<sub>4</sub> solution with 12ml of D5W or 09% Normal saline to make 20% solution)
- Follow promptly with 10 g of 50% Magnesium Sulfate (MgSO<sub>4</sub>) solution, 5 g in each buttock as deep IM injection with 1 ml of 2% Lignocaine in the same syringe.
- If convulsions recur after 15 minutes, give 2 g Magnesium Sulfate (50% solution) IV over 5 minutes

Note that after administering the loading dose, health centers should **immediately refer** the mother to hospitals to continue with the maintenance dose and for other critical treatments at the referral level.

#### **Maintenance dose:**

- 5 g Magnesium Sulfate (50% solution) + 1 m Lignocaine 2% IM every 4 hours into alternate buttocks.
- Continue treatment with Magnesium Sulfate for 24 hours after delivery or the last convulsion, whichever occurs last.

**Precautions to be taken:** Before repeating administration, ensure that:

- Respiratory rate is at least 16 per minute.
- Patellar (kneecap) reflexes are present.
- Urinary output is at least 30 mL per hour over 4 hours.

**Note:** Withdraw or delay treatment if any of above three conditions are not fulfilled. MgSO<sub>4</sub> should not be given to women with myasthenia gravis <sup>5</sup>or known cardiac problems. Women with impaired renal function should be given the initial loading dose but should not be given maintenance therapy, as they may develop Magnesium toxicity.

**Side effects**: Side effects, like sweating, flushing, headache, and nausea are common but severe toxicity is rare. Side effects may be increased if MgSO<sub>4</sub>is given with Beta Agonists or Calcium Channel Blockers such as Nifedipine.

### **Management of MgSO<sub>4</sub> toxicity:**

Assist ventilation (mask and bag, anesthesia apparatus, intubation) and give **calcium gluconate** 1 g (10 mL of 10% solution) IV slowly to antagonize the effects of magnesium.

**Note** that severe toxicity is rare. If MgSO<sub>4</sub> toxicity occurs at the level of health center, the patients should be referred to hospital immediately. The pharmacy should assure availability of calcium gluconate as antidote.

**b. Diazepam:** In the absence of Magnesium Magnesium Sulfate, Diazepam could be used for treating convulsion in eclampsia and pre-eclampsia.

#### **Dose and Administration**

### Loading dose

Diazepam 10 mg IV slowly over 2 minutes.

<sup>&</sup>lt;sup>5</sup> A chronic progressive disease characterized by chronic fatigue and muscular weakness (especially in the face and neck); caused by a deficiency of acetylcholine at the neuromuscular junctions

If convulsions recur, repeat loading dose.

#### Maintenance dose

 Diazepam 40 mg in 500 ml IV fluids (normal saline or Ringer's lactate) titrated to keep the woman sedated but rousable

#### Precautions to be taken.

- Maternal respiratory depression may occur when dose exceeds 30 mg in 1 hour: Assist ventilation (mask and bag, anesthesia apparatus, intubation), if necessary.
- Do not give more than 100 mg in 24 hours.

#### **Rectal administration**

- The patient should be given Diazepam rectally when IV access is not possible. The loading dose is 20 mg in a 10-ml syringe. Remove the needle, lubricate the barrel, and insert the syringe into the rectum to half its length. Discharge the contents and leave the syringe in place, holding the buttocks together for 10 minutes to prevent expulsion of the drug. Alternatively, the drug may be instilled in the rectum through a catheter.
- If convulsions are not controlled within 10 minutes, administer an additional 10 mg per hour or more, depending on the size of the woman and her clinical response.
- **c. Antihypertensive drugs:** If the diastolic pressure is 110 mm Hg or more, antihypertensive drugs should be given for a woman. The goal of antihypertensive drug is to keep the diastolic pressure between 90 mm Hg and 100 mm Hg to prevent cerebral hemorrhage. In this case, Hydralazine is the drug of choice.

#### 1) Hydralazine:

#### **Dose and Administration**

Hydralazine 5 mg IV slowly (3-4 minutes). If it is not possible to administer intravenously, give IM. Repeat the dose at 30-minute intervals until diastolic BP is around 90 mmHg. Do not give more than 20 mg in total. If **hydralazine is not available**, Labetalol or Nifedipine Immediate Release tablets/capsules can be used as an alternative.

### 2) Methyldopa or Nifedipine

The oral forms of these medications are recommended for non-severe hypertension

#### **Dose and Administration**

- Methyldopa, 250 mg every six to eight hours. The maximum dose is 2000 mg per 24 hours
- Nifedipine immediate-release capsule, administer 10–20 mg every 12 hours. The maximum dose is 120 mg per 24 hours

#### Note:

- Women with pre-eclampsia who have been managed with methyldopa during pregnancy should discontinue treatment within 2 days of birth.
- Methyldopa is not suitable for the rapid control of hypertension as it requires 24 hours
  to achieve therapeutic levels. As the dose of methyldopa increases the adverse effects,
  particularly sedation and depression increase.

## **5.3.5** Effect of Medicines during Pregnancy



#### 1. Brainstorming for 5 minutes

What are the effects of medicines during pregnancy?

## 2. Think-pair-share

Discuss in pair for 5 minutes on classification of drug safety on pregnancy based on the following paragraph.

Most drugs and chemicals pose a threat to the developing fetus. It is not advisable to take any form of medicine during pregnancy if possible. Sensitivities to the drugs usually depend on the gestational age of the fetus. During the first 3 months of pregnancy, the chance of physical malformations is increased, because this is the critical stage of physical development. Later in gestation, risk of functional and behavioral abnormalities increases because of the continuous growth and development of the central nervous system.

Therefore, identifying the effects of medicines on the fetus is a prime concern. Clinicians should take caution on the safety of the medicines before their administration. Based on the safety profile of drugs on pregnancy, Food and Drug Administration (FDA) categorized the medicines as follow.

Table 5.11. Classification of drug safety in pregnancy

Category	Definition
Category A	Generally acceptable. Controlled studies in pregnant woman show no
	evidence of fetal risk.
Category B	May be acceptable. Either animal studies show no risk but human studies
	not available or animal studies showed minor risk and human studies done
	and showed no risk to the fetus.
Category C	Use with caution: These drugs should be given only if the potential
	benefit of the drug justify the potential or unknown risk to the fetus.
Category D	Use in life threatening emergencies when no safer drug available. There
	is positive evidence of fetal risk, but there may be certain situations where
	the benefit might outweigh the risk (life-threatening or serious diseases
	where other drugs are ineffective or carry a greater risk).
Category X	Do not use in pregnancy: There is definite fetal risk based on studies in
	animals or humans or based on human experience, and the risk clearly
	outweighs any benefit in pregnant women

See appendix 1 for List of Drugs with Their Pregnancy Category

# 5.4 Therapeutic use and safety of medicines during labor and delivery

## **5.4.1.** Management of Normal Labor



## 1. Brainstorming for 5 minutes

Which problems related to labor, delivery and postpartum periods do you know or have ever seen in your service delivery?

How was it therapeutically managed? What was your contribution?

Did you see any gaps in the medical management of the observed conditions?

#### 2. Individual reading

Write the natural process that happens during labor and compare with information in the following paragraphs.

Labor consists of a series of rhythmic, involuntary, progressive contractions of the uterus that cause effacement (thinning and shortening) and dilation of the uterine cervix. Normal labor, with adequate supportive care from the skilled service provider, can go smoothly. However, labor may turn abnormal at any time. Therefore, making ready all the required medications and ensuring appropriate utilization is an important component of labor management.

The most important preventive intervention in labor is Active Management of Third Stage Labor (AMTSL). It consists of interventions designed to facilitate the delivery of the placenta by increasing uterine contractions and to prevent Post-Partum Hamorrhage by averting uterine atony. AMTSL is a standard management of third stage labor for all women who come for delivery at the health facilities.

## 5.4.2. Induction / Augmentation of Labor



#### 1. Paired discussion for 10 minutes

- Be in pairs and discuss and reflect on: Induction and Augmentation
  Group discussion for 10 minutes
  - Be in small groups and discuss on medicines used for Induction and Augmentation

Induction of labor refers to techniques for stimulating uterine contractions to accomplish delivery prior to the onset of spontaneous labor. Delivery before the onset of labor is indicated when the maternal/fetal risks associated with continuing the pregnancy are thought to be greater than the maternal/fetal risks associated with early delivery.

Poor progress in active phase of labor is defined as when the cervix dilates at a rate of <1 cm/hour in the active phase. Augmentation is indicated when there is poor progress in the active phase of labor.

## Medications used for induction or Augmentation of labor

In induction, the goal is to initiate uterine contraction for causing the cervix to open and make it favorable for delivery. Various pharmacologic or mechanical methods can be used for labor induction. In augmentation, the goal is to bring sufficient uterine contraction when the definitive cause of poor labor progress is due to lack of sufficient power in uterine contraction. Uterotonics<sup>6</sup> medicines are the choice of drugs for induction or augmentation.

## Medicines used for induction/Augmentation

Oxytocin in low or high doses OR

Misoprostol 25 mcg vaginally every 3 to 6 hrs

## **Indications for Oxytocin Infusion in labor:**

- Women in spontaneous labor failing to progress in first stage of labor.
- Failure to progress in the second stage of labor (thorough assessment should be taken prior to starting oxytocin in second stage to exclude cephalopelvic disproportion or obstructed labor).
- Women with induced labor, not progressing after ARM (artificial rupture of membranes).

*Table 5.12. Oxytocin administration protocol and precautions* 

Oxytocin administration protocol for induction or augmentation of labor

• Add oxytocin 5 units to 1 L of Ringer-Lactate.

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<sup>&</sup>lt;sup>6</sup> A medicine that strengthens or give energy for producing desired tone on the uterus

- Start infusion at a rate of 25 ml/hr (≈2 mU/minute or 6 drops/minute using a 15 drops/ml set).
- Increase the infusion rate by increasing by 50 m/hour every 30 minutes 50, 100, 150, 200 ml/hour until 3-4 strong contractions (more than 40 seconds) are achieved.
- Do not increase the infusion rate once strong contractions are achieved.
- If the infusion rate reaches 200 ml/hour and strong contractions are not achieved, increase the
  dose by starting an infusion of 10 units in 1 litre at 150 ml/hour, increasing to 200 ml/hour if
  necessary.
- Do not increase the infusion rate beyond 200 ml/hour of oxytocin 10 units/L.

## **Precautions:**

- Owing to the increased risk of uterine rupture, Oxytocin should only be administered with caution for women with previous caesarean section or multiparous women
- Avoid prolonged administration in oxytocin-resistant uterine inertia, to prevent postpartum haemorrhage.
- With doses more than 40 milliunits/min, excessive water retention may lead to water intoxication. Use of Oxytocin must be supervised to prevent uterine tachsystole (more than 5 contractions in 10 min averaged over 30 min)

## **Contraindications for use of Oxytocin in labor:**

- Hypertonic uterine contractions
- Mechanical obstruction to delivery
- Fetal distress
- Severe pre-eclampsia or severe cardiovascular disease
- Any condition where spontaneous labor or vaginal delivery inadvisable

#### 5.4.3. Preterm Labor



#### Paired discussion for 10 minutes

 Discuss the doses and administration of medicines used for management of preterm labor Preterm labor refers to the onset of labor before the 37 completed weeks of gestational age. Preterm labor complicates up to 10% of all pregnancies. It is by far most common cause of prematurity which is one of the three most important causes of neonatal morbidity and mortality. Preterm labor also leads to considerable maternal morbidity. The risk of maternal and neonatal morbidity and mortality from preterm labor is higher the earlier the gestational age at which labor ensues.

## **Respiratory Distress Syndrome**

Babies born before 37 completed weeks of gestation are therefore considered preterm babies. The primary problem that preterm babies face is Respiratory Distress Syndrome (RDS) – difficulty of breathing due to underdevelopment of the lungs. This occurs because preterm babies do not have enough surfactant in their lungs, which helps the lung to expand during breathing.

## Medications for respiratory distress in preterm births

#### **Dexamethasone:**

- Injection 4 mg/ml, 8mg/2ml Dexamethasone phosphate;
- Tablet 0.5mg, 1mg, 2mg

Nifedipine, Immediate release capsule, 10mg

**Note:** Betamethasone can also be used for the same regimen, but it is less available and more expensive than dexamethasone. Other steroids do not cross the placenta and therefore are not effective.

#### **Dexamethasone:**

- Dexamethasone is a steroid therapy for stimulation of surfactant production and hence lung maturity in premature labor. Corticosteroids can reduce death in preterm babies by more than 30% through speeding maturity of fetal lungs.
- Management for preterm labor requires hospital care, where adequate preterm care is available for the newborn: resuscitation, thermal care, feeding support, infection treatment, and safe oxygen use.

#### **Dose and Administration:**

- For Gestational Age (GA) less than 34 weeks, initial dose of Dexamethasone 6mg IM should be given to the mother to improve fetal lung maturity.
- Immediate referral to higher hospitals is required

**Indication:** Woman less than 34 weeks of GA at risk of birth in the next 7 days should be offered Dexamethasone. The following conditions must be ascertained for administering Dexamethasone

- Gestational Age < 34 weeks.
- High confidence that she has a condition likely to lead to birth in the next 7 days
- There is no suspicion of maternal infection (chorioamnionitis<sup>7</sup> or sepsis)

**Precautions:** increased susceptibility to and severity of infection.

**Contraindications:** untreated systemic infection (unless the condition is life threatening);

**Side effects:** nausea, dyspepsia, malaise, hiccups, hypersensitivity reactions including anaphylaxis, perineal irritation after intravenous administration.

**Nifedipine:** Is used to slow down or stop contractions of uterus for a short time (up to 48 hours). It will not prevent preterm birth but may delay labor for at least 48 hours to help dexamethasone produce the intended effects.

**Dose and Administration:** Oral- initial 20mg loading dose, followed by 10-20 mg three to four times daily, adjusted according to uterine activity for up to 48 hours. A total dose of 60 mg appears to be associated with 3-4-fold increased risks to sever hypotension, shortness of breath and headache.

**Indication:** It is usually indicated for uncomplicated cases of preterm birth, less than 34 weeks of gestation to prolog pregnancy for short time.

## **Precautions: Do not give Nifedipine to a woman:**

- With cardiac problems
- In active labor (> 4cm dilation)
- Receiving MgSO4 or another tocolytic<sup>8</sup>

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<sup>&</sup>lt;sup>7</sup>Inflammation of the chorion and the amnion, the membranes that surround the fetus. Chorioamnionitis usually is associated with a bacterial infection.

• If prolonging pregnancy is dangerous to the woman or the baby

## **5.4.4.** Premature Rupture of Membrane (PROM)



## **Brainstorming for 5 minutes**

What is premature rapture of the membrane?

PROM refers to rupture of the membranes and leakage of liquid prior to the onset of labor. It can occur at different gestational ages including after 37 completed weeks of gestation (Term PROM) and before 37 weeks of gestation and after 28 weeks of gestation (Preterm PROM). PROM is associated with one-third of preterm births; and approximately one-third of women with PROM develop infections.

## Medicines used for management of PROM

Medical Management of PROM depends on the gestational age (term or preterm); presence of complications of PROM and presence or absence of other obstetric risk conditions.

Table 5.13 Dose and administration of medicines for management of PROM

Gestational Age when PROM occurs	Sign of infection	Treatment
Pregnancy is less than 37 weeks	No sign of infection	Erythromycin 250 mg by mouth three times per day for 7 days; PLUS  Amoxicillin 500 mg by mouth three times per day for 7 days;
Pregnancy is less than 35 weeks	No sign of infection	Dexamethasone 6 mg IM, four doses 6 hrs apart; OR  Betamethasone 12 mg IM, two doses 12 hrs

<sup>&</sup>lt;sup>8</sup>Tocolytics (also called anti-contraction medications or labor suppressants) are medications used to suppress premature labor. They are given when delivery would result in premature birth.

		apart;
	No sign of infection, but If	Prophylactic antibiotics to reduce infection
	the membranes have been	in the neonate
	ruptured for more than 18	A manifestition 2 as TW assume Changes OD
	hours.	Ampicillin 2 g IV every 6 hours; OR
		Penicillin G 2 million units IV every 6
Pregnancy is 37 weeks		hours until delivery
or more	TC .1	A STATE OF THE STA
of more	If there is infection and	Ampicillin 2 g IV every 6 hours; PLUS
	the woman is in labor	Gentamicin 5 mg/kg body weight IV every
		24 hours;
		If the woman delivers, continue antibiotics
		until the woman is fever-free for 48 hours.
Pregnancy is less than	If there is infection	Ampicillin 2 g IV every 6 hours;
37 weeks		PLUS
		FLUS
		Gentamicin 5 mg/kg body weight IV every
		24 hours;
		PLUS
		Metronidazole 500 mg IV every 8 hours

# Review questions on medicines used for Management of PROM

- 1. What is the right drug and dosage when the gestational age is 35-37 weeks and there is no infection?
- 2. What is the right drug and dosage when Pregnancy is 37 weeks or more and rupture membrane is stayed for 18 hrs?
- 3. What is the right drug and dosage when Pregnancy is less than 35 weeks and there is no infection?
- 4. What is the right drug and dosage when there is sign of infection?

