National Training on Antimalarial Pharmaceuticals Management

Participants Manual

Federal Democratic Republic of Ethiopia

Ministry of Health

September 2018

APPROVAL STATEMENT OF THE MINISTRY

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

As part of the national IST quality control process, this National Training on Antimalarial Pharmaceuticals Management training package has been reviewed based on the standardization checklist and approved by the Ministry in September, 2018.

Dr Getachew Tollera
Human Resource Development Directorate Director
Federal Ministry of Health, Ethiopia

Foreword

Healthcare is a team work. The national malaria control program requires that all health professionals working at all levels of the health system should provide required care for the successful implementation of the prevention, control, and elimination of malaria from Ethiopia. The role of pharmacy professionals in availing the necessary program inputs such as medicines and related supplies is critical to the success of the program. Pharmacists are also required to provide pharmaceutical care services that ensure the rational use of antimalarial medicines resulting in efficient and safe use of available resources.

Accordingly, pharmacy professionals should be knowledgeable about the national malaria program and its strategies. They also need to be familiar with how malaria is diagnosed and treated at each level of the healthcare system. Moreover, the pharmacy personnel should be aware of strategies to promote the rational use of antimalarial medicines and how to properly dispense these medicines. Recently, there are new developments on malaria case management and medicines to use for treating malaria patients. As a result, the national malaria treatment guideline has been revised and updated in to improve the patient health outcomes and attain the goals of national strategies including malaria elimination by 2030. Health professional including pharmacists should have up-to-date information concerning the current treatment protocols for managing malaria patients. Towards this end, it has been found necessary to develop standard training materials to enhance the capacity of pharmacy professionals in proper management of antimalarial medicines and related pharmaceuticals as well as the provision of pharmaceutical care. It is the Ministry's belief that pharmacy professionals, managers, educators, and trainers will benefit from this manual.

Dr. _____

_____

Federal Ministry of Health (FMOH)

Acknowledgements

The Federal Ministry of Health would like to express its heartfelt gratitude to all participants and their organizations who actively participated in the design and development of this training course. FMOH would also like to thank USAID's Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) Project for the unreserved financial and technical support during the development of this training course.

It is with great appreciation that we acknowledge the following professionals (alphabetically listed) that were involved in the design, development, and standardization of the training course as per FMOH's standard for in-service training instructional curriculum design.

- Alexyv Gizachew, GHSC-PSM
- Anteneh Tsige, FMOH/GHSC-PSM
- Azmeraw Mulualem, PFSA
- Belete Ayalneh, GHSC-PSM
- Dagim Damtew, FMOH
- Dufera Nigisia, AIDSFree
- Elias Geremew, GHSC-PSM
- Fikadu Deme, GHSC-PSM
- Masresha Asrat, PFSA/CHAI
- Raey Yohannes, PFSA/GHSC-PSM
- Redwan Mohamed, PFSA/AIDSFree
- Tayachew Shasho, PFSA
- Yidnekachew Degefaw, FMOH
- Zelalem Nigussie, GHSC-PSM

Acronyms and Abbreviations

ACT	Artemisinin-based Combination Therapy
ADE/R	Adverse Drug Event/Reaction
AL	Artemether- Lumefantrine
AMC	Average Monthly Consumption
AMM	Antimalarial Medicines
AMP	Antimalarial Pharmaceuticals
API	Annual Parasite Incidence
DIS	Drug Information Service
DTC	Drug and Therapeutics Committee
FDC	Fixed Dose Combination
FEFO	First-to-Expire, First-Out
FMHACA	Food, Medicines, and Healthcare Administration and Control Authority
FMOH	Federal Ministry of Health
HC	Health Center
HCMIS	Health Commodity Management Information System
HEP	Health Extension Program
HF	Health Facility
HIV/AIDS	Human Immune Deficiency Virus/Acquired Immune Deficiency Syndrome
HMIS	Health Management Information System
HPMRR	Health Post Monthly Report and Re-supply Form
HSTP	Health Sector Transformation Plan
iCCM	Integrated Community Case Management
IFRR	Internal Facility Report and Resupply Form
IPLS	Integrated Pharmaceuticals Logistics System
IPTP	Intermittent Preventive Treatment of Malaria during Pregnancy
IRS	Indoor Residual Spraying
KPI	Key Performance Indicator
LLIN	Long-Lasting Insecticide-treated Net

LMIS	Logistics Management Information System
LSI	Look Ahead Seasonality Indices
MOS	Months of Stock
MUE	Medicine Use Evaluation
NMCP	National Malaria Control Program
NMTG	National Malaria Treatment Guideline
NSP	National Strategic Plan
PFSA	Pharmaceuticals Fund and Supply Agency
PHEM	Public Health Emergency Management
PMIS	Pharmaceutical Management Information System
RAR	Rapid Assessment and Response
RBC	Red Blood Cells
RDT	Rapid Diagnostic test
RHB	Regional Health Bureau
RRF	Report and Requisition Form
ScHO	Sub-city Health Office
SCM	Supply Chain Management
SDP	Service Delivery Point
SOH	Stock on Hand
SOP	Standard Operating Procedure
STGs	Standard Treatment Guidelines
WHO	World Health Organization
WoHO	Woreda Health Office
ZHD	Zonal Health Desk

Table of Contents

List of tables

List of figures

Introduction to the training manual

Malaria is among the leading causes of morbidity and mortality in Ethiopia that affects people of all age groups with children and women at particularly high vulnerability. The Government of Ethiopia has given due emphasis to the prevention and control of malaria and has been working to accelerate malaria prevention, control, and elimination activities. Currently, the National Malaria Control Program is integrated at all levels of the health system and has the role of developing and disseminating policies, strategies, treatment guidelines and is also involved in capacity development at all levels.

For effective management of malaria patients, health workers at all levels of the health care delivery system are expected to understand and apply the principles and procedures outlined in national malaria diagnosis and treatment guidelines. However, the effective management of malaria also depends on availability and rational use of pharmaceuticals. Accordingly, the role played by pharmacy professionals is of paramount importance.

There are reports that show absence of continuous capacity building trainings and lack of updates on the new information regarding malaria case management and medicines used for treating patients. In addition, assessments conducted to examine the providers` knowledge of the first-line malaria treatment at health facilities also showed presence of significant gaps at dispensing units. In line with this, the training need analysis done by the experts of the national malaria technical working groups also re-affirmed the presence of these gaps. This lack of capacity building has contributed to improper supply chain management and irrational use of antimalarial medicines.

This training is designed to address these gaps in addition to giving current information on malaria case management and medicines used to treat malaria patients. The training will introduce the trainees to the national malaria program, diagnosis and management of the malaria cases and the supply chain management of antimalarial pharmaceuticals. The course will also enable the training participants to ensure rational use of antimalarial medicines and good dispensing practices.

Core Competencies

At the end of this training, the participants will have the following core competencies:

- Implement the national malaria strategic plan
- Promote adherence to the national malarial treatment guidelines and patient adherence to treatment regimens
- Improve the supply chain management of AMPs
- Monitor and evaluate performance of antimalarial pharmaceutical management

Course Syllabus

Course Description

This four days AMPM training is designed to equip the participants with the national malaria program of Ethiopia, pharmacotherapy, and supply chain management, rational use of antimalarial medicines and monitoring and evaluation of antimalarial pharmaceuticals.

Course Goal

The goal of this course is to provide participants with necessary knowledge, skills, and attitude to properly manage antimalarial medicines and related pharmaceuticals.

Learning Objectives

By the end of this training, participants will be able to:

- Describe the national malaria strategic plan
- Describe malaria case management as per the national treatment guideline
- Apply proper supply chain management practice of AMPs
- Apply principles of rational use of antimalarial medicines
- Monitor and evaluate AMPM

Training Methods

- Interactive presentations/lectures
- Audiovisual demo
- Small and large group discussions
- Brainstorming
- Small group exercises and presentations
- Role plays
- Case studies/scenarios
- Demonstrations
- Individual reading
- Health facility visit

Learning Materials

- Antimalarial Pharmaceuticals Management (AMPM) Training Participant Manual
- Antimalarial Pharmaceuticals Management (AMPM) Training Facilitator's Guide
- National Malaria Treatment Guidelines
- National Malaria Strategic Plan (2017-2020)
- Standard Operating Procedures (SOP) Manual for the Integrated Pharmaceuticals Logistics System in Health Facilities of Ethiopia
- LCD Projector
- Video
- Flipchart
- White board
- Markers
- Laptop
- Stationeries (Note pad, pens, etc)

Participant Selection Criteria

Participants of this training course shall be:

- Pharmacy personnel working in health facilities (hospitals and health centers)
- Pharmacy personnel working as forecasting and capacity building officers and distribution officers at PFSA
- Pharmaceutical supply management/pharmacy service personnel at RHBs, ZHDs, and WoHOs.
- University lecturers working on clinical pharmacy and DSM

Trainer Selection Criteria

Trainers of the basic AMPM training will be:

- Member of the AMPM material development technical working group
- Professionals who have TOT certificate on AMPM training
- Professionals who have TOT certificate on malaria case management training for health professionals

Methods of Evaluation:

Course Evaluation:

The course will be evaluated by:

- Daily feedback on the course filled by the participants
- End of course evaluation
- Participant oral feedback at the end of training
- Daily and post-training debriefing by trainers

Participant Evaluation:

The participants of this course will be evaluated by:

Formative

- Group activity performance
- Case studies
- Role plays
- Quizzes
- Review of works/assignments completed/developed by participants

Summative

- Continuous assessment/feedback by trainers: 10%
- Mid-course assignment: 20%
- Written exam (post-test): 70%

Certification Criteria

Certification for this course will be based on the following criteria.

- Full attendance of the course (100%)
- Overall summative assessment
    - 70% and above for basic
    - 80% and above for TOT

Duration of the Training

The training will last for 4 days.

Suggested Class Size

- The suggested class size for the basic training is 25-30 participants
- The suggested class size for the TOT is 20-25 participants
- The suggested number of trainers' composition is four

Training Venue

The training will be conducted at accredited Continuous Professional Development (CPD) provider having proper AMPM practice.

Course Schedule

National Training Course on Antimalarial Pharmaceuticals Management (AMPM) for Pharmacy Professionals Organized by _____

Dates: _____; Venue: _____

Time schedule	Activity	Trainers	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		
10:45-12:30 PM	Chapter 1: Overview of the National Malaria Program		Organizers
12:30 – 2:00 PM	Lunch		
2:00 -3:30 PM	Session 2.1 Malaria Diagnosis and Treatment		Organizers
3:30-3:45 PM	Tea Break		
3:45 – 5:15 PM	Session 2.1 Malaria Diagnosis and Treatment		Organizers
5:15 – 5:30 PM	Daily feedback		
Day Two: _____			
8:30 – 8:45 AM	Recap of Day 1/Introduction to Day 2		Organizers
8:45- 10:15 AM	Chapter 2 - Session 2.1 Malaria Diagnosis and Treatment		
10:15- 10:30 AM	Tea Break		
10:30- 11:00 AM	Session 2.1 Malaria Diagnosis and Treatment		
11:00-12:30 PM	Session 2.2. Clinical Pharmacology of Antimalarial Medicines		Organizers
12:30 – 2:00 PM	Lunch		
2:00-4:00 PM	Session 2.2. Clinical Pharmacology of Antimalarial Medicines		Organizers
4:00-4:30PM	Tea Break		
4:30 – 5:15 PM	Session 2.2. Clinical Pharmacology of Antimalarial Medicines		Organizers
5:15 – 5:30 PM	Daily feedback		
Day Three: _____			
8:30 – 8:45 A.M.	Recap of Day 2/Introduction to Day 3		Organizers
8: 45-10:15	Chapter 3. Supply Chain Management of AM Pharmaceuticals		
10-15-10:30 AM	Tea Break		
10:30–12:30 PM	Chapter 3. Supply Chain Management of AM Pharmaceuticals		Organizers
12:30 – 1:30 PM	Lunch		
2:00-3:30 PM	Chapter 4. Rational Use of Antimalarial Medicines		Organizers
3:30-3:45 PM	Tea Break		
3:45-5:30 PM	Chapter 4. Rational Use of Antimalarial Medicines		Organizers
Day Four:_____			
8:30-8:45 AM	Recap of Day 3/Introduction to Day 4		Organizers
8:45 – 10:15 PM	Chapter 5. Monitoring and evaluation of AMPM		Organizers
10:15-10:30	Tea Break		
10:30-12:30 PM	Chapter 5. Monitoring and evaluation of AMPM		Organizers
12:30-2:00 PM	Lunch		
2:00- 4:00PM	Follow up planning (material)		
4:00-4:30 PM	Tea Break		Organizers
4:30-5:00 PM	Post Test		
5:00-5:30 PM	Course Evaluation		Organizers

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.

- Why CRC a transformational agenda?

  Time Allowed 10 minutes

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
First	**Patients**	• When health professionals are compassionate, patients are less anxious • Adherence to medical advice and treatment plans • 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 • Hostile emotional states in patients delay the healing processes • Quality of health professionals –patient communication with increased physical functioning, emotional health and decreased physical symptoms of pain in patients
Second	**Health Professionals**	• Health care Professionals satisfaction with their relationships with patients can protect against professional stress, burnout, substance abuse and even suicide attempts • Burnout is strongly associated with poorer quality of care, patient dissatisfaction, increased medical errors, lawsuits and decreased expressions of compassion • Participation in a mindful communication associated with short-term and sustained improvement in well-being and attitudes associated with patient care • 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 care facilities**	• Patient satisfaction will rise • Quality of health care will be improved • 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 multi-pronged approach in order to make CRC as a culture, self-driven inner motive and a legacy that the current generation of practitioners leaves to their successors.

NATIONAL STRATEGY AND APPROACHES FOR CRC

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

1.2. Healthcare Ethics

1.2.1. Principles of health care ethics

Individual reflection

- What is ethics?
- What is health care ethics?

Time: 5 Minutes

Ethics:

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

Health care ethics:

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

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

1. Autonomy
2. Beneficence
3. Non-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

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.
Question:
1. How do you manage such an individual?
2. Discuss situations that breach confidentiality.
Time: 5 Minutes

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

Informed Consent

Informed consent is legal document whereby a patient signs written information with 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

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

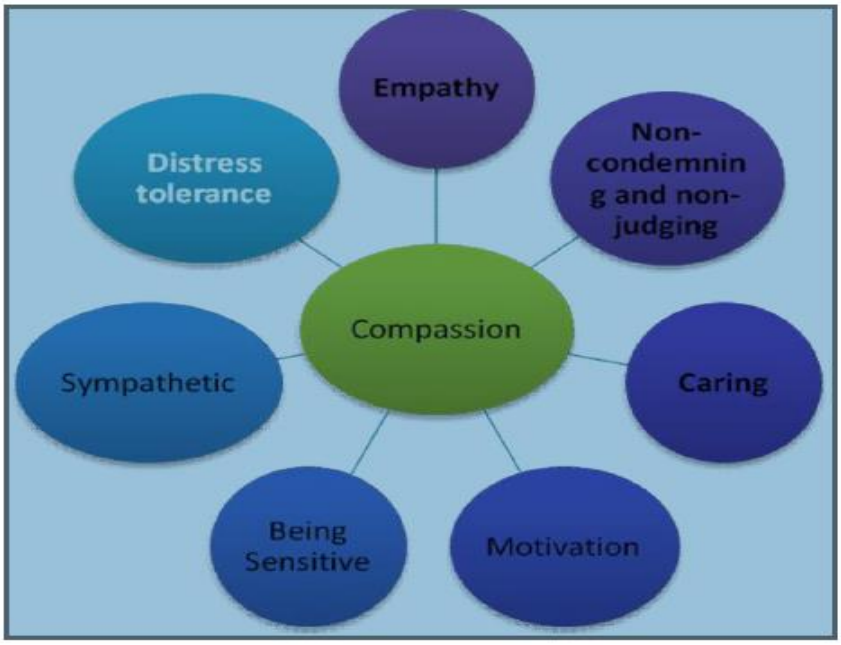


Figure 1:1 Qualities of compassion

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 multi-factorial suffering''. Attending to patients' needs has three interrelated themes:

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

1.3.3. Principles of compassionate care

Individual reflection

What are the principles of compassionate care?

Time Allowed: 5 Minutes

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

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?

Time Allowed: 10 minutes

Definition of Dignity (□□□□)

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 (□□□□□)

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

The action meanings of the word respect are:

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

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

- Rights and freedoms
- 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?

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

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

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.

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

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

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

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

- CRC thrives in an environment that supports teamwork and respect for other people, regardless of their position in the organization.

- Leaders demonstrate their commitment to CRC and set expectations for those who work in the organization. Leaders evaluate the culture on a regular basis.
- Leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Disruptive behavior that intimidates others and affects morale or staff turnover can be harmful to patient care.
- Leaders must address disruptive behavior of individuals working at all levels of the organization, including management, clinical and administrative staff, licensed independent practitioners, and governing body members.

Creating an Organizational culture of empowering employees for CRC

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

Employee empowerment encourages communication, participation in shared decision-making and enabling physicians and staff to reach their full potential by creating 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 the National Malaria Program

Chapter Description:

This chapter provides an overview of the national malaria program. It starts by explaining the national malaria program and epidemiology of the disease. Then the chapter dwells on factors affecting malaria transmission, trend of malaria in Ethiopia, and malaria stratification in detail. The chapter continues with the description of the National strategic plan for Malaria. Finally, the chapter concludes with introducing the supply chain management of antimalarial pharmaceuticals.

Primary Objective:

The primary objective of the chapter is to introduce the national malaria program and national malaria strategic plan in line with supply chain management of antimalarial pharmaceuticals.

Enabling Objectives:

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

- Discuss the National Malaria Program
- Describe the epidemiology of malaria in Ethiopia
- Discuss factors affecting malaria transmission.
- Discuss National Strategic Plan (NSP) for malaria.
- Explain the supply chain management of antimalarial pharmaceuticals.

Chapter Outline:

- Overview of the national malarial program
- Epidemiology of malaria in Ethiopia
- Factors affecting malaria transmission
- National Strategic Plan for malaria
- Overview of Supply chain management of antimalarial pharmaceuticals
- Chapter Summary

2.1. Overview of the National Malaria Program

Brainstorming Questions:

- What do you know about the current malaria prevention control and elimination in Ethiopia?
- Do you think Ethiopia has a national strategic plan?

Malaria is one of the major public health concerns in Ethiopia. It is among the leading causes of morbidity and mortality and affects all people regardless of age and sex; but children and women are particularly vulnerable due to various reasons. Malaria, based on its transmission pattern is divided into Stable and Unstable.

Stable (endemic): Transmission is generally high, could be seasonal but not subject to annual fluctuations, and the resulting population immunity is high. Under endemic conditions, children under the age of five years, and pregnant mothers, are most likely to be infected as they have weaker immunity.

Unstable (epidemic): Malaria transmission is variable, being subject to marked annual fluctuations. Consequently, the collective population immunity is low. Malaria epidemics generally occur when the population in an area has weak immunity to the disease, because so many people in the population will be vulnerable to malaria. However, it is important to remember that children and pregnant women are always at most risk, so they need particular attention.

The Government of the Federal Democratic Republic of Ethiopia has given due emphasis to prevention and control of malaria and has been working on various endeavors to accelerate malaria prevention, control and elimination activities. Currently, the Malaria Control Program is integrated at all levels of the health system in the country.

At the Federal Ministry of Health (FMOH) level, the malaria program is organized under disease prevention and control directorate. The role of national malaria control program (NMCP) is to develop, update, and disseminate policy and strategies. The NMCP produces and disseminates malaria related national guidelines and monitors and evaluates implementation and impact of interventions. Furthermore, NMCP is involved in building the capacity of program managers at regional levels and, at times, the capacity building could extend to zonal, district and selected health facilities. Besides, the NMCP provides leadership to all stakeholders and implementing partners working on malaria prevention and control activities.

NMCP works in collaboration with other institutions and key units within FMOH. Regional Health Bureaus (RHB) and District Health Offices have malaria teams or focal persons at regional and district levels. These regional and district level teams and focal persons are primarily responsible for handling malaria-related matters in their respective catchments and for implementing strategies and guidelines.

At primary health care level, the malaria program is integrated into the health system via the Health Extension Program (HEP). Since its launch in 2005, the HEP is serving as the core of the health system. Health Posts are linked to health centers through the primary health care unit and they are linked to District Health Office at the woreda level. There is referral links and feedback mechanisms from lower to higher levels in the health system. The referral linkage is particularly utilized for management of severe malaria.

Under the malaria program, in addition to diagnosis and treatment, prevention is the main strategy to prevent and control malaria transmission. To expedite the efforts in prevention of malaria transmission, the World Bank and other donors have embraced a concept of heavy up-front effort as opposed to a more incremental approach and the concept has been termed as Scaling-Up for Impact" or "SUFI". Ethiopia is one of the first countries to adopt this concept for malaria control and around 90 million LLINs have been delivered to households since 2005. In addition, the Indoor residual Spraying (IRS) programme has been scaled- up in targeted areas.

For effective management of malaria patients, health workers at all levels of the health care delivery system should understand the principles and follow the procedures outlined in malaria diagnosis and treatment guidelines. At the hospitals and health centers level, clinicians should make an accurate diagnosis of malaria based on the result of microscopic examination of patient blood smears rather than relying on clinical assessment alone. All clinicians should strictly follow the treatment approaches outlined in the Malaria Treatment Guidelines. Nurses working at health facilities must provide optimal nursing care for hospitalized patients and laboratory technicians should undertake microscopic investigation to identify species of malaria and density of parasite. Pharmacy professionals should also play a critical role in ensuring availability and proper use of antimalarial pharmaceuticals.

At the health post level, it is the role of the Health Extension Workers (HEWs) to make diagnosis of malaria by multi-species Rapid Diagnostic Test (RDT), not by clinical assessment alone. For patients needing referral to health facilities, with more advanced capabilities, because of severe malaria, a pre-referral treatment should be given by the HEW. In addition to this, health workers at all levels should provide patients with appropriate knowledge and skills on prevention and control of malaria as well as on promoting adherence to effective malaria treatment as per the national Social Behavioral Change Communication (SBCC) principles.

The National Malaria Strategic Plan (NSP) 2017-2020 incorporated implementation of elimination of malaria in 239 districts in six regions and additional 200 districts will be enrolled to malaria elimination program in 2020. The plan has also envisioned eliminating malaria from Ethiopia by 2030.

2.2. Epidemiology of Malaria in Ethiopia

Brainstorming Questions:

- How do you classify Ethiopia based on malaria transmission/prevalence?
- What are the peak periods for malaria transmission in Ethiopia and how does this affect the supply chain management of antimalarial pharmaceuticals.

In 2015, a total of 214 million malaria cases and 438,000 malaria deaths reported globally and 90% of deaths occur in Sub-Saharan Africa and 70% deaths are children under five. The incidence rate of malaria is estimated to have decreased by 37% globally between 2000 and 2015. Malaria death rates have decreased by 60% over the same period (WHO, 2015).

Malaria transmission in Ethiopia mainly occurs below 2000m elevation but can also occasionally affect areas up to 2300m elevation. However, the levels of malaria risk and transmission intensity within these geographical ranges show marked seasonal, inter-annual and spatial variability because of large differences in climate (temperature, rainfall, and relative humidity), topography (altitude, surface hydrology, land vegetation cover, and land use, etc.) and human settlement and population movement patterns.

In most parts of the country, the peak periods of malaria incidence occur from September to December, following the main rainy seasons (June–September). There is also a minor transmission season from March to May. However, the main rainy season in some south and south west lowlands is February-March, resulting in malaria peaks in April–May.