# 5.5 Therapeutic use and safety of medicine during post-partum

## 5.5.1 Post-Partum hemorrhage



## Brain storming and sharing for large group (15 minutes)

- Which problem/s is/are responsible for most maternal morbidity and deaths after delivery?
- Have you seen any case of PPH in your health facility? What measures were taken and what was the outcome?

#### PPH is defined as

- The loss of 500 ml or more blood from the genital tract after normal delivery or Caesarean Section; or
- Any amount of vaginal bleeding after child birth that is sufficient enough to make the patient symptomatic and/or results in sign of hypotension.

A woman with normal Hgb will tolerate blood loss better; but, the loss of the same amount of blood would be fatal for an anemic woman. It is estimated that, if untreated, death occurs on average within 2 hours.

# **Classification of Post-Partum Hemorrhage**



Reading and Reflection (10 minutes)

• Read and identify the classification and causes of PPH

**Primary PPH**: This is defined as excessive blood loss from the genital tract during the first 24 hours after delivery. Primary PPH further divided into immediate and delayed PPH. Immediate PPH is when excessive bleeding occurs within 4 hours of delivery while delayed PPH is when the bleeding occurs after 4 hours. The immediate PPH involves heavier bleeding and is associated with greater morbidity and mortality than the delayed one. Immediate PPH is mostly caused by uterine atony<sup>9</sup>.

<sup>&</sup>lt;sup>9</sup>Lack of normal muscular tension or tone on the uterus. It is the cause for failure of uterine contraction after delivery.

**Secondary PPH**: This is defined as when cases of PPH occurring after 24 hours of delivery till 6 weeks of postpartum period. Mostly, secondary PPH is due to retained placental fragments or infection or both conditions combined.

#### **Causes of PPH**

The causes can be called 4 T's

- Tone (Uterine Atony attributing to 75-90% of PPH)
- Trauma (Surgical or assisted vaginal delivery)
- Tissue (Retained Placenta)
- Thrombosis (coagulation failure)

#### Medications used for Prevention and Treatment of PPH

Depending on the causes of the PPH, different medications can be used to prevent and treat the condition of PPH. The Oxytocics (Oxytocin, Ergometrine and Misoprostol) are the medicines of choice to prevent and treat PPH caused by Uterine Atony. Other medications and treatments can be used for PPH caused by other factors.

Oxytocin 10 IU IM

Misoprostol, 200 mcg

Ergometrine, 0.2mg, IM

## Active management of the third stage of labor for preventing PPH

All pregnancies are at risk of PPH even if no predisposing factors are present. Hence, active management of the third stage of labor must be applied, i.e., from the time of delivery of the fetus until the delivery of the placenta. Active management of the third stage of labor helps in preventing PPH by averting the occurrence of uterine atony. It is recommended that the practice of active management including prophylactic administration of oxytocic (oxytocin or misoprostol), Control Cord Traction (CCT)<sup>10</sup> and uterine massage should be routinely followed. By carrying out active management of the third stage of labor it has been found that the length of the third stage and the incidence of PPH are significantly reduced.

<sup>&</sup>lt;sup>10</sup> Controlled Cord Traction is an important intervention in Active Management of the Third Stage of Labor, where a gentle traction or pulling is applied on the cord by one of the hand while the other hand is applying a counter traction just above the symphysis pubis.

The medicine should be administered within one minute after the birth of the baby without waiting for sign of placental separation in 3rd stage of labor.

- Oxytocin 10 IU IM
   If oxytocin is not available:
- Ergometrine 0.2 mg IM, or syntometrine (1 ampoule) IM

or

• Misoprostol 400-600 mcg orally.

#### **Precaution:**

- Oxytocin should not be given in the presence of any additional fetus. Presence or absence
  of an additional fetus must be checked before administration.
- Ergometrine should not be given to women with pre-eclampsia, eclampsia, or high blood pressure because it increases the risk of convulsions and cerebrovascular accidents

## **Drug interactions:**

• Ergometrine use with efavirenz increased risk of ergotism (avoid concomitant use).

#### **Treatment of PPH**

Utero-tonic medicines are the choice of medicines for management of PPH as 80% of PPH cases are occurring due to lack of physiologic contraction in the uterus (atonic uterus). If the uterus is contracted but the bleeding continues, the cause may not be atonic. Rather, it may be due to traumatic PPH, secondary vaginal/cervical/perineal tears or lacerations, ruptured uterus, etc. It is also caused by retained placenta or inversion of the uterus. In these cases, the therapeutic management depends on the specific causes.

Table 5.15 Administration of medicines for treatment of PPH

	0 4	Ergometrino	e/	MISOPROSTOL	
Oxytocin		Methylergometrine		(CYTOTEC)	
<b>Dose and route</b>	IV: Infuse 20 u	nits in 1 L IV	IM or IV (slowly):	Oral/sublingual	
	fluids at 60 drops per minute		Intravaginal/Recta		

	IM: 10 units	0.2 mg	1 800mcg
<b>Continuing dose</b>	IV: Infuse 20 units in 1 L IV	Repeat 0.2 mg IM after	200mg
	fluids at 40 drops per minute	15 minutes. If required,	Every 4 hours
		give 0.2 mg IM or IV	y
		(slowly) every 4 hours	
Maximum dose	Not more than 3 L of IV	5 doses (Total 1.0 mg)	2000mg
	fluids containing oxytocin		
Precautions/	Do not give as an IV bolus	Pre-eclampsia,	Asthma
Contra-	should not be given in the presence of any additional	eclampsia, hypertension, heart	Heart Disease
indications	fetus.	disease	
		Not to be given with	
		Efavirenz	

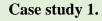
#### Note:

- Oxytocin is choice of drugs as it has fast action, minimal side effects and can be used in all women. Oxytocin 10 IU should be given IM within one minute after the birth of the baby without waiting for sign of placental separation in 3<sup>rd</sup> stage of labor.But, presence or absence of an additional fetus must be checked before administration.
- If oxytocin is not available, Ergometrine 0.2 mg IM, or Misoprostol 400-600 mcg orally can be given
- Ergometrine and Oxytocin differ in their actions on the uterus. In moderate doses, oxytocin produces slow generalized contractions with full relaxation in between; Ergometrine produces faster contractions superimposed on a tonic contraction.
- If Ergometrine is given to women with pre-eclampsia, eclampsia, or high blood pressure, the risk of convulsions and cerebrovascular accidents will increase
- When Ergometrine is used with Efavirenz, it increases risk of ergotism; hence concomitant use should be avoided.
- High doses of Oxytocin and Ergometrine substances produce sustained tonic contractions.

Oxytocin is recommended for routine use in the control of postpartum and post-abortion hemorrhage since it is more stable than Ergometrine. However, Ergometrine may be used if oxytocin is not available or in emergency situations.

Misoprostol is less heat sensitive than oxytocin and is an ideal medicine in facilities where
there is no cold chain for oxytocin storage. Misoprostol is susceptible to spoilage from
exposure to humidity, which can easily occur when the tablets are not stored or packaged
properly.

#### **CASES FOR GROUP WORK**



**Instruction**: Be in groups; Read and discuss the cases in groups and provide the responses for questions given under each cases

A lady who is, 28 years old Para 4, gravida 4 gave birth to a full-term newborn 2 hours ago at home. Her birth attendant was a TBA, who has brought the lady to the health center because she has been bleeding heavily since childbirth. The duration of labor was 12 hours, the birth was normal, and the placenta was delivered 20 minutes after the child birth. Placenta and membranes delivery were complete. Based on the assessment and clinical findings, the diagnosis is confirmed PPH due to atonic uterus. All the required medicines are available.

## Questions

- 1. What is the drug of choice for managing this case?
- 2. What are the recommended doses and administration of this medicine
- 3. What do you think are the indications, significant side effects, precautions/contraindications of this medicine?
- 4. What further information as counseling point would you suggest about these drugs?



## Case study 2.

**Instruction**: Read and discuss the cases in groups and provide the responses for questions given under each cases

A mother who is 30 years old Para 2, gravida 2. She gave birth at the PHC to a newborn weighing 4.2 Kgs. Placenta was delivered 10 minutes later. She was given Ergometrine 0.2 mg IM after the delivery of placenta. Half an hour after the delivery, the mother reported that she has heavy vaginal Bleeding. When the Midwife keeps a hand on the lower abdomen, she recognized that the uterus is soft and is not contracted. The diagnosis is PPH due to uterine atony. The only available drug in the facility was Ergometrine.

## **Ouestions**

- 1. What is the recommended dose and administration?
- 2. What is the indication, side effect, contraindications, precautions, and significant drug interaction?
- 3. What further information would you provide as a counseling point



## Case study 3.

**Instruction**: Read and discuss the cases in groups and provide the responses for questions given under each cases

A young mother who is, 20-year-old, recently delivered her first child at home with TBA assistant. 4 hours after her delivery, she started to feel pain in abdomen followed by bleeding through vagina. When she arrives at the health center the bleeding was heavy, and on physical examination, the uterus is found to be soft and is not contracted. The diagnosis was primary PPH due to uterine atony. At the time of her arrival, the available medicines were Misoprostol.

## Questions

- 1. What is the dose and route of administration
- 2. What are the indications, precautions, side effects, and contraindication?
- 3. What further information would you provide as a counseling

## 5.5.2 Maternal Sepsis



## Paired discussion for 10 minutes

Discuss on signs and symptoms of maternal sepsis

Maternal sepsis is a life-threatening condition defined as organ dysfunction resulting from infection during pregnancy, childbirth, post-abortion, or postpartum period. Infection that occurs just after childbirth is also known as puerperal sepsis.

## Sign and symptoms

If any two or more of the following signs and symptoms are present, it is an indication for maternal sepsis:

- Fever of 38.5 °C or higher, measured orally on any one occasion;
- Abnormal vaginal discharge (lochia);
- Abnormal smell, foul odor of the vaginal discharge;
- Pelvic pain;
- Delay in the rate of reduction of the size of the uterus (sub-involution of the uterus; <2 cm/day).</li>

## Mild maternal sepsis

Clinical features include:

- mild uterine tenderness without evidence of peritonitis,
- heart rate < 100/minute,
- temperature < 38.5 degrees Centigrade, and</li>
- offensive lochia (discharge)

## Severe maternal sepsis

Clinical features include temperature  $\geq 38.5$  degrees Centigrade and a heart rate  $\geq 100$ /min in the presence (not always) of offensive lochia and uterine/abdominal tenderness. After initial assessment and emergency management, patients with severe maternal sepsis should be referred to higher hospital after the initial management of the patient with IV antibiotics within 1 hour.

# Treatment of maternal sepsis

Women will die of maternal sepsis and septicemia if appropriate antibiotic therapy is not given early enough. The aim of starting antibiotic therapy immediately is to manage/treat the current infection and to stop it from spreading further. The medicines used for treatment of maternal sepsis are indicated in the box below.

## **Medicines used for maternal sepsis**

## Severe maternal sepsis

Ampicillin: Powder for injection, 250 mg, 500mg and 1gm (as sodium salt) in vial

Gentamycin: Injection 40mg/2ml,80mg/2ml

Metronidazole: Intravenous infusion, 5mg/ml in 100ml

Ceftriaxone: Powder for injection, 250 mg, 500 mg, and 1gm (as sodium salt) in vial

Clindamycin: Injection, 150 mg/ml in ampoule

## Mild maternal sepsis

Amoxicillin, 500 mg, Orally, Metronidazole 500mg, Orally

Erythromycin 500 Mg, for Penicillin allergic

Table 5.16 Dose and administration of medicines used for managing maternal sepsis

Level of severity	Treatment protocol	Notes
Mild maternal sepsis	Amoxicillin 500 mg 3 times daily orally and Metronidazole 500 mg 3 times daily orally for 5 days  For patients allergic to penicillin, erythromycin 500 mg 4 times daily orally instead of Amoxicillin.	If not improving after 36 to 48 hrs, the patient should be admitted for management of severe maternal sepsis.
Severe maternal	Ampicillin, 1gm IV: four times a day. PLUS  Gentamicin80 mg, IV three times a day PLUS	Ampicillin is 1 <sup>st</sup> line of drug for maternal sepsis

sepsis	Metronidazole, 500 mg, IV three times a day	and Ceftriaxone is 2 <sup>nd</sup>
	If there is progress after 36-48 hrs, Continue with	line, and used when there
	treatment protocol of mild sepsis.	is no improvement with
	treatment protocor or mild sepsis.	ampicillin
	Ceftriaxone 1gm, IV: two times a day for 7-10	Clindomyoin is on
	days in combination with	Clindamycin is an
		alternative drug to
	Gentamicin, 80 mg, IV three times, and	Metronidazole
	Metronidazole 500 Mg IV three times a day or	
	clindamycin 450mg IV, four times a day.	

# 5.6 Summary:

- Obstetric complications, particularly hemorrhage, require fast interventions in less than 2
  hours from the onset of bleeding, otherwise deaths. Emergency Obstetric and Newborn
  Care (EmONC) is a package of high impact interventions designed for managing most of
  the direct cause of obstetric complications.
- ANC is the complex of interventions assuring every pregnancy to culminate in the delivery of a healthy child without impairing the health of the mother.
- Complications such as bleeding, anemia and hypertension occur during antepartum which require close follow-up and therapeutic management.
- The most important preventive intervention in labor is Active Management of Third Stage Labor (AMTSL).
- Depending on the causes of the PPH, different medications can be used to treat the condition such as Oxytocin, Ergometrine, and Misoprostol.

# Chapter 6: Rational Use of Neonatal and Child Health Pharmaceuticals

## **Chapter Description:**

This chapter deals with the identification of therapeutic use, safety and interactions of neonatal and child health medicines. It also emphasizes on disease conditions and medicines for use in under-five children.

## **Primary Objective:** By the end of this chapter, participants will be able to:

Discuss the rational use of child health pharmaceuticals used for IMNCI and iCMNCI programs

# **Enabling Objectives:**

- Discuss rational use of medicines in neonates and children
- Discuss the therapeutic management of essential newborn care and young infants health problems
- Describe the therapeutic use and safety of cough or difficulty breathing medicines
- Describe the therapeutic use and safety of diarrhea and dysentery medicines
- Identify common nutritional problems and their management
- Discuss expanded program on immunization and vaccines

## 6.1 Introduction to Rational Use of Medicines in Neonates and Children



## Brain storming and sharing for large group (20 minutes)

- What is the age range for a child?
- What are the main differences of children and neonates compared to adults in medicine use?
- List the common diseases affecting children and neonates in Ethiopia
- Mention the common medicines of choice to be used in children and neonates for the stated diseases above?

In the use of medicines in neonates and children, the following major facts should be taken into consideration:

- Medicines should be prescribed only when they are necessary and the benefits outweighs the risk
- The use of medicines depends on an appreciation of both the physiological immaturity and the developmental maturation that influence drug disposition and pharmacologic effects
- Drug pharmacodynamics in children may differ from those in adults, e.g. Antihistamines and barbiturates that generally sedate adults may be excitatory in children.
- Drug pharmacokinetics is altered possibly requiring substantial alteration in the dose or dosing regimen to safely produce the desired clinical effect, e.g., dose of aminoglycosides (Gentamycin) must be reduced to avoid toxic drug accumulation
- Unique features of childhood development also may provide special vulnerabilities to drug toxicity; for example, tetracycline can permanently stain developing teeth, and glucocorticoids can attenuate linear growth of bones.

Over two-third of childhood deaths in Ethiopia are caused by few and easily preventable conditions, mainly: infection, neonatal condition and malnutrition. Many of these conditions could be treated with safe and effective medicines. On the other hand, irrational use of the available medicines has led to adverse drug reactions and drug resistance which requires

promotion of RMU in children. RMU in children is important since the clinical trials generate limited data for children during development of medicines.

According to national programmatic guidelines (CBNC, ICCM and IMNCI), diagnosis of neonatal and child health conditions are classified based on sign and symptoms. This chapter uses IMNCI as a reference to classify the neonatal and child health conditions.

# 6.2 Therapeutic use and safety of medicines used for essential newborn care and young infant problems



## **Interactive Discussion (10 minutes):**

- What are the essential new born care components?
- What are the medicines involved in essential new born care?
- What are the common very severe disease for young infants?

#### 6.2.1 Essential newborn care

## Medicines used for prevention of umbilical cord infection

Chlorhexidine gel umbilical cord care has replaced dry cord care as an essential newborn care action immediately after birth. Ensuring optimal cord care at birth and during the first week of life, including use of chlorhexidine, is a crucial strategy to prevent life-threatening sepsis and cord infections and avert preventable neonatal deaths. Chlorhexidine gel reduces local bacterial infection of the umbilical cord and also replaces non hygienic traditional applications on the umbilical cord. The IMNCI/ICCM/CBNC guide recommends applying chlorohexidine on the cord for 7 days starting from immediate birth born at both health facilities and at home.

Chlorhexidine should be applied immediately after cutting the cord. It is an antiseptic used for newborn umbilical cord care and cleansing effective in preventing umbilical cord infection when used at home and health facilities. Continue application once daily through the first week of life.

For best outcome chlorhexidine gel should be applied within 30 minutes after birth but it can be applied until 24 hours after birth. Application of chlorhexidine gel after 24 hour of birth does not demonstrate any favorable outcome.

The appropriate formulation for cord care is 7.1% chlorhexidine digluconate gel, delivering 4% chlorhexidine in 21gm tube. The product has a long shelf-life in all climatic zones and does not require cold chain. It can be easily stored at any level of the supply chain.

**Precautions**: Chlorhexidine gel should not be applied to any part of the body other than the umbilical cord. **Avoid contact with ears and eyes.** If applied to eyes it can cause blindness

Side effects: It has a well-established safety record.

## Medicines used for eye care at birth

Ophthalmic ointments containing tetracycline have been used for the prophylaxis of neonatal conjunctivitis. The IMNCI/ICCM/CBNC training manuals recommend applying tetracycline eye ointment. The newborn's eyes are carefully cleaned immediately after birth and within 1 hour of age, a single application of 1% tetracycline hydrochloride eye ointment should be applied once on both eyes. Eye care protects the baby from serious eye infection which can result in blindness. Contaminating the tip of the ointment tube should be avoided.

## Medicines used for prevention of hemorrhage in newborn



## **Individual Exercise:**

• What is the effect of hemorrhage in a newborn and how can be prevented?

Hemorrhage in the newborn may result from sever transient deficiencies in vitamin k-dependent factors. It is characterized by bleeding from the gastrointestinal, nasal or post circumcision. Warning signs (mild bleeding) may occur before serious hemorrhage. To prevent hemorrhage in the newborn, the newborn should be given Vitamin K 1mg IM on anterior mid-thigh. If the newborn is very low weight (<1500g) and/or very preterm (gestational age below 32 weeks), should be given single dose Vitamin K 0.5mg IM.

## A case study on Chlorhexidine gel



## Case study

**Directions:** Read and analyze this case study individually. When the others in your groups have finished reading it, discuss and answer the question. Choose one person in your group to share your answers to the large group.

W/ro Aster who is the health extension worker at the health post in your catchment requests Chlorhexidine gel from your pharmacy store. If you are the pharmacy practitioner in the store, what will be your answers for the following questions raised by W/ro Aster?

- 1. What is the use of Chlorhexidine gel?
- 2. When to apply to the cord of the newborn?
- 3. How many times a day and for how long should it be applied?
- 4. What are the counselling points for W/ro Aster and the newborn mother?
- 5. How should Chlorhexidine gel should be managed and placed at the health post?

## **6.2.2 Young Infant Problems**



## **Individual Exercise and reflections (10 minutes):**

- Mention **very severe diseases** in young infants.
- What is the treatment for a young infant with very severe disease?

# 6.3. Therapeutic use and safety of cough or difficulty breathing medicines



## Brain storming and sharing for large group (20 minutes)

**Instruction**: Classify the following signs of breathing problems as per IMNCI.

- A 4-month infant unable to breastfeed?
- An 8-month infant with no sign of very severe disease, respiratory rate of 35 per minute
- A 4-year old child with no sign of very severe disease and fast breathing of respiratory rate of 50 per minute

Respiratory infections can occur in any part of the respiratory tract such as the nose, throat, larynx, trachea, bronchi or lungs. A child with cough or difficult breathing may have pneumonia or other severe respiratory infection.

There are many children who come to the health facility with less serious respiratory infections. Most children with cough or difficult breathing have only a mild infection. For example, a child who has a cold may cough because nasal discharge drips down the back of the throat. These children are not seriously ill. They do not need treatment with antibiotics. Their families can treat them at home. It is important to identify the few, very sick children with cough or difficult breathing who need treatment with antibiotics.

## Classification of cough or difficult breathing

There are three possible classifications for a child with cough or difficult breathing:

- a. Severe pneumonia or very severe disease
- b. Pneumonia,
- c. Cough or cold

Table 6.1 Classification table for cough or difficult breathing

Signs	Classify as	Treatment
<ul> <li>Any general danger         sign (unable to drink or         breast feed, vomit         everything, convulsion,         lethargic or         unconscious)         or         Stridor (a harsh noise         made when the child         breaths IN) in a calm         child</li> </ul>	Severe  pneumonia  or very  sever  disease	<ul> <li>Should be provided first dose of IV/IM         Ampicillin and Gentamycin * Refer         Table 5.3 for dosing schedule for severe         pneumonia or very severe disease</li> <li>The antibiotic helps to prevent severe         pneumonia from becoming worse</li> <li>Refer urgently to hospital         (If pulse oximetry is available, oxygen         saturation should be determined and if it is         below 90% the patient should be referred)</li> </ul>
		• Should be given oral Amoxicillin for 5 days

<ul> <li>Fast breathing or</li> <li>Chest in-drawing</li> </ul>	Pneumonia	<ul> <li>If wheezing, should be provided with inhaled bronchodilator for five days e.g. Salbutamol</li> <li>Sooth the throat and relieve the cough with a safe remedy. e.g. warm tea with sugar</li> <li>If coughing is ≥ 14 days or there is contact with TB patient, refer for TB assessment         Or</li> <li>Refer to hospital for further assessment-asthma, pertussis (whooping cough) or other</li> </ul>
<ul> <li>Very sever disease or</li> <li>Pneumonia</li> </ul>	Cough or cold	<ul> <li>No need of antibiotic treatment</li> <li>If wheezing, should be provided with inhaled bronchodilator for five days e.g. Salbutamol</li> <li>Sooth the throat and relieve the cough with a safe remedy</li> <li>If coughing is ≥ 14 days or there is contact with TB patient, refer for TB assessment</li> <li>Or</li> <li>Refer to hospital for further assessment – asthma, pertussis (whooping cough) or other</li> </ul>

Table 6.2 Dosing schedule for severe pneumonia or very severe disease

Weight	Ampicillin	Gentamycin		
	Dose: 50mg per Kg to vial of 250mg Add 1.3ml sterile water=250mg/1.5ml	10 mg/ml	ter to 2 ml vial containing ng/ml  Age > 7 days  Dose: 7.5mg per kg	
1<1.5kg	0.4 ml	0.6 ml*	0.9 ml*	
1.5 - <2kg	0.5 ml	0.9 ml*	1.3ml*	
2 -<2.5kg	0.7 ml	1.1 ml*	1.7 ml*	
2.5 - 3kg	0.8 ml	1.4 ml*	2.0 ml*	
3 -<3.5 kg	1.0 ml	1.6 ml*	2.4 ml*	
3.5 -<4kg	1.1 ml	1.9 ml*	2.8ml*	
4 - <4.5kg	1.3 ml	2.1 ml*	3.2 ml*	

<sup>\*</sup> Avoid using undiluted 40mg/ml gentamycin. The dose is ¼ of that listed.

Almost all cases of pneumonia can be identified by checking for these two signs: fast breathing and chest in-drawing.

Table 6.3 Respiratory rate for "fast breathing" in children

Age of child	Breathing is fast when respiratory rate is:
2 months -12 months	50 breaths per minute or more
13 months – 5 years	40 breaths per minute or more

**Note** – Pneumonia is the leading cause of death among children under five in Ethiopia, contributing 18.6% of the deaths (approximately 35, 000 under five deaths). Yet antibiotic coverage remains low with only 7% of children under five with acute respiratory infection receiving treatment.

## Medicines used in treatment of pneumonia and severe pneumonia

## Medicines used in Pneumonia

**Amoxicillin:** Dispersible, scored tablets, 125 mg, 250mg; Syrup, 125mg/5ml, 250 mg/5ml

#### Medicines used in Severe Pneumonia

Ampicillin: Powder for injection, 250 mg, 500mg and 1gm (as sodium salt) in vial

**Gentamicin:** Injection, 20mg/2ml, 80mg/2ml

Oxygen: Medicinal gas

## Amoxicillin

*Precautions:* maintain adequate hydration with high doses (risk of crystalluria).

Side effects: Common: diarrhea, nausea, rash, urticarial and allergy

Dose and Administrations: Amoxicillin should be given two times a day for 5 days as indicated in table 5.4.below. Give the first dose at the clinic and teach the mother how to give the other doses at home.

Table 6.4 Dosing schedule for Amoxicillin

	Amoxicillin: Give two times daily for 5 days			
Age or weight	Dispersible	Dispersible Tablet	Syrup 125	Syrup 250mg
	Tablet (DT)	(DT) 250mg	mg in 5 ml	in 5 ml
	125mg			
2 months up to 12	2	1	10ml	5ml
months (4-10kg)				

12 months up to 3	4	2	20ml	10ml
years (10-14kg)				
3 years up to 5	6	3	30ml	15 ml
years (14-19kg)				

Dispersible tablet (DT) is that can be dispersed in liquid before administration giving a homogenous dispersion. Amoxicillin DT can be dissolved in water or a small amount of breast milk and usually disintegrate within minutes. Health care workers should be trained to explain and demonstrate how to dissolve dispersible tablets to caregivers.

Amox DT is a child-friendly formulation tablet that has various advantages:

- Simple-to-use (easily dissolves in as little as a tablespoon of water or breast milk)
- More palatable, easy to split, and easy to swallow for children under five
- Easier to administer to patients as it comes in set dosages and does not require manual measuring or mixing
- Costs less and is easier to transport and store because it is packaged in blister strips.

#### Note:

- For sever pneumonia or very severe disease use Amoxicillin as pre-referral treatment if IV or IM Ampicillin and Gentamycin not available.
- In line with the WHO 2015 recommendation, Ethiopia has updated the National Standard Treatment Guidelines (STG), IMNCI, CBNC and ICCM guidelines. Amoxicillin, when provided with appropriate case management, can reduce deaths from pneumonia by 70 percent.
- The new guideline replaced Co-trimoxazole with Amoxicillin as first-line drug of choice
  in the treatment of pneumonia due to its efficacy and increasing high resistance to Cotrimoxazole (Amoxicillin dispersible tablet and Amoxicillin oral suspension) as the firstline treatment for childhood pneumonia.
- WHO document (2014) on revised classification and treatment of pneumonia witnessed results collected from different studies demonstrate that amoxicillin given in a twice-

daily dosage regimen is as effective as regimens of three- or four-times daily, provided that the total daily dosage of amoxicillin is the same. A twice-daily schedule has advantages for caregivers and programs as it may result in improved adherence.

## **Ampicillin**

Powder for injection, 250 mg, 500mg and 1gm (as sodium salt) in vial

Precaution: History of allergy Side effect: diarrhea, nausea, rash, urticaria, pain and inflammation at injection site

Dose and Administration: IM or IV: 50 mg/kg every 6 h for at least 5 days together with Gentamicin.

- IV administration is preferred. If IM injection is required, lidocaine can be used to reconstitute the injection to reduce local pain.
- When using doses greater than 50 mg/kg it should be given over 30 minutes to avoid CNS toxicity, including convulsions.
- IV penicillins are physically incompatible with many substances (including aminoglycosides), hence separate IV administration by 1 hour preferably, due to inactivation of the aminoglycoside by the penicillin.
- For dosing details refer Table 5.3 above.

#### Gentamicin

Injection, 10mg/2ml, 20mg/2ml, 80mg/2ml

*Precautions:* in premature infants and neonates; renal impairment; neonates and infants (use with caution and monitor renal, auditory and vestibular function); avoid prolonged use

Contraindications: previous allergic reaction to one aminoglycoside

Drug Interactions: increased risk of ototoxicity with furosemide

Common Side effects: nephrotoxicity, ototoxicity (auditory damage: loss of hearing, ringing or buzzing a feeling of fullness in the ears), Vestibular damage (clumsiness, dizziness, nausea, vomiting, unsteadiness).

*Dose and Administration:* Determine the strength of Gentamycin by reading the vial. It should be checked whether to be used undiluted or diluted with sterile water. When ready to use the strength should be 10 mg/ml. For detail dosing and administration refer Table 5.3.

Storage: store at room temperature and protect from freezing.

Oxygen: Medicinal gas

*Indications:* oxygen is given to correct hypoxia (inadequate oxygen at the cellular level) in conditions such as severe pneumonia that cause under-ventilation of the lungs. Oxygen should be given to all children with oxygen saturation < 90% as measured by pulse oximetry.

*Precautions:* any fire or spark is highly dangerous in the presence of increased oxygen concentrations especially when oxygen is used under pressure. Metal cylinders containing oxygen should be fitted with a reducing valve by which the rate of flow can be controlled

*Side effects:* Retinopathy of prematurity which is an alteration of the normal retinal vascular development, mainly affecting premature neonates (32 weeks gestation or 1250g birth weight), which can lead to lead to visual impairment and blindness.

Dose and Administration: use nasal prongs as the preferred method of oxygen delivery to young infants; if not available, a nasal or nasopharyngeal catheter may be used. Use a pulse oximetry to guide oxygen therapy (to keep oxygen saturation > 90%). If a pulse oximeter is not available, continue oxygen until the signs of hypoxia (e.g., inability to breastfeed or breathing rate  $\geq$  70/min) are no longer present. Remove oxygen for a trial period each day for stable children while continuing to use a pulse oximeter to determine oxygen saturation.

Discontinue oxygen if the saturation remains stable at > 90% (at least 15 min on room air). It should be checked every 3 hour that the nasal prongs are not blocked with mucus and are in the correct place and that all connections are secure.

Note: The two main sources of oxygen are cylinders and oxygen concentrators. It is important that all equipment is checked for compatibility and properly maintained, and that staff are instructed in their correct use.

# 6.4 Therapeutic use and safety of medicines for diarrhea and dysentery



## **Individual Exercise and Group Discussion (20 minutes)**

- What is diarrhea?
- o Describe the symptoms of diarrhea.
- In a group, discuss on the medicines used for diarrhea treatment including precaution, drug interaction, counseling points and storage.
- o In a group, read and discuss on the given case study about difficult breathing and diarrhea.

Diarrhea occurs when stools contain more water than normal. Frequent passing of normal stools is not diarrhea. The number of stools normally passed in a day varies with the diet and age of the child.

Diarrhea is defined as three or more loose or watery stools in a 24-hour period. It is common in children, especially those between 6 months and 2 years of age.

Diarrhea is more common in babies under 6 months who are drinking cow's milk or infant feeding formulas. Babies who are exclusively breastfed often have stools that are soft; this is not diarrhea. The mother of a breastfed baby can recognize diarrhea because the consistency or frequency of the stools is different than normal. A young infant with diarrhea is assessed for how long the child has had diarrhea and blood in the stool to determine if the young infant has dysentery and signs of dehydration. **Diarrhea causes dehydration and if left untreated can lead to death in young children.** 

#### Diarrhea classification

To assess, diarrhea compare the infant's signs to the signs listed in the tables below and choose one classification for dehydration.