Due to the unstable and seasonal pattern of malaria transmission, the protective immunity of the population is generally low, and all age groups are at risk of infection and disease. In Ethiopia, most malaria cases are observed in persons over five years of age, but with respect to severity, children under five years of age and pregnant women are most vulnerable to the severe effects of the disease.

In Ethiopia, the unstable nature of malaria transmission has been characterized by frequent focal and cyclical epidemics which reach national scale at irregular intervals of 5–8 years. In the Ethiopian highlands, several large-scale epidemics have been documented since 1958. In 1958, an estimated 150,000 people died during a widespread epidemic of malaria in the highlands. Several major epidemics have been reported since then. But, since 2003/2004, no major epidemics have been reported in the country.

In addition to being a health problem, malaria is also a significant impediment to social and economic development in Ethiopia. In endemic areas, malaria has affected the population during planting and harvesting seasons, cutting down productive capacity, at a time when there is the greatest need for agricultural work. The disease has also been associated with loss of earnings, low school attendance, and high treatment cost.

Malaria is caused by five species of Plasmodium parasites. These are Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, Plasmodium ovale and Plasmodium knowlesi. Among these, the two most dominant malaria parasites in Ethiopia are P. falciparum, P. vivax. They are prevalent in all malaria endemic areas in the country with P. falciparum representing about 77 percent or more of the total reported malaria cases. Relative frequency of P. falciparum and P. vivax vary in time and space within a given geographical range. P. malariae and P. ovale are rare and account for <1 percent of all confirmed malaria cases. The major malaria vector in Ethiopia is Anopheles arabiensis; in some areas A. pharoensis, A. funestus and A. nili also play minor roles in transmission of malaria.

Malaria Prevalence

Surveys showed that malaria parasite prevalence deceased significantly. It was 1.3 percent in MIS 2011 and 0.5 percent in 2015. In recent years, a significant reduction in malaria prevalence and death has been observed. ***Trend of malaria in Ethiopia***

The annual number of malaria cases varies from year to year. The 2015 HMIS report indicated that total malaria cases reported across all health facilities was 1.9 million cases with over 95% completeness report. There has been a consistent decline in the number of malaria cases in the past four years despite a significant increase in health facilities with increased access to diagnosis and case management (Figure 1). Furthermore, there has also been a dramatic reduction in number of admissions and deaths in health facilities.

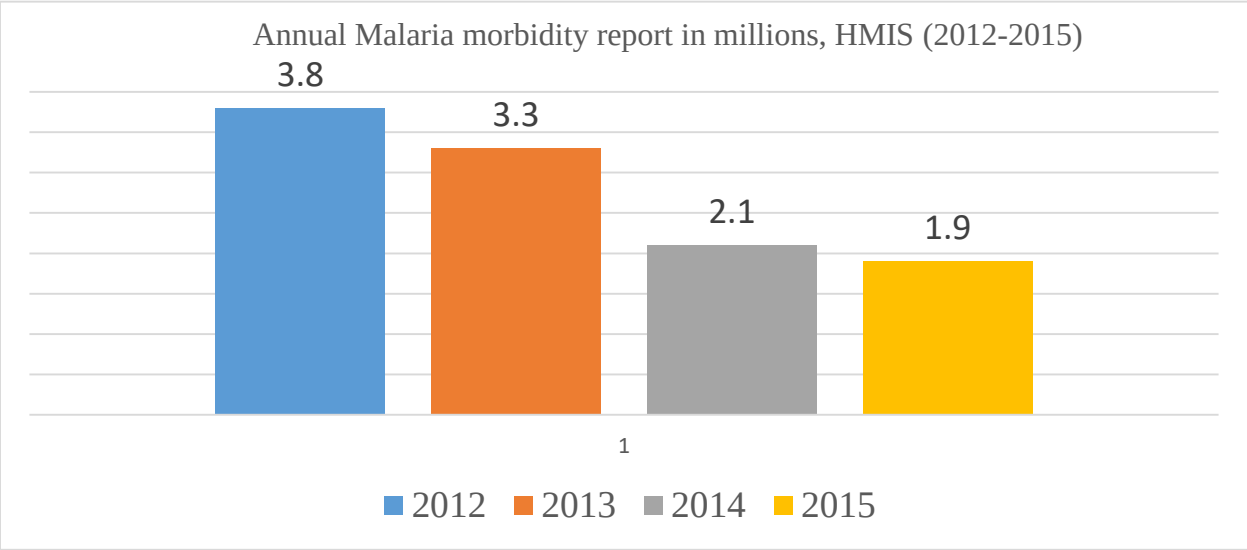


Figure 1. Annual Malaria Morbidity in millions, HMIS (2012-2015)

Since 2004, there was no large-scale epidemic reported in Ethiopia which has been coinciding with the scaling up of major malaria interventions such as vector control and diagnosis and treatment.

Malaria Stratification and Mapping

The diverse ecology of the country supports a wide range of transmission intensities, ranging from low-hypo-endemic transmission in the highlands and semi-arid regions to high-endemic perennial transmission in the lowland regions and valley floors. Accordingly, the current stratification of malaria in Ethiopia has been developed using *Woreda*/district-level Annual Parasite Incidence (API) data. Data from Public Health Emergency Management (PHEM) and HMIS were used to determine API level of each *Woreda.*

Based on Woredas' API, four broad strata are identified. These strata are: malaria-free; low; moderate; and high-transmission strata. Total population and districts falling in each stratum with the proposed interventions are indicated in Table 1.

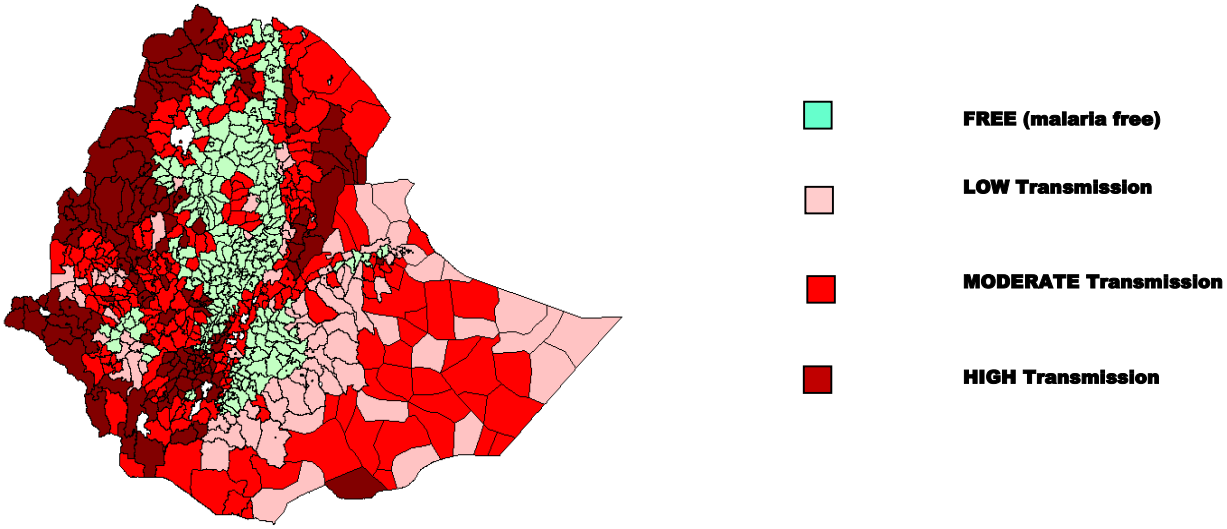


Figure 2. Map of Malaria Strata in Ethiopia. (FMOH, 2014)

Table 2. Malaria Stratification and Proposed Interventions by Stratum.

Malaria Strata	API	Elevation (m)	Population (2017)	% Population	No. of Woreda	% Woreda	Interventions					
							LLIN	IRS	Larval Control	Case Mx	Surveillance	IEC/ BCC
FREE	0	>= 2000 asl	37,083,083	40.3%	280	33.1%	-	-	-	X	X	X
LOW	>0 & <5	< 2000 asl	17,115,269	18.6%	146	17.3%	X	X*	WA	X	X	X
MODERATE	>=5 & <100	< 2000 asl	34,782,644	37.8%	365	43.2%	X	X**	WA	X	X	X
HIGH	>=100	< 2000 asl	3,036,580	3.3%	54	6.4%	X	X	WA	X	X	X
Total			**92,017,576**	**100%**	**845**	**100%**						

*Only 32% of at risk population in highland fringe/epidemic-prone areas will be covered by IRS

**Only 14.8% of districts at boundary of high stratum will be considered from moderate stratum by IRS

WA: where applicable; asl: above sea level; IEC: information, education, and communication; BCC: behaviour change communication

2.3. Factors Affecting Malaria Transmission

Altitude and climate

- Rainfall, temperature and relative humidity
- Are the most important determinants of malaria transmission.
- Transmission is seasonal and largely unstable in its characteristics. The major transmission of malaria follows the June to September rainy season and occurs between September and December; while the minor transmission season occurs between April and May.
- Areas with bimodal pattern of transmission are limited and restricted to a few areas that receive the small/Belg rains.

Age and Immunity

- Are host factors affecting risk of morbidity.
- Individuals who are exposed to repeated malaria infection, over a period of several years, become semi-immune. This means that although they are still at risk of infection when bitten by an infected mosquito, they either do not have symptoms (are asymptomatic), or their symptoms are not severe.
- This kind of partial immunity is not common in Ethiopia because of the unstable nature of the disease. When a person with partial immunity lives for few years in non-endemic area, the partial immunity will be lost and become susceptible.

2.4. National Strategic Plan (NSP) for Malaria Prevention, Control, and Elimination

The 2017–2020 National Strategic Plan is the updated version of the 2014-2020 National Malaria Strategic Plan (NSP). Updates to the NSP were made based on recent global, regional, and national developments. Accordingly, the NSP is fully aligned to the Health Sector Transformation Plan (HSTP) of 2015, the National Insecticide Resistance Monitoring and Management Strategy of 2016, the Global Technical Strategy (GTS) of 2016; the African Malaria Strategy (AMS) of 2016, and the National Malaria Elimination Roadmap of 2016. Moreover, the NSP is the product of a strong collaboration between all stakeholders that are engaged in the fight against malaria in Ethiopia. The 2017–2020 NSP builds on the achievements to date and, through sustained control, will move towards malaria elimination through an integrated health system and community health approach. This will be achieved through continued provision of malaria prevention tools (long-lasting insecticidal nets [LLINs] and indoor residual spray [IRS]). Early diagnosis and case

detection, prompt treatment, and increased utilization of interventions will only be possible by a community mobilization effort.

The core strategies of the NSP include diagnosis and prompt treatment; selective vector control; epidemic prevention and control. Cognizant of the importance of community empowerment and active participation, the Ethiopian government has given due attention to behavioral change communication. Hence, IEC/BCC is considered as one of the priority interventions for malaria control.

The goals of the national strategic plan are:

- By 2020, to achieve near zero malaria deaths in Ethiopia (*near zero malaria death is defined as no more than 1 confirmed malaria death per 100,000 population at risk*).
- By 2020, to reduce malaria cases by 40 percent from baseline of 2016.
- By 2030, to eliminate malaria from Ethiopia.

The priority interventions that will be targeted in the national strategic plan are summarized as follows:

- Community empowerment and mobilization
- Diagnosis and treatment
- Prevention or vector control
- Elimination of malaria
- Surveillance, monitoring and evaluation
- Supply chain management

2.5. Overview of Supply Chain Management of Antimalarial medicines

Brainstorming questions:

- How is the AMPs supply chain management system in Ethiopia?
- Is it vertical or integrated in to IPLS?

Effective malaria prevention, control, and elimination activities require continuous and sustainable availability of antimalarial medicines and related supplies, which depend on efficient supply chain management (SCM). Access to pharmaceuticals is critical to reach universal health coverage and is also recognized as a key building block of a strong health system.

FMOH through Pharmaceuticals Fund and Supply Agency (PFSA) started implementing Integrated Pharmaceuticals Logistics System (IPLS) since 2009. IPLS integrates the management of essential pharmaceuticals which were managed vertically. These include HIV/AIDS, Malaria, TB and Leprosy, EPI, Family Planning and other pharmaceuticals that are managed under the Revolving Drug Fund scheme. Other program pharmaceuticals' management is in the process of being integrated into the IPLS. Antimalarial pharmaceuticals management had been integrated as part of the IPLS since October 2015.

Key Target:

- 100% of anti-malaria commodities needed for the planning period will be procured, cleared, and distributed to health facilities.
- 0% of health facilities in malarious areas will face stock-outs of anti-malaria drugs.
- 0% of health posts will have stock-outs of key integrated community case management (iCCM) commodities.

Key Outcome Indicators:

- Proportion of health facilities reporting no regular stock-outs of anti-malarials as per the national guidelines.
- Proportion of health facilities with adequate storage capacities.
- Proportion of health facilities with trained staff.
- Proportion of health posts reporting no stock-outs of key iCCM commodities.

Pharmaceutical management involves several basic functions including selection, quantification, procurement, warehousing, distribution, inventory management, LMIS and use. The goal of every public health logistics system is to ensure that every customer is able to obtain and use quality essential health supplies whenever he or she needs them.

Key SCM Activities

- Timely forecasting.
- Procurement, custom clearance, storage and distribution.
- Ensuring the quality of antimalarial pharmaceuticals and their rational use.

2.6. Chapter Summary:

- Malaria is one of the major public health concerns in Ethiopia.
- P. falciparum and P. vivax are the two most dominant malaria parasites in Ethiopia
- The current stratification of malaria in Ethiopia has been developed using Woreda/district-level API data.
- Currently, Ethiopia is implementing the National Malaria Strategic Plan: 2017–2020.
- Effective malaria prevention, control, and elimination activities require continuous and sustainable availability of AMMs and related supplies, which depend on efficient SCM.

Chapter 3. Pharmacotherapy of Malaria

Chapter Description

This chapter discusses about the pharmacotherapy of malaria. First it describes Malaria Diagnosis and Treatment whereby the etiology, pathogenesis, clinical presentation, diagnosis, and treatment of malaria in Ethiopia are dealt. In the second part, it discusses Clinical Pharmacology of Antimalarial Medicines available in Ethiopia.

Chapter Outline

- Malaria Diagnosis and Treatment
- Clinical Pharmacology of Antimalarial Medicines

Session 3.1. Malaria Diagnosis and Treatment

Session Description

This session describes the first part of the pharmacotherapy of malaria, i.e., etiology, pathogenesis, clinical presentation, and diagnosis of malaria. Then, it continues to discuss treatment of uncomplicated malaria, severe malaria, and malaria in special groups. Finally, chemoprophylaxis of malaria is discussed.

Primary Objective

The primary objective of this session is to discuss malaria diagnosis and treatment in Ethiopia.

Enabling Objectives

By the end of this session, participants will be able to:

- Identify the pathogenesis of malaria
- Explain clinical presentation of malaria
- Describe the diagnosis of malaria
- Discuss the treatment malaria in the Ethiopian context
- Identify chemoprophylaxis approaches of malaria

Session Outline:

- Introduction
- Pathogenesis of malaria
- Clinical presentation of malaria
- Diagnosis of malaria
- Treatment of Malaria
- Chemoprophylaxis of Malaria
- Session summary

Introductory case

AB is 53-year-old man who recently returned from a trip to Jimma town visited your clinic with complaints of episodic fever, chills, malaise, and muscle pain which were present since one week. He had also experienced episodic headaches as well as intermittent epigastric pain.

On physical examination, the patient appeared to be in no acute distress but was sweating profusely. His temperature was 39.2^{o}C. He appeared slightly jaundiced. No hepatosplenomegaly was identified.

The principal laboratory findings are the following:

Test		Patient's Results	"Normal" Reference Range
Hematoloy	WBC count	1.9 x 10^3/µL	4.0-11.0 x 10^3/µL
	RBC count	3.2	4.2-5.9 x 10^6/µL
	Hematocrit	31.7	38.2-50.3%
	Hemoglobin	10.0	13.2-16.7 g/dL
	MCV	85	82-96 fL
	Platelet count	65	146-394 x 10^3/µL
	Differential cell count:		
	• Segmented neutrophils	61	40.0-80.0%
	• Band neutrophils	10	0.0-6.0%
	• Lymphocytes	24	15.0-50.0%
	• Monocytes	3	2.0-11.0%
	• Eosinophils	2	1.0-7.0%
Chemistry	ALT	192	30-65 U/L
	AST	178	15-37 U/L
	Bilirubin, total	12.4	0.2-1.2 mg/dL
Urinalysis	Hemoglobin	2+	Negative

WBC, white blood cell; RBC, red blood cell; MCV, mean corpuscular volume; ALT, alanine aminotransferase; AST, aspartate aminotransferase; fL, femtoliter.

Questions:

1. What is (are) this patient's most pertinent clinical and laboratory finding(s)?
2. Based on this patient's travel history and clinical signs and symptoms, which additional laboratory test(s) should be performed to diagnose the cause of this patient's illness?
3. What is this patient's most likely diagnosis?
4. What are the characteristic clinical and laboratory features associated with AB's disease?
5. What is the treatment and outcome of treatment for individuals with this patient's condition?

3.1. Introduction

Malaria case management, consisting of early diagnosis and prompt effective treatment, remains a vital component of malaria control and elimination strategies. Ensuring prompt and effective treatment will prevent most cases of uncomplicated malaria from progressing to severe and fatal illness. To avoid this progression, treatment must begin as soon as possible, generally within 24 hours after symptom onset. Effective treatment requires effective diagnosis of malaria; well-trained health workers in both the public and private health sectors; and constant availability of highly efficacious medicines as close to the patient as possible to ensure prompt access. Communities should be aware of the importance of seeking timely diagnosis and treatment, and adhering to prescribed medicine regimens for malaria.

3.2. Pathogenesis of Malaria

- **What are the types of malaria parasites worldwide?**
- **Which of them are common in Ethiopia?**

3.2.1. Etiology

Malaria is an infectious disease caused by protozoan parasites of the genus *Plasmodium* and is transmitted by mosquitoes. The five *Plasmodium* species of human malaria transmitted from person to person are: *P. falciparum, P. vivax, P. ovale, P. malariae* and *P. knowlesi*. Plasmodium falciparum and P. vivax are the two most common etiologies in Ethiopia.

3.2.2. Biological and clinical characteristics of malaria species

Reading Exercise

Read aloud Biological Characteristics of Malaria Species

The parasite incubation period, known as the intrinsic incubation period, differs for each parasite species. The incubation period of the common parasites in Ethiopia, *P. falciparum* is 9–14 days, *P. vivax* 12–17 days. The erythrocytic cycle, which is responsible for clinical paroxysms, takes about 48 hours in *P. falciparum, P. vivax.*

The malaria parasite species also differ in the number of merozoites they produce in the exoerythrocytic and erythrocytic phases and the type of the red blood cells they invade. *P. falciparum* produces the greatest number of merozoites in both phases followed by *P. vivax. P. falciparum,* which is responsible for the severe forms of malaria, infects red blood cells of all ages, unlike *P. vivax* which infects young red cells.

3.2.3. Mode of Transmission

There are three modes of malaria transmission:

- The bite of an infected female anopheles mosquito (the main method of transmission)
- Accidental transmission via blood transfusion or needle stick injury; and
- Congenital transmission from mother to child during pregnancy or parturition

3.2.4. Life Cycle of malaria parasite

Humans commonly acquire malaria from sporozoites transmitted by the bite of an infected female anopheles mosquito. The sporozoites then travel through the bloodstream to the liver within about 30 minutes, where they invade hepatocytes and mature to become tissue schizonts (pre-erythrocytic schizogony). Tissue schizonts are a central feature of all plasmodium species that

infect humans. They amplify the infection by producing large numbers of merozoites (10,000 – 30,000) from each sporozoite-infected hepatocyte.

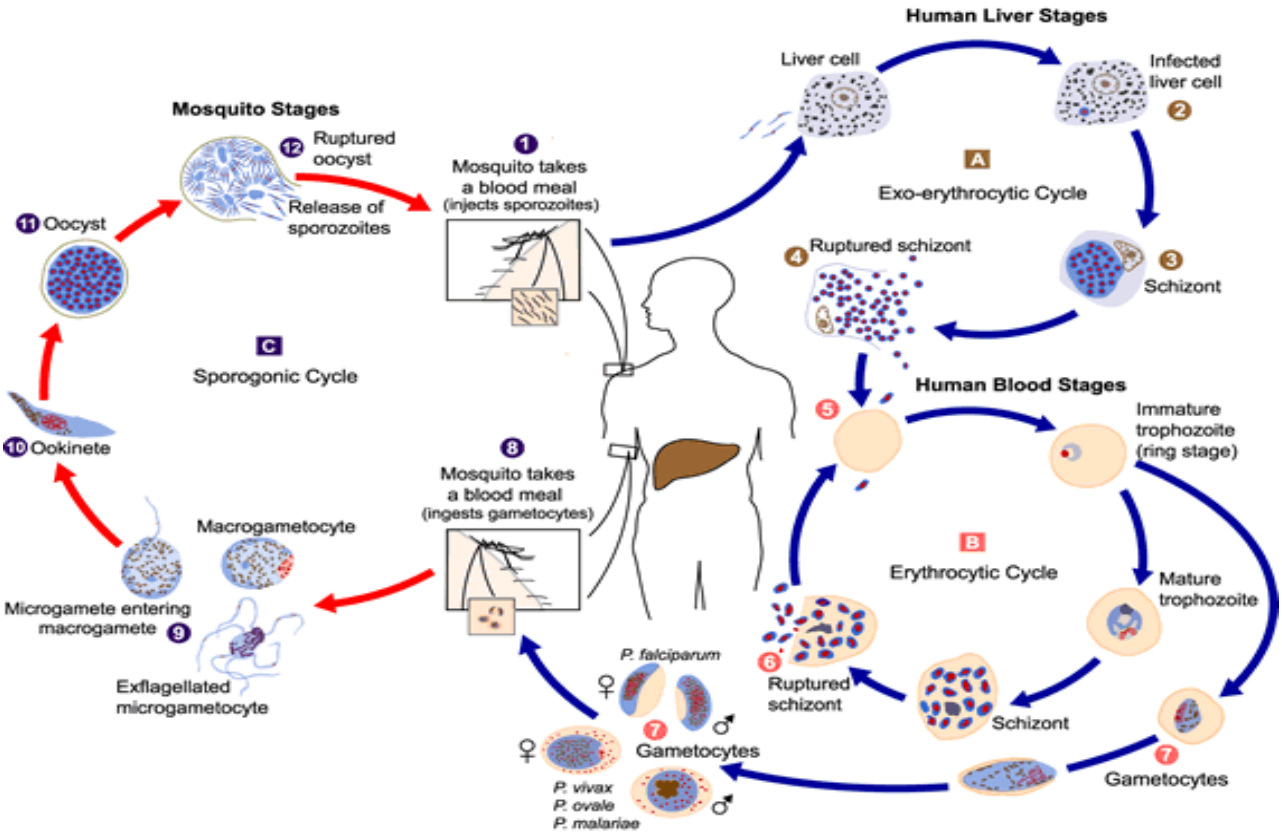


Figure 3. Life cycle of malaria parasite*

**Adopted from CDC – Global Health – Division of parasitic disease and malaria, August, 2018*

Each merozoite released from the liver infect a human red blood cell (RBC) and establishing the asexual cycle of replication in the red blood cells. The asexual cycle starts with merozoite invasion and continues to schizont rupture (merozoite → ring stage → mature trophozoite → schizont → merozoites), leading to invasion of more red blood cells. Some intraerythrocytic parasites develop into the sexual forms, the gametocytes, which are necessary for the sexual reproductive cycle that takes place in the vectors.