Table 6.5 Classification of Diarrhea for infants less than 2 months

SIGNS	CLASSIFY AS	TREATMENT (Urgent pre-referral treatments are
		in bold print)
Two of the following	SEVERE	► If infant has another severe classification:
signs:	DEHYDRATI	- Should be Referred URGENTLY to hospital with
• Movement only	ON	mother giving frequent sips of ORS on the way
when stimulated,		- Mother should continue breastfeeding more
or no movement		frequently and keep the young infant warm on the
even when		way to hospital
stimulated		► If infant does not have any other severe
• Sunken eyes		classification; should be given IV fluid for severe
• Skin pinch goes		dehydration
back very slowly		
Two of the following	SOME	► If infant has another severe classification:
signs:	DEHYDRATI	- Should be Referred URGENTLY to hospital with
• Restless, irritable	ON	mother giving frequent sips of ORS on the way
• Sunken eyes		- Mother should continue breastfeeding more
• Skin pinch goes		frequently and keep the young infant warm on the
back slowly		way to hospital
		► If infant does not have any other severe
		classification;
		- Should be given fluid for some dehydration and
		Zinc supplement
		- Mother should be advised when to return
		immediately
		- Follow-up in 2 days
Not enough signs to	NO	► Mother should be advised when to return
classify as some or	DEHYDRATI	immediately
severe dehydration	ON	► Follow-up in 5 days if not improving
		► Should be given oral fluids to treat diarrhoea at
		home and Zinc supplement

Diarrhoea lasting 14	SEVERE	► Should be given first dose of IM Ampicillin and
days or more	PERSISTENT	Gentamycin
	DIARRHOEA	► Should be treated to prevent low blood sugar
		► Should be <b>advised</b> how to keep infant warm on
		the way to the
		hospital
		► Should be <b>Referred to hospital</b>
Blood in stool	DYSENTERY	► Should be given first dose of IM Ampicillin and
		Gentamycin
		► Should be treated to prevent low blood sugar
		► Should be advised how to keep infant warm on
		the way to the hospital
		► Should be <b>referred to hospital</b>

Table 6.6 Classification of Diarrhea for a child between 2 months and 5 years

Signs	Classify as	TREATMENT
		(Urgent pre-referral treatments are in bold print)
Two of the		If child has no other severe classification:
following signs:		- Should be given fluid for severe dehydration OR
• Lethargic or		If child also has another severe classification:
unconscious	SEVERE	☐ Should be <i>Referred URGENTLY to hospital with</i>
• Sunken eyes	DEHYDRATION	mother giving frequent sips of ORS on the way.
• Not able to		☐ The mother should continue breastfeeding.
drink or		► If child is 2 years or older, and there is cholera
drinking poorly		in your area, should be given antibiotic for
• Skin pinch goes		cholera.
back very		
slowly		
		► Should be given fluid, Zinc supplements and food
Two of the		for some dehydration

following signs:		If child also has a severe classification:
• Restless,	SOME	- Should be Referred URGENTLY to hospital with
irritable	DEHYDRATION	mother giving frequent sips of ORS on the way.
<ul> <li>Sunken eyes</li> </ul>		The mother should continue breastfeeding.
• Drinks eagerly,		► Mother should be advised when to return
thirsty		immediately.
<ul> <li>Skin pinch goes</li> </ul>		► Follow-up in 5 days if not improving.
back slowly		
		► Should be given fluid, Zinc supplements and food
Not enough signs to	NO	to treat diarrhea at home
classify as some or	DEHYDRATION	► The mother should be advised when to return
severe dehydration		immediately
		► Follow-up in 5 days if not improving
		► Should treat dehydration before referral unless
	SEVERE	the child has another severe classification
Dehydration present	PERSISTENT	► Should be <i>given Vitamin A</i>
	DIARRHOEA	► Should be <i>Referred to hospital</i>
		► The mother should be advised on feeding
		recommendation for a child who has PERSISTENT
	PERSISTENT	DIARRHOEA
No dehydration	DIARRHOEA	► Should be given Vitamin A, therapeutic dose
		► Should be given Zinc for 10 days
		► The mother should be advised when to return
		immediately
		► Follow-up in 5 days
		► Should be <b>treated for 3 days with</b>
Blood in the stool	DYSENTERY	Ciprofloxacin
		► The mother should be advised when to return
		immediately
		► Follow-up in 2 days

#### Medicines used in diarrhea

**Oral Rehydration Salts (ORS):** Sachets containing powder for dilution in 1 liter.

*Indications:* replacement of fluid and electrolyte loss in diarrhea. For the prevention and treatment of mild to moderate dehydration from acute diarrhea of any cause, in all age group.

**Precautions**: ORS is not appropriate for patients with gastrointestinal blockade, inability to drink, or when parenteral rehydration therapy is indicated as in severe dehydration or persistent vomiting. While giving ORS, swelling of face or eyelids indicate excess. It should be discontinued until face or eyelids swelling disappear. Carbonated drinks are not recommended to a child with diarrhea.

Side effects: vomiting can occur after administration of ORS and it may indicate too rapid administration.

**Dose and Administration**: Reconstitute one sachet by adding sufficient water (freshly boiled and cooled) to make 1 liter Oral Rehydration Solution. Only water should be used to make the solution (never to use fruit, sugary or fizzy drinks). Do not boil the prepared solution.

## How to Prepare ORS

- Always wash your hands before preparing the ORS.
- *Use clean water (boiled, and then cooled).*
- Measure 1 liter of water into a clean container.
- Add the contents of a sachet of ORS powder into the water and stir, using a clean spoon.
- Put the prepared solution into a clean bottle or container with a lid.
- Use all the solution on the same day that it is prepared; any solution left over should be discarded; prepare new solution the next day.

*Dose:* According to fluid loss, give orally (by cup and spoon in young children) as much fluid as the child wants until diarrhea stops after each loose stool. If the child is less than 2 years, advise the mother to give a spoonful of ORS solution frequently. If the child is older, advise her to give frequent sips from a cup.

Storage: at room temperature in a dry place out of direct sunlight. In high humidity, the ORS may lump or become hard. If the powder is hard, even if it is white, the ORS has deteriorated and it should not be used. The solution should be kept in a closed container in a cool place and discard any remaining solution after 24 hours.

# Zinc Dispersible Tablet, 20 mg

*Indication:* zinc supplementation is used in combination with ORS for the management of acute diarrhea in children. When given during an acute episode, zinc supplements reduce the severity and duration of the episode, as well as reducing the incidence of new episodes of diarrhea in the 2–3 months following treatment.

Zinc DT is easily dispersible in liquid (clean water or breast milk) and can be administered to children with a spoon. Diarrhea mortality is reduced by 23 percent when zinc tablets are administered.

## Drug interactions:

Calcium salts: Reduced absorption of zinc sulfate

Ferrous salts: Absorption of zinc and of oral ferrous salts reduced if used concomitantly (administer Zinc before 2 hours of iron supplement)

Side effects: Stomach upset, heart burn, nausea, metallic taste

Dose and Administration:

# Give zinc tablets (20 mg) once a day for 10 days according to the age of the child

*Table 6.7 Zn dosing for diarrhea managment* 

Age	Zinc 20mg
Less than 6 months	½ tablet
6 months and above	1 tablet

#### Note:

• For infants younger than 6 months, dissolve the tablet in a small amount (5 mL) of expressed breast milk, ORS, or clean water in a small spoon.

- For children older than 6 months, tablets can be chewed or dissolved in a small amount of clean water in a small spoon.
- Remind the care-taker that it is important to give the full 10 days treatment to the child even if the diarrhea stops.
- Administer with food if gastrointestinal upset occurs.

## Counseling points for patients with diarrhea:

- Tell the mother to breast feed frequently and for longer at each feed
- If the child is exclusively breast feed, give ORS in addition to breast milk
- If the child is not exclusively, breast feed give one or more of the following: ORS solution, food based fluids (such as soup, rice water and yoghurt drinks), or clean water
- Tell the mother how much Zinc to give
- *Show the mother how to give Zinc:* 
  - Infants: dissolve tablet in small amount of expressed breast milk, ORS, clean water in a cup
  - Older children: Tablet can be chewed or dissolved in a small amount of water in a cup
  - Encourage the mother to continue feeding
- Tell the mother to give extra fluids as much as the child takes
- Explain how to reconstitute oral rehydration salts
- Mother and her family should be advised on hygiene and general hand washing
- Tell the mother to return back if they are appointed by the health care provider or if the child's diarrhea is not improved

## **Quick facts**

- ORS prevents dehydration and the need for intravenous therapy.
- Antibiotics may not be necessary in treating diarrhea
- Antibiotics are required for treating dysentery
- Never give anti-diarrheal and ant-emetics to children and infants

- Zinc decreases the duration and severity of diarrhea and the likelihood of future diarrhea
  episodes in the following 2-3 months by replacing zinc frequently lost during a bout of
  diarrhea.
- All children age 0 59 months with diarrhea should receive ORS and zinc together since
   Zinc decreases the length and severity of diarrhea.

## Ciprofloxacin

The first line drug for dysentery/bloody diarrhea is changed from Co-trimoxazole to Ciprofloxacin due to documented resistance to Co-trimoxazole.

Table 6.8 Ciprofloxacin dosing for dysentery management

	Ciprofloxacin  Give 15mg/kg two times daily for 03 days		
Age			
	250mg Tablet	500mg Tablet	
Less than 6 months	1/2	1/4	
6 months up to 5 years	1	1/2	

#### Note:

- Treat if there is dehydration by ORS as described above.
- In the young infant < 2months should be referred to a hospital after first dose of Ampicillin and Gentamycin. If the child is above 2 month treat with Ciprofloxacin for 3 days.
- Tell the mother or care taker to return the child back after 2 days for follow-up.
- Advise the mother or care taker to return back the child immediately, if:
  - Not able to drink or breastfeed
  - Becomes sicker
  - Drinking poorly

## Ciprofloxacin is not contraindicated in children



## **Case study**

**Directions:** Read and analyze this case study individually. When the others in your groups have finished reading it, discuss and answer the question. Choose one person in your group to share your answers to the large group.

A man came to your dispensary with a prescription order of:

- AMX 250mg DT; 1X3 for 5 days
- ORS 1 sachet

In order to know the person's disease classification and identify the treatment choice, you brought his card for your review. The card indicates that he is an 18 months old male child with 11.5 kg weight and 77 cm height. His temperature is 37.5°C. His mother brought him to the Health facility because he has cough and diarrhea. He does not have any general danger signs (able to drink, no vomiting, not convulsing, not lethargic or unconscious). The cough is with trouble breathing for 6-7 days and diarrhea was for a week. This is his initial visit for this illness.

The number of his breaths in a minute was 41 breaths per minute. (Since child is over 12 months of age, the cut-off for determining fast breathing is 40). He has fast breathing but has no chest in-drawing and stridor. There is no blood in the stool. He is irritable during the visit, but his eyes are not sunken. He is able to drink, but he is not thirsty. A skin pinch goes back slowly.

- What is/are the disease classification for the child?
- Do you think the prescription is right to be dispensed as ordered? If yes, why? If no, why not?
- What are the counselling points for the mother?

## 6.5 Common nutritional problems in children

#### 6.5.1 Introduction to malnutrition



## **Interactive Discussion (5 minutes)**

o Define malnutrition and describe its classifications.

Malnutrition refers to all deviations from adequate nutrition and can exist in two forms: over nutrition and under nutrition of Macronutrients and/ or Micronutrients. Macronutrients provide the energy required for growth and replacement of cells, which are required in large amounts and include protein, carbohydrate and fat. Malnutrition also encompasses specific deficiencies (or excesses) of essential nutrients such as vitamins and mineral (collectively referred to as micronutrients). Micronutrients are nutrients which are required in much smaller amounts and ensure the healthy functioning of organs and body processes. In the context of these session, the term malnutrition always makes reference to under nutrition. A child with acute malnutrition has a higher risk of many types of disease and death. Even children with mild and moderate malnutrition have an increased risk of death. Identifying children with malnutrition and treating them can help prevent many severe diseases and death. Some malnutrition cases can be treated at home. Severe cases need referral to Health Centers or hospital for special feeding, blood transfusion, or specific treatment of a disease contributing to malnutrition.

## **6.5.2** Causes of Malnutrition

Under nutrition is the result of many causes, not solely related to food. The three layers of the determinants of nutritional status adapted from UNICEF are :

- **1. Immediate Causes:** are causes which act on individuals. These include inadequate dietary intake and infection or disease. Malnutrition is often exacerbated by a vicious cycle between these two factors. Inadequate food intake can lead to a higher risk of infection or disease, and conversely disease can lead to inadequate food intake.
- **2. Underlying Causes:** they influence households and communities. The main underlying causes of malnutrition include shocks, such as drought, flooding, household food insecurity, inadequate social and care environment, inadequate access to health services and environmental factors, such as poor water and sanitation facilities.

**3. Basic Causes:** they influence communities and societies. The basic causes of malnutrition include the country's social, economic and political situation, for example, the formulation and implementation of policies to address issues such as lack of capital (financial, human, physical, social, agro-ecological, technical).

In Ethiopia malnutrition mainly develops when the child is not getting enough nutrients from his food to meet his nutritional needs. A child whose diet lacks recommended amounts of essential vitamins and minerals can develop malnutrition. A child who has had frequent illnesses can also develop malnutrition. In such conditions, the child's appetite decreases, and the food that the child eats is not used efficiently. Malnutrition is common in Ethiopia and can be manifested as wasting (acute malnutrition), stunting (chronic malnutrition), underweight and/or deficiencies of essential vitamins and minerals.

#### **6.5.3** Classification of malnutrition

Children are classified for malnutrition based on the presence or absence of edema and wasting. Wasting is assessed by determining weight for height in all children and Mid Upper Circumference (MUAC) in those aged 6 to 59 months.

Malnutrition in children can be classified as:

- Severe Acute Malnutrition (SAM)
- Moderate Acute Malnutrition (MAM)



## **Individual Exercise and Group Discussion (20 minutes)**

• What is the difference between SAM and MAM?

**Severe Acute Malnutrition SAM:** Description of malnutrition level encompassing children 6-59months with < -3 z-scores, and/or MUAC < 11.5 cm, and/or bilateral pitting nutritional oedema. Persons with SAM have higher morbidity and mortality risks.

**Moderate Acute Malnutrition MAM:** Description of malnutrition level encompassing children 6-59 months with < -2 to  $\ge$ -3 z-scores and/or MUAC >11.5 and < 12.5; and Pregnant and Lactating Women (PLW) with MUAC < 23.0 cm.

## 6.5.4 Management of SAM and MAM and Essential medicines their management

## 6.5.4.1 Management of SAM

SAM is one of the most common causes of morbidity and mortality among children under the age of 5 years worldwide. Many children with SAM die at home without care, but even when hospital care is provided, mortality rates may be high.

Children with SAM often die because clinicians unknowingly use practices that are not suitable for most children, but highly dangerous for severely malnourished children. With appropriate case management in hospitals and follow-up care, the lives of many children can be saved, and Therapeutic Feeding Unit or severe malnutrition wards can dramatically lower case fatality rates. In certain hospitals that have used these case management methods, the mortality rate has been reduced from over 30% to less than 5%. The health conditions/interventions and products for Nutrition include

Table 6.9 Essential medicines for SAM and MAM management

Condition	Medicines	
I. Uncomplicated severe acute	Amoxicillin DT	
malnutrition	RUTF (Plumpy nut or BP-100)	
	De-worming (Mebendazole 500 mg	
	tablet, Albendazole 400mg tablet)	
	Vitamin A	
	Folic acid	
	Measles Vaccine	
II. Complicated severe acute		
malnutrition child with		
	F-75	
Hypoglycemia	10% glucose or 10% sucrose	
SAM plus watery diarrhea and/or	ReSoMal	
STITE Plus Waterly distribut und of	100011111	

vomiting and Dehydration	
	Oxygen
SAM with shock	Glucose 5 ml/kg by IV
	IV fluids
	Blood transfusion
SAM with Severe Anemia (hemoglobin	Blood transfusion
concentration of < 4 g/dl or hematocrit	
<12%).	
SAM with corneal clouding and	Vitamin A
ulceration	Chloramphenicol or tetracycline
	Atropine 1%
SAM with Heart failure	Furosemide 1 mg/kg
SAM with Infections	
No Medical Complications	Amoxicillin
Failed Appetite Test: Medical	Gentamycin IV or IM
Complications	Ampicillin IV
( Unable to feed , Vomiting everything	Amoxicillin
shock, Convulsions, lethargic/very weak,	
pneumonia/severe pneumonia,	
hypoglycemia, hypothermia, dermatosis	
with raw skin/fissures, jaundice, bleeding	
tendencies, complicated measles,)	
If the child has medical complications	Oral Amoxicillin
other than mentioned above,	IM Gentamicin
(dehydration, dysentery, persistent	IV Ampicillin
diarrhea, fever other than malaria,	
measles without complication)	
If child fails to improve within 48	Chloramphenicol IV or IM
hours	Ceftriaxone 100 mg/kg IV or IM +
	Gentamicin

If a specific infection requires an	Specific antibiotic as indicated Plus
additional antibiotic, ALSO GIVE:	F75
	F100
Children with MAM	Cereal plus (CSB+)
	Super Cereal plus or (Corn Soy Blend
	(CSB++)) or
	RUSF such as plumpy Sup

## Feeding: Therapeutics Milks (F-75 and F-100) and RUTFs to SAM Children

Feeding is a critical part of managing severe malnutrition children specially during managing SAM children with complication.

- In Phase one feeding must begin cautiously with F-75, in frequent small amounts.
- Transition to F-100 or RUTF during transition phase, and continue with free-feeding on F-100 or RUTF during phase 2 of inpatient care.

Table 6. 1 WHO SAM Treatment Phases and Duration

Phase	Stabilization Phase 1	Recovery and Rehabilitation
		Phase 2
Therapeutic Milk Formula	F-75	F-100
Approximate Duration	Days 1-7	Weeks 2-6

F-75 is specially made to meet the child's needs without overwhelming the body's systems in the initial stage of treatment and the use of F-75 prevents death. F-75 contains 75 kilocalorie (kcal) and 0.9 g protein per 100 ml.

As soon as the child is stabilized on F-75, F-100 is used as a "catch-up" formula to rebuild wasted tissues during transition phase and phase 2. F-100 contains more calories and protein: 100 kcal and 2.9 g protein per 100 ml.

The Therapeutic milk (F-75 and F-100) is a commodity used for treatment of children with Severe Acute Malnutrition (SAM) with medical complications in an inpatient setting. Both

products require reconstitution with clean water before use and trained health care staff for their administration.

The previous sachet package of F-75 and F-100 is now changed to tin form with an added advantage. With the new formulation reconstitution with hot water at 70 °C is made possible which reduces the potential risk of contamination as bacteria are killed when in contact with water over that temperature. Also the new packaging of TM in tins can reduce wastage of TM compared with the sachet formulation as the tin can be used for four (4) weeks, versus 24 hours for sachets.



Fig 6:1 right packaging of Therapeutic Milk (TM

## **Rehydration solution for malnutrition (ReSomal)**

ReSoMal is a rehydration solution for children with SAM. ReSoMal contains less sodium, more sugar, and more potassium than standard ORS and is intended for severely malnourished children with diarrhea. It should be given by mouth or by NG tube. Do not give standard ORS to severely malnourished children unless they have cholera or profuse watery diarrhea.

ReSoMal can either be prepared from a ready-to-dilute sachet (as per supplier's instructions) or prepared with one sachet of WHO low-osmolarity oral rehydration solution plus 2 liters of water with an added 50 g sugar and 40 ml mineral mix or one level scoop of combined minerals and vitamins.

Contents of ReSoMal as prepared from standard ORS:

Water 2 liters, WHO-ORS One 1 liter packet, Sugar 50g and Mineral mix solution 40 ml or one leveled scoop combined vitamins and minerals (CMV).

## **Ready to Use Therapeutic Food**

RUTF is high-energy, nutrient-dense food used for nutrition rehabilitation during phase 2 of inpatient and outpatient care. It does not need to be cooked or mixed with water, which prevents growth of bacteria and makes it good for out-patient or home management of SAM.

RUTF Plumpy'nut has 500 kcal and 12.5 gm of protein per one sachet of product (92 gms). The principle behind the recipes is to provide the energy and protein needed for stabilization and catch-up.

For out-patients explain to the caretaker how to give the RUTF at home:

- RUTF is a food and a medicine for malnourished children only. It should not be shared with the other family members even if the child does not consume all the diet offered.
- Opened packets of RUTF can be kept safely and eaten at a later time the other family members should not eat any that is left over at a particular meal.
- Wash with soap child's hand and face before feeding. Keep food clean and covered.
- These children often only have moderate appetites and eat slowly. Give small regular meals of RUTF and encourage the child to eat as often as possible (every 3 to 4 hours).
- The child can keep the RUTF with him/her and eat steadily throughout the day it is not necessary to have set meal times if the food is with the child all the time. Tell the mother how much her child should eat each day as per the prescription.
- RUTF is the only food the child needs to recover during his time in the programme. It is not necessary to give other foods; a lot of other foods will delay the recovery of your child. If other foods are given, always give RUTF before other foods.
- For breastfed children, always give breast milk before the RUTF
- Always offer plenty of clean water to drink while eating RUTF

## **Vitamin A Supplementation**

Vitamin A deficiency (VAD) is a disease caused by lack of adequate vitamin A intake. Vitamin A deficiency has long been known to cause blindness, but more importantly, recent studies reveal that vitamin A deficiency is closely associated with increased mortality and morbidity

among young children. Studies conducted have shown that vitamin A supplementation reduces overall child mortality due to infections ailments by 24%.

Another cause of vitamin A deficiency and its symptoms is when the ingested vitamin A is not absorbed by the small intestines or when it is not released by the liver when needed.

The main strategies which have been adapted globally to control and eliminate vitamin A deficiency are:-

- Supplementation of Vitamin A Capsules
- Promote and support optimal breastfeeding
- Food Diversification for Vitamin A;
- Food fortification with vitamin A, and
- Infection Control.

Supplementation of Vitamin A Capsules: Vitamin A supplementation program is the main pillar of child survival efforts. When children receive a twice-annual dose of vitamin A, the child mortality rate drops by a range of 12-23% in vitamin A deficient populations. It can also reduce child blindness by up to 70%. For this reason, provision of high-strength vitamin A supplements is recognized as one the most cost-effective ways to improve child survival.

## **Doses and schedules for vitamin A supplements**

*Table 6.11 Vitamin A dosing for prevention:* 

Age	Dose	Frequency
Children 6-11 months	100,000 IU (1 capsule of 100,000 IU)	Once
Children 12-59 months	200,000 IU (2 capsules of 100,000 IU)	Once every 4 to 6 months

Do not give VAS if the child has been supplemented through EOS/CHD/HEP within one month and have Edema

Side effects: occasionally, some children may experience side effects such as headache, loss of appetite, vomiting or a bulging fontanel (in infants). These symptoms have been investigated by researchers and confirmed to be minor, harmless and transitory, and require no special treatment.

#### Folic Acid

Folic acid sometimes referred to as folate is a water soluble B vitamin (B9). Folic acid is involved in producing the genetic material called DNA and in numerous other bodily functions. Folic acid is used for preventing and treating low blood levels of folic acid (folic acid deficiency), as well as its complications, including "tired blood" (anemia) and the inability of the bowel to absorb nutrients properly. Folic acid is also used for other conditions commonly associated with folic acid deficiency, including ulcerative colitis, liver disease, alcoholism, and kidney dialysis.

Amount given: There is sufficient folic acid in F75, F100 and RUTF to treat mild folate deficiency. On the day of admission, one single dose of folic acid (5mg) can be given to children with clinical signs of anaemia.

## 6.5.4.2 Management of Moderate Acute Malnutrition

Individuals with MAM no medical complications are supported and provided with dry takehome rations (or in some cases on-site feeding) and simple medicines.

The management of MAM has two main aims; first to treat the MAM, itself while the other aim is to prevent individuals with MAM from developing SAM. It can also be used as an opportunity to provide nutrition/health education and opportunities for counseling. Children with MAM have a greater risk of dying because of their increased vulnerability to infections as well as the risk of developing SAM, which is life threatening.

## **Supplementary Feeding Interventions**

At present, the most common interventions for the management of MAM are SFP. Supplementary feeding is the provision of nutritious rations to vulnerable children (usually classified at 6-59 months) or those with special dietary needs (e.g. PLW, individuals with HIV/AIDS, etc.). SFPs also provide vital links to ongoing SAM treatment programs. In most situations, SFPs are implemented in order to prevent excess mortality amongst vulnerable groups. SFPs can either be blanket or targeted and aim to supplement the energy and nutrients missing from the diet due to various reasons.

## **Types of Supplementary Feeding Programs (SFPs)**

SFPs aim to rehabilitate individuals with MAM or to prevent a deterioration of nutritional status of the most at-risk groups by meeting their additional needs. In practice, SFPs focus on young children and PLW, due to their nutritional vulnerability.

There are two types of SFPs: Blanket or Targeted. Blanket SFPs target a food supplement to all members of a specified at risk group, regardless of whether they have MAM.

## **Targeted Supplementary Feeding Program (TSFP)**

Admission criteria for TSFP Admission to TSFPs for children 6-59 months rely on two types of anthropometric indicators of acute malnutrition; MUAC and WFH z-score.

Table 6:12 Summary of routine medicines for MAM children 6 -59 months

Name of Medicine	When	Age	Dose	Prescription
Albendazole	On admission	≥ 24 months	400 mg	Single dose on
OR				admission
Mebendazole	On admission	≥ 24 months	500 mg	Single dose on admission
Measles vaccination	On admission	9-59 months	Single dose	If vaccination card is not available
Vitamin A	On admission	9-59 months	Single dose	If not provided within the last six month

The TSFP should always provide routine medicines, such as, de-worming tablets, Vitamin A supplementation and routine immunizations and each medicine with specifications of when to give and the dosage required (stated in detail here below table). Pregnant women must be referred to the nearest health facility for Ante-Natal Care (ANC) to receive additional services, such as iron/folate supplementation and tetanus vaccinations.

## 6.6. Expanded program of immunization

## 6.6.1 Basic EPI Program Implementation



#### **Individual reflection -5 minutes**

- What is EPI? Why is it important?
- What are the diseases prevented by vaccines?

Ethiopia launched EPI in 1980 with the aim of reducing morbidity and mortality of children and mothers from vaccine preventable diseases. The target group when the program started were children under two years of age until changed to under one year in 1986 to be in line with the global immunization target.

There is an established immunization system in the country starting from the Federal level down to the Primary Health Care Unit (PHCU) level. The immunization system broadly encompasses quality service delivery, the cold chain and vaccine supply, communication, and monitoring and evaluation. The service is being rendered in all public health facilities and outreach services for the community residing beyond 5-15 KM from the health facilities. Mobile immunization services are being given in geographically inaccessible parts of the country. Immunization services are provided free of charge in the public sectors and few NGOs operating in the field of health.

In 2007, penta-valent formulations containing DPT-HepB-Hib was introduced. Later in October 2011 and November 2013, PCV and Rota-virus vaccine were introduced into the routine immunization program respectively. Currently, the number of total antigens available to infants comprise to ten.

- DPT-HepB-Hib,
- PCV
- BCG
- Polio,
- Measles and
- Rota

The country is planning to introduce Intravenous Polio Vaccine (IPV), Human Papyloma Virus (HPV), MOPV2 and school TD vaccine in the near future. Immunization service provision has

shown gradual increment since 2004 reaching 87% administrative coverage of penta3 in 2014 (FMoH).

Supplemental Immunization Activities (SIAs) are being conducted for different priority target disease like Polio, measles and MNTE to augment the Routine Immunization (RI) efforts and as an outbreak response. Maximum campaign quality is being ensured and the SIAs are believed to strengthen the existing RI to create acceptable herd immunity.

## **6.6.2** Major Vaccines Preventable disease initiatives



## **Individual reflection -5 minutes**

• What are the diseases targeted for eradication and elimination?

Currently diseases targeted for eradication and elimination are included in the national list of diseases for surveillance:

- Poliomyelitis
- Measles and
- NNT

The above vaccine preventable diseases contribute substantially to under five mortalities as well as morbidity. Diarrhea (18%), pneumonia (18%), Measles (1%) and meningitis are the leading causes of child mortality in the country. As a result of the ten vaccines introduced, complementary with other interventions, many deaths due to vaccine preventable disease are being averted than ever before. It was able for the country to meet the MDG 3 targets three years ahead of set time.

#### Polio Eradication

Four doses of Oral Polio Vaccine (OPV) are required to immunize a child beside additional doses recommended in SIAs. As the world is close to polio eradication and in view of the end game strategies, Ethiopia has planned to introduce IPV in to the routine program as per Strategic Advisory Group Experts (SAGE) recommendations. IPV induces immunity in a proportion of children which will protect them against polio caused by vaccine derived viruses (VAPP and cVDPVs) and polio caused by wild poliovirus. Schedule recommended for IPV is a single dose injection which is given at or after 14 weeks of age, in addition to the four doses of OPV in the primary vaccination series. All children who are behind on their schedule should receive one dose

of the IPV at the first immunization contact after 14 weeks of age. IPV does not replace ANY of the OPV doses. Based on epidemiological evidences and global directions, the strategic direction by the year 2016 is to switch tOPV to bOPV.

In the fight to eradicate polio from the World, four strategies are globally adopted:

- Reaching and maintaining at least 90% coverage with three doses of OPV in children aged <1 year through routine EPI services.
- Conducting SIAs to interrupt transmission of poliovirus. In such campaigns repeated doses of OPV will be usually given to children 0 -59 months and also based on epidemiologic data children up to 15 years age receive the vaccine irrespective of their immunization status with an interval of four weeks
- Surveillance for Acute Flaccid Paralysis (AFP) cases, including collection and examination of stool specimens for isolation of polio-viruses
- Mopping-up immunization campaigns: Surveillance data will be used to identify where the
  last cases of polio occur in order to focus on the activities to be under taken. Areas where
  wild polio viruses were identified, and neighboring areas will be targeted for mop up.

#### Accelerated measles elimination strategies with targets

In Ethiopia, a single dose of measles vaccine at nine months of age is given in the routine immunization program. Since first opportunity per is not sufficient for the control, second opportunity should be given through SIAs strategy. Pre-elimination and elimination of measles is expected to be achieved by 2015 and 2020 respectively. The following strategies and targets set for the accelerated measles elimination efforts are recommended:

Keep up: increasing routine measles immunization coverage among infants of under the age of one year. To reach 90 % measles containing vaccine at nine months of age coverage at national level and 80% in every Woreda.

- a) Catch up: conducting measles mass immunization campaigns (NIDs, SIAs): including 95% coverage in every measles SIAs.
- b) Follow up: conducting follow up campaigns (SIAs) every 2-3 years.
- c) Improving Case Management and Vitamin A Supplementation

d) Measles case based surveillance. Achieve the surveillance performance targets of at least one suspected case reported per 100,000 population per year. At least 80% of zones per year serum sample adequacy reached for Measles IgM

#### Neonatal Tetanus Elimination

Elimination of Neonatal Tetanus (NNT) is an effort exerted to bring the level of NNT to less than one case for every 1,000 live births in each Woreda throughout the country. Promotion of deliveries by skilled birth attendants and immunizing child bearing age women, elementary school girl and pregnant women against tetanus are critical steps in preventing NNT. A child protected at birth against NNT is a child that is born within the period of protection (TT2+) provided by the last valid dose of Tetanus Toxoid (TT) given to the mother. (*please refer Session* 

## Schedules of Vaccines given to children

The principle of immunization is to achieve protection of the youngest age group at risk from developing the vaccine preventable diseases with adequate antibody response with minimal adverse effects from the vaccines. The immunization schedules for all infants is to receive one dose of BCG, three doses of DPT-HepB-Hib, three doses of pneumococcal, two doses of Rota virus vaccine, four doses of OPV, one dose of IPV and one dose of measles before the age of one year. The **minimum interval** between each dose of the vaccines should be four weeks; however, there is no **maximum interval** between the doses as long as it is given before the age of one year

Table 6.13 IMNCI vaccine schedule

	AGE	VACCINE		
	Birth	BCG	OPV - 0	
IMMUNIZATION	6weeks	DPT1-HepB1-Hib1, PCV-1	OPV – 1, Rota -1	
SCHEDULE:	10 weeks	DPT2-HepB2-Hib2, PCV-2	OPV – 2, Rota -2	
	14 weeks	DPT3-HepB3-Hib3, PCV-3	OPV - 3	
	9 months	Measles	Vitamin A	
			(if not given with in last 6	
			months)	

Source: IMNCI Chart booklet 2015.

## **6.6.3** Conditions and contraindications to immunization Contraindication

Contraindications can be permanent, such as known allergies to a vaccine component, or temporary, such as an acute febrile illness to vaccination is a rare condition in a recipient that increases the risk for a serious adverse reaction. Ignoring contraindications can lead to unavoidable vaccine reactions. Most contraindications are temporary, and the vaccination can be administered later.

The only contraindication applicable to all vaccines is a history of a severe allergic reaction after a prior dose of vaccine or to a vaccine constituent. Precautions are not contraindications but are events or conditions to be considered in determining if the benefits of the vaccine outweigh the risks. Precautions stated in product labelling can sometimes be inappropriately used as absolute contraindications, resulting in missed opportunities to vaccinate.



## Reading and individual reflection (10 minutes):

- What are the critical sign that contraindicate with immunization?
- What are the condition not contraindication to vaccines?
- What are the absolute contraindication to EPI?