When potent gametocytes are ingested by a female anopheline mosquito during a blood meal, micro- and macrogametocytes mature to become male and female gametes. Fertilization of the female gametes produces diploid zygotes which mature to become ookinetes. Ookinetes then

undergo a meiotic reduction division to produce haploid sporozoites, which migrate to the salivary glands of the mosquito and subsequently re-infect humans.

In the *P. vivax* and *P. ovale* life cycles, some sporozoites can lie dormant in the liver cells for months or years after the initial bloodstream infection and do not cause symptoms during this time. The dormant forms, called hypnozoites, eventually mature to become tissue schizonts which release infectious merozoites, resulting in a clinical relapse.

3.3. Clinical presentation of malaria

Brainstorming Question

Describe signs and symptoms common in malaria patient?

Malaria infection can be either uncomplicated or severe. They have the following features:
Uncomplicated malaria is symptomatic malaria with parasitaemia without signs of severity (see under severe malaria) or evidence of vital organ dysfunction.

- The main manifestation of uncomplicated malaria is fever.
- Other symptoms include chills, rigor, headache, and body pain, malaise, nausea, vomiting, and joint weakness.
- Physical examination may reveal pallor and hepatosplenomegaly.
- In young children, malaria may also present with lethargy, poor feeding, and cough.

At this early stage of disease progression, with no evidence of vital organ dysfunction, a rapid, full recovery is expected, if prompt, effective antimalarial treatment is given. If ineffective or poor-quality medicines are given or if treatment is delayed, particularly in P. falciparum malaria, the parasite burden often continues to increase, and the patient may develop potentially lethal severe malaria. Disease progression to severe malaria may take days but can occur within a few hours.

Severe malaria is characterized by, evidence of vital organ dysfunction. If left untreated, severe malaria is fatal in most of cases. Severe malaria should be diagnosed if there are asexual forms of p. falciparum in a patient's blood film showing any of the following clinical/laboratory findings.

Clinical signs of severe malaria include:

- Impaired consciousness or unarousable coma
- Prostration, i.e. generalized weakness so that the patient is unable to walk or sit up without assistance (affected children are unable to feed);
- Multiple convulsions – more than two in 24 hours;
- Deep breathing, respiratory distress (acidotic breathing);
- Circulatory collapse or shock, systolic BP < 70mmHg in adults and < 50mmHg in children;
- Jaundice with evidence of another vital organ dysfunction;
- Abnormal spontaneous bleeding;
- Pulmonary edema (rapid breathing (>30 /min) or oxygen saturation <90 % at room air);
- Severe anemia (paleness of palms is most reliable symptom in children);
- No urine output in the last 24 hours;

Laboratory findings of severe malaria include:

- Hypoglycemia (blood glucose < 40mg/dl);
- Metabolic acidosis (plasma bicarbonate < 15mmol/liter);
- Severe normocytic anemia (Hb < 5g/dl, packed cell volume < 15%);
- Hemoglobinuria (dark color of urine/cola color urine in the absence of hematuria)
- Hyperparasitemia (>2% of red blood cells parasitized or >100,000 parasites per µL);
- Hyperlactatemia (lactate > 5mmol/liter);
- Acute kidney injury (serum creatinine >=3 mg/dl).

Note that:

- Each of the individual clinical features is important for the diagnosis of severe malaria.
- An individual patient may have any single complication, or any combination of the complications listed above.
- A patient with one or more of the complications may go on to develop others.
- Other possible diagnoses in such a patient must be carefully considered.
- Waiting for a blood smear result must not be allowed to delay the start of treatment unduly: if clinical features strongly suggest severe falciparum malaria, treatment may be started before the results are available.
- Occasionally blood films may be negative even though the patient is suffering from severe falciparum malaria. Following a negative result, blood films should be repeated, e.g. every 6 hours. Parenteral artesunate may be initiated in such patients.

- A positive blood film does not prove that severe falciparum malaria is the only cause of the severe illness. Other possible causes should also be considered.

Risky groups for severe falciparum malaria

Any infection with P. falciparum can become severe if treatment is delayed or inadequate. However, people who have been repeatedly exposed to falciparum malaria develop partial immunity and are less likely to experience severe falciparum malaria. Those most at risk are indicated in box 2.1.

Box 2.1: Risk groups for severe f. malaria

- People of all ages in areas of low endemicity (like most malaria endemic places in Ethiopia);
- Residents of areas where there is little or no falciparum malaria who travel to a high transmission area. This may involve travel within the country or between countries;
- Non-immune pregnant women (at risk of some specific complications);
- Internally-displaced persons moving from an area of low transmission to high transmission;
- Children in areas of high endemicity – especially those aged from 6 months to 5 years;
- People returning to highly endemic areas after a few years' residence in area with little or no falciparum malaria;
- Patients who have had a splenectomy.

3.4. Diagnosis of malaria

Individual Reading

Read diagnosis of malaria for two minutes

Prompt and accurate diagnosis of malaria is part of effective disease management. All patients with suspected malaria should be treated based on a confirmed diagnosis of a blood sample by microscopy at hospitals and health centers or RDT testing only at health posts. Correct diagnosis in malaria-endemic areas is particularly important for the most vulnerable population groups, such as young children and non-immune populations, in whom malaria can be rapidly fatal. High specificity will reduce unnecessary treatment with antimalarial medicines and improve the

diagnosis of other febrile illnesses in all settings. Malaria diagnosis is made by proper history taking and physical examination (clinical diagnosis) and laboratory (parasitological diagnosis).

Individual Reading

Read clinical and parasitological diagnosis of malaria for five minutes

3.4.1. Clinical diagnosis of malaria

A clinical diagnosis entails making a clinical assessment by taking an accurate history of the illness and performing a physical examination. Clinical diagnosis of malaria is made in a patient who has fever or history of fever in the last 48 hours and lives in malaria-endemic areas or has a history of travel within the last 30 days to malaria-endemic areas. Malaria treatment based on clinical diagnosis must be the last option when there is no availability of microscopy. Other possible causes of fever should be considered and manage the cases accordingly. Malaria should still be considered, even if the individual has another obvious cause for the fever. Clinical diagnosis alone increases the chances misdiagnosis, hence over treated and increases risk of AMMs resistance.

3.4.2. Parasitological diagnosis of malaria

It is required for confirmation of the diagnosis of malaria. It is recommended for all suspected malaria cases in all settings. The two main methods in routine use for parasitological confirmation of malaria are light microscopy and rapid diagnostic tests (RDTs).

N.B. Patients with negative microscopy results do not need antimalarial medications.

3.5. Treatment of Malaria

The primary goal in the treatment of malaria is the rapid diagnosis of the plasmodia species by blood smears to initiate timely antimalarial therapy and eradicate the infection within 48 to 72 hours and to avoid complications such as hypoglycemia, pulmonary edema, and renal failure that are responsible for increased mortality in malaria. In addition, the public health goals of treatment are to prevent onward transmission of the infection to others and to prevent the emergence and spread of resistance to AMMs.

3.5.1. Treatment of uncomplicated malaria

First line treatment of uncomplicated malaria:

***P. falciparum* positive:** If the microscopy test indicates a P. falciparum infection, then the patient should be treated with appropriate dose of Artemether-lumefantrine (AL).

AL tablets are given according to body weight in six doses over three days as indicated below in the table. Depending on the patient's body weight, the dose ranges from 1 tablet to 4 tablets taken every 12 hours for 3 days. In addition, for reducing transmission of P. falciparum, a single dose of 0.25 mg base/kg primaquine (PQ) should be administered for such patients to ensure elimination of the parasite.

Table 3. Tablet containing 20 mg Artemether + 120 mg Lumefantrine as FDC

Weight (Kg)	Age	Day 1		Day 2		Day 3		Color code
		Immediate	After 8 hrs	Morning	Evening	Morning	Evening	
<14 kg	Up to 2 years	1Tablet	1Tablet	1Tablet	1Tablet	1Tablet	1Tablet	Yellow*
15-24 kg	3 to 7 years	2 Tablets	2 Tablets	2 Tablets	2 Tablets	2 Tablets	2 Tablets	Blue*
25-34 kg	8 to 10 years	3 Tablets	3 Tablets	3 Tablets	3 Tablets	3 Tablets	3 Tablets	Brown
>35	>= 10 years	4 Tablets	4 Tablets	4 Tablets	4 Tablets	4 Tablets	4 Tablets	Green

*Yellow and blue flavored pediatric dispersible tablets of AL is available for enhancing its use in young children.

Note: AL is available in co-formulated tablets as fixed dose combination (FDC) containing artemether 20 mg and lumefantrine 120 mg per tablet.

P. vivax and others positive but not P. falciparum: Chloroquine treatment should be dispensed at a total dose of 25 mg base/kg, also ensuring that oral medicine is tolerated. In addition, Primaquine (PQ) at 0.25mg/kg daily for 14 days is given at elimination targeted areas with close clinical and laboratory follow up. The doses of chloroquine and PQ are presented below in the tables.

Mixed infection: Mixed infection of *P. falciparum* and *P.vivax* should be treated with AL. Pregnant women in the first trimester should be treated with oral quinine when *P. falciparum* infection or mixed infection is present. Chloroquine is safe in pregnancy and for infants.

NB: When there is a negative laboratory result by microscopy for malaria, no malaria medications should be provided, but a thorough search for other causes of acute febrile illness, such as

pneumonia, should continue; referral to higher level may be necessary. By testing as many patients as possible with clinically suspected malaria by microscopy, and by treating patients according to malaria laboratory test result, the waste of antimalarial medications can be reduced and eliminated. Over time, the number of patients treated with suspected malaria but without laboratory confirmation should approach zero, and the number of patients who must be treated for presumptive malaria without laboratory confirmed diagnosis should eventually approach zero.

Table 4. Chloroquine dose

Weight (kg)	Age	Day 1	Day 2	Day 3
5 – 6	< 4 months	½ tablet *OR* 5 ml syrup	¼ tablet *OR* 5 ml syrup	¼ tablet *OR* 2.5 ml syrup
7 – 10	4 – 11 months	½ tablet *OR* 7.5 ml syrup	½ tablet *OR* 7.5 ml syrup	½ tablet *OR* 5 ml syrup
11 – 14	1 – 2 years	1 tablet *OR* 12.5 ml syrup	0.5 tablet *OR* 12.5 ml syrup	0.5 tablet *OR* 7.5 ml syrup
15 – 18	3 – 4 years	1 tablet *OR* 15 ml syrup	1 tablet *OR* 15 ml syrup	1 tablet *OR* 15 ml syrup
19 – 24	5 – 7 years	1 ½ tablets *OR* 20 ml syrup	1 ½ tablets *OR* 20 ml syrup	1 tablet *OR* 15 ml syrup
25-35	8-11 years	2 ½ tablets	2 tablets	1 tablet
36-50	12-14 years	3 tablets	2 tablets	2 tablets
51+	15 years + adult	4 tablets	4 tablets	2 tablets

Note:

- One 250 mg chloroquine phosphate tablet (salt) contains 150 mg chloroquine base.
- 5 ml of chloroquine phosphate syrup (salt) contains 50 mg chloroquine base.
- Never take more than four 250 mg chloroquine phosphate tablets in one day.

Table 5. Primaquine Treatment Schedule

		Number of tablets	
Weight (kg)	**Age (years)**	**7.5 mg tablet**	**15 mg tablet**
8-18	07 months to – 4 years	½	¼
19 – 24	5 – 7	¾	½
25 – 35	8 – 10	1	½
36 – 50	11 – 13	1 ½	¾
50+	14+	2	1

Note:

- PQ is contraindicated to pregnant women, infants aged < 6 months and women breastfeeding infants aged < 6 months.
- All dose of PQ is not dispended at once. i.e. on the first day a dose enough for 3 days is dispensed, on the 2nd visit a dose enough for four days is dispensed, on the 3rd visit a dose enough for two days will be dispensed.

Individual exercise

- **Write supportive treatments are needed to patients with uncomplicated malaria?**
- **Discuss general patient advice pharmacy professionals should provide with respect to malaria, its prevention and treatment in addition to medication adherence counseling?**

Supportive treatment

If patients, especially children are present with axillary temperature ≥37.5°C, treat with antipyretics and, if necessary, fanning, and tepid sponging. Paracetamol (acetaminophen) 15 mg/kg every 4 hours is widely used; it is safe and well-tolerated, given orally or as a suppository. Pain should be treated, and the patient should be encouraged to take food and fluids.

Patient advice

Pharmacy professionals should make patients understand the importance of taking medicines in malaria treatment. In addition, depending on the context and time, pharmacy professionals should provide the following messages to patients and/or caregivers about malaria and its treatment:

- Malaria is a killer disease if treatment is not sought early and treatment is taken properly.
- Whenever a family member has a fever, take them to the nearest health facility, immediately or at least within 24 hours.
- Do not interrupt taking medication. Take full course of the AMMs given by the health personnel.
- Do not share medicines with others, including family members.
- Come back to the health facility after three days of malaria treatment if no improvement in symptoms or any time if there is worsening of symptoms.
- Patients taking PQ should return to the health facility on the appointed visit dates to collect the remaining dose of the medicine and should report severe adverse events of the drug (e.g. change in urine color, yellow discoloration of the eye, pale palm)

- All family members, especially women and children should sleep under LLINs every night.

Referral

It is important that all patients are assessed for the presence of danger signs (see Box below). If a patient presents with danger signs or is found to have any of the following danger signs, they require URGENT medical attention and hence should be referred as soon as possible to the next level if they are in health post or health center. Any patient presenting with any of the danger signs, regardless of whether the RDT result is negative or positive, should be given pre-referral treatment (see below) and be referred to the next higher-level health facility as soon as possible. REMEMBER that a delay in referral could cause unnecessary death of the patient.

Box 2.2: Danger signs of severe malaria

- Altered consciousness (e.g. sleepiness, confusion, drowsiness, coma)
- Prostration, i.e. generalized weakness so that the patient is unable to walk or sit up without assistance
- Unable to eat or drink
- Repeated vomiting, resulting in inability to retain oral medication, to eat or drink
- Severe dehydration
- Convulsion or recent history of convulsions
- Difficult breathing
- Jaundice (yellowish discoloration of the eyes)
- Anemia (paleness of palms is most reliable symptom in children)
- Hemoglobinuria (cola colored urine)
- Abnormal spontaneous bleeding
- No urine output in the last 24 hours

Second line treatment of uncomplicated malaria:

Second-line treatment is used when the first-line treatment is not available, or during failure or non-responsive to first-line treatment. The second-line treatment for both *P. falciparum* and *P. vivax* is oral quinine.

Treatment failure: Treatment failure is defined as failure of AMMs to resolve fever and/or parasitaemia. Treatment failures may result from AMM resistance, poor adherence, or inadequate medicine exposure (i.e. from under-dosing, vomiting or unusual pharmacokinetic properties in that

individual), medicine interaction, misdiagnosis, or substandard/counterfeit AMMs. Monitoring treatment failure is very important because it can signal the appearance of AMM resistance.

Antimalarial medicines resistance can cause treatment failure but not all treatment failure is due to parasite resistance to medicines. Antimalarial medicine resistance refers to the ability of a parasite strain to survive and/or multiply despite the administration and absorption of a medicine given in doses equal to or higher than those usually recommended, but within tolerance of the subject, and the medicine must gain access to the parasite or the infected red blood cell for the duration of the time necessary for its normal action.

Chloroquine-resistant *P. falciparum* (CRPF) is widespread and present in almost all malaria-endemic areas of the world. *P. falciparum* malaria resistant to chloroquine and mefloquine has been isolated. Chloroquine-resistant *P. vivax* is an emerging problem also.

Individual Reading for five minutes

- **Treatment failure within 14 days of treatment and treatment failure after 14 days of treatment**

Treatment failure within first 14 Days: Owing to the potency of AL, treatment failure within 14 days of receiving an AL is very unusual. Most of treatment failures occur after 2 weeks of initial treatment. Recurrence of *P. falciparum* malaria may be the result of a reinfection, or a recrudescence (i.e. treatment failure). In an individual patient it may not be possible to distinguish between recrudescence and reinfection, although if fever and parasitaemia fail to resolve, or recur within 2 weeks of treatment, then treatment is considered to have failed. Wherever possible, treatment failure should be confirmed parasitologically, preferably by blood slide examination. It is also important to determine from the patient's history whether the antimalarial was vomited or whether the full course was not completed.

Treatment failure after 14 Days: Most of treatment failures occur after two weeks of initial treatment. Such failures can result from either recrudescence or a new infection. This distinction can only be made through parasite genotyping by PCR which is not routinely used in patient management in Ethiopia. Thus, to simplify operational management and medicine deployment, all presumed treatment failures after two weeks of initial treatment should be considered as new infections, and be treated with the first-line antimalarial medicine, which is AL.

Management of treatment failure: Appropriate management of treatment failure is important because the patient may progress to severe malaria, and resistant parasites may be present and transmitted to others. The following recommendations should be followed after a full history, clinical assessment and laboratory examination is done.

- If a cause for treatment failure is identified (e.g. AMM is vomited), such cause must be addressed, and treatment reinstituted with a first-line AMM.
- If a P. falciparum or P. vivax-infected patient returns to the health facility with fever or history of fever between day 4 to 14 of treatment, a microscopic blood examination should be made (Note: do not use RDTs). If parasites are detected, the treatment should be changed to the second-line medicine, i.e. quinine tablets. Blood smears should be saved, labelled, and dated for further analysis by laboratory experts.
- In patients who are suspected to have treatment failure after 14 days, use the first-line AMMs as it may be caused because of re-infection.
- If the blood smear is negative and no other obvious causes are found, the patient should be re-evaluated, or referred to the next level of health care for proper management.

Management of Treatment failure within 14 days:

- Uncomplicated P. falciparum is treated with AL if complete course of AL was not taken or patient had vomiting. Otherwise it is treated with second line AMM which is Quinine tablet.
- P. vivax is treated with Chloroquine if complete course was not taken or patient had vomited. Otherwise it is treated with second line AMM which is Quinine tablet. In this case, patient should complete the already started radical cure.
- Mixed cases (P. falciparum+ P. vivax) are treated in the same manner as for P. falciparum.

Management of treatment failure More than 14 days:

- P. falciparum: AL + single dose of primaquine
- P. vivax: CQ + Primaquine for 14 days
- Mixed: AL + Primaquine for 14 days

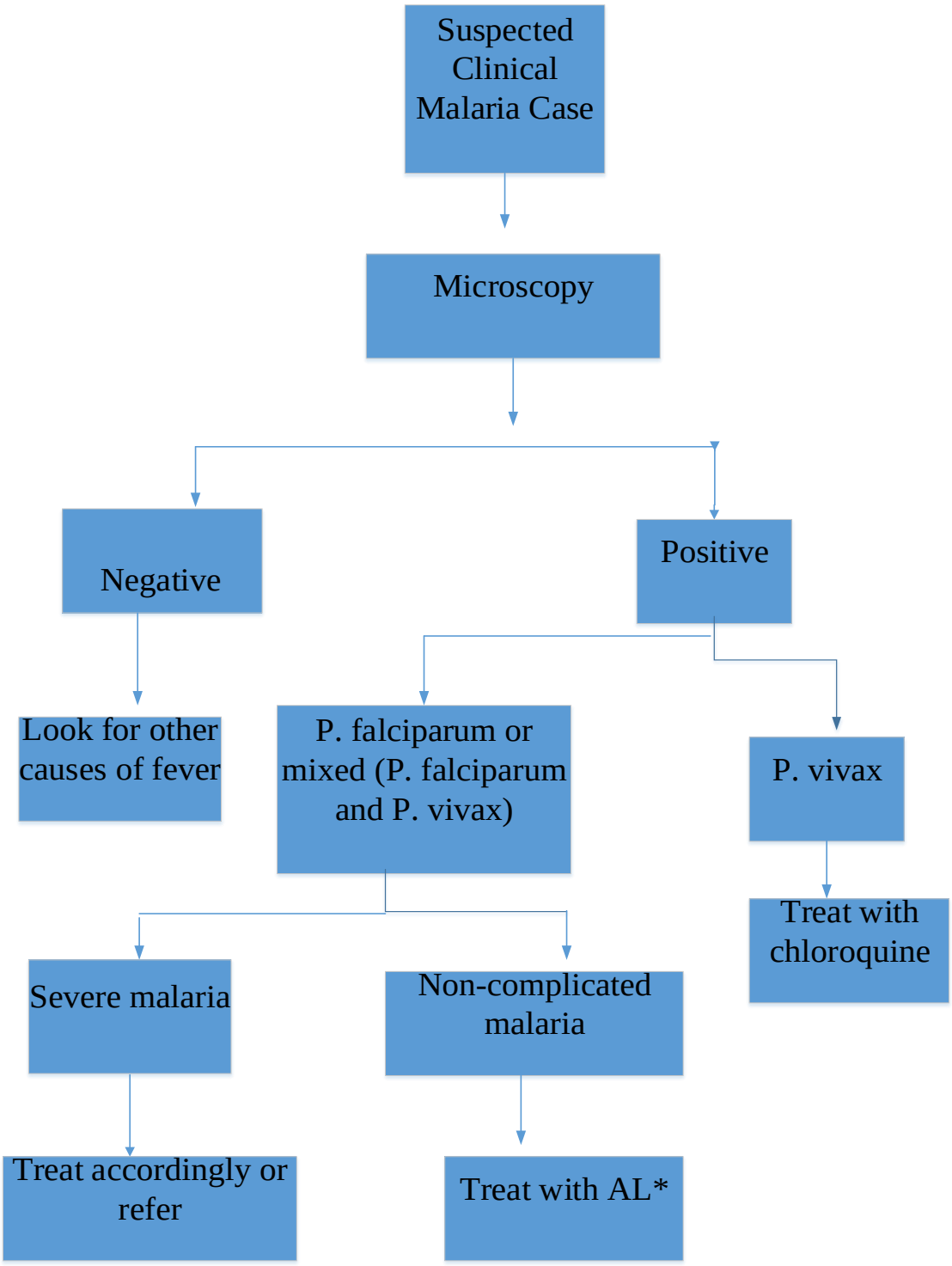


Figure 4. Algorithm for diagnosis and treatment of malaria

3.5.2. Treatment of Severe Malaria

Pair Reading for 10 minutes

Treatment of severe malaria

The primary objective of treatment is to prevent the patient from dying; secondary objectives are prevention of recrudescence, transmission or emergence of resistance and prevention of disabilities. Special attention is required because severe falciparum malaria is a common cause of avoidable death and because early treatment and careful nursing can greatly improve the outcome.

Although P. falciparum usually causes severe malaria illness, occasionally, *P. vivax* infection can also result in severe malaria illness. Severe malaria illness should be treated in the same manner whether it is due to *P. falciparum* or *P. vivax* infection: intravenous artesunate as preferred therapy at hospital or health center.

General principles of treatment

The patient presenting with severe malaria needs **URGENT** medical attention. A delay in diagnosis and treatment is serious and can lead to unnecessary death of the patient. Many suspected severe malaria cases can be managed either at the health center or primary hospital level. Cases that develop serious complications need referral, for better management, to a general or specialized hospital.

The following special measures are indicated:

- Antimalarial medicines should be given parenteral if possible, under close supervision;
- Treatment should be undertaken in hospital if possible;

Specific treatment of severe malaria

For children under 20kg or under 3 years of age: the dose of Artesunate is 3mg/kg. Artesunate reduces mortality in both adults and children, has fewer side effects and is easy to administer as compared to quinine infusion. It is available in ampoules, containing 60mg anhydrous artesunic acid with a separate ampoule of 5% sodium bicarbonate solution.

Artesunate Reconstitution: the vial of Artesunate powder should be mixed with 1ml of 5% sodium bicarbonate solution (provided) and shaken 2–3 minutes for better dissolution. The solution should be prepared freshly for each administration and should not be stored. Then:

- IV administration: add 5ml of 5% glucose or normal saline to make the concentration of artesunate as 10mg/ml and administer by slow infusion;
- IM administration: add 2ml of 5% glucose or normal saline to make the concentration of artesunate as 20mg/ml (See video on Artesunate preparation)
- IM artesunate (2.4 mg/kg on time 0 (admission), 12h and 24h after admission, then plan to change to full dose oral AL. If the patient can't take AL for any reason, complete treatment with seven days course of quinine tablets.
- IV quinine infusion: 20mg salt/kg (loading dose) diluted in 10ml isotonic fluid/kg by IV infusion over 4 hours; followed by 8 hourly maintenance dose of quinine 10mg salt/kg over 4 hours, calculated from the beginning of the previous infusion, until the patient can swallow.
- IM quinine: this is the last option in case of no Artesunate or Artemether, and IV access can't be established, and patient can't be referred. If for any reason quinine cannot be administered by IV infusion, quinine dihydrochloride can be given in the same dosages by IM injection in the anterior thigh (not in the buttock). The dose of quinine should be divided between two sites – half the dose in each anterior thigh. If possible, for IM use, quinine should be diluted in normal saline to a concentration of 60–100mg salt/ml.
- Parenteral antimalarials in the treatment of severe malaria should be given for a minimum of 24 hours (48 hours for quinine), once started (irrespective of the patient's ability to tolerate oral medication earlier).

Under ideal conditions the severely ill patient, especially one who is comatose, should be managed in an intensive care unit. Where this is not possible, as in most places in Ethiopia, the health worker must provide emergency care. Meticulous nursing care can be life-saving, especially for the unconscious patient.

Box 2.3. Important points about quinine infusion when used as alternative therapy

- Rapid administration of quinine is not safe and may cause sudden death due to arrhythmia or refractory hypotension. Each dose of parenteral quinine must be given as a slow, rate-controlled infusion (usually diluted in 5% dextrose and infused over 4 hours). The infusion rate should not exceed 5 mg salt/kg body weight per hour. If possible, continuous infusion should be given.
- For all patients with severe malaria, IV infusion should be given at least for the first 48 hours.

- In patients requiring more than 48 hours of parenteral therapy, the quinine maintenance dose should be reduced by one-third to one-half (i.e. 5-7 mg salt/kg of body weight every eight hours). It is unusual to continue IV infusions of quinine for more than 4-5 days.
- A loading dose of quinine should not be used if (i) the patient received quinine within the preceding 24 hours; (ii) mefloquine within the preceding 24 hours; or (iii) mefloquine within the preceding seven days;
- Quinine is not given by subcutaneous injection;
- Quinine is safe in pregnancy and anemic patients if doses are calculated by body weight.

REMEMBER:

- Always ensure that dose of artesunate injection is calculated according to the body weight/age of the patient. Thus, advice the prescriber and the nurse on how to calculate and properly reconstitute artesunate injection.
- In collaboration with other health professional / multi-disciplinary team, monitor the progress of the patient and therapeutic outcome

Immediate supportive treatment

In severe malaria, the patient has several life-threatening complication(s) which can be fatal if not urgently treated. Some of the most urgent measures that will be required are to:

- Start immediate resuscitation measures, paying attention to the airways;
- Establish an intravenous infusion, which is necessary to administer medicines and fluids;
- Correct hypoglycemia if present by infusing dextrose over a period of 3–5 minutes. This can be done by any one of the following procedures:
  - 4ml/kg of 10% dextrose given by slow IV infusion over several minutes in children;
  - 40–60ml of 40% dextrose given as intravenous bolus in adults;
  - Where intravenous access is impossible, give sugar solution by nasogastric tube (NGT);
  - Re-check blood glucose 2–4 hourly during treatment, particularly in comatose patients.
- Control convulsions**:**
  - Correct hypoglycemia if it is present and give rectal paracetamol if the temperature is above 39°C.

- If the convulsions continue for more than 5 minutes give diazepam by slow intravenous injection (0.15ml/kg body weight, maximum 10mg for adults). In children always calculate according to weight to avoid dangerous respiratory depression.
- Diazepam can be given intra-rectally (0.5–1.0mg/kg) only if injection is not possible. Monitor the breathing carefully. If the first dose of diazepam fails to control convulsions, a second dose may be given after 10 minutes.
- If seizures continue, give phenytoin (18mg/kg infused over 20 minutes as a loading dose, followed by 2.5mg/kg twice daily for 48 hours).
- If you have given two doses of diazepam and seizures continue, and if phenobarbitone is the only additional anticonvulsant medicine available, you may give phenobarbitone (15mg/kg IM or IV loading dose, then 5mg/kg daily for 48 hours), but extreme vigilance is necessary because these two medicines (phenobarbitone and diazepam) in combination may cause respiratory arrest. Monitor breathing continuously and be ready to give assisted ventilation.

Continued supportive treatment

- Assess the patient's fluid requirements. The rate of infusion will be determined based on the degree of dehydration. Children with severe metabolic acidosis may benefit from a resuscitation bolus of fluid, preferably a plasma expander, e.g. normal saline. The usual route for fluid infusion is intravenous; if this cannot be achieved alternatives are intraosseous or nasogastric infusions.
- Reduce body temperature if greater than 39.5ºC to prevent convulsion. This is best done by giving paracetamol, Po if possible, alternatively by suppository. In addition, remove the patient's clothes and start tepid sponging and fanning from the sides or back of the patient.
- Consider the need for blood transfusion. The most common indication for blood transfusion is severe anemia (Hb < 5g/dl).
- Consider antibiotics if there is a suspicion of concomitant bacterial infections.
  - Patients diagnosed with concomitant infections like pneumonia, UTI, meningitis
  - Patients suspected to have infections (shock which is not responding to fluid management, metabolic acidosis with hypotension especially if not responding to fluid management, comatose patients when CSF analysis is not possible).

Assessment of the patient's recovery

The records and observations will provide some indications of patient recovery e.g. lowering temperature, decreasing parasite count, and an improving coma score. In addition, the patient's ability to drink, eat, talk, sit, stand or walk should be evaluated and recorded. When a patient has recovered, an assessment should be made of possible sequelae of the disease or the treatment neurological examination and vision and hearing assessment. While being discharged, provide prescribed discharge medications and counseling.

3.5.3. Treatment of Malaria in Special Groups

Malaria in Pregnancy

The symptoms and complications of malaria in pregnancy vary according to transmission intensity and the level of acquired immunity. Pregnant women living in areas of low or unstable malaria transmission (like many malarious areas in Ethiopia) have little or no immunity to malaria, and are at higher risk of developing severe malaria than are non-pregnant adults living in the same area.

In these areas, malaria is a major cause of maternal anemia, spontaneous abortion, stillbirth, premature delivery, low birth weight (LBW) < 2.5kg, neonatal death and maternal death. In non-immune women, severe malaria symptoms (hypoglycemia, cerebral malaria, and pulmonary edema being particular problems) are more common in pregnancy.

In stable transmission settings, the deleterious impact of malaria is particularly apparent in first and second pregnancies. Partial clinical immunity acquired during years of exposure to the malaria parasite prior to pregnancy does not prevent infection, but does reduce the risk of severe disease. Clinical malaria is not, therefore, a prominent feature of infection during pregnancy, and the major detrimental effects of infection are LBW and maternal anemia.

HIV infection impairs pregnant women's ability to control *P. falciparum* infection. Women with HIV infection are more likely to have symptomatic malaria infections and to have an increased risk of an adverse birth outcome due to malaria. In the presence of HIV infection, placental malaria appears to be independent of the number of pregnancies, so that the risk of placental malaria is similar in HIV-infected multigravida and HIV-negative primigravida.

Severe anemia, exacerbated by malaria, is an important complication of pregnancy in many tropical countries. Especially in communities where chronic hookworm anemia is prevalent,

high output anemic cardiac failure may develop in late pregnancy. Asymptomatic hypoglycemia may occur in pregnant women with malaria before antimalarial treatment, and pregnant women with uncomplicated or severe malaria are particularly vulnerable to quinine-induced hypoglycemia. There is an increased risk of pulmonary edema precipitated by fluid overload or by the sudden increase in peripheral resistance, or auto transfusion of hyperparasitaemic blood from the placenta which occurs just after the delivery.

***Treatment of uncomplicated malaria in pregnancy*:** Pregnant women with symptomatic acute malaria are a high-risk group, and require effective antimalarial medication. There is insufficient information on the safety and efficacy of most antimalarial medicines in pregnancy, particularly for exposure in the first trimester, and treatment recommendations differ from those for non-pregnant adults. Therefore, as a standard practice for the administration of any medicine for pregnant women, all women of child-bearing age should be asked whether they are, or could possibly be, pregnant before an antimalarial medicine is prescribed.

The following are the antimalarial medicines recommended for the treatment of uncomplicated malaria during pregnancy:

Falciparum:

- In the first trimester, give a 7-day course of quinine. Artemether-lumefantrine (AL) is not recommended as routine treatment in early pregnancy because its safety has not been fully established. AL is indicated only if (i) it is the only treatment immediately available, (ii) if treatment with 7-day quinine fails, or (iii) if there is uncertainty about the patient's compliance with a 7-day course of treatment.
- In the second and third trimesters, give AL.

Vivax:

- Chloroquine, which is the treatment of choice for *P. vivax* (chloroquine-sensitive), *P. ovale* and *P. malaria*, is safe in pregnancy.
- **Primaquine** is contraindicated during pregnancy.

***Treatment of severe malaria in pregnancy and breast feeding*:** A pregnant woman with severe malaria should be given a parenteral antimalarial medicine in full doses without delay. Parenteral artesunate is more effective than parenteral quinine in reducing the risk of death from severe malaria.

Although safety data on the use of artemisinins in the first trimester are limited, saving the mother's life is the primary objective. Therefore artesunate (IV or IM) is the preferred medicine for all severe forms of malaria in all trimesters of pregnancy. IM Artemether is the second option while Quinine (IV or IM) may be considered as the last option. After 24 hours of parenteral medicine administration, treatment should be completed with full dose of AL in the second and third trimesters and quinine tablets for seven days during the first trimester.

The amount of antimalarial medicines passed into breast milk and consumed by the breast-feeding infant is very small. So, the treatment during breastfeeding is the same as the non-pregnant adults except primaquine which should be avoided during breastfeeding.

***Prevention of malaria during pregnancy*:** Pregnant women should be given priority in LLIN utilization. Although intermittent preventive treatment of malaria during pregnancy (IPTP) is recommended in high transmission areas, it is not recommended in Ethiopia because of resistance developed to the medicine used for IPTP, sulfadoxine-pyrimethamine (Fansidar).

Malaria and Malnutrition

Malaria and malnutrition frequently coexist. Malnutrition may result in inaccurate dosing of medicines if we use age or weight of the child. Different conditions may hamper the absorption of antimalarial medicines if given orally or parenteral, e.g. chronic (persistent) diarrhea, vomiting, rapid gut transit or atrophy of the small intestine villi (enteropathy). Diminished muscle mass may also make repeated intramuscular injection difficult. Hypoalbuminemia may also lead rapid clearance of the medicines as some medicines need albumin for binding. Although these findings are concerning, they are insufficient to warrant dose modification of any antimalarial medicines in a patient with malnutrition. However, their response to treatment should be monitored more closely.

Malaria and HIV

There is geographical overlap between malaria and HIV, and many people are co-infected. Worsening HIV related immunodeficiency may lead to manifestation of severe malaria. In areas of stable malaria transmission, patients have more frequent and higher density infection due to partial immunity while in unstable transmission area such as in Ethiopia, HIV infection is associated with increased risk for severe malaria and malaria related death.

Early studies suggested that HIV related immunosuppression was associated with decreased response to AMMs but now there is insufficient information to change the medicines and dose of antimalarial medicines we used for non-HIV infected individuals. Treatment of malaria is similar in HIV-infected and HIV-uninfected patients. There is limited information regarding medicine interaction between antimalarial and anti-retroviral medicines. Pharmacovigilance is recommended to document observed interactions.

Malaria and TB

There are evidences that show patients taking rifampicin with quinine, ACTs and mefloquine have a three to nine-fold decrease of the AMMs in the serum as well as higher recrudescence rate. However, there is insufficient evidence to change the medicine and dosing in patients who are taking anti-TB medicines. But these patients are at higher risk of recrudescent infection, hence they should be monitored closely.

3.6. Chemoprophylaxis of Malaria

Persons who travel to malaria-endemic areas are at risk of acquiring malaria. Health workers should advise all persons traveling to such areas to avoid mosquito bites, specifically by using mosquito repellents and sleeping under LLINs at night. Chemoprophylaxis is an option and mefloquine and atovaquone-proguanil can be used as antimalarial chemoprophylaxis in Ethiopia. Chemoprophylaxis should be given 2 weeks before departure, continued throughout stay and 4 weeks after return.

NB: *If the* person *develops fever while on chemoprophylaxis he/she should seek medical advice.*

Table 6. Mefloquine dose for chemoprophylaxis: 5 mg /kg mefloquine salt once weekly

Weight (Kg)	Age (approx.)	Number of tablets per week
<9	< 3 months	Not Recommended
9 – 19	3 – 23 months	¼
20 – 30	2 – 7 year	½
31 – 45	8 – 10 year	¾
36 – 50+	11 – 14+	1

Table 7. Atovaquone-proguanil dose for chemoprophylaxis

Weight (kg)	Atovaquone/Proguanil HCl	Dosage Regimen
11-20	62.5 mg/25 mg	1 Pediatric Tablet daily
21-30	125 mg/50 mg	2 Pediatric Tablets as a single dose daily
31-40	187.5 mg/75 mg	3 Pediatric Tablets as a single dose daily
>40	250 mg/100 mg	1 Tablet (adult strength) as a single dose daily

Session summary

- Early diagnosis and prompt treatment is a vital component of malaria control and elimination strategies
- Malaria is an infectious disease caused by protozoan parasites of the genus Plasmodium and is transmitted by mosquitoes.
- Malaria infection has three modes of malaria transmission: *bite by mosquito, blood transfusion, and from mother to child.*
- Uncomplicated malaria has the following symptoms: fever, chills, headaches, body pain, malaise, vomiting, etc.
- Malaria has to be confirmed by laboratory examination (microscopy at hospitals and health

Session 3.2. Clinical Pharmacology of Antimalarial Medicines

Session Description

This session discusses clinical pharmacology of antimalarial medicines available in Ethiopia. The session starts by describing the classification of AMMs. Then, detailed discussion is made on specific antimalarial medicines used in Ethiopia focusing on their pharmacokinetics, clinical uses, adverse effects, contraindications, cautions, and medicine interactions.

Primary Objective

The primary objective of this session is to discuss clinical pharmacology of antimalarial medicines used in Ethiopia.

Enabling Objectives

By the end of this session, participants will be able to:

- Classify the current AMMs in Ethiopia
- Discuss uses and characteristics of specific antimalarial medicines

Session outline

- Classification of current AMMs
- Specific Antimalarial Medicines used in Ethiopia
- Session summary

3.2.1. Classification of current AMMs

Brainstorming Question:

How do you classify current AMMs?

AMMs can be categorized by the stage of the parasite that they affect and by their intended use for either prophylaxis or treatment. The various stages of malaria life cycle that occur in humans differ from one another not only in their morphology and metabolism but also in their medicine sensitivity. For this reason, the classification of AMMs is best done in the context of the life cycle of the malaria.

The spectrum of antimalarial medicines activity leads to several generalizations. The first relates to prophylaxis: Since none of the medicines kills sporozoites, it is not truly possible to prevent infection but only to prevent the development of symptomatic malaria caused by the asexual erythrocytic forms. The second relates to treatment of an established infection: None of the antimalarial is effective against all liver and red cell stages of the life cycle that may coexist in the same patient. Complete cure therefore may require more than one medicine.

Aside from their anti-parasitic activity, the use of antimalarial medicines for prophylaxis or therapy is dictated by their pharmacokinetics and safety. For example, quinine and primaquine, which have short half-lives and common toxicities, generally are reserved for treatment of established infection, and not used for prophylaxis in a healthy traveler.

Based on the action of AMMs on the life cycle of the parasite, AMMs can be classified as:

- **Tissue schizonticides**: That eliminate developing or dormant liver forms e.g. primaquine-for radical cure.
- **Blood schizonticides**: Act on erythrocytic parasites e.g. chloroquine, quinine-symptomatic treatment.
- **Gametocides**: That kill sexual stages and prevent transmission to mosquitoes e.g. chloroquine, quinine and primaquine.

3.2.2. Specific Antimalarial Medicines used in Ethiopia

A. Artemisinin derivatives

Artemisinin **(qinghaosu)** is the active component of a herbal medicine that has been used as an antipyretic in China for over 2000 years.

Pharmacokinetics

Artemisinin is insoluble and can only be used orally. Its derivatives have been synthesized to improve solubility and efficacy. These derivatives include *artesunate and artemether*: **Artesunate** (water-soluble; useful for oral, intravenous, intramuscular, and rectal administration); **Artemether** (lipid-soluble; useful for oral, intramuscular, and rectal administration). The analogs are rapidly absorbed, with peak plasma levels occurring in 1-2 hours. Half-lives after oral administration are 30–60 minutes for artesunate and dihydroartemisinin, and 2–3 hours for artemether. Medicine levels appear to decrease after several days of therapy. Artemisinin and analogs are very rapidly acting blood schizonticides against malaria parasites.

Clinical uses

The efficacy of the artemisinins is limited somewhat by their short plasma half-lives. Recrudescence rates are unacceptably high after short-course therapy, and these medicines are generally best used in conjunction with another agent. Also because of their short-half lives, they are not useful in chemoprophylaxis. Artesunate has also been effective in the treatment of severe malaria when administered rectally and parenterally.

Adverse effects

Artesunate and artemether appear to be better tolerated than most Antimalarials. The most commonly reported adverse effects have been dizziness and fatigue, anorexia, nausea, vomiting, and diarrhea. Others include abdominal pain, palpitations, myalgia, sleep disorders, arthralgia, headache, and rash.

Contraindications and Cautions: see below

Medicine interactions: under investigations

Lumefantrine

Lumefantrine, is available as a fixed-dose combination with artemether as Coartem® in some countries including Ethiopia. Lumefantrine is a drug with structural similarities to mefloquine.

Pharmacokinetics

The half-life of lumefantrine, when used in combination, is 4.5 hours. Oral absorption is highly variable and improved when the medicine is taken with food.

Clinical use

Artemether-lumefantrine (Coartem®) is highly effective in the treatment of P. Falciparum. Due to its reliable efficacy against this parasite, it is the first-line therapy for malaria in many countries including Ethiopia. Persons with severe and complicated malaria should not be treated with oral medications such as Artemether-lumefantrine(AL).

Contraindications

Artemether-lumefantrine:

- As malaria prophylaxis, either alone or in combination;
- For persons with a previous history of reaction after using the medicine;
- For pregnant women in the first trimester.

B. Quinine

Quinine is an alkaloid derived from the bark of the Cinchona tree, a traditional remedy for intermittent fevers from South America. Quinine was purified from the bark in 1820, and it has been used in the treatment and prevention of malaria since that time.

Pharmacokinetics

After oral administration, quinine is rapidly absorbed, reaches peak plasma levels in 1-3 hours, and is widely distributed in body tissues. The use of a loading dose in severe malaria allows the achievement of peak levels within a few hours. The half-life of quinine ranges between 11 hrs. (in healthy controls) -18 hrs. (in patients with severe malaria). The pharmacokinetics of quinine varies among populations. Individuals with malaria develop higher plasma levels of the medicine than healthy controls, but toxicity is not increased, apparently because of increased protein binding.

The volume of distribution is less in young children than in adults, and the rate of elimination is slower in the elderly than in young adults. In patients with acute malaria the volume of distribution is reduced, and systemic clearance is slower than in healthy subjects; these changes are

proportional to the severity of the disease. As a result, plasma quinine levels are higher in patients with malaria. Protein binding of quinine is increased in patients with malaria because of an increased circulating concentration of alpha-1 acid glycoprotein. Thus, the half-life of quinine is longer in those with severe malaria (18 hours) than in healthy controls (11 hours). Excretion is increased in acid urine. Small amounts appear in the bile and saliva.

Antimalarial action

Quinine is a rapidly acting, highly effective blood schizonticide against the four species of human malaria parasites. The medicine is gametocidal against *P. vivax* and *P. ovale* but not *P falciparum*. It is not active against liver stage parasites. The mechanism of action of quinine is unknown.

Clinical uses

Parenteral treatment of severe falciparum malaria

Quinine dihydrochloride is a second line treatment for severe falciparum malaria in the absence of artesunate. Quinine can be administered slowly intravenously or, in a dilute solution, intramuscularly. The medicine can be administered in divided doses or by continuous intravenous infusion; treatment should begin with a loading dose to rapidly achieve effective plasma concentrations. Therapy should be changed to oral quinine as soon as the patient has improved and can tolerate oral medications.

Oral treatment of falciparum malaria

Treatment of uncomplicated P. Falciparum malaria in pregnant women in the first trimester.

Adverse Effects

Therapeutic dosages of quinine commonly cause tinnitus, headache, nausea, dizziness, flushing, and visual disturbances, a group of symptoms termed **cinchonism**. Mild symptoms of cinchonism do not warrant the discontinuation of therapy. More severe findings, often after prolonged therapy, include more marked visual and auditory abnormalities, vomiting, diarrhea, and abdominal pain. Hypersensitivity reactions include skin rashes, urticaria, angioedema, and bronchospasm. Hematologic abnormalities include hemolysis (especially with G6PD deficiency), leukopenia, agranulocytosis, and thrombocytopenia.

Therapeutic doses may cause hypoglycemia through stimulation of insulin release; this is particularly a problem in severe infections and in pregnant patients, who have increased sensitivity to insulin. Quinine can stimulate uterine contractions, especially in the third trimester. However,

this effect is mild, and quinine remains the medicine of choice for severe falciparum malaria during pregnancy in the first trimester; or beyond if artesunate is not available. Intravenous infusions of drugs may cause thrombophlebitis. Severe hypotension can follow too-rapid quinine IV infusions.

Contraindications and Cautions

- It should be discontinued if signs of severe cinchonism, hemolysis, or hypersensitivity occur.
- It should be avoided (if possible) in patients with underlying visual or auditory problems.
- It should be used with great caution in those with underlying cardiac abnormalities.
- Dosage should be reduced in renal insufficiency.

Medicine Interactions

- Quinine should not be given concurrently with mefloquine and should be used with caution in a patient with malaria who has previously received mefloquine chemoprophylaxis.
- Aluminum-containing antacids may block absorption.
- Quinine can raise plasma levels of warfarin and digoxin.

C. Chloroquine

Chloroquine has been the medicine of choice for treatment of malaria since the 1940s, but its utility against P falciparum has been seriously compromised by resistance. It remains the medicine of choice in the treatment of P. vivax.

Pharmacokinetics

It is rapidly and almost completely absorbed from the gastrointestinal tract, reaches maximum plasma concentrations in about 3 hours. It is rapidly and extensively distributed to the tissues, including the placenta and breast milk, and is slowly released from tissues. Chloroquine is metabolized in the liver and it is principally excreted in the urine with an initial half-life of 3-5 days but a much longer terminal elimination half-life of 1-2 months.

Clinical uses

Chloroquine is the drug of choice in the treatment of non-falciparum malaria. It rapidly terminates fever (in 24-48 hours) and clears parasitemia (in 48-72 hours). Chloroquine does not eliminate dormant liver forms of *P vivax* and *P ovale*, and for that reason primaquine must be added for the radical cure of these species.