*Table 6.14 Conditions and contraindications to immunization* 

#### Conditions which are not contraindication Absolute contraindications **EPI** to immunization vaccines Infants who developed severe reactions Minor illnesses such as upper respiratory tract infections, diarrhea and fever < 38.5° (convulsion, anaphylaxis, shock. C<sub>.</sub> encephalopathy) soon after or within three days administration of vaccines Allergy, asthma other atopic containing Pentavalent and PCV vaccine manifestations, hay fever or "snuffles" injection, should not get vaccine Prematurity, small for date infant containing the whole component of Child being breastfed Pertusis and PCV, if available only DT Family history of convulsions/child history should be given. of convulsion

- Treatment with antibiotics, low dose corticosteroids or locally acting drugs (e.g. topical or inhaled steroids)
- Dermatosis, eczema or localized infections
- Chronic disease of the heart, lung, kidney and liver
- Stable neurological conditions such as cerebral palsy and Dawn's syndrome
- History of jaundice after birth.
- Having multiple injection in a single vaccination session

- Infants who develop anaphylaxis following measles immunization
- Infants who had anaphylactic reactions such as generalized urticaria, difficulty in breathing, swelling of the mouth and the throat, hypotension or shock following ingestion of egg should not take yellow fever vaccination.
- Reported hypersensitivity following previous administration of the vaccine or to any of the vaccine components and history of intussusceptions (Rota virus vaccine).

## **6.6.4** EPI implementation strategies

All the EPI strategies are closely interrelated to the disease control objectives, which require high and sustained routine immunization coverage every year. The strategies outlined here are applicable in all EPI Plus program.

- Strategies for increasing immunization access and coverage
- Strategies to reduce drop out/ Defaulter tracing
- Increasing the quality of immunization services
- Improve public awareness and community participation through appropriate program communication
- Strategies to sustain high immunization coverage

## **6.6.5** Role of Pharmacy professionals



#### **Individual reflection -5 minutes**

• What are the Role of pharmacist on EPI implementation

Pharmacists can play an important role in disease prevention by advocating immunizations. Such activities are consistent with the preventive aspects of pharmaceutical care and have been part of pharmacy practice for over a century. These guidelines address the pharmacist's role in promoting and conducting proper immunization of patients in all organized health care settings.

## Mothers Counseling

- Mothers will children in need of immunization should be advised of their infection risk and encouraged to accept the immunizations they need. Mother's concerns about vaccine safety and efficacy should be discussed and addressed.
- o Pharmacy professionals should serve as a valuable source of information.
- Pharmacy professionals should educate and recommend to mothers the importance of and need for receiving vaccinations.
- Adverse Events Following Immunization (AEFI)
  - AEFI should be documented, investigated and monitored at health facility levels.
     Appropriate management and communication should follow the detection of immunization adverse events with parents, health workers and with the community.
  - AEFI should be reported regularly at all levels; however, severe cases of AEFI should be reported immediately to EPHI/FMOH.
- Store and distribute vaccines in an appropriate storage conditions
  - As a supply chain expert, Pharmacist are expected to keep the right conditions for all immunization vaccines. The pharmacist roles and responsibilities on the storage and distribution of vaccines will be discussed under chapter 6.

## **6.7 Summary**

- Unique features of childhood development may pose special vulnerabilities to drug toxicity. Hence, rational use of medicines in children is very important.
- Critical medicines used for prevention of essential newborn care include Chlorhexidine, Tetracycline eye ointment and Vitamin K
- Cough and breathing problems should be classified and managed according to IMNCI management protocol. Amoxicillin, Ampicillin and Gentamycin are drugs of choice for the management of pneumonia.
- Diarrhea, if left untreated, causes dehydration and can lead to death in young children.
   ORS, Zinc, Ampicillin and Gentamycin are drugs of choice for the management of diarrhea based on severity.
- A child with malnutrition has a higher risk of disease and death. Classification and management of SAM and MAM are important interventions to reduce malnutrition.
- EPI strategies are closely interrelated to the disease control objectives requiring high and sustained routine immunization coverage every year. Pharmacists can play an important role in disease prevention and vaccines management.

# Chapter 7: Chapter Six: RMNCH Pharmaceuticals Supply Chain Management

## **Chapter Description:**

This chapter discusses on RMNCH pharmaceuticals supply chain management that require special considerations and the role of pharmacists in their management.

Duration 210 minutes

**Primary Objective**: By the end of this chapter, participants will be able to:

• Apply the supply management system to manage RMNCH pharmaceuticals

## **Enabling Objectives:**

At the end of the chapter, participants will be able to:

- Describe the national supply chain system
- Practice logistics activities for RMNCH pharmaceuticals
- Discuss program updates that require logistic management consideration
- Identify role of pharmacy professionals in RMNCH pharmaceuticals management

## **Chapter outline**

- 6.1. National supply chain system
- 6.2. Logistic activities for RMNCH pharmaceuticals
- 6.3 Program updates requiring logistic management consideration
- 6.4. Role of pharmacy professionals for RMNCH pharmaceuticals
- 6.5. Summary

## 7.1 National supply chain system



## **Interactive Discussion (5 minutes):**

- What do we mean by Supply Chain Management?
- What we mean by logistics management

**Supply Chain Management (SCM)** is defined by the Council of Supply Chain Management Professionals (CSCMP) as: "SCM encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Pharmaceutical supply chain management follows the same principle with the addition of public health concept and the sensitivity of pharmaceuticals".

**Logistics management** as defined by CSCMP, is part of SCM that plans, implements, and controls the efficient, effective forward and reverse **flow** and **storage** of goods, services, and related **information** between the point of origin and the point of consumption in order to meet customers' requirements".

Successful RMNCH programs are only possible if all health facilities providing the service are equipped with an uninterrupted and sustained supply of high-quality RMNCH pharmaceuticals. Ensuring adequate and continuous availability of RMNCH pharmaceuticals is a critical role of supply chain management system. The increasing health service seeking behavior by the community, unmet family planning needs, progressive increase in CPR and the targets set in RMNCH strategy necessitate an uninterrupted supply of RMNCH pharmaceuticals. This can be achieved only if efficient pharmaceuticals supply chain management system is designed and implemented at all levels of the health system. The efficient SCM system will significantly contribute in minimizing wastage of resources as we are living in resource limited country.

FMOH through Pharmaceuticals Fund and Supply Agency (PFSA) started implementing Integrated Pharmaceuticals Logistics System (IPLS) since 2009. IPLS is the term applied to the single pharmaceuticals reporting and distribution system based on the overall mandate and scope of PFSA. Before the existence of IPLS, there were so many problems in the management of pharmaceuticals that lead to frequent stock out and wastage of health pharmaceuticals. IPLS is

developed in response to the problems that Ethiopia had been suffering from lack of supply management system.

IPLS integrates the management of essential pharmaceuticals including the following pharmaceuticals that were used to be managed vertically: HIV/AIDS, Malaria, TB and Leprosy, EPI, FP and MCH. It is the primary mechanism through which all public health facilities obtain essential and vital pharmaceuticals. This system ensures that all Ethiopians receive the pharmaceuticals they need when they are visiting service delivery points by ensuring the six rights of logistics system are fulfilled.

## 7.2 Logistic Activities

Logistics activities are the operational components of SCM including selection, quantification, procurement, inventory control system, LMIS, receiving, and storage. These logistics activities are briefly discussed below in relation to RMNCH pharmaceuticals.

#### 1. Selection



## Think-pair-share 5 minutes

What is the current practice related to selection of RMNCH pharmaceuticals at HFs?

RMNCH pharmaceuticals are selected at national level by considering their safety, efficacy, quality, and cost. Accordingly, the National Essential Medicines List (EML) should be updated whenever new RMNCH pharmaceuticals are included. Health facilities through Drug and Therapeutics Committee (DTC) are expected to make sure RMNCH pharmaceuticals are included in their facility specific medicines list depending on the level service they provide as per the national guidelines which are based on national and WHO recommendations.

## 2. Quantification



# Interactive Discussion (5 minutes)

What are health facilities' contributions for quantification of RMNCH pharmaceuticals?

National quantification of RMNCH pharmaceuticals is conducted by PFSA in collaboration with FMOH and other stakeholders. The quality of quantification depends on availability of quality data. Accordingly, it is important to have detail report on consumption and stock on hand data, demographic data, and service level data. Most of the data required emanates from health facilities and it is crucial to ensure the timeliness, accuracy, and completeness of logistics data to conduct a successful quantification.

#### 3. Procurement:

The procurement of RMNCH pharmaceuticals is executed by PFSA and other partners as necessary. The procurement process follows the national and international procurement regulations. Health facilities also execute procurement of RMNCH pharmaceuticals from PFSA or other private suppliers. Health facilities should follow the national procurement regulation. The health facility pharmacy department should have to have an updated list of suppliers for RMNCH products.

## 4. Inventory control system



## Interactive Discussion (5 minutes)

What is the purpose of inventory control system?

The purpose of an inventory control system is to inform personnel when and how much of a pharmaceutical to order and to maintain an appropriate stock level so as to ensure availability of pharmaceuticals. A well designed and well operated inventory control system helps to prevent shortages, oversupply, and expiry of pharmaceuticals.

The inventory control system for IPLS is a Forced Ordering Maximum/Minimum inventory control system. This system is designed to ensure that quantities of RMNCH pharmaceuticals in health facilities fall within an established maximum and minimum range and facilities are required to report on a fixed schedule. All products are re-supplied each time a report is completed. In emergencies, an emergency order can be placed.

Health centres and hospitals calculate their own order sufficient quantities for selected RMNCH pharmaceuticals along with other programs to bring stock levels up to the maximum level, and required to report and order every two months.



## Interactive Discussion (5 minutes)

• What is the purpose of LMIS?

## **5. Logistics Management Information System (LMIS)**

Information is the engine that drives the entire logistics cycle. We collect information to make decisions; the better information we have, the better decisions we can make. The purpose of LMIS is to 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 pharmaceuticals are availed.



## Think-pair-share (10 minutes)

- What are the LMIS formats used for recording and reporting logistics data?
- What are the essential data items for logistics activities and why they are needed?
- Where do we get these essential data items?

## Records and reports

Keeping good records helps everyone to understand the flow of supplies into and out of the facility. Bin Cards and Stock Record Cards are used to account for products held in storage, including their receipt and issue. Internal facility report and resupply form (IFRR) is used within the facility by dispensing units to report and be resupplied by the store, and should be appropriately documented. Health post monthly reporting and resupply form (HPMRR) is used by health post to report and be resupplied by the catchment health center.

Valuable information used to make re-supply decisions is recorded on the Bin Card, Stock Record Card and IFRR; data from these records are used in reporting, calculating reorder quantities, for monitoring stock levels, quantification and make informed logistics decisions. Reporting and Requisition Form (RRF) is used by health facilities for reporting and requisition of selected RMNCH pharmaceuticals.

## Data quality



## **Brainstorm and reflections (5 minutes):**

What are the dimensions of data quality?

Data is generally considered high quality if it is "fit for its intended uses in operation, decision-making and planning. In relation to essential data items in IPLS, it refers to the timeliness, completeness and accuracy of IFRR and Health Post Monthly Report and Resupply Form (HPMRR) submitted to store in a facility and RRF reported to PFSA hubs for making sound decision in resupplying products.



## Interactive Discussion (10 minutes):

Describe what do we mean by timeliness?

Describe what do we mean by Completeness?

Describe what do we mean by Accuracy?

The logistics data for RMNCH pharmaceuticals listed on RRF should be captured from bin card and physical count, and logistics data for IFRR and HPMRR should be captured from bin card in the DU and physical count.

- **Timeliness:** is preparing and submitting reporting and requesting formats (RRF), following reporting period within 1-10th days of the month and for HPMRR within 1-5th day of the month; for DUs at the agreed day in the schedule set for IFRR.
- Completeness means all data items required are available (i.e. no missing cell). It refers to the level of transferring the essential data items to all RMNCH pharmaceuticals listed in reporting and requesting formats.

Accuracy is all about the correct posting of data and arithmetic calculations on RRF, IFRR and
HPMRR of RMNCH pharmaceuticals data entry. Data are accurate when the data measure what they
are intended to measure as well as provide required sufficient detail. Accurate data minimizes or
avoids error.



## **Group Discussion (10 minutes):**

- Discuss consequences of poor data quality
- Discuss factors contributing to poor data quality

## Consequences of poor data quality

- Proper logistics decisions cannot be made
- The required products can't reach or be received timely, in right quantity to fill the stock to the maximum which result in stock outs
- Compromise the stocks kept at PFSA hubs
- Wastage of resource due to overstock and simultaneously exposing shortage to others

#### **Factors contributing to poor data quality**

The following issues can contribute for challenge in acquisition of quality reports and needs to be sought as areas of intervention for improving data quality

- Factors related to delay in reporting timely
  - Lack of awareness on the benefits of timely reporting
  - Lack of staff commitment
  - Low enforcement by the management (non-functional DTC)
  - Lack of ownership
  - Negligence
- Factors related to completeness and data accuracy
  - Lack of due attention,
  - o Knowledge gaps (program items)

- Not maintaining bin card for all products
- Lack of regular bin card updating
- o Error created while transferring data from bin card to reports
- Data manipulation

The above mentioned challenges are not explicit but the major ones. Since health facilities have a huge role on the success of IPLS, pharmacy professionals must make sure the data reported is of the required quality.

#### 6. Receiving

Health facilities will receive selected RMNCH pharmaceuticals every two months based on RRF submitted to PFSA hubs. The RRF has to be complete and accurate, and submitted in a timely manner. Health facilities will receive the products directly from PFSA or through Woreda. Health facilities are expected to follow their stock status and keep records regularly. The logistics data for RRF should always come from bin cards and IFRR. The quality of the data is very crucial as it will be used for making informed logistics decisions and quantifying future consumption.

Maternal health pharmaceuticals distribution plan is done centrally for all public health facilities based on the delivery service reported through Health Management Information System (HMIS). PFSA hubs deliver the pharmaceuticals directly to hospitals whereas for health centers the hubs deliver it to Woreda Health Office from which health centers collect their allocation.

#### 7. Storage

Storage is an important activity of the integrated supply chain management of pharmaceuticals. The conditions under which pharmaceutical are manufactured and stored can have a major impact on their quality. Pharmaceutical must be stored under conditions that prevent contamination and, as far as possible, deterioration. Pharmacy professionals should take precautions for maintaining the appropriate storage condition especially in relation to the effects of the atmosphere, moisture, heat and light. Proper storage, including refrigeration, is critical to maintain the quality of pharmaceuticals.

Pharmaceuticals should be stored as per the 13 storage guidelines in IPLS (Annex\_). The constant complaint from health facilities is lack of storage space to meet the mentioned storage

guidelines. The ability to use the available space effectively and efficiently will have a huge impact on the storage of pharmaceuticals.

#### Storage space utilization



#### Paired discussion and reflections:

- Discuss on ways to improve storage space utilization.
- Link your experience with what you read and share your experiences with the large group.

Efficient Storage space utilization is very important for health facilities. Without spending any extra funds on store management in the health facility, the following ways can significantly improve the storage space utilization and can bring a significant change in storage space utilization.

**Avoid Overstock:** manage inventory efficiently and avoid requesting stock beyond the maximum quantity set as per IPLS (i.e. 4 months of stock).

## Logical organization of pharmaceuticals in the store by:

- Organizing the storage area into zones as needed: a cold storage area for vaccines and
  other supplies requiring cold storage; a secure room or locked cage for narcotics and
  controlled substances; a zone in which to store flammable materials, ideally in a separate
  building or room.
- Organizing the storage area pharmacologically so pharmaceuticals can be found and restocked easily.

**De-junking:** means getting rid of the unusable pharmaceuticals in the store, including damaged and expired products and non-pharmaceutical items in the store. De-junking can greatly increase storage space.

Ethiopia has had major success in de junking across the country. At some facilities, storage space was increased by 100%.

**Use the Vertical Space of the store:** make sure you're using all the vertical space available as per IPLS storage guideline.

## Using locally available resources for shelves and pallets for storing pharmaceuticals

## 7.3. Program updates requiring logistics management considerations



Interactive Discussion (5 minutes):

Which RMNCH products are integrated into IPLS?

## 7.3.1. Child Health Pharmaceuticals Integration to IPLS

As the result of the integration, the stocks out rates of the different program pharmaceuticals have been reduced significantly. Based on the evidence from integration of other program pharmaceuticals, child health pharmaceuticals are integrated in to IPLS to improve availability and utilization. The integration will require both PFSA and health facilities to hold stock within the minimum and maximum stock level to ensure continuous availability of the pharmaceuticals. Integration of child health pharmaceuticals is justified for the gains in the following supply chain management functions:

## Quantification

- To properly quantify; proper recording, requesting and reporting of child health pharmaceuticals is very important.
- Integrating child health pharmaceuticals into IPLS will encourage health facilities to properly record, request and report child health pharmaceuticals. Proper recording allows to track consumption data which is the base for quantification.