Adverse Effects

Chloroquine is usually very well tolerated, even with prolonged use. Pruritus is common, primarily in Africans. Nausea, vomiting, abdominal pain, headache, anorexia, malaise, blurring of vision, and urticaria are uncommon. Dosing after meals may reduce gastrointestinal disturbances.

Contraindications and Cautions

Chloroquine is contraindicated in persons with known hypersensitivity and persons with a history of epilepsy, psoriasis, or porphyria, in whom it may precipitate acute attacks of these diseases. Generally, it should not be used in those with retinal or visual field abnormalities or myopathy. Chloroquine should be used with caution in patients with a history of liver disease or neurologic or hematologic disorders. Chloroquine is considered safe in pregnancy and for young children. Dosage must be reduced in renal insufficiency.

Medicine interactions

- It should not be administered with calcium and magnesium containing antacids as they interfere with the absorption of chloroquine.
- It may raise plasma levels of warfarin and digoxin.
- Reduced metabolism and clearance with cimetidine;
- An increased risk of acute dystonic reactions with metronidazole;
- Reduced bioavailability of ampicillin and praziquantel;
- Reduced therapeutic effect of thyroxine;
- A possible antagonistic effect on the effects of carbamazepine and sodium valproate;

D. Primaquine

Primaquine is the medicine of choice for the eradication of dormant liver forms of P vivax and P ovale. However, anti-relapse therapy with primaquine for *P. vivax* malaria is not currently recommended in malaria-endemic areas except in malaria elimination-designated districts.

Pharmacokinetics

Primaquine is readily absorbed from the gastrointestinal tract. Peak plasma concentrations occur around 1–2 hrs. after administration and then decline, with a reported elimination half-life of 3–8 hrs. Primaquine is widely distributed into body tissues. It is rapidly metabolized in the liver. The major metabolite is carboxy-primaquine, which may accumulate in the plasma with repeated administration.

Antimalarial action

Primaquine is active against hepatic stages of all human malaria parasites. It is the only available agent active against the dormant hypnozoite stages of P vivax and P ovale. Primaquine is also gametocidal against the four human malaria species. Primaquine acts against erythrocytic stage parasites, but this activity is too weak to play an important role. The mechanism of antimalarial action is unknown.

Clinical uses

Prevention of relapse of P. vivax and P. ovale malaria

Standard chemoprophylaxis does not prevent a relapse of vivax or ovale malaria, as the hypnozoite forms of these parasites are not eradicated by mefloquine and other available agents. To markedly diminish the likelihood of relapse, the use of primaquine after the completion of travel to an endemic area.

Pair Reading for 5 minutes

Treatment of severe malaria

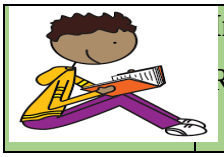
Adverse Effects

- The most important adverse effects are hemolytic anemia in patients with G6PD deficiency, other defects of the erythrocytic pentose phosphate pathway of glucose metabolism, or some other types of haemoglobinopathy variants, hemolysis may be much more severe.
- Therapeutic doses may also cause abdominal pain if administered on an empty stomach. Larger doses can cause nausea and vomiting and relatively rare at daily doses up to 0.25 mg base/kg.
- Methemoglobinemia may occur. Other uncommon effects include mild anemia and leukocytosis. Over dosage may result in leukopenia, agranulocytosis, gastrointestinal symptoms, hemolytic anemia and methemoglobinemia with cyanosis.

Contraindications and Cautions

- Primaquine should be avoided in patients with a history of granulocytopenia or methemoglobinemia, in those receiving potentially myelosuppressive medicines (e.g. quinidine), and in those with disorders that commonly include myelosuppression.
- It is never given parenterally because it may induce marked hypotension.

- Patients should be tested for G6PD deficiency before primaquine is prescribed. When a patient is deficient in G6PD, treatment strategies may consist of withholding therapy and treating subsequent relapses, if they occur, with chloroquine; treating patients with standard dosing, paying close attention to their hematologic status; or treating with weekly primaquine (45 mg base) for 8 weeks.
- G6PD-deficient individuals of Mediterranean and Asian ancestry are most likely to have severe deficiency, while those of African ancestry usually have a milder biochemical defect. This difference can be taken into consideration in choosing a treatment strategy.
- In any event, primaquine should be discontinued if there is evidence of hemolysis or anemia.
- Primaquine should be avoided in pregnancy because the fetus is relatively G6PD-deficient and thus at risk of hemolysis.
- Medicines liable to increase the risk of hemolysis or bone marrow suppression should be avoided.



ndividual Reading for five minutes

Read Mefloquine and Atovaquone-Proguanil

E. Mefloquine

Mefloquine is one of the recommended chemoprophylactic medicines for use in Ethiopia.

Pharmacokinetics

It can only be given orally because severe local irritation occurs with parenteral use. It is well absorbed, and peak plasma concentrations are reached in about 18 hours. Mefloquine is highly protein-bound, extensively distributed in tissues, and eliminated slowly. The terminal elimination half-life is about 20 days, allowing weekly dosing for chemoprophylaxis. With weekly dosing, steady-state levels are reached over a number of weeks. Mefloquine and acid metabolites of the medicine are slowly excreted, mainly in the feces. The medicine can be detected in the blood for months after the completion of therapy.

Antimalarial Action

Mefloquine has strong blood schizonticidal activity against *P falciparum* and *P vivax*, but it is not active against hepatic stages or gametocytes. The mechanism of action of Mefloquine is unknown.

Clinical Uses

Mefloquine is effective in prophylaxis against most strains of *P falciparum* and probably all other human malarial species as well. Eradication of *P vivax* and *P ovale* requires a course of primaquine.

Adverse Effects

Weekly dosing with mefloquine for chemoprophylaxis may cause nausea, vomiting, dizziness, sleep, notably insomnia and abnormal dreams and behavioral disturbances, epigastric pain, diarrhea, abdominal pain, headache, rash, dizziness, neuropsychiatric toxicities and leukocytosis, thrombocytopenia, and aminotransferase elevations have been reported.

Contraindications and Cautions

Mefloquine is contraindicated if there is a history of epilepsy, psychiatric disorders, arrhythmia, cardiac conduction defects, or sensitivity to related medicines. Mefloquine use is safe throughout pregnancy, although experience in the first trimester is limited. Mefloquine should be discontinued if significant neuropsychiatric symptoms develop.

Medicine interactions

There is a possible increase in the risk of arrhythmia if mefloquine is given together with beta blockers, calcium channel blockers, amiodarone, digoxin, or antidepressants; there is also a possible increase in the risk of convulsions with chloroquine and quinine. Mefloquine concentrations are increased when given with ampicillin, tetracycline, and metoclopramide. Caution should be taken with alcohol.

F. Atovaquone-Proguanil

Atovaquone-proguanil can be used as antimalarial chemoprophylaxis in Ethiopia.

Pharmacokinetics

Atovaquone-proguanil is only administered orally. Its bioavailability is low and erratic, but absorption is increased by fatty food. The medicine is heavily protein-bound and has a half-life of 2-3 days. Most of the medicine is eliminated unchanged in the feces.

Antimalarial action

The mechanism of action of atovaquone is uncertain.

Clinical uses

A fixed combination of atovaquone (250 mg) and proguanil (100 mg) is highly effective for chemoprophylaxis of falciparum malaria in persons greater than 40 Kgs. For chemoprophylaxis, Atovaquone-proguanil must be taken daily. It has an advantage over mefloquine in requiring shorter periods of treatment before and after the period at risk for malaria transmission, but it is more expensive than the other agents. It should be taken with food.

Adverse Effects

Atovaquone-proguanil is generally well tolerated. Adverse effects include abdominal pain, nausea, vomiting, diarrhea, headache, and rash, and these are more common with the higher dose required for treatment.

Contraindications and Cautions

The safety of atovaquone in pregnancy is unknown. Reversible elevations in liver enzymes have been reported.

Medicine interactions

Plasma concentrations of atovaquone are decreased about 50% by co-administration of tetracycline or rifampin.

Session summary

- AMMs can be categorized by the stage of the parasite that they affect and by their intended use for either prophylaxis or treatment.
- AMMs are categorized into
    - Tissue schizonticides
    - Blood schizonticides
    - Gametocides
- AMMs have specific pharmacokinetics, antimalarial action, clinical uses, adverse effects, contraindications and cautions, and medicine interactions that need to be considered while prescribing and dispensing.

Chapter 4. Supply Chain Management of Antimalarial Pharmaceuticals

Chapter Description:

This chapter describes an overview of supply chain management (SCM) of Antimalarial Pharmaceuticals (AMPs) in relation to peculiarities of selection & quantification, procurement, inventory management, warehousing, distribution, and LMIS. It also deals with the malaria peculiarities affecting supply chain management of AMPs.

Primary objective

The primary objective of this chapter is to enable participants describe the supply chain management of antimalarial pharmaceuticals available in Ethiopia.

Enabling objectives:

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

- Identify product, disease, and service peculiarities of AMPs and how these affect SCM of AMPs
- Describe how selection, quantification, and procurement is conducted at national level
- Discuss Reporting, Requesting, and Distribution of AMPs
- Describe the pharmaceutical management information system (PMIS)
- Describe good storage practices and Inventory management of AMPs

Chapter outline

- Peculiarities of AM pharmaceuticals that affect SCMs
- Selection, Quantification and Procurement
- Reporting, Requesting, and Distribution
- Pharmaceuticals Management Information System (PMIS)
- Receiving and Storage of AMPs
- Inventory Management
- Chapter Summary

4.1. Peculiarities of AMPs that affect SCMs

4.1.1. Background

Antimalarial pharmaceuticals, particularly Artemisinin-based combination therapies (ACTs) and rapid diagnostic test kits (RDTs) have special characteristics that influence their shelf life, packaging, and cost. Thus, they may require special handling or modifications to the existing supply chain. Furthermore, compared to many diseases, malaria and its control have peculiar characteristics, such as seasonality, heterogeneous transmission, and a history of treatment provided at the community level. The particular nature of the disease, and related services and products, influence supply chain management for malaria as outlined below.

4.1.2. Product Characteristics

Describe characteristics of AMPs that affect the SCM?

Artemisinin-based combination therapies (ACTs)

- **Presentation:** Available multiple formulations and presentations include fixed-dose combinations (FDCs), co-blistering, and packaging by weight bands. Various presentations must be managed separately and are often presented in a single setting. Often, during stock outs, these presentations may be cut or combined to provide treatments. But, it should be noted that cutting or crushing these tablets would lead to instability and inaccurate dosages. Combining of different weight bands may also more than double or triple a dose if a caregiver is not careful with dosages being combined. Such practices might also create stock shortages or wastages at different levels.
- **Packaging:** ACTs are bulky, requiring larger storage spaces because they are typically in blister packs, often with patient information printed on the packaging. Despite recent efforts to reduce package size, ACTs require more space than other essential medicines.
- **Storage:** Room temperature storage conditions (15°C-25°C) are recommended to ensure full length of shelf life.
- **Shelf life:** Most ACT formulations have a relatively shorter shelf life than other essential medicines (24-month shelf life).

- **Manufacturers:** Multiple manufacturers produce ACTs, but only a few offer pharmaceutical preparations approved by a stringent regulatory authority (SRA) or WHO prequalified creating challenges in accessing quality AMPs.
- **Cost:** ACTs have significantly high value relative to most essential medicines and thus potentially more susceptible to pilferage.
- **Resistance:** AMPs are susceptible for resistance. In Ethiopia, ACT resistance is not yet detected.

Rapid diagnostic test kits (RDT)

- **Storage:** RDT packaging tends to be bulky and requires larger storage spaces. Furthermore, some products require storage temperature between 2°C and 30°C.
- **Shelf life:** RDTs have a relatively short shelf life of about 24 months at ambient temperatures. Shelf life varies by manufacturer and type.
- **Cost:** RDTs are high cost (not value), so limiting waste and damage is critical.
- **Kitting**: Some RDTs require additional consumables such as capillary tubes and buffer solution not included as part of a kit or consumed at a different pace than other items in the kit. Thus, it may be necessary to procure these consumables separately and/or be careful to avoid wastage.
- **Quality assurance:** High rates of substandard, counterfeit medicines are found in public and private sectors.

4.1.3. Disease Characteristics

What peculiar characteristics of Malaria do you know and how they affect the SCM?

- **Patterns:** In terms of disease patterns and manifestations, variations can occur in prevalence, seasonality, and geographic distribution within a country and contribute to different methods used.
  - ***Endemic vs. epidemic:*** Based on type of exposure, the disease can have different appearances. Its endemicity may impact testing and treatments policies, and disease presentation in the population (e.g., susceptibility of patients and percentage of febrile patients with malaria). Those in turn impact supply chain functions like selection and quantification. Furthermore, recent intensive preventive measures are

expected to have an impact, shifting prevalence from endemic to epidemic manifestations.

- ***Seasonality:*** The disease has seasonal fluctuations in some areas, with increased cases after the rainy seasons.
- ***Geography:*** Certain regions of a country—lower altitude, wetter, more dense foliage—may provide more hospitable environments for malaria-carrying mosquitoes. Urban areas may have a lower magnitude of transmission than rural areas

- **Transmission:** Disease transmission is difficult to prevent and can affect all groups of a population. The most vulnerable groups are children under five years of age, pregnant women and the immuno-compromised, such as people with HIV and AIDS.
- **Treatment:** For uncomplicated malaria, ACTs are recommended. Complicated or severe malaria is often treated with injectable artesunate or quinine.

4.1.4. Service Model Characteristics

What peculiar characteristics of the service model affect the AMP SCM?

- **RDT use policy**
- **Malaria diagnosis:** Microscopy remains the golden standard for parasitological confirmation to diagnose malaria. Regardless of increased use of RDTs, microscopy will still be a key component of national lab standards for use at higher level facilities (hospital and health center) and in areas of low transmission
- Simultaneous expansion of prevention efforts using LLINs and indoor residual spraying (IRS), improved diagnosis, and rapid, effective treatment**:**
- **Treatment:** While treatment of uncomplicated malaria can be administered at all levels of the health system, severe malaria cases are generally referred to a higher level of care.
- **Community case management:** the Health Extension Program (HEP) package has been expanded to include prevention and treatment of malaria.

Hence, some of the above peculiarities affect the supply chain management activities, particularly quantification, storage, distribution and efficient utilization of antimalarial pharmaceuticals.

4.2. Selection, Quantification and Procurement

What is the current practice of AMPs selection in their respective workplaces?

Selection of AMPs

Selection involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual AMMs formulation and presentation, cost of AMMs.

Selection of AMPs is done at a national level considering prevalent malaria species, resistance to AMMs, and national and global treatment recommendations. Accordingly, health facilities should develop their own facility-specific list and, based on the local context, they should include essential medicines, including AMPs, in their list and based on the level of health facility. At health facility level, AMPs selection should be the responsibility of Drug and Therapeutics Committees (DTCs).

Quantification of AMPs

Quantification involves estimating the quantities needed of specific AMPs, the funding required, and when the AMPs should be delivered to ensure an uninterrupted supply for the program. Proper AMPs quantification helps to minimize stock out of AMPs, to plan, mobilize and secure financial resources, to guide timely, appropriate supply plans and procurement, and to inform manufacturers on the national demand.

Quantification of AMPs is conducted nationally by FMOH and PFSA in collaboration with other stakeholders. It is done every three years and is revised every year based on recent data. Data sources for AMPs quantification

- Health Management Information system (HMIS) data
- Malaria Public Health Emergency management (PHEM) data
- Malaria Consumption data
- Survey data
- Program policy and plans: National malaria Strategic plan,

Most of the data required come from health facilities and it is crucial to ensure the accuracy and completeness of the data to conduct a successful quantification.

Quantification has the following phases:

- *Preparation*: Describe the program, define the scope, and purpose, collecting the required data
- *Forecasting*: organize, analyze, and adjust data, build forecasting assumption, calculate the forecasted consumption for each items, reconcile forecasts to produce final estimate
- *Supply Planning:* Organize, analyze and adjust data, build supply planning assumptions, calculate the total antimalarial pharmaceuticals requirement and cost, develop supply plan, compare costs to available fund.

Procurement

The procurement of AMPs is executed mainly by PFSA. The procurement process follows the national and international procurement regulations through international competitive bid. But health facilities request AMPs from PFSA based on their consumption according to the IPLS principles.

4.3. Reporting, Requesting and Distribution

Reporting and requesting in AMPs Management

Basically, reporting and requesting process in AMPs management is conducted as per the IPLS. Hence, except on the peculiar characteristics, all the principles of IPLS are implemented in the management of AMPs. Hence, in order to manage the AMPs properly, keeping good patient data, consumption and other records and also implement the IPLS principles efficiently at all levels is very critical.

Look Ahead Seasonality Indices (LSI) Model

Diseases like malaria have a unique feature of seasonal variations. In some periods there will be only few cases of the disease and during other periods higher number of cases will be registered. In such conditions, it is difficult to distribute AMPs based on mere monthly consumptions because facilities may end up in under- or over-stocks (see Figure 5). Hence, to adjust the historical consumption for such seasonal variations would be mandatory.

Look-Ahead Seasonality Indices (LSI) are sets of supply chain, tier-specific indices that adjust current consumption rates to create a look-ahead forecast for consumption by taking seasonality of the disease and current level of consumption of AMPs into considerations. Accordingly, each resupply period will have its own index to adjust the historical consumption. LSI is developed

annually at central level considering PHEM data. The LSI figures will be shared to PFSA hubs and health facilities.

Hence, the concept of LSI is to adjust historical calculated consumption or AMC for seasonal variability to be used for *resupply decisions* and *stock status assessment*. Resupply decision for AMPs are based on IPLS records and forms; but, it takes the malaria seasonality into consideration.

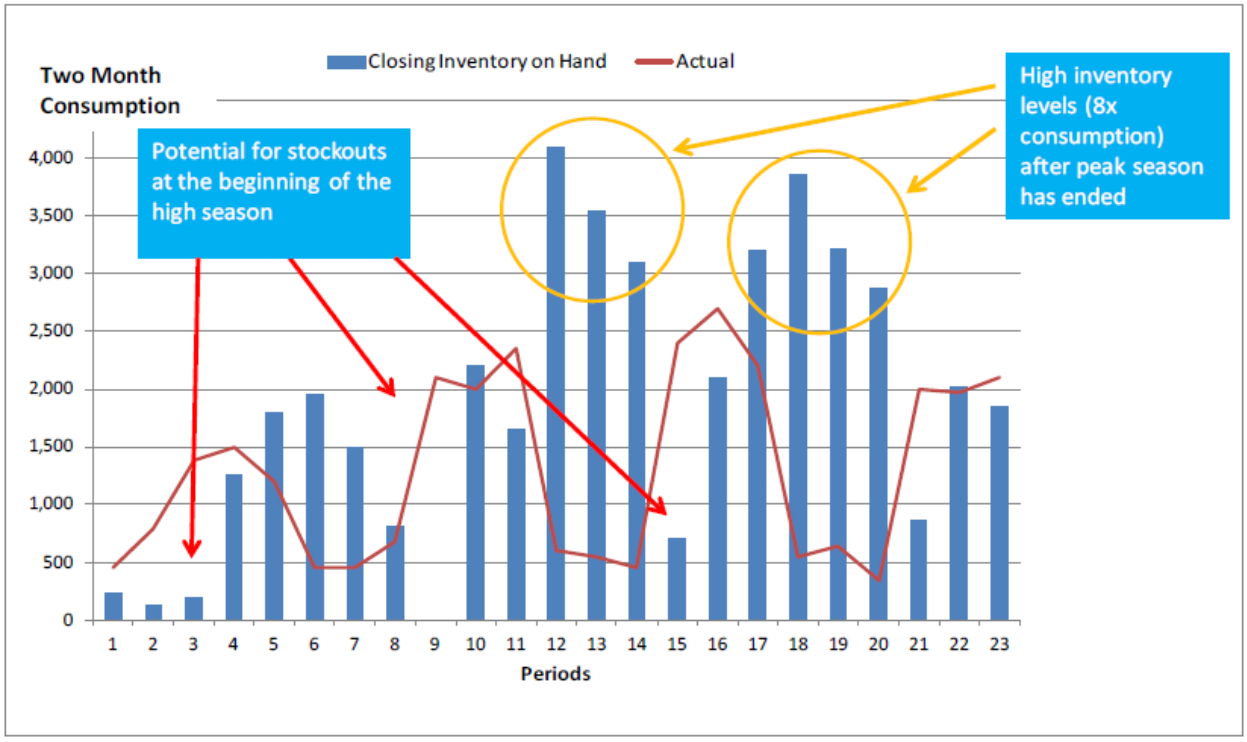


Figure 5. Variation of AMC of AMPs across different months in the year

Exercise on Reporting and Requesting of AMPs using LSI?

LSI is used for both resupply decisions and stock assessment of AMP.

A. Resupply decisions:

Order Quantity = (120*CC) / (60 – DOS) *LSI (Specific to the resupply period) – SOH

Where, CC – Calculated Consumption

DOS – Days Out of Stock

Example: Suppose a Health Center had a calculated consumption of 40 doses and Stock on hand (SOH) at store and dispensary is 86 doses on *June 1- July 30* for AL-6x4 presentation. Assume the HF was not stocked out during the period and the health center is being resupplied with even categories of the branch. LSI for *August -September* is 1.60. Calculate order quantity for a Health center.

1. Without LSI: resupply Quantity = (120*CC) / (60 – DOS) – SOH.

   = (120*40)/ (60-0)-86

   =80-86

   = (-) 6…no resupply quantity needed.

2. With LSI: resupply quantity= (120*CC) / (60 – DOS) **LSI*) – SOH.

   = (120*40)/ (60-0)*(1.60)-86

   = (80*1.60)-86

   =42 doses….Quantity to be resupplied.

In the above example, If LSI was not used, the HF would not have requested additional quantity and hence, the facility might face stock out of AMPs.

B. Stock Assessment:

Months Of Stock = SOH ÷ (CC*LSI)

Example: The store manager is doing stock assessment on May 26, 2015, and found calculated consumption for a month March-April of a health center for AL was 114 doses and the SOH is 37 doses. Assume there was no stock out during the period and LSI for May – June is 1.60

a. Without LSI: MOS=SOH/AMC: 37/57= 0.64
b. With LSI: MOS= SOH/(AMC*LSI): 37/(57*1.60)=0.40

The store manager should request emergency order immediately when LSI is used for assessing the stock status. Otherwise, the health facility might have resulted in stock out soon.

Distribution of AMPs

In general, distribution of AMPs from the Central PFSA to branches and from branches to health facilities or district health offices (for *pass through districts*), and ultimately to health facilities, is conducted following requests from branches and health facilities or district health offices using

Reporting and Requesting Forms (RRF) within the review period, as per the principles of IPLS. LLINs and Insecticide Residual Spray (IRS) chemicals are distributed based on national targets and risk factors.

For efficient management of AMPs, health facilities should update their records routinely, monitor their consumption patterns for AMPs, assess their stocks closely, and request regularly and periodically to get AMPs on timely manner.

4.4. Pharmaceuticals Management Information System (PMIS)

Introduction to PMIS for AMPs Management

Effective PMIS integrates pharmaceutical data collection, organization, analysis/synthesis and reporting to facilitate evidence-based decision making to manage pharmaceuticals and services. This requires getting relevant, accurate, and timely information.

Effective pharmaceutical management requires policy makers, program managers and health care providers to monitor information related to patient adherence, drug resistance, availability and use of medicines and laboratory supplies, patient safety, product registrations, product quality, financing, and program management, among other issues.

Logistic management information system (LMIS) is product information system which primarily supports the logistic management decision making processes. The three essential data elements that are required to make a supply management decisions are: Stock on Hand, Consumption and Losses/Adjustments.

Dispensing registration book is the primary source of information for medicines dispensed to malaria patients. The registration enables the health facility to correctly document each medicines dispensed to patients. This in turn will help the pharmacy department to know the exact consumption of the medicines during the specified period. The following data can be captured from the registration book

- Patient data,
- Actually dispensed medicine,
- Diagnosis

To enhance the efficiency of supply chain management in malaria program, morbidity data should be used along with LMIS data for logistics decision and monitoring of the program performance. The morbidity data can be captured from HIMS Unit, in patient ward, outpatient ward and different dispensing unit. Moreover, data from medicine dispensing register , stock on hand at the dispensary

and store room should be used in addition to stock on hand or balance on the inventory records in pharmacy stores while computing quantity of stock to be ordered. The data from the two sources shall be triangulated for better data quality.

Data quality for AMPs supply management decision

Brainstorming Questions

What are the factors for poor data quality with respect to data completeness, accuracy, and timeliness?

The ultimate target for data quality should be to generate quality data which can be usable for decision making at different levels in the supply chain management.

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, HPMRR, RRF and other inventory records for making sound decision.

- **Timeliness** indicates filling the IPLS forms and reporting within agreed days in the schedule.
- **Completeness** refers to the degree of transferring the essential data items in the forms and reports.
- **Accuracy** is all about the correct posting of data and arithmetic calculations.

Contributing factors for poor data quality include:

i. Delay in reporting due to:
   - Lack of awareness on the benefits of timely reporting
   - Forgetfulness
   - Low staffs' commitment and
   - Low enforcement by the management

ii. Challenges related to data completeness and accuracy
   - Negligence
   - Knowledge gaps (program items)
   - Lack of regular bin card updating
   - Data manipulation

Therefore, to address these data quality problems, proper monitoring and capacity building activities should be implemented at all levels. Health professionals' commitment and the management support are very critical in this regard.

4.5. Receiving, Storage and Inventory management of AMPs

Experience Sharing
Describe the procedures you conducted during receiving of newly arrived AMPs at the health facility?

Receiving of AMPs

To receive AMPs by the health facility, health professionals should conduct the following:

- A visual inspection of the AMPs
- Counting the quantities of each AMPs
- Verifying the quantities against the invoices and request. Sometimes the quantity to be resupplied may differ from the requested quantity as PFSA decide resupply quantity taking in to consideration LSI.
- Recording damaged and short received AMPs and report
- Updating bin cards and stock card for the received AMPs and quantities.
- Storing AMPs appropriately

Good Storage Practices

Well-functioning warehouses and storerooms at various levels should have sufficient space, acceptable storage conditions, explicit QA mechanisms, adequate product security, and standard storage procedures.

The following recommendations consider special characteristics of malaria products.

- Sufficient storage space should be allocated for ACTs and RDTs considering SOH and stock in pipeline.
- ACTs require storage at room temperature (15°C - 25°C), while some RDTs and suppositories require cool storage (2°C-30°C). RDTs should be kept in the coolest part of the store but may not require refrigeration and should never be frozen. AMPs, in general, should not be stored under direct sunlight and humid conditions. There should also be adequate ventilation.

- Some malaria products such as ACTs and RDTs are significantly high value relative to most essential medicines managed through supply chains and thus appropriate security during storage and distributions required.
- RDTs generate infectious waste, such as sharps and blood collection devices, and non-infectious general waste, such as packaging (envelope), buffer and carton boxes. These types of waste should be handled and disposed of separately. For waste management of AMPs adhere to FMHACA waste management directives.
- In addition to visual inspection being done during receiving, to ensure the quality of the product in a store, visual inspection should be conducted when any of the following occur:
    - Conducting a physical inventory
    - Dispensing AM products to a client
    - Issuing AMPs from store to internal dispensing units
    - Receiving complaints from customers
    - AMPs are about to expire, show signs of damage
- You can refer to IPLS SOP for better understanding of storage guideline

Inventory Management

A well designed and well operated inventory control system helps to prevent shortages, over stock, and expiry of pharmaceuticals. To efficiently manage their inventory, health professionals should keep their inventory records up to date and monitor stock status closely to avoid frequent emergency orders. The inventory control system for the IPLS is a Forced Ordering Maximum/ Minimum inventory control system meaning health facilities are required to report on a fixed schedule (monthly at health posts, every other month at health centers and hospitals) for AMPs. But, if the stock on hand for AMPs falls below a set emergency order point before the end of the reporting period, an emergency order should be placed immediately.

Stock status Analysis

To assess the stock status of AMPs, two pieces of data are needed to calculate the Months of stock (MOS):

- Stock on hand (physical inventory)
- Average monthly consumption (AMC)

Formula for MOS

$$\frac{Stock\ on\ hand}{AMCxLSI\ for\ current\ reporting\ period} = Months\ of\ stock$$

Note

- We need to make sure that actual patient level consumption data is recorded and reconciliation of consumption data and morbidity data is done as discussed in PMIS section.
- If Months of Stock on Hand is less than 0.5, an emergency order is needed.

4.6. Chapter Summary

- The peculiar nature of the disease, and related services and products present particular logistics and program management challenges for malaria.
- Resupply decisions for AMPs should consider seasonal nature of the disease
- Selection, Quantification and procurement of AMPs are conducted at national level
- Basically, reporting and requesting process, in AMPs management, is conducted according to the IPLS using existing reporting formats.
- *Look-ahead Seasonality Indices (LSI) Model* is employed for AMPs resupply decisions and stock status assessments
- Good Storage Principles should be maintained for AMPs considering their peculiar nature

Chapter 5. Rational Use of Antimalarial Medicines

Chapter Description

This chapter discusses about rational use of antimalarial medicines (AMMs). The chapter systematically identifies and discusses instances of irrational use of AMMs, underlying causes, and consequences of irrational use of AMMs. Then, it discusses on the interventions to promote the rational use of AMMs. Finally, steps in good dispensing practice of AMMs is described.

Primary Objective

The primary objective of this chapter is to enable participants promote rational use of AMMs through the practice of good dispensing practices and related interventions.

Enabling Objectives

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

- Discuss rational use of AMMs
- Apply good dispensing practices of AMMs.

Chapter outline

5.1. Overview of Rational Use of AMMS

5.1.1. Introduction to rational use of AMMs

The medicine use process includes prescribing, dispensing, and use by the patient. According to WHO, rational use of medicines requires that "patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community"

Rational use of AMM requires:

- Appropriate indication (prescribing is based on sound and appropriate medical considerations that includes thorough patient clinical history taking, laboratory diagnosis and confirmation, and adherence to laboratory test findings)
- Appropriate medicine selection based on the identified malaria parasite (the medicine is of suitable efficacy, safety, and cost).
- Appropriate dosage, route of administration, and duration of therapy.
- Appropriate patient (no contraindications exist, and the likelihood of adverse drug event is minimal).
- Appropriate dispensing (patients are properly counseled on the prescribed AMMs including dose, route and frequency of administration, duration of therapy and storage condition, etc.)
- Patient adherence to treatment (patients taking the prescribed and dispensed medicine following the information given by the prescriber and dispenser)

In summary, rational use of AMMs demands individual and collaborative effort of prescribers, pharmacy professionals, and the patient/client.

5.1.2. Irrational use of AMMs, causes, and its consequences

Experience Sharing
Irrational use of AMMs, causes, and consequences (prescribing, dispensing, and patient use)

Irrational use of AMMs

Irrational use of medicines is a major problem worldwide. The problem is much more significant in developing countries like Ethiopia. It occurs in health facilities or at home. In general, it is estimated that more than half of all medicines are prescribed, dispensed, or sold inappropriately. It is also estimated that half of all patients fail to adhere to treatment regimens.

Irrational use of AMMs may involve:

- the use of these medicines when they are not needed and/or when laboratory result shows negative for malaria parasites;
- the use of wrong and ineffective AMMs such as use of chloroquine for treating p. falciparum malaria;
- the use of unsafe drug, for example use of Artemether + lemefantirine (AL) during first trimester of pregnancy;
- the use of unnecessarily too many AMMs (use of chloroquine and AL tablets to treat mixed cases of malaria);
- the use of wrong dosage or route of administration (use of oral dosage forms to treat severe malaria cases or use of injectables to treat uncomplicated malaria);
- the use of adult formulation/presentation for pediatric and vice versa.
- The use of RDT for diagnosis of malaria at hospitals and health centers.
- under use of effective and available medicines (e.g. Patients interrupting taking full course of therapy when the symptoms subside); etc.

Within a health facility, it is important that prescribers, dispensers, and the management, recognize the existence of a problem. Problems can be recognized through indicator studies, economic analysis (ABC analysis), patient satisfaction survey, etc. Therefore, establishing a consensus that there is a problem for which action is needed and securing support from all interested parties are important tasks. This should be done through the DTC.

Causes of irrational use of AMMs

Many interrelated factors influence medicines use. Underlying causes and motivating factors must be investigated and understood before suggesting intervention strategy. This can be identified through qualitative studies such as focus group discussions, interviews, and observations. An intervention that is applied prior to identifying underlying the cause and motivating factors will not be successful. The prescriber, the dispenser, the patient, the community, and the health system are all involved in the therapeutic process and can contribute to irrational use of AMMs.

Health System

Health system related factors include unreliable supply of medicines, shortages, expiry, and availability of counterfeit and ineffective medicines, poor diagnostic facilities, and absence of treatment guidelines etc.

Prescriber

Prescriber related factors include inadequate training on current malaria treatment protocols and poor adherence to treatment guidelines. In addition, prescribers could be influenced by biased medicine information provided by medical representatives. Moreover, heavy patient load and pressure to prescribe from peers, and patients are some of the factors related to prescribers.

Dispenser

The quality of dispensing may be affected by the training and supervision the dispenser has received and the drug information available to the dispenser. A shortage of dispensing materials and short dispensing time due to heavy patient load may also have an adverse impact on quality of dispensing.

Patient and Community

Patient related factors that contribute to irrational medicine use include:

- non- adherence to treatment
- poor interaction between provider and patient,
- patient demands treatment and the prescriber feels obliged to give what is available, even if the drug is not the correct one to treat the condition.
- medicine misinformation
- sociocultural beliefs
- beliefs about the efficacy of certain drugs or routes of administration.

E.g. many patients prefer injections with a belief that injections are more powerful than oral dosage forms.

Consequences of irrational medicine use

Irrational use of medicines has adverse consequences some of which can be serious. These problems include but are not limited to the following:

- Compromises the quality of patient care
- Decreases outcome of treatment
- Increases the likelihood of adverse drug reaction
- Deaths and sufferings might increase
- Increased the likelihood of emergence of drug resistant organisms such as chloroquine resistance for P. falciparum and sulfadoxine-pyremethamine for p. vivax and p. falciparum.

- Early stock out and creates erratic supply. Ex. AL face such a problem.
- Wastage of resources. AMMs are not cheap; they are funded by donors and available for free.
- Prolonged disease and hospitalization, which intern aggravates suffering and resource wastage
- Transmission of the disease to other persons also increases.
- Psycho-social impact associated with irrational medicine use. People may develop a feeling that they need drug for any type of ailments they are having even for trivial ones. Excessive reliance on drugs and the belief that there is "a pill for every ill" might lead to a vicious cycle.
- There will be a loss of trust on the program or health system by the society.

If AMMs are used irrationally, all the efforts, time and money spent on other medicine supply management functions will lose their objectives in addition to wastage of resources.

5.1.3. Interventions to promote the rational use of AMMs

Types of interventions

Four major types of strategies exist for improving drug use (see box below). These are educational, managerial, economic, and regulatory interventions. Depending on the type of the problem identified, one or more of these strategies could be suggested to alleviate a known problem on drug use.

Interventions need to be chosen considering the following factors:

- the effectiveness with which it addresses the underlying causes of the problem;
- its success rate in similar situations, areas, or countries;
- its cost; and
- whether or not it can be sustained with available resources (human, material, and financial resources)

Outcomes should be monitored during and after implementing interventions. Depending on the results of the evaluation, restructure your interventions or improve your diagnosis of the underlying causes. In general, due to the complexity of factors involved, it is unlikely that any single intervention will work in every situation to avoid or reduce irrational use of AMMs.

Interventions to improve rational use of AMMs include: Educational Strategies, Managerial Strategies, Economic Strategies, and Regulatory Strategies (see box below).

Reading Exercise and large group revision

Read box 4.1: Strategies to improve medicine use for five minutes

Box 4.1: Strategies to improve medicine use:-

Education Strategies	**Managerial Strategies**
Training of prescribers and dispensers • Pre-service (formal education) • In-service (continuous professional development) • Supportive supervision visits • Group lectures and seminars on selected RMU topics **Printed materials** • Clinical literature and newsletter • Malaria treatment guidelines and medicine formularies • Illustrated materials to guide malaria treatment decisions (flyers, brochures) **Approaches based on face-to-face contact** • Medicine use education for patients • Influencing opinion leaders (clinical department heads) on the rational use of AMMs	**Monitoring, supervising, and feedback** • Coordinated by drug and therapeutics committee (DTC) • Also led by Woreda, Zonal and Regional health bureau health teams • With the involvement of health facility management • Self-assessment **Selection, procurement, and distribution of AMMs** • Adherence to national recommendations during selection and procurement **Prescribing and dispensing practices** • Applying malaria STGs and formularies • Medicine use review and feedback • Course of therapy packaging **Regulatory Strategies** • Medicine registration (obtaining medicines from registered sources) • Limited list of AMMs lists • Prescribing restrictions (by level of qualification) • Dispensing restrictions (by level of qualifications)

A. Rapid assessment and response (RAR)

Rapid assessment and response (RAR) is one way of making a comprehensive assessment of a specific public health issue and behavior within a short time frame. It is part of the retrospective medicine use evaluation (MUE) process that is applied to identify problems in the use of medicines; and propose and implement interventions. It involves focusing on the characteristics of the health problem, the population groups affected, key settings and contexts, health and risk behavior and social consequences.

MUE is an ongoing, systematic, criteria-based medicine evaluation technic that ensure appropriate medicine use

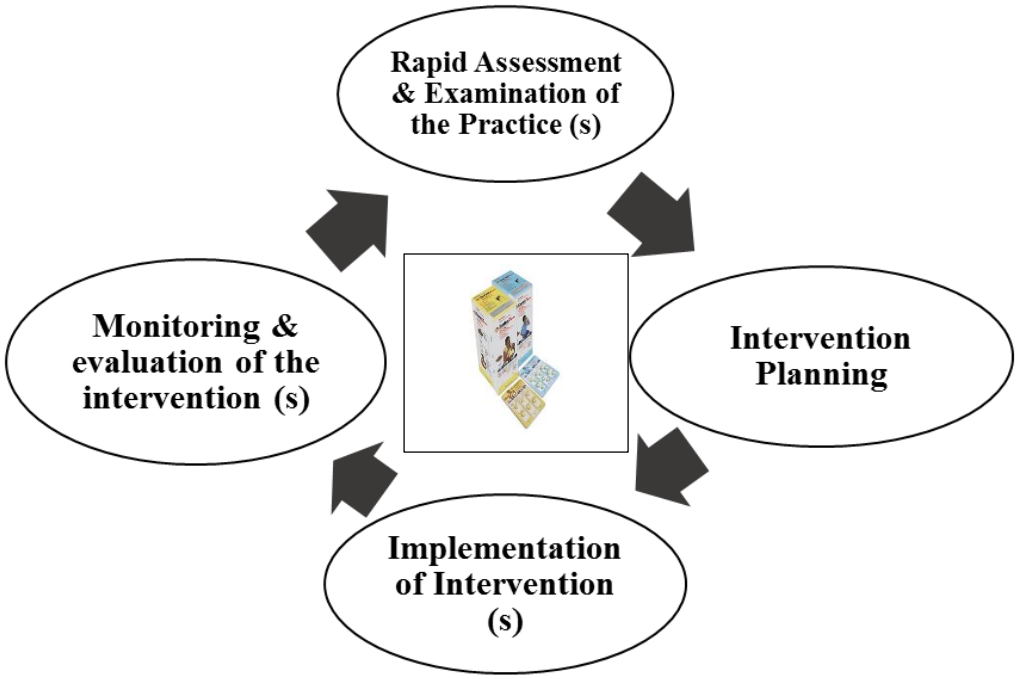


Figure 6. RAR Process

While evaluating the use of AMMs, RAR requires developing criteria for AMMs use in collaboration among prescribers, laboratory staff, pharmacy staffs and others according to the national malaria treatment guidelines (NMTGs) to be considered as a standard.

Criteria to define correct medicine use should be developed in terms of the following:

- *Appropriate AMM for the specific malaria parasite,*
- *Correct dose,*
- *Duration/quantity dispensed,*
- *Appropriate laboratory test,*
- *Contraindication,*
- *Medicine interactions, and others.*

In addition, individual malaria medication orders/patient charts are reviewed against the criteria. RAR follows the following steps:

- Collecting, analyzing, and evaluating malaria patient-specific data to identify antimalarial medicines prescribing, dispensing and use related problems.
- Interpreting and reporting findings in antimalarial medication-use processes.
- Intervention planning and implementation including providing materials (diagnostic equipment and supplies, copies of NMTGs) and training and taking other corrective measures based on the findings.

The indicators that can be used in AMMs RAR include:

Indicator 1. Availability of national malaria treatment guidelines (NMTGs)

- The indictor measures availability of NMGs at various malaria case management units including adult and pediatric OPDs, inpatient wards, and dispensing units.
- Theoretically, all of the outpatient, inpatient and dispensing units of every facility should have latest copy of national treatment guidelines.
- This indicator is used to measure the level of access to information to promote effective care and treatment of malaria.
- Although the presence of guidelines does not mean that the staff uses them, and although they do not exclusively ensure rational prescribing/dispensing, treatment guidelines do provide a reference source that supports more appropriate diagnosis, prescribing and dispensing practices.

Indicator 2. Percentage of malaria encounters treated in line with NMTGs

- This indicator measures the level of adherence to the national malaria treatment guidelines in terms of the appropriateness of AMMs selected, dose**,** frequency of administration, and duration of therapy.
- This indicator can be used to measure dispensing or prescribing practices. Also note that specific findings related to medicines selected, dose, frequency and duration of therapy shall be used for intervention.

Indicator 3. Percentage of malaria cases managed using clinical diagnosis only (without lab confirmation)

- This indicator measures the level of AMMs prescribing practice based on confirmation with laboratory diagnosis.

Note that:

- High percentages of indicator 1 and 2 indicates a positive behavior that should be reinforced whereas low percentages identify the need for improvement. But, high percentage of indicator 3 implies empirical prescribing practice that needs intervention.
- HMIS data can be used to measure the level of empirical/clinical malaria treatment.
- The findings of the rapid assessment should be shared with all pertinent staffs including the prescribers, laboratory and dispensing staffs and the management of the health facility.

Individual Reading Exercise and large group discussion

Read Medicine use education, DIS, Pharmaceutical care, Adverse drug event monitoring and reporting for 10 minutes.

B. Medicine Use Education on AMMs

Rational use of AMMs should be part of the health education program of the health facility. Patients need to know why they take the medicine, how to take medicine, expected benefits, common and serious side effects, how to store the medicines, the need of to complete course of treatment, not to share medicines and when to return if needed. In addition, patients should be educated to use medicine obtained from legal sources, AMM resistance, and adherence to AMMs, prevention and proper use of LLINs. But, most importantly the pharmacy team should include malaria topics in their health education program for the facility.

C. *Providing drug information service (DIS)*

Access to clinically relevant, up-to-date, objective, and unbiased medicine information is essential for rational use of AMMs. Although access to good drug information does not guarantee appropriate medicine use, it is certainly a basic requirement for rational drug use decisions. Identifying and accessing the sources of different types of drug information are important activities for a drug management program. Some of the activities are answering therapeutic and pharmaceutical queries from health care provider and patients related to AMMs, preparing, and disseminating drug alerts, newsletter and therapy updates related AMMs, preparing and providing regular medicine use education, and support pharmacovigilance activities, conduct and disseminate medicine use studies and support clinical pharmacy services.

D. Providing Pharmaceutical Care

The provision of pharmaceutical care for patients with malaria includes calculating the correct dose and reconstitution of Artesunate injection for severe malaria, recommending IV to PO switch for patients to be discharged, monitoring the response and toxicity of AMMs in admitted patients and providing ongoing and discharge medication use counseling in the inpatient wards. In addition, in the outpatient setting, pharmacy professionals should evaluate appropriateness of prescriptions and provide AMMs use counseling to promote adherence, hence treatment outcome.

E. Adverse drug event monitoring and reporting

Pharmacy professionals should coordinate efforts to prevent, detect, manage, and report adverse drug events (ADE) related the use of AMMs. ADE includes adverse drug reaction, medication error and product defect. ADE should be recorded and reported using the standard ADE reporting format to the regulatory authority (EFMHACA) and the feedback should be communicated to health care providers.

Group Exercises on RAR

Exercise 1 for Group 1

Exercise 1 for Group 1

Give the exercise on HMIS to Group 1 and tell them to use the HMIS report on annex 2 to measure the level of empirical/clinical malaria treatment and answer Question 1-3 below. The group has to complete the Health facility level Quarterly national malaria treatment guidelines adherence.

Q.1 Does this HMIS data help you identify any problem related to rational use of antimalarial medicines?

Q2. If yes, identify and explain the problem.

Q3. Is this HMIS data adequate to plan intervention to solve the problem identified? If no, what additional step do you have to do to get to the root cause of the problem?

Exercise 2 for Group 23. RAR exercise for p. falciparum

Instruct Group 2 to use the treatment register (Annex 3X) to evaluate the adherence to malaria treatment guidelines for patient with p. falciparum and identify which patient(s) received wrong treatment (wrong drug, wrong dose, wrong treatment duration, etc) in comparison with the

national malaria treatment guideline. Provide the group with the p. falciparum RAR (Annex 4) template to be used for analysis of the medicine use problem

Exercise 3 for Group 3. RAR exercise for P. vivax

Instruct Group 3 to use the treatment register (Annex 3X) to evaluate the adherence to malaria treatment guidelines for patient with p. vivax and identify which patient(s) received wrong treatment (wrong drug, wrong dose, wrong treatment duration, etc.) in comparison with the national malaria treatment guideline. Provide the group with the p. vivax RAR template (Annex XXX5) to be used for analysis of the medicine use problem

Exercise 4 for Group 4. RAR exercise for P. falciparum pregnant 1st trimester

Instruct Group 4 to use the treatment register (Annex 3) to evaluate the adherence to malaria treatment guidelines for pregnant patient in 1st trimester with p. falciparum and identify which patient(s) received wrong treatment (wrong drug, wrong dose, wrong treatment duration, etc.) in comparison with the national malaria treatment guideline. Provide the group with the pregnant patient RAR template (Annex 6) to be used for analysis of the medicine use problem

Exercise 5 for Group 5. RAR exercise for severe malaria

Instruct Group 5 to use the treatment register (Annex 3X) to evaluate the adherence to malaria treatment guidelines for patients with severe malaria and identify which patient(s) received wrong treatment (wrong drug, wrong dose, wrong treatment duration, etc) in comparison with the national malaria treatment guideline. Provide the group with the severe malaria RAR template (Annex XXXX7) to be used for analysis of the medicine use problem

Exercise 6 for Group 6. RAR exercise for mixed malaria

Instruct Group 6 to use the treatment register (Annex 3X) to evaluate the adherence to malaria treatment guidelines for patients with mixed malaria and identify which patient(s) received wrong treatment (wrong drug, wrong dose, wrong treatment duration, etc.) in comparison with the national malaria treatment guideline. Provide the group with the mixed malaria RAR template (Annex XXXXXX8) to be used for analysis of the medicine use problem

5.2. Good Dispensing Practice

Introduction

Dispensing practice plays a central role in the provision of rational AMMs use thereby ensuring effective treatment outcomes. All the resources required to bring the AMMs to the patient are wasted and patients suffer from ADRs if we do not implement good dispensing practice.