#### • Procurement and Distribution

- Procurement and distribution of child health pharmaceuticals were being primarily done by developmental partners (UNICEF, Micro nutrient initiative and others) often using separate channels from PFSA.
- The fragmented procurement and distribution of child health pharmaceuticals is believed to have led to overstock and expiry leading to wastage of resource.
- PFSA will procure and distribute child health pharmaceuticals based on the forecasted national need of child health pharmaceuticals.

## Child health pharmaceuticals integrated to IPLS

- Amoxicillin Dispersible Tablet (125mg, 250 mg)
- Chlorhexidine Di gluconate Gel (4%)
- Gentamicin Injection (20mg/2ml)
- Oral Rehydration Salt (ORS)
- Zinc Dispersible Tablet 20mg
- Tetracycline eye ointment 1% (4g)

## **7.3.2.** Family Planning

Family planning products have been integrated to IPLS since 2009. There is significant improvement in IPLS implementation and product availability though there is a gap in regularly reporting and requesting resupply as well as poor data quality by health facilities.

One of the long acting family planning products, Implanon, is replaced by next generation Implanon (Implanon next). Health facilities are expected to report and request, and to closely monitor the stock status of implanon next as per IPLS.

## 7.3.3. Reimbursement protocol

Reimbursement protocol is a mechanism in which facilities can use pharmaceuticals needed for delivery service provision and comprehensive abortion care, and in-kind replacement will be made for pharmaceuticals they use to provide the service. The rationale for the issuance of this protocol is to ensure that mechanisms in which health facilities get reimbursed for pharmaceuticals they used for the delivery service provision and comprehensive abortion care. This is expected to bridge the service provision gap which occurs due to lack of essential pharmaceuticals and most importantly, to get the services accessibility closer to the community.

Based on health facilities HMIS report on delivery and Cesarean Section performed, a distribution plan is prepared biannually for hospitals and PFSA deliver the products accordingly. Health centers will get these pharmaceuticals through distribution plan from biannually whenever the pharmaceuticals are available.

## 7.3.4. Guideline updates and new medicines introduction

RMNCH continuum of care guidelines are being revised regularly. During revision, addition of a new medicine and new treatment protocol, omission of a previously used medicine and adoption of a new strategy can be there. The logistics system is required to be dynamic enough to incorporate these changes.

Health facilities are expected to update themselves and share information internally for the betterment of the service. The pharmacy department is responsible to update newly introduced and omitted medicines to other health professionals, and record, report and request the medicines accordingly.

## 7.3.5. Sustainability of funding

Sustainability of funding is the main determinant for ensuring continuous availability of RMNCH pharmaceuticals. RMNCH pharmaceuticals for which sustainable funding is ensured are integrated in IPLS. The remaining pharmaceuticals will also be integrated to IPLS when sustainability of funding is ensured.

#### 7.3.6. Vaccine Distribution Transition

Previously vaccine used to be distributed by each regional health bureaus to the lower level following the administrative structure. FMOH in collaboration with PFSA and development partners has managed to transit the distribution of vaccine through PFSA. This means PFSA will distribute the vaccines directly to woreda health office. In turn, Health facilities get resupply from woreda by using vaccine requisition form (VRF).

All health facilities and stores handling EPI vaccines need to monitor the temperature of the vaccine in the cold chain at least twice daily for timely action. All institutions and health facilities handling EPI services should use standard refrigerators to store vaccines.

## 7.4. Impact of poor logistics management practice



## Paired reading, discussion and reflections (15 minutes):

• Read the section on *Impact of Poor Logistics Management Practice* and discuss.

Efficient pharmaceutical logistics management is mandatory to avail the required pharmaceuticals in a continuous manner. The logistics activities should be performed in a quality manner to ensure the quality, safety and efficacy of pharmaceuticals.

Poor logistics management of pharmaceutical results in the following impacts:

- Compromise quality and potency of drugs
- Pilferage, theft or losses,
- Resource wastage due to pharmaceuticals expiry and damage
- Frequent stock out of pharmaceuticals
- Overstock of pharmaceuticals
- Client dissatisfaction and loss confidence in the health facility
- Health worker dissatisfaction and lack of motivation
- Irrational medicine use
- Poor treatment outcome
- Death of mothers and children
- Unintended pregnancy because of unavailability of contraceptives

## 7.5. Role of pharmacy professionals on RMNCH logistics management



## **Individual Exercise (10 minutes):**

What are roles of pharmacy professionals on RMNCH management?

Pharmacy professionals have the following roles in ensuring availability and rational use of RMNC pharmaceuticals.

- Advocating inclusion of RMNCH pharmaceuticals to the facility specific essential medicines list
- Setting a feasible schedule between Dispensing Unit (DU) and store for resupply, and adhering to the agreed schedule
- Supporting DU in filling and submitting IFRR to store as per the agreed schedule
- Supporting health posts in filling and submitting HPMRR to the health center every month
- Supporting health posts in proper management of RMNCH pharmaceuticals
- Ensuring the proper storage of RMNCH pharmaceuticals as per the manufacturer requirement
- Updating bin card whenever a product is issued or received, or during physical count
- Regularly following the stock status of RMNCH pharmaceuticals to avoid overstock or stock out
- Preparing and sending quality RRF timely to PFSA hubs
- Place emergency order when needed
- Disposal of unusable and expired medicines including health posts as per the disposal directive

## 7.6. summary

## **Chapter summary**

- IPLS is the national Supply Chain Management System that integrates the management
  of essential pharmaceuticals including the following pharmaceuticals that were used to be
  managed vertically.
- Logistics activities that enable us to ensure the availability include selection, quantification, procurement, inventory control system, LMIS, receiving and storage.
- Since logistics management is designed to achieve the objectives of the program, when there are any changes or updates the logistics management system should accommodate them
- Poor logistics management affects the availability of quality, safe and efficacious pharmaceuticals.
- Pharmacy professionals play a vital role in the logistics management of RMNCH pharmaceuticals

# Chapter 8: Ethical and professional standards throughout RMNCH Services

**Chapter Description:** This chapter will address and discuss on the ethical professional standards that are expected from the pharmacy professional during service provision.

**Primary Objective**: By the end of this Chapter, participants will be able to:

 Apply ethical standards and effective communication throughout RMNCH continuum of care

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

- Demonstrate use of effective verbal and non-verbal communications
- Differentiate the ethical practice from unethical one

## **Chapter outline**

- 8.1 Effective communication skill
- 8.2 Ethical practice in RMNCH
- 8.3 Summary

## 8.1 Effective communication



## **Brain storming (5 minutes)**

## What is communication?

## What are factors affecting effective communication?

Communication is a vital aspect of health care. It is the sharing of information, ideas, thoughts, and feelings. It involves not just the spoken word, but also what is conveyed through change of tone of voice, facial expression, body posture, and other behavioral responses. Just look around you at your colleagues and notice the degree to which they communicate effectively. More painfully, perhaps, look at yourself as you talk to patients, clients or colleagues. Most of us can benefit from a little self-analysis and a bit of rethinking about taken-for-granted aspects of how we come across to others.

The goal of all communication is understanding. For one person to understand a message composed by another, the receiver must do more than recognize the words used in the message by the sender. Effective communication occurs only when the meaning of a message is held in common by the participants. When a person wishes to share information with another, the sender must choose how to transmit that message. The **medium** of the message can be written, oral, nonverbal, or electronic. If the sender decides to transmit the message through words, the sender must encode the message by choosing the words that best convey the intended meaning to the receiver.

Once the information is encoded and transmitted, the sender loses control of the message because its meaning comes from the receiver's decoding of it. If the receiver responds to the message, that response acts as feedback to the sender. This gives the sender as an opportunity to clarify and correct any misunderstanding. This sequence of encoding, transmitting, and decoding messages continues as long as sender and receiver continue to communicate.

We may face difficulties in making effective communication due to several reasons. Among these are:-

## Environmental factors

- o Lack of privacy- dispensaries with no counseling rooms or areas
- Physical barriers- The distance between people when communication occurs is very important. Dispensing through windows is a very important physical barrier prevalent in most health facilities in Ethiopia.

## Patient related factors

- o Inferiority feeling of the patient
- Low literacy level
- Anxiety
- o Misconception
- o Forgetfulness
- o Physical impairment that may cause a barrier in communication

## Time factor

o It is always important to check what time patients have before starting any communication. That way you can make the best of what time is available.

## 8.1.1 Effective communication with the client



## Paired reading, discussion and reflection for 10 minutes

What are characteristics of effective communication with client?

All patients, not just those with low health literacy, will benefit from the following strategies:

- Explain things clearly in plain language.
- Focus on key messages and repeat.
- Use a "teach back" or "show me" technique to check understanding
- Effectively solicit questions
- Use patient-friendly educational materials to enhance interaction

Together, these strategies and others will help ensure the environment is patient-friendly and shame-free for ALL patients.

Effectiveness of one communication could be assessed using the following six characteristics of effective communication

## 1. Explain things clearly in plain language

Make effort to avoid medical/pharmaceutical jargons and vague instructions. Present new information a little more slowly. Practical examples can help give a sense of reality to abstract concepts or things that patients can't see in their own body. Also pay attention to the patients' own terminology and use those terms yourself in the discussion. Just what *exactly* does it mean to take a medication on an empty stomach? Be as specific as possible when providing instructions.

## 2. Focus on key messages and repeat

Keep it short and simple. Only tell patients what they need to know, not what is nice to know. Don't try to explain everything to a patient at one visit. Select just a few key points, reinforcing and repeating them during the discussion. Less is more. Identify the one or two most important things to the patient and address those. Patients are far more likely to remember the answers to their own questions and concerns. Combine the patient's priority items with your top one or two things to develop a manageable list of just a few things to discuss. Focus on behaviors- what do you want the patient to do and review each point at the end- summarize and reinforce.

## 3. Use a "teach back" or "show me" technique to check understanding

Asking patients to "teach back" what they have learned improves medical outcomes. Teach back is used to assess patient understanding. Asking patients to repeat something in their own words is a far better way to gauge comprehension than simply asking, "Do you understand?" After explaining a new concept, we should assess the patient's recall and understanding, clarify our explanation as needed, reassess comprehension, and continue to clarify until the patient expresses satisfactory understanding.

## **4.** Effectively ask questions

Most health professionals probably feel that they give patients a chance to ask questions, but some simple techniques can enhance patients' comfort level in asking questions. As a provider wrap up a patient encounter, they often collect questions from the patient, in part to check patient's comprehension of the information that has been covered. Unfortunately, we often do this in a closed-ended way with a yes/no prompt such as:

- "Do you have any questions?" or
- "Any questions?"

Remember, patients are often hesitant to admit that they don't understand something or they're afraid to ask what might be considered a "stupid question." This is most true for patients with low health literacy. Open the door for them by effectively soliciting patient questions. Ask, "What questions do you have?"

## 5. Use patient-friendly educational materials to enhance interaction

Because everyone has different learning styles, verbal messages should be reinforced with written information and pictures whenever possible. Everyone learns better if information is reinforced in multiple ways. Provide easy-to-understand information for ALL patients.

Written materials are easy-to-read if they use:

- Few messages
- Short, simple, and familiar words
- Easy-to-understand phrasing of numeric information
- Large fonts
- Short lines and lots of white space
- Simple illustrations that are directly applicable to the text

## 6. Be a good listener

Listening appropriately to the patient is hard work, but it is extremely important to effective communication. The dispenser must allow the patient to speak without interruption and concentrate on the words and meaning of the patient's message. He/she should avoid distractions, ask clarifying questions where appropriate, and avoid jumping to conclusions or judging the patient's word.

Good listening skills on the job help you get better information, save time, solve problems, and reduce errors. On the other hand, poor listening creates misunderstandings, wastes time, and

creates mistakes. In the health care profession mistakes have the potential for serious effects on the lives of patients.

The following are keys to effective listening:

- Take personal responsibility for understanding what you hear.
- Concentrate and make a good effort to focus on the person speaking.
- Listen without interrupting, disagreeing, or offering explanations.
- Use body language (nonverbal gestures) to show that you are involved in the conversation.
  - o Example: nod your head, keep eye contact, and keep hands at side.
- Ask questions to be certain you are interpreting the message correctly.
  - o Example: summarize and paraphrase what you heard.
- Take notes as necessary. This will help you remember or document what was said. But avoid focusing on only your writing.

## 8.1.2 Effective Communication with other Healthcare Providers



## **Interactive discussion 5 minutes**

What should be an effective communication with health providers

Pharmacy professionals work in teams of health providers who have unique professional responsibilities in managing patients' health problems. Poor communication with the healthcare team leads to frustration and lack of interest between professionals as well as compromise of patient care. Remember that professionals may have trouble communicating with one another. As much as it depends on them, dispensers should strive to make the communication smooth. To communicate effectively, dispensers must be comfortable with their role on the health care team and confident in their unique knowledge and contributions to patient care.

The dispenser should be prepared with specific questions or facts and recommendations and stay within the pharmacist's area of expertise. It is important that dispensers choose the right time and place for the conversation. Also make sure that you never interrupt a physician-patient interaction, except in a life-threatening situation.

When communicating with other providers:

- Begin by identifying yourself
- Identify the patient you are to discuss
- Present the issue or concern that you have identified
- Do not be judgmental
- Use professional rapport to gain respect
- Be prepared to discuss the issue at a professional level
- Propose a solution
- Await feedback

## Note that:

- You may not always have all the answers to the questions that follow
- Be comfortable saying that you do not know the answer now, that you will look into it and get back to the provider as soon as you can
- The provider will respect that you provide only information about which you are confident

Over time, you will build a working relationship with the healthcare team members that you work with.

## 8.2 Ethical practice in RMNCH service



## **Brainstorming – 5 minutes**

- Do you think professional competency is an ethical issue or a personal willingness?
- Is universal access to comprehensive reproductive health a human right or the government's duty, what did you think?

Ethics is the science of moral value. The basic foundation of ethical behavior is the basic concept: "Do Good and Avoid Evil". Ethics and law are related in that both share the social purpose of encouraging the right conduct. Whereas law attempts to achieve its purpose through the sovereign power of the government, ethics, especially professional ethics, attempts to achieve it without the intervention of the government. Therefore, law is enforced by the government, while ethics is a principle achieved by the voluntary self-discipline of professionals.

Professional ethics is the moral principle, which should guide members of the profession in their dealings with each other and with their patients, the patrons, the state etc. One characteristic of members of a profession is a collective and disciplined concern of the group. The attitude of the professional should be altruistic and an unselfish concern for the welfare of others. Ethics is therefore, an inherent characteristic of professional behavior.

The services provided by the profession of pharmacy directly affect the life of every individual. These professional, social and economic interactions between pharmacists and the public must be governed by certain rules.

To this end, the government disseminates laws, and institutes regulatory bodies to overlook the activities of the professionals and the quality of services rendered, thus safeguarding the interest of the public. In addition to these, the welfare of the public has to be protected by the professionals themselves who impose upon themselves certain norms and standards of behavior in their practice.

# The 12 principles of ethics Integrity Loyalty Transparency Confidentiality Honesty Accountability Serving public interest Exercising legitimate Authority Impartiality Respecting the law Responsiveness Leadership

Table 8. 2 Ethical practice in service provision

SN	Ethical practices	Description					
1	Promotes the good of	A pharmacy professional places concern for the well-being of the					
	every patient in a	patient at the center of professional practice. In doing so, He/She					
	caring, compassionate,	considers needs stated by the patient as well as those defined by					
	respectful and	health science.					
	confidential manner.	A pharmacy professional is dedicated to protecting the dignity of the					
		patient. With a caring attitude and a compassionate spirit, a					
		pharmacist focuses on serving the patient in a private and					
		confidential manner					
2	The pharmacy	The professional promotes the right of self-determination and					
	professional respects	recognizes individual self-worth by encouraging patients to					
	the autonomy and	participate in decisions about their health. He/She communicates					
	dignity of each patient	with patients in terms that are understandable. In all cases, he/she					
		respects personal and cultural differences among patients.					