Introductory question:

What important points do you check on prescriptions while dispensing AMMs?

Introductory Case:

A male patient diagnosed with P. vivax and dyspepsia came to a pharmacy with a prescription for chloroquine and an antacid (magnesium hydroxide suspension). Because the dispenser was busy, no instruction about the medicines usage was given to the patient. After a week, the patient consulted his prescriber for no improvement of symptoms although he was taking both medicines together for the specified duration.

Question for Discussion

1. What possible reasons can you identify for the patient's lack of improvement?
2. What possible interventions do you recommend to minimize/avoid such drug therapy problems?

Steps of good dispensing practice of AMMs

Activities to be followed during proper dispensing of AMMs to the patient are described below:

a. Interpretation and evaluation of prescription with AMMs

- Check the prescription with AMM and evaluate for legality, legibility, and completeness.
- Confirm the diagnosis to make sure the medication is appropriate for the parasite type (also check the patient whether lab test has been done or not).
- Check the dose, frequency, and duration of treatment are correct.
- Check the weight band based on the age of the patient for dosing is appropriate.
- Ask the patient whether he/she took the same medication within two weeks or not.
- Ask whether any allergy/ADR the patient experienced while taking AMMs before.
- Check any contraindication on the medicine. E.g. AL during 1st trimester.
- Check any drug interaction on the prescription or with any medication the patient is taking.

b. Selection and manipulation of AMMs

Selection and manipulation of antimalarial medicines includes: -

- Do not select antimalarial medicine according to the color of medicine or container.
- Read the label on the package at least twice during the dispensing process.
- Check the expiry date.
- Open and close antimalarial medicine containers once at a time.
- Count AMMs on clean counting tray and spoon. Avoid short or over counting.

c. Labeling of AMMs

The purposes of a label for prescribed AMMs are to describe its identity, contribute to optimal therapeutic outcome and avoid medication errors, achieve appropriate handling and storage, and allow the product to be traced if there are problems with the manufacturing, prescribing or dispensing process. Labels on AMMs should be clear and legible and should always be written in a local language that patients easily understand.

Minimum medicine label information should include the following:

- Patient name
- Generic name, strength, and dosage form of the medicine
- Dose, frequency, and duration of therapy

- Quantity of the medicine dispensed
- How to take or administer the medicine
- Storage condition

d. Provision of information and instructions

All medicines should be dispensed with adequate and appropriate information and counseling. Written information should be provided to supplement verbal communication as appropriate. Adherence to malarial medication is related to knowledge about malaria, access to information on medication for malaria, and the perceived benefit of taking antimalarial medication. To ensure appropriate intake of prescribed drugs, direct observation of treatment is also important, especially for the first dose. However, as the patient load could sometimes be beyond the capacity of the health facility, there will be a need to give drugs to patients/caregiver on hand.

The following counseling points should be given during dispensing or beyond:

- Tell the patient or the caregiver about the benefit of taking the AMM.
- Instruct how to take the AMM. E.g. AL should be taken with food or milk.
- Inform the correct dose and frequency of the AMM.
- Inform the correct duration of treatment.
  - Emphasize that full course of treatment should be completed even if the patient feels well.
- Advise patients to consult healthcare workers before taking other medications while on AMMs.
- Give the first dose with direct observation if possible.
- If patient vomits within 30 minutes of taking a dose, then they should repeat the dose.
- Advise them to return immediately if symptoms persist or get worse.
- Inform the importance of taking antipyretics as recommended and fluid intake at home.
- Counsel to ensure good feeding or breast feeding.
- Counsel on measures to avoid mosquito bites
  - Remain indoors between dusk and dawn (mosquitoes carrying malaria bite at night).
  - Wear long-sleeved clothing, long trousers and socks when going out at night.
  - Sleep under LLIN.
- Inform appropriate storage condition (AMMs should be stored at temperatures of below 30^{o}C and should not be removed from the blister if it is not going to be used immediately).
- Check that patient or caregiver has understood the instructions before leaving the facility.

e. Recording the transaction

Antimalarial prescriptions should be recorded and documented as proof of transaction between the patient and the dispenser. The dispensing unit should have a standardized Antimalarial Medicines Dispensing Register (shown below) for recording every antimalarial medicine issued to a patient. Information obtained from the dispensing register should be used for monitoring rational use of AMMs. The information can also be used for quantification and efficient utilization of resource.

Chapter Summary

- Irrational use of AMMs problems include but are not limited to the following: Compromises the quality of patient care, decreases outcome of treatment, increases the likelihood of adverse drug reaction, deaths and sufferings might increase, increased the likelihood of drug resistance, etc.
- Interventions to promote the rational use of AMMs: -
    - Rapid assessment and response (RAR),
    - Medicine use education on AMMs ,
    - providing drug information service (DIS),
    - providing Pharmaceutical Care and adverse drug event monitoring and reporting
- The dispensing process ensures that antimalarial medicines are given out to the patient in a rational manner.
- The dispensing process has the following critical steps that should be followed at all times during dispensing of AMMs:
    - Interpretation and evaluation of prescription with AMMs
    - Selection and manipulation of AMMs
    - Labeling of AMMs
    - Provision of information and instructions
    - Recording the transaction

Chapter 6. Monitoring and evaluation of AMPM

Chapter description

This chapter will discuss monitoring and evaluation (M&E) of antimalarial pharmaceuticals management. The chapter starts by explaining importance of M&E in strengthening the supply and proper use of AMPs. Next, it describes the indicators that are used in monitoring and evaluation of AMPM. As part of assessing and following up on the activities on AMPM, the chapter concludes by giving highlights of supportive supervision and roles and responsibilities of stakeholders in monitoring and evaluating of AMPM.

Primary Objectives

The primary objective of this chapter is to enable participants describe Monitoring and Evaluation of AMPM.

Enabling Objectives

By the end of this session, participants will be able to:

- Explain the importance of M & E in strengthening AMPM.
- Recognize indicators used for monitoring and evaluating AMPM
- Describe supportive supervision at HFs
- Identify roles and responsibility of stakeholders in monitoring and evaluating of AMPM

Chapter outline

- Importance of M & E in strengthening AMPM
- indicators used for monitoring and evaluating AMPM
- Provision of supportive supervision at health facilities
- roles and responsibility of stakeholders in monitoring and evaluating of AMPM
- Session summary

Brainstorming

What is M&E system??

Do you have any M&E system to monitor and evaluate activities related to AMPM at your facility?

6.1. Importance of M & E in strengthening AMPM

Individual reading

- Read individually Importance of M&E in strengthening AMPM for five minutes

Monitoring and Evaluation (M&E) of AMPM refers to a process by which supply management and malaria treatment related data are collected and analyzed in order to provide the information necessary for effective malaria program planning and management. M&E helps to improve performance and achieve results. M&E of AMPM focuses on assessing inputs and implementation processes.

Purpose of AMPM M&E Framework

- To assess and measure the SCM and RMU of AMPs
- To improve performance
- To effectively manage the outcomes and outputs known as development results
- To support evidence based decision making process.

M&E generates new knowledge by identifying factors (individual, organizational, programmatic) that influence antimalarial pharmaceuticals supply management and malaria treatment outcomes in addition to justifying use of allocated resources (increasing cost-effectiveness). Hence, M&E should be taken as a backbone of antimalarial pharmaceuticals supply management and malaria treatment outcome that enables effective and efficient implementation of all interventions.

6.2. Indicators for Monitoring and Evaluation of AMPM

An indicator in AMPM is a variable that measures one aspect of a supply chain or rational use of antimalarial medicines and is related to the program's goal and objectives. Indicators provide M&E information crucial for decision-making at every stage of program implementation.

The first four indicators from the below listed ones are included in the national Pharmaceuticals Supply Chain Management, Pharmacy Service and Medical Equipment management M&E framework, and will be reported through Demographic and Health Information System 2 (DHIS2) which recently replaces HMIS and directly reaches to FMOH. They can be contextualized to malaria program.

Health facilities should use this indicators to assess and improve their performance. The indicators can be disaggregated by program, in this case malaria to specifically follow the performance towards malaria treatment service provision.

The remaining indicators will be assessed and used by the health facility for their own consumption and to improve patient treatment outcome. The assessment of these indicators is done by administrative bodies like Woreda Health Office (WOHO), Sub-city health office (ScHO), Zonal Health Department (ZHD) and Town Health Office, and will be reported to higher level as appropriate.

1. Essential drugs availability

Indicator	Essential drugs availability						
Definition	The number of months in which a tracer drug was available averaged over all tracer drugs during the month						
Formula	∑ the number of months tracer drugs are available in the review period / (Number of months in period x number of tracer drugs) *X 100*						
Interpretation	Essential drugs should always be available. Essential drug availability is the proportion of months in the time period under consideration for which a given tracer drug was available throughout the month. The availability can be averaged over several tracer drugs to give a general picture of availability. The type of essential drug that needs to be available differs by type of health facility. This indicator measures product availability (or absence) over a period and serves as a proxy indicator of the ability of a program to meet clients' needs with a full range of products and services. If a product is not available (stocked out) for one day in the month, then it's considered as not available for the whole month. Evaluators may assess reasons for stock outs to help program managers address the underlying causes for this logistics system performance.						
Disaggregation	By each product, program products						
Sources	BIN card, HCMIS, and tracer drug availability sheet						
Method of data collection	DHIS2						
Frequency of Reporting	HP	HP	HP	HP	HP	HP	HP
	Monthly	Monthly	Monthly	Monthly	Monthly	Monthly	Monthly

N.B. AL is included as one of the tracer medicines and can be further disaggregated by presentation

2. Wastage rate

Indicator	Wastage rate of health products						
Definition	The percentage of the stock of products, in value, that are unusable because of expiration or damage during a period to the total value of the products received during the same period plus the quantity of the products found during the beginning of the period.						
Formula	Unusable stock of products during a period in monetary value / Beginning stock plus received stock during the same period in monetary value *X 100*						
Interpretation	This indicator can be calculated for any facility that manages pharmaceutical of interest. It can be measured over any period but it is preferable to be calculated for unusable stock with in a quarter. It is usually calculated whenever a physical inventory is taken. Unusable stock that has been accumulated for long period and were not disposed previously (expired and damaged items that were transferred from previous quarter) should not be included during calculation of this indicator. In addition, Items that were unusable during the quarter reviewed but were disposed with in the quarter should be taken in to consideration during calculation. This indicator is one of the performance indicator to have efficiency gain and one of the HSTP indicators to measure reduction of wastage from 8% to 2%.						
Disaggregation	By program, RDF						
Sources	Bin cards, stock cards, Model 19, inventory sheet, disposal reports, HCMIS						
Method of data collection	DHIS2						
Frequency of Reporting	HP	HC	Hospital	WoHO	ZHD/ ScHO	RHB	FMOH
		Quarterly	Quarterly	Quarterly	Quarterly	Quarterly	Quarterly

N.B. disaggregation can be done for anti-malaria commodities and monitor the wastage rate

3. Supplier fill rate

Indicator	Supplier fill rate						
Definition	The percentage of all items ordered by health facility from a distribution source (PFSA, or other private supplier) over a period that are filled correctly up to 80% in terms of quantities requested of those items						
Formula	Number of line items delivered in full (up to 80%) / Total no. of line items requested						*X 100*
Interpretation	This indicator measures supplier's ability to fill orders completely in terms of items and quantity during a definite period of time. This indicator measures the percentage of items ordered that are received to determine whether an order is filled in the correct quantities with the correct products at least 80%. For suppliers, it may be necessary to identify which items are causing the most problems and find another mechanism for obtaining those items.						
Disaggregation	By supplier (PFSA, others) and by Programs						
Sources	RRF report, Receiving voucher of HF, approved procurement request by DTC or HF head						
Method of data collection	DHIS2						
Frequency of Reporting	HP	HC	Hospital	WoHO	ZHD/ScHO	RHB	FMOH
		Quarterly	Quarterly	Quarterly	Quarterly	Quarterly	Quarterly

N.B. disaggregation can be done for anti-malaria products

4. Percentage of clients with 100% prescribed drugs filled

Indicator	Percentage of clients with 100% prescribed drugs filled					
Definition	Percentage of clients who get all the prescribed medicines (100%) from dispensary among all the clients who received prescriptions in a given time period.					
Formula	Number of clients who received 100% of prescribed drugs / Total number of clients who received prescriptions					*X 100*
Interpretation	This indicator measures the ability of the health facility (and the health system) to make better access to pharmaceuticals. The indicator shows access to affordable medicines. Getting prescribed medicines within the facility pharmacy enhances patient treatment outcomes and improves patient satisfaction and overall trust and confidence in the health sector. The indictor assumes that all patients treated at the health facility should obtain 100% of prescribed medicines from the dispensary.					
Disaggregation	By level of health facility (health center, hospital), by program (anti-malaria)					
Sources	Prescription registration book, survey (observation by exit interview)					
Method of data collection	DHIS2					
Frequency of Reporting	HC	Hospital	WoHO	ZHD/ ScHO	RHB	FMOH
	Monthly	Monthly	Monthly	Monthly	Monthly	Monthly

N.B. disaggregation can be done for malaria and antimalarial pharmaceuticals

5. Availability of the current national malaria guidelines

Indicator	Availability of national malaria guidelines						
Definition	The percentage of health facilities who have recent edition of national malaria treatment guideline during the time of visit						
Formula	Number of health facilities with recent national malaria treatment guideline / Total number of health facilities in the administrative level						*X 100*
Interpretation	The purpose of this indicator is to measure the extent to which copies of national malaria treatment guideline is available in the health facility. The availability of malaria treatment guideline in a health facility can be used as proxy indicator for rational prescribing practice of anti-malarial pharmaceuticals. The target is 100%.						
Target	100%.						
Disaggregation	By OPD, IPD, dispensing unit						
Sources	Survey or supportive supervision (biannually) by administrative bodies						
Method of data collection							
Frequency of Reporting	H P	HC	Hospital	WoHO	ZHD/ ScHO	RHB	FMOH
		Biannually	Biannually	Biannually	Biannually	Annually	Annually

6. Adequacy of dispensed antimalarial medicine labeling

Indicator	Percentage of antimalarial medicines adequately labeled						
Definition	Percentage of antimalarial medicine packages that are labeled with adequate information to enable the rational use of medicines by patients.						
Formula	Number of antimalarial medicines with adequate label / Total number of antimalarial medicines dispensed					*X100*	
Interpretation	The purpose of this indicator is to measure the degree to which dispensers record essential information on dispensed antimalarial medicine packages. It is very important that antimalarial medicines are labelled with the necessary information that enable their rational use by patients. At a minimum, dispensed antimalarial medicines should be labelled with patient name, name of the medicine, dose, frequency, and duration of use/quantity dispensed, and expiry date. This information is obtained by observing packages of the medicines dispensed to the sampled number of encounters during exit interview. Antimalarial medicine information written directly on blisters and strips by the manufacturer or dispenser cannot be considered as labeling information.						
Target	100%						
Disaggregation	By hospital, health center						
Sources	Observation of dispensed medicine (survey by exit interview)						
Method of data collection							
Frequency of Reporting	HP	HC	Hospital	WoHO	ZHD	RHB	FMOH
		Biannually	Biannually	Biannually	Biannually	Biannually	

7. Percentage of malaria patients who received pharmaceutical care

<table>
<tr><td>Indicator</td><td colspan="7">Percentage of malaria patients who received pharmaceutical care</td></tr>
<tr><td>Definition</td><td colspan="7">Percentage of admitted malaria patients in a facility who received pharmaceutical care from clinical pharmacy service providers as part of the MDT in an ongoing basis from admission to discharge in the reporting period.</td></tr>
<tr><td>Formula</td><td colspan="6">Number of malaria patients who received pharmaceutical care
Total number of admitted malaria patients in a facility</td><td>X 100</td></tr>
<tr><td>Interpretation</td><td colspan="7">This indicator measures the activity of clinical pharmacy services which is patient-oriented services developed to promote the rational use of medicines, and more specifically, to maximize therapeutic benefits and minimize risk. Pharmaceutical care involves the following logical processes:
✓ Assess the patient’s drug therapy needs
✓ Identify actual and potential drug therapy problems (DTP)
✓ Develop and implement a care plan to resolve and/or prevent the DTPs
✓ Monitor and evaluate the care plan
Pharmaceutical care is considered as performed when it is provided, recorded on all of the following forms and documented within patient medical cards:
✓ Inpatient medication profile form
✓ Pharmaceutical care progress note recoding sheet
✓ Medication reconciliation form
The target for this indicator is 80%.</td></tr>
<tr><td>Disaggregation</td><td colspan="7">By level of health facility</td></tr>
<tr><td>Sources</td><td colspan="7">Patient medical record card</td></tr>
<tr><td>Method of data collection</td><td colspan="7"></td></tr>
<tr><td rowspan="2">Frequency of Reporting</td><td>HC</td><td>Hospital</td><td>WorHO</td><td>ZHD/ ScHO</td><td>RHB</td><td colspan="2">FMOH</td></tr>
<tr><td>--</td><td>Quarterly</td><td>--</td><td>Quarterly</td><td>Biannually</td><td colspan="2">Biannually</td></tr>
</table>

8. Stock out duration

Indicator	Stock out duration for tracer drugs						
Definition	The number of days in which the tracer drugs were not available, averaged over all specific tracer drugs in a certain period						
Formula	Sum of stock out days of tracer drugs						
	Number of tracer drugs						
Interpretation	The availability of tracer drugs is a measure of service availability. Tracer drugs should always be available at the health facility. If there is any stock out of tracer drugs the facility should act to identify and address the cause. This indicator provides a proxy measure of the ability of a program to meet clients' needs with a full range of drugs.						
Disaggregation	By tracer product, program products						
Sources	Bin card, HCMIS and summary stock out tally sheet						
Method of data collection	Review of documents and routine report						
Frequency of Reporting	HP	HC	Hospital	WoHO	ZHD/ ScHO	RHB	FMOH
		Quarterly	Quarterly	Quarterly	Quarterly	Quarterly	Quarterly

9. Percentage of households with at least one LLINs

Indicator	Percentage of household with at least one LLINs						
Definition	Percentage of households with at least one LLINs is the proportion of household who have at least one LLINs						
Formula	Total number of household who have at least one LLINs / Total number of households X100						
Interpretation	The availability of bed nets is a measure of malaria prevention activity. Bed nets should always be available at household to prevent infection from malaria. The net also kills the mosquito which is responsible for the transmission of malaria. If there is a household without net the appropriate administrative body should act immediately to identify and address the cause as each household needs to be protected by nets. This indicator measures one of the prevention activity undertaken to prevent transmission of malaria and serves as an indicator of the ability of a program to prevent the transmission of the infection.						
Target	≥ One LLIN per household						
Disaggregation	By woreda, Kebele						
Sources	Survey						
Method of data collection							
Frequency of Reporting	HP	HC	Hospital	WoHO	ZHD/ ScHO	RHB	FMOH
				Annually	Annually	Annually	Annually

6.3 Provision of supportive supervision at health facilities

As a strategy to strengthen M&E system, supportive supervision of AMPM and integration of AMPM with joint supportive supervision have been done at selected health facilities. Malaria program, supply chain specific and integrated joint supportive supervision helps in guiding and encouraging staff working at health facilities to improve their performance and meet the defined standards of AMPM.

Supportive supervisions at the health facility level (and in fact at any level of the system) can alert malaria program and supply managers of potential problems within the AMPM system. It provides a unique opportunity for the supervisors to learn how health facility staff are performing their routine pharmaceutical management functions, including inventory management, storage and rational use of antimalarial medicines. During a supervision visits, the supervisor can also provide on-the-job training to facility personnel to help them improve their inventory management and pharmacy service skills.

The following are major areas to focus during supportive supervision

- Availability of AMPs
- Storage of AMPs
- Inventory management
- PMIS
- Dispensing practice
- RMU

6.4 Roles and responsibility of stakeholders in AMPM monitoring and Evaluation

All stakeholders including FMoH, PFSA, RHBs, ZHDs, WoHOs, ScHO, Town health office and health facilities have roles to play in the effective implementation of AMPM M&E system. These stakeholders should support and strengthen the M & E, and use the information to guide decision making and planning for performance improvement of the AMPM.

Hospitals and Health Centers

Hospitals and health centers are expected to improve their internal logistics and pharmacy services management systems to provide a standard service. They should self-assess attainment of pharmaceuticals supply chain and service standards as per the M&E framework and submit these reports to the respective administrative body through the appropriate channel. It is advisable to present the result in form of tables and charts that show the progress towards the achievement over time.

The pharmacy department is responsible not just for reporting the indicator data, but also for reflecting on the information and collaborating with colleagues to improve performance. Together with health facility management and other relevant colleagues should analyze the performance and develop actions that need to be taken to improve performance. The facility performance management or quality committee will support to oversee performance monitoring and improvement functions across the hospital.

Administrative body

After receiving hospital and health center reports, WoHO, ZHD, ScHO and town health office should compare the reports to monitor progress over time. RHBs in turn should compare the reports to monitor changes over time and calculate regional averages. Each administrative body should collect and analyze M&E reports from all hospitals and health centers in the catchment, give feedback to hospitals and health centers, and calculate average indicator results based on the hospital and the health center data. Each administrative body could present the reports at review meetings and discuss on them.

RHB should give feedback to each ZHDs/hospitals on the indicator reports, asking for clarification or further information where required. RHB should use the indicator reports to identify areas for action. Indicator reports should be used as input for health centers visit, hospital site visits, WoHOs visits and regional review meetings.

PFSA

To strengthen the supply chain management of AMPs, it requires monitoring of the quality of order request (RRF) data from health facilities. At PFSA level, the following indicators can be used to monitor and evaluate the quality of RRF data from health facilities.

1. Completeness: RRF is said to be complete if all the required columns (Beginning balance, quantity received, ending balance, Calculated Consumption, Max Quantity, Quantity to reach max filled for 70% of the items.
2. Accuracy: RRF is accurate if the calculations on the RRF are correct for the 90% of tracer pharmaceuticals for all programs
3. Timeliness: RRF is timely when it is available on time (i.e. RRF is timely if it is submitted before or on the 10^{th} day following the reporting period. If it is submitted between 10^{th} and 15^{th} day of the month, it can be considered as “late”. If it is submitted after the 15^{th} day, it can be marked as “very late”.
4. Legibility: RRF is legible if the handwritings or prints on the RRF are clear enough to read.

Legality: The RRF is legal if it has an official stamp and signature of the person who completes the report, the person who verify the report and facility in charge.

Chapter Summary

- Monitoring and Evaluation is a back bone of for strengthening of AMPM
- Indicator based regular reports have to be produced, analysed and used to support decision making in AM
- Supportive supervision is one of the methods used to monitor and evaluate AMPM activities at health facilities and program level
- All stakeholders including FMoH, PFSA, RHBs, ZHDs, WoHOs, and health facilities have roles to play in the development and effective implementation of AMPM monitoring and evaluation system.

References

1. IPLS - SOP - Nov - 2015.pdf.
2. Logistic Handbook.pdf.
3. Guide for Malaria logistics Management System.pdf.
4. The Supply Chain Managers Handbook, A Practical Guide to the Management of Health Commodities 2017.pdf.
5. Managing drug supply (Yellow Book).pdf.