3	Respects the covenantal	Considering the patient-professional relationship as a covenant					
	relationship between	means that a pharmacist has moral obligations in response to the gift					
	the patient and	of trust received from society. In return for this gift, a pharmacy					
	pharmacy professional	professional promises to help individuals achieve optimum benefit					
		from their medications, to be committed to their welfare, and to					
		maintain their trust.					
4	Professional	A pharmacy professional has a duty to maintain knowledge and					
	competence	abilities as new medications, devices, and technologies become					
		available and as health information advances.					
5	Pharmacy professional	When appropriate, the practitioner asks for the consultation of					
	works collaboratively	colleagues or other health professionals or refers the patient. He/She					
	with other health	acknowledges that colleagues and other health professionals may					
	professionals to	differ in the beliefs and values they apply to the care of the patient.					
	optimize the health						
	outcomes of patients						

## 8.2.1 Specific ethical issues with respect to RMNCH

A pharmacy professional is expected to provide counseling and necessary drug related information for women coming to a facility for family planning service, for pregnant women, for care givers of sick neonate and child during dispensing of medications. In general, privacy and confidentiality shall be maintained while pharmacists dispense and counsel contraceptive methods in general and emergency contraceptives in particular. But do not forget to counsel about the risk of STI such as HIV/AIDS during the dispensing of emergency contraceptives and the importance of testing and counseling. Also inform the benefit and risk of this contraceptive. To mention some:

Do not supply any medicinal product to a child unless satisfied that the product will be used safely.

- Universal access to contraceptives is a human right. Hence, a woman has the right to take an informed decision on the choice of contraceptives and has the right to fulfill her needs of contraceptives. This includes:
  - Access to safe, effective, affordable and acceptable methods of birth control
  - o Access to appropriate health care services of sexual, reproductive medicine and
  - o Implementation of health education programs
- ❖ Breast feeding should not be compared to formula feeding. Always inform that breast milk is the gold standard and it is complete nutritionally



## Role play (25 minutes)

**Instruction:** One participant will take the role of a pharmacist and another participant will take the role of a pregnant mother who come for getting emergency pill service. Other participants should observe and note the discussion.

## Roles:

## **Pharmacist**

## A mother who come for getting emergency pills service

## **Situation:**

Tesfaye is the only Pharmacist in a small rural town where he has been practicing for 12 years. One morning 18-year-old girl came to health center's pharmacy where Tesfay is practicing. She looks nervous and ill at ease, she said to Tesfaye quietly, "I am afraid I might be pregnant."

"So you are here to get a pregnancy test?" Tesfaye asked.

She shakes her head, "No, I want you to give me the morning-after pill so I don't have to get a pregnancy test or have an abortion." She had heard from her friends that if she take post-pill within 72hrs of unprotected sex she cannot be pregnant

Tesfaye shouted angrily and asked her to say it again loudly. She then explains to him that she was out at a party, had a few too many drinks, and ended up having unprotected sex with her boyfriend yesterday. She says she is worried about the possibility of being pregnant and wants the Plan B® pill (Post pill).

"I don't want to have a baby right now. I'm too young. I have to finish school," she says. "And I don't want to have to make a decision about an abortion. I want to just take this pill and move

on."

Tesfaye listens to her concerns and then says, "I understand why you are here. You should have to know that I have always a firm stance of not performing abortions, I don' assist by giving the morning-after pill, because my belief is that Post pill is abortifacient. If you really want the emergency contraceptive pill I can give you the address of a friend I know in Bahirdar Hospital who will help you."

"Bahirdar?" She says. "But Bahirdar is 85Km away. How will I get there without telling my parents why I am going? how will I get there soon enough for the post pill to work?"

Then Tesfaye, blaming her for all her wrong doings he left her on the pharmacy window and decline not to talk more.

- · Did Tesfaye demonstrated an ethical behavior with Aster
- What Ethical issues Tesfaye have breached

What counseling will you provide to her for her health benefit?



## **Case Study**

**Instruction**: Read and analyze the case study individually, then discuss and answer the questions in a group.

A 33years married women who lived with her husband and has two kids. 2 weeks ago, she started experiencing unusual signs that includes burning during urination, a yellowish vaginal discharge, redness and swelling of the genitals and itchy vaginal areas. She came to nearby health center and diagnosed for Gonorrhea. She was given the prescription from a health care provider who was so busy and informed her the pharmacist will tell her the detail of the drug and how it works. She came to the health center pharmacy with a prescription of Ceftriaxone 250 mg IM in a single dose + Azithromycin 1 g orally in a single dose combination drug.

A pharmacist in the health center received her prescription and become hesitant to dispense the medication. She was expecting him to provide her the drugs with adequate information as told by the clinician. He started questioning her that why is the 250mg lower dose prescribed for someone at her age and Azithromycin 1gm higher dose. She replied that she told by her clinician that the pharmacist will provide her more details on the drug and other preconditions. The pharmacist raised his voice and ordered her to go back to the nurse and change the prescription to adult dose. She got so confused and beg him at least to go together and explain the situation to the clinicians. The pharmacist got so angry and started insulting the health care service providers always making mistake on dosage. She continued explaining how busy the clinician was and it will be better that she go with him to explain the situation and change the prescription since they may not allow her to go in again. He shouted on her and claims that he is helping her for her own sake not to take the wrong dose. In all his conversation he was talking to her with loud voice and he was urging her to change her prescription.

## **Questions**:

- 1. What was the ethical flaws that was observed in this encounter
- 2. How would you comment on his communication style, and how would you correct it
- 3. What will be confidence of Client on the pharmacist as well as on prescriber
- 4. Do you think the pharmacist is able to provide sufficient counselling for his client?
- 5. What will you advise the client had you been in the pharmacist's place?

# **8.3. Summary**

- Effective communication occurs only when the meaning of a message is held in common by the participants. To communicate effectively; barriers related to environmental factors, patient related factors and time related factors should be addressed.
- Ethics is the science of moral value, founded on "Do Good and Avoid Evil" principle

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## Maternal health references

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## Child health references

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Ethiopian reproductive, maternal, newborn and child health (RMNCH-N) medicines formulary. 1stedn (FMHACA, 2016)

Integrated management of newborn and childhood illness; (FMOH, 2015)

Reproductive, Maternal, Newborn and Child Health: A Training Course for Community Pharmacists; (EPA, 2016)

Standard treatment guideline for health center; FMOH, 2015

# Appendix 1: Pregnancy Category of Medicines List of Drugs with Their Pregnancy Category

Medicine	Pregnancy Category	Comment			
Acyclovir	В	Not known to be harmful -manufacturers advise use only			
Acyclovii	D	when potential benefit outweighs risk			
Albendazole	С	Contraindicated in cestode infections; First trimester:			
THOCHADOTO		avoid in nematode infections			
Amoxicillin	В	Not known to be harmful			
Ampicillin	В	Not known to be harmful			
Artemether	X	First trimester: Avoid			
Artemether	С	First trimester: Avoid			
+lumefantrine		That difficater. Avoid			
Artesunate	NA	First trimester: Avoid			
Benzathine	В	Not known to be harmful			
Penicillin	D	Not known to be narmful			
Betamethasone	С	Benefit of treatment, for example in asthma, outweighs			
Betamethasone	C	risk			
Cefotaxim	В	Not known to be harmful			
Ceftriaxone	В	Not known to be harmful			
Chloroquine	NΙΛ	First and third trimesters: Benefit of prophylaxis and			
Cinoroquine	NA	treatment in malaria outweighs risk			
Cinnefloyeein	C	Avoid (arthropathic in animal studies); safer alternatives			
Ciprofloxacin	С	available			
Clindamycin	В	Not known to be harmful			
		First trimester: Teratogenic risk (trimethoprim is a folate			
Cotrimoxazole		antagonist)			
(Sulfamethoxazole	D	Third trimester: Neonatal hemolysis and			
+ Trimethoprim) methemoglobinemia; fear of increased r		methemoglobinemia; fear of increased risk of kernicterus			
		in neonates appears to be unfounded			

		Benefit of treatment, for example in asthma, outweighs				
		risk; risk of intrauterine growth retardation on prolonged				
Dexamethasone	C	or repeated systemic treatment; corticosteroid cover				
		required by mother during labour; monitor closely if fluid				
		retention				
Erythromycin	В	Not known to be harmful				
Ethambutol	С	Not known to be harmful				
Fluconazole	D	Avoid (multiple congenital abnormalities reported with				
Tuconazoic		long-term high doses)				
		Second and third trimesters: Auditory or vestibular nerve				
Gentamicin	D	damage; risk probably very small with gentamicin, but				
Gentamiem		avoid unless essential (if given, serum gentamicin				
		concentration monitoring essential)				
Hydrologino	С	Avoid during first and second trimesters; no reports of				
Hydralazine		serious harm following use in third trimester				
		Avoid unless potential benefit outweighs risk				
	C; D at ≥30	Third trimester: With regular use closure of fetal ductus				
Ibuprofen	weeks'	arteriosus in utero and possibly persistent pulmonary				
	gestation	hypertension in the newborn; delayed onset and increased				
		duration of labour				
Isoniazid	С	Not known to be harmful				
Magnesium		Third trimester: not known to be harmful for short- term				
sulfate	D	intravenous administration in eclampsia but excessive				
surface		doses may cause neonatal respiratory depression				
Mebendazole	С	Manufacturer advises avoid -toxicity in animal studies.				
Methyldopa	В	Not known to be harmful				
Metoclopramide	В	Not known to be harmful				
Metronidazole	В	Avoid high-dose regimens				
Mifepristone	X	Indicated for use in the termination of pregnancy				
Misoprostol	X	Avoid-potent uterine stimulant (has been used to induce				
	i e					

		abortion). Teratogenic risk in first trimester.
Morphine	C; D (If used near term)	Third trimester: Depresses neonatal respiration; withdrawal effects in neonates of dependent mothers; gastric stasis and risk of inhalation pneumonia in mother during labour
Nifedipine	С	Some dihydropyridines are teratogenic in animals, but risk to fetus should be balanced against risk of uncontrolled maternal hypertension; may inhibit labour (used for premature labour)
Paracetamol	В	Not known to be harmful
Pyrazinamide	С	Use only if potential benefit outweighs risk
Quinine	X (First trimester)	First trimester: High doses are teratogenic; but in malaria benefit of treatment outweighs risk
Rifampicin	С	First trimester: Very high doses teratogenic in animal studies  Third trimester: Risk of neonatal bleeding may be increased
Tinidazole		Pregnancy manufacturer advises avoid in first trimester
Zinc sulfate	С	Crosses placenta; risk theoretically minimal, but no information available

# Annex 2 : Calculating Estimated RUTF Needs

Estimated ready-to-use therapeutic food (RUTF) needs for outpatient care per facility per month are based on a RUTF diet (Plumpy'nut®) of 200 kilocalories (kcal) per kg per day per child on average

A	Number of outpatient care	A
	beneficiaries per facility	
В	Monthly consumption per child (20	80 Sachets
	packets/child/week)	
С	Monthly packet consumption for	AXB
	outpatient per facility	
D	Monthly carton consumption for	C/150
	outpatient care	
Е	Monthly net weight (MT) (13.8	D x 13.8/1000
	kg/carton)	
F	Monthly gross weight (MT) (14.9	D x 14.9/1000
	kg/carton)	

## Example

A	Number of outpatient care	100
	beneficiaries per facility	
В	Monthly consumption per child (20	80 Sachets
	Sachets/child/week)	
С	Monthly Sachets consumption for	80X100= 8000 Sachets
	outpatient per facility	
D	Monthly carton consumption for	8000/150= 53.3 Cartoon
	outpatient care	
Е	Monthly net weight (MT) (13.8	53.3 x 13.8/1000= 0.73 MT
	kg/carton)	
F	Monthly gross weight (MT) (14.9	D x 14.9/1000= 0.01 MT
	kg/carton)	

# Annex 3: Daily Participant feedback form

Course Title: Reproductive, Maternal, Neonatal and Child Health Program Overview and Pharmaceuticals Management Training for Pharmacy Professionals

Venue:	; Town:	; Date:	
	•	m is to gather your input on to suggestion to improve the r	
Please respond to the your input.	ne following question	ns about the sessions presen	ited <b>TODAY</b> . Thank you for
Date:	(GC)		
1) What did you enj	oy most about today	?	
2) What did you lea	rn today that you wil	ll use in your work?	
3) What did you not	understand?		
4) What do you war	nt to see improved for	r tomorrow?	
4) Any questions/co	omments?		

# Annex 4: Overall Course Evaluation Form

Course Title: RMNCH Training for Pharmacy Professionals							
Venue: _	; Town:	; Date:	-				
Dear particij	pant: Now that you have completed the training	ng course, please take a few minutes to	fill				
the following e	valuation.						
Please comple	te the following by ticking the column of you	ır choice.					

**1. Please rate the** RMNCH Training for Pharmacy Professionals **using the following overall parameters**: Please write your explanations in the *Comments* column.(**Evaluation Point**: 0= Poor, 1= Fair, 2= Good, 3= Very good, 4= Excellent)

Items	0	1	2	3	4	Comments
Overall content of workshop						
Overall training objectives were met						
Overall time allocation						
Quality of slides						
Quality of participant handbook						
Overall facilitation by trainers/ facilitators						
Group discussions						
Overall Organization/conduction of the workshop						

## 2. Evaluate subject matter, presenters and allocated time

Evaluation Relevance of Presenter skill		Presenter skill	Duration (Allocated Time)				
Point	Subject	& knowledge					
	Matter						
0	Not useful	Poor	Too short; couldn't learn enough in such a short time.				
1	May be useful	Fair	A little too short				
2	Useful	Good	Just fine				
3	Very useful	Very good	A little too long				
4	Essential	Excellent	Definitely too long; the concepts could be learned in much less time.				

Session Title	Subject	Presenter	Allocated

		Matter					Time											
		0	1	2	3	4		0	1	2	3	4		0	1	2	3	4
	Overview of strategies and program						_											
	directions on RMNCH Services																	
	1.1 RMNCH programs, strategies,																	
	targets and interventions																	
	1.2 Essential RMNCH service																	
	package at each tier system																	
I	1.3RMNCH priority						-											
	pharmaceuticals																	
	1.4Role of Pharmacy																	
	Professionals in																	
	RMNCH																	
	Rational Use of Family planning						_											
	pharmaceuticals																	
II	2.1Types of family																	
	planning products																	
	Syndromic Management of Sexually																	
	Transmitted Infections																	
III	3.1 Management of STIs																	
	3.2STI Syndromes																	
	Rational use of Maternal Health																	
IV	Pharmaceuticals																	
	4.1Introduction to																	

	Obstetric and Newborn										
	care services										
	4.2 Therapeutic use and safety of										
	medicines during antepartum										
	4.3 Therapeutic use and safety of										
	medicine during post-partum										
	Rational Use of Neonatal and Child										
	Health Pharmaceuticals										
	5.1Introduction to Rational										
	Use of Medicines in										
	Neonates and Children										
	5.2 Therapeutic management of										_
	essential newborn care and young										
	infant problem medicines										
	5.3Therapeutic use and										
	safety of cough or										
V											
	difficulty breathing										
	medicines										
	5.4Therapeutic use and										
	safety of medicines for										
	diarrhea and dysentery										
	5.5Essential newborn care										
	5.5 Essential newborn care										
		_	$\perp$						_	_	
	5.7Malnutrition in										
	children under five										
	years of age										
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	RMNCH Pharmaceuticals Supply									
	Chain Management									
	6.1National supply chain									
	system									
	System									
	( ) T ! - A - A - A ! - ! A !									
	6.2Logistic Activities									
	6.3Program updates									
	requiring logistics									
VI	management									
VI	considerations									
	6.4Impact of poor logistics									
	management practice									
	6.5Role of pharmacy									
	professionals on									
	RMNCH logistics									
	management									
	8									
VII	Ethical and professional standards								$\dashv$	$\dashv$
V 11	throughout RMNCH Services									
	7.1Effective									
	communication									
	7.2Ethical practice in								$\dashv$	
	_									
	RMNCH service									

	Do you think this training was useful for your practice?	Yes	s 🗆		No	
l. ]	If Yes to Q3, how much will this training help you to better	contrib	ute to tl	ne follov	ving	
	competency areas (Evaluation Point:0= Poor, 1= Fair, 2= Good, 3					
SN	Parameter	0	1	2	3	4
1	Contribute to the attainment of RMNCH program and strategic					
	targets					
2	Provide medicine information to relevant healthcare providers					
	and patients					
3	Manage the supply chain of RMNCH commodities					
4	Promote the rational use of RMNCH medicines					
5	Exercise good dispensing practices for mothers and children					
6	Identify and manage potential interactions with RMNCH					
	medicines					
7	Identify and manage side effects of RMNCH medicines					
8	Request, receive, and store RMNCH pharmaceuticals					
9	Strengthen referral linkages for RMNCH services					
10	Promote ethical practices throughout the RMNCH spectrum of					
	care					
11	Effectively communicate with healthcare providers and patients					
5. ]	If No to the Q3, please explain why?	I			· L	<u>.l</u>
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7. Any other comments?

Thank you for completing this form