6. Kasahun, Asnake; Fekadu Abebe. 2014. Ethiopia: Needs Assessment for Implementation of a Public–Private Partnership in Health Care Waste Management in Addis Ababa City. Arlington, VA: AIDSTAR-One.)

7. Red cross medical waste management manual of International Committee of the Red Cross

8. Medicines Waste Management and Disposal Directive, Food, Medicine and Healthcare Administration and Control Authority of Ethiopia, August 2011,Addis Ababa).

9. Malaria Case Management Training Manual for Health Professionals in Ethiopia, Participants Manual)

10 Guidelines for Managing the Malaria Supply Chain A Companion to the Logistics Handbook,USAID Deliver project)

11. Introduction to Materials Management, S I X T H E D I T I O N, J.R. Tony Arnold, P.E., CFPIM, CIRM, Fleming College, Emeritus, Stephen N. Chapman, Ph.D., CFPIM, North Carolina State University, Lloyd M. Clive, P.E., CFPIM, Fleming College)

Annex

Annex 1. HMIS report

S.N.	Disease	Morbidity in OPD						Mortality in OPD						
		Male			Female			Male			Female			
		0-4 years	14-May years	>=15 years	0-4 years	14-May years	>=15 years	0-4 years	14-May years	>=15 years	0-4 years	14-May years	>=15 years	
100	**Priority infectious diseases**													
	Epidemic prone diseases													
101	**Malaria (clinical without laboratory confirmation) q'ly total**	**28**	**22**	**42**	**22**	**16**	**33**	0	0	0	0	0	0	0
	month 1	9	8	17	8	6	12	0	0	0	0	0	0	0
	month 2	9	6	8	6	4	9	0	0	0	0	0	0	0
	month 3	10	8	17	8	6	12	0	0	0	0	0	0	0
102	**Malaria (confirmed with P. falciparum) q'ly total**	**27**	**21**	**42**	**20**	**15**	**31**	0	0	0	0	0	0	0
	month 1	10	8	17	8	6	12	0	0	0	0	0	0	0
	month 2	9	7	14	7	5	10	0	0	0	0	0	0	0
	month 3	8	6	11	5	4	9	0	0	0	0	0	0	0
103	**Malaria (confirmed with species other than P. falciparum) q'ly total**	**24**	**19**	**37**	**18**	**13**	**27**	0	0	0	0	0	0	0
	month 1	8	6	11	5	4	9	0	0	0	0	0	0	0
	month 2	7	6	12	6	4	8	0	0	0	0	0	0	0
	month 3	9	7	14	7	5	10	0	0	0	0	0	0	0

Annex 2. Antimalarial Medicines Dispensing Register

Name of the Health Institution: _____ Month:_____ Year:_____

Serial Number	Date (DD/MM/YY) E.C	Card Number	Patient's Name	Weight (Kg)	Sex			Age				Type of visit		Diagnosis					Quantity of AMM dispensed									
					Female		Male	3month - 2 yrs	3 – 7 years	8 – 10 years	>10 years	Regular	Referral	P.falciparum Uncomplicated	P.falciparum severe	P.vivax	Mixed	Other	AL 1x6 (strips)	AL 2x6 (strips)	AL 3x6 (strips)	AL 4x6 (strips)	Artesunate injection (vials)	Chloroquine 150 mg tab	Chloroquine 50mg/5ml Syrup (bottle)	Quinine 300/600mg tablet	Primaquine 7.5mg tablet
					Pregnant	Non -pregnant																						
1	1-Jan-17	12BNV123	Chala Haro				✓		✓			✓		✓					1									¾
2	1-Jan-17	12BNV124	Hagos Girmay				✓			✓		✓		✓								1						1
3	3-Jan-17	12BNV125	Zemedkun Tase				✓				✓	✓				✓								10				
4	4-Jan-17	12BNV126	Chalachew Yigletu				✓	✓					✓		✓				1				2					½
5	5-Jan-17	12BNV127	Tesema Taye				✓			✓		✓		✓							1							1
6	6-Jan-17	12BNV128	Helen Tase		✓ (2months)						✓	✓		✓								1						2
7	7-Jan-17	12BNV129	Mahlet Tache		✓						✓	✓				✓								10				
8	7-Jan-17	12BNV130	Dinkinsh Tefera			✓					✓	✓		✓								1						2
9	7-Jan-17	12BNV131	Helen Makuanint		✓(7months)						✓	✓			✓							1	4					2
10	10-Jan-17	12BNV132	Taye Dandi				✓				✓	✓					✓					1		10				2
11	11-Jan-17	12BNV133	Tola Guracha				✓			✓		✓		✓							1							2
12	12-Jan-17	12BNV134	Chung Dagne				✓			✓		✓		✓							1							2
13	13-Jan-17	12BNV135	Hirut Taye			✓					✓	✓		✓								1						2
14	14-Jan-17	12BNV136	Rahel Bonsa			✓					✓	✓		✓								1						2
15	15-Jan-17	12BNV137	Ketema Lema				✓		✓			✓		✓						1								¾
16	16-Jan-17	12BNV138	Lema Derese				✓			✓		✓		✓							1							1
17	17-Jan-17	12BNV139	Yinenbeb Raeiyu				✓		✓			✓		✓						1								¾
18	17-Jan-17	12BNV140	Darge Berhan				✓				✓	✓		✓								1						2
19	17-Jan-17	12BNV141	Yihun Gizew				✓	✓				✓		✓					1									½
20	17-Jan-17	12BNV142	Sifan Tolera			✓					17	✓				✓								10				
21	21-Jan-17	12BNV143	Pawlos Ujulu				✓				46	✓				✓								10				
22	22-Jan-17	12BNV144	Asafw Markos				✓				32	✓				✓								10				
23	22-Jan-17	12BNV145	Eskel Yohanis				✓			8		✓				✓								3				
24	22-Jan-17	12BNV146	Mohammed Oumer				✓		4			✓				✓									1			
25	25-Jan-17	12BNV147	Tesfaye Yosef				✓	✓				✓		✓					1									½
26	25-Jan-17	12BNV148	Imanu Hassen				✓			✓		✓					✓				1							1
27	25-Jan-17	12BNV149	Worku Mohammed				✓			✓		✓		✓							1							1
28	28-Jan-17	12BNV150	Husen Abdella				✓		✓			✓		✓						1								¾
29	29-Jan-17	12BNV151	Seble Abebe			✓					✓		✓		✓								4					
Total	Count																											
	Sum (consumption)																											

Annex 3 : RAR/DUE criteria and data collection form for Uncomplicated case P. falciparum malaria case management

	RAR/DUE Criteria (indicators) for Uncomlicated case p.F malaria case management				
	Medicine Prescribed	**AL+PQ**			
	Age category	3 months - 2 yrs	3 - 7 yrs	8 - 10 yrs	>10 yrs
	Dose	1tab AL + single dose PQ	2tabs AL + single dose PQ	3tabs AL+ single dose PQ	4tabs AL + single dose PQ
	Frequency	Twice a day	Twice a day	Twice a day	Twice a day
	Duration	3 days	3 days	3 days	3 days

Data collection form for Uncomlicated case p.F malaria case management

Patient encounter #	Age category				Medicine Prescribed	Dose	Frequency	Duration
	3 months - 2 yrs	3 - 7 yrs	8 - 10 yrs	>10 yrs				
Total Count								
%								

Annex 4: RAR DUE criteria and data collection form for Uncomplicated case p.Vivax malaria case management with Chloroquine

	RAR DUE Criteria for Uncomlicated case p.V malaria case management with Chloroquine												
	Medicine prescribed	Chloroquine											
	Age		4 – 11 months		1 – 2 years		3 – 4 years		5 – 7 years		8-11 yr	12-14 yr	15 yr + adult
	Dose	Day 1	½ tablet or	7.5 ml syrup	1 tablet or	12.5 ml syrup	1 tablet or	15 ml syrup	1 ½ tablets or	20 ml syrup	2 ½ tablets	3 tablets	4 tablets
		Day 2	½ tablet or	7.5 ml syrup	0.5 tablet or	12.5 ml syrup	1 tablet or	15 ml syrup	1 ½ tablets or	20 ml syrup	2 tablets	2 tablets	4 tablets
		Day 3	½ tablet or	5 ml syrup	0.5 tablet or	7.5 ml syrup	1 tablet or	15 ml syrup	1 tablet or	15 ml syrup	1 tablet	2 tablets	2 tablets
	Frequency		once per day	once per day	once per day	once per day	once per day	once per day	once per day	once per day	once per day	once per	once per day
	Duration		3 days	3 days	3 days	3 days	3 days	3 days	3 days	3 days	3 days	3 days	3 days

Data collection form for Uncomlicated case p.V malaria case management with Chloroquine

Patient encounter #	Age category							Medicine Prescribed	Dose	Frequency	Duration
	4 – 11 months	1 – 2 years	3 – 4 years	5 – 7 years	8-11 yr	12-14 yr	15 yr + adult				
Total Count											
%											

Annex 5: RAR DUE criteria and data collection form for uncomplicated case p. falciparum malaria case management in pregnant mothers in 1st trimester

DUE Criteria Uncomlicated case p.F malaria case management in preganant mothrers in 1st trimester	
Medicine Prescribed	Quinine tablet
Dose	2 tabs
Frequency	Three times per day
Duration	7 days

Data collection form for Uncomlicated case p.F malaria case management in preganant mothrers in 1st trimester

Patient encounter #	Medicine Prescribed	Dose	Frequency	Duration
Total Count				
%				

Annex 6: DUE criteria and data collection form for Treatment for severe malaria

RAR DUE Criteria for Treatment for severe malaria	
Medicine Prescribed	Artesunate inj
Dose	3 mg/kg
Frequency & Duration	On admission (time = 0), then at 12h and 24h, then daily for up to five days
Note: Once a patient has received at least 24 h of parenteral therapy and can tolerate oral therapy, the treatment should be completed with 3 days full dose of an AL based on the age of the patient. Thus, adherence to standard treatment should be evaluated accordingly.	

Data collection form for Treatment for severe malaria								
Patient encounter #	Age category				Medicine Prescribed	Dose	Frequency	Duration
	3 months - 2 yrs	3 - 7 yrs	8 - 10 yrs	>10 yrs				
Total Count								
%								

Annex 7: DUE criteria and data collection form for uncomplicated mixed case malaria management

Criteria for Uncomlicated mixed case malaria management				
Medicine Prescribed	AL+PQ			
Age	3 months - 2 yrs	3 - 7 yrs	8 - 10 yrs	>10 yrs
Dose	1tab AL + single dose PQ	2tabs AL + single dose PQ	3tabs AL+ single dose PQ	4tabs AL + single dose PQ
Frequency	Twice a day	Twice a day	Twice a day	Twice a day
Duration	3 days	3 days	3 days	3 days

Data collection form for Uncomlicated mixed case malaria management								
Patient encounter #	3 months - 2 yrs	3 - 7 yrs	8 - 10 yrs	>10 yrs	Medicine Prescribed	Dose	Frequency	Duration
Total Count								
%								

Annex 8: Reporting and Requesting for AMP

Annex 8A: Exersice for Reporting and Requesting for AMP											
Supply Hub: Dire Dawa Hub								**Facility:** X -Hospital			
Resupply Month: Even (June)								**LSI :** 1.5 (Hypothetical value)			
Reporting Period: Miaziya 1- Ginbot 30,2010											
Product Description	Unit of Issue	**Report Part**						**Requisition Part**			
								Maximum Stock Quantity		**Quantity Needed to Reach Max**	
		Beginning Balance	Quantity Received	Loss/ Adjustment	Ending Balance	Calculated Consumption	Days Out of Stock	Without LSI	With LSI	Without LSI	With LSI
		A	B	C	E	F= A+B ±C - D- E	G	H=(120xF)/(60-G)	H*=(120xF)/(60-G)*LSI	I=H-E	J =H*-E
Artemether + lumefanthrine (20 +120)mg 6X1 Tablet	30	10	15	0	5		0				
Artemether + lumefanthrine (20 +120)mg 6X2 Tablet	30	10	15	0	0		10				
Artemether + lumefanthrine (20 +120)mg 6X3 Tablet	30	5	10	0	2		5				
Artemether + lumefanthrine (20 +120)mg 6X4 Tablet	30	20	25	0	5		2				

Annex 8B: Exersice for Reporting and Requesting for AMP

Supply Hub: Gondar Hub | **Facility:** X -Hospital

Resupply Month: Even (June) | **LSI :** 2.23

Reporting Period: Miaziya 1- Ginbot 30,2010

Product Description	Unit of Issue	Report Part						Requisition Part			
								Maximum Stock Quantity		Quantity Needed to Reach Max	
		Beginning Balance	Quantity Received	Loss/ Adjustment	Ending Balance	Calculated Consumption	Days Out of Stock	Without LSI	With LSI	Without LSI	With LSI
		A	B	C	E	F= A+B ±C - D- E	G	H=(120xF)/(60-G)	H*=(120xF)/(60-G)*LSI	I=H-E	J =H*-E
Artemether + lumefanthrine (20 +120)mg 6X1 Tablet	30	20	30	0	30		0				
Artemether + lumefanthrine (20 +120)mg 6X2 Tablet	30	20	30	0	20		0				
Artemether + lumefanthrine (20 +120)mg 6X3 Tablet	30	20	30	0	20		0				
Artemether + lumefanthrine (20 +120)mg 6X4 Tablet	30	50	60	0	40		0				

Annex 8C. Exersice for Reporting and Requesting for AMP

Supply Hub: Jigjiga Hub | **Facility:** X -Hospital

Resupply Month: Odd (Ginbot) | **LSI :** 1.2

Reporting Period: Megabit1-Miaziya 30,2010

Product Description	Unit of Issue	Report Part						Requisition Part			
								Maximum Stock Quantity		Quantity Needed to Reach Max	
		Beginning Balance	Quantity Received	Loss/ Adjustment	Ending Balance	Calculated Consumption	Days Out of Stock	Without LSI	With LSI	Without LSI	With LSI
		A	B	C	E	F= A+B ±C - D- E	G	H=(120xF)/(60-G)	H*=(120xF)/(60-G)*LSI	I=H-E	J =H*-E
Artemether + lumefanthrine (20 +120)mg 6X1 Tablet	30	30	40	-40	20		0				
Artemether + lumefanthrine (20 +120)mg 6X2 Tablet	30	20	30	-30	5		0				
Artemether + lumefanthrine (20 +120)mg 6X3 Tablet	30	15	20	0	10		0				
Artemether + lumefanthrine (20 +120)mg 6X4 Tablet	30	50	60	0	20		0				

Annex 8D: Exersice for Reporting and Requesting for AMP											
Supply Hub: Semera Hub									**Facility:** X -Health Center		
Resupply Month: Odd(July)									**LSI :** 0.9		
Reporting Period: Ginbot 1-Sene 30,2010											
Product Description	Unit of Issue	**Report Part**						**Requisition Part**			
								Maximum Stock Quantity		**Quantity Needed to Reach Max**	
		Beginning Balance	Quantity Received	Loss/ Adjustment	Ending Balance	Calculated Consumption	Days Out of Stock	Without LSI	With LSI	Without LSI	With LSI
		A	B	C	E	F= A+B ±C - D- E	G	H=(120xF)/(60-G)	H*=(120xF)/(60-G)*LSI	I=H-E	J =H*-E
Artemether + lumefanthrine (20 +120)mg 6X1 Tablet	30	15	35	20	25		0				
Artemether + lumefanthrine (20 +120)mg 6X2 Tablet	30	20	45	0	30		0				
Artemether + lumefanthrine (20 +120)mg 6X3 Tablet	30	15	30	0	27		0				
Artemether + lumefanthrine (20 +120)mg 6X4 Tablet	30	50	85	0	45		0				

Federal Democratic Republic of Ethiopian
Ministry of Health

Annex 9. Health Facility Dispensing Registration Book

Region _____ Woreda _____ Name of Health Facility _____

S.N	MRN	Patient Name	Age	Sex	Diagnosis (NCoD)	Medicines Prescribed	Therapeutic Category	Level of Importance by VEN			Dispensed (Y/N)	Overall * (1,0)	Remark
								Vital (√)	Essential (√)	Non essential(√)			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
1	12BNV123	Chala Haro	5	M	Malaria - uncomlicated P. Falciparum	AL (1*6) strip	anti-malaria	x			Y		
						Primaquine 7.5mg -3/4	anti-malaria	x			N		
2	12BNV124	Hagos Girmay	9	M	Malaria - uncomlicated P. Falciparum	AL (4*6) strip	anti-malaria	x			Y		
						Primaquine 7.5mg	anti-malaria	x			Y		
3	12BNV125	Zemedkun Tase	14	M	Malaria - P.Vivax	Chloroquine 150 mg tablet #10	anti-malaria				Y		
4	12BNV126	Helen Tase (Pregnant 2 month)	25	F	Malaria - uncomlicated P. Falciparum	AL (4*6) strip	anti-malaria	x			Y		
						Primaquine 7.5mg tablet #2	anti-malaria	x			Y		
						Paracetamol 500mg strip	analgesics		x		N		
5	12BNV127	Mahlet Tache (pregnant)	30	F	Malaria - P.Vivax	Chloroquine 150 mg tablet #10	anti-malaria	x			Y		
6	12BNV128	Dinkinsh Tefera	27	F	Malaria - uncomlicated P. Falciparum	AL (4*6) strip	anti-malaria	x			Y		
						Primaquine 7.5mg tablet #2	anti-malaria	x			N		
7	12BNV129	Helen Makuanint (pregnant)	32	F	Malaria - Severe P. Falciparum	Artesunate Injection # 4 vial	anti-malaria	x			Y		
						Quinine 3oo mg tablet #42	anti-malaria	x			Y		
8	12BNV130	Taye Dandi	18	M	Malaria - Mixed	AL (4*6) strip	anti-malaria	x			Y		
						Chloroquine 150 mg tablet #10	anti-malaria	x			Y		
9	12BNV131	Tola Guracha	10	M	Malaria - uncomlicated P. Falciparum	AL (3*6) strip	anti-malaria	x			Y		
						Primaquine 7.5mg tablet #2	anti-malaria	x			Y		
10	12BNV132	Hirut Taye	20	F	Malaria - uncomlicated P. Falciparum	AL (4*6) strip	anti-malaria	x			Y		
						Primaquine 7.5mg tablet #2	anti-malaria	x			Y		
Count total patient										Count Total 1			

Note **Overall*: Enter '1' only if all the prescribed medicines are dispensed and enter '0' if one or more medicines not dispensed.**

Federal Democratic Republic of Ethiopian
Ministry of Health

Annex 10: Tracer drug availability tally sheet

Woreda---------- **Facility Name----------** **Month----------** **Year----------**

S/No	Tracer drug list	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	Overall* (1,0)	Duration of stock out
1	Amoxicillin dispersable tablet	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
2	Oral Rehydration Salts	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
3	Zinc dispersible tablet	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
4	Gentamycin Sulphate injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
5	Co-trimoxazole	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
6	Magnesium Sulphate injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
7	Oxytocin injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
8	Enalapril tablets	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
9	Medroxyprogesterone Injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
10	Glibenclamide tablet	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
11	Adrenaline injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
12	Pentavalent vaccine	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
13	Glucose 40%	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
14	Dextrose in normal saline	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
15	Ferrous sulphate + folic acid	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
16	Ciprofloxacin tablet	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
17	Ceftriaxone injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
18	Hydralazine injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
19	TDF/3TC/EFV adult	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
20	RHZE/RH (TB patient kit)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
21	Tetanus Anti toxin (TAT)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
22	Tetracycline Eye Ointment	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
23	Arthmeter + Lumfanthrine (Coartem) tablet (any packing)	x	x	x	x	x			x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
24	Artesuante Injection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x		x	x	x	x	x	x	x	x	x		
25	Implanon NXT	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
	Conut total number of medicines applicable																										**Count Total 1**						
																											total duration of stockout						

Annex 11: Prescriptions

Annex: PRESCRIPTIONS

Annex 11 A: PRESCRIPTION PAPER

Ser. No 1112

Name of the Health Institution: Mieso Hospital Date: 12/02/10

Patient's Name: Sheilah Nabiyu Sex: F Age: 32

☐

Weight: 56 Card No. 0001 ☐ Start Repeat

☐ Inpatient ☐ Outpatient

Diagnosis (ICD code No.) P.Vivax

Address: Region: Oromia Town Mieso Woreda 02 Kebele 01

House No. 514 Tel. No.: 203045

Treatment given (Drug name, strength, dosage form, dose, duration and quantity)	Price of each item (For dispenser's use only)	
Rx		
1. Chloroquine 250 mg, 1gm P.O. stat,		
1gm after 24 hrs and then 0.5gm the 3rd day		
(4,4,2)		

Prescriber's

Full name Biruk Derese

Qualification Internist

Registration 21297

Signature

Dispenser's

Additional Comments:

The patient is pregnant

Annex 11 B: PRESCRIPTION PAPER

Ser. No 1113

Name of the Health Institution: Shire Hospital Date: 12/02/10

Patient's Name: Yosef Kebede Sex: M Age: 24

Weight: 56 Card No. 0002 ☐ Start ☐ Repeat

☐ Inpatient ☐ Outpatient

Diagnosis (ICD code No.) P.Falciparum

Address: Region: Tigray Town Shire Woreda 10 Kebele 12

House No. 501 Tel. No.: 0116621111

Treatment given (Drug name, strength, dosage form, dose, duration and quantity)	Price of each item (For dispenser's use only)	
Rx		
• Artemether-Lumefantrine 20mg/120mg,		
4 tabs P.O. BID for 3 days		
followed by Primaquine 15mg single dose.		

Prescriber's

Full name Hussen Teklemariam

Qualification Internist

Registration 21278

Signature

Dispenser's

Additional Comments:

Annex 11 C: PRESCRIPTION PAPER

Ser. No 1113

Name of the Health Institution: Felegehiwot referal Hospital Date: 14/02/10

Patient's Name: Tigist Chane Sex: F Age: 30

Weight: 65 Card No. 0004 ☐ Start ☐ Refill

☐ Inpatient ☐ Outpatient Pregnant: No

Diagnosis (ICD code No.) P.Vivax

Address: Region: Amhara Town Kolladiba Woreda 02 Kebele 02

House No. new Tel. No.: 0115384290

Treatment given (Drug name, strength, dosage form, dose, duration and quantity)	Price of each item (For dispenser's use only)	
Rx		
Chloroquine 250 mg, 1gm P.O. stat,		
1gm after 24 hrs and then 0.5gm the 3rd day		
Followed by primaquine 15mg, 1 tab		
P.O. daily for 14 days		

Prescriber's

Full name Demelash Gedu

Qualification Internist

Registration 21457

Signature

Dispenser's

Additional Comments:

PRESCRIPTION PAPER **Ser. No** 1114

Name of the Health Institution: Hawassa Hospital Date: 15/02/10

Patient's Name: Paulos Petrose Sex: F Age: 36

Weight: 58 Card No. 0005 ☐ Start ☐ Refill

☐ Inpatient ☐ Outpatient Pregnant: yes (1st trim.)

Diagnosis (ICD code No.) P.f

Address: Region: SNNPR Town Leku Woreda 04 Kebele 02

House No. 443 Tel. No.: 0115723836

Treatment given (Drug name, strength, dosage form, dose, duration and quantity)	Price of each item (For dispenser's use only)	
Rx		
Quinine 600mg P.O. TID for 7days		

Prescriber's

Full name Samuel Muhammed

Qualification Internist

Registration 21297

Signature

Dispenser's

Additional Comments: