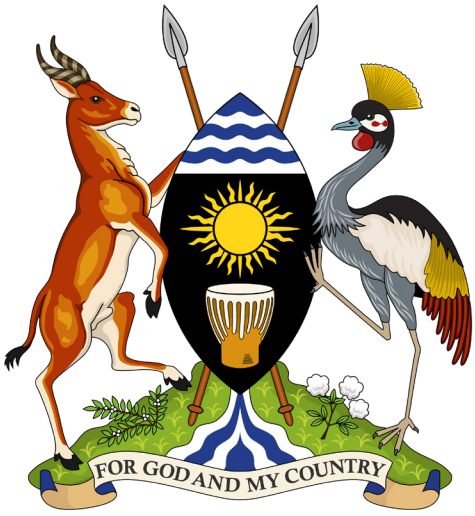

REPUBLIC OF UGANDA

MINISTRY OF HEALTH

GUIDELINE TO IMPLEMENT ACTIVITIES FOR MEDICINE AND THERAPEUTICS COMMITTEE IN A HEALTH FACILITY

JUNE 2025

GUIDELINE TO IMPLEMENT ACTIVITIES FOR MEDICINE AND THERAPEUTICS COMMITTEE IN A HEALTH FACILITY

Published by the Ministry of Health, Republic of Uganda

First edition: 2020

Copies may be obtained from:

Department of Pharmaceuticals and Natural Medicines,

Ministry of Health Headquarters,

Plot 6 Lourdel Road, P.O.Box 7272

Kampala, Uganda

Tel: +256-417-771330

Email: ugandaantimicrobialsurveillanceplan@gmail.com

Website: www.health.go.ug

Foreword

Uganda has made significant strides in advancing access to essential medicines and health supplies (EMHS) for the population. In line with the National Health Policy, the Ministry of Health remains committed to achieving universal health coverage by providing quality health services that are efficient, equitable, and accessible. This second edition of the guideline to implement activities for medicine and Therapeutics committee in a health facility is a key instrument in achieving this objective, aligning with the National Medicines Policy (NMP) and the National Pharmaceutical Services Strategic Plan (NPSSP) (2020/21–2024/25), which prioritize optimal and evidence-based medicine use.

The National Pharmaceutical Services Strategic Plan (NPSSP) (2020/21–2024/25) emphasizes the establishment of a robust, functional national program for appropriate medicines use. Such a program is crucial in enabling prescribers, dispensers, and consumers to derive maximum therapeutics benefit from medicines through scientifically grounded and cost-effective practices. Central to this initiative is the formation of Medicine and Therapeutics Committees (MTCs), which are essential in promoting effective medicine management and informed decision-making at health facilities across the country.

This second edition of the guideline to implement activities for medicine and Therapeutics committee in a health facility, along with its comprehensive training curriculum, provides invaluable guidance on the operationalization of quality improvement initiatives in the appropriate use of medicines and health technologies. By strengthening the logistical and clinical management of medicines and health technologies, this guideline contributes to resource efficiency, better healthcare outcomes, and enhanced population health.

Ministry of Health extends its appreciation to all health workers and stakeholders involved in the development of this guideline. We therefore urge all health workers, Health facility leadership, and partners in the health sector to adopt and implement this guideline as part of our collective commitment to achieving Uganda's health goals.

Dr Charles Olaro
DIRECTOR GENERAL HEALTH SERVICES
MINISTRY OF HEALTH

Acknowledgements

The Ministry of Health reviewed guidelines to implement activities for medicine and Therapeutics committees in a health facility (formerly Medicine and Therapeutics Committee Manual) in collaboration with health partners. Special thanks go to the team from the Department of Pharmaceuticals and Natural Medicines: Dr Martha Grace Ajulong, Dr Akello Harriet, Dr Rodney Tibaruha Tabaruka, and Dr Aguma Daniel for their expertise, technical guidance, and coordination during the review of the guideline to implement activities for medicine and Therapeutics committee in a health facility. We also thank Dr Rony Bahatungire and Dr Elizabeth Katwesigye from the Department of Clinical and Curative Services, and Dr Susan Nabadda, Dr Saudah Namubiru and Mr Mugerwa Ibrahim from the National Health Laboratory and Diagnostic Services for their leadership and contribution during the development of the guideline. We further thank Dr Harriet Akello for leading and coordinating the secretariate and the different stakeholders during the review of the guideline.

We extend our sincere appreciation to the UK Government's Fleming Fund and the United States Government for their generous financial and technical support in the development of this document. We also extend profound thanks to all the institutions that supported us throughout the development of the manual. Specifically, we thank Dr Winnie Nambatya and Dr Bruhan Kaggwa of the Makerere University Pharmacy Department, Dr Kisame Rodgers and Dr Moses Mukiibi from the Baylor Foundation Uganda and Dr Vivian Bazanye Twemanye from the Infectious Disease Institute, Dr Isabirye Michael from Management Sciences for Health, Mr Joshua Musasizi and the technical teams from the National Medical Stores and the National Drug Authority for their input.

We appreciate the leadership of the hospital directors, medical superintendents, chairpersons, secretaries, and members of the Medicines and Therapeutics Committees from both the public and private health facilities for providing valuable information and for their active participation in the review of this document.

MARTHA GRACE AJULONG
Ag. COMMISSIONER HEALTH SERVICES: PHARMACEUTICALS AND NATURAL MEDICINES

Table Of Contents

FOREWORD		**3**
ACKNOWLEDGMENTS		**4**
ACRONYMS AND ABBREVIATIONS		**8**
CHAPTER 1. OVERVIEW OF MANAGEMENT OF MEDICINES AND HEALTH TECHNOLOGIES IN UGANDA		**9**
1.1	Medicine And Therapeutics Committees: An Overview	9
1.1.1	Scope Of The Roles Of The Medicine And Therapeutics Committee In The Medicines Management Cycle	9
1.2	Roles And Functions Of The Medicine And Therapeutics Committee	10
1.3	Benefits Of The Medicine And Therapeutics Committee	11
1.4	Structure, Organization And Functioning Of The The Medicine And Therapeutics Committee	12
1.4.1	Principles For Setting Up The Medicines And Therapeutics Committee	12
1.4.2	Composition Of The Medicine And Therapeutics Committee	12
1.4.3	Subcommittees Of The Medicine And Therapeutics Committee	13
1.4.4	Operations Of The Medicine And Therapeutics Committee	13
1.4.4.1	How to conduct Meetings of the Medicine and Therapeutic Committee	14
1.4.5	Implementing The Medicine And Therapeutics Committee Activities	15
1.4.6	Work-Planning And Performance Assessment Of The The Medicine And Therapeutics Committee	15
1.4.7	Practical Tips To Ensure Functional Medicine And Therapeutics Committee	16
1.5	Common Challenges To The Medicine And Therapeutics Committee Operations And How To Address Them	17
1.6	Roles And Responsibility Of Key Players In Relation To The Medicine And Therapeutics Committee Functions	18
CHAPTER 2: ANTIMICROBIAL STEWARDSHIP		**19**
2.1	Introduction To Antimicrobial Resistance	19
2.2	Antimicrobial Stewardship Programs In The Health Facility	19
2.2.1	Structure And Composition Of The Antimicrobial Stewardship In Uganda	19
2.2.2	Goal And Functions Of The Antimicrobial Stewardship Subcommittee	20
2.2.3	Antimicrobial Stewardship Team	21
2.3	Leadership And Governance Of Antimicrobial Stewardship At Each Level Of Care	22
2.3.1	National Referral And Specialized Health Facilities	22
2.3.2	Regional Referral Hospital And Lower Levels Of Care	23
2.3.3	Community Level	24
2.4	Setting Standards – Treatment Guidelines And Principles Of Antibiotic Prescribing	25
2.5	Role Of The Laboratory In Antimicrobial Stewardship	25
2.6	Stewardship Interventions	26
2.7	Monitoring And Evaluation	26
2.8	Role Of Infection Prevention And Control In Medicine And Therapeutics Committee	30
2.8.1	Collaboration Between Infection Prevention And Control In Medicine And Therapeutics Committee	30
CHAPTER 3: PHARMACOVIGILANCE WITHIN THE HEALTH FACILITY		**34**
3.1	Introduction	34
3.2	Structure And Composition Of The Pharmacovigilance Subcommittee	34
3.2.1	National Level	34
3.2.2	National Level	35
3.3	Mandate Of The Pharmacovigilance Subcommittee	35
3.4	Quality Of Medicines	36
3.5	Aims Of Pharmacovigilance	36
3.6	Medicine Errors	38

3.7	Adverse Drug Reactions	40
3.7.1	Steps In Assessing Adverse Drug Reaction	41
3.7.2	Guidance on ADR prevention	43
CHAPTER 4: SUPPLY CHAIMANAGEMENT FOR MEDICINES AND HEALTH TECHNOLOGIES		**45**
4.1	Introduction	45
4.2	Logistics Reports For Mtc	46
4.2.1	Stock Report: Availability/Stock Outs And Stock Status	46
4.2.2	Consumption Reports: Average Monthly Consumption And Abc Report	47
4.2.3	Expiry/Losses And Adjustment Report	47
4.3	Pharmaceutical Flow	48
4.4	Tracking And Accountability	49
4.5	Procurement Planning And Budget Tracking	53
4.6	Policies And Procedures	54
CHAPTER 5: HEALTH TECHNOLOGIES MANAGEMENT		**55**
5.1	Introduction	55
5.2	Goal Of Health Technologies Management (Htm) Subcommittee	56
5.3	Composition Of The Health Technologies Subcommittee	56
5.4	Scope Of Health Technologies To Be Managed By The Health Technologies Subcommittee	56
5.5	Roles Of Health Technologies Management Subcommittee	56
5.6	Benefits Of Healthcare Technology Management (Htm)	58
5.7	Monitoring And Evaluation For Health Technologies Subcommittee	58
CHAPTER 6: QUALITY IMPROVEMENT FOR PHARMACEUTICALS MANAGEMENT		**59**
6.1	Introduction	59
6.2	Quality In Healthcare	59
6.2.1	How To Begin: Define Standards And Implement The 5s	60
6.2.2	Continuous Quality Improvement	61
6.3	Quality Improvement Tools	62
6.4	Quality Improvement In Medicine Management And Use	64
6.4.1	Step 1. Examine: Measure, Identify, Prioritize	65
6.4.2	Step 2. Diagnose: Investigate Specific Problems And Causes	69
6.4.3	Step 3. Treat: Design And Implement Interventions	71
6.4.4	Step 4. Follow Up: Measure Changes In Outcomes	72
CHAPTER 7: APPROPRIATE USE OF MEDICINES, AND HEALTH TECHNOLOGIES		**73**
7.1	Definition And Principles	73
7.1.1	Defining Appropriate Medicines Use	74
7.1.2	Examples Of Inappropriate Medicines Use	74
7.1.3	Factors That Influence Appropriate Medicine Use (Amu)	75
7.1.4	The Impact of Inappropriate Medicines Use	75
7.2	Key Strategies To Improving Medicines Use	76
7.3	Standard Treatment Guidelines (Stgs)	76
7.3.1	Potential Benefits Of Standard Treatment Guidelines	76
7.3.2	Uganda Clinical Guidelines (Ucg)	77
7.3.3	Principles And Use Of The Ucg	77
7.4	Essential Medicines	78
7.5	The Ven Concept	79
	CHAPTER 8: INSTITUTIONAL MEDICINES LISTED (IML)	**80**
8.1	Medicines Information: Practical Guidelines For Dispensing	80

8.2	Development Of Clinical Guidelines And Essential Medicines And Health Supplies List	81
8.3	Selection Of Medicine List: The Formulary Process	81
8.4	Benefits Of Appropriate Selection	82
8.5	Selection Of Medicines At Facility Level	82
8.6	Developing And Implementing An Institutional Medicine List	83
8.7	Procedure For Adding And Deleting Products	84
8.8	Improving Adherence To An Institutional Medicine List	85
	CHAPTER 9: INVESTIGATING MEDICINES USE PROBLEMS	**86**
9.1	Introduction	86
9.1.1	Challenges In Data Collection	87
9.2	General Investigations Aggregate Data Methods	88
9.2.1	Abc Analysis	88
9.2.2	The Ven Analysis	90
9.2.3	Therapeutic Category Analysis	97
9.3	General Investigations: Indicator Studies	98
9.3.1	Inrud/Who Drug Use Indicators	100
9.3.2	Antimicrobial Use Indicators	100
9.3.3	Drug Administration Audits	105
9.4	In-Depth Investigations Of Medicine Use Problems	106
9.4.1	Medicine Use Evaluation And Prescription Audits	107
9.4.2	Qualitative Methods	112
9.4.3	Root Cause Analysis	114
	CHAPTER 10: HOW TO IMPROVE THE USE OF MEDICINES AND HEALTH SUPPLIES	**116**
10.1	Introduction	116
10.2	Overview Of Intervention Strategies	117
10.2.1	Educational Strategies	117
10.2.2	Managerial Strategies	120
10.2.3	Regulatory Strategies	121
10.2.4	Financial Or Economic Strategies	122
10.3	Choosing An Intervention	122
10.4	Planning An Intervention	124
10.5	Work Plan And Budget Preparation	124
10.6	Monitoring And Evaluating Interventions	127
	ANNEX	**134**
	ANNEX 1.1: PERFORMANCE ASSESSMENT INDICATORS FOR MEDICINE AND THERAPEUTIC COMMITTEE WITHIN THE HEALTH FACILITY	134
	ANNEX 1.2: MODEL TERMS OF REFERENCE FOR MEDICINES AND Therapeutics COMMITTEES	137
	ANNEX 1.3: APPROVAL OF TERMS OF REFERENCE OF THE HEALTH FACILITY MEDICINES AND Therapeutics COMMITTEES	142
	ANNEX 1.4: EXAMPLE OF A DECLARATION OF INTEREST FORM	143
	ANNEX 1.5 REPORTING TEMPLATE FOR MEDICINES AND Therapeutics COMMITTEES MEETINGS	144
	ANNEX 1.6: TEMPLATE WORK PLAN FOR MEDICINES AND Therapeutics COMMITTEES AND EXAMPLE	145
	ANNEX 3.1 DEFINITIONS IN PHARMACOVIGILANCE	148
	ANNEX 3.2: ADVERSE REACTION REPORT/ADVERSE EVENT FOLLOWING IMMUNIZATION FORM	149
	ANNEX 4.1: 6-MONTH AVAILABILITY/STOCK OUT REPORT AND STOCK STATUS FOR TRACER ITEMS	152
	ANNEX 8.1: TEMPLATE FOR APPLICATION FORM FOR ADDITION OR DELETION OF A PRODUCT IN IML/EML	159
	ANNEX 9.1: ABC VEN	160
	ANNEX 9.2: STUDY OF MEDICATION ADMINISTRATION	166

Acronyms and Abbreviations

ACT	Artemisinin combination treatment
ADR	Adverse Drug Reaction
AMC	Average Monthly Consumption
AMR	Antimicrobial Resistance
AMU	Appropriate Medicines Use
AMS	Antimicrobial stewardship
ART	Antiretroviral Treatment
ATC	Anatomical Therapeutics Classification
AWaRe	Access, Watch, Reserve
BS	Blood smear test
CME	Continuous Medical Education
CQI	Continuous Quality Improvement
DDD	Daily Defined Dose
Dhis2	District Health Information System 2
DTC	Drug and Therapeutics Committee
EMHSL	Essential Medicines and Health Supplies List
EML	Essential Medicines List
FGD	Focus Group Discussion
HMIS	Health Management Information System
IMCI	Integrated Management of Childhood Illnesses
IML	Institution Medicines List
INRUD	International Network of Rational Drug Use
IPD	Inpatient Department
IPC	Infection Prevention and Control
IV	Intravenous
JMS	Joint Medical Stores
M&E	Monitoring and Evaluation
MCH	Maternal and Child Health
MoH	Ministry of Health
MOS	Months of Stock
MTC	Medicine and Therapeutics Committee
MUE	Medicine Use Evaluation
NAP	National Action Plan
NDA	National Drug Authority
NMS	National Medical Stores
OPD	Outpatient Department
NPC	National Pharmacovigilance Centre
OTC	Over the counter
PDSA	Plan Do Study Act
PGD	Practical Guidelines for Dispensing
PID	Pelvic Inflammatory Disease
PPS	Point Prevalence Surveys
PUD	Peptic Ulcer Disease
QI	Quality Improvement
RDT	Rapid Diagnostic Test
RRH	Regional Referral Hospital
RTI	Respiratory Tract Infection
SPARS	Supervision Performance Assessment Recognition Strategy
STG	Standard Treatment Guidelines
STI	Sexually Transmitted Infection
SSTI	Skin and soft tissue infection
TB	Tuberculosis
TOR	Terms of reference
VEN	Vital, Essential, Necessary
URTI	Upper Respiratory Tract Infection
UTI	Urinary Tract Infection
WHO	World Health Organization

CHAPTER 1

Overview of Management of Medicines and Health Technologies in Uganda

1.1 : Medicine and Therapeutics Committees: An Overview

The Medicine and Therapeutics Committee (MTC) is one of the standing committees in health facilities responsible for managing medicines and health technologies. The aim of establishing MTC is to promote the availability, accessibility, and accountability of safe, effective, efficacious, quality, and cost-effective medicines and health technologies within the health facilities.

1.1.1 Scope of the roles of the Medicine and Therapeutics Committee in the medicines management cycle

In a health facility, the MTC will provide oversight throughout the medicines and health technologies management cycle as illustrated in Figure 1.1 below:

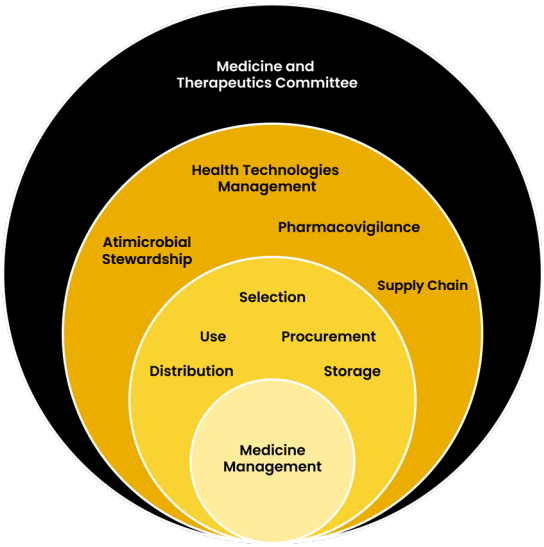

Figure 1.1: Scope of the roles of the Medicine and Therapeutics Committee in the Medicines management cycle

The MTC is directly responsible and accountable for the selection, procurement, storage, distribution and use of medicines and health technologies. To achieve this, the MTC delivers on four priority areas including pharmacovigilance, antimicrobial stewardship, medicines and health technologies supply chain management. It therefore has four core subcommittees as shown in figure 1.1 above. To deliver on these responsibilities, the MTC will take on the following activities among others:

- Operational research
- Dissemination of information
- Providing evidence based advisory role
- Carry out implementation of best practices
- Design institutional policies, guidelines, medicines lists and SOPs
- Provide overall stewardship over the Sub-committees

1.2 Roles and Functions of the Medicine and Therapeutics Committee

The detailed functions per role are described in the following table.

Table 1*: *Functions of Medicine and Therapeutics Committees

ROLES	FUNCTIONS
Operational Research	• Identify medicines, health supplies and technology management problems at any point in the cycle (refer to figure 1.1) • Investigate the identified problem(s) (refer to table 2.3) • Analyze and triangulate routine HMIS data to determine medicine use patterns, accountability, availability and quality of service within the health facility • Analyze, and monitor, expenditures on medicines, health supplies and technologies to ensure cost-effective use of resources
Dissemination of information	Disseminate national and locally developed policies, guidelines, SOPs, Job Aids, and research findings to facility management, facility committees and all health care workers. Ensure the availability and access to current standard treatment guidelines (Uganda Clinical Guidelines)
Evidence-based advisory	Advise health facility staff on appropriate use of medicines, health supplies and technologies
Implementation of best practices	• Conduct effective interventions to improve the use of medicines, health supplies and technologies (educational, managerial, regulatory and financial programs) • Develop evidence based annual health facility quantification and procurement plans for medicines, health supplies and technologies. • Periodically review health facility warehouse orders i.e. NMS & JMS to ensure that HFs needs are adequately addressed

	• Conduct pharmacovigilance activities (identity, report, and manage medication errors, adverse drug reactions, treatment failures, drug quality issues, substance abuse, and poisoning/toxicity) • Design and implement antimicrobial stewardship activities (formulary restrictions, stewardship rounds, parenteral to oral switch, de-escalation of antimicrobials)
Design institutional policies, guidelines, medicines list and SOPs	• Develop or adopt/adapt and monitor policies and procedures e.g.: » Pharmaceutical promotion » Medicine donations » Selection, quantification, procurement planning, storage, distribution and re-distribution, and accountability systems • Expiries and disposal of pharmaceutical products • Develop institutional medicines, health supplies and technologies list (IML) • Develop criteria for inclusion and exclusion of essential medicines and health supplies and technologies onto the institutional medicines list (IML) • Develop a facility-based antibiogram to guide antibiotic selection

1.3 Benefits of the Medicine and Therapeutics Committee

A functional and active MTC will have several benefits including:

- Availability of effective, safe, and cost-effective medicines and health technologies
- Improved accountability of medicines and health technologies.
- Control of the spread of antimicrobial resistance
- Improved staff and patient knowledge on rational medicine use.
- Increased monitoring and reduction in Adverse Drug Reactions and adverse events following immunization
- Reduction of medication errors
- Improved medicine quantification, procurement, and inventory management
- Improved management and control of pharmaceutical and health supplies expenditures

All this will contribute to better quality of service and more cost-effective and efficient resource use.

1.4 Structure, organization and functioning of the the Medicine and Therapeutics Committee

For the MTC to function effectively, the membership should be multidisciplinary and technically competent and officially appointed. It is essential to define and document:

- Roles, responsibilities, and functions of the MTC
- The membership of the MTC, including the chairperson and secretary
- Criteria for membership
- How the MTC will operate and report
- The funding sources and incentives
- The relationship of the MTC with other committees (e.g., Infection Control and Quality Improvement committees) for specific areas of work
- A process for self-assessment and evaluation
- An operational and costed work-plan

1.4.1 Principles for setting up the Medicines and Therapeutics committee

The following principles should be followed when setting up the MTC:

- Technical competency: Members will need to bring their expertise and skills to the committee and contribute constructively to its work.
- Multidisciplinary approach: Sensitive to the local situation: the committee should have a wide representation of cadres and departments (clinicians, nurses, pharmacy, biomedical engineers, Logistics and procurement, administration, laboratory, records/statisticians etc.)
- Transparency and commitment to good service: The success of the MTC will depend upon its being active, working and meeting regularly in a consistent direction and making sound decisions in a transparent way. All committee members should be required to sign a declaration of conflict of interest.

Consider the following:

- All MTC work must be documented and widely disseminated,
- MTC members should not be influenced by external parties, especially by drug advertisements, promotional activities, or personal financial influences.
- Clear organization of work and division of tasks within the MTC: All members should have formal appointments and clear terms of reference with defined roles and responsibilities. (see annex 1.2 for TOR)

All duly appointed members of the MTC should accept in writing to demonstrate their commitment to serve.

1.4.2 Composition of the the Medicine and Therapeutics Committee

The MTC is made up of multidisciplinary professionals representing various departments/units in the health facility. These include but not limited to:

- Medical and clinical staff, representatives of the major specialties (Chair of the committee)
- Pharmacist/pharmacy technicians (the secretary to the committee)

- Nursing personnel
- Biomedical Engineers
- Records officers/statistician
- Laboratory staff
- Store in charge
- Administration representatives.

This multidisciplinary approach will provide an all-round input from the diverse segments of the health facility. The MTC or these sub-committees may co-opt a member from the community.

The Chair of the MTC will be a senior clinician appointed by the health facility management. The person should be technically competent and motivated to take up the leadership. For National Referrals and Specialized institutions, the directorates shall be comparable to a standalone health facility and will have their own MTCs.

The Pharmacist/Pharmacy Technicians and/or store in-charge will be the secretariat to the MTC. It is advisable to appoint a deputy chairperson and deputy secretary within the committee. The chairperson, secretary and their deputies will form an executive committee to handle administrative tasks.

The recommended number of MTC members is 12 to 15; however, this number is dependent on the level of care, and this can be adjusted to allow adequate representation while keeping the number manageable. Additional staff can be co-opted in case of specific issues or included in sub-committees.

A template for Terms of reference for a health facility medicine and Therapeutics committee is presented in Annex 1.5.

1.4.3 Subcommittees of the Medicine and Therapeutics Committee

The MTC works through its sub-committees, as detailed below:

Standing (permanent) committees:

- Antimicrobial stewardship sub-committee
- Pharmacovigilance sub-committee
- Supply chain sub-committee
- Health technologies sub-committee.

1.4.4 Operations of the Medicine and Therapeutics Committee

This section gives guidance on the establishment and operationalization of the MTCs across all levels of care.

There are 3 important principles underlying effective MTC work:

Leadership: only strong leadership by the secretariat will ensure that problems are addressed, solutions are developed and implemented. Decisions must be taken, tasks assigned and followed up at the subsequent meetings. Effective management of meetings means that discussions must be carefully moderated and directed towards productive decisions. Appropriate minute taking and reporting, and follow-up on previous decisions, are key action points.

Effective organization of work: the MTC will meet at least quarterly to discuss issues and take decisions., The sub-committees will meet monthly to carry-out the day to day-to-day functions of the MTC i.e. identify and investigate issues, prepare reports, design and implement interventions. The MTC meeting is the plenary forum to brainstorm, present, report, discuss, analyze, make decisions, and follow up, but members should be ready to commit some extra time to implement the decisions taken. The organization of sub-commitments allows division of work among members and hence makes it manageable.

Communication: Communication amongst the members, with the management and with the rest of the hospital staff is paramount in ensuring that the actions taken by the committee are accepted and implemented. The MTC works in a much wider environment and many stakeholders are involved in the process of medicines management and use, and all of them need to be brought on board. Any action, decision, policy change, and even intervention plan should be shared with the rest of the health facility. The choice of communication modalities rest on the MTC itself: memos, general staff meetings, circulars through administration etc.

1.4.4.1 How to conduct Meetings of the Medicine and Therapeutics Committee

Effective meetings require preparation, communication, control, documentation and follow up as shown in table 2.

Table 2 : Key rules for conducting effective meetings

STEP	KEY RULES
BEFORE	Prepare and Communicate • Decide the purpose (the reasons for the meeting) and the expected outcome (what do you want to achieve/accomplish) • Formulate an agenda, in consultation with the chairperson, specifying agenda items, the person responsible, and time allocation for each item • Communicate date and venue in advance (at least 1 week) • Organize equipment and any logistics that may be involved • Send agenda and accompanying material in advance • Send reminders to all members two days before and on the meeting day
DURING	Control • All members should keep time (arrival and time dedicated to each agenda point) • Give an overview of the objectives of the meeting • Receive feedback from all subcommittees • Direct and keep the discussion focused on the agenda items (put additional issues in parking lot for another meeting) • Encourage participation of all members by prompting and probing • Control and direct the discussion to achieve the desired outcomes • Document discussions and interventions • Agree on the way forward for each item, record decisions, and give assignments as necessary

	• Make conclusions, action points, and responsible persons at the end of the meeting. • Review and adopt the minutes of the preceding meeting. Chairperson and the secretary should sign.
AFTER	Document and Follow-up • Write and circulate minutes within 72 hours after the meeting, highlighting the way forward and action points (who, what, when) • Report (in summary form) to health facility director/administrator and heads of units. • Follow up action points

The secretariat is responsible for running meetings and ensuring effectiveness of operations, especially by following up action points and other administrative issues.

1.4.5 Implementing the Medicine and Therapeutics Committee activities

The MTC will:

- Discuss and take decisions, by consensus or voting. Decisions will take the form of recommendations to management/administration for approval e.g. MTC can formulate policies and guidelines
- Conduct a survey and use the findings to guide recommendations, e.g., a recommendation to restrict antibiotic prescribing following point prevalence survey.
- Routinely provide reports to the facility top management for decision making. The report should summarize updates on the four core areas.

Other reports can be forwarded to the Ministry of Health for action.

A sample template for reporting MTC findings, to the hospital administration and MOH relevant departments, is presented in Annex 1.5.

1.4.6 Work-planning and performance assessment of the the Medicine and Therapeutics Committee

Work planning

The MTC should formulate annual work plans, detailing both routine activities and specific issues to be addressed. It should develop and submit a budget to administration/top management for approval. The MTC work plan should be included in the health facility work plan and budget; this will guarantee the allocation of some resources for the committee functioning and guide its work throughout the year.

Detailed descriptions of most of the activities are presented in the following chapters, and an example of a work plan for a newly instituted MTC is presented in Annex 1.3 for guidance. Examples of MTC activities are presented in table 1.3 below.

Table: 1.3 Example Of Mtc Activities

Routine activities	Ad hoc activities
• Review the institutional medicine list • Prepare annual procurement plan • Annual drug use indicator surveys • Annual PPS survey (antibiotic use in in-patient wards) • Annual VEN and ABC (consumption) analysis • Review quarterly report of expiries • Review of periodic (weekly/monthly) availability and stock outs reports • Pharmacovigilance report	• Formulate an institutional medicine list (if not present) • Specific prescription audits (e.g. malaria in OPD, severe malaria, surgical prophylaxis) • Medicine use surveys (e.g. Ceftriaxone, artesunate, etc.) • Interventions to modify prescription practices • Setting up of in-patient pharmacy • Formulate or adapt policy for management of donated items • Review tracking and accountability of products in the wards • Any emerging issue (e.g. product quality, etc.)

The MTC will often address emerging issues, however, it is critical to have a plan for the routine activities and for the specific issues to be addressed in a certain period. It won't be possible to address all the problems at once, therefore prioritization and planning are key: for example, it may not be possible to address more than 1 or 2 prescription problems each year, which allows adequate time to investigate, decide and implement interventions, and assess and consolidate the results.

Monitoring and Evaluation of the Medicine and Therapeutics Committee

MTC performance should be assessed and documented, based on the agreed goals and work plans. This should be done within the facility (self-assessment) and by external health authorities (district authorities or Ministry of Health). Performance can be assessed at various levels, through different indicators. For practical purposes, the assement has been divided into six domains related to the functions of the MTC :

1. MTC Governance & Structure
2. MTC Operationalization & Reporting
3. Antimicrobial Stewardship (AMS) & Appropriate Medicines Use (AMU)
4. Pharmacovigilance (PV)
5. Supply Chain Oversight
6. Health Technologies Management (HTM)

It is important to note that while the assessment of these domains is useful to monitor if an

MTC is "functional" and implementing its work plan, the real assessment will be on outcomes since the goal of the MTC is to ensure that quality and safe medicines are available and used appropriately.

Annex 1.1 shows the MTC Standard Unit of Output and weighted performance measures.

1.4.7 Practical tips to ensure functional Medicine and Therapeutics Committee

The keys to MTC success are ACTION and RESULTS: showing the benefit of MTC work will motivate the MTC members, gain recognition of the team within the health facility, and motivate other staff.

Practical tips for MTC success

- Develop your MTC according to the local situation. Start with what you have (e.g. few members) even if not perfect/complete.
- Start collecting data to assess/demonstrate problems
- Choose a problem that can easily be analyzed and addressed
- Share your work to ensure transparent decision-making: e.g. after identifying and analyzing a problem share findings with all the staff (e.g. during a CME)
- Distribute the tasks: e.g. form different sub-committees for conducting the investigations of problems and implementing solutions.

1.5 Common challenges to the Medicine and Therapeutics Committee operations and how to address them

The following challenges have been identified as hindering successful MTC operations. Some suggestions on how to tackle them are also presented in Table 1.4 below.

Table 1.4 Challenges And Solutions To Mtc Operations

CHALLENGE	SUGGESTIONS
Lack of motivation, ownership, and commitment by MTC members	Purposive selection of members Official appointment
Lack of support from management Low MTC profile within the organization	Discuss with management the purpose and benefit of MTC
Confusion about roles and responsibilities	Clarify with members' roles and responsibilities Using MOH guidelines, formulate and disseminate clear Terms of Reference
Limited awareness of medicine use problems and interventions	Use availed guidelines, training, and support offered by MOH and partners
Lack of clear guidelines and operating procedures	Use MOH guidelines, ask for support from other MTCs and MOH
Lack of resources/funds for MTC activities	Prepare a work plan to be included in the health facility work plan and budget Lobby for support from implementing partners
Lack of incentives/rewards	Clarify expectations when members are appointed
Poor intra-health facility communication	Include MTC communications in general staff meetings, inform all health facility staff about MTC purpose and activities Regularly report to administration
Over-reliance on pharmacy to implement	Divide tasks and responsibilities according to competencies and time
workload	Address a few issues at a time, keeping into account other engagement of the MTC members. Involve students, and interns where possible, and ask for support from Implementing Partners
High staff turnover of trained MTC members	Keep a library of MTC guidelines to be used to induct members Share knowledge after training

1.6 Roles and Responsibility of key players in relation to the Medicine and Therapeutics Committee functions

- MoH – Department of Pharmaceuticals and Natural Medicines
- Provide overall leadership in the MTC operationalization process
- Map out and coordinate partners› support for MTC
- Provide the guidelines and targets for the operationalization of MTCs
- Monitoring and evaluation of MTC activities
- Lobby for funding
- Support capacity building activities MTC members

Health facility

- Lead MTC operations at the facility
- Plan and budget for MTC activities
- Coordinate activities of the respective MTC subcommittees
- Make decisions to improve the use of medicines and health supplies at the facilities
- Provide quarterly reports to MOH
- Support capacity building of lower facility MTCs

Central Warehouse including National Medical Stores (NMS) and other private warehouses

- Participate in training of MTC members in areas of pharmacovigilance, antimicrobial stewardship, and Supply chain.
- Collaboration with other stakeholders to support MTC e.g. NDA, MoH
- Continuous support supervision of MTCs (including attending scheduled meetings).
- Participate and report in the national performance review meetings for antimicrobial use and consumption

Health Partners

- Support peer-to-peer learning between facilities
- Offer MOH and HFs technical and logistical support as and when needed
- Provide capacity building for health facilities
- Participate and report in the national performance review meetings for AMU

Academia and professional bodies

- Inclusion of MTC concepts in training curricula for health professionals
- Conduct training in medicine use and management for health practitioners
- Conduct research in medicines use and management

References

1. ***Moroto Regional Referral Hospital Medicine and Therapeutics Committee, terms of reference, July 2017***
2. ***SIAPS technical brief. Developing better terms of reference to improve the performance of pharmaceutical sector committees: case studies from South Africa. September 2017***
3. ***Drug and Therapeutics Committees, a practical guide. WHO 2003***
4. ***Drug and Therapeutics Committees training material WHO 2008***

CHAPTER 2

Antimicrobial Stewardship

2.1 Introduction to Antimicrobial Resistance

An antimicrobial is an agent that kills microorganisms or stops their growth. Antimicrobial medicines can be grouped according to the microorganisms they act primarily against; antivirals (against viruses e.g. HIV), antifungals (against fungi e.g. Candida spp), antibiotics/antibacterials (against bacteria) and antiparasitics (against parasites such e.g. P. falciparum, etc.).

Antimicrobial resistance (AMR) is the ability of a microorganism (like bacteria, viruses, fungi, and parasites) to stop an antimicrobial (such as antibiotics, antivirals, antifungals, and antiparasitics) from working against it (WHO, 2021).

Antimicrobial Stewardship (AMS) is a "coherent set of actions which promote the responsible use of antimicrobials (WHO, 2019).

The National Action Plan 2024-2029 (NAP 2024-2029) provides guidance on how AMS can be implemented in the human, animal, and environment. The National Antimicrobial Stewardship (AMS) manual guides the implementation of the AMS activities in health facilities and communities. As an arm of the MTC, this guideline demonstrates how the AMS is linked to other MTC activities.

2.2 Antimicrobial Stewardship Programs in the Health facility

2.2.1 Structure and composition of the Antimicrobial Stewardship in Uganda

National level

At national level, technical coordination, governance, and decision making for AMS is the responsibility of the Medicines Management and Procurement Technical Working Group (MPM-

TWG), clinical care and health information technical working group (HIF-TWG), and the health promotion TWG of MoH (National Antimicrobial Stewardship Manual, 2024).

Subnational level

At the health facility level, the AMS will be governed by the AMS subcommittee.

Composition of the Antimicrobial Stewardship subcommittee

Members of the AMS subcommittee will be appointed by the MTC. The chairperson and secretary of the AMS subcommittee will be appointed from the MTC members. The director/head of the health facility will officially appoint the members of the AMS subcommittee as deemed necessary according to the health facility needs.

The members of the AMS subcommittee should include the following – but not limited to:

- Clinicians,
- Pharmacists/pharmacy technicians,
- Laboratory staff (preferably microbiologists)
- Nurses,
- Community health focal person,
- Epidemiologists,
- Data analyst
- Representative from the hospital IPC committee (IPC focal person).
- AMS team leads (co-opted)
- Quality Improvement Specialists: Assist in data collection, analysis, and the development of strategies to improve antimicrobial prescribing practices.
- Infectious Disease Physicians: Provide expertise in the treatment of infections and guide appropriate antimicrobial therapy.
- Educators/Trainers: Provide training and education to healthcare staff and patients about responsible antimicrobial use.

Important Note: The AMS subcommittee should be small but agile, which will work within the MTC and the wider quality improvement framework, to promote the AMS agenda.

2.2.2 Goal and functions of the Antimicrobial Stewardship subcommittee

The goal of an AMS subcommittee is to ensure rational use of antimicrobials at the facility, and specifically to ensure that:

- Safe, effective, cost-effective antimicrobials are made available.
- Antimicrobials are used only when clinically indicated, at the correct dose and for the appropriate duration of time.
- Correct information is given to on how to take antimicrobials correctly.

Below are the functions of the Antimicrobial Stewardship Subcommittee

Functions of Antimicrobial Stewardship Subcommittee of MTC
• Advise the MTC and medical staff on all aspects of antimicrobial use and misuse and managing the effects • Assist in evaluating and selecting antimicrobials for the formulary and standard treatment guidelines, as guided by the antibiogram. • Develop policies concerning the optimal use of antimicrobials for approval by the MTC and medical staff. Policies should specifically include sections on methods to limit and restrict the use of antimicrobials in the hospital and primary care clinics. • Monitor and assess consumption and use through prescribing quality assurance programs and medicine use evaluations to ensure the use of effective antimicrobials of adequate quality only when clinically indicated, in the correct dose, route, and for the appropriate duration. • Participate in educational programs for healthcare staff. • Collaborate with the IPC committee and laboratory departments to monitor and prevent/ limit the emergence and spread of resistant microorganisms. • Implement the AMS strategy and guidelines. • Data collection and reporting. Collect and analyze data connected with antimicrobial use and resistance by providing reports to stakeholders to inform decision-making. • Research and quality improvement. Engage in research initiatives to assess the impact of stewardship activities and contribute to quality improvement projects. • Multidisciplinary collaboration.

2.2.3 Antimicrobial Stewardship Team

The AMS team will manage the health facility's AMS programme at a day-to-day level and will be responsible for enacting the strategy to achieve the goals determined by the AMS subcommittee. The AMS team leader should be a member of AMS subcommittee.

Roles of the Antimicrobial Stewardship team include:

1. Developing the AMS action plan.
2. Implementing AMS strategies and performing interventions as required.
3. Establish, maintain, and enforce a formulary of restricted antimicrobials and any approval systems.
4. Developing and maintaining clinical treatment guidelines and pathways.
5. Education of staff, students, and consumers.
6. Provide expert advice on patient management, including reviews of patients prescribed restricted antimicrobials.
7. Monitoring and analyzing the effectiveness of AMS strategies and interventions, including antimicrobial usage and appropriateness.
8. Reporting and feedback to the AMS committee or other executive groups.
9. Research and Innovation: Supporting research efforts aimed at discovering new antimicrobials, alternative therapies, and understanding resistance mechanisms

10. Cost-Effectiveness: Minimizing unnecessary costs associated with prolonged hospital stays, ineffective treatments, and managing side effects or complications from inappropriate antimicrobial use.
11. Collaborative Care: Promoting interdisciplinary teamwork among healthcare providers, including pharmacists, to ensure comprehensive patient management.
12. Monitoring and Surveillance: Tracking antimicrobial usage and resistance patterns to inform guidelines and policies

Composition of the Antimicrobial Stewardship team

All health facilities should have AMS team(s). The number of AMS teams will depend on the level of care of the facility (e.g. National and Regional Referral Hospitals will have AMS team per department, the General Hospitals and Health Center IVs shall have an AMS team at wards)

Among the AMS team members, there will be an AMS team leader (AMS champion) who must be co-opted to the AMS subcommittee.

The AMS team members will be appointed by the director/health facility in charge.

2.3: Leadership and governance of Antimicrobial Stewardship at each level of care

2.3.1 National Referral and specialized health facilities

The implementation of AMS in this category of health facilities is complex given the structural arrangement. The MoH recommends that the MTCs for these institutions is constituted at directorate level. For example, in Mulago NRH we will expect multiple MTCs under each directorate and corresponding AMS sub-committees per directorate such as pediatrics, surgery, etc. The head of the health facility, institution will be responsible to appoint the MTC coordinating mechanism which will be responsible with overseeing and making necessary AMS recommendations on all the MTCs from all the directorates. The MOH recommends that such mechanisms meet and report to the hospital administration / board quarterly. The surveillance data should be reported quarterly to AMS and AMR national sub-committees and for the alert organisms, these should be reported immediately as soon as they are identified as per MoH guidelines.

The MTC coordination mechanism will be composed of:

- The head of the health facility,
- The chairpersons of the directorate MTC,
- The secretaries of the directorate MTC,
- Members of the hospital administration and finance

• And other relevant stakeholder as advised by the hospital administration.

The MTC coordinating mechanism will be chaired by the head of the health facility and the secretary will be the head of pharmacy. This mechanism will be responsible for decision making related to antimicrobial use, microbiology services, diagnostic stewardship, and IPC.

The organogram for national referral hospital is shown in Figure 2.1

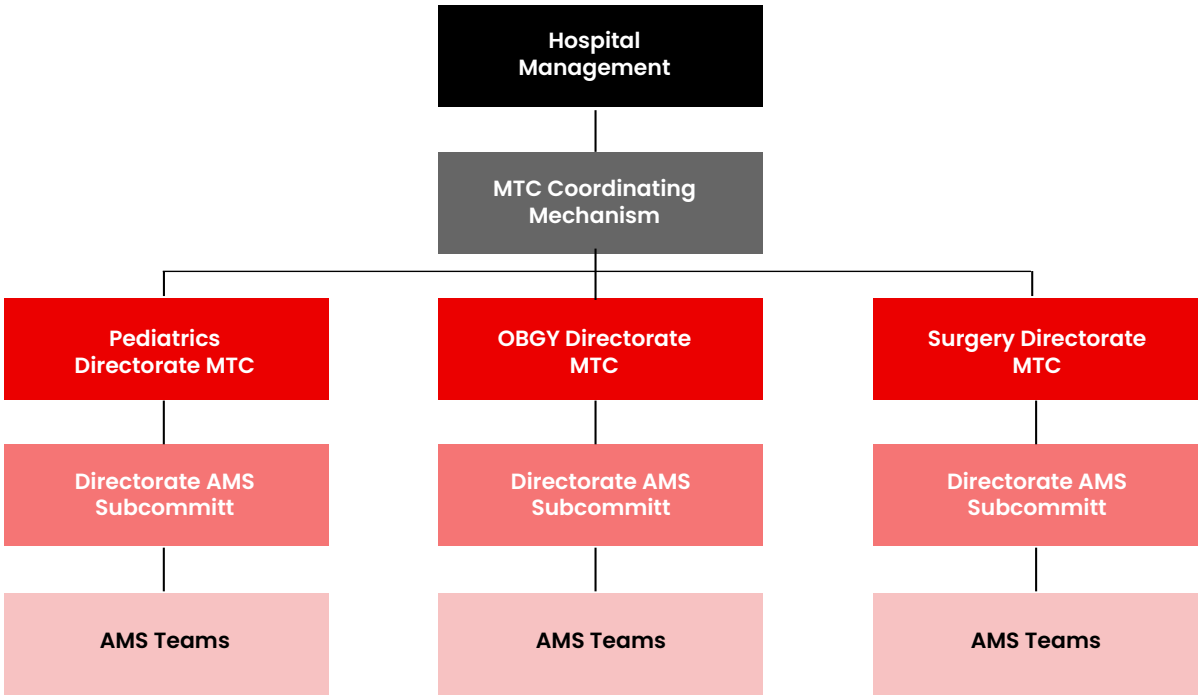

Figure 2.1 Ams Governance Structures At The National Referral Hospital

2.3.2 Regional Referral Hospital and lower levels of Care

The composition of the AMS subcommittee will be guided by the respective Level of Care. It may include health workers from AMR surveillance, diagnostic stewardship, AMU&C, and IPC. The number may vary as per the level of care depending on the number of operational units/wards. The surveillance data should be reported quarterly to AMS and AMR national sub-committees and for the alert organisms, these should be reported immediately as soon as they are identified as per MoH guidelines.

The organogram for regional referral hospitals and other level-of-care health facilities is shown in Figure 2.2

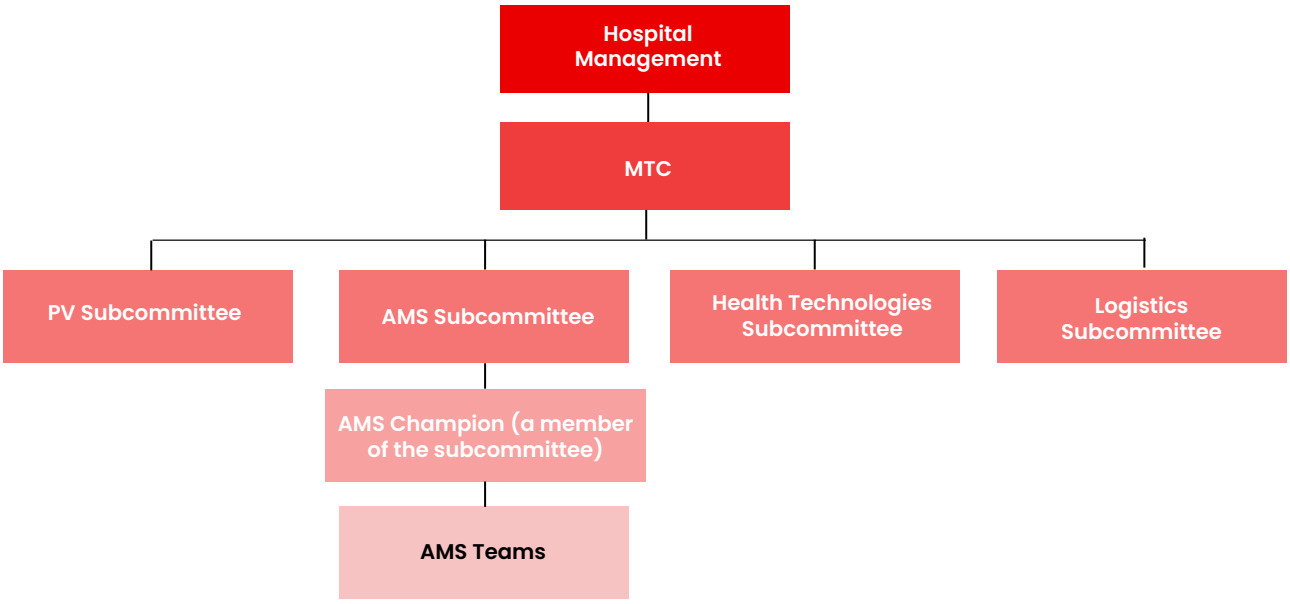

Figure 2.2 Ams Governance Structures At The Regional Referral Hospital

2.3.3 Community level

The community comprises; the community health workers (CHEWs) locally known as Village health Teams (VHTs), private health providers, and the consumers. The private health service providers will include the private drug outlets (pharmacies and Drug shops), the private clinics, private laboratories.

The community health workers (CHEWs) are mandated to optimize antimicrobial consumption and use through consultations, recommendations of the use of the relevant treatment guideline e.g Integrated Community Case Management (iCCM), promoting awareness about antimicrobial consumption and use under the supervision of their respective health facility.

The private drug outlets are mandated to optimize use antimicrobial consumption and use through consultations, recommendations of the use of the relevant treatment guidelines, promoting patient referral and awareness about antimicrobial resistance.

The dispensing of antimicrobials should be done on valid prescription only. Drug outlets should source their supplies from licensed distributors.

The private clinics are tasked to ensure adherence to the standard treatment guidelines and rational prescribing. They should observe the national referral system.

The private laboratories will promote AMR surveillance (including pathogen identification and antimicrobial susceptibility testing) and advise clinicians on the right antimicrobial to be used as per the national guidelines.

The consumers include the patients, and the public who are involved directly or indirectly in the consumption and use of antimicrobials. Their major role is to adhere to treatment, seek medical care from licensed health service providers, report and promote rational use of antimicrobials by alerting the prescribers at different points of care and any other relevant regulatory authorities on any possible irrational use of antimicrobials.

Secondly, the community through their local leaders, CHEWs and community-based organizations shall advocate for proper use of antimicrobials and propose relevant actions to be adopted by the community leadership to improve AMS in the community. The supervision of the CHEWs will be under the District Health Teams.

The structure for community AMS will be as displayed in Figure 2.3

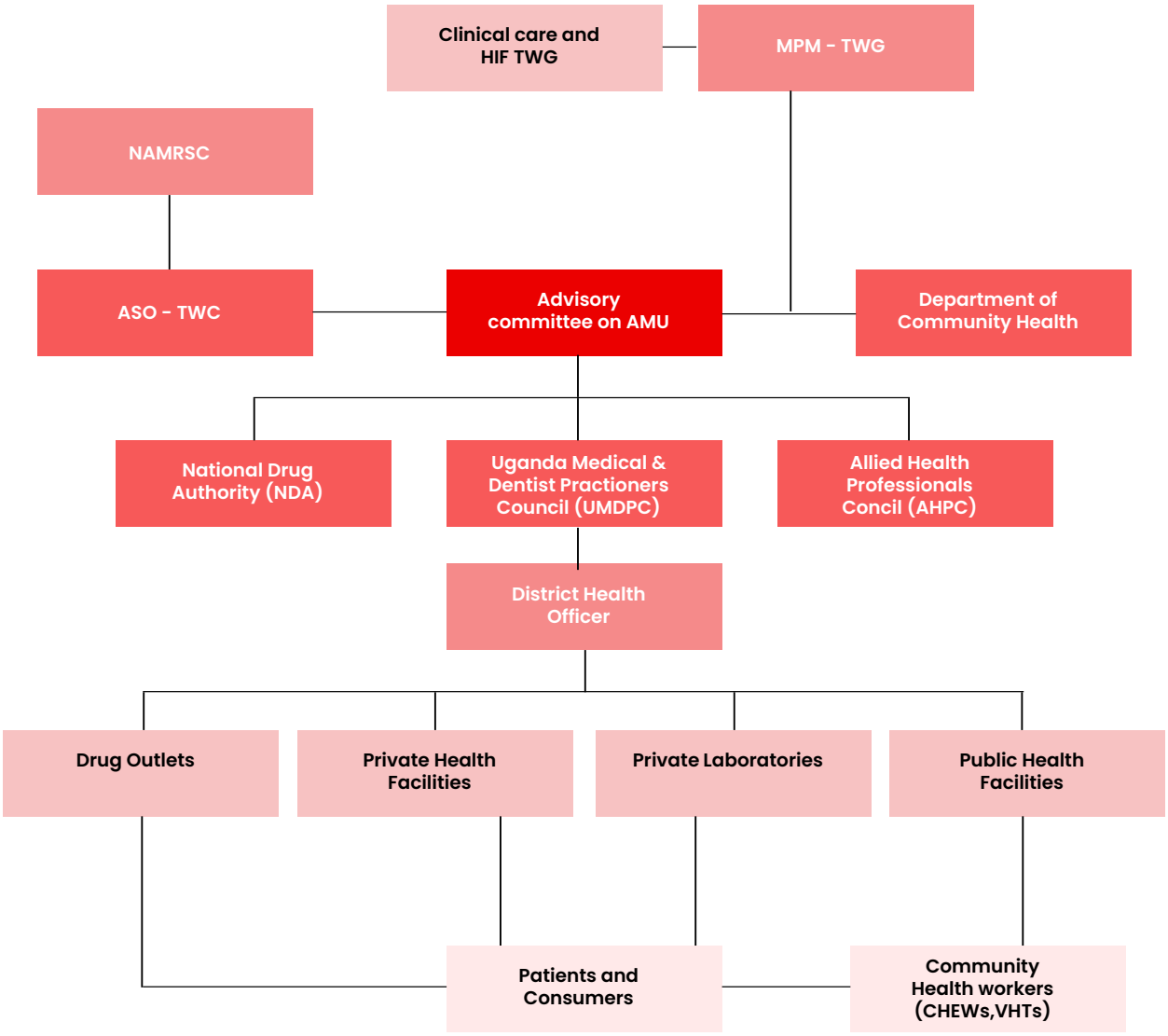

Figure 2.3; The Structure For Community Ams

2.4: Setting standards – treatment guidelines and principles of antibiotic prescribing

Development of antimicrobials, and in particular antibiotic treatment guidelines present unique challenges, since it often requires updated information about the common causative organisms and their pattern of sensitivity and resistance, which may change between countries, regions, and even between institutions. Such information can be provided only through laboratory investigations which, in most cases, may not be commonly available. For many infectious syndromes, international guidelines exist and may be applicable in a variety of settings (e.g. WHO guidelines) and can be relied upon for guidance where local data does not exist.

Note: it is advisable that the health facility uses the facility-generated data to set/customize its own standards at the regional/local level to guide prescriptions.

2.5 Role of the laboratory in antimicrobial stewardship

Laboratory services have a fundamental role against AMR:

- At clinical care level: Reduce diagnostic uncertainty and hence inappropriate/excessive use of antimicrobials, ensure rapid diagnosis with clear guidance for treatment, and target antimicrobial therapy according to the type of microorganism and sensitivity (make facility antibiogram).

- At the infection control level: To set additional precautions (isolation, decolonization).
- At the public health surveillance and research level: Detect and monitor the emergence and spread of resistant microorganisms, timely reporting of detected microorganisms of public health concern.

The lack of diagnostic tools is a recognized driver for excessive and inappropriate use of antimicrobials. At the individual/patient level, diagnosis is often based only on history and examination, and even in the presence of a clear-cut infection, the choice of antimicrobial is presumptive, or empirical. Similarly, at the system level, the lack of epidemiological data on causative organisms and their patterns of resistance prevents the informed development of therapeutics guidelines.

Several tests can help to differentiate between a viral and bacterial disease for example:

- A raised white blood cell count with neutrophilia can suggest a bacterial cause, but it is very non-specific, and many other conditions can cause raised neutrophils.
- Very elevated C-reactive protein (CRP) can suggest bacterial infection, but again it can not be a specific and the current "threshold" used in recommendations is quite high (> 100 mg/L).
- Pro-calcitonin: it is a promising test for the diagnosis of bacterial infections but not widely available in our setting.
- Culture and sensitivity tests can help in the identification of the causative microorganism and in the assessment of its sensitivity to antimicrobials, but in most cases, they are not widely available, and results can take several days (e.g. for the result of a blood or urine culture with antibiogram).
- On the other hand, these tests provide a double level of information:
    - They can help confirm the diagnosis and deescalate/target the antibiotic treatment of the individual patient according to the type of organism identified and its sensitivity pattern
    - They provide epidemiological data about microorganisms and resistance which, if aggregated, can be used to develop a cumulative antibiogram.

2.5 Antibiogram

An antibiogram is a profile of antimicrobial susceptibility testing results of a specific microorganism to a series of antimicrobial drugs. Data from multiple tests (a threshold of at least 30 isolates per organism per sample per year, Truong et al., 2021) can be summarized periodically and presented showing percentages of organisms tested that are susceptible to a particular antimicrobial drug and can inform the development of guidelines for antimicrobial treatment for the specific setting (health facility, region or ward) from which the data was obtained.

2.6 Stewardship interventions

Implementing health facility antimicrobial stewardship interventions involves a systematic approach that requires an action plan.

The healthcare facility AMS committee will develop an AMS action plan, based on a situational analysis to ensure accountability, prioritize activities, and measure progress.

The AMS action plan should provide an overview of the facility AMS program with overall goals, how they will be reached by whom, and how progress will be measured over a specific period.

AMS activities or interventions should be applied in a phased manner, starting with the simplest and eventually advancing to more complex activities. The action plan should include targets that are time-bound.

The development of interventions to improve antimicrobial use will depend on local needs or issues identified, the available skills/expertise and other resources. Issues may need to be prioritized based on severity and size but also based on how "solvable" they are, starting with easy and simple approaches which are targeted to the factors identified as drivers of inappropriate practices.(see the present manual, and the National Antimicrobial Stewardship Manual, 2024).

Target areas for stewardship interventions include:

- High-priority conditions e.g. those which clinicians commonly deviate from best practices by overprescribing (e.g. URTIs, acute bronchitis, viral pharyngitis).
- Areas where the wrong antibiotic agent, dose, or duration is inappropriately prescribed (e.g., surgical prophylaxis).
- Focus on parenteral to oral switch (if excessive/prolonged use of parenteral is identified as an issue).
- Documentation of diagnosis and review dates.
- Adherence to "AWaRe classification": antibiotics in the Watch and Reserve groups should be a focus for stewardship due to the higher risk and need to preserve their effectiveness.

As detailed in Chapter 10, Interventions can be generally classified into educational, managerial, regulatory and economic/financial. It was also observed that multi-pronged interventions, combining multiple strategies, are significantly more effective than single strategy initiatives, and caution must be exercised with regulatory approaches, to avoid unintended negative consequences (e.g. patients not receiving the antibiotic they need in time because the person to pre-authorize is not there!).

AMS strategies in addition have been classified into two groups as in table 2.1 below:

"Front-end strategies": happening before the prescription.

"Back-end strategies": happening after the prescription

Table 2.1 – Examples Of Antimicrobial Stewardship Strategies

FRONT END STRATEGIES: HAPPENING BEFORE →	ANTIBIOTIC PRESCRIPTION AND USE →	BACK END STRATEGIES: HAPPENING AFTER

Front End Strategies	Back End Strategies
• Formulary restriction • Prescription restriction (no OPD, only by specialist) • Pre-authorization • Clinical guidelines/protocol • Education (CMEs) • Antimicrobial order forms • Policies for de-escalation/antibiotic review/parenteral to oral switch • Selected antibiogram reporting • Computerized decision support	• Audit (retrospective or prospective) and feedback • Stewardship rounds • Parenteral to oral conversio • Post authorization program • Consultation with ID specialist microbiologist • Surveillance of consumptions • Review after laboratory results (targeted therapy) for de-escalation

Table 2.2 Stewardship Core Intervention

Intervention	Description
Formulary Restriction and Pre-authorization	• Use of certain antibiotics is restricted in terms of indication and authorizing prescriber. • For example, Reserve antibiotics could only be prescribed by specialists in infectious diseases in selected indications and based on microbiological investigations. In the Ugandan setting, meropenem and piperacillin/tazobactam are available at referral facilities and their use should be regulated e.g. only prescribed by consultants. Such restrictions should not prevent timely administration of life-saving treatment so the pre-authorization procedure should not cause unnecessary delays. • Antibiotics selection for the facility institutional medicine list and restriction in terms of departments/prescribers (see Chapter 3), a simple and effective form of this strategy can also be considered.
Prospective audit and feedback	• Prospective audit and feedback engage the provider after an antibiotic is prescribed • Typically includes external reviews of antibiotic therapy by an expert such as a clinical pharmacist with infectious disease training or an infectious disease physician/doctor. • Requires the availability of expertise and this may be more difficult in smaller facilities, so innovative approaches should be used e.g. engaging external experts. • This strategy is labor intensive, and the identification of appropriate patients for intervention can be challenging. The audit and feedback intervention can be conducted periodically on a limited scale. • Providing individual feedback with peer-to-peer comparisons may also be effective. • Example: In South Africa pharmacists had a successful audit and feedback program in 47 private rural and urban hospitals, where they provided feedback to doctors on individual prescription of antibiotics, focusing on some “low-hanging fruits” such as: » reducing redundant coverage (using more than one antibiotic with a similar spectrum) » optimizing duration (avoiding un-necessary long treatments), and, conducting culture before starting treatments
De-escalation or antibiotic time-out	• De-escalation is the alteration of antimicrobial therapy once culture results are available, choosing the antibiotics with the narrowest spectrum which is effective in treating the identified organism. • Automatic stop orders/antibiotic time out are ways to prompt the review of treatment and prevent unnecessary long courses. • Again, these strategies depend on structure, staffing and resources, and can become a risk of treatment interruptions for patients. • In our setting, where ward pharmacist is rare, the inpatient • pharmacy is a good point for review of antibiotic prescriptions e.g. could query parenteral antibiotics lasting more than 7 days.

Parenteral to oral conversion	• Developing clinical criteria and guidelines that allow for switching from parenteral to oral agents can decrease the length of hospital stay and health care costs. • When the situation is appropriate and when the antibiotics show good oral absorption (e.g., fluoroquinolones, trimethoprim-sulfamethoxazole, linezolid, etc.), switching to oral medications improves patient safety by reducing the need for IV access. • Such a program can be also incorporated into inpatient pharmacy activities, which can audit prescriptions and recommend changes according to agreed criteria.
Alerts for duplications of coverage and drug interactions, dose optimization	• In some settings, use of multiple antibiotics with duplication of coverage is common, and may often be done "inadvertently" (e.g. antibiotics are switched but stop orders are not clearly written, or multiple providers write different prescriptions) • Again, the inpatient pharmacy could be a good audit and verification point as the sole "dispenser" point. With adequate training, pharmacists can also provide alerts on risky interactions as well as verifying appropriate dosages (e.g. based on weight).

Other Interventions to Improve Antimicrobial Use

In line with general principles and strategies as stated Chapter 6, other interventions include:

- **Improving diagnostic skills and accuracy:** training on diagnostic protocols allows more accurate diagnosis and targeted treatment. A study in Northern Uganda showed that training of health workers in adhering to Integrated Management of Childhood Illnesses (IMCI) protocols for correct management of respiratory symptoms decreased the use of antibiotics in children under 5 years.
- **Improving availability, use and correct interpretation of diagnostic tests:** the laboratory plays a big role in antimicrobial stewardship, as it allows more accurate diagnosis, targeted treatment and development of guidelines fitting the local epidemiology and sensitivity patterns. In settings where microbiological services are newly introduced, prescribers need to be trained on the correct use and interpretation of tests. Laboratory reports can become tools of stewardship e.g. by selective reporting of susceptibility results, so that results for second antibiotics - either costlier or broader spectrum - are only reported if an organism is resistant to the primary-first line antibiotic. The use of rapid testing for identification of causative agents of infection is currently available only for selected microorganism (e.g. malaria parasites, streptococcus pyogenes in the throat) but it seems to improve rates of appropriate treatment and decrease inappropriate prescriptions.
- **Disease specific protocols and guidelines:** e.g. protocols for 1st line treatment of pneumonia, indications on management of asymptomatic bacteriuria (usually not requiring antibiotics), management of diarrheal diseases (in most cases not requiring antibiotics).
- **Educational activities:** an important part of stewardship but should be used to complement other activities. Collection and sharing of facility-specific data (e.g. prescribing patterns from surveys, cumulative antibiograms) and collaborative development of facility-based guidelines can motivate prescribers to adhere to agreed protocols by promoting ownership. Access to the necessary expertise is essential: e- learning courses are provided as references at the end of this chapter, but innovative strategies will have to be availed (e.g. Toll-free Treatment and Information Call centers).

2.7 Monitoring and Evaluation

A range of measures for evaluating performance of antimicrobial stewardship programs are proposed in the table below. The choice will depend on the targets chosen for the interventions. Table 2.3 shows some examples of indicators.

Table 2.3 Some Examples Of Indicators, Divided By Category

Indicator	Example
Structural indicators	Availability of a multi-disciplinary AMS team, availability of guidelines, provision of education through CMEs
Process measures	Quantity of antibiotic consumption, quality of antimicrobial prescriptions (adherence to guidelines), number of adverse events reported
Outcome measures	Rates of surgical site infections (SSIs) and C. difficile infections, mortality, readmissions within 30 days of discharge, prevalence of resistance, rate of adverse events.

2.8 Role of Infection Prevention and Control in Medicine and Therapeutics Committee

Infection Prevention and Control is a scientific evidence-based approach and practical solution designed to prevent harm caused by infection to patients, healthcare workers, and visitors. This is achieved through the establishment and implementation of policies and procedures and the education and monitoring of staff adherence to the procedures to reduce infection among patients, healthcare workers, and visitors.

To prevent the spread of resistant infections, it is important to implement infection prevention programs in all healthcare facilities.

Strong IPC, including standard precautions and Health Care Associated Infections (HAI) surveillance, is the most effective approach to controlling the spread of AMR. Safer hospitals mean fewer infections and every infection prevented is an antibiotic avoided.

2.8.1 Collaboration between Infection Prevention and Control in Medicine and Therapeutics Committee

The collaboration between Infection Prevention and Control (IPC) and the Medicines and Therapeutics Committee (MTC) fosters a proactive approach to patient safety by promoting safe medication practices, minimizing infection risks within healthcare facilities, and ultimately improving patient outcomes and a safer healthcare environment.

The following are key aspects of this collaboration:

1. Antimicrobial Stewardship:

IPC is an integral component of antimicrobial stewardship. IPC and MTC work closely to design and implement antimicrobial stewardship programs, monitoring antibiotic prescribing patterns and promoting the responsible use of antibiotics. This teamwork is crucial in combating antimicrobial resistance (AMR).

HAI Surveillance, a fundamental role of IPC is a systematic and continuous collection, analysis , and interpretation of HAI data for decision-making, policy, and research. HAI surveillance plays a key role in antimicrobial stewardship and ultimately AMR prevention as shown in the figures below.

IPC teams collect data on infection rates, antibiotic resistance patterns, and healthcare-associated infections (HAIs). Sharing this data with the MTC allows for evidence-based decisions on medication protocols and supports adjustments to antimicrobial guidelines as infection trends evolve especially in high infection-risk areas like intensive care units.

Hence it is key to have representation of IPC on the AMS and MTC Committees.

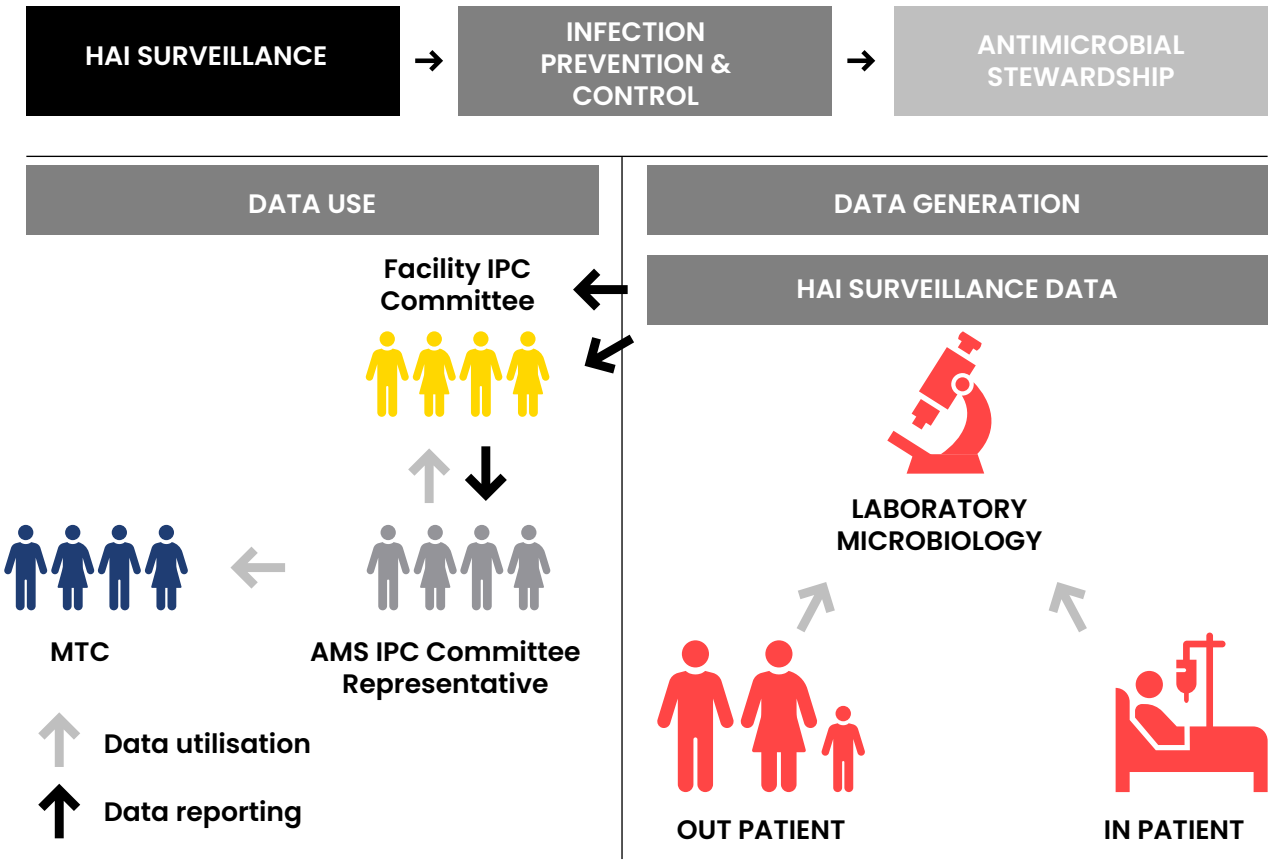

Figure 2.4 Collaboration Between Health Facility Ipc Committee And Ams Subcommittee Of The Mtc

Note: More details on the role of IPC in antimicrobial stewardship in the AMS manual

2. Joint Policy Development:

Both IPC and MTC jointly develop policies on medication administration and infection prevention. IPC provides expertise on infection risk, while MTC brings in clinical pharmacology knowledge to ensure policies that support both safe and effective medication use. In addition, IPC aids in creating policies and protocols that govern the safe administration of medications, including guidelines for aseptic techniques, drug preparation, and administration procedures.

3. Educational Initiatives:

IPC collaborates with the MTC to deliver training programs for healthcare staff on infection prevention, safe medication handling, and aseptic techniques. This joint effort reinforces good practices in both medication use and infection control.

4. Evaluation of Medications and Therapeutics:

When new medications or therapeutics protocols are introduced, the IPC team assesses potential infection risks, especially for injectable medications or therapies requiring special handling including delivery systems and any associated devices, ensuring they meet infection prevention standards. This helps the MTC make decisions that account for both efficacy and infection control.

5. Response to Outbreaks and Infection Trends:

In cases of outbreaks or emerging infection patterns, the MTC and IPC coordinate to review medication practices, adjust prescribing protocols, and implement targeted interventions to control and prevent the spread of infections.

6. Continuous Quality Improvement:

IPC and MTC regularly review and refine policies, based on ongoing surveillance, audit results, and feedback from healthcare staff, to improve medication practices and infection control measures continually.

For more details on monitoring AMS interventions refer to Chapter 9 of the National Antimicrobial Stewardship Manual, 2024.

References

1. ***Antimicrobial stewardship - from principles to practice. British Society for Antimicrobial Chemotherapy. 2018. ISBN: 978-1-78926-984-0 (available at: bsac.org.uk/antimicrobial-stewardship-from-principles-to- practice-e-book/, last accessed: September 17, 2024)***
2. ***Antimicrobial stewardship programmes in health-care facilities in low- and middle-income countries. A practical toolkit. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.***
3. ***Anderson M, Ljungqvist G, van Kessel R, Saint V, Mossialos E. The socioeconomic drivers and impacts of Antimicrobial Resistance (AMR): Implications for policy and research. Copenhagen: WHO Regional Office for Europe; 2024. Licence: CC BY-NC-SA 3.0 IG***
4. ***Centers for Disease Control and Prevention (U.S.) (2013). Antibiotic resistance threats in the United States, 2013.***
5. ***Critically important antimicrobials for human medicine, 6th revision. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.***
6. ***E-training: antimicrobial stewardship for South Africa: https://www.openlearning.com/courses/clinical-antibiotic-stewarship-for-south- africa (videos with both general topics and disease based CMEs, very practical)***
7. ***Gerding DN. The search for good antimicrobial stewardship. Jt Comm J Qual Improv. 2001 Aug;27(8):403-4. doi: 10.1016/s1070-3241(01)27034-5. PMID: 11480201.***
8. ***Kiguba R, Karamagi C, Bird SM, 2016. Extensive antibiotic prescription rates among hospitalized patients in Uganda: but with frequent missed-dose days. J Antimicrob Chemother 2016; 71: 1697-1706***
9. ***Global antimicrobial resistance and use surveillance system (GLASS) report 2022. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.***
10. ***Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050, Naghavi, Mohsen et al. The Lancet, Volume 0, Issue 0***
11. ***Holmes AH, Moore LS, Sundsfjord A, Steinbakk M, Regmi S, Karkey A, Guerin PJ, Piddock LJ. Understanding the mechanisms and drivers of antimicrobial resistance. Lancet. 2016 Jan 9;387(10014):176-87. doi: 10.1016/S0140-6736(15)00473-0. Epub 2015 Nov 18. PMID: 26603922.***

12. *Irfan M, Almotiri A, AlZeyadi ZA. Antimicrobial Resistance and Its Drivers-A Review. Antibiotics (Basel). 2022 Oct 5;11(10):1362. doi: 10.3390/antibiotics11101362. PMID: 36290020; PMCID: PMC9598832.*

13. *Ridge KW, Hand K, Sharland M, Abubakar I, Livermore DM. Antimicrobial resistance in: Davies SC, editor. Annual Report of the Chief Medical Officer, Volume Two, 2011, Infections and the Rise of Antimicrobial Resistance. London: Department of Health; 2013.*

14. *Truong WR, Hidayat L, Bolaris MA, Nguyen L, Yamaki J. The antibiogram: key considerations for its development and utilization. JAC Antimicrob Resist. 2021 May 25;3(2): dlab060. doi: 10.1093/jacamr/dlab060. PMID: 34223122; PMCID: PMC8210055.*

15. *WHO Antimicrobial Stewardship_ A competency-based approach: https://openwho.org/courses/AMR-competency (brief and interesting videos with general topics and disease-based guidelines)*

16. *WHO Bacterial Priority Pathogens List, 2024: bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance. Geneva: World Health Organization; 2024. Licence: CC BY-NC-SA 3.0 IGO.*

17. *WHO methodology for point prevalence survey on antibiotic use in hospitals. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.*

18. *WHO policy guidance on integrated antimicrobial stewardship activities. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO (available at: https://www.who.int/publications/i/item/9789240025530, last access 16th september 2024).*

CHAPTER 3

Pharmacovigilance Within the Health Facility

3.1 Introduction

Pharmacovigilance denotes the science and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other medicine-related problems (WHO, 2004).

The MTC through the Pharmacovigilance subcommittee shall establish a file/database of all ADRs at the facility. The Pharmacovigilance subcommittee should routinely conduct causality assessments for all ADRs and propose a management plan for the different ADRs.

When a medicine is prescribed, the expectation is that:

- The medicine has a positive effect on the patient(efficacious)
- The medicine does not cause harm (adverse reaction).

To achieve this, it requires that medicine of the right quality is correctly, dispensed and administered to the right patient (as clearly explained in the Appropriate use Chapter). If any of these conditions is not observed, the consequences may be therapeutics failures and/or adverse drug events, causing poor quality of care, injury or even death and waste of resources. The coordination of pharmacovigilance activities at National Level is by the National Pharmacovigilance subcommittee hosted by the National Drug Authority, while at the facility level coordination is by Pharmacovigilance subcommittee of the MTC.

3.2 Structure and composition of the Pharmacovigilance subcommittee

3.2.1 National level

At national level, technical coordination, governance, and decision making for Pharmacovigilance is the responsibility of the Medicines Management and Procurement Technical Working Group (MPM-TWG), clinical care, and health information technical working group (HIF-TWG).

3.2.2 National level

The health facility Pharmacovigilance subcommittee should be multidisciplinary but not limited to Clinicians, Nurses, Pharmacy, Laboratory etc. The size of the Pharmacovigilance subcommittee varies with level of care.

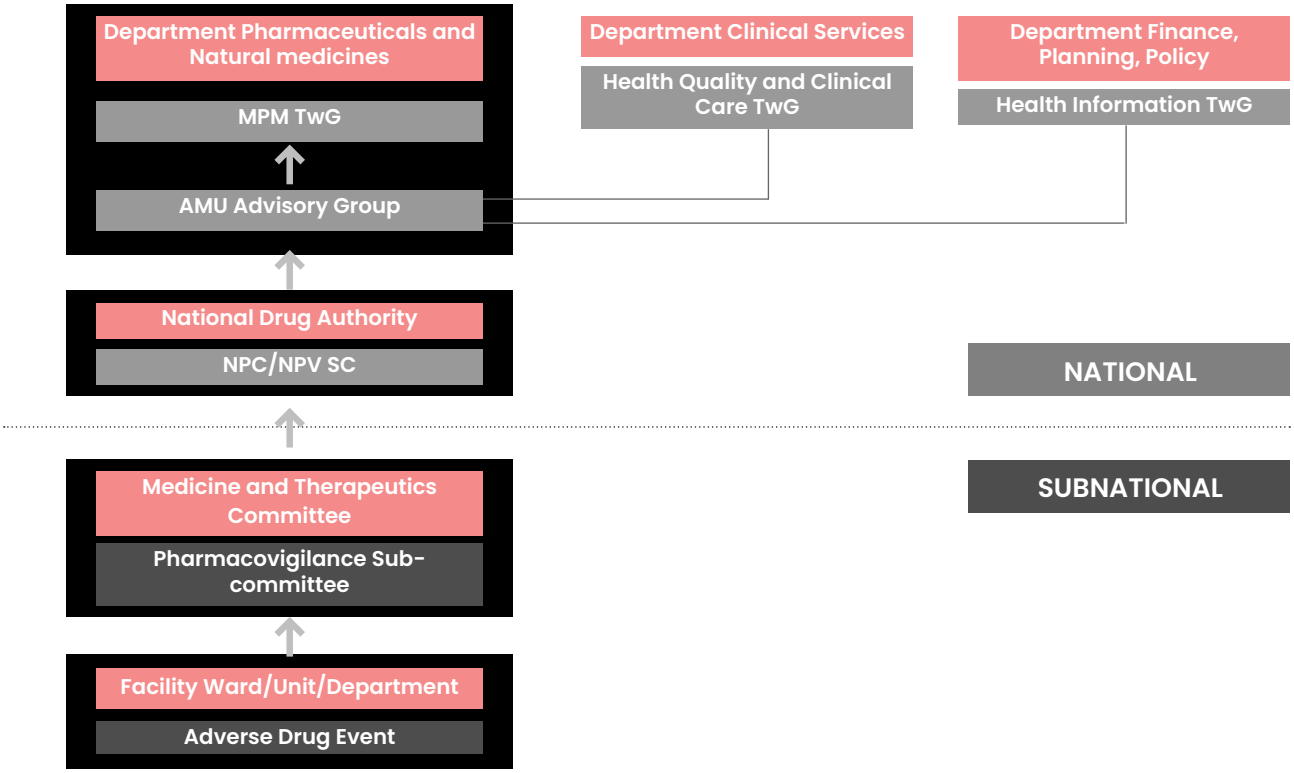

Figure 3.1 Structure And Coordination Of Pharmacovigilance

3.3 Mandate of the Pharmacovigilance subcommittee

The Pharmacovigilance subcommittee is mandated to:

- Ensure identification, management and reporting of adverse events
- Advise the supply chain subcommittee on Pharmacovigilance supplies.
- Develop facility specific protocols to report Medication errors, Substance abuse, Poisoning and Drug resistance

MEDICINES, DRUGS, VACCINES, MEDICAL SUPPLIES AND DEVICES

Under pharmacovigilance, medicine, drug and vaccine are interchangeably used. It is important to note that medical supplies and devices are prone to defects and falsification. These are quality issues which must be detected and reported. These quality issues also can lead to serious medication errors which are detrimental. It is therefore critical that management, reporting, and mitigation mechanisms are developed and adopted.

3.4 Quality of medicines

Quality of medicine refers to the purity, potency, uniformity of dosage form, bioavailability and stability, and the correct labeling concerning identity and source (manufacturer)

Quality problems concerning medicines can be classified into:

- Falsified medicines: is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. It applies to both branded and generic products and may include products without the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging (World Health Organization, 1999).
- Substandard medicines: Authentic medicines produced by manufacturers authorized by the national regulatory authority, but which do not meet the quality specifications set for them by national standards for such products, for example: reduced or increased concentration of active ingredients, reduced stability and bioavailability, presence of impurities, contaminants, unknown ingredients.

Counterfeit and sub-standard medicines can lead to adverse events, and treatment failures, promote antimicrobial resistance, undermine confidence in the efficacy of medicines, and waste of resources.

Therefore, the Pharmacovigilance subcommittee under the coordination of the MTC is mandated to; Advise the supply chain subcommittee on proper storage and distribution of products e.g. By monitoring temperature, humidity, and light, expiry dates, appropriate pre-packaging, to avoid any environmental factors which could affect the quality of the products. Supplies should be accepted only if the supplier can guarantee that they have been stored and handled appropriately.

Ensure that suspected poor-quality medicines (visual deterioration of the products, unsatisfactory therapeutics effect, adverse reactions) are followed up and reported for further investigations (see NDA Market Complaint Form Annex 3.3). When a quality issue of a product is suspected, it is important to first: Observe and note any visual alteration of the product including the packaging, labeling, etc.

3.5 Aims of Pharmacovigilance

Pharmacovigilance aims to improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions. This is done through.

- Learning about medication-related problems (medication errors, quality issues) and creating knowledge to prevent problems and promote the safe use of medicines,
- Improving public health and safety in relation to the use of medicines,
- Detect problems related to the use of medicines and communicate the findings promptly,
- Contributing to the assessment of the benefit, harm, effectiveness, and risk of medicines, leading to the prevention of harm and maximization of benefit,
- Encouraging the safe, rational, and more effective (including cost-effective) use of medicines,
- Promoting understanding, education, and clinical training in pharmacovigilance and its effective communication to the public.

The process of pharmacovigilance consists of 3 steps. It is critical that the Pharmacovigilance subcommittee owns and implements these steps:

- Data collection: By spontaneous reporting or specifically designed activities corresponding to the "identify and measure" phase of the quality improvement cycle,
- Causality assessment and signal management: Investigation to identify if the reported event is significant and to determine the cause,
- Risk mitigation: Development and implementation of interventions to eliminate/reduce the risk and consequences of medicine-related problems.

Figure 3.2 Pharmacovigilance Activities

Pharmacovigilance activities are therefore within the scope of the MTC. The Pharmacovigilance subcommittee of the MTC works as the reference and coordinating point, identifying key safety issues which will then require collective action by the MTC. Need for further action can be:

- Serious ADRs (fatal or life-threatening outcome).
- Cluster of events (even unusually high incidence of known side effects).
- Unusual aspects of known ADRs, expected public health impact.

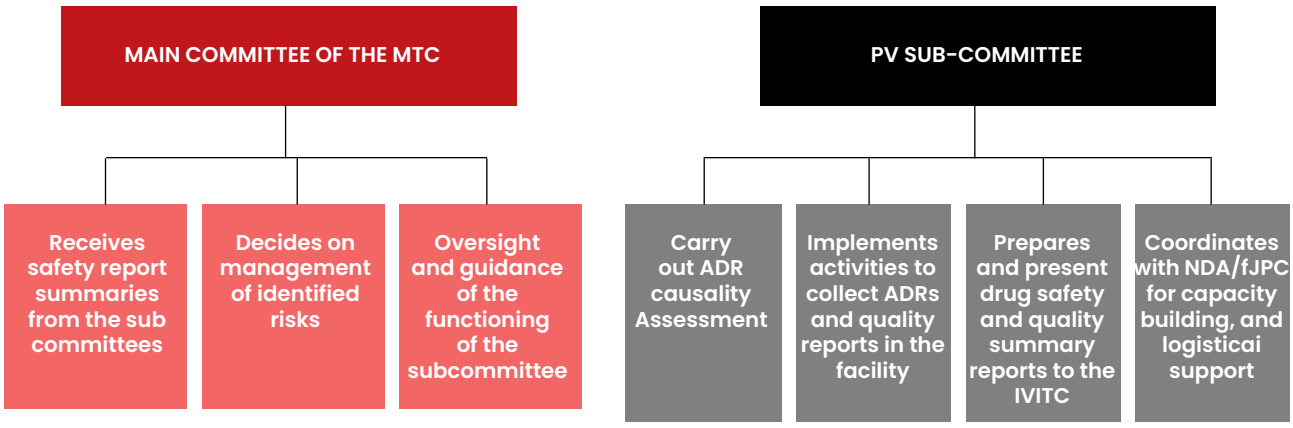

Figure 3.3 Role Of Pharmacovigilance Committee On The Mtc

3.6 Medicine Errors

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer (WHO, 2022).

Medication errors are classified according to the stage in the sequence of the medicine use process, as shown in the table 3.1 below.

Table 3.1 Medication Errors And Examples

Type of Error	Example
Prescription errors	• Wrong diagnosis, wrong dose, wrong drug, wrong indication, wrong frequency, wrong patient, known drug interaction, known allergy • Illegible prescription, misuse of zeros and decimals • Inappropriate abbreviations
Preparation errors	• Incorrect preparation of the drug or infusion fluid • Wrong drug or infusion fluid, incompatible drug or infusion fluid • Miscalculation of required volume of drug or infusion fluid
Administration errors	• Wrong route, wrong dose, wrong time, wrong drug, incorrect frequency, wrong patient, drug not administered incorrectly set infusion pumps • Non-compliance to the administration technique
Dispensing errors	• Incorrect drug, wrong patient, expired drug, • Labeling errors, misinterpreted prescriptions
Monitoring errors	Tests are not carried out at recommended frequencie

Often, medication errors are linked to health systems issues such as workload, poor communication, and lack of effective drug policies and procedures. Systems must be built to minimize errors and to protect patients from the consequences of human error. The MTC can address these problems by taking the following measures:

Develop, implement and regularly review clear policies and procedures for drug administration and use e.g.:

- Treatment charts requiring allergy notation.
- Intravenous (IV) medicine preparation and administration guidelines.
- Standardized notation for dosages and frequencies.
- Clear labeling and organized storage of products (especially for look-alike and sound-alike products).
- Pre-authorization and multiple checks for high-risk medicines.
- Conduct medicine use audits and studies – through chart reviews or direct observations (refer to chapter 5) to assess adherence to policies and procedures and design interventions if problems are found.
- Collect, record and report medication errors to the NPC.

- Follow up any safety issues arising from medication errors and,
- Address possible medication errors arising from the investigations.
- Develop standard operating procedures to handle common medication errors.

Not all medication errors cause adverse events, so many may go undetected until a catastrophe happens. It is important to prevent all possible errors rather than having to later face a problem that may harm or cost the life of a patient. This can be done by reporting not only incidents but also any medication error that is observed even if no harm has happened on that occasion. A system of voluntary reporting, blame-free and non-confrontational, should be established so that appropriate investigations and action can be undertaken to prevent similar future occurrences. Standard operating procedures to handle common medication errors.

Any medication error should be reported using the standard Adverse Drug Reaction report form (see Annex 3.1). These reports can be submitted using any of the platforms below.

Figure 3.4 Platforms To Report Adrs

Handling medication errors

The MTC through the Pharmacovigilance subcommittee should coordinate the process of detection, documenting, managing and reporting medication errors plus making recommendations.

3.7 Adverse Drug Reactions

According to the WHO definition, an Adverse Drug Reaction (ADR) is defined as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of diseases, or for the modification of physiological function".

An adverse reaction is defined as serious if it results in death, congenital anomalies (birth defects), requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is life-threatening.

The risk factors for ADRs include gender, narrow therapeutics windows, polypharmacy (high risk of drug interactions), HIV infection, extremes of age, kidney, liver and heart diseases, pregnancy, alcohol consumption, etc.

As said before, it is important to try to clarify if the reaction is linked to a medication error or a quality issue (refer to sections 3.3 above) or if it is a direct outcome of the body's physiological response to the drug, which can be classified as in the table below:

Table 3.2 Types of Adverse Drug Reaction

Type of ADR	Example
Type A reactions	• Exaggerated but otherwise known pharmacological response to the effects of the medicine given in therapeutics doses. • Can cause significant morbidity but are rarely severe. • Relatively frequent, have a dose-effect relationship, and are reproducible. • Usually occurs when the drug concentration in the body exceeds the recommended therapeutics window, e.g., when the dose of the drug administered is higher than the recommended, or when there is increased sensitivity of the target in an individual even if the concentration of the drug in the plasma or tissues is in the normal range. • Examples: bronchospasm and bradycardia with beta-blockers, palpitations with beta-agonists, ototoxicity due to overdose or accumulation of aminoglycosides, hypoglycemia with antidiabetics, constipation with opioids, etc. • Often reduction of the dose or corrective measures can solve the problem. • Standard protocols for early detection and recognition should be put in place e.g. education of patients on side effects, regular clinical and/or laboratory monitoring during follow-up visits, periodic liver or renal function checks as needed
Type B reactions	• Bizarre, unpredictable, unrelated to doses, and often immune-mediated in nature. They are rare but often severe and cause high mortality. • Mechanism and causality are often uncertain, and they may not be reproducible. Individual host factors (genetic predisposition) may play a big role. • Examples include aplastic anaemia by chloramphenicol, anaphylactic shock by penicillin, Steven-Johnson syndrome by Cotrimoxazole. • The suspected drug involved MUST be stopped and supportive measures started. • They may not have been recorded in clinical trials, so their detection is based on post-marketing surveillance and spontaneous reporting.

Type C reactions	• These are caused by accumulation of the drug in the body over a period of time. They are also known as chronic reactions. • Examples: hypothalamic-pituitary-adrenal axis suppression by corticosteroids, chronic liver damage from prolonged use of paracetamol, kidney damage due to prolonged use of non-steroidal anti-inflammatory Medicines
Type D reactions	• Delayed onset: These reactions become apparent after some long time of using the medicines and thus are more difficult to detect. • For example, bladder cancer after treatment with cyclophosphamide.
Type E reactions	End-of-use reactions: Occurs after the medicine has been withdrawn. For example, seizures after stopping phenytoin.

3.7.1 Steps in Assessing Adverse Drug Reaction

When a patient is on medication, any appearance of a new sign or symptom, clinical or laboratory, or a worsening of a pre-existing one, could be due to an ADR. It can be difficult, and sometimes impossible, to distinguish an ADR from the disease being treated or prevented, but clinicians need to be on high alert.

When to suspect an ADR

In case of new or worsening signs/symptoms in a patient, always consider the possibility of an ADVERSE DRUG REACTION.

Any SUSPECTED adverse drug reaction should be assessed in the following way:

- Collect a detailed history of the patient as per standard ADR report (Annex 8.2). Include clinical history, comorbidities, if and how medications have been taken/administered, all medications the patient has taken, risk factors, and differential diagnosis.
- Describe and document the reaction, including the time relationship, how the reaction was managed, and events after discontinuation, and compare with the literature.
- Assess the severity (severe: fatal or life-threatening; moderate: requiring antidote, medical procedure, or hospitalization; mild: requiring only discontinuation; incidental: very mild symptoms that do not necessarily require discontinuation).
- Assess the likelihood of causality e.g. using the WHO Uppsala Monitoring Centre causality assessment method as shown in table 9.7 that follows.
- Check the medicine for possible quality issues through visual inspection (check for changes in color, packaging, expiry date, foul smell, consistency, etc.).
- Assess the possibility of a medication error, investigating preparation and administration/ dispensing procedures.
- If possible, compare rates of ADRs between departments and with other facilities, eventually following up with the regulatory body, to help with investigations.

Table 3.3 Causality Categories

Causality term	Assessment criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (ie. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/likely	• Event or laboratory test abnormality, with reasonable time relationship to Likely drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required Possible
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality Unclassified • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory Unclassifiable • Data cannot be supplemented or verified

All suspected adverse events should be reported using the national ADR reporting form (annex 3.2) to the National Pharmacovigilance Center (NPC) through the various reporting methods including the NPC hotline, WhatsApp, Email, and web link. Internally, the pharmacovigilance sub-committee should generate and submit regular summary reports to the MTC and support it to make informed decisions.

Besides reporting to NDA, the MTC action will depend on the investigation results as below:

- If a quality issue was found/suspected, it should be addressed, depending on the cause. The quality problem should be reported to the NDA and the supplier.
- If a medication error is found, investigate and correct processes e.g. by educating staff, standardizing procedures, introducing protocols and checks, restricting use, etc.

- Changing to a safer medication.
- Educating staff and patients on adverse reactions, risk factors, and how to prevent, recognize and manage them.

It is important to recognize that more than half of adverse reactions are preventable (often linked to wrong dose or administration to patient with known allergy). Therefore, the reporting of ADR is not only bureaucratic requirement but an important opportunity for quality improvement.

What should be reported?

All suspected ADRs experienced by patients on all drugs including vaccines and other health products should be reported even if not certain on whether the drug caused them or not.

- For "new" drugs - report all suspected reactions, including minor ones.
- For established or well-known drugs - report all serious and unexpected suspected ADRs.
- Report if an increased frequency of a given reaction is observed even if it is known or previously documented.
- Report all suspected ADRs associated with drug-drug, drug-food, or drug-food supplements (including herbal and complementary products) interactions.
- Report ADRs in special groups like pregnant or lactating mothers and children, or special fields such as drug abuse.
- Report on when suspected ADRs are associated with drug withdrawals.
- Report ADRs occurring from overdose or medication error.
- Report when there is a suspected lack of efficacy (treatment failure) or quality-related problems including suspected contamination, questionable stability, defective components, poor packaging, or labeling.

When to report

All serious reactions (resulting in death, hospitalization, disability, congenital anomalies, life-threatening) MUST be reported within 48 hours (about 2 days) of notification.

Non-serious reactions should be reported within 7 days of notification.

3.7.2 Guidance on ADR prevention

Most ADRs can be prevented by following the basic principles of appropriate use of medicines, which is the main goal of the MTC work:

- Ensure appropriate prescribing (right medicine for the right patient, right dose, route, timing, duration) through adherence to standard guidelines.
- Use as few drugs as necessary, through rational selection of an institutional medicine list.
- Ensure prescribers and patients have good knowledge of the medicine use and risk factors for adverse reactions.
- Establish, implement, and monitor policies and procedures to ensure the quality of medicines (procurement and storage) and to prevent medication errors.
- Educate prescribers and patients to recognize early signs of adverse events and manage them appropriately.

For further information refer to the UGANDA NATIONAL TRAINING MANUAL FOR HEALTH WORKERS ON PHARMACOVIGILANCE

References

1. *Angamo MT, Chalmers L, Curtain MC, Bereznicki LRE. Adverse-Drug-Reaction-related Hospitalization in developed and Developing Countries: a review of prevalence and contributing factors. Drug saf (2016) 39:847-857*
2. *World Health Organization. Safety of medicine: a guide to detecting and reporting adverse drug reactions. Geneva: WHO:2002*
3. *Uganda National Training Manual for Health Workers on Pharmacovigilance, NDA 2018*

CHAPTER 4

Supply Chain Management for Medicines and Health Technologies

4.1 Introduction

This chapter provides practical orientation for MTC members to effectively oversee and support pharmaceutical management and is complementary to the MOH Essential Medicines and Health Supplies Management Manual. In addition, this chapter presents the issues that the MTC may be called to advise upon and assess and introduce the type of reports and documents needed to do so.

The stores and pharmacy department perform the day-to-day work of pharmaceutical and health supplies management. The MTC should create a logistics or supply chain subcommittee to manage supply chain-related issues. To perform its oversight function, the MTC should be knowledgeable about the medicine management cycle, its principles, and how to monitor and assess its performance.

Since the detailed technicalities of the medicine management cycle are the competency of the store/pharmacy staff, it is their task to provide the information and explanations that may be necessary to address the issues. The MTC does not handle routine tasks but only:

- Receives or requests for reports on performance
- Discuss problems and difficulties which cannot be handled routinely
- Develop policies

The roles of the MTC in the supply chain include:

- Develop, implement, and monitor policies and procedures for the management and use of medicines and health supplies such as.
  - Pharmaceutical promotion
  - Medicine donations
  - Selection, quantification, procurement planning, storage, distribution, accountability systems
  - Prescription, dispensing, and administration of medicines e.g. restrictions and permissions for different cadres
  - Expiries and disposal of pharmaceutical products.
- Regulate and monitor availability, tracking, and accountability fo
- pharmaceuticals within the health facility
- Analyze, monitor, and regulate expenditures on medicines to ensure cost-effective use of resources

4.2 Logistics reports for MTC

The MTC should ask for and understand some fundamental reports used in pharmaceutical management such as:

- Stock report: availability/stock out and stock status
- Consumption reports
- Expiry/Losses and adjustments
- Budget performance reports

4.2.1 Stock report: Availability/stock outs and stock status

The overall purpose of the supply chain is to avail medicines of good quality, in sufficient quantities, and at affordable cost. The availability of the medicines, measured in terms of % of time a medicine was available, and/or in terms of the % of time the item was stocked out, is therefore the indicator to monitor the overall performance of the supply chain. In fact, at the national level, the availability of 50 "tracer items" at the facility level (see section 6 of HMIS 105) is monitored as an indicator of the performance of the national supply chain system in the period considered.

The stock status report will give information about the current stocks, and it is generally expressed in absolute quantities but also in "months of stock", that are available based on the average monthly consumption rates of the last 3-6 months. The two reports complement each other to provide a comprehensive picture of the situation in terms of medicine stocks. (Refer to Annex 4.1)

The overall objective of the pharmacy/store department will be:

- To have 100% availability for all items (meaning 0% stock-out rates) and acceptable levels of stock at hand, meaning between 2 and 4 months; not below 2 months (minimum stock level), because there would be the risk of stock outs, not above 4 months (maximum stock level) because there may be a risk of overstocking and expiries (which is inappropriate use of resources).

- Monitoring availability quarterly, six-monthly, and annually will allow the MTC to monitor and assess the performance of the supply system, and monitoring stock status even more frequently (often monthly) will allow it to identify items at risk of stock outs or overstocking and act. Stock status is also the basis for procurement, since orders are based on the amount of stock on hand and on average consumptions and will also inform the clinicians on which items are available to guide them in the prescription.

It is important to note that availability is affected by many factors such as budget allocation, suppliers (warehouses), patient load (e.g. due to seasonal increase in morbidity). It is the task of the pharmacy/store departments and of the MTC to evaluate and assess the need for corrective measures within the power of the health facility when analyzing availability reports. Also to note, appropriate medicine use should ideally result in increased availability in the long run, because it usually reduces and rationalizes consumptions, allowing more cost-effective use of resources.

4.2.2 Consumption reports: Average Monthly Consumption and ABC report

Consumption reports provide information about the average monthly consumption (AMC), and about quantities consumed in a certain period, by the health facility as a whole or even by department. When the analysis is done also for their money value, we have an ABC analysis (see Chapter 9).

- An ABC analysis provides information on the quantities and value of the items the health facility has consumed in each period. Beware that items that have been out of stock may appear on the ABC as being minimally/not consumed, which can give a false picture.
- An AMC (Average Monthly Consumption) report adjusts consumption taking into consideration the period of stock-outs and indicates the average monthly consumption assuming the item was never out of stock. This reflects better the real NEED of the facility. Usually, AMC is calculated considering periods of at least 3 months, to get an average.

Formula for AMC:

$$\frac{\text{(quantity consumed in the period)} \quad X\ 30}{\text{(Number of days in the period considered - days out of stock)}}$$

AMC data can be used in the procurement planning and ordering process, to know the ideal "requirements" of the facility.

Consumption analysis can be used to analyze general expenditures on pharmaceutical products (ABC analysis) or in performing specific analysis e.g. consumptions of antibiotics, medicines for non-communicable diseases, antimalarial commodities, or ART commodities.

4.2.3: Expiry/losses and adjustment report

Expired medicines are a double, or even a triple, loss. Not only does the health facility lose the money used to buy them, missing the chance to buy more useful items, but often disposing of expired items has a cost, which further decreases the budget for medicines.

The quantities and values of expired items are therefore a good indicator of how well the pharmaceutical system is performing: it shows how realistic and accurate the procurement planning and ordering process is and how effective the inventory management system is. Ideally, we should aim at having NO stock expiring.

The MTC should receive from the pharmacy or store departments a periodic update about items, quantities, and values that expired (expired stock), analyze the explanations provided, and discuss eventual corrective measures. For example:

- If expiries are due to uncontrolled donations, a strict policy on donation management should be enforced.
- If expiries are due to re-distribution from health centers, a more effective re-distribution policy should be put in place, and charges for disposing of expired items should be re-distributed as well.
- If expiries are linked to inaccurate ordering or changes in consumptions, reasons should be investigated and corrected.

The pharmacy/store should also regularly monitor the expiry risk of the stocks (expiry risk report, short expiry items: electronic store management systems should be able to automatically produce a list of the items expiring soon. Action can then be taken before items expire, e.g.:

- By making sure no short-expiry items are accepted from suppliers
- Items are issued in order of expiry date, and,
- Short-expiry items are re-distributed or exchanged.

In addition to the expiry of medicines, the MTC should also monitor other causes of loss of medicines such as theft/pilferage, and adjustments such as donations and redistributions. This will enable MTC to undertake corrective actions. Losses refer to the quantity of stock removed from the store for any reason other than consumption by clients or use at the service delivery point (due to expiration, theft, damage, etc.). Adjustments are the quantity of stock issued to or received from other facilities. The adjustments may also be administrative corrections made to stock-keeping records for example, when you count stock and find a different amount from the quantity listed on the stock cards. For this reason, adjustments may involve either positive or negative changes to stock. In addition, the reasons for the adjustments must be indicated on stock cards under the remarks section.

4.3 Pharmaceutical Flow

Uganda has national guidelines for the management of medicines and health supplies, detailing how items are ordered, received, and issued from stores, and dispensed. Specific guidelines on the flow of commodities within the facility that detail how medicines move from the store and pharmacy to the patient and tracking and accountability at the user level are also available. These systems include dispensing per chart, use of modified dispensing logs, and electronic dispensing systems. The MTC is charged with overseeing the implementation and performance of these systems and current guidelines and tools.

It is the responsibility of the pharmacy and store department to clearly show how commodities flow within a facility, as well as how the documentation trail and accountability/reconciliation are done at every level.

Figure 4.1 below shows a model of the pharmaceutical flow within a facility and the documentation used at each stage.

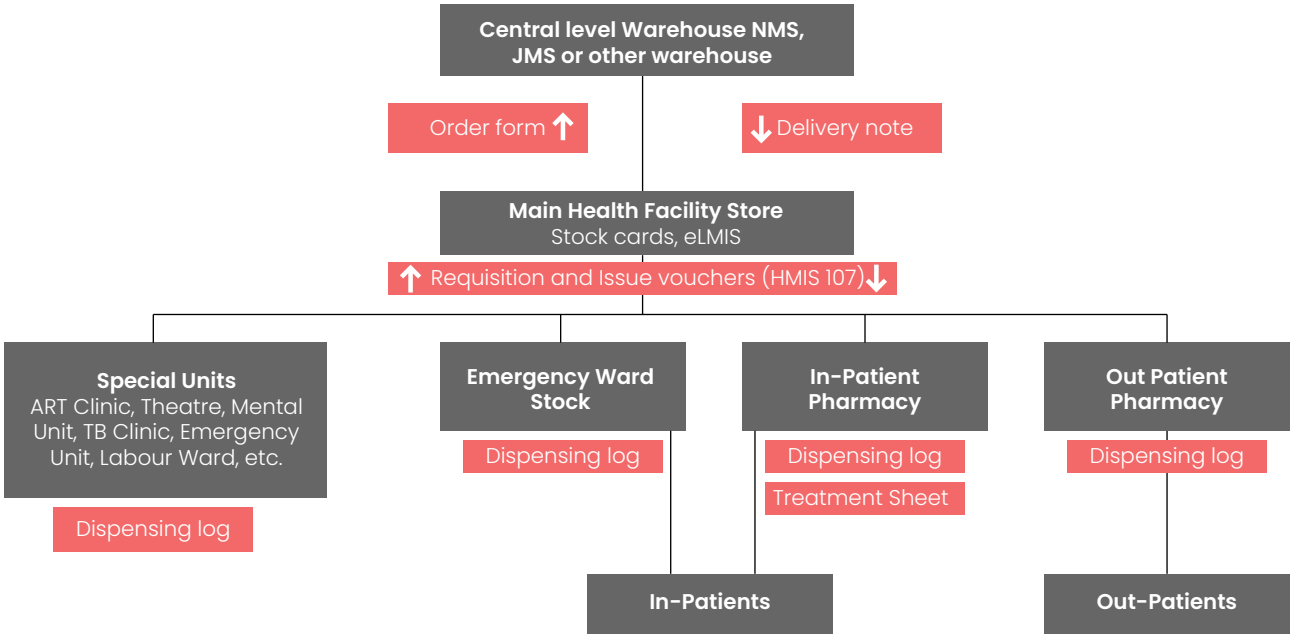

Figure 4.1 Facility Pharmaceutical Flow

Note:

1. The small arrows indicate the "direction" of the use of the documentation (e.g. in this case the Issue and Requisition Voucher is both used by the store to document issues and by wards and pharmacies to requisition items)
2. The dispensing log is used as an internal accountability/reconciliation tool for wards and pharmacies and as a dispensing record.
3. It is recommended that facilities with in-patient (IP) services dispense medicines per patient chart from the in-patient pharmacy. The exception is given for special units (emergency departments, pediatric ward, mental unit, etc) that need to receive their medicines in bulk from stores, and for emergency (lifesaving) medicines that will be issued by In-Patient pharmacy to the wards in limited quantities. In the absence of a casualty/emergency unit to attend after-hours admissions, the wards are also allowed to keep small quantities of other essential medicines.

Every station that stocks pharmaceuticals is required to document and reconcile items received and dispensed on the most current dispensing log (HMIS 016) and record dispensed or administered medicines on the patients' charts or medical forms.

4.4 Tracking and Accountability

The MTC is responsible for tracking the use and ensuring accountability for commodities.

Tracking: the flow of a commodity can be traced from delivery to storage and finally to the patients, with quantities reconciled at every step, that is:

- Quantities received from the central warehouse or other suppliers
- Quantities entered in stock cards in the store
- Quantities received, issued, and balances in store
- Quantities received, dispensed, and balances in IP, OPD pharmacy, or other wards

Accountability: commodity consumption is documented and justified by the related clinical activity. This can be done by:

- Following administration/dispensing of each unit of product at the patient's level, checking whether dispensing records match clinical records
- Comparing aggregated data of quantities consumed in a period with related clinical cases over the same period (estimating the average dose used per case). This is usually possible only for commodities with very specific indications e.g.:
  - Cases of OPD malaria versus consumption of ACT in OPD
  - Cases of severe malaria versus consumption of artesunate injection
  - Consumption of antiepileptic versus visits to epilepsy clinic.

Tools and methods depend on the commodity targeted, the pharmaceutical flow, and on the levels (warehouse, store, pharmacy, ward) to be investigated. The examples below provide some guidance on how to conduct such studies.

DATA QUALITY AND ACCURATE DOCUMENTATION:

The quality and accuracy of documentation is fundamental to carrying out tracking and accountability studies.

Discrepancies and inconsistencies may be due to misuse or "losses", but also due to inaccurate or incomplete data!

Example 1

Tracking and accountability exercises for artesunate in three health facilities are shown in table 4.1 and figure 4.2 below.

Table 4.1: Tracking And Accountability Of Artesunate In Three Health Facilities

ARTESUNATE (Jan-May 2024)	Hospital 1	Hospital 2	Hospital 3
Vials received from NMS	8,200	9,000	2,000
Total Number of Vials issued from the store	1,780	9,264	2,026
Number of Vials issued from store to OPD	50 (3%)	53 (0.5%)	180 (9%)
Number of Vials issued from store to IP (pharmacy or wards)	1,730	9,211	1,846
IP malaria cases reported (DHIS 2)	377	1,059	387
Expected consumption based on IP cases reported (assumption: 5 vials of artesunate 60 mg per case; based on weighted average)	1,885	5,295	1,935

The assumptions are that:

- Artesunate is used for severe malaria and all severe malaria cases are admitted, so in-patient (IP) malaria cases are a good measure of artesunate need. OPD use is considered inappropriate.
- The average number of vials per case is 5, (considering a weighted average of morbidity.

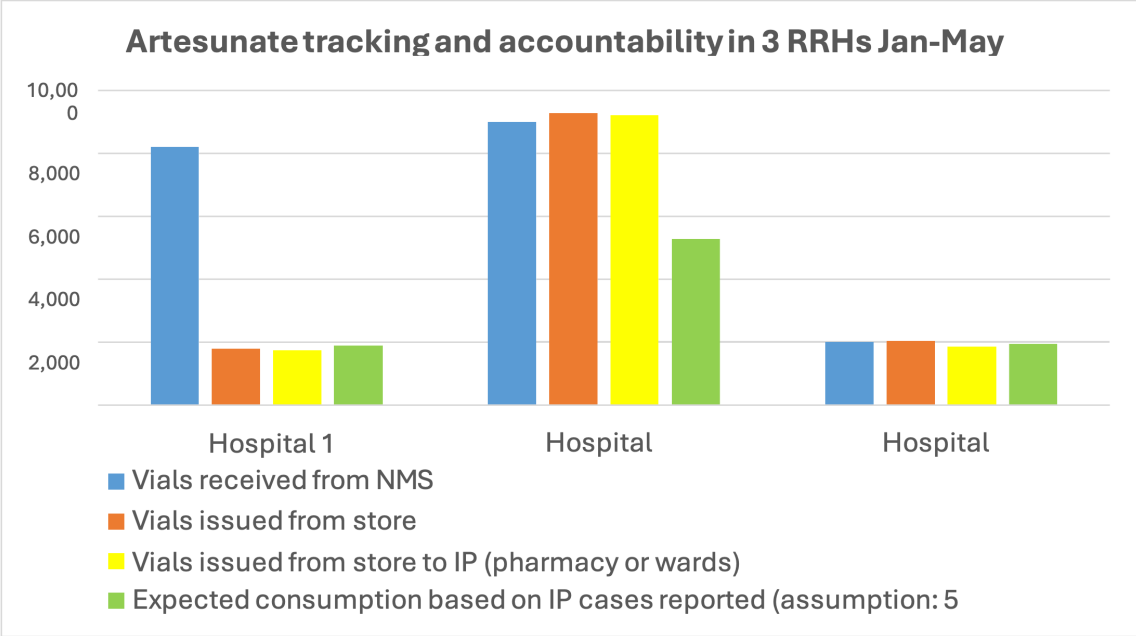

Figure 4.2 Artesunate Tracking And Accountability In Three Facilities

Hospital 1:

- Artesunate consumption (using quantity issued from store to department) corresponds to the expected consumption based on IP cases reported.
- A small amount of artesunate goes to OPD, which is somehow inappropriate since uncomplicated malaria should not be treated with artesunate and severe malaria cases should be immediately admitted to the in-patient ward and not treated at OPD.
- Much larger quantities are supplied by NMS compared to consumption and cases.
- Further investigations revealed that the health facility was significantly overstocked, due to a combination of decreasing cases, backlog consignments being delivered, and inappropriate ordering.
- The health facility, therefore, instituted corrective measures: some pending orders were canceled, re-distributed some quantities, and hence the stock was adjusted to adequate quantities.

Hospital 2:

- All the artesunate received in the period was issued out
- Minimal quantities went to OPD
- Issued quantities were much higher (double!) than the expected consumption as per cases reported.
- Further investigations revealed that the IP pharmacy dispensed artesunate to OPD patients with uncomplicated malaria: actually, half of the artesunate dispensed used to go to OPD patients!

Hospital 3:

- Consumptions were proportional to the in-patient cases reported.
- A few vials of artesunate were issued inappropriately to OPD.
- Further investigations revealed that one outpatient clinic was ordering the artesunate needlessly, and this was stopped.

Example 2

In figures 4.3 and 4.4 below, consumption of artesunate and ACT are compared with cases of malaria. Before February there is a huge discrepancy between cases reported and doses of antimalarial commodities issued. The hospital changed the pharmaceutical flow in March 2018: since then, the discrepancy between doses issued and cases reduced significantly as can be seen from the monthly trend and from the aggregate analysis before and after.

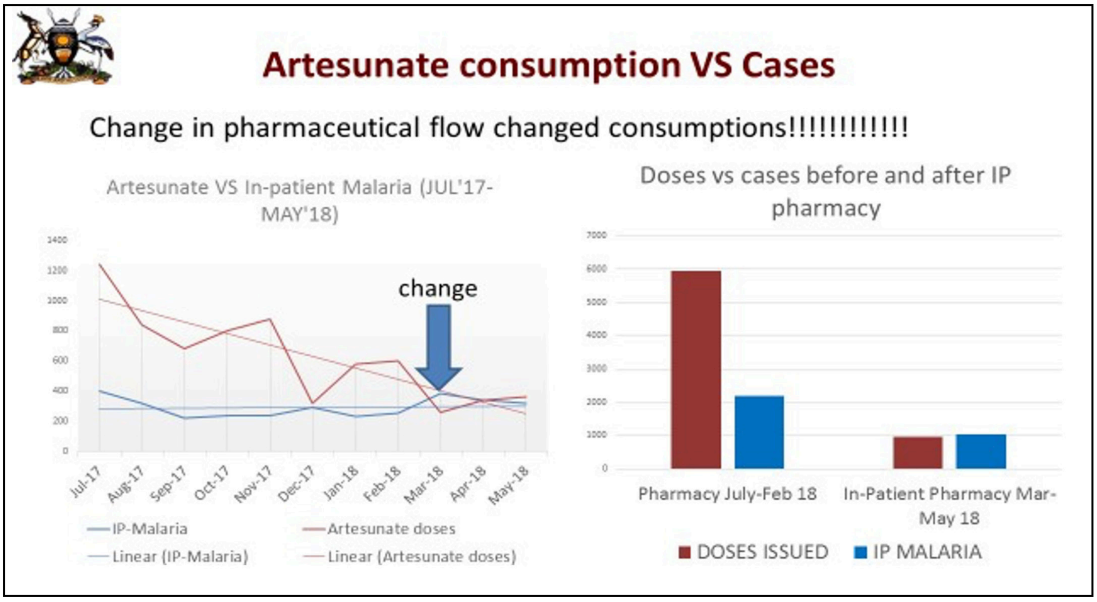

Figure 4.3 Act Consumption Vs Cases

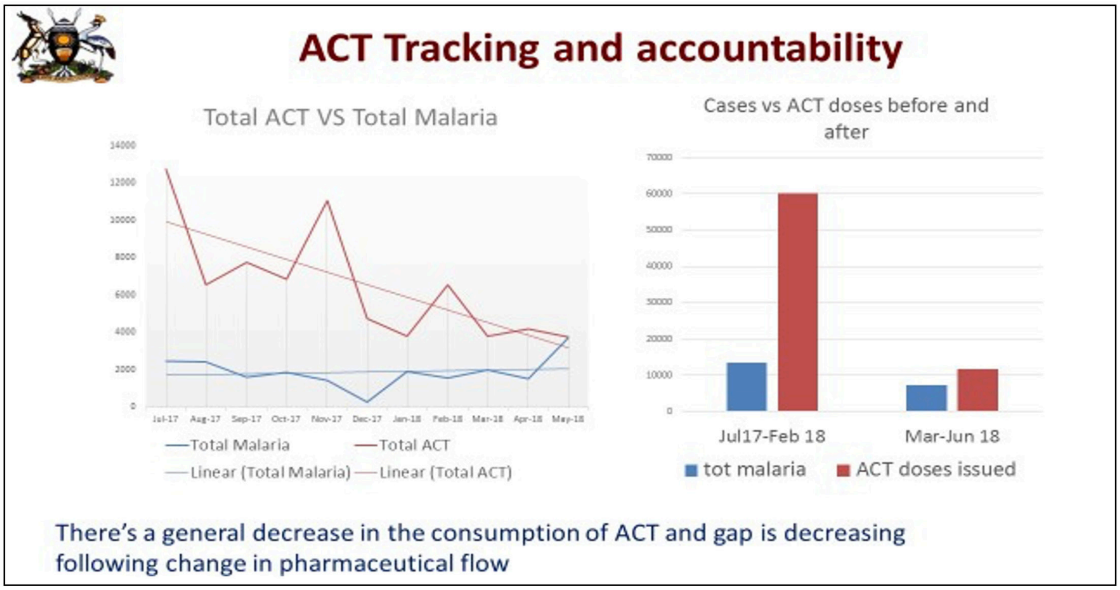

Figure 4.4 ACT Tracking and Accountability

Example 3

Figure 4.5 highlights a gap in doses of artesunate issued and cases of inpatient malaria reported in dhis2 (first and second graph). An analysis of the issues by demander shows that most artesunate goes to IP pharmacy and pediatric ward. The MTC tracked all IP malaria cases directly from IP registers in the wards and discovered that the cases reported in HMIS 108 and dhis2 were significantly less than the actual ones recorded in the wards, and that explained the discrepancy!

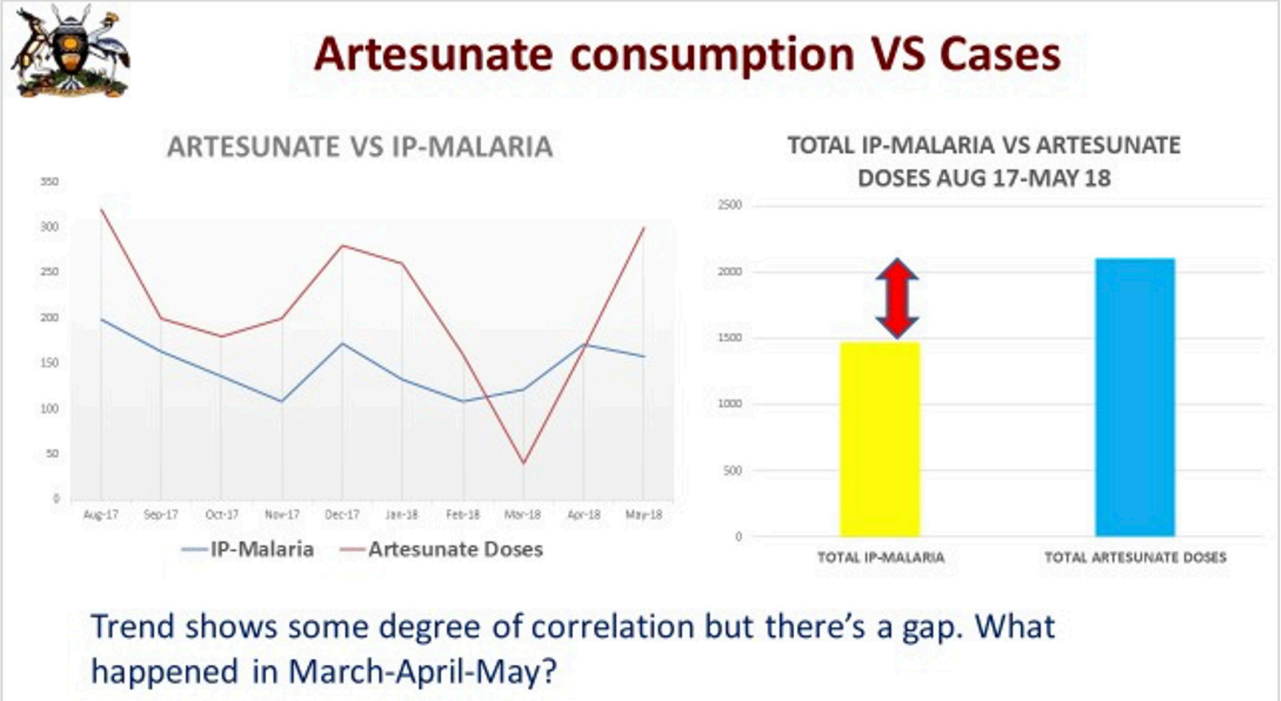

Figure 4.5: Artesunate Consumption Vs Malaria Cases Reported In Hmis 108 In Dhis2

In several cases inaccurate or incomplete data are the cause of the discrepancy between reported cases and actual consumption and the MTC must engage in improving the quality of both pharmaceutical and clinical data.

4.5 Procurement planning and budget tracking

The MTC is expected to provide oversight for the procurement planning process, which involves selection, quantification, costing, and aligning requirements to the available budget.

1. Selection is based on the Essential Medicines and Health Supplies List of Uganda, Institutional Medicine List, Supplier Catalogs, and the VEN classification.
2. Quantification can be estimated in different ways, but the two main methods are:

- Consumption or issue method: based on consumption/issues data from stores or dispensing points, adjusted for periods of stock-outs. Well-filled stock books, dispensing logs, or a functional computerized system will be able to provide these data, which can then be adjusted based on expected changes in usage. This is the most used method.
- Morbidity-based method: requirements are calculated based on the anticipated number of patients suffering from a specific disease or requiring a certain medication/intervention. This method is suitable for selected conditions that have only one intervention or standard treatment protocol for their management, such as TB or immunization. It should be based on accurate morbidity data and adjusted as needed.

3. Costing: a price must be attached to each item, based on the most recent information from the supplier. The total costs can then be calculated.

4. Aligning with available budget allocation: if the total estimated costs are higher than the available budget, adjustments must be made to reduce the quantities and fit into the allocated amount. The process is guided by the VEN criteria: Vital items should be prioritized, and adjustments should be made to reduce N (necessary or non-essential) medicines and eventually E (essential) medicines.

While the logistics and supply chain staff are responsible for performing calculations and preparing the necessary data on consumptions and costs, it is the MTC who can advise on selection, consumption, and morbidity-based estimates and quantity adjustments.

MTC is also responsible for monitoring how the allocated budget is utilized for example by:

- Using the ABC and VEN analysis (relative expenditure on vital, essential and necessary commodities)
- Comparing discrepancies in prices and quantities between orders and deliveries
- Keeping track of budget utilization using a budget monitoring sheet and commitment register
- Ensuring adherence of orders to the annual procurement plan.

Specific tools and methods to use are described in the MOH Pharmaceutical Financial Management Manual. The Supply Chain subcommittee is responsible for the compilation of this information that is presented to the MTC for discussion and necessary action.

4.6 Policies and Procedures

The MTC has the responsibility to develop and/or adapt policies. In most cases, blueprints or standard policies already exist, and the MTC then must ensure they are implemented e.g. Guidelines; for the management of donations, pharmaceutical promotion, current NDA regulations refer to the production of promotional material by medical/drug representatives, but MTC can recommend how to deal with advertising material and medical representatives, for example by:

- Directing drug representatives to speak to the pharmacy in charge first
- Presenting to clinicians during CMEs rather than to individual prescribers, and,
- Regulating display of pharmaceutical adverts, which cannot be put in areas accessed by patients.

In other cases, the MTC will have to develop policies and procedures specific to their situation, e.g. for restrictions and permissions in prescription, administration and dispensing of certain medications in the health facility, etc.

IMPORTANT TIP:

The MTC should consult the Pharmacy Department, Ministry of Health, for technical support. In addition, sharing information and learning from experiences of MTCs from other health facilities can also be helpful.

References:

1. ***Management of Medicines and Health Supplies Manual, MOH, 2023***
2. ***Pharmaceutical Financial Management Manual 2013***
3. ***In-Patient Pharmacy Implementation Guidelines 2018***

CHAPTER 5

Health Technologies Management

5.1 Introduction

According to WHO, Health Technologies include medicines, medical devices, assistive technologies, techniques and procedures developed to solve health problems and improve the quality of life. Such technologies are used in all types of health facilities, play a major role in contemporary health-care systems, and contribute directly to the quality of patient care. However, their use needs to be complemented by good staff training and effective organization of health services.

Previously, the Medicines and Therapeutics Committees (MTC) had three core areas including antimicrobial stewardship, pharmacovigilance and Supply chain management of medicines and health supplies. This leaves little attention to other Health Technologies such as medical devices which make up a high percentage of health expenditure. Besides cost, it is important to ensure that health technologies are effective and safe to both the health personnel and clients. This can be achieved through procurement of good quality Health Technologies and their appropriate use. There is also a need for accountability and traceability of these Health Technologies.

Health Technology management is the systematic process of planning for and managing healthcare technology assets to enable the highest quality of care at the best cost. The health technologies subcommittee of the MTC will oversee Health Technologies Management ensuring safe, effective and rational use of the health technologies.

5.2 Goal of Health Technologies Management (HTM) Subcommittee

The overall goal of HTM subcommittee is to ensure that appropriate health technologies are deployed to solve healthcare problems using suitable, cost effective, safe and functional equipment at minimal risk to users, patients and the environment. The subcommittee is essential to ensure that health technologies continue to function effectively in a good working condition. For example, proper maintenance can extend the life of health technologies which is essential for providing good health services and saving scarce resources.

5.3 Composition of the health technologies subcommittee

The tasks of HTM subcommittee are multidisciplinary in nature and will be carried out by healthcare professionals and biomedical engineers. The members of the HTM subcommittee will include but not limited to.

1. Administration (Chairperson)
2. Biomedical Engineer (Secretary)
3. Procurement
4. Clinician (Surgeon, Ortho, ENT, Ophthalmology, anesthesiologist, radiologist)
5. Nurse
6. ICT staff
7. Lab staff

Note: Members can be coopted from user departments whenever needed.

5.4 Scope of health technologies to be managed by the health technologies subcommittee

The broad meaning of health technologies encompasses devices, drugs, medical and surgical procedures and the knowledge associated with these used in the prevention, diagnosis and treatment of disease as well as in rehabilitation, and the organizational and supportive systems within which care is provided (Kwankam, Y, et al, 2001). This definition includes both the 'hardware' and the 'software'. But since pharmaceuticals and sundries are sufficiently covered by other subcommittees of the MTC, the HTM subcommittee will focus on all or some of the "physical pieces of hardware and software" as shown in box 1.

Box 1: Scope of technologies to be managed by the health technologies sub-committee

Medical devices, e.g. ventilators, medical equipment (diagnostic equipment e.g. microscopes; medical imaging e.g. ultrasound) and walking aids e.g. wheelchairs. The scope will also include software that is associated with health technologies management and ehealth/ telemedicine including Electronic Health and Medical Records.

5.5 Roles of Health Technologies Management Subcommittee

The HTM involves a cycle of activities as shown in Figure 5.1. The roles of the HTM subcommittee will revolve around the activities of the cycle.

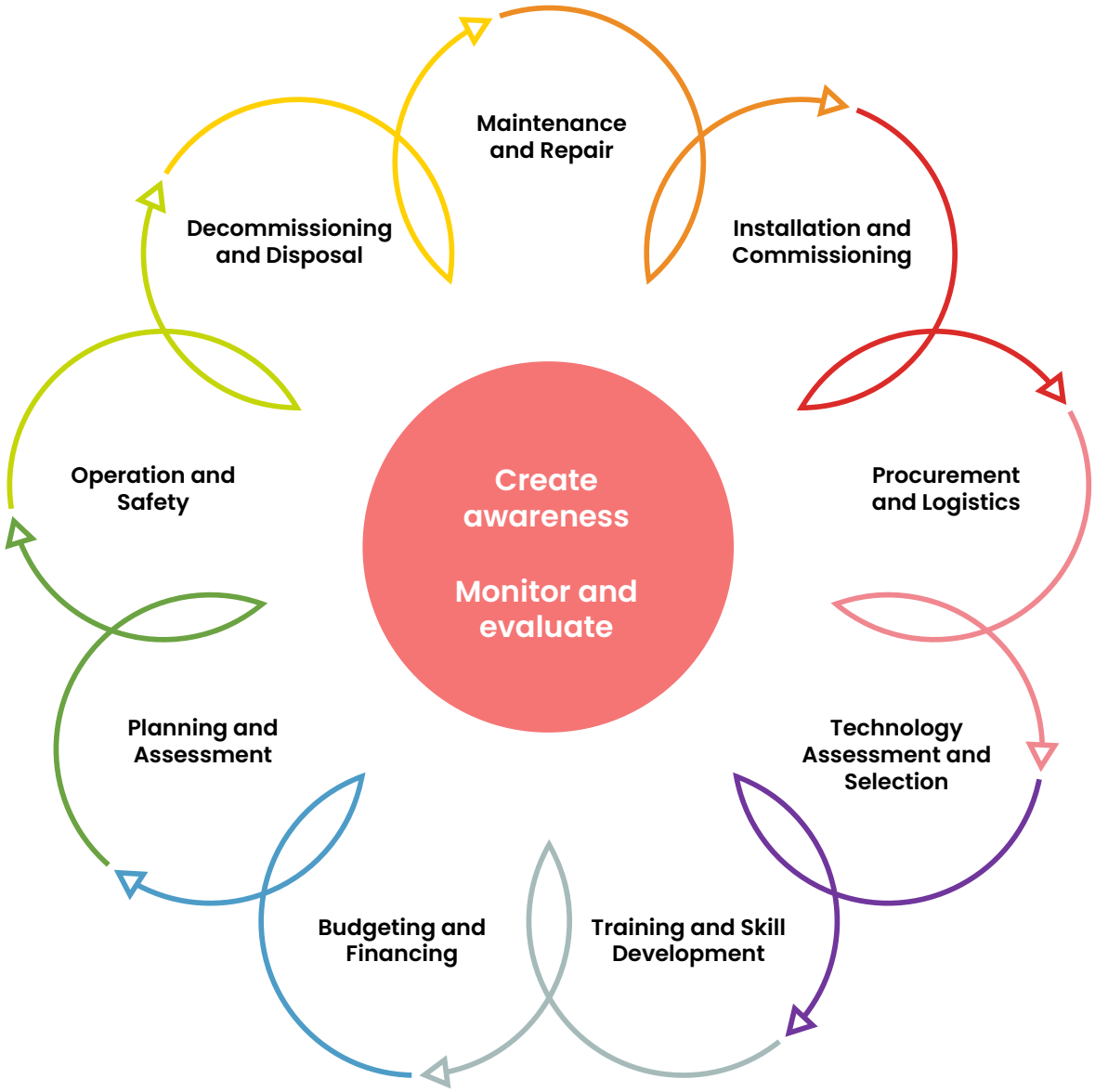

Figure 5.1: The Healthcare Technology Management Cycle

1. Routine assessment and advice on new technologies, assistive technologies, and new equipment to be adopted by the facility.
2. Develop ideas on how to adopt and adapt to promote effective and efficient use of technologies
3. Ensure adherence to maintenance schedules of the health technologies within the facility
4. Recommend and Advise on specifications of health technologies to be procured and used within the health facility
5. Provide relevant information to support selection and procurement of health technologies
6. Support training and capacity building in the use of technologies
7. Monitor and evaluate the use and performance of technologies
8. Risk assessment of all technologies to assess safety and efficacy
9. Track and monitor biosafety and biosecurity of the health technologies in the facility
10. Advise on quality improvement areas regarding Health Technologies

11. Recommend and advise health facilities on the disposal of Health Technologies

5.6 Benefits of Healthcare Technology Management (HTM)

1. Health facilities can deliver a full service, unimpeded by non-functioning healthcare technology.
2. Equipment is properly utilized, maintained, and safeguarded.
3. Staff make maximum use of equipment, by following written procedures and good practice.
4. Health service providers are given comprehensive, timely, and reliable information on: the functional status of the equipment, the performance and the maintenance services, the operational skills and practice of equipment-user departments, and the skills and practice of staff responsible for various equipment-related activities in a range of departments including finance, procurement, stores, and human resources.
5. Staff control the huge financial investment in equipment, and this can lead to a more effective and efficient healthcare service.

5.7 Monitoring and Evaluation for Health Technologies Subcommittee

Role of Health Technologies Subcommittee in functioning of EMR

Table 5.1: Health Technology Management Indicators

Input indicators	Process indicators	Output indicators	Outcome indicators
• Number of health technologies procured • Total cost of health technologies • Training provided to staff • Infrastructure availability (e.g., power, water)	• Maintenance schedule adherence • Equipment uptime percentage • User satisfaction surveys • Technical support requests	• Number of patients treated with health technologies • Quality of care improvement • Number of staff trained in Health Technologies use and management • Number of user units with the required infrastructure	• Improved health outcomes (e.g., reduced mortality) • Enhanced patient safety • Reduced healthcare costs • Increased accessibility to healthcare

References.

Dyro, J.F. 2004. Introduction to medical devices: utilization and service. Clinical engineering handbook. J.F. Dyro, Ed. Burlington, NJ.: Elsevier Academic Press. 371–372.

Kwankam, Y, et al, 2001, 'Health care technology policy framework', WHO Regional Publications, Eastern Mediterranean Series 24: Health care technology management, No. 1)

Lenel, A., et al. «Guide 1: how to organize a system of healthcare technology management. '.» How to Manag Ser Healthc Technol 167 (2005).

WHO. 2014. Health intervention and technology assessment in support of universal health coverage

Hussain, S., Mubeen, I., Ullah, N., Ud Din Shah, S.S., Khan, A. B., Zahoor, M., Ullah., Khan, F.A., Sultan, M.A. (2022). Modern diagnostic imaging technique applications and risk factors in the medical field; a review. Retrieved from: https://pmc.ncbi.nlm.nih.gov/articles/PMC9192206/.

CHAPTER 6

Quality Improvement for Pharmaceuticals Management

6.1 Introduction

The National Health Sector Quality Improvement (QI) framework and Strategic Plan 2015/16– 2019/20 identifies the MTC as a quality Improvement Team (WIT) for the area of Therapeutics, working under an overall facility Quality Improvement Committee, and inter-linked with other committees, e.g. the Infection prevention and control committee.

This chapter presents some basic information about the quality improvement framework ,methods and how they can be applied by MTC to address medicine problems. More comprehensive information can be found in the MOH document "The Quality Improvement Methods: A Manual for Health Workers in Uganda, 2015".

6.2 Quality in Healthcare

Good quality of care enhances clients' satisfaction and improves their use of services at the healthcare facility. It also increases job satisfaction and motivation among service providers, leading to effective and efficient utilization of resources.

Appropriate Medicines Management and Use contributes to ensuring good QUALITY OF CARE, which is defined as the "degree to which health services for individuals and populations increases the likelihood of desired (positive) health outcomes and is consistent with current professional knowledge of best practice".

Ensuring the maximum achievable quality is called QUALITY ASSURANCE, and it is based on three core interrelated activities:

- Defining quality

- Measuring quality
- Improving quality.

Appropriate Medicine Management and use is part of quality assurance dealing with the use of pharmaceuticals, and follows the standard steps, as shown in table 6.1 below.

Table 6.1 Quality Assurance In Medicines Management And Use

	Quality Assurance	Appropriate medicines Management and use
Defining quality	Setting standards, procedures, regulations	Standard Treatment Guidelines, Essential Medicine List, Medicine Management policies and guidelines
Measuring quality	Quantifying current level of performance and compliance with expected standards, to identify gaps and monitor / evaluate change	Investigating the management and use of medicines
Improving quality	Identifying, prioritizing, and analyzing the problems, designing and implementing solutions: continuous quality improvement.	Improving management and use of the medicines

6.2.1 How to begin: Define standards and implement the 5S

It is important to define standards against which performance can be measured. Standards can be guidelines (local, national, or international), policies, or procedures. In most cases, standards do not need to be developed afresh but are available at the national level and just need to be adopted.

The 5S methodology (Sort, Set, Shine, Standardize, and Sustain) is recommended as the first basic management tool for quality improvement (QI), and it is always a good way to start the process of re-organizing the workplace. Examples of the activities involved in the 5S methodology are shown in table 6.2 below

Table 6.2 The 5s Methodology For Quality Improvement

5 S	Definition/activities
SORT	Eliminate all unnecessary tools, parts, and equipment, keeping only essential items neatly organized in easily accessible places.
SET	Set to flow, arrange the work, the workers, the equipment, the parts, the steps of a process, and the instructions so that the work flows smoothly. This can be applied to the: • Organization of services (e.g. in OPD registration and triage at the entrance, followed by consultation, then by lab, and pharmacy at the end…) • Organization of supplies and equipment (e.g. in the ward IV medications, IV, and cannulation sets should all be stored in an easily accessible place near the nurse and emergency area • In the theatre all the equipment and medicines for resuscitation should be organized in a crash trolley) and, organization of work (e.g. nurses should check vital parameters and fluid balance before the doctors' round so that data is available when needed)
SHINE	Clean and keep everything organized and tidy

STANDARDISE	Ensure uniform procedures and protocols
SUSTAIN	Maintain the place in an organized manner

The 5 S methodology is done in a stepwise approach. Without these basic actions, it is almost impossible to proceed to any other QI activity, since it will be difficult to assess situations when the environment is disorganized, and processes are chaotic and heterogeneous (see references at the end of this chapter for more information on this).

KEY MESSAGE

START QUALITY IMPROVEMENT BY:

Setting standards

Cleaning and organizing your place and workflow!

6.2.2 Continuous Quality Improvement

The next step is the real core of the process: continuous quality improvement (CQI), is a progressive, and incremental improvement based on a system approach, using scientific and standardized tools to analyze and improve processes and outcomes.

Quality improvement activities can be one-off interventions by one individual or a small team focused on a specific problem, especially when there is an urgent issue to be tackled, or it can be a systematic, continuous process by a permanent team that takes responsibility for quality improvement in a determined area of care, (e.g., the MTC, the infection control committee, the ART QI committee).

The quality improvement cycle

The quality improvement cycle involves 4 steps:

Identify the problem: according to priority criteria like magnitude (number of people affected) , severity of consequences, financial impact, etc....but also on the possibility of addressing it: choose an issue that is within your reach, for example, noncompliance to prescription guidelines. Problems such as underfunding of the health sector may be beyond the possibility of intervention by a single MTC! (see below how to prioritize). Then measure the problem, in order to be able to assess the burden and also to get a baseline that allows you to monitor change when interventions are put in place.

Analyze the problem further and investigate the determinants/causes: Focus on system issues why the problem exists (e.g. lack of staff? knowledge? O material? Of protocols? Of rules? Of standard operating procedures?), rather than individual issues. This is the most neglected phase: there is often a rush/pressure to DO! DO! DO! without having really understood the root causes of the problem! The results, in this case, may not be what we expect.

More often, problems are caused by a complex combination of factors, not by an individual making a mistake. Root causes must be investigated and understood to develop effective interventions.

Design and implement an intervention: This entails reflecting on the root causes identified and planning how to address at least some of them. You may need to try different approaches and see which one is yielding results. In this phase, you can use the Plan, Do, Study, Act cycle. which is a structured learning approach to testing changes:

Plan: based on the knowledge you gained in the previous steps, develop a plan for the change (Who, What, How, When, Where)

Do: implement the plan! Start implementing on a small scale to test the effect

Study: verify the effects of the change, successes, and challenges

Act: if successful, continue implementation, eventually at a larger scale, and include the change in the mainstream, making sure that the new approach becomes routine. If the results are not the expected, go back to the drawing board and re-design, learning from the failed trial.

Continue monitoring and evaluating: And when reasonably satisfied, start on another problem! Keep monitoring – it takes time for good practices to be firmly established, and often improvements do not last and there is always the risk of going backward.

The continuous quality improvement cycle is shown in Figure 6.1 below.

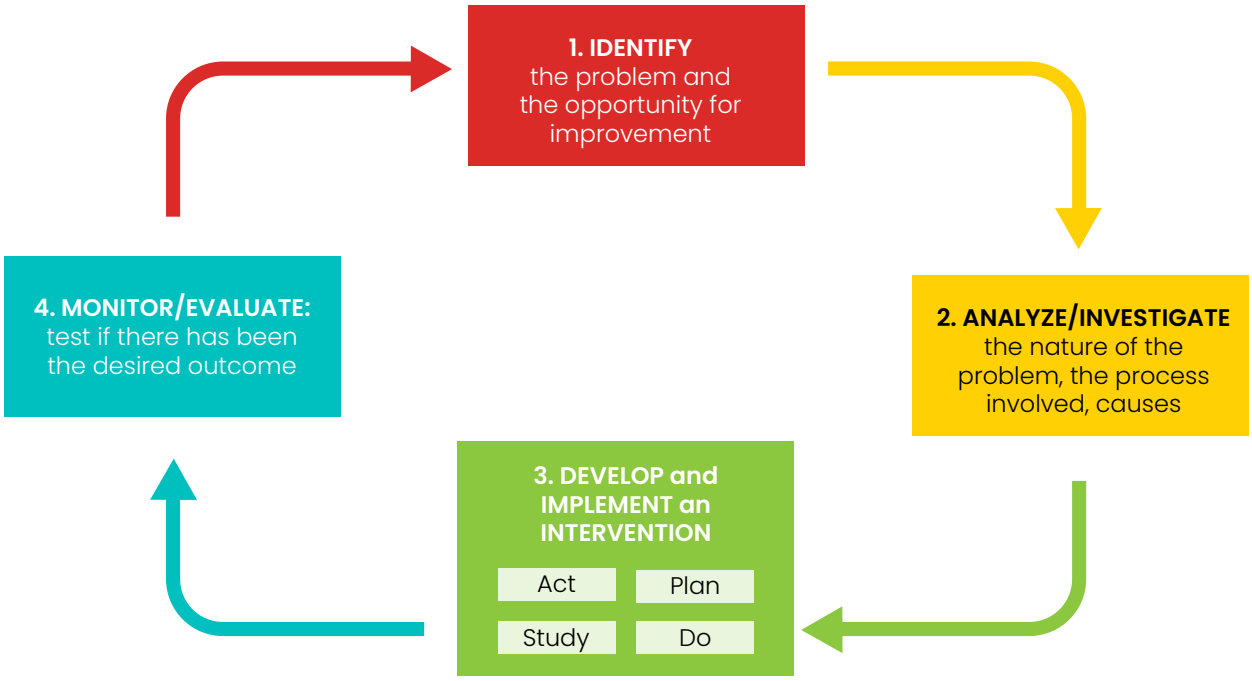

Fig 6.1: Continuous Quality Improvement Cycle

The CQI process is a demanding task, especially in the initial stages, and a lot of learning and innovation are involved. These should be shared, and this can be done through:

Standardization e.g., using the work of one MTC to create standards to be adopted in other facilities Through a collaborative approach, e.g., through organizing several teams (MTCs) to work on the same area (improve management and use of medicines), with common methods, objectives, and indicators, and periodically share and discuss the results and challenges.

6.3 Quality Improvement Tools

There are many QI tools and methodologies, which can be used at the different stages of the CQI process. They are presented here briefly and in the following chapters, their application to the area of appropriate medicine management and use will be demonstrated.

Table 6.1 shows a summary of different methods of identifying and analyzing problems, to identify the root causes and see the relationships between the different factors, and to formulate possible solutions and interventions.

Table 6.1 Methods of identifying and analyzing problems

Method	Description	Use	Example
Brainstorming	• Discussion on a selected topic/idea, to generate as many ideas as possible in a short time. • After ideas are exhausted, the group will then categorize priorities and select the best ideas e.g. through an affinity diagram.	Problem identification Problem analysis Intervention design/ selection	Which are the most common/important medicine management and use problems in the facility? Why is there a high percentage of malaria cases diagnosed and treated without testing? How can we change the situation?
Affinity diagram	Organization of a large amount of data or ideas (e.g. generated by a brainstorming session, or from qualitative studies) into groups based on their natural relationship	Problem identification Problem analysis	The problems can be categorized into OPD and IP issues, general or disease-specific issues, etc. The causes of treatment without testing can be grouped into issues concerning staff, supply, knowledge, service organization…
Prioritization matrix/ Ranking/ Rating	• Method to choose which problems need to be worked upon first or which issues/problems/ intervention may have the higher gain. • A list of possible issues/ interventions should be made. Criteria for the choice should be set. A scoring system can be set, and scores are attributed to each criterion. Total scores are calculated, and issues are prioritized by the scores.	Problem prioritization Intervention design and Implementation	In prioritization of problems, there can be impact on morbidity/ mortality, economic impact, quality of care, etc. The intervention chosen is based on feasibility, affordability, degree of impact, acceptability, etc.
Cause- Effect Diagram/ Fishbone Diagram/ Problem tree	• The technique is used to discover the possible causes of a problem, often using data generated from brainstorming. • Define the problem (the head of the fish), define 3 to 6 main categories of factors (the main spines) and for each one drill down the root causes: each major spine/branch usually has another 3 or 4 sub-branches.	Problem analysis	If the problem is treating malaria without testing, the main causes could be prescriber-related causes, laboratory-related causes, patient-related causes, etc.

5-WHYs	• Tool for root cause analysis: keep asking why something is happening… until a possible root cause is identified. • A root cause is something that if intervened upon will cause a change in the problem! • Some root causes cannot be intervened upon… select the ones you can change!	Problem analysis	• Why are prescribers treating malaria without testing? Because it takes too long to get the results from the laboratory • Why does it take too long to get the results? Etc.…
FLOW CHARTS	Way of analyzing a problem by breaking it down into steps, to be able to analyze each one of them and identify bottlenecks, inefficiencies, and Causes	Problem analysis	What is the process of care for an OPD patient with a fever?
Plan-Do-Study-Act (PDSA) Cycle	A structured approach to testing a change, learning to know whether a change has worked or not, and to learn and act upon any new information as a result.	Intervention design and implementation	How can we change that practice? Does this work?

6.4 Quality Improvement in medicine management and use

The process of identifying, understanding, and changing medicines management and use problems is the same as for any quality improvement approach and is like the process of diagnosing and treating a clinical illness. A logical series of activities and questions, starting from the initial identification of a problem to the diagnosis of its causes through further investigations and then to implementation of an intervention to «treat» the problem, and then ending with evaluation of the outcome(s) and a re-start of the process if necessary. This process includes the following four steps as in shown Figure 6.2

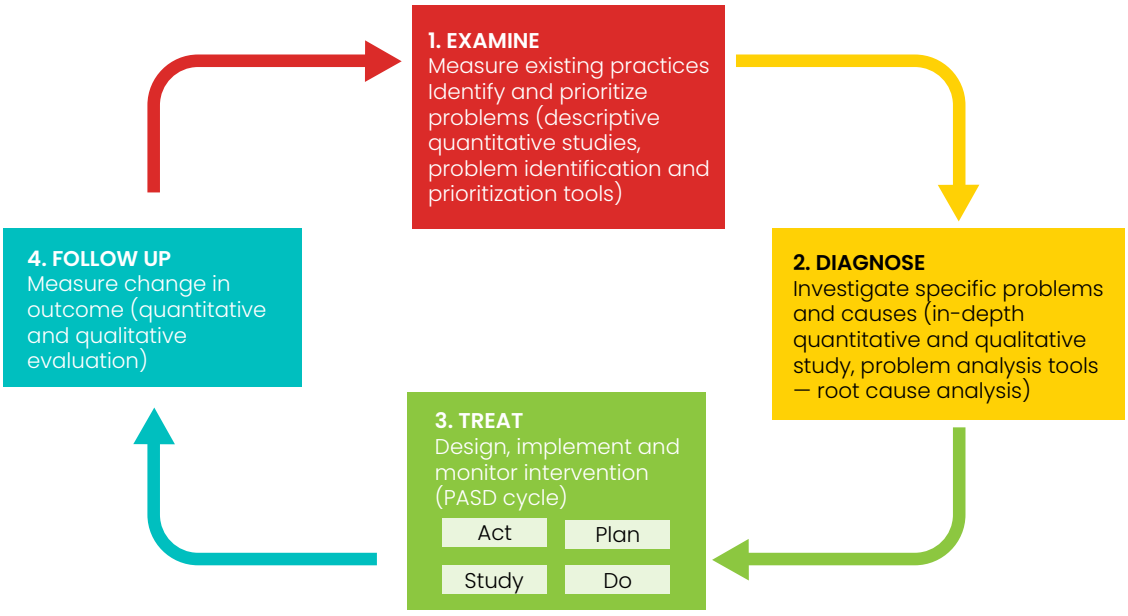

Figure 6.2 The Quality Improvement Cycle

In the following paragraphs each step is explained. Some are common to the QI approach, while others (especially data collection and analysis tools) are specific for the area of medicines management and will be presented in details in Chapter 10.

6.4.1 Step 1. Examine: Measure, Identify, Prioritize

A problem is regarded as a difference between the actual situation and the desired situation. Obviously to define this difference we need to know what the ideal (desired) situation is, that is the STANDARD. The first step in quality assurance is defining quality, and in appropriate medicine management and use this is represented by standard treatment guidelines, dispensing guidelines and medicines management policies.

How to Identify Problems:

Problems with medicine management and use at the health facility can be identified through:

- Brainstorming during a stakeholders' meeting, such as MTC, any other meetings Results from simple surveys
- Findings from routine data analysis (e.g. HMIS for malaria, HIV…) Observation and report by any stakeholders

Brainstorming

Brainstorming is a free discussion which can generate a lot of ideas. Some of the questions that can guide a discussion on problem identification are:

- What are the common conditions/illnesses seen at the facility?
- What medicines are used to treat these conditions?
- What are the most common medicines used in the facility? To what extent are these medicines used appropriately?
- Which medicines are most expensive/ dangerous/difficult to use?
- What do health workers believe are medicines management and use problems at the facility?
- What are the problems identified at national level/other facilities?
- Do STGs exist for common illnesses? Are they available to the prescribers?

The ideas generated will then need to be organized in groups/categories: by location, by staff involved, by type of medicines involved e.g. antibiotic problems, OPD problems, dispensing problems. This is called doing an affinity diagram.

Measuring

Medicine management and use problems may be difficult to detect on a day-to-day basis unless they are obvious, so specific methodologies have been developed to assist in this process. These methods provide information on possible problem areas and are also used to monitor the effect of the interventions implemented to address the problems. The methods (presented in chapter 4) include:

Aggregate data on medicine consumptions (in terms of total costs, therapeutics category, ABC-VEN analysis and VEN classification)

Drug use surveys (OPD drug indicator surveys, hospital antibiotic use survey, point prevalence surveys, prescription and medicine audit/evaluation)

Stakeholder involvement

Several stakeholders within the facility are involved with medicines management and use including managers/policy makers, clinical officers, doctors, nurses, pharmacists, dispensers, stores personnel, laboratory personnel, record/biostatisticians, patients and other staff.

It is important that all these people are involved from the initial phases of identifying and understanding the problem because:

- Different stakeholders can see different problems or different aspects of the same problem
- Involvement of stakeholders early on helps to ensure that they all understand that a problem exists, and that they are an integral part in rectifying the situation.

Prioritizing Problems

To select and develop strategies to improve medicine management and use in the health facility, it is important that the problems listed are prioritized and choices made about which problems to address.

In order to do so, criteria that are relevant to the operational setting in which the problem is to be addressed, and the people affected by it should be developed. The following criteria are commonly used, but you can always think of others to use in setting your priorities (Table 6.4).

Table 6.4 Criteria For Prioritizing Problems

Prioritization Criteria	Definition
Scale of the problem	How many people are affected by the medicine misuse problem? Is misuse common or rare? Does it concern a common health problem, and therefore affect many people?
Seriousness of health consequences of the problem	The seriousness of the consequences of a problem, in terms of health outcomes, should be considered, for example: Are consequences dangerous for life? Are there serious side effects? No major change in outcome for the single patient?
Public health consequences	Consider the possible effects beyond the single individual, e.g.: Antimicrobial misuse carries risk of development of resistance. Inappropriate treatment of some infectious disease carries the risk of increasing the spread of disease in the population (e.g. TB, HIV etc.)
Economic impact	Here we ask ourselves how much the problem may be significant in terms of resource use. Does it cause a significant amount of wastage? What would be the economic impacts of not addressing the problem?
Potential for impact and Solvability	How deeply rooted are the problems? How likely is it that an intervention would be able to change them? Is it a relatively simple problem, or may it be extremely difficult to address?
Feasibility of intervention and Available resources	Can the problem be addressed with the available resources? Is the resolution of the problem within the means of the facility? It is always important to look for solutions within the available means.

Tools to help in prioritization

Ranking and rating are useful ways of shedding light on a difficult choice. These tools help you to understand your choices and to provide you with a framework for discussing priorities. A ranking or rating exercise always needs to be carried out with a full and open discussion and with sufficient background information to make the discussion useful.

1. Rating the problems: Here, problems are prioritized by scoring them according to the criteria you have selected. Each problem is examined in the light of the criteria and awarded a mark or a rating (for instance on a scale of 1 – not significant to 5 – very significant). If you do this for each of your problems, you will come up with a number of points for each problem which can enable you to make a quantitative comparison for priority setting. The problem with the highest total rating should be the most important.

You will need to consider whether all the criteria are of equal value. If for example, you decide that one of your criteria - e.g. seriousness of health risk - is essential, you may focus your discussion on the problems that score high on that criterion, and then check which ones score high on other criteria as well.

The table 6.5 below shows an example of a rating exercise of three problems against set criteria:- On a scale of 1 – not significant to 5 – very significant.

Table 6.5 Example Of A Problem Rating Exercise

Rating	Treatment of malaria without testing	Low adherence to guidelines in hypertension treatment	Overuse of antibiotics in OPD
Scale of the problem	3	2	3
Seriousness of health consequences	2	1	2
Public health consequences	3	1	3
Economic impact	3	2	3
Solvability	3	2	2
Feasibility of intervention	2	2	1
Total	16	10	14

The rating exercise above is suggesting that addressing the issue of malaria may be considered the top priority, followed by the over prescription of antibiotics.

2. Ranking the problems: For each criterion you rank the problems, assigning a rank from higher number (most important) to lower number (least important). The difference with rating is that you can only assign a rank once so results are more clear-cutting. This method leads to a much livelier discussion on which problem is most important as problems are compared with each other and a choice has to be made between problems (Table 6.6).

Table 6.6 Example Of A Problem Rating Exercise

Rating	Treatment of malaria without testing	Low adherence to guidelines in hypertension treatment	Overuse of antibiotics in OPD
Scale of the problem	3	1	3
Seriousness of health consequences	2	1	3
Public health consequences	2	1	3
Economic impact	3	1	2
Solvability	3	2	1
Feasibility of intervention	3	2	1
Total	16	8	12

Note! The result (on which problem is top priority) is similar to the previous method.

3. Prioritization matrix: Another simple way of prioritizing problems is by use of the matrix (see figure 6.3 below). The identified problems are discussed and categorized based on the importance of the problem and its solvability. The problems falling in box B would then be considered first to tackle.

Prioritization Matrix

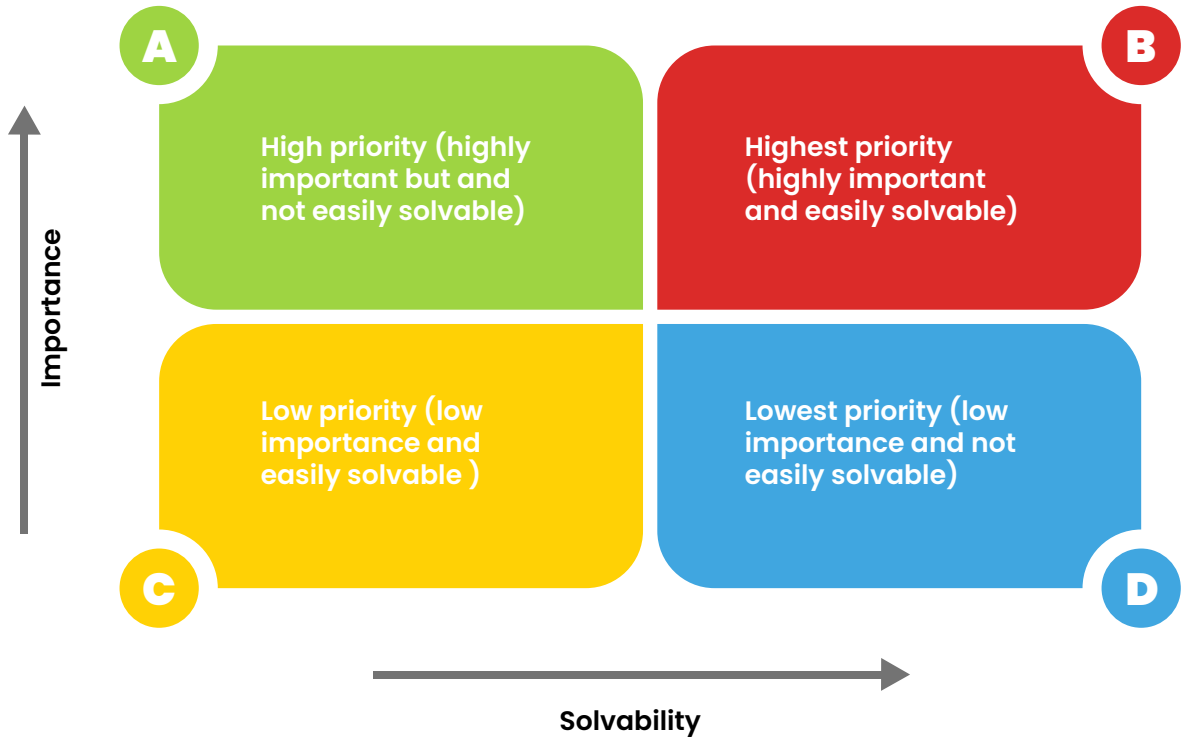

Figure 6.3 Problem Prioritization Matrix

6.4.2 Step 2. Diagnose: Investigate specific problems and causes

The previous activities may have highlighted a possible problem but the information may be incomplete. For example, an OPD drug indicator survey may have revealed excessive use of antibiotics or injections, but in order to understand the problem we may need more information on which antibiotics and for which conditions, and therefore we may plan:

A more detailed analysis of antibiotic consumptions in the OPD

Prescription surveys on the most common infections in the OPD

A medicine management and use evaluation of the most commonly used antibiotics.

These methods will be presented in more detail in Chapter 5. At this point, we may have enough information to formulate in clear terms what the problem is and go a step further.

Problem Statement

A problem statement is a clear concise description of the issue(s) that need(s) to be addressed. It is used to focus the team at the beginning, keep the team on track during the effort, and is used to validate that the effort delivered an outcome that solves the problem as summarized in table 6.7 below.

Table 6.7 Formulation Of A Problem Statement

Element	Description
The problem of …	Describe the problem: what is happening? When? Where? Who is involved? Why is it a problem? Include specific data/measures and how they have been obtained
Affects …	Identify stakeholders affected by the problem
And results in …	Describe the impact of this problem on stakeholders and business activity
Benefits of a solution	How changing the situation will benefit the facility/patients/ community

Root Cause Analysis

Usually what people consider a problem is only a symptom of an underlying problem or problems, which is referred to here as the root cause. Treating the symptoms will not solve the problem. The process of determining the root cause and the barriers to improvement is a necessary part of designing interventions that are intended to improve medicine use.

Investigating a problem is not a fault-finding and blame-apportioning exercise. The task is to find explanations in order to design solutions

Techniques for root cause analysis

There are many techniques used for root cause analysis. It is a matter of preference what you choose to use, but a combination of many techniques may be necessary.

The “5 Whys» technique: This technique involves asking the question “why” 5 times, while listing down the reasons given by different stakeholders. Then to each answer, the “why” is asked again until a root cause is reached. It helps to determine the relationship between different root causes of a problem. It also has the additional advantages of being simple and quick to use and easy to complete without statistical analysis.

Note that a given problem may have many root causes. Although this technique is called «5 Whys,» you may find that you will need to ask the question fewer or more times than five before you find the issues related to a problem. Sometimes an answer is a dead end so you may want to go a step back and try another one.

The fish bone analysis (Ishikawa diagram): This is a quite intuitive and simple method for discovering all the possible causes for a certain problem: the fish head is the stated problem, the big spines represent possible categories of contributing factors, and primary and secondary causes are then added in the diagram as shown in figure 6.4 below.

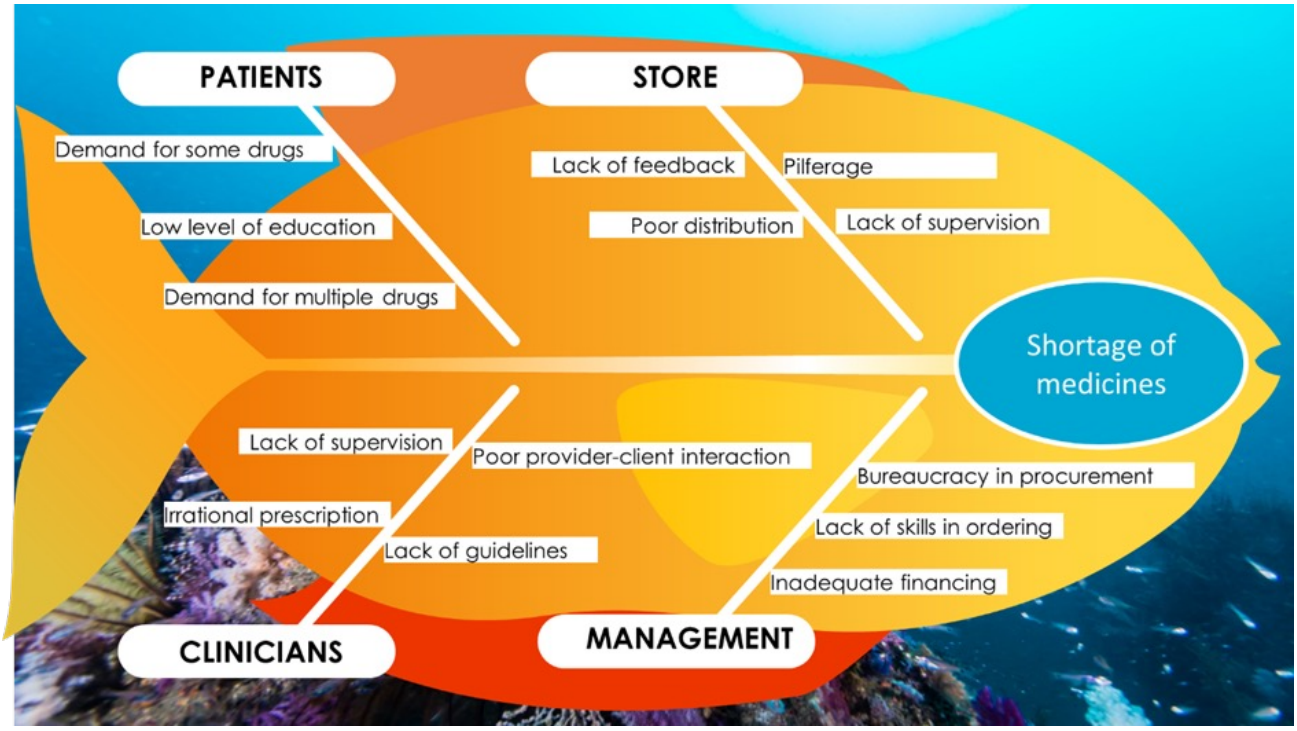

Figure 6.4 The Fish Bone Analysis

Cause-Effect diagram: This technique helps to describe the identified problems more elaborately. You should identify the factors that contribute to the core problem and clarify the relationship between the problem and the contributing factors, and among the contributing factors.

To develop a problem analysis diagram, the core problem and factors contributing to the problem may be placed in boxes. The relationships between the factors can be indicated by one-way or two-way arrows. You can identify the core problem with a double line around it. See Figure 6.5 below as an example.

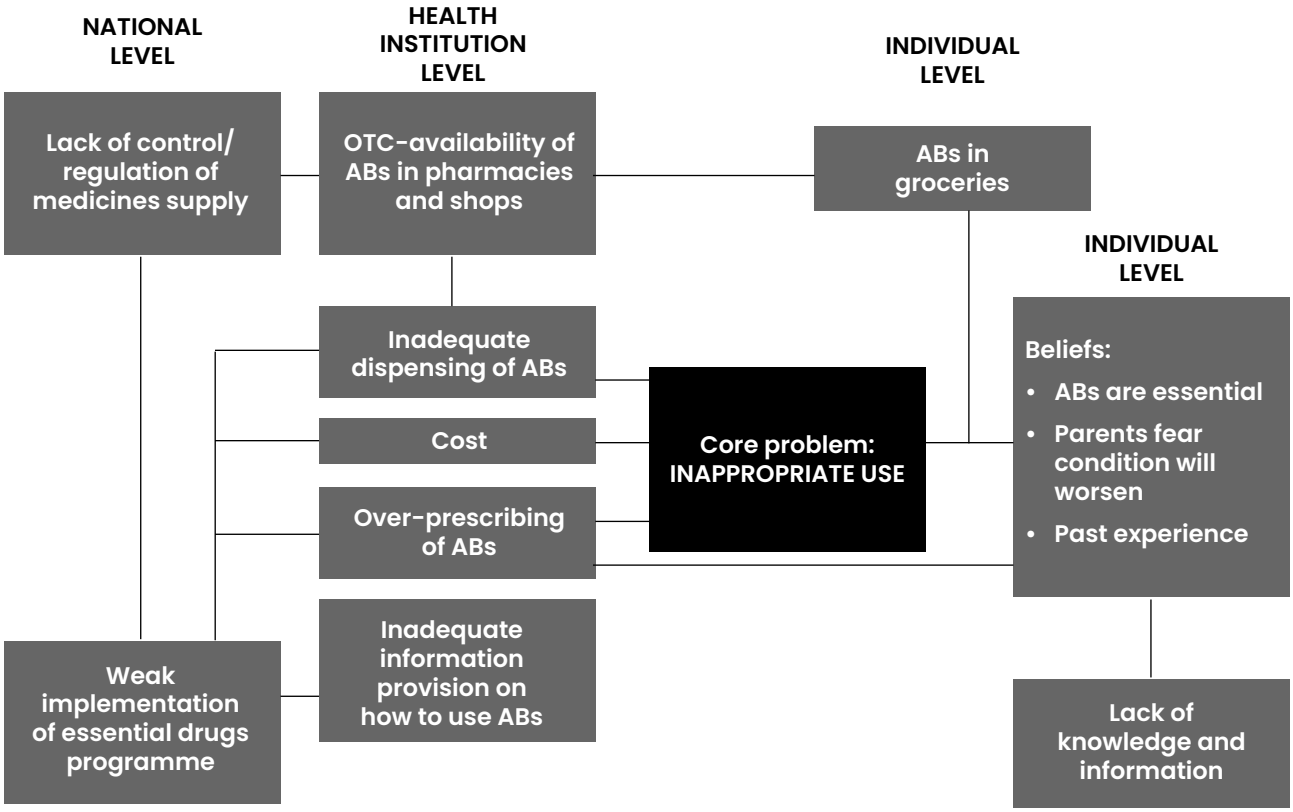

Figure 6.5 Cause-Effect Diagram

Diagrams are important tools as they present information in a readily understandable visual form. The usefulness is twofold. First the participatory act of constructing the diagram is an analytical procedure and second, the diagrams become a means of creating communication and discussion.

The problem analysis diagram can be used as a point of departure in describing the problem in detail. It can also be used to create formative questions that can be used to collect more information about the problem using structured medicines management and use study methods.

NOTE:

During root cause analysis, the answers to these questions should be provided:

What are the factors involved?

What are the constraints to change (economical, supply chain, cultural)?

What are the opportunities for change? Which factors are liable to

Sharing findings of root cause analysis

It is important at this point to share the findings with the management and possibly with all the hospital staff, so that everyone becomes aware of the issue, to which they may want to contribute. They will also be more open to collaboration during the intervention phase.

6.4.3 Step 3. Treat: Design and Implement Interventions

Once the problem has been identified, prioritized, measured, fully investigated and analyzed for root causes, it is time to plan an intervention to address it.

The formulation of an intervention will be informed by all the data already collected, and will use similar principles and methods used in the previous paragraphs, such as:

Brainstorming for generating ideas for solutions

Prioritization techniques to choose the best solution

Which behaviors can be changed most cost effectively?

What are the possible economic consequences?

What are the most appropriate interventions, given their different costs, complexities, and chances of success?

What personnel will be required, and the training they will need?

Plan-Do-Study-Act cycle: conduct pilot tests to determine the acceptability and effectiveness of an intervention, analyze results, modify intervention if not successful to implement on large scale if successful. The type of interventions which can be designed will be described in details in Chapter 10.

6.4.4 Step 4. Follow up: Measure Changes in Outcomes

Last but not least, we have to monitor and assess that the intervention has worked and that the improvement is sustained:

If routinely collected data allows the monitoring and evaluation of the issue addressed, (e.g. % of malaria confirmed by positive tests is routinely collected in the HMIS), the MTC should make sure to regularly receive that data.

If the intervention addressed over-consumption of a certain medicine, routine consumption analysis will provide the information needed.

In other cases, the same general or in-depth survey methods used for problem identification and investigations may need to be repeated periodically.

The same tools used for measuring and investigating the problem will be used for measuring the change. A complete evaluation should be able to answer the following questions:

Was the intervention implemented as planned, e.g., the number of educational sessions or supervisory visits?

What are the measurable changes, e.g., in knowledge, beliefs, patient satisfaction, clinical results, expenditures, etc.?

How cost effective is the intervention compared to other strategies?

How generalizable are the results to other settings?

Dissemination of results

The results of the activities involved in identifying and intervening to change a medicines management and use problem should be shared with all the facility staff, with other facilities, the district health team and with the Ministry of Health so that they can be used/shared for learning purposes.

References

1. ***Uganda National Health Sector Quality Improvement (QI) framework and Strategic Plan 2015/16 – 2019/20***
2. ***The quality improvement methods: a manual for health workers in Uganda, 2015***

CHAPTER 7

Appropriate Use of Medicines, and Health Technologies

7.1 Definition and Principles

Pharmaceuticals, health supplies, and technologies take up to 40-60% of healthcare budgets. Medically inappropriate, ineffective, and economically inefficient use of pharmaceuticals is commonly observed in healthcare systems. WHO estimates that more than half of all medicines are prescribed, dispensed, or sold inappropriately and that half of all patients fail to take them correctly? The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards.

Promoting Appropriate Medicine Use (AMU) in the health care system is needed not only because of the financial reasons that policy makers and managers are usually most concerned with but also is an essential element in achieving quality of health and medical care for patients and the community. Actions or intervention programs to promote the appropriate use of medicines should, therefore, be continuously implemented and systematically incorporated as an integral part of the health care system.

This chapter serves as an introduction to the entire concept of AMU in the health facilities and it covers:

- Definition, examples, causes, and consequences of inappropriate use of medicines
- Core strategies to promote Appropriate Medicines Use
- Essential Medicines Concept
- Standard Treatment Guidelines

7.1.1 Defining Appropriate Medicines Use

The terms «appropriate» and «rational» use of medicines are sometimes used interchangeably. People may have different perceptions and meanings regarding appropriate use of medicines, or more specifically regarding "rational" prescribing. The requirements for appropriate use will be fulfilled if the processes of diagnosing, prescribing, dispensing and administration of the medicine are appropriately followed.

This means that the following criteria must be met:

- Right patient: selecting appropriate medicines for age, sex, dosage, administration route and duration, no contraindications, acceptability to the patient
- Right diagnosis: defining a patient's medical problem correctly is important or else it would set off a cascade of inappropriate use of medicines.
- Right medicine: prescribing cost-effective, safe and affordable medicines. The issue of costs must be considered since resources are limited; we need to make sure that we get the maximum benefit for the maximum number of people within available resources.
- Right dosage and duration of treatment: The appropriate dosage and treatment duration are key in ensuring AMU. The dose appropriate for the age, weight, sex etc. provides a platform ration medicine use. The duration of treatment should be clear and therefore made known to the patient. This enhances adherence to the prescribed treatment.
- Right documentation: valid prescription, right reporting of adverse drug events, right treatment notes

7.1.2 Examples of Inappropriate Medicines Use

Inappropriate use occurs when any of the criteria mentioned above are not met. This can occur at any stage of the medicine›s use process, i.e., during diagnosis, prescribing, dispensing or patient adherence. Some examples of inappropriate use are listed below:

Drug use when no medicine therapy is required, e.g., antibiotics for viral infections.

The use of the wrong medicine for a specific condition e.g., treatment of simple non- bloody diarrhea with antibiotics.

- The use of medicines with doubtful or unproven efficacy e.g., use of multivitamins without evidence of deficiencies.
- The use of medicines of uncertain safety status e.g., unlabeled medicines and unsealed medicine bottles.
- The unnecessary use of Watch and Reserve antimicrobials when an access antimicrobial would work, e.g. the use of a third generation, broad-spectrum antimicrobial when a first-line, narrow spectrum agent is required
- Over-use of injections when oral formulations would be more appropriate
- Multiple or over-prescription per patient (polypharmacy)
- Dispensing/administration mistakes: incorrect dose, route of administration, duration, wrong label, incomplete instructions to patients
- Inappropriate use at patient's and community level: poor compliance, incorrect route/dose, sharing of medicines, self-medication.

7.1.3 Factors That Influence Appropriate Medicine Use (AMU)

There are several factors influencing the use of medicines. These factors can be categorized into six main areas; Prescriber factors, Patient factors, workplace system factors, industry factors, regulatory factors, supply chain factors as well as social and cultural dynamics and information about medicines. The infographic in figure 7.1 below describes the interaction between the different factors stated above.

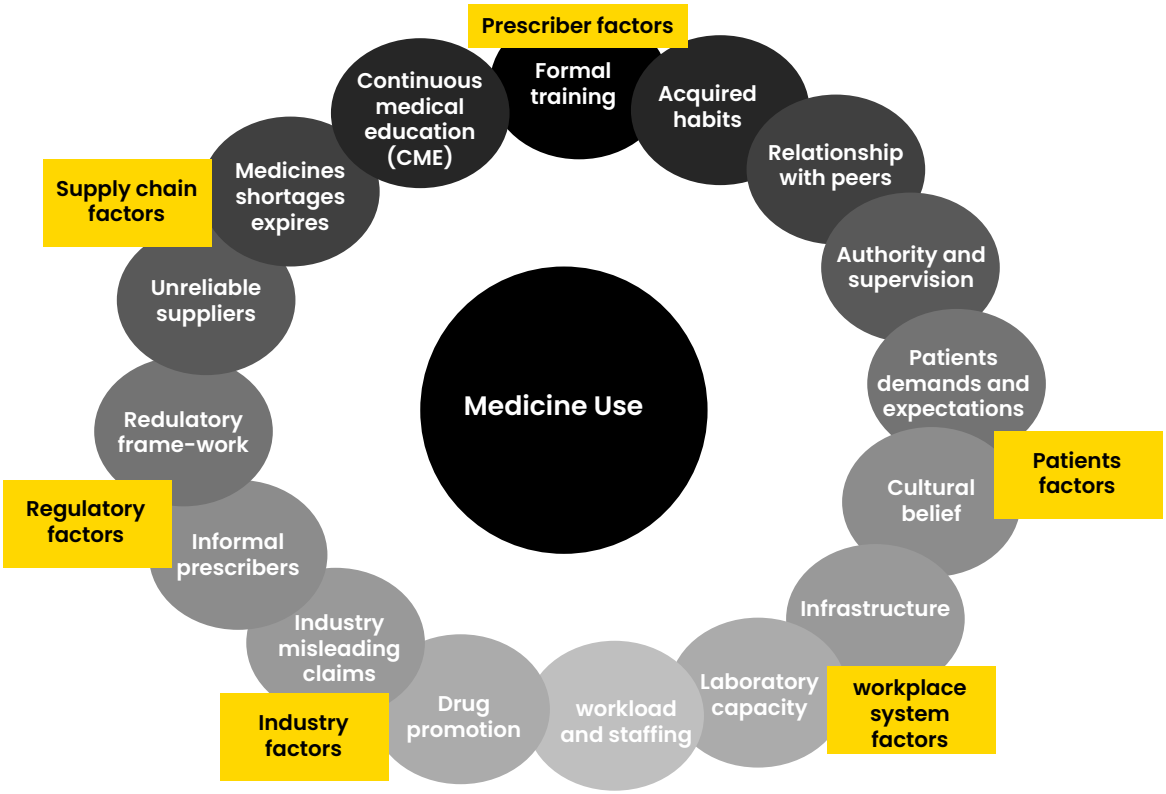

Figure 7.1 The Interaction Between The Different Factors Influencing Amu.

7.1.4 The Impact of Inappropriate Medicines Use

The impact of irrational use of medicines can be seen in many ways

1. Increased morbidity and mortality.
2. Wastage of resources leading to reduced availability and stock out of vital medicines.
3. Prolonged hospital stays.
4. Increased risk of adverse medicine reactions
5. emergence of medicine resistance, e.g., malaria or multidrug resistant tuberculosis
6. Psychosocial impacts, such as when patients come to believe that there is "a pill for every ill." This may cause an increased demand for medicines and more inappropriate use, often by self and unauthorized prescription.
7. Irrational use of medicines can also compromise trust in the health system.

IMPORTANT TO NOTE

Medicine use is the end of the therapeutics consultation. Ensuring that the correct medicine is given to the correct patient is a high priority for all health professionals. Improving medicine use improves the quality of care and lowers the cost of treatment.

7.2 Key Strategies to Improving Medicines Use

The World Health Organization (WHO) advocates 12 key interventions to promote rational use of medicines. The Uganda National Medicines Policy 2015-2020 also proposes these strategies to ensure that end-users receive maximum therapeutics benefits from medicines through their scientifically sound and cost-effective use by prescribers, dispensers and consumers. The WHO Core strategies for improving medicine use are summarized in table 7.1 below.

Table 7.1: Who Core Interventions For Promoting Rational Medicines Use

WHO Core Interventions for Promoting Rational Medicines Use
1. Establish a multidisciplinary national body to coordinate policies on medicine use
2. Use of clinical guidelines.
3. Development and use of National Essential Medicines and Health Supplies List
4. Establishment of drug and Therapeutics committees (also called Medicine and Therapeutics Committees) in all health facilities.
5. Inclusion of problem-based pharmacotherapy training in undergraduate curricula.
6. Continuing in-service medical education as a licensure requirement.
7. Supervision, audit and feedback on medicines use.
8. Use of independent information on medicines.
9. Public education about medicines.
10. Avoidance of perverse financial incentives.
11. Use of appropriate and enforced regulation.
12. Sufficient government expenditure to ensure availability of medicines and staff

In Uganda, the Department of Pharmaceuticals and Natural Medicines of the Ministry of Health is the institutional body responsible for implementing the Appropriate Medicine Use program. The Appropriate Medicines Use Unit, Pharmacy department was created in 2016, in line with the National Medicines Policy 2015-2020 recommendations, with the task of coordinating all AMU activities.

7.3 Standard Treatment Guidelines (STGs)

Standard Treatment Guidelines are systematically developed statements that assist prescribers in deciding on appropriate treatments for specific clinical problems. These guidelines usually reflect the consensus on the optimal treatment options within a health facility or health system. The information is disease-centered, emphasizing the common conditions, their diagnosis and the various treatment alternatives.

They provide the "standards" used to assess appropriateness of medicine use and are therefore at the core of any work in appropriate medicine use.

7.3.1 Potential benefits of Standard Treatment Guidelines

STGs promote high quality of care across the health system by:

- Linking scientific evidence to clinical practice.
- Forms a basis of the EMHSL and institutional formulary.
- Promoting appropriate use of resources.
- Guiding procurement/supply of pharmaceuticals.

- Guiding training on AMU.
- Promoting standards of care.

The benefits of using standard treatment guidelines are summarized in table 7.2 below.

Table 7.2 Benefits Of Standard Treatment Guidelines For Different Stakeholders

7.3.2 Uganda Clinical Guidelines (UCG)

For health officials/practitioners	**For Managers**
• Evidence based guidance • Improved diagnostic accuracy • Effective and safe therapy • Standardized information for patient management. • To guide on designing the hospital formulary.	• Tools to measure, monitor and improve performance and quality of care. • Standardized basis for quantifying, ordering and procuring supplies • Basis for health workers' training. • Basis for resource mobilization. • Tool to enhance efficiency/appropriate use of resources.
For supply chain management staff	**For Patients**
• Identifies which medicines should be available for the most treated problems. • Guides appropriate allocation of resources during quantification.	• Optimal treatment, better outcomes at lower costs • Consistent quality of care across health system which encourages adherence • Better availability of medicines • Prevention of development of resistance for antimicrobials. • Monitoring and enhancing safe drug use and monitoring. • Aids prediction of adverse events

Uganda has had six editions of national Standard Treatment Guidelines published in 1993, 2003, 2010, 2012, 2016 and 2023 respectively. The Uganda Clinical Guidelines (UCG) is a comprehensive document containing information on features, diagnosis and management of most common conditions in Uganda.

The intended users are health workers in all health facilities in public and private sectors at all levels of care but largely targeted for primary health care. Specialist conditions and treatments are not covered by the UCG, even though early recognition and diagnosis of some specialist conditions may be mentioned.

The UCG also indicates for each condition the level of care at which the necessary expertise and medicines to manage a given condition are available, which in turn helps health workers to refer patients to the appropriate level of care when needed. Since 2016, the UCG has also been harmonized with "laboratory test menu", which indicates the tests available at the different levels of care.

7.3.3 Principles and use of the UCG

The principles on which the Uganda Clinical Guidelines (UCG) are built include:

- Health priorities: conditions are selected based on their prevalence/incidence (how many people are affected) and their severity (the risk of death or disability, the effect on quality of life).
- Scientific evidence for effectiveness of the treatment for a given condition (evidence-based medicine). The steps of identifying and assessing scientific evidence are generally entrusted with the academic specialists (experts) for each given therapeutics area and the vertical programs of the MOH. In addition, Uganda largely adopts/adapts WHO recommendations for the management of many conditions, which have already undergone the critical appraisal processes
- Cost-effectiveness: alternatives are selected based on the relationship between the cost and the outcome. Options which provide more value (outcome) for money are obviously preferred!
- Appropriateness/ability to implement for in our setting and the level of care within the Ugandan health care system; the selected alternative must be affordable, implementable (the conditions for its implementation must exist; e.g. in terms of infrastructure, staffing etc.), and acceptable, both to health workers and patients.

Uganda Clinical Guidelines are used to guide clinical practice but also provide standards against which quality of care can be assessed, in medicine use.

7.4 Essential Medicines

Essential medicines are those that satisfy the priority health care needs of the population. They therefore must be available at all times, in adequate amounts and in the appropriate dosage forms, (WHO 2002).

The Essential Medicines Concept (EMC) is a public health principle that promotes efficient use of resources by establishing and using a limited list of carefully selected medicines. The concept is based on the observation that:

- The medicines are intended to always be available within the context of functioning health systems in adequate amounts in appropriate dosage forms
- The medicines should be of assured quality and with adequate information
- The medicines should be at a price the individual and community can afford
- The medicines should be able to address most health problems of the community

Benefits of the Essential Medicines Concept

- Better therapy as clinicians become more knowledgeable with an adequate number of medicines.
- Procurement and distribution are more efficient and cost effective with fewer medicines.
- Medicine ordering and storage at the facility is also easier with a limited number of medicines.
- Patients can be better informed when fewer medicines are used.
- Formal education and in-service training of health professionals and of public education is easier.

Uganda has implemented the Essential Medicines Programme since 1985. The first EMLU was published in 1991, and subsequently in 1996, 2001, 2007, 2012, 2016, and 2023. From 2012 the EMHSLU

also contains the health supplies and laboratory supplies that are needed at the health facilities. This was to ensure a comprehensive document that can suitably guide procurement by the warehouses (National Medical Stores, Joint Medical Store) and assure availability of all supplies needed to deliver optimal care to patients.

Important note: The UCG editions since 2012 have been harmonized with the EMHSL to ensure that all medicines recommended in the UCG are in the EMHSL, which in turn ensures that they are procured and availed at the health facilities. In addition, the EMHSLU also contains specialist medicines required for treatment of conditions where diagnosis, treatment specialized or monitoring is required, such as cancer, ophthalmology and dialysis. The items in the EMHSLU are therefore classified by "level of care", which indicates the lowest level of health facility at which the medicine will be available, basing on the expected level of expertise at different levels in terms of qualification of staff, diagnostic capability, laboratory equipment and allocated budget.

The main inclusion criteria for medicines on the EMHSLU overlap with the principles used to develop the STG such as:

Efficacy: the capacity of the medicine to effectively treat the diagnosed condition.

- Safety: the nature, frequency and severity of expected side-effects.
- Quality: compliance of the drug presentation with internationally accepted standards of purity, composition, and consistency.
- Cost-effectiveness: in terms of available and effective alternative medicines or dosage-forms.
- Appropriateness: the overall suitability of the medicine within the local context taking account of various factors including morbidity patterns in Uganda, changing morbidity patterns, likely compliance with dose regimen, development of resistance, type of dose form/method of administration, socio-economic factors.

7.5 The VEN Concept

In many cases the facility budget will not be enough to buy all the essential medicines that meet the estimated requirements. In such a situation, the Vital, Essential, Necessary (VEN) classification aims to prioritize items by the magnitude of their clinical relevance to guide procurement by warehouses and drug ordering by health facilities. The aim is to ensure that the most vital medicines are given priority when procuring so that they are always available at all times. The VEN principle applies to all health commodities including sundries, laboratory chemicals and consumables.

- V: Vital drugs are potentially lifesaving, and unavailability would cause serious harm and side effects, therefore must be available always
- E: Essential drugs are effective against less severe but nevertheless significant forms of illness but are not vital to providing basic health care;
- N: Necessary (or sometimes called non-essential) drugs are used for minor or self- limiting illnesses, are of questionable efficacy, or have a comparatively high cost for a marginal therapeutics advantage.

CHAPTER 8

Institutional Medicines List (IML)

The EMHSLU of Uganda is developed at central level, and it contains a wide range of medicines/ formulations, and supplies, (784 medicines,738 health supplies and 1350 laboratory supplies). Not all these items may be required at all facilities, and therefore it is expected that each hospital develops its own institutional medicines list (IML, sometimes called hospital formulary), out of the national EMHSLU. This has the benefits of streamlining procurement within a limited budget, easing stock monitoring, fostering adherence to treatment guidelines, and easing training of health workers.

The same criteria used for the national EMHSLU may be adopted for selecting items for the institutional medicines list, for example:

- Morbidity patterns of the hospital›s patients. Allocated budget for pharmaceuticals (medicines and sundries)
- Available expertise at the hospital (e.g., is there a dental clinic, eye clinic, etc.)
- VEN classification of the items.

8.1 Medicines Information: Practical Guidelines for Dispensing

To use medicines appropriately, healthcare professionals and the public need access to up-to-date, unbiased, accurate, and evidence-based information about these medicines. Drug promoters from manufacturers and suppliers often and aggressively provide biased information, over-emphasizing the advantages and under-emphasizing the adverse effects of the medicines they are promoting. This can pressure prescribers into prescribing expensive or unnecessary medicines that are outside of the essential medicines list.

The Department of Pharmaceuticals and Natural Medicines at the Ministry of Health has therefore developed and distributed two medicines information reference books:

- The Practical Guidelines for Dispensing (PGD) for lower-level health facilities (2014)
- The Practical Guidelines for Dispensing (PGD) for higher-level health facilities (2015)".

These provide information and instructions about the medicines in the Uganda Essential Medicines and Health Supplies List, such as indications, dosage, side effects, important interactions, special instructions for patients, use during pregnancy and breastfeeding, and special cautions to look out for while using those medicines.

The PGD is designed to serve as a quick reference book, with only the most critical information included, aggregated from across several reliable and evidence-based sources of information. All health workers can use the PGD. Prescribers can crosscheck information on indication and doses, dispensers can use it to crosscheck dosing information and provide adequate patient instructions, and nurses can check for drug administration or reconstitution procedures.

8.2 Development of clinical guidelines and Essential Medicines and Health Supplies List

Clinical guidelines and the EMHSLU list are the result of a process of review of scientific evidence and local factors influencing the selection of priority conditions and their preferred therapeutic options.

It usually involves policy makers, academicians, and scientists, but also clinicians and all cadres of health workers. Inputs from facilities, through direct consultations during the review process or continuously from MTC, provide important information about arising needs, issues, and acceptability and feasibility of options.

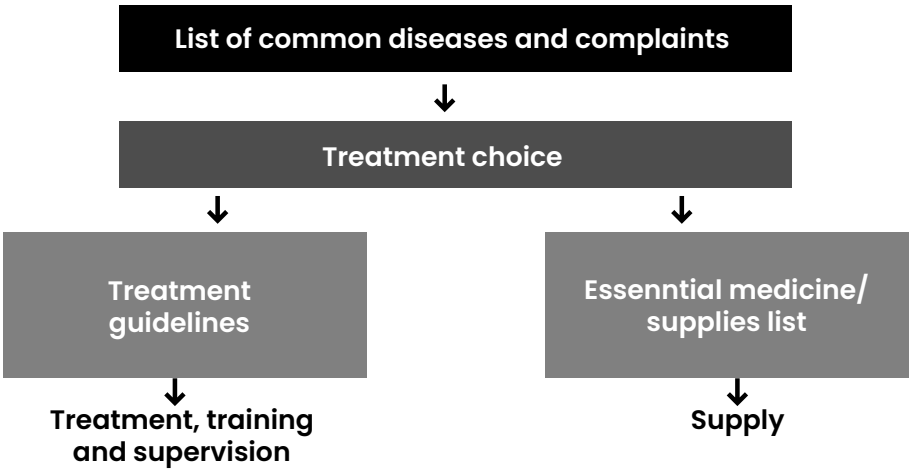

Figure 8.1 Development of clinical guidelines and Essential Medicines and Health Supplies List

8.3 Selection of medicine list: the formulary process

The formulary process is key to good pharmaceutical management and appropriate medicine use and therefore critical to good health care. It consists of developing and implementing:

- A formulary list consisting of the most cost-effective, safe, locally available drugs of assured quality that will satisfy the healthcare needs of most of the patients. At national level, this corresponds to the Essential Medicines and Health Supplies List and at facility level this corresponds to the Institutional Medicine (and Supplies) List
- A formulary manual containing summary information on medicines. At national level, this corresponds to the Practical Guideline for Dispensing for lower and higher-level health centers, containing information on the medicines in the Essential Medicines and Health Supplies List of Uganda, and to the National formulary, containing information on all the medicines available in the country.

- Standard treatment guidelines containing essential information on how to manage common diseases choosing the most appropriate therapies and selecting the most cost-effective good-quality medicines leads to better quality of care and more efficient, equitable use of resources (Uganda Clinical Guidelines).

A facility formulary (IML) should be developed, and maintained based on recommended treatments from standard treatment guidelines, using explicit medicine selection criteria that have been agreed upon previously by all departments.

Standard treatment guidelines can be adopted or adapted from elsewhere, which is less work, or developed from scratch, which involves a great deal of work but may result in more acceptability and use due to a sense of ownership. A hospital may choose to use the national guidelines as a base but develop facility-based guidance for selected conditions. Critical to future use by health workers is their involvement in the development and updating process, the quality of the content, a user-friendly format, adequate distribution and follow-up supervision. More details about the principles and development of standard treatment guidelines and essential medicine lists are presented in Chapter 7.

8.4 Benefits of appropriate selection

It is difficult to achieve efficiency in the hospital pharmaceutical system if there are too many medicines. All aspects of medicine management, including procurement, storage, distribution and use, are easier if fewer items must be dealt with.

Appropriate selection of medicines can achieve the following results:

- Cost containment and enhanced equity: procuring fewer appropriately selected items in larger quantities may improve availability at lower costs and stock management, thereby improving access to medicines and so benefiting those who are in most need.
- Improved quality of care: patients will be treated with fewer but more cost-effective medicines for which information can be better provided and prescribers better trained. Prescribers gain more experience with fewer medicines and recognize drug interactions and adverse reactions better. The quality of care will be further improved if medicine selection is based on evidence-based treatment guidelines.

8.5 Selection of medicines at facility level

Facilities need to develop their own Institutional Medicine List, using the national Essential Medicine and Health Supplies List as a starting point. The principles for developing an Institutional Medicine List are the same used to develop the national one: medicines that satisfy the priority health care needs of the population served by that hospital, selected with due regard to disease prevalence, scientific evidence of efficacy, safety, comparative cost- effectiveness, and available resources.

In Uganda, most of the "selection" work is done at national level, and an essential medicines list is produced, that also specifies the VEN classification and the minimum level of care where these medicines should be available. In turn, the National Essential Medicine List relies significantly on the WHO Essential Medicine List, which is reviewed every two years by a team of world experts and is therefore considered a reference document. In-depth discussions of the process of selection of medicines can be found in the WHO manual "Drug and Therapeutics Committee, a practical guide" chapter 3.

Facilities should develop their own IML taking into consideration their local situation in terms of:

- Disease patterns and priorities (e.g. some infectious diseases may be more prevalent in some areas but not in others, some hospitals may be specialized in some areas, so they need selected medicines). Morbidity records, ABC and VEN analysis (see Chapter 9) can give inputs to this process.
- Availability of a reliable supplier (in the case of a government facility, inclusion of the item in the National Medical Stores procurement list should be verified).
- Availability of financial resources
- Availability of equipment and expertise to handle the medicines.

8.6 Developing and Implementing an Institutional Medicine List

An institutional medicine list should be drafted by the MTC (or a subcommittee) following the criteria above, discussed in plenary MTC, then submitted to all heads of departments for comments, reviewed, and finally sent to management for approval. It will then be disseminated to all staff and form the basis for the procurement plan and inventory management.

It is very important all hospital staff are informed and involved, to avoid prescribers requesting medicines outside the list and thereby forcing patients to buy them outside the hospital: if this occurs, it may mean there is a problem either with prescribing practices or with the selection of medicines.

Adherence to the IML can be monitored through the procurement department (by checking orders outside the IML) and through periodic surveys (e.g. OPD drug indicator survey, that specifically monitors the percentage of prescribed medicines outside EMHSLU or IML).

Ideally, an institutional medicine list should have the VEN level and the level of care, which at the facility level may be the department that can use the specific product or the cadre that is allowed to prescribe it. For example, a hospital may choose to restrict the prescription of certain injectables to in-patients or restrict the prescription of specific antibiotics to consultants or certain medicines to specialist cadres. An example is provided in table 8.1 below.

Table 8.1 Developing And Implementing An Institutional Medicine List

No	Generic name	Category (EMHSLU)	Strength	Dosage form	VEN	Level of Care
1	Amoxicillin	Anti-bacterial	250 mg	Dispersible tablet	V	OPD/IP - Clinical Officer MCH: nurse/midwife
2	Oxytocin	Oxytocics	10 IU/ml	Injection	V	Obstetrics: midwife Medical Officer

The IML should be reviewed periodically (usually annually, to coincide with the annual procurement planning), considering:

- Requests for addition/deletion
- Review of the EMHSLU (to which the IML should be aligned as much as possible)
- Changes in disease patterns, priority, and availability of resources (e.g. if the medicine budget is increased, or a new specialist clinic is opened, etc.).

A standard procedure should be established for request of addition/deletion of products and if applicable, for requests of medicines not included in the list in case of exceptional or emergency situations. Government facilities already have a list of a selected range of medicines they can procure (NMS procurement list), according to the level of care. Private facilities may have a wider range, but the same principles apply, and they should as much as possible adhere to the national EMHSLU.

8.7 Procedure for adding and deleting products

All applications to add medicines to the list must be made on an official standard application form (see annex 8.1 at the end of the chapter). Individual clinicians (or even pharmacists) making an application must get the endorsement of their head of department. The application should include the following information:

- Effectiveness and safety of the medicine for the proposed indication and why the medicine is superior to those already on the formulary list – including cost-effectiveness, cost-utility, cost-benefit,
- Whether the hospital has the necessary clinical expertise and laboratory services to use the medicine, what role specialists should play to regulate therapy, the criteria and guidelines for its prescription,
- The availability of the product of acceptable quality (product has to be registered by NDA, available from suppliers, etc.)
- The facility should clearly define the VEN classification of the item being added,
- Declaration of interest as to whether the applicant has received any financial support from the supplier, i.e. the manufacturing company or wholesaler.

The request should be sent to the MTC secretary who will arrange for the request to be formally evaluated by the MTC according to the criteria used to establish the IML. The secretary should coordinate the compilation of further information if necessary.

When a new item is added, always remember to consider if it can replace a previous one (which could then be deleted). In case of doubts or failure to reach a consensus, technical support could be requested from the AMU unit of the MOH.

Summary Principles of Formulary List (Institutional Medicine List) Management

- Select medicines according to the needs of patients.
- Select the medicine of choice for the condition identified.
- Avoid duplications, both therapeutic and pharmaceutical (dosage forms).
- Use explicit selection criteria, based on proven efficacy, safety, quality, and cost
- Use evidence-based information whenever possible.
- Be consistent with the national Essential Medicine List and Standard Treatment Guidelines.
- Consider requests for addition of new products only when made by healthcare staff, not by the pharmaceutical industry.
- Require that requests for the addition of new products are justified using documented evidence on efficacy, relative efficacy, safety, and comparative cost-effectiveness and that the person requesting declare any conflict of interest.
- Carry out annual systematic reviews of all therapeutic classes to avoid duplication.

Requests for addition or deletion of items submitted to facility MTCs should also be forwarded to the Pharmacy Department-Appropriate Medicine Use to provide input for national revision and update of Standard Treatment Guidelines and Essential Medicine List.

8.8 Improving Adherence to an Institutional Medicine List

The existence of a well-maintained IML does not mean that prescribers will adhere to it. Even though procurement is limited to the items included in the list, prescribers may still choose to prescribe outside the list. This should be monitored through surveys (e.g. OPD drug indicator surveys) and, if the hospital has a system for authorizing purchase/procurement of items outside IML, the magnitude of the use of products outside IML.

To efficiently maintain an IML, the MTC should:

- inform, educate, and involve prescribers in the development of the IML,
- review and act on all non-formulary medicine use; action may include adding the medicine to the formulary, educating the prescriber about the non-formulary status of the medicines or banning the use of the medicine within the hospital,
- prohibit the use of non-formulary medicine samples left by drug promoters in the hospital,
- establish procedures and approved drug product lists for therapeutic interchange or substitution.

CHAPTER 9

Investigating Medicine Use Problems

9.1 Introduction

This chapter focusses on the first two steps of the cycle (examination and diagnosing medicine use problems.

The first steps in addressing issues with appropriate use of medicine and health technologies are to Identify, Measure and Investigate problems, followed by the development and implementation of Intervention and the Monitoring and Evaluation of the result as summarized in figure 9.1.

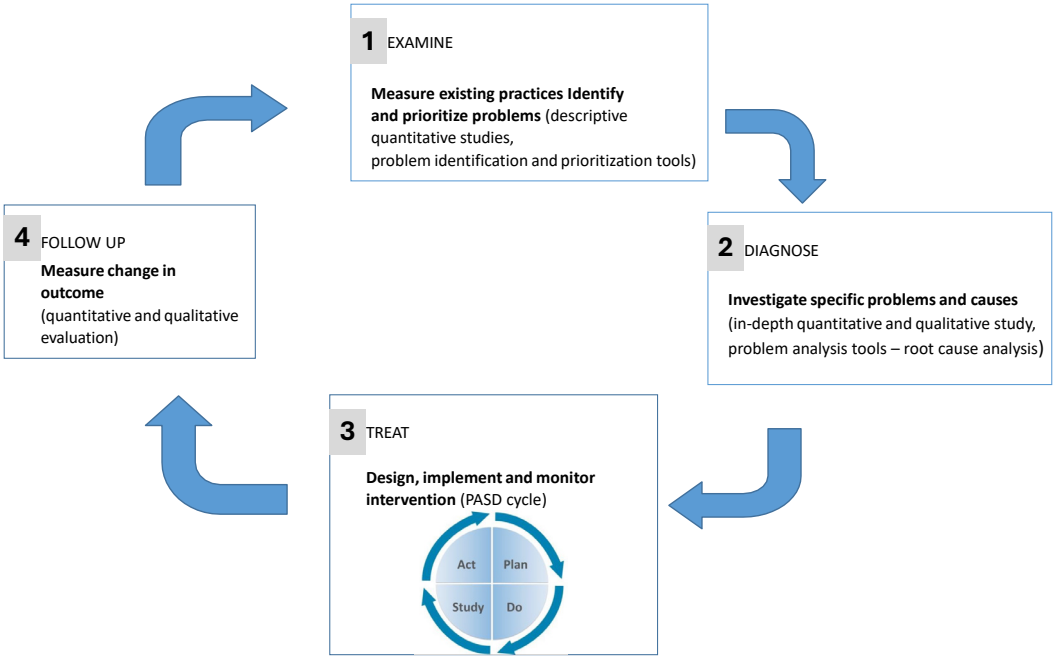

Figure 9.1 Investigating Medicine Use Problems

Medicine use problems may be difficult to detect on a day-to-day basis, except a few obvious ones, and so specific methods have been developed to assist in this process. The same methods are then used to monitor the effect of the interventions implemented to address the problems.

Medicines use investigation methods that can be broadly categorized into two groups as shown in table 9.1 below.

Table 9.1 Medicines Use Investigation Methods

Category	Examples
General investigations to measure existing practices and identify possible problem areas (for step 1)	Aggregate data methods: these use routinely generated data from the medicine management system and give a broad overview of medicine use at the facility or department level. These include ABC analysis, VEN, therapeutic category analysis
	Indicator studies: data is collected on a limited number of standardized indicators from individual prescriptions, which provides an overview of prescribing practices in certain areas. They include INRUD/WHO drug use indicators, antimicrobial use indicators, and drug administration audits
In-depth quantitative and qualitative studies to investigate the magnitude and nature of a specific problem and the possible causes (for step 2)	Prescription audits: analysis of individual patient data to assess the treatment of a specific disease and its compliance with standard guidelines
	Medicine Use Evaluation: detailed analysis of individual patient data to assess if a certain medicine is used according to a standard set of criteria
	Qualitative methods: methods used to investigate the causes of the problems. They can be focus-group discussions, in-depth interviews, questionnaires, observation, and simulation activities.
Other studies	Tracking and accountability studies: these consist of following the flow of a certain commodity and reconciling amounts from ordering to delivery from the warehouse to issues from store to ward/pharmacies, to administration/dispensing to patients. The consumption of a commodity is then justified with the related clinical activity, either by comparing reports data or checking use dose by dose (accountability). Since they cover both supply chain and use aspects, that are addressed in chapter 4.

INRUD-International Network of Rational Use of Drugs

It is up to the MTC to choose the combination of methods most suited to the type of problem to be investigated and to the type of data available, for example:

- When issues have not been clearly identified or are unknown, the general methods can be first applied to identify the nature and magnitude of problems.
- For an "obvious" problem, or if a certain disease or medicine is a national concern, the MTC can proceed directly to in-depth quantitative and qualitative methods

9.1.1 Challenges in data collection

Most of the methods described in these chapters require data collection activities from facility manuals or electronic documents: stock cards, invoices, patients' registers, dispensing logs, patients' files, etc.

In many cases, data will be incomplete, inaccurate, and sometimes even missing. Nevertheless, it will still be possible to collect some meaningful information, even with some mistakes, as the real examples in this chapter will show, and often documentation improvement is one of the quality improvement interventions that will emerge as necessary.

9.2 General Investigations Aggregate Data Methods

These methods use data routinely collected in the medicines management system to generate information on medicines use. They are called "aggregate" because singular data are added up and summarized, to generate meaningful information. For example, all quantities of ceftriaxone dispensed in a certain period are summed up to give the total consumption of ceftriaxone.

They are relatively easy and quick to obtain if the records on procurements and dispensing are accurate. Possible sources of these data are:

- Procurement records
- Warehouse records
- Store stock book/cards
- Computerized stock management systems e.g. Rx solution
- Pharmacy dispensing records.

Based on the level of disaggregation of data, we can obtain information on consumption at the facility level or at the department level. Generally aggregate analysis is done on medicines, but it should also be done on laboratory items and health supplies and technologies, together or separately, since health supplies often take a big proportion of the EMHS budget.

These methods can provide answers to the following questions:

- On which items is the most money spent?
- Which are the most expensive items?
- What are the most expensive therapeutic categories?
- What is the percentage of the budget spent on certain items? (e.g. antibiotics)
- Are we buying/spending significant money on non-essential items?
- Are we buying expensive items when there are equivalent ones that are less expensive?
- Does item consumption match the expected consumption according to morbidity records?

9.2.1 ABC analysis

ABC analysis is the breakdown of the consumption of medicines and supplies and their cost for a certain period (commonly one year), to determine which items, account for the greatest proportion of the budget. It is based on the "Pareto principle", (also known as the 80/20 rule, or law of the vital few) that describes how cause and effect, input and outputs, and generally everything in life is unevenly distributed: 80% of wealth is in the hands of 20% of the population, 20% of customers are driving 80% of the sales, 80% of your daily work is done in 20% of your time, etc.

In this case, 70-80% of the budget is spent on a limited number of items (10-20% of all the medicines on the facility formulary), either because they are very expensive or because they are consumed in very high quantities, or both. Those are the items an MTC may want to concentrate on initially to identify possible problems, because of the possible clinical and economic impact.

It also allows the MTC to identify possible inappropriate use such as:

- High consumption of items not reflecting the priority needs of the population or not consistent with standard guidelines
- High consumption/expenditures on items when more cost-effective alternatives exist.

Interpretation of ABC results requires knowledge of the local situation and disease burden, and it is only the MTC that has the necessary mix of expertise and skills to be able to raise, and answer, the questions an ABC analysis may highlight.

This method is called ABC analysis because it classifies medicines and supplies into 3 categories, as shown in table 9.2 below:

Table 9.2 Guidence for ABC analysis

Category	A items	B items	C items
Percentage of budget	70-80%	15-20%	5-10%
Percentage of medicines used	10-20%	10-20%	60-80%
Description	Medicines classified A: a high percentage of funds are spent on a few large-volume and/ or few high-cost items. In this category, one can easily identify expensive medicines that are used irrationally or excessive consumptions, so there is a great potential for saving and quality improvement.	Medicines in the B category are bought in moderate numbers and/or have a moderate cost so they take up a relatively small part of the budget	Medicines in this category make up most of the inventory; however, a low percentage of the budget is allocated to buying them.

Medicines in class A are simply the medicines accounting for a big percentage of the expenditures, so they represent the first target for further investigation considering the potential for impact and savings. The ABC analysis does not classify items by "importance" but only by expenditure: life-saving medicines may as well be in class B or class C. An ABC analysis is simply a way of prioritizing further investigations based on the possible consequences in terms of numbers and money, since class A medicines are the most expensive/consumed.

ABC analysis can be done manually from records (stock cards, stock books, and invoices) or obtained from an electronic store management system.

Practical instructions for (manually) performing an ABC Analysis

Step 1: List all items purchased or consumed, depending on your source of data, and enter the unit cost, specifying VEN classification. The units will depend on how your records are: you can enter the tins (if you are using store records) or single tablets/vials (if using dispensing data). Specify the period (e.g., over a year, 6 months etc.).

CAUTION!

Be careful to enter the appropriate unit cost according to the unit you are using, i.e., if you are entering a tin of 1000 tablets, enter the price of the tin, not the single tablet. This is a common mistake that leads to wrong results

Step 2: Enter quantities for each item consumed or purchased, in the period you are analyzing.

Step 3: Calculate the monetary value of consumption for each item by multiplying the unit costs by the number of units consumed or purchased for each item.

Table 9.3 Generating the monetary value of each item

No	Medicine	VEN	Unit cost	Quantity consumed (in a specified period)	Total cost
1	Amoxicillin 250mg 1000 tab	V	5,000	17	5,000 * 17 = 85,000
2	Paracetamol 500 mg 1000 tab	E	4,000	25	4,000 * 25 = 100,000
3	Nifedipine R 20 mg 100 tab	V	7,000	5	7,000 * 5 = 35,000
4	Insulin Mixtard vial 1000/ ml SC	V	2500	12	2500 * 12 = 30,000

Step 4: Sum up all the total values of each item to get your total expenditure.

Step 5: Calculate the percentage of total value represented by each item by dividing each total value per item by the total expenditure, then multiply by 100.

Table 9.4 Generating percentage contribution of each item to the total value

No	Medicine	VEN	Unit cost	Quantity consumed	Total cost	% of total cost
1	Amoxicillin 250mg 1000 tab	V	5,000	17	85,000	(85,000/ 250,000) *100 = 34%
2	Paracetamol 500 mg 1000 tab	E	4,000	25	100,000	(100,000/250,000) *100 = 40%
3	Nifedipine R 20 mg 100 tab	V	7,000	5	35,000	(35,000/250,000) *100 = 14%
4	Insulin Mixtard vial 1000/ ml SC	V	2500	12	30,000	(30,000/250,000) *100 = 12%
	TOTAL				250,000	

Step 6: Sort the list in descending order by total value for each item (from the items you have spent more money on to the items you have spent less money on).

Step 7: Calculate the cumulative percentage of total value for each item: beginning with the second item, add its percentage to the one of the previous items.

5.5 Example of ABC analysis of medicines

Table 9.5 Generating the cumulative percentage of the total value

No	Medicine	VEN	Unit cost	Quantity consumed	Total cost	% of total cost	Cumulative % of costs
1	Paracetamol 500 mg 1000 tab	E	4,000	25	100,000	40%	40%
2	Amoxicillin 250mg 1000	V	5,000	17	85,000	34%	34% + 40% =74%
3	Nifedipine R 20mg 100 tab	V	7,000	5	35,000	14%	14% + 74% = 88%
4	Insulin Mixtard vial 1000/ml SC	V	2500	12	30,000	12%	12% + 88% = 100%
	TOTAL				218,500	100%	

Step 8: Using the cumulative percentage, categorize your items into:

A: those accounting for 70-80% of the total budget

B: those accounting for the next 15-20% of the budget

C: those accounting for the remaining 5-10% of the budget

Table 9.6 Categorization of items based on cumulative percentage

No	Medicine	Unit cost	Quantity consumed	Total cost	% of total cost	Cumulative % of costs
A	Paracetamol 500 mg 1000 tab	4,000	25	100,000	40%	40%
	Amoxicillin 250mg 1000	5,000	17	85,000	34%	34% + 40% =74%
B	Nifedipine R 20mg 100 tab	7,000	5	35,000	14%	14% + 74% = 88%
C	Insulin Mixtard vial 1000/ ml SC	2500	12	30,000	12%	12% + 88% = 100%
	TOTAL			218,500	100%	

Analysis and interpretation of ABC results

Your ABC analysis will be a list of items, the quantities, and the total amount spent over the period chosen, ordered by decreasing amount. We are mainly interested in 'A' items: scrutinize your A items critically to identify possible problem areas. Consider the following questions:

1. What are we spending our money on?
2. Do we spend significant money on N (necessary/non-essential) items? Or on items with cheaper alternatives?
3. Could some items be over-consumed?
4. Are consumptions matching the morbidity and activity patterns of the facility?

The ABC analysis will not give you answers, but it is a pointer to indicate where to investigate further and identify the areas that have the potential for more cost-saving and impact.

Sources of data

Ideally, the ABC analysis is conducted using cost and consumption data, which are the quantities issued from the central facility store to the user departments/wards. There are different ways to get this data:

- If you have a functional computerized store management system and the data has been filled correctly for a sufficient period, the program should be able to give the ABC report automatically – provided that the report settings are correct.
- If your data sources are manual, consumption data for a certain period can be obtained from the stock book, or stock cards, and entered in an EXCEL FILE (with headings as in the tables above). The unit price will be extracted from invoices/order forms and calculations done as described above. If prices have changed during the period under analysis, since it is very difficult manually to calculate weighted averages, you may choose to consider the most recent price.

An ABC analysis is usually done on data on quantities issued from the store (which should reflect what is consumed in the facility), but can also be done on:

- Items received from warehouse: you can group in a single file all the invoices, order by item, merge the quantities and amount spent for each item, and proceed with the

ABC analysis. National Medical Stores (NMS) provides an annual summary of quantities ordered/ received for the previous year so once prices are added it is possible to perform the analysis. This analysis will approximate your ABC based on consumptions if you do not have large stocks of unused items lying around in the stores.

- Items ordered: you can do an ABC analysis using your annual procurement plan. This will help you to analyze projected consumptions and verify your choices and adjust if necessary.

ABC Analysis on other items:

While ABC analysis is traditionally done on medicines, it should also be applied to other medical supplies, especially considering that often more than half of the budget for pharmaceuticals is spent on supplies (e.g. gloves, cannulas, syringes etc.) and many clinical activities cannot be performed without them.

Limitations of ABC Analysis

The ABC analysis has some limitations:

1. ABC analysis results are as accurate and reliable as the data they are based upon. Sometimes strange results may help identify mistakes in records, usually related to pack size and price used in stock cards (see examples below).
2. An ABC analysis is an extremely time-consuming and cumbersome exercise, if done manually. A well-used computerized store management system should be able to produce a report with a simple click! On the other side, an ABC analysis does not need to be repeated often: a 6-month or yearly exercise will give adequate information.
3. Periods of out-of-stock for a certain item will affect consumption, causing an underestimation. If an item has been out of stock for a long time, its consumption will obviously be low. Periodic ABC analysis should be able to compensate for this limitation. An alternative is the use of a procurement plan to do the ABC analysis.
4. Donated items may end up being excluded if a value is not attached, and since they do not impact the medicine budget they are often not considered. There are different solutions to this: give a market value and include it in the analysis (but the total would then be different from the total value spent) or perform a separate analysis. It is a good exercise to calculate the value of donated items separately: if it is a significant amount, it could be worth investigating their use and making sure they are used optimally. Examples in the Ugandan setting are antimalarials, HIV, TB, and reproductive health commodities, that are usually paid for by donors and do not infringe on the allocated Vote 116 funds per facility.

Example 1: ABC Analysis of Hospital A

This is a real ABC analysis carried out in a Ugandan Hospital. This analysis is only on medicines, and only class A is shown. The total number of medicines in the ABC was 245. 23 items (10%) are responsible for 80% of the total medicine expenditure, and the first 3 items alone represent almost a third of the medicine budget! (Table 9.7)

Table 9.7: ABC Analysis of Hospital A

No	Description	QTY	VEN	Total cost	% of total cost	Cumulative %
1	Sodium Chloride/Normal Saline 0.9% Infusion 24 bags	1,067	V	30,422,304	12%	12%
2	Ceftriaxone Sodium 1g Powder for Inj. 1 Vial	25,800	V	27,923,340	11%	23%
3	Metronidazole 500mg/100ml Infusion 1 bottle	17,300	V	15,606,676	6%	29%
4	Amoxicillin 250mg Capsule 1000 tin	325	V	14,040,000	5%	34%
5	Bupivacaine HCl 0.5% In Dextrose 8.0% Inj Solution, 4ml Ampoule, Spinal 20 amp	96	V	12,317,184	5%	39%
6	Sodium (Ringers) Lactate Compound Infusion24 bags	415	E	10,756,800	4%	43%
7	Paracetamol 500mg Tablets tin 1000	787	E	9,774,540	4%	46%
8	Isoflurane 250ml Inhalation	81	V	9,688,505	4%	50%
9	Ferrous Sulphate/Fumarate 150-200 Mg+Folic Acid 0.25 -0.4mg Tab tin 1000	490	V	8,289,056	3%	53%
10	Glucose (Dextrose) 5% Infusion 500ml 24 bags	211	V	7,520,040	3%	56%
11	Co-Packaged Ors and Zinc Tablets	3,288	V	6,329,729	2%	59%
12	Suxamethonium Chloride 100mg/2mL Injection 100 amp	32	V	6,225,777	2%	61%
13	Insulin Mixtard Human 100iu/mL 1 vial	420	V	6,004,030	2%	63%
14	Metronidazole 200mg Tablet tin 1000	464	V	5,754,755	2%	65%
15	Rabies Vaccine + Solvent 0.5mL Inj 1 Dose	220	V	5,747,986	2%	68%
16	Ampicillin 500mg Powder For Reconstitution IV/IM/Infusion 100 vial	139	V	5,679,534	2%	70%
17	Magnesium Sulphate 50% 5ml Inj	840	V	4,855,990	2%	72%
18	Halothane Inhalation 250ml	45	V	4,590,098	2%	73%
19	Lidocaine HCl 2% Injection	1,925	V	4,536,359	2%	75%
20	Midazolam 5mg/mL Injection 3ml Ampoule	58	E	4,196,880	2%	77%
21	Water For Injection 10ml 100 amp	428	V	3,697,920	1%	78%
22	Ephedrine 30mg/mL 1 mL Ampoule 10 amp	75	E	2,912,592	1%	79%
23	Oxytocin 10IU/mL Injection 100 amp	124	V	2,545,296	1%	80%

Several observations can be made from these results: it is very evident that ABC will not give answers but can point to possible problems and to the need to investigate more:

- IV fluids (item 1, 6, 10 and 21) represents 20% of the medicine expenditure. This may call for an investigation on the use of IV fluids, by analyzing the consumption by ward and comparing consumptions and workload of inpatient wards. Further analysis could be done through interviews, review of patient files, and direct observation of work.
- Antibiotics are heavily consumed: they represent 3 of the 5 top items. This may call for further analysis: the total % of expenditure on antibiotics, antibiotic use in OPD (indicator studies and OPD antibiotic use, and a medicine use evaluation of the top antibiotics to assess the appropriateness of use, followed by prescription audits for the most common infections (see following sections and chapter 2)
- Anesthetic drugs represent a significant percentage of the A medicines: does this correspond with the surgical activities performed in this facility? Are there cheaper alternatives? Is their use appropriate? Is there any waste that can be prevented?
- Insulin is among the A drugs: does the consumption correlate with the number of diabetic patients seen?

Table 9.8 Example 2 Abc Analysis Of Hospital

No	Description	VEN	Issued Qty	UNIT PRICE	Total cost	%	Cumulative %
1	Ceftriaxone 1g Vial; 1 Vial [INJ]	V	21,100	1,051	22,170,614	10%	10%
2	Epinephrine (Adrenaline) 1mg/mL Ampoule; 100 Ampoule [INJ]	V	160	88,227	14,116,338	6%	16%
3	Rabies Vaccine + Solvent 0.5mL Vial; 1 Dose [INJ]	V	495	27,093	13,411,154	6%	22%
4	Amoxicillin 250mg Capsule; 1000 Capsule [PO]	V	277	46,301	12,825,288	6%	28%
5	Meropenem 500mg Injection, Sol; 1 Vial [INJ]		724	11,007	7,969,329	3%	31%
6	Erythromycin Stearate 250mg Tablet.1000 Tablet [PO]	N	68	109,501	7,446,063	3%	34%
7	Hydrocortisone Sod Succinate 100mg/2mL Vial; 50 Vial [INJ]	V	109	66,119	7,206,984	3%	37%
8	Paracetamol 500mg Tablet; 1000 Tablet [PO]	E	552	12,420	6,855,840	3%	40%
9	Anti-Snake Bite Sera Polyvalent 10mL Ampoule; 1 Ampoule [INJ]	E	33	197,280	6,510,240	3%	43%
10	Ampicillin 500mg Vial; 100 Vial [INJ]	V	161	38,441	6,189,072	3%	46%
11	Water for Injection 10mL Vial; 100 Vial [INJ]	V	696	8,700	6,055,200	3%	48%
12	Hydrogen Peroxide 6% Solution; 200 mL	E	152	34,957	5,313,415	2%	51%
13	CO-PACK ORS & Zinc Tablets 20mg Tablet; 1 Tablet [PO]	E	3,228	1,574	5,079,904	2%	53%
14	Cefuroxime 500mg Tablet; 100 Tablet [PO]	E	37	123,864	4,582,968	2%	55%
15	Tetracycline 1% Eye Ointment; 3.5g Tube [OPTH]	V	3,765	1,128	4,245,113	2%	57%

16	Ciprofloxacin 500mg Tablet; 100 Tablet[PO]	V	457	9,203	4,205,721	2%	59%
17	Gentamicin 80mg/2mL Vial; 100 Vial[INJ]	V	300	13,842	4,152,672	2%	60%
18	Griseofulvin 500mg Tablet; 100 Tablet [PO]	N	176	22,314	3,927,190	2%	62%
19	Normal Saline 0.9% Infusion; 24 Bag [IV]	V	112	32,659	3,657,830	2%	64%
20	Metronidazole 200mg Tablet; 1000 Tablet [PO]	V	249	14,580	3,630,420	2%	65%
21	Metronidazole 500mg/100mL Vial; 1 Vial [INJ]	V	3,645	951	3,465,083	2%	67%
22	Chlorhexidine Gluconate () 0.2% MouthWash; 1 Bottle [TOP]	N	438	7,775	3,405,450	1%	68%
23	Co-Trimoxazole 480mg Tablet; 1000 Tablet [PO]	V	111	30,628	3,399,664	1%	70%
24	Atropine Sulphate 1mg/mL Ampoule; 1 Ampoule [INJ]	V	252	13,280	3,346,626	1%	71%
25	Alcohol Handscrub Liquid, External; 60mL [TOP]	N	678	3,900	2,644,200	1%	72%
26	Metronidazole 200mg/5mL Suspension. 100 mL [PO]		567	4,088	2,317,896	1%	73%
27	Penicillin, Benzyl 1MU/600mg Vial; 10 Vial [IM]	E	984	2,318	2,280,912	1%	74%
28	Quinine 300mg Tablet; 1000 Tablet [PO]	E	14	160,561	2,247,858	1%	75%
29	Bupivacaine, Dextrose 0.5%/8%(0.5mg/72mg); 4mL Injection. 20 Ampoule [INJ]	V	350	6,420	2,247,000	1%	76%
30	Insulin Mixtard Human 100U/ml 10mL Vial; 1 Vial [SC]	V	130	16,650	2,164,543	1%	77%
31	Glucose (Dextrose) 5% 500mL LVP; 24 Bag [INJ]	V	51	35,640	1,817,640	1%	78%
32	Tramadol 100mg/2mL Injection, Sol; 5 Ampoule [INJ]		347	4,848	1,682,377	1%	79%
33	Fentanyl 50mcg/mL 3mL Injection, Sol.1 Ampoule [INJ]	V	60	24,800	1,488,000	1%	79%
34	Dexamethasone 4mg/mL Ampoule; 100 Ampoule [INJ]	E	17	78,914	1,341,534	1%	80%

In this ABC analysis, the A medicines are 34 (16% of a total of 211 medicines). Ceftriaxone is still at the top, while the second item is adrenaline/epinephrine. Is it possible that a hospital has consumed 16,000 vials of adrenaline in a year? This is most likely a mistake in data entry: the hospital has probably consumed 160 vials (not 160 boxes of 100 vials) but both unit of issue and price were entered wrongly!

Other observations which should prompt further investigations include the following:

- Meropenem appears in EMHSLU as a specialist medicine. Its presence in the A list deserves to be investigated: it is an expensive third line antibiotic to be used in selected situations and probably in facilities with ICU and culture and sensitivity.

- Rabies vaccine is among the top consumed items: its use should be verified. Are animal bites that common?
- Antibiotics represent 4 of the top 6 items and represent at least 38% of the total medicine expenditure. Further investigations on antibiotic use in OPD and IP may be warranted (the results of the Drug Indicator Survey for the same hospital are presented in the next chapter).

It is obvious that only the facility MTC will have the knowledge, the information and the experience to interpret the findings and assess if they are "expected", and therefore acceptable, or whether further investigations are needed.

Table 9.9 Example 3: Abc Analysis Of Hospital C

No	Description	VEN	Issued Qty	UNIT PRICE	Total cost	%	Cumulative %
1	Gloves Examination Latex Medium Non Sterile; 100 gloves	V	6551	12,080	79,133,288	10.2	10.2
2	Gloves Surgeon 71/2 Sterile, 50 gloves	V	2125	30,102	63,965,889	8.2	18.5
3	Ceftriaxone 1g vial, 1 vial	V	45200	1,119	50,581,147	6.4	24.9
4	Normal Saline 0.9% Infusion; 24 bags	V	1638	25,103	41,119,342	5.3	30.2
5	Amoxicillin 250 mg capsule;1000 capsule	V	1065	37,137	39,742,840	5.1	35.2
6	Insulin Mixtard Human 100IU/ml, 10 mL vial; 1 vial	V	3020	12,622	38,117,713	4.8	40.1
7	Gauze W.O.W. Hydrophilic 90 cmX50 m; 1 roll	V	1977	15,919	31,472,554	4.0	44.1
8	Syringe Auto Disable 5 ml; 100 syringe	V	2737	10,412	28,496,914	3.8	47.9
9	Safe delivery (maternity) standard kit; 1	V	2133	11,400	24,316,200	3.1	51.0
10	Plaster Adhesive Zinc Oxide 75 mmX5m; 1 roll	V	4540	3,669	16,791,685	2.1	53.1
11	Metronidazole 200 mg tablet; 1000 tablet	V	1490	9,662	14,395,666	1.8	54.9
12	Suture PGA(1) 90 cm, 3140TH; 12 suture	V	290	46,535	13,495,277	1.8	56.7
13	Wool cotton BP; 1 roll	V	2020	6,977	14,093,893	1.8	58.5
14	Syringe Auto Disable 2 mL; 100 syringe	V	1851	7,167	13,266,186	1.7	60.2
15	Suture PGA (2) 70 cm 3240TH;12 suture	E	335	39,322	13,172,875	1.7	62.0
16	Paracetamol 500 mg tablet; 1000 tablets	E	1349	9,758	13, 164,009	1.7	63.6
17	Metronidazole 500 mg/100 mL vial; 1 vial	V	16900	767	12,963,242	1.7	65.3
18	Sodium (Ringer) Lactate Comp. LVP; 24 bags	V	540	23,335	12,600,963	1.6	66.9
19	Suture PGA (2/0) 75 cm, 3230 TF;12 suture	V	191	58,176	11,111,644	1.5	68.4
20	Glucose (Dextrose) 5% 500 mL; 24 bags	V	407	28,428	11,570,160	1.4	69.8

This ABC has been done on medicine and supplies concurrently: 11 of the first 20 items are supplies, and the top 2 are gloves! The complete ABC shows that two-thirds of the expenditures are on supplies and only a third is on medicines. Analyzing and improving the use of supplies is therefore VERY IMPORTANT to overall cost-savings on the pharmaceuticals budget.

9.2.2 The VEN Analysis

In the context of limited resources, it is essential to prioritize medicines and health supplies (including laboratory supplies): this is reflected by the Vital, Essential, Necessary (VEN) classification. Items are classified into 3 categories, according to the health impact:

- V: Vital items are used to diagnose and treat life-threatening conditions, or are considered medicine of choice or" first line" items in their therapeutic category. Their unavailability would cause serious harm and side effects. They must ALWAYS be available.
- E: Essential items are important, they are used to treat common illnesses, maybe less severe but significant, or which are second-line items in their therapeutic categories.
- N: Necessary (or sometimes called non-essential) items are used for minor or self-limiting illnesses, or diseases with less impact on the population, or items with a high cost for marginal therapeutic benefit, or a more cost-effective or cheaper medication is already included in vital/essential categories.

The VEN classification is intended to guide health facilities to prioritize items during procurement and verify that purchases are done according to correct priority criteria: vital items take priority, because their unavailability can lead to death of a patient or irreparable injury. Essential items have second priority; if these items are not available, the patient could suffer pain or great discomfort. Necessary items are needed and therefore on the order form; however, they are third priority for procurement.

The VEN analysis can be done on its own or combined with the ABC analysis and can be done on the procurement plan or on expenditure data. The VEN analysis answers a big question: are we buying what is most important?

A VEN analysis will allow the MTC to:

- Assess the formulary/institutional list and the procurement plan: priority in purchase should be given to V and E items.
- Review if resources are used for vital items or non-essential, indicating how the hospital prioritizes its resources.

Practical instructions for performing a VEN analysis on the ABC Analysis

Step 1: Classify each of the items on your institutional medicine list into vital, essential or non-essential, as described above.

Note:

All the items of the EMHSLU 2023 already have a VEN classification, so normally the MTC can just adopt it.

In some situations, especially in high-level facilities, the MTC may want to review the VEN classification: for example, some items that are not essential at the HC3 level may be vital at the regional referral level because of the availability of different or specialized skills, diagnostic possibilities, or because that specific region has high morbidity of a particular disease.

Step 2: Analyze your ABC analysis by VEN category and calculate the percentage of expenditures on Vital, Essential, and Non-essential medicines. There are no specific guidelines on how many N medicines can be bought, but in situations of limited resources, the funds spent on N medicines should be minimized. This can be done by making sure your procurement plan contains mainly V and E medicines.

Step 3: Check the A medicines from your ABC analysis. Is there any N medicine among the A items? If yes, either the VEN classification is wrong or there is inappropriate use. This is a pointer to investigate the issue more deeply.

Example of VEN analysis

Consider the ABC analysis of example 1 Hospital A above (see full ABC in Annex 9.1). The total number of items is 245. Note that the items that were ordered but not delivered/received appear with zero total cost in the ABC. Donated items, even though are expensive, as well often appear with zero total costs at the bottom of the list because there is no attached value deducted from the hospital budget allocation and often even from the delivery invoice. However, this does not mean they are not significant, only that the ABC (and VEN) analysis cannot say anything about them.

If we want to do a VEN analysis on the ABC, we group the medicines by VEN category and sum up the percentages, and we end up with the results in Table 9.9:

Table 9.10 Guidence on VEN categorization based on ABC analysis

Category	% of budget
V	79%
E	18%
N	3%

Also, it can be observed that there is no N medicine in the group A medicines, and of the 14 N medicines bought, only 2 are in the B category and the rest in the C category, so having a very limited impact on the total expenditure. The VEN analysis of this budget is very good!

9.2.3 Therapeutic Category Analysis

The therapeutic category analysis evaluates medicines by therapeutic group (i.e., antibiotics, anti-hypertensives, anesthetics, etc.). It answers the question: what type of medicines are we consuming?

Such analysis will allow the MTC to:

- Identify duplications or inappropriate use within a certain category
- Identify therapeutic categories accounting for the highest consumption and expenditures
- Cross-check consumptions with morbidity patterns.

Practical instructions for performing a therapeutic category analysis

- Steps 1 to 5: As for the ABC analysis above
- Step 6: Assign a therapeutic category to each drug following the EMHSLU (which mirrors the classification used in the WHO Essential Medicine List) or the Anatomical Therapeutic

Chemical classification system (an international classification of medicines). Some medicines are quoted in more than one category, so you may choose the one that seems relevant for your setting, or in certain cases, you may want to group/simplify categories (e.g. anti-epileptics and anti-migraines could be grouped with medicines for mental and neurological disorders), or modify some classes e.g. sulfadoxine-pyrimethamine may go with other obstetrics medicines as oxytocin and magnesium sulfate since it is mainly used in obstetric care.

- Step 7: Sort the medicines so that items from the same therapeutic category are grouped together.
- Step 8: Sum the percentages in each category to obtain the % of the total budget spent on each category.
- Step 9: Look at each category and consider if the % of the budget spent on it reflects the morbidity pattern. Also look within each category and identify unnecessary duplications (having medicines of the same chemical nature e.g. lisinopril, enalapril and captopril, or

For example, to compare different ACE inhibitors, compare the cost of an average daily dose and not single tablets! e.g. captopril 25 mg BD or TDS should be compared with enalapril 20 mg once a day

The DDD (defined daily dose analysis) is another methodology which allows to analyze the consumption on medicines based on a standardized daily dose. It is mostly used for monitoring and comparison purposes, especially of antibiotics, and it will be explained in Chapter 2.

Example of ATC analysis on the ABC of Hospital A

A detailed ATC analysis (using EMHSLU 2016 categories) is presented in Annex 5.1 at the end of this chapter. The summary table 9.11 is presented below.

Table 9.11 Atc Analysis On The Abc Of Hospital A

Class/category	% of budget	Class/category	% of budget
Anesthetics	18%	Mental	2%
Anti-allergy medicines	0%	Muscle relaxant	0%
Anti-infectives	31%	Obstetrical	3%
Blood medicines	4%	Ophthalmological	2%
Cardiovascular	1%	Pain killers	5%
Dermatological	0%	Poison	0%
Disinfectant	0%	Respiratory	1%
Endocrinology	6%	IV fluids/solutions	21%
Gastrointestinal	3%	Vitamins/minerals	0%
Immunological	2%	TOTAL	100%

Anesthetics represents 18% of the total expenditures, IV fluids 21%, anti-infectives 31%. This is consistent with the ABC analysis, to which this is complementary. Since the essential medicine list is already very controlled and limits duplications, most likely there is not much additional information in this case, but it may give more insight in hospitals with a wider institutional list (e.g. in private facilities).

9.3 General Investigations: Indicator studies

Indicator studies involve the collection of relatively simple standardized indicators from samples of prescriptions and are intended to measure selected aspects of the prescribing and dispensing practices.

9.3.1 INRUD/WHO drug use indicators

These are a set of indicators for the outpatient setting of health care facilities developed in the 1980s by WHO and the International Network for Rational Drug Use (INRUD). They have been extensively field-tested and found to be relevant, easily generated and measured, valid, consistent, reliable, representative, sensitive to change, understandable and action oriented. They answer the questions: how are we using medicines in primary care practice? Are there any potential problems to investigate? They allow the MTC to:

- Assess and describe current practices (in one facility or in groups of facilities)
- Compare facilities or individual prescribers
- Monitor trends over time
- Assess the impact of interventions.

The INRUD/WHO indicators measure performance in three areas of appropriate medicine use: prescribing practices by health practitioners, key elements of patients' care and facility specific factors, as shown in the table 9.12 below.

Table 9:12 Inrud/Who Drug Use Indicators

Category	Example
Prescribing indicators	• Average number of medicines per encounter • % of medicines prescribed by generic name • % of encounters with an antibiotic prescribed • % of encounters with an injection prescribed • % of medicines prescribed which are from the EML or formulary list
Patient care indicators	• Average consultation time • Average dispensing times • % of medicines dispensed • % of medicines that are adequately labeled • % of patients who know how to take their medicines
Facility indicators	• Availability of essential medicine list • Availability of key set of indicator medicines • Availability of standard treatment guideline (STG)

Additional drug use indicators

Additional indicators have been developed but they are more difficult to define, measure, and collect, and are therefore not standardized

Table 9.13 Additional drug use indicators

Category of indicator	Example
Complementary indicators	% of patients treated without medicines
	Average medicine costs per encounter
	% of medicine cost spent on antibiotics
	% of medicine cost spent on injections
	% of prescriptions by STG
	% of patients satisfied with care provided
	% of facilities with access to impartial information

The objective of the indicator study will determine the sample size, the time frame, and the modality of data collection: data can be collected retrospectively (based on records of previous encounters) or prospectively (based on observation of cases on the day of the survey). Patient care indicators and facility indicators can be collected only prospectively, while prescribing indicators are more often collected retrospectively. This chapter focuses on the prescribing indicators only.

Practical instructions for collecting prescribing drug use indicators

- **Step 1:** Define the type of encounters under investigation. Normally these indicators are applied to general OPD visits. Antenatal visits, immunization, well-baby, specialist and routine clinics (diabetes clinic, HIV clinic, and epilepsy clinic) are excluded because their prescription practices may be very different due to their specialized nature. OPD visits resulting in admissions and re-attendances are also excluded.
- **Step 2:** Define the purpose and the sample size. The MTC is mainly interested in analyzing the prescription practices of its facility so a sample of 100 prescriptions can give a good overview.
- **Step 3:** Clarify the definitions of indicators:
  - Are combinations counted as one medicine? (standard combinations like antimalarials e.g. artemether-lumefantrine, antibiotics e.g. cotrimoxazole are usually counted as one)
  - Which medicines should be considered as antibiotics? (e.g. is metronidazole counted)?
  - Are tetanus toxoid and anti-rabies counted as medicines? As injections?
- **Step 4:** Define the time frame: for an initial assessment, longer time frames (up to one year) are recommended but not very practical. For practical purposes, 3 months can do. For monitoring purposes and for assessing the impact of intervention, smaller numbers and shorter time frames can be used.
- From HMIS 105, get the number of OPD (new) visits for the 3 months you have decided to investigate: e.g. 3456 new OPD visits in the period January to March 2024.
- Divide the total number by the number of prescriptions you want to sample and round the result: e.g. 3456/100 = 34.56 rounded down to 34.

- Choose a random number from 1 to 9 (the common method is to take out a banknote and take the last figure of the serial number) and sample one patient every 35 (in this example) starting from the patient number indicated by the random number. Skip re-attendances and admissions while counting.
- Decide what to do in case the prescription does not fit the definition (e.g. if it is an admission case), i.e., choose the previous prescription or the next.
- **Step 5:** Collect and analyze the data using the attached form and formulas. There are no pre-set absolute thresholds or standards for the value of the indicators, since they depend on several factors. The MTC should be able to interpret the results and decide if they point to a possible problem or not. For example, an antibiotic prescription rate above 70-80% may be excessive in a normal situation but may be normal in a refugee camp in which most patients are severely malnourished children! Comparing with similar facilities may help to interpret the results.

QUICK TIP:

Most of the WHO/INRUD indicators are collected in the SPARS supervision, a structured supervision and performance assessment strategy on medicine management implemented by the Pharmacy department through Medicine Management Supervisors.

For initial information, check the SPARS performance data of your facility!

Since you may want to do further analysis on this data set, the most practical approach is to copy the complete prescription of your sampled patients and complete the indicator table thereafter. This will allow you to keep the raw data and re-analyze or conduct further analysis later.

Suggested blueprints with examples are presented in the next pages. Table 9.14 below shows an example of data for a drug use survey.

Table 9.14 Table of raw data collection for drug use indicators survey (prescribing indicators). Examples from actual data

OPD No.	Initials of patient	Age	Sex	Diagnosis (write all diagnoses if more than one is on the prescription)	Treatment (copy the original prescription as it is written, including dose duration)
46	SF	47	F	UTI (Urinary Tract Infection)	Ciprofloxacin 500 mg BD 5 days Metronidazole 400 mg TDS 5 days Paracetamol 500 mg TDS days
78	NR	3	M	RTI (respiratory tract infection)	Amoxicillin 125 mg TDS 5/7 Paracetamol 250 mg TDS 3/7
111	NM	20	F	Gastritis, PID	Ciprofloxacin 500 mg BD 3/7 Metronidazole 400 mg TDS 1/52 Amoxicillin 500 mg TDS 5/7
145	DS	61	F	Rheumatism	145 DS 61 F Rheumatism Prednisolone 5 mg TDS 5/7 Calcium lactate 1 tab OD 2/52 Hifenac 50 mg TDS 5/7

Table 9.15 Drug Prescribing Indicator Survey Assessment

Patient Number	No. of medicines prescribed	No. of medicines prescribed by generic name	No. of antibiotics prescribed	No. of injections prescribed	Number of medicines not in the UCG/EMHSL	Diagnosis recorded Y/N
1	3	3	1	0	3	Y
2	2	2	1	0	2	Y
3	3	3	2	0	3	Y
4	3	2	0	0	2	Y
5						
6						
Total no. medicines	A	B	C	D	E	
Total no. patients	F		G	H		I
Indicator	AVERAGE NUMBER OF MEDICINES PER PATIENT (Total meds /#patients) =A/F	% OF MEDICINES PRESCRIBED BY GENERIC NAME =(B/A) *100	% PATIENTS RECEIVING 1 OR MORE ANTIBIOTICS =(G/F) *100	% PATIENTS RECEIVING 1 OR MORE INJECTIONS =(H/F) *100	% OF MEDICINES NOT IN THE UCG=(E/A) *100	% DIAGNOSIS RECORDING =(I/F) *100
			% of medicines being antibiotics =(C/A) *100	% of medicines being injections =(D/A) *100		

Example 1: Drug indicator survey results in Uganda

Table 9.16 Below Presents The Results Of A Survey Of Prescribing Indicators Performed By The Pilot Mtcs Of Three Hospitals In Uganda.

INDICATORS	Hospital 1	Hospital 2	Hospital 3	WHO Standard
Sample size (number of patients)	200 in 2 months	200 over 3months	110 over 3months	At least 100 in one facility
Average No. of medicines/ patient	3	2.8	3.5	2.5-3
% of medicines prescribed by generic name	67%	98%	76%	100%
% patients receiving 1 or more antibiotics	75.5%	86%	79%	≤ 45% (Uganda)
% patients receiving 1 or more injections	6%	16%	12%	≤ 15%
% of medicines not in the UCG/EMHSL	7%	0%	12%	0%

Comments

1. Average Number of medicines per patient
   - Hospital 3 has a higher number of medicines per patient, above the standard (WHO standard is 2.5-3).
2. % of medicines prescribed by generic name:
   - Excellent in hospital 2, but unsatisfactory in hospital 1 and 3. Ideally, medicines should always be prescribed by generic name.
   - % patients receiving Antibiotics: over-prescription in all the 3 hospitals. An acceptable range of 30-50% (45% in SPARS) so this was recognized as the most problematic indicator for all the three hospitals surveyed.
3. Injections: moderately high rate in hospital 3. The recommended WHO standard is below 15%. Currently, there is little justification for using injectable medicines at the OPD level so injection use should be scrutinized.
4. % of medicines not in the UCG/EMHSLU: optimal in hospital 2 (0%) but significant in hospital 3. Since national procurement is based on UCG/EMHSLU, if patients are prescribed a medicine outside the approved lists, they need to buy it by themselves, which may not be affordable to the patient.

The indicator survey does not provide answers, but it points to possible problems (e.g., high use of antibiotics, high use of injections, high number of prescriptions outside the essential medicines list) that may need to be further investigated.

Patient care indicators

These indicators are very useful to assess the quality of dispensing, which is also an important step in medicine use and subject to mistakes: wrong dose and quantities, wrong label, incomplete or not understood instructions. Time dedicated to patients for consultation and dispensing is also assessed because of its effect on the quality of care.

Table 9.14 describes the indicator and how to collect them. They need to be collected prospectively, in a number not lower than 30 (up to 100). These indicators are routinely collected under SPARS, and staff who have undergone the training for Medicine Management Supervisors will have good knowledge on the methods.

Table 9:17 Guidence On Collecting Patient Care Data

Indicator	Description
Average consultation time	Time at least 30 individual encounters (from the moment the patient enters the clinician's room to the moment he/she leaves it) and calculate the average
Average dispensing time	Time at least 30 individual dispensing encounters (the actual time the patient spends with the staff, from arriving to leaving at the dispensing counter) and calculate average
Percentage of medicines dispensed	Compare the number of medicines dispensed by the number of medicines prescribed. Since the current dispensing log only records of dispensed medicines, this information can be extracted from patients' forms only. Or, retrospectively, by comparing data from the OPD register and dispensing log.
Percentage of medicines adequately labeled	Percentage of medicine packages adequately labeled (with patient name, medicine name, dose, and time)
Patients' knowledge of correct dosage	% patients who can report the correct dosage schedule for all their medicines

9.3.2 Antimicrobial Use Indicators

This is a more recent and more complex set of indicators recommended by the International Conference for Improving Use of Medicines. They focus on antibiotic use at the hospital level, for several reasons:

- Antibiotics constitute a significant percentage of the medicines used in hospitals (and therefore an important health expenditure)
- They are often lifesaving and so essential for the provision of care
- They are affected by many problems of inappropriate use
- They are responsible for a significant percentage of adverse reactions and,
- Finally, the overuse and misuse of antibiotics is one of the main drivers of antimicrobial resistance, which is a major public health threat of this century.

The indications and use of antimicrobial use indicators are like the ones described above and include:

- Describe antimicrobial prescribing practices in the hospital
- Compare performance among hospitals or prescribers
- Monitor performance and orient supervision
- Assess changes resulting from interventions

As above, they are not able to provide comprehensive answers about a specific prescription problem but can detect problem areas and orient further investigations. More details about these indicators, and about the newly introduced Point Prevalence Survey, will be provided in the Antimicrobial Stewardship Manual.

9.3.3 Drug Administration Audits

Appropriate medicine use refers not only to appropriate prescription but also to appropriate dispensing and administration, so investigations in these latter areas should be conducted to detect eventual inappropriate practices that can potentially cause adverse effects including therapeutic failure. From the point of view of safety and pharmacovigilance, these are called medication errors (see Chapter 3).

Investigations in administration and dispensing can be conducted through:

- Chart review (paper or electronic)
- Direct observation

In both cases, standards of practice must be established (e.g. based on the national guidelines) and then crosschecked either with the written records or the activities being observed. The details of the investigations and tools depend on the setting and on the focus of the investigations, which can be "general", to assess administration practices in a certain ward, or more targeted at a specific issue following reports (or suspicions) of problems in a certain area.

For example, the MTC may want to investigate times or frequency of administration of certain antibiotics. For instance, Kiguba et al investigated antibiotic prescription and administration in the national referral hospital, which showed that only 62% of ceftriaxone, 35% of ciprofloxacin, and 27% of metronidazole prescribed doses were administered (Kiguba R et al, 2016).

The Supervision, Performance Assessment, and Recognition Strategy (SPARS) by the MOH Pharmacy department regularly assesses dispensing practices of health facilities in the OPD, based on the

INRUD/WHO drug use indicators. These include:

- Dispensing time
- Availability of packaging (dispensing envelopes)
- Availability of dispensing material (spatula or spoon, counting tray, gloves)
- Labelling
- Patient knowledge
- Correct filling of dispensing log (OPD/IP number, medicine name, quantity dispensed, dispenser's initials).

In a wider investigation, the following components may also be assessed:

- Integrity of medicine containers, covers, or packs
- Labels prints
- Dosage instructions: directions for using medicines clearly stated
- Prescription verification measures when needed
- Appropriate cautions and warnings
- Use of universal precautions of infection control
- Risk assessments (e.g. drug allergies)
- Accessibility of medicines to other health workers
- Administration instructions and guidelines
- Competency of administering personnel
- Dispensing/administration tools and equipment – availability and use
- Measures to ensure patients receive the correct medicines (e.g. double checks of injectable medicines)
- Medication administration chart (updated or comprehensiveness)
- Doses checked for appropriateness (e.g. weight registered on administration chart)
- Checks for possible interactions
- Assessment for drug allergies (e.g. allergy section on medicine administration chart)
- Record of administration, refusal, or postponement of treatment.

Examples of tools to aid in dispensing and administration audits, adapted from international literature, are presented in Annex 9.2

9.4 In-Depth Investigations of Medicine Use Problems

The following methods allow us to investigate the nature and reasons for specific problems, which may have been identified by different mechanisms e.g.:

- Through the general studies described above.
- Already known to the MTC because of prescribers' experience, data from other facilities or routinely collected data (e.g. malaria, HIV, and TB data).

- Adverse drug reaction reports: which may indicate the need for a review of the use of the medicine, (e.g., multiple reports on a drug toxicity may prompt a review of the regimen, doses, and indications).
- Persistent stock-outs: which may indicate the need to verify the appropriateness of use. For example, persistent stockouts of a second-line antidiabetic may prompt a review of the treatment protocols for diabetes.
- Poor clinical outcomes: which may indicate the need to review treatment protocols, (e.g., a high % of surgical site infection may prompt a review of surgical prophylaxis protocols).

9.4.1 Medicine Use Evaluation and Prescription Audits

A medicine use evaluation (MUE) involves assessing the use of a certain medication according to an established set of criteria. Criteria may relate to prescription (indication, dosages, frequency, etc.) or even administration/dispensing criteria (adherence to administration schedule, correct preparation and administration procedure, etc.). The same system could be applied to supplies, a laboratory test or a diagnostic procedure.

A prescription audit is a similar process, but the focus is to assess if a certain disease is treated according to set standard guidelines. It can be considered a partial "clinical audit", which also involves a much wider assessment including structures, processes, competencies, skills, and outcomes in the management of certain conditions.

The purpose is to identify a performance gap by comparing the current practice and the standard, followed by further investigations of the possible reasons for it, with the aim of developing appropriate interventions to address the problems encountered.

Practical instructions for MUE and prescription audit

- **Step 1:** Identify a priority condition or item (it can be a diagnosis e.g. malaria, diarrhoea, or a medicine e.g. an expensive antibiotic, a drug with narrow therapeutic index etc.). Define the scope of the activity, which refers to the parameters you are going to assess, i.e. prescribing criteria, dispensing, and administration. The choice depends on the problem you are looking at.
- For example, if the problem pointer is a high number of adverse reactions, you may want to investigate indication but also dosages, and the way it is administered/prepared. Be as specific as possible, e.g., you may only be able to investigate an issue in one department at a time.
- **Step 2:** Detail the standard management criteria according to guidelines (IMCI, UCG, PGD). To avoid complications, limit to 3-5 criteria. The evaluation spans across different areas of competences so multiple MTC members must be involved. Create a simple data collection tool based on the established criteria.
- **Step 3:** Set the threshold below which the adherence to standard would be considered insufficient: often 100% is unrealistic, and 90%-95% is sufficient in most cases.
- **Step 4:** Describe how the data will be collected. This is an important consideration because while some data are easy to collect retrospectively, some others can only be collected prospectively
- **Step 5:** Establish the number of prescriptions to be analyzed: a minimum of 30, but up to 100 for common conditions/medicines, and in big facilities with multiple prescribers.
- **Step 6:** For retrospective studies: for a prescription audit, establish the period you want to investigate (usually 1-3 months). Obtain the total number of cases with the condition under

investigation from the HMIS for that period and divide it by the number of prescriptions you want to collect: the result will be your sampling interval.

Example: if you are doing a prescription audit on Urinary Tract Infection (UTI) or malaria, and you want 50 prescriptions from a period of 1 month: check how many UTI or malaria cases are recorded in HMIS 105 for that month (e.g. 346) and divide by 50. That is, 346/50 = 7, so you will record every 7th case of UTI or malaria from the OPD register.

For a medicine use evaluation, establish the period you want to investigate, check how many patients have been prescribed the medicine in the period of interest, divide it by the number of prescriptions you want to collect and use the result for your sampling interval. For example: you want to do a prescription survey on metformin. You may get the number of patients dispensed metformin in a certain period from the pharmacy dispensing log e.g. 155. Divide the number by the number of prescriptions you are targeting (30) to obtain your sampling interval. That is, 155/30 = 5, so you will every 5th patient prescribed metformin from the OPD register.

NOTE:

If the condition or medicine under investigation is not common, you can simply check all the prescriptions you find in a certain period.

- **Step 6:** For prospective studies. These are often based on observation, and the sample size may depend on the amount of time available, and the number of cases per day. Usually when health workers are aware to be observed, they may change their behaviour but they soon get used and revert to usual practices. So it is advisable to start collecting data after having done some observations. Prospective methods have risks of bias since data are collected in a short period and there is a limited chance of random sampling, so they are used in case of absence of retrospective data (poor records) or to study certain practices (e.g. how nurses prepare and administer injectable medicines).
- **Step 7:** Collect data (retrospectively or prospectively) and tabulate them for analysis. If documentation is poor, the only way to collect data is prospectively. Analyse percentage of adherence to criteria and compile a report with recommendations.
- **Step 8:** if the problem has a straightforward solution, share the report with prescribers, then design and implement an intervention. If the reasons of the problem have to be investigated, design and conduct qualitative studies to inform the development of the intervention.
- **Step 9:** Repeat the medicine use evaluation or the prescription audit during and after the intervention for monitoring and evaluation purposes. Remember that data collection, analysis and feedback to prescribers by itself it is an intervention because it can influence prescribers' behaviour.

Examples of data collection tools and indicators tables are provided below.

Example 1: ACT Medicine Use Evaluation

Malaria is one of the priority conditions in Uganda and has a quite straightforward and standardized management protocol, especially uncomplicated malaria in OPD.

The criteria for an ACT Medicine Use Evaluation in OPD are summarized in Table 9.19 below:

Table 9.19 Act Medicine Use Evaluation

No.	Criteria	Indicator	Standard
1	Patients who receive ACT should have been diagnosed with malaria	% of cases receiving ACT with a diagnosis of malaria in the OPD register	100%
2	Patients who receive an ACT should have been tested for malaria	% of pts who received ACT with malaria test recorded in OPD register or lab	95%
3	Patients who receive ACT should have a positive test for malaria	% patients who received ACT with positive malaria tests	95%
4	Patients with a single diagnosis of malaria should not get antibiotics	% single malaria receiving antibiotics	0%

The sampling frame would be to sample all patients who have received ACT (from the treatment column in the OPD register) in the period considered. An example of the data collection tool is shown in Table 9.20 below.

Table 9.20 Example of data collection tool

No	Initials or name	OPD No	Date	Age	Sex	Test (RDT or B/S or none	Result (POS or NEG or Not Applicable)	Diagnosis (copy exactly as written in OPD Register)	Anti-malarial treat given	Antibiotic Treatment (name of Ab prescribed)
1										
2										

The summary table from the data collection tool above would then look like this (real example in table 9.21)

Table 9:21 Summary of the data collected

	Description	No	%
1	Total number of patients prescribed ACT	200	
2	Total number of patients given ACT with malaria diagnosis	191	95%
3	Total number of patients given ACT without malaria diagnosis (A-B)	9	5%
4	Total number of patients treated clinically (without test)	111	56%
5	Total number of patients tested	89	44%
6	Total number of patients with a positive test	28	14%
7	Total number of patients negative among the tested	61	30%
8	Total number of patients given ACT and having another diagnosis beside malaria (including the ones without malaria diagnosis)	149	75%
9	Total number of patients given antibiotics	136	68%
10	Number of patients with a single diagnosis of malaria and given antibiotics	7	14%

Here is the graph (figure 9.2) for an ACT Medicine Use Evaluation done in 3 hospitals (the middle column has results from the summary table above).

- In all the 3 hospitals more than half of patients receiving ACT were not tested. In the first column/hospital, almost all cases are clinically diagnosed!
- In the middle hospital, a significant number (30%) of patients receive ACT even though they have a negative malaria test.

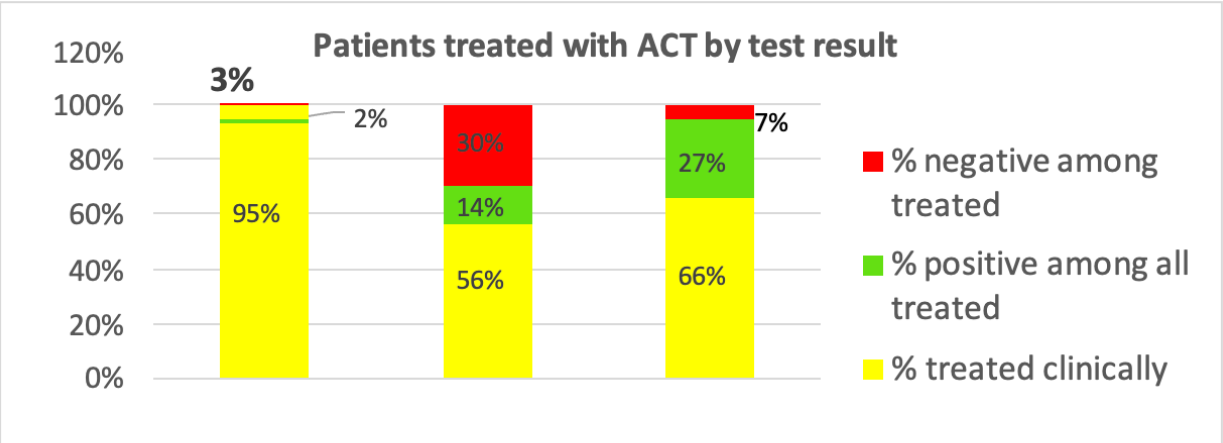

Figure 9.2 An Act Medicine Use Evaluation Done In 3 Hospitals

If instead of an MUE, a malaria prescription audit was done, the sampling frame would be "all patients diagnosed with malaria", from the diagnosis column in the OPD register.

The data collection tool would be the same, but the summary table 9.18 and indicators could look like the following:

Table 9.22 Summary data for malaria prescription audit

No.	Description	No	%
1	Total number of patients diagnosed with malaria	100	
2	Total number of patients given ACT	95	95%
3	Total number of patients given other antimalarials	9	9%
4	Total number of patients given artesunate	7	7%
5	Total number of patients treated clinically (without test)	55	55%
6	Total number of patients tested	45	45%
7	Total number of patients tested positive	28	28%
8	Total number of patients tested negative	17	17%
9	Total number of patients having only malaria diagnosis	47	47%
10	Number of patients given antibiotics among single diagnosis	14	30%
11	Total number of patients given antibiotics	68	68%

Example 2: Urinary Tract Infection Prescription audit

Table 9.19 below reports the data collected retrospectively from the OPD register for a UTI (Acute cystitis) prescription audit from a Ugandan Hospital over a period of 3 months. The exercise in this case did not focus on dose and duration but only on the type of medicines prescribed.

The standard guidelines for UTI treatment (UCG 2023) are presented in figure 9.3 below. In this case, it was not possible to assess the quality of the diagnosis, and therefore assume that the diagnosis was correct, and therefore only checked if the treatment is consistent with the diagnosis

Treatment	LOC
Uncomplicated UTI (cystitis) in non-pregnant women • Ensure high fluid intake First line agents: • Nitrofurantoin 100 mg 6 hourly for 5-7 days[advise patient to take after meals] Child: 3 mg/kg/day 6 hourly for 7 days Second line agents • Ciprofloxacin 500 mg 12 hourly for 7 days (adults) Children: amoxicillin 125-250 mg 8 hourly for 7 days If poor response or recurrent infections • Refer for investigation of culture and sensitivity and further management	HC2
Note • For urinary tract infection in pregnancy, see section 16.2.6	

Figure 9.3: Treatment of acute cystitis according to UCG 2023

Observations

- Only 3 patients (10%) received nitrofurantoin (the first-line treatment as per UCG 2023), in one case with associated ampicillin.
- 1 patient received ceftriaxone alone, 1 received cefixime alone, 2 received metronidazole alone, and the rest were treated with ciprofloxacin +/- metronidazole +/- doxycycline.

The conclusion is that adherence to UCG 2023 guidelines seems very low and there seems to be overlapping and confusion between treatment for UTI and treatment for STI syndromes (sexually transmitted infections). It is, therefore, necessary to sensitize the prescribers on the standard treatment guidelines for UTIs, and on the differentiation between UTIs and STIs. It is also important to investigate the reasons for the observed practices, e.g., was the first line of medicine available in the stores/pharmacy?

Example 3: Artesunate Medicine Use Evaluation

The purpose of this study would be to assess the appropriateness of the use of artesunate in terms of indication (patients receiving a diagnosis of malaria, and tested), dosage, and duration and frequency. These parameters were assessed based on the prescription. An additional criterion could have been to verify if all the prescribed doses were administered and if at the prescribed time, based on the records.

As for other studies, the easier approach is to collect the raw data and do coding and analysis later. An example is presented in Table 9.23 below.

Table 9:23 Artesunate medicine use evaluation

No	Initials	Age/ sex	Weight (Kg)	Admission diagnosis	Discharge diagnosis	Artesunate prescription (mg, doses and frequency)	Number of doses given from administration records	Test done and result
1	D.B	8 F	25	Pneumonia Malaria		60 mg 12 hourly 3 doses	2 doses	RDT positive
2	C.A.	25 F	55		Malaria	132 mg 12 hourly 1 stat	1 dose	B/S positive
3	V.B.	3M	15	Bacterial infection	Pneumonia	Artesunate 45 mg 12 hourly	3 doses	RDT negative

Patients who received artesunate would be selected from registers (if treatments given are recorded) or by chart review (anyone who was prescribed artesunate). Once data are collected, various indicators can be analyzed e.g.:

- % patients who have a diagnosis of malaria (in admission or discharge)
- % patients that have been tested and confirmed
- % patients with correct dose based on weight, standard duration, and frequency, and,
- % doses prescribed which have been administered.

If too much data is missing from the charts or records, a prospective/observation study may need to be done.

9.4.2 Qualitative methods

Qualitative methods focus on collecting data to understand the nature and reasons for a certain problem. They answer the question: why is this problem happening?

Understanding the causes of the problem is fundamental to designing and implementing an intervention to change it. Prescribing behavior is complex and is affected by multiple factors, so an understanding of the causes is essential to be able to address any issue comprehensively.

There are four methods to conduct qualitative studies and collect relevant information as summarized in table 9.24 below:

Table 9.24 Methods for conducting qualitative studies

Type of method	Explanation
Focus Group Discussion	A group discussion lasting 1-2 hours on a certain topic. The group is generally homogeneous, and a moderator guides the discussion on pre-defined topics (e.g. a group of prescribers for investigating the reasons for a certain prescribing behavior or a group of patients to assess the acceptability of a certain treatment or the attitude towards a certain treatment). FGDs can be used to identify beliefs, opinions, and motives behind a certain situation or behavior.
In-depth interviews	These are generally one-on-one in-depth discussions between a knowledgeable interviewer and a person who has an important role in the problem being investigated. Usually, there are several open-ended questions to guide the discussion so that a certain range of topics are covered. For example, if the problem seems related to a supply issue, an in-depth interview of the store manager may be necessary.
Structured questionnaires	A standardized set of questions is used on a sample of respondents to get quantitative data on beliefs, knowledge, and behaviors. For example, assessing the level of knowledge on a certain topic among health workers
Structured observation	This method is usually used to assess the interaction between prescriber/patient and requires an independent observer to record data on a predefined tool. It allows to record what happens versus what is stated to happen, but it has its limitations (e.g., an observer may be biased, and the observed person may change his/her behavior from usual). For instance, if we want to investigate the implementation of IMCI, an observer may observe if the health worker follows a pre-defined set of steps.

In-depth descriptions of these methods are beyond the scope of this guideline also because appropriate design and implementation of these studies may require expertise that is not routinely available at the facility level. It is anyway important for MTCs to be able to consult the literature and understand how to use these kinds of methods and eventually collaborate with research institutions.

At practical level, the MTC can conduct simple studies through group discussions or interviews, or even observation studies

EXAMPLE 1:

After finding out that in OPD the testing rate for malaria was very low, the pharmacist of a regional hospital organized a focus group discussion with all the OPD prescribers to discover why the testing rate was low.

EXAMPLE 2:

Another pharmacist, concerned about the high consumption of gloves in his hospital, conducted simple observations in the wards, tallying number of gloves used by different staff, and discovered that a significant percentage was used by student nurses. With this data, he was able to lobby for contribution for gloves from nursing schools.

Interviews with key informants (in-charge of departments, dispensers) can also give deep insights into some prescribing behaviors: e.g. an OPD dispenser often knows the prescribing patterns of most clinicians; the in-charge of a surgical ward explained that ceftriaxone is the most prescribed antibiotic simply because it is administered once daily, which is convenient, while antibiotics given 3 or 4 times daily end up not being given as required.

Last but not least, since most departments and cadres are represented in the MTC, most of the points of views and experiences may be already represented in the meeting discussion: e.g. the clinical officer in the MTC may have already quite a good understanding of the WHYs behind certain prescribing behaviors in OPD.

9.4.3 Root Cause Analysis

The principles and methods for conducting a root cause analysis have been presented in Chapter 6. The key message is trying to understand the "deep" causes behind a certain problem and not just stop at the surface. It is rare that a problem is linked only to the attitude of individuals: more often there is a complex web of structural/system and behavioral issues ending up in undesirable actions. Recognizing the root causes will often indicate how to address the problem.

A real example of root cause analysis using the "Fish bone technique" is presented on the next page:

- The fish head is the problem: the lack of adherence to the test and treat policy of malaria in OPD (as may be found with the ACT MUE described above).
- The big spines represent the categories of problems: prescriber, laboratory, patient and documentation problems. Categories can be pre-defined or can emerge from the discussion.
- The small spines are the primary and secondary causes.

Some of the root causes identified may not be amenable to solutions (e.g. hiring more staff): the MTC will have to focus on issues which can be solved within the means of the MTC/hospital itself.

IMPORTANT!!

Find out the causes of the problem is fundamental to understand how the issue can be addressed and solved. Without identifying the root factors involved, it very unlikely that any action will be able to improve the situation.

The figure below shows the Root cause analysis of non-adherence to test and treat policy of malaria using the fish bone technique.

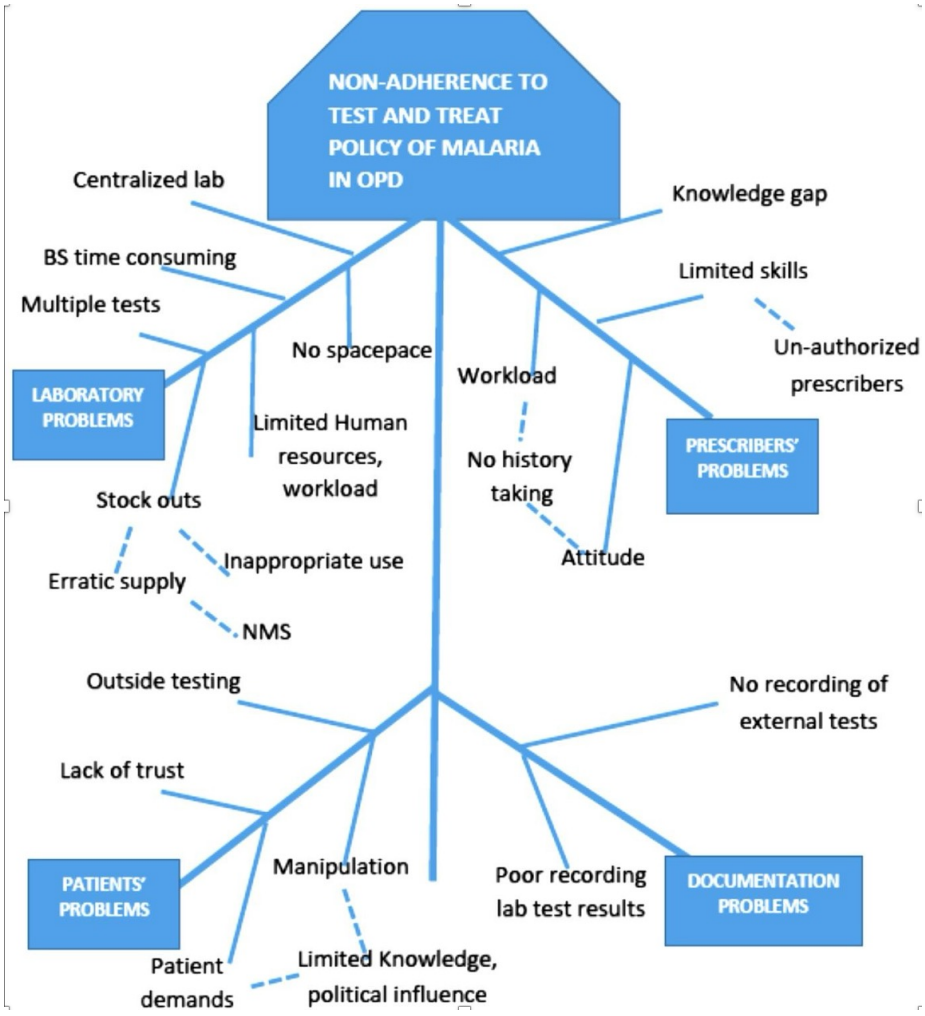

Figure 9.3 Root Cause analysis for non-adherence to test and treat policy

References

1. ***DRUG and THERAPEUTIC COMMITTEES – A practical guide. WHO-MSH 2003***
2. ***How to investigate drug use in health facilities. Selected drug use indicators. WHO 1993***
3. ***How to Investigate antimicrobial use in Hospitals: selected indicators. MSH 2012***
4. ***Ministry of Health The Quality Improvement methods: a manual for health workers in Uganda MOH 2015***

CHAPTER 10

How to improve the use of medicines and health technologies

10.1 Introduction

This chapter describes in detail the different types of intervention strategies, developing interventions, and implementing and evaluating the outcomes of the interventions.

The overall aim of the Medicines and Therapeutics Committee (MTC) is to ensure appropriate medicine management and use. Appropriate medicine use includes correct diagnosis, prescribing, dispensing, and patient adherence. We already know that many factors affect medicine use at different levels. Promoting appropriate medicine use and obtaining the desired change therefore requires that the behavior of all persons involved in each of the medicine use stages (prescribers, laboratory personnel, nurses, pharmacy personnel, and patients) and the various pertinent factors are addressed. In the previous chapters, we have seen how the MTC can identify and investigate medicine use problems to define their extent and root causes.

So, what next? After problem identification and investigation, it is important to present the findings to the stakeholders and prepare a plan of action. The MTC should develop conclusions about the differences between the actual results found through the investigations and the desired results as per the guidelines or standards. The MTC should recommend interventions with specific steps to correct the medicines use problems and lead the implementation.

IMPORTANT!!

Before thinking about an intervention, make sure to have conducted a proper root cause analysis and the factors involved have been clearly identified and described.

The interventions developed by the MTC usually fall within these four categories:

- Educational: to inform/persuade
- Managerial: to guide decisions
- Regulatory: to restrict decisions
- Financial/economical: to influence decisions through incentives (positive or negative).

As the interventions are being implemented, it is important to follow-up and monitor whether the intended objectives are being achieved. Usually, the monitoring involves repeating the medicines use studies that were done to identify the problems and thereby measuring the change. During the follow-up, you may find that the studies/intervention need to be modified. If an intervention is not achieving the desired outcomes, then it is better to modify or discontinue.

10.2 Overview of Intervention Strategies

This section describes the four types of interventions to ensure appropriate medicines use which include: Persuasive/Educational, Managerial, Regulatory and Financial/Economical.

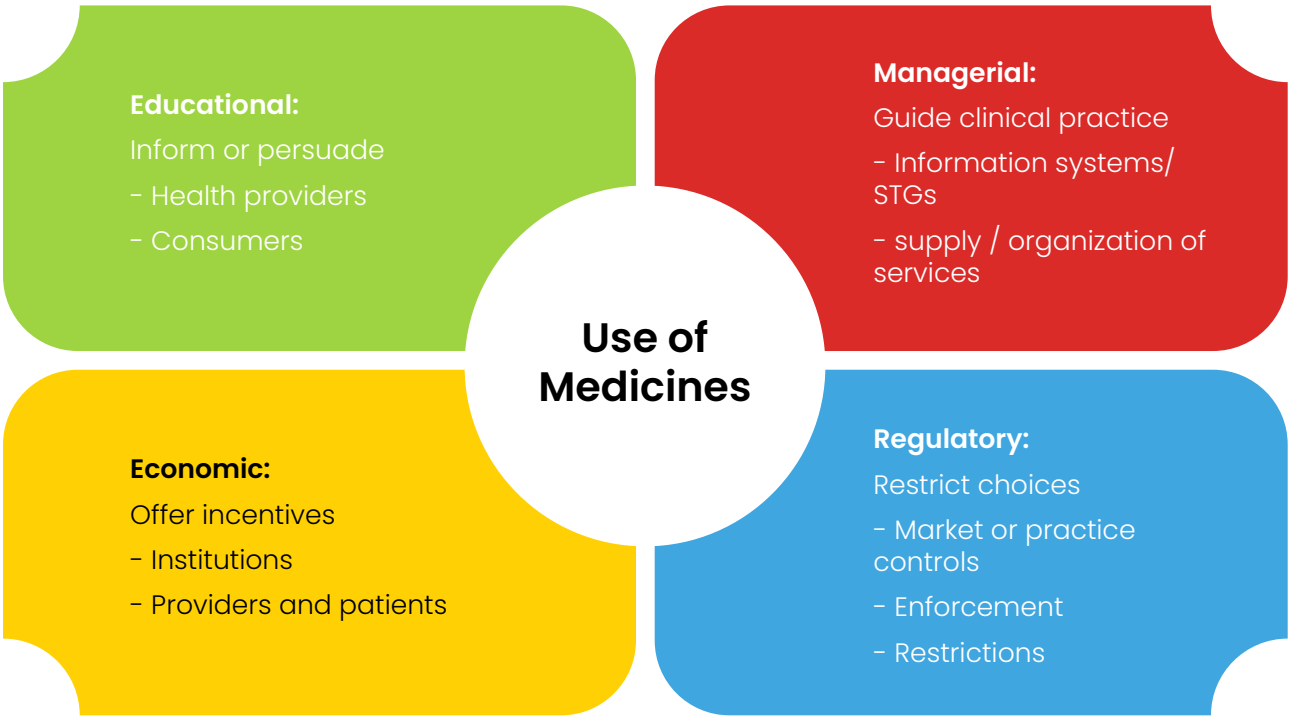

Figure 10.1 interventions to address medicine use problems

10.2.1 Educational strategies

Educational strategies aim to inform and persuade prescribers, dispensers, or patients to use medicines in an appropriate way. Providing information passively by simply sharing facts rarely changes behaviour. Persuasive messages on the other hand encourage people to try new behaviours and motivate them to maintain these behaviours, so they are a fundamental component of most interventions. Even then, persuasive messages are most effective in combination with other methods. When implemented in isolation they often have minimal effect, because knowledge gap alone is rarely the most important barrier to appropriate medicine use.

Educational strategies rely on availability of standard treatment guidelines or protocols in order to set the standards of care to which prescribers should adhere.

In all educational interventions, the following principles apply:

1. Focusing on specific problems and targeting the prescribers
2. Emphasize only a few key messages
3. Addressing the underlying specific knowledge gap (not a general lecture!)
4. Allowing an interactive discussion that involves the targeted audience
5. Using concise and authoritative materials to augment presentations
6. Giving sufficient attention to solving practical problems encountered by prescribers in real settings i.e. the facility/system specific issues (not textbook knowledge!)

Table 10:1 AMU improvement strategies and key principles

Educational Strategy	Key Principles
Training for prescribers/ patients: in-service educational programmes, workshops, seminars (CMEs)	• Useful for both updating staff on new knowledge and also addressing problems identified by the MTC. • Success of educational interventions depends on how the information is presented. Visual and audio aids (posters/power point presentations) can be useful. • A problem-based approach (e.g. through actual case studies on real patients) is more likely to be effective than textbook lectures. • Small group meetings are also more effective than large group meetings • Educational programmes should be provided along with guidance and policies and the tools and structures needed to follow them (e.g. if the message is to prescribe medicine A instead of medicine B, medicine A must be made available!). • Patient education influences medicine prescribing. All health workers should regularly/routinely provide patient education on appropriate therapy and adherence to drug regimens, so leading to improved health outcomes.
Face-to-face persuasive outreach	• Face-to-face individual teaching is the most effective (e.g. as done by medical representatives), though time-consuming. It usually targets prescribers, has few key messages to convey and is usually followed up with a reinforcement visit two or three times to strengthen the likelihood of behaviour change. • Influencing opinion leaders has been shown to influence prescribing habits significantly. Junior officers tend to copy the habits of their senior, so a face-to-face with an opinion leader may have a cascade effect.
	• The printed educational materials include; treatment guidelines, newsletters, bulletins, clinical literature, illustrated persuasive material (flyers, poster). • Can be valuable in providing accurate and unbiased drug information. • Unlikely to be effective in changing behaviour unless combined with a more interactive teaching method. Having a reliable source of unbiased and updated information augments other educational activities. • There should be a small drug resource centre/library with at least 2-3 current authoritative books.

	• The most current edition of the Uganda Clinical Guidelines (UCG), Practical Guideline for Dispensing and Essential Medicines and Health Supplies List should be available. • Local bulletins can be periodically produced by the MTC or provided by an external source (e.g. MOH, WHO). • Good, printed materials: Information should be concise, simple and brief; key points should be repeated, not lengthy; they should have short but catchy headings, visually appealing illustrations; the information should be oriented towards actions and decisions. They should have respected sponsors e.g. MOH, WHO.
Media based approaches	• Posters, audio tapes, plays, radio, TV, social networks • Used especially for patient education • Can reach many people but not very effective in changing behaviour

The following table (Table: 10.2) presents a summary of the advantages and disadvantages of the most used educational strategies. These were provided by actual MTC members.

Table: 10.2 Advantages and disadvatages of different education strategies

STRATEGY	ADVANTAGES	DISADVANTAGES	COMMENTS
POSTER LEAFLETS	• Many people can access • Summarized information • Easy to produce • Simple information, easy to understand • Long lasting, portable • Easy to interpret and visualize • Used as reminders e.g. SOP posted everywhere • Used for IEC/SOP/new staff/ mentorship	• Easily destroyed, removed, spoilt or lost • May be overlooked or ignored if people are busy or if the right people not targeted specifically • Language problem • May have little effect on behavior or attitudes • Illiterate or blind people excluded • Sometimes not easy to interpret or misinterpreted • Can be costly	Good in association with other methods
"BIG" TRAINING	• Many people reached at the same time • A lot of ideas can be shared • Good for brainstorming • Multiplier effect can be big	• Costly • Poor concentration by participants (requires very good trainers) • Hard to manage large numbers • Cannot confirm understanding/ (information can get distorted) • Some people may be too vocal • Not very effective and time consuming • Sometimes it is difficult to reach consensus	Good to disseminate policy changes, new SOPs etc.

SMALL TRAINING	• Easy to manage, organize and evaluate • Good attention and concentration • Free discussion • Less costly, easy to get feedback • Quick decision making	• Few people getting information • difficult to reach everyone • Can be expensive / time consuming	Good to train people on specific issues
FACE TO FACE	• Very effective! Active participation. Improves relationship. • High concentration. • Can cause attitude change • Easy to obtain ideas and feedback • Easy to target people	• Time consuming, tedious and demanding • Overall impact may be small • May create fear or discomfort • Very dependent on emotions or relationship • Need someone with experience and skills to deliver message	Good to persuade opinion leaders

10.2.2 Managerial strategies

Managerial strategies guide and structure decisions through the use of specific processes, procedures, forms, packages, that make it easier to act as recommended.

In health institutions, these usually involve formulation and implementation of treatment protocols, introduction of standard operating procedures, changes in workflow and organization, improved supervision with performance feedback and better information systems.

The key to success is to make the right choice the easiest, so that it becomes the "automatic" choice. This may require some effort at the beginning because it involves change, but choosing the easiest path comes natural after some time.

Table: 10.3 Guidence of implementation of managerial intervation

Managerial Intervention	Description
Selection, Procurement and Distribution of pharmaceuticals	• Use of institutional medicines list extracted from the national EMHSLU • Consumption-based and Morbidity-based quantification to guide medicines supply • Pipeline monitoring and stock movement monitoring • Medicines procurement review and feedback to managers
Diagnosis	• Ensuring availability of diagnostic equipment and supplies • Availability of laboratory test menu and standard operating procedures
Procedure and processes	• Use of structured order /prescription forms, standard operating procedures and checklists • Prescribing and dispensing procedures: pre-packaging, pre-labelling, use of generic names, generic substitutions, writing diagnoses and patient biodata • Changes in workflows, organization of spaces or human resources, e.g. task shifting • Introduction of new equipment/procedures

Strategies aimed at prescribers: supervision*, audit and feedback	• Targeted face-to-face supervision with medicine use audit, peer group monitoring • Monitoring drug use and giving feedback to stakeholders on data collected. Audit and feedback may range from: • Monitoring and supervision of adherence to procurement plan, storage, distribution, often using aggregate data. • Monitoring and supervision of prescribing habits before and after intervention. • Medicines use evaluation (for drugs and supplies) and prescription audit/adherence to STGs (for disease conditions). • Feedback is then given to managers and all prescribers

*Note that while simple supervision, even face to face, is considered an educational strategy, supervision with performance monitoring and feedback is more of a managerial strategy.

10.2.3 Regulatory strategies

Regulatory strategies aim at controlling decisions. However, they can work only if there is a system for enforcing rules and regulations. They can be very effective in quickly changing some prescribing and dispensing practices. However, they require a lot of resources to enforce and monitor adherence and, if not accompanied by managerial and educational interventions, there is the risk that people find ways to circumvent the rule.

Another challenge is the possibility of unexpected consequences, so these strategies must be carefully thought before being used. For example, in a certain country, the prohibition to using an anti-diarrheal medicine resulted in an increase of prescription of antibiotics for simple diarrheas. Severe restriction on prescribing can also limit access to certain medications in case of need, for example, if certain antibiotics can be prescribed only by the specialist, but the specialist doctor is not available half of the time, patients in need may miss their treatment.

Table: 10.4 Guidence on implementation of regulatory intervations

Regulatory strategy	Description
Medicine regulations: the MTC will monitor and enforce these regulations.	• Drug registration • Bans of inappropriate medicines • Regulations of prescription-only medicines and over the counter • Enforce guidelines on handling expired or obsolete medicines • Enforcement of guidelines on donations
Prescribers and Dispenser regulations	• Restrictions on prescriptions by qualification (e.g. only a specialist doctor can use some medicines) • Dispensing controls on select medicines e.g. dispensing high value medicines only after the approval
Hospital policy on pharmaceutical promotion	• Regulation of promotional activities from pharmaceutical industry to avoid inappropriate influence (e.g. drug promoters can only talk to clinicians at pre-set times and venue only, no advertising material should be hung on facility walls)

10.2.4 Financial or Economic strategies

Financial (or economic) strategies are based on the use of incentives to promote or avoid certain behaviour ("the carrot or the stick"). An incentive is any factor that influences a behavior choice, and it can be:

- Financial e.g.: bonuses, performance or result based financing etc.
- Moral e.g. recognition, awards etc.
- Coercive e.g. fines etc.

Financial incentives can promote or maintain unsatisfactory behavior ("perverse" incentives): for example, if the salary of a prescriber depends on the sales of medicines, the prescriber may be influenced to prescribe more medicines, and this may cause over-prescription. While flat user fees on one side may promote access and equity, they may encourage polypharmacy because the same amount is charged irrespective of the number and quantities of medicine used.

Financial and coercive incentives (i.e. bonuses or fines) cannot feasibly be used by the MTC, but moral incentives can be easily used to recognize good performance and improvement of individuals and/or departments.

10.3 Choosing an Intervention

The choice of an intervention will depend on the type of medicine use problem and the reasons why the problem exists. A comprehensive analysis of the problem should be done, with a root cause analysis that highlights the possible causes and, consequently, the issues to address.

Not all interventions are equally effective. For example, improving knowledge is often NOT

accompanied by a change in behavior. Studies have shown that:

- A single-shot educational strategy is usually not very effective and the impact not sustainable.
- The use of printed materials alone is not enough.
- Similar strategies may produce different results in different settings.
- A combination of strategies, for example educational plus managerial, is usually more effective than a single approach
- Focused small-group and face-to-face interactive workshops have been shown to be effective.
- Monitoring, feedback and peer review are very effective strategies but require the agreed use of certain standards (e.g. STGs) against which to judge the prescribing.
- Economic incentives can be very powerful ways of changing behavior; however, poorly thought-out incentives may lead to unexpected behavior and the promotion of inappropriate use.

Remember

A combination of different strategies is more effective than a single approach

The following factors should be considered in choosing strategies:

Table: 10.5 Factors Considered In Choosing Strategies

Factor	Description
Expected magnitude of Impact	• If an intervention is successful, will it affect only a few medicines, a few providers, save only a small amount of money? Or will the impact be great?
Likelihood of success	• All things considered, how likely is success? Will opposition be so great or the task so complex that success is unlikely?
Unintended effect	• What are the unintended effects that might occur? How can these effects, if any, be minimized?
Political and cultural feasibility	• How acceptable is the strategy in the local context? Will political and cultural factors favor development and implementation of the strategy, or will they severely hinder it?
Technical feasibility	• What are the technical requirements of the strategy? A highly developed information system? How much technical help (people, systems, and equipment) will be needed?
Cost (economic feasibility)	• What is the cost, particularly compared to available resources and to the potential benefits for successfully implementing the strategy?
Potential for donor support	• Will donor support be needed? Requested? How likely is it that the donors with whom you work will support the proposed approaches?

Testing an intervention where possible should be done. The PDSA (Plan, Do, Study, Act) cycle provides a framework for testing changes and progressively learning and improving the intervention (see Chapter 6).

It is also important to involve key decision makers at intervention design stage, to allow ownership of results and obtain support for the intervention. It is often useful to check the literature or consult other hospitals to see which interventions have worked well elsewhere and assess whether they can be adapted.

The matrix below suggests which type of interventions could be effective to address different categories of root causes. The top rows show common factors affecting use of medicines, and the first column shows a list of possible interventions:

For example, if the main causes identified are linked to the workload and organization of work and supplies, an educational intervention will have minimal effect.

Useful Tip:

It is advisable to implement educational strategies AFTER the managerial and administrative requirements for the intervention are available.

For example:

- If you want to strengthen test and treat for malaria in your facility, make sure that the means to do that (test kits, microscopes, lab staff…) are available before doing a CME.
- If you want to change the protocol for surgical prophylaxis, make sure that the medicine of your new protocol is available in sufficient quantities BEFORE introducing the protocol.

Table: 10.6 Examples Of Possible Causes And Proposed Intervention

	Characteristics of Providers		Social Structure of Providers		Provider-Patient Interactions		Work Environment		Marketing
	Lack of Knowl-edge	Acquired Habits	Authority and Power	Peer Norms and Relations	Cultural Attitudes and Beliefs	Patient Demands	Medicines Availability	Workload	Influence of Industry
Prequalification Training	X				X				
In-Service Education in Large Group Seminars	X								
In-service Education, One-on-One, Small Groups		X	X	X	X				
Patient and Community Education Program					X	X			
Monitoring Practices/ Supervision/ Feedback	X	X							
Group Development of Norms of Practice		X	X	X					X
Restrictions on Which Medicines Are Available							X		X
Re-organization workflow and staffing, task shifting								X	
Prioritization of vital medicines							X		

10.4 Planning an intervention

Once the likely root causes and the most suitable strategies have been identified, you can proceed to plan and implement the intervention. The steps are summarized below.

Steps to follow when planning an intervention

1. Define the problem (problem identification and investigation).
2. Identify the motivations and constraints that affect the problem (root cause analysis).
3. List possible interventions that could be undertaken.
4. Choose an intervention or a combination.
5. Prepare a work plan for the intervention and a time schedule: decide what will happen, when, where, how, the resources needed, and who is responsible.
6. Prepare a budget
7. If possible, initially test the intervention on a small scale.
8. Plan how to monitor and evaluate the intervention, usually using the same methods used in the problem investigation.

10.4.1 Work plan and budget preparation

Use a convenient format for your work plan. The following points should be well-defined:

Table: 10.7 Critical Variables For A Work Plan

Area	Description
Objectives	Write what you hope to achieve, in measurable terms, from your Intervention (SMART Objectives)
Type of strategy	Educational, managerial, regulatory or financial? This helps to plan a suitable combination of interventions
Description of strategy	The approaches/interventions to achieve the objectives for example training of providers on the new malaria policy (educational strategy); Decentralization of testing services to point of care (managerial strategy)
Activities	The practical steps needed (see Steps to follow in the previous table)
Resources	What is needed to implement the activities? This information is useful for the budget.
Responsible persons	Who drives the specific activities or strategy?
Timeline	The times when the implementation will happen, broken down into different phases if necessary
Output	What you expect as a direct result of the implementation of each activity? This will help to monitor the progress of intervention implementation

Below is an example of objectives and work plan. These are summarized from actual work plans from three hospital MTCs to address the poor adherence to the test and treat policy of malaria.

EXAMPLE: Summary of Intervention Strategies to Improve Adherence to Test and Treat Policy in Regional Referral Hospitals.

Objectives:

- Increase % of testing for suspected malaria cases from XX to XX within 12 months
- Increase % of confirmed malaria cases (tested positive) from XX to XX within 12 months
- Decrease the number of malaria cases without co-morbidities treated with antibiotics from XX to XX within 12 months

Table: 10.8 An Example Of A Work Plan

Type of strategy	Strategy description	Activity	Resources needed	Responsible person	Timeline	Expected output	Expected outcome
Educational	Reorientation of all staff on test-treat and Track Policy	Meeting with all clinicians and lab staff on test and treat policy	• PowerPoint presentation • Refreshments • Stationery • Venue • UCG/ malaria management manual	Head of clinical services	Month 1	One meeting conducted	Increased knowledge Increased testing rate Increased adherence to test results Increased accuracy of records Reduced patient demand for ACTs Increased uptake of malaria tests
		Meeting with record staff (and everyone involved) on proper documentation at OPD and clinicians to transfer results in the patient's medical form		Head of records	Month 1	One meeting conducted	
	Patients' education	Health education sessions for patients in OPD on malaria and test and treat policy, other causes of fever, and risks of overuse of antimalarials	• Staff • Posters • flip charts	OPD in charge		Weekly sessions in OPD	
		Radio talks (on the same topic)	Radio talk time Staff	Nursing, Health Promotion		10 radio talks conducted	

Manage-rial	Feedback on ACT MUE/ malaria prescription audit	Meeting with all staff to present and discuss results of MUE/prescription audit and present intervention NOTE: This activity can be combined with the above and repeated periodi-cally for monitoring purposes	As above	MTC chair and secre-tary	Month 1	Three meetings conducted Feedback given and consensus reached on the inter-vention	Increased testing rate. Reduced turn-around time for lab results
	Decentralize testing ser-vices to OPD (or establish a lab at OPD)	Procurement of RDT	RDT test kits	Pharmacy in charge Head of clinicians OPD in-charge	Month 1	RDT kits are available as per pa-tients' load	
		Organization of space and staff to conduct RDTs	Appropriate space/furniture	Lab in-charge Admin-is-tration	Month 1	Testing points available in OPD with reasona-ble waiting time	
			Trained staff (lab or other) in RDT and recording				
Edu-ca-tional / Man-ag-erial:	Develop pro-tocol or SOP for the man-age-ment of fever and RDT-negative malaria	Sub-committee to develop SOP for management of fe-ver and/or manage-ment of RDT-nega-tive malaria in OPD	Latest UCG/ MOH Malaria Manage-ment guidelines Stationery Refresh-ments Internet		Month 1	SOP devel-oped CME conducted SOP dis-played	Decreased rate of treatment of test-negative cases with antimalarials. Reduction in antibiotic use in single diagnosis of malaria cases
		CME on above for all staff	As above	Head of clinical ser-vices			
		Lamination and display of SOP	Lamination paper	Ad-mini-stra-tor			
	Restrict ACT dispensing at the phar-macy	MTC to draft a cir-cular on dispensing ACTs at the pharma-cy (no ACTs without testing and prescrip-tion)		MTC chair		Circular signed by man-age-ment and dis-played in pharmacy	Decrease of ACT dis-pensed with-out testing
		Management to sign and disseminate to relevant stakehold-ers		Medical di-rector/ ad-mini-stra-tor			
	Regulation of authorized prescribers	Have a full list of prescribers' names, specimen signa-tures, contacts, and units at the dispens-ing point	Stationery	Senior dis-penser HR/ Admin		List pre-pared and displayed	Reduction in unauthorized prescriptions
		Pharmacy dept meeting to dissemi-nate policy		Senior dis-penser			
		Communication to all staff (CME, notice board)	Stationery	MTC chair			

Monitoring: monthly sample ACT MUE (20-30 cases) e.g. from the last week of the month.

Evaluation: repeat MUE (sample of 100 patients/prescriptions) after 3 months, 6 months, and at 1 year.

10.5 Monitoring and Evaluating of Interventions

It is important to evaluate interventions to assess whether they are effective or not in correcting a targeted medicine use problem. In addition, regular monitoring of processes during implementation helps to:

- Ensure that all activities are executed in alignment with the established plan to the greatest extent possible.
- Find out if there are unexpected difficulties
- Adjust plans if necessary.
- Identify and assess any unforeseen challenges or obstacles that may arise during implementation

Ideally, interventions should be initially implemented on a small scale (e.g. one ward) to assess how they work and scaled up if effective or reviewed if not (PDSA cycle, see chapter 2).

The intervention must be designed in such a way that data can be collected, and also in a way where it can be judged if the observed changes are due to the intervention or some other factor (a confounder). The following guidelines can ensure that you include evaluation components in your program in an appropriate way:

Guidelines for Incorporating Evaluation Aspects into Intervention Design

- Decide at the beginning of an intervention how you are going to evaluate it.
- Prepare a set of realistic, achievable, and measurable outcome measures that relate directly to your intervention objectives.
- If possible, use also routinely collected data (even though often they may be inaccurate or incomplete, it is a good chance to improve them!).
- Focus on key outcome measures, not all possible changes. Identify in advance the key behaviors the intervention aims to change.
- Evaluate both the process of the intervention and its effects.
- Look for changes in the short as well as long term; find out if any benefits are long-lasting
- Encourage participation of target groups in all stages of your evaluation.
- Share your successes and failures with others. Always provide feedback on the results of the intervention (positive or negative) to stakeholders.

How to conduct the evaluation

The same studies/surveys done before the intervention should be repeated. The methods described in Chapter 5 are used, i.e.: medicines use evaluations, drug indicator surveys, semi- structured interviews, focus group discussions, and direct observations.

To evaluate if an intervention has produced the desired results, there are different approaches, simplified in the table below.

Table: 10.9 Approches For Conducting An Evaluation

Approach	Type of Study design	Description
Control vs intervention group	Randomized controlled trial	• Scientific gold standard • There is a test (intervention) group and control group – where intervention is not implemented • Participants randomly selected • Not very implementable within a hospital, i.e. for logistical reasons or ethical reasons, but could be used in a group of hospitals (some implement the intervention, some do not)
Before and After	Before-after study or time series	• Data is collected before and after the intervention (once or several times) • It is assumed that any differences/changes seen are due to the intervention • Useful when it is not possible to have a control group • Easier to implement than randomized controlled trial

Example 1: Intervention to Correct a Medicine Use Problem in a Hospital - adherence to test and treat policy for malaria in Ugandan Hospitals

The graphs below show the results of an intervention to improve the adherence to test and treat policy of malaria in two different hospitals whose ACT MUE is presented in Chapter 9.

In the first graph, the % of patients with a positive test increased over the months, while the % of patients treated clinically or with negative tests decreased.

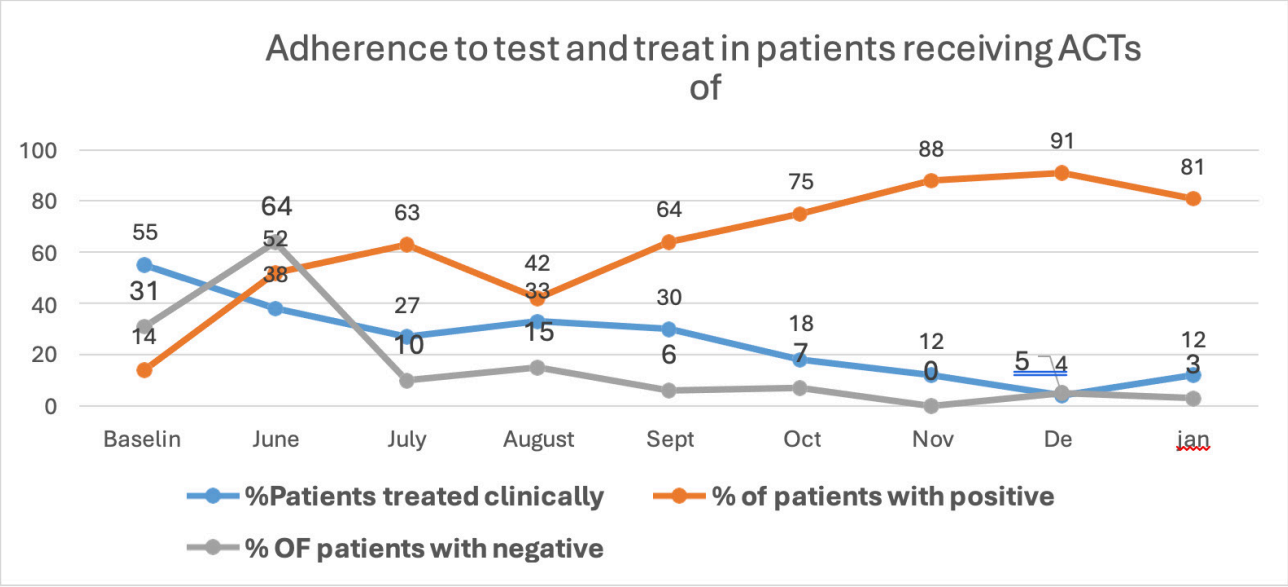

Figure 10.2 Trend Analysis Of The Percentage Of Patients With A Positive Malaria Test

In the second graph below, an initial improvement was followed by a return to almost baseline levels: the intervention was not sustained, and the situation rapidly reverted to where it was before!

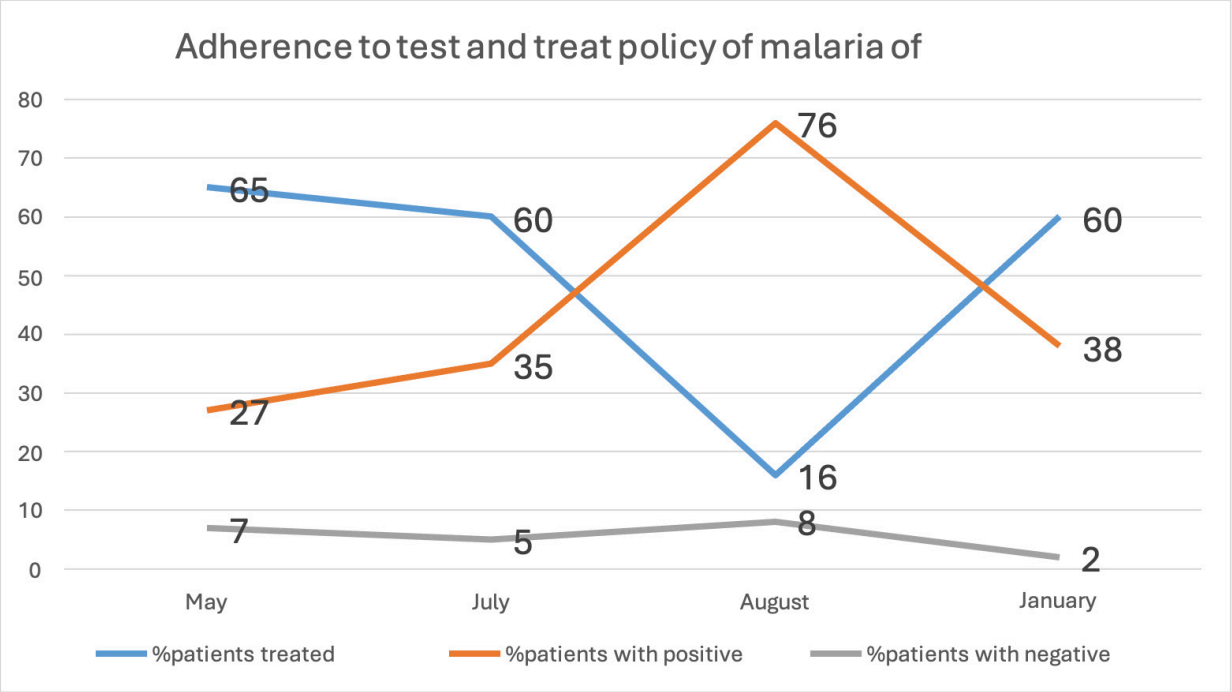

Figure 10.3 Trend Analysis Of Adherence To The Test And Treat Policy

Exercise 1: Correcting Antibiotic Misuse in XY Referral Hospital

The example below shows a theoretical but realistic scenario, that demonstrates how some intervention strategies can "backfire" (have unintended consequences).

Several officials in the Ministry of Health are interested in studying the extent of misuse of antibiotics prescribed in government hospitals in the country. In XY Hospital, their first step was to collect prescription data from medicines prescription forms during a 15-day period from all the major clinics/departments. These forms contained information on the condition being treated, medicines prescribed, dose, duration of therapy, and prescriber name.

The Director was surprised by the initial tabulations of the data: ceftriaxone injections were the second most frequently prescribed antibiotic despite its relatively high cost and the availability of alternative oral medications. Further analysis of the data revealed that the most common problems being treated with ceftriaxone were: respiratory tract infections, urinary tract infection and "bacterial infection" (not better identified), all problems that could be treated with much safer and inexpensive medicines.

Concerned about the negative impacts of these practices on costs and quality of care, the Director subsequently analyzes the data by the prescriber and learns that only a few clinicians are responsible for over two-thirds of the use of ceftriaxone injections. He immediately calls the responsible clinicians and informs them that they are among the «worst» prescribers of antibiotics. He directs them to reduce this practice immediately or face the possibility of being disciplined.

Three months later, the Director repeats a 10-day survey of prescriptions and finds that the use of ceftriaxone injections has declined by 70 percent. Satisfied that the problem had been solved, he planned no further follow-up or communication with these clinicians.

One year later, a new 10-day survey of prescription forms was conducted. Unfortunately, it was found that ceftriaxone injections have risen again to nearly their former level. In addition, the prescription forms no longer contain readable names of the prescribers.

1. *What type of strategy was used to improve prescribing?*
2. *What were the possible motivations for physicians to prescribe in the way they did?*
3. *What were the motivations for physicians to comply with the recommendation of the Ministry of Health staff?*
4. *What were the overall strengths and weaknesses of this approach?*
5. *Overall, do you think this would be a successful strategy in your health facility? Why or why not?*
6. *What are some of the risks of the type of communication used with the physicians?*
7. *What other strategies might have been used to feed back the results of the audit to prescribers?*
8. *Would you have approached this problem differently in your health units? If so, how?*

CHAPTER 11

Monitoring and Evaluating the Implementation of the Guideline to Manage Medicines and Health Technologies within Health Facilities

Table 11.1 National Indicators For Management Of Medicines And Health Technologies Within Health Facilities

Indicator	Indicator Definition	Responsible Institution	Level of care	Data Source	Baseline	Target	Frequency
Functionality of the Medicine and Therapeutic Committee							
Proportion of Health facility with functional Medicine and Therapeutics committee	The indicator measures the proportion of Health facilities with functional MTC	MOH/Department of Pharmaceutical and Natural Medicines	HCIII and above	MTC assessment reports	56%	90%	Bimonthly
Proportion of Hospitals with Institution Medicines and Health Technology list	This measures the proportion of health facilities with Institution Medicines and Health Technology list	Health Facilities (Chair MTC)	HC IV	Assessment Report	NA	70%	Annually
Antimicrobial Stewardship-Laboratory							
Percentage of Hospitals who have antibiogram and disseminated	This indicator measures the proportion of hospitals monitoring how susceptible a series of organisms are to different antimicrobials	Health Facility (Chair AMS Subcommittee)	Hospital	Assessment Report	N/A	40%	Annual

Indicator	Indicator Definition	Responsible Institution	Level of care	Data Source	Baseline	Target	Frequency
Percentage of Hospitals that have conducted at least one environmental swabbing	This indicator measures the proportion of hospitals monitoring the presence of pathogens within the Health Facility environment	Health Facility (Chair IPC Committee and Chair AMS Subcommittee)	HCIV and above	Assessment Report	N/A	40%	Annual
Proportion of Hospitals submitting summary trends of antimicrobial susceptibility test (AST) results	This indicator measures the proportion of hospitals submitting summary trends of antimicrobial susceptibility test (AST) results	Health Facility (Chair AMS Sub-Committee)	Hospital	HMIS Section 10		100%	Monthly
Percentage of Hospitals submitting quarterly AMR patient-level data to the Ministry of Health	This measures the proportion of hospitals submitting Quarterly patient-level data to MOH	Health Facility	Hospital	MOH Quarterly Reports		100%	Quarterly
National patient-level data submitted to GLASS	This indicator tracks the submission of national patient-level data to GLASS-AMR	MOH/UNHLS	MOH HQ	Health Facility Reports		100%	Annual
Antimicrobial Stewardship-Antimicrobial Use							
Proportion of Health Facilities conducting Point Prevalence Survey (PPS)	This measures the proportion of health facilities conducting point prevalence survey	Health Facilities (Chair AMS sub-committee and AMS teams)	HC III and above	Assessment Report	26%	70%	Hospitals and above - twice a year . HCIIIs & HCIVs - once a year
Proportion of Health Facilities conducting prescription and medicine use	This measures the proportion of health facilities conducting point prevalence survey	Health Facilities (Chair AMS sub-committee and AMS teams)	HC III and above	Assessment Report	NA	70%	Hospitals and above - twice a year HCIIIS & HCIVS - once a year
Antimicrobial Stewardship-Antimicrobial consumption							
Proportion of health facilities with disseminated consumption reports for antimicrobials	This measures the proportion of health facilities with published consumption reports for antimicrobials	Health Facility (Chair MTC)	HC III	Stock card/ issue data	NA	70%	Annual
National consumption data submitted to GLASS	This indicator tracks the submission of national consumption data to GLASS-AMC	MOH/Department of Pharmaceutical and Natural Medicines	MOH HQ	Import data from NDA and Warehouse data from NMS and JMS	NA	100%	Annual

Indicator	Indicator Definition	Responsible Institution	Level of care	Data Source	Baseline	Target	Frequency
Pharmacovigilance							
Proportion of Health Facilities submitting targeted ADR/AEFI reports monthly to NDA	This measures the proportion of health facilities submitting targeted ADR/AEFI reports monthly to NDA	Health Facilities (Chair PV sub-committee)	HC III and above	Assessment Report	26%	70%	Hospitals 16 Reports monthly and HCIVs - 8monthly and HCIII 4 Monthly
Proportion of Hospitals conducting casualty assessment	This measures the proportion of health facilities conducting casualty assessment	Health Facilities (Chair PV sub-committee)	Hospitals	Assessment Report	NA	70%	Hospitals 2 reports monthly
Health Technologies Management							
Proportion of Health facility with functional Electronic Medical Record	This measures the proportion of health facilities with functional Electronic Medical Record	Health Facilities (Chair HTM subcommittee	HC IV	Assessment Report	NA	70%	Annually
Supply Chain management							
Proportion of Health Facilities submitting timely submitting of HMIS 105 and HMIS 103B	This measures the proportion of health facilities submitting timely submitting of HMIS 105 and HMIS 103B	Health Facilities (Chair Supply Chain sub-committee)	HC II and above	Assessment Report	50%	70%	ALL level of care monthly
Proportion of Hospitals conducting self audit for Stores and stock Management	This measures the proportion of health facilities conducting self audit of Stores and stock Management	Health Facilities (Chair Supply Chain sub-committee)	HC IV	Assessment Report	NA	70%	Bimonthly
Proportion of health facility conducting annual procurement plan for EMHS	This measures the proportion of health facilities conducting annual procurement plan for EMHS	Health Facilities (Chair Supply Chain sub-committee)	HCII and above	Annual Needs assessment report	100%	100%	Annual
Proportion of health facility conducting monitoring of ordering and budget	This measures the proportion of health facilities conducting monitoring of ordering and budget	Health Facilities (Chair Supply Chain sub-committee)	HCII and above	Assessment Report		100%	Bimonthly

Annexes

Annex 1.1: MTC Standard Unit of Output: Weighted Performance Measures

This framework provides a weighted measure of Medicines and Therapeutics Committee (MTC) performance in Ugandan health facilities. Indicators are categorized into six thematic areas, with assigned integer scores reflecting their relative importance based on Ministry of Health guidelines and the situational analysis. The total possible score for all indicators sums to 100.

Calculation of Overall MTC Performance Score:

For each MTC, sum the points earned across all indicators within each thematic area.

1. Domain 1: MTC Governance & Structure Score: Sum of points from Section A (Max 10)
2. Domain 2: MTC Operationalization & Reporting Score: Sum of points from Section B (Max 20)
3. Domain 3: Antimicrobial Stewardship (AMS) & Appropriate Medicines Use (AMU) Score: Sum of points from Section D (Max 20)
4. Domain 4: Pharmacovigilance (PV) Score: Sum of points from Section E (Max 20)
5. Domain 5: Supply Chain Oversight Score: Sum of points from Section C (Max 20)
6. Domain 6: Health Technologies Management (HTM) Score: Sum of points from Section F (Max 10)

Overall MTC Performance Score = Domain 1 Score + Domain 2 Score + Domain 3 Score + Domain 4 Score + Domain 5 Score + Domain 6 Score

This calculation will yield a total score out of 100 for each MTC, providing a weighted and structured measure of their overall performance based on key responsibilities and activities outlined in the official MoH guidelines.

Domain 1: MTC Governance & Structure (Total Possible Score: 10)

This section assesses the foundational and structural elements necessary for an MTC to operate effectively.

Indicator	Scoring	Justification/ Reference	Score	Notes
MTC Functional Status:	Max 8 points	MTCs are standing committees responsible for managing medicines and health technologies to promote their safe, effective, and cost-effective use in health facilities.		Fully functional: Score 8 - Ensures availability of safe/cost-effective medicines, improves accountability, controls AMR, and enhances rational medicine use, leading to better quality of service and efficient resource use. Partially functional: Score 4 - Some benefits are realized, but full effectiveness and impact are not achieved due to incomplete functionality. Non-functional or Not in place: Score 0 - Intended benefits are not realized, leading to potential issues in medicine management.
Official Appointment & Terms of Reference (ToRs):	Max 2 points	Effective MTC function requires multidisciplinary, technically competent, and officially appointed members with defined roles and responsibilities.		MTC officially appointed AND has clear ToRs: Score 2 - Ensures members are recognized and understand roles, enhancing commitment and accountability. Only one is present: Score 1 - Lacking either element can lead to ambiguity or ineffective operation. Neither is present: Score 0 - Indicates severe lack of foundational structure.

Domain 2: Operationalization & Reporting (Total Possible Score: 20)

This section measures the MTC's active operation, planning, and formal reporting processes.

Indicator	Scoring	Justification/ Reference	Score	Notes
Regularity of Meetings:	Max 7 points	Regular meetings are pivotal for MTCs to provide strategic leadership, guide EMHS management, and ensure effective decision-making, minute-taking, and follow-up.		Meets at least bi-monthly with documented minutes: Score 7 - Vital for consistent strategic leadership, decision-making, and follow-up. Meets less frequently but with minutes OR meets bi-monthly without minutes: Score 3 - Suboptimal operationalization due to inconsistency or lack of documentation. Infrequent meetings or no minutes: Score 0 - Critical failure in operational efficiency.

Work Plan & Budget Integration:	Max 7 points	MTCs must formulate annual work plans and budgets, integrated into the facility's overall plan, to guarantee resources and guide activities.		MTC work plan and budget integrated into overall hospital plan/budget: Score 7 - Ensures MTC activities are recognized, prioritized, and adequately resourced. MTC has a work plan but no integrated budget: Score 3 - Planning exists but may lack guaranteed resources. No structured work plan or budget: Score 0 - Hinders effective planning and resource allocation.
Availability of Policies & Procedures (Operational & Clinical):	Max 6 points	MTCs develop and monitor policies and procedures for EMHS management and use (e.g., promotion, donations, procurement, accountability).		All key policies (EMHS use, National STGs, MTC guidelines, AMS, PV guidelines) in place: Score 6 - Provides necessary standards and benchmarks, guiding MTC operations and staff. Some policies missing: Score 3 - Can lead to inconsistencies, gaps in practice, and reduced effectiveness. Most/all policies missing: Score 0 - Indicates a weak regulatory framework, undermining MTC effectiveness

Domain 3: Antimicrobial Stewardship (AMS) & Appropriate Medicines Use (AMU) (Total Possible Score: 20)

This section measures the MTC's efforts in promoting rational medicine use and combating antimicrobial resistance.

Indicator	Scoring	Justification/ Reference	Score	Notes
Availability of AMS Guidelines:	Max 3 points	MTCs design and implement AMS activities, guided by the National Antimicrobial Stewardship Manual.		AMS guidelines are in place: Score 3 - Provides the necessary framework for promoting responsible antimicrobial use and combating AMR. AMS guidelines are not in place: Score 0 - Impedes effective AMS implementation
AMS Sub-committee Functionality:	Max 3 points	AMS is a core MTC subcommittee, working within the quality improvement framework to promote the AMS agenda.		Very functional: Score 3 - Ensures active management of antimicrobial use, including policy development, monitoring, and educational programs. Partially functional: Score 1 - Sub-optimal performance in key AMS activities. Available but not functional/Not in place: Score 0 - Critical gap in addressing AMR.

Conducting Surveys on Medicines Use and Stewardship (e.g., overuse of injectables/ antibiotics, recording administered medicines, overstock/ understock):	Max 3 points	MTCs assess medicine use through surveys (e.g., on overuse of injectables/ antibiotics) to identify problems. Overuse/misuse of antibiotics is a main driver of AMR.		Regularly (annually) conducted: Score 3 - Provides crucial data for identifying problems, evaluating prescribing patterns, and guiding targeted interventions. Irregularly conducted: Score 1 - Limits ability to track trends and evaluate interventions effectively. Not conducted: Score 0 - Lacks objective data to address medicine use problems.
MTC Interventions on Appropriate Medicine Use (through CMEs/ mentoring):	Max 3 points	MTCs conduct educational interventions to improve medicine use, aiming to inform and persuade prescribers, dispensers, and patients.		CMEs and mentoring activities regularly conducted: Score 3 - Key strategy to enhance knowledge, change behavior, and promote rational drug use. CMEs and mentoring activities irregularly conducted: Score 1 - May lead to sporadic improvements but lacks sustained impact. No such interventions: Score 0 - Failure to actively promote appropriate medicine use.
Monitoring of Medicines Use (General):	Max 4 points	MTCs monitor drug use and provide feedback to stakeholders, including supervising prescribing habits.		Consistently monitors prescriptions at OPD and adherence to STGs: Score 4 - Ensures compliance with guidelines, tracks changes, and allows for timely intervention. Monitors irregularly: Score 2 - Leads to missed opportunities for corrective action. Does not monitor: Score 0 - No oversight of medicine use practices, risking inappropriate use.
Presence and Use of Antibiograms:	Max 4 points	MTCs develop facility-based antibiograms to guide antibiotic selection and inform formulary decisions and standard treatment guidelines.		Facility-based antibiogram is developed and consistently used to guide antibiotic selection and formulary decisions: Score 4 - Provides evidence-based local data for optimizing antimicrobial use. Facility-based antibiogram is developed but used inconsistently or not regularly updated: Score 2 - Limits effectiveness in guiding appropriate antibiotic therapy. No facility-based antibiogram is developed or used: Score 0 - Antibiotic selection not guided by local resistance patterns, potentially contributing to inappropriate use.

Domain 4: Pharmacovigilance (PV) (Total Possible Score: 20)

This section assesses the MTC's role in monitoring drug safety and managing adverse events.

Indicator	Scoring	Justification/ Reference	Score	Notes
Availability of PV Guidelines:	Max 5 points	Pharmacovigilance "denotes the science and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other medicine-related problems". The PV subcommittee shall establish ADR databases.		PV guidelines are in place: Score 5 - Provides the framework for identifying, assessing, and preventing adverse events, crucial for patient safety. PV guidelines are not in place: Score 0 - Compromises the facility's ability to manage drug safety effectively
Pharmac-ovigilance Sub-committee Functionality:	Max 5 points	The PV sub-committee is a core MTC subcommittee with the mandate to ensure identification, management, and reporting of adverse events.		Very functional: Score 5 - Actively engages in detection, assessment, and management of ADRs/medication errors, directly contributing to patient safety. Partially functional: Score 2 - May result in underreporting or inadequate management of adverse events. Available but not functional/Not in place: Score 0 - Critical gap in the facility's drug safety system.
Reporting of All ADR/AEFI to NDA:	Max 5 points	Reporting all ADR/ AEFI to the National Drug Authority (NDA) is a key routine activity. All suspected adverse events should be reported to the National Pharmacovigilance Center (NPC).		Reports submitted as per target (monthly for hospitals): Score 5 - Vital for national drug safety surveillance, enabling early detection of safety signals. Reports submitted irregularly: Score 2 - Undermines accuracy and comprehensiveness of national pharmacovigilance data. No reports submitted: Score 0 - Compromises patient safety and public health surveillance.

Conducting Causality Assessment for Adverse Drug Events:	Max 5 points	Causality assessment to improve management of Adverse Drug Events is a key routine activity. The PV subcommittee should routinely conduct causality assessments for all ADRs and propose a management plan.		Regularly conducted (as per target): Score 5 - Allows appropriate management of ADRs and informs interventions. Irregularly conducted: Score 2 - May lead to missed opportunities for understanding and preventing ADRs. Not conducted: Score 0 - MTC cannot effectively learn from or prevent future adverse drug events.

Domain 5: Supply Chain Oversight (Total Possible Score: 20)

This section assesses the MTC's oversight and involvement in the efficient management of medicines and health supplies.

Indicator	Scoring	Justification/ Reference	Score	Notes
MTC Involvement in EMHS Selection/ Needs Analysis:	Max 4 points	MTCs develop and manage the institutional medicine list (selection component), including criteria for inclusion/exclusion, and advise on selection based on consumption/ morbidity.		Consistently involved (always): Score 4 - Ensures EMHS selection aligns with facility needs, national guidelines, and promotes cost-effective use. Sometimes involved: Score 2 - May lead to sub-optimal selection (shortages or overstocking). Not involved: Score 0 - Undermines rational medicine use and efficient resource allocation.
MTC Involvement in Procurement Planning & Quantification:	Max 4 points	MTCs develop evidence-based annual quantification and procurement plans, overseeing the process to align requirements with available budget.		Consistently involved (always): Score 4 - Ensures evidence-based, cost-effective procurement plans, preventing stock-outs and expiries. Sometimes involved: Score 2 - Can lead to inaccuracies in quantification or misallocation of budget. Not involved: Score 0 - Results in inefficient procurement and waste.

MTC Involvement in Reviewing Orders & Oversight of EMHS Use:	Max 4 points	MTCs periodically review facility warehouse orders and oversee EMHS use, implementing and performing systems and guidelines.		Consistently engaged (always): Score 4 - Ensures adherence to policies, prevents misuse, and promotes accountability. Sometimes engaged: Score 2 - May allow deviations or inefficiencies to go unaddressed. Not engaged: Score 0 - Increases risk of inappropriate medicine use, losses, and poor accountability.
MTC Produces Regular Reports on Stock Availability & Expiries:	Max 4 points	MTCs monitor and regulate EMHS availability, tracking, and accountability, receiving periodic updates on expired stock for analysis and corrective measures.		Consistently produces reports (always): Score 4 - Crucial for proactive inventory management, preventing waste, and timely redistribution. Sometimes produces reports: Score 2 - Limits ability to intervene promptly on stock issues. Does not produce reports: Score 0 - Indicates a significant gap in oversight and accountability.
Self-Audit for Stores and Stock Management:	Max 4 points	MTCs ensure traceability and proper stock management for EMHS, which involves tracking use and accountability for commodities.		Conducts self-audit regularly (bimonthly): Score 4 - Improves data quality, identifies discrepancies, and ensures proper stock-keeping practices. Conducts self-audit irregularly: Score 2 - May lead to undetected errors and inefficiencies. Does not conduct self-audit: Score 0 - Results in poor accountability and data inaccuracies.

Domain 6: Health Technologies Management (HTM) (Total Possible Score: 10)

This section assesses the MTC's oversight of health technologies, including medical devices and electronic systems.

Indicator	Scoring	Justification/Reference	Score	Notes
Health Technologies Sub-committee Functionality:	Max 5 points	The Health Technologies subcommittee is a core MTC subcommittee with the goal to ensure appropriate, cost-effective, safe, and functional equipment at minimal risk to users and patients.		Very functional: Score 5 - Ensures safe, effective, and efficient use of health technologies, impacting quality of care. Partially functional: Score 2 - May lead to sub-optimal management and associated risks. Available but not functional/Not in place: Score 0 - Indicates a critical gap in health technologies oversight
Functional Electronic Medical Record (EMR) System:	Max 5 points	The HTM subcommittee's scope includes software for health technologies management and ehealth/telemedicine, including Electronic Health and Medical Records.		Functional EMR system in place: Score 5 - Key technology for modern healthcare, improving data collection, analysis, clinical decision support, and overall efficiency. EMR system partial/non-functional or not in place: Score 0 - Significantly hampers data availability, traceability, and robust monitoring/ evaluation.

Annex 1.2: Model Terms of Reference for Medicines and Therapeutics Committees

Name	Medicine and Therapeutic Committee of..... (name of Health Facility)
Status/ accountability	The MTC is a standing health facility committee, established as per guidance of Ministry of Health, and accountable, through its chairperson, to the health facility director
Purpose/ mandate/ goal	The purpose/mandate of the MTC is to ensure the safe, effective and efficient management and use of medicine and health supplies in the facility under its jurisdiction.
Roles(aims) and responsibilities (strategies)	The roles of the MTC will be: • Evaluating and improving the clinical use of medicines • Developing and/or monitoring policies and procedures for management and use of medicines and health supplies • Developing and managing an institutional medicine list. • Setting (by developing or adopting) standards (policies, guidelines, standard operating procedures) which will serve as the criteria for appropriate performance • Assessing adherence to standards • Developing recommending and/or implementing interventions to improve practice.
Functions/ Objectives	Evaluating and improving the clinical use of medicines • Formulate, implement, and monitor policies and guidelines for appropriate use of medicine and supplies in the health facility • Develop, implement, and monitor the use of standard treatment guidelines • Assess medicine use through surveys and medicine use evaluations/ prescription audits to identify problems (prescriptions, administration, use, availability, etc.) • Conduct effective interventions to improve medicine use (educational, managerial, regulatory, and financial programs) • Conduct pharmacovigilance activities in the areas of medication errors, adverse drug reactions, treatment failures, drug quality • Design and implement antimicrobial stewardship activities • Advise medical, pharmacy, and administrative staff on appropriate medicine use • Conduct appropriate research on medicine use Developing and or monitoring policies and procedures for the management and use of medicines and health supplies • Regulate and monitor availability, tracking, and accountability of pharmaceuticals within the health facility • Analyze, monitor, and regulate expenditures on medicines to ensure cost-effective use of resources Develop and monitor policies and procedures on: • Pharmaceutical promotion • Medicine donations • Selection, quantification, procurement planning, storage, distribution, accountability systems,

Name	Medicine and Therapeutic Committee of..... (name of Health Facility)
Status/ accountability	The MTC is a standing health facility committee, established as per guidance of Ministry of Health, and accountable, through its chairperson, to the health facility director
Purpose/ mandate/ goal	The purpose/mandate of the MTC is to ensure the safe, effective and efficient management and use of medicine and health supplies in the facility under its jurisdiction.
Roles(aims) and responsibilities (strategies)	The roles of the MTC will be: • Evaluating and improving the clinical use of medicines • Developing and/or monitoring policies and procedures for management and use of medicines and health supplies • Developing and managing an institutional medicine list. • Setting (by developing or adopting) standards (policies, guidelines, standard operating procedures) which will serve as the criteria for appropriate performance • Assessing adherence to standards • Developing recommending and/or implementing interventions to improve practice.
Functions/ Objectives	Evaluating and improving the clinical use of medicines • Formulate, implement, and monitor policies and guidelines for appropriate use of medicine and supplies in the health facility • Develop, implement, and monitor the use of standard treatment guidelines • Assess medicine use through surveys and medicine use evaluations/ prescription audits to identify problems (prescriptions, administration, use, availability, etc.) • Conduct effective interventions to improve medicine use (educational, managerial, regulatory, and financial programs) • Conduct pharmacovigilance activities in the areas of medication errors, adverse drug reactions, treatment failures, drug quality • Design and implement antimicrobial stewardship activities • Advise medical, pharmacy, and administrative staff on appropriate medicine use • Conduct appropriate research on medicine use Developing and or monitoring policies and procedures for the management and use of medicines and health supplies • Regulate and monitor availability, tracking, and accountability of pharmaceuticals within the health facility • Analyze, monitor, and regulate expenditures on medicines to ensure cost-effective use of resources Develop and monitor policies and procedures on: • Pharmaceutical promotion • Medicine donations • Selection, quantification, procurement planning, storage, distribution, accountability systems,

	• Prescription, dispensing, administration of medicines e.g. restrictions and permissions for different cadres • Expiries and disposal of medicines and supplies Developing and managing an institutional medicine list • Develop criteria for inclusion and exclusion of essential medicines and health supplies onto the IML • Develop and review an institutional medicines list (IML) based on the national EMHSLU • Develop a facility-based antibiogram to guide antibiotic selection
Compositions	The committee will be composed of members representing the following department/cadres: • Pharmacy/store • Clinical services (specialists, medical officers and clinical officers) • Nursing (including midwives) • Laboratory • Biomedical Engineers • Administration • Records • Community/public health • Community representative (optional) The number of members will be between 12 and 15. Additional members can be co-opted by MTC or sub-committees if deemed necessary for specific matters. These members will not have voting power.
Appointment of members, terms of membership, and termination	The health facility director/administrator will appoint a chairperson. Heads of department will nominate prospective members, the chairperson shall then recommend, and the health facility director/administrator will appoint them in writing, to ensure adequate representation and commitment. The head of pharmacy is an ex-officio member and the secretary of the committee except otherwise recommended by the chairperson. The head of the store is also an ex-officio member. MTC members do not have necessarily to be heads of departments, but they will ensure representation and feedback communication between MTC and respective departments. The duration of membership will be of 3 years, and it can be renewed. Members who wish to resign will do so by written communication to the health facility Administrator/Director through the chairperson. The Chairperson may resign by a written communication to the health facility Administrator/Director. Termination will happen in the following situations: • Members no longer available (transferred, retired, study leave etc.) • Members not holding anymore the position in virtue of which he/she was appointed • Absence without apology for 3 or more consecutive meetings • Behavior detrimental to the aims and objectives of the committee (e.g. conflict of interest). The chairperson, supported by elected members, will investigate any wrongdoing or misconduct by members.

	Proposal for termination or suspension will be advanced by the chairperson and confirmed in writing by the health facility Administrator/ Director. Vacancies occasioned will be reviewed in line with the skill base requirements and additional appointments be made when necessary.
Portfolio holders and functions	Chairperson The chairperson will be a (senior) clinician appointed by the health facility Administrator/Director. The chairperson will nominate a deputy chairperson from among the MTC members. The chairperson will be responsible for: • Setting agenda in collaboration with the secretariat • Call the meetings as per agreed schedule • Chair and moderate the meeting, guide decision-making • Review and endorse minutes and MTC reports • Report to health facility Administrator/Director • Facilitate and monitor the implementation of decisions and interventions. Secretary: The head of pharmacy will, by default, be the committee secretary except if otherwise directed by the health facility Administrator/ Director. He/she will nominate a deputy preferably from the pharmacy/store staff. Secretariat The pharmacy/store department will constitute the secretariat The secretariat will be responsible for: • Organizing meetings (sending invitations at least 1 week in advance and reminder 2 days before, preparing materials, arrange for logistics etc.) • Setting agenda in collaboration with chairperson • Compile draft minutes and reports, submit to chairperson for review and disseminating them for review and action within 72 hours from the meeting. Comments and corrections should be sent back within a week. • Follow up implementation of actions by the persons/subcommittees responsible and informing the chairperson of progress and challenges • Liaising with the MOH technical department in charge (Pharmacy department). Executive The chairperson, secretary and deputies will constitute the executive committee. The executive subcommittee will be responsible to handle relationship with administration and to address and respond to urgent matters, byattending the request if possible (and ratify action at next MTC meeting) or by calling an emergency meeting.

Subcommittee(s)	The following subcommittees are recommended: • Supply chain and logistics • Antimicrobial stewardship • Pharmacovigilance (a focal person is acceptable in smaller settings). • Health technologies • Sub committees will be chaired by an MTC member, as by decision of the plenary. Other subcommittees can be formed ad hoc, on a temporary or permanent basis, by deliberation recorded in the minutes of the committee itself (e.g., survey committee, education and training, etc.). Subcommittees will be the action arms of the MTC, will implement action decided during the MTC plenary (surveys, interventions, etc.) and report to the plenary as required
Meetings (number conducting meetings, minutes, agenda standing items)	The frequency of meetings will be at least bi-monthly, according to an annual schedule included in the health facility's annual work plan. The executive committee can call emergency meetings. Invitations should be sent at least one week before the meeting, and the agenda and materials should be shared at least three days before. Appointed members are expected to attend in-person; substitutions are not acceptable. Apologies must be submitted at least 24 hours before the meeting. The agenda will be set by the secretary and chairperson and will include, among others: • Updates from executive committee • Follow up of previous decisions and issues and signing of minutes • Logistics/supply chain reports • Updates from other subcommittees
Decision making	• Quorum will be set at 50% of the members. • Decision will be taken by consensus. If no consensus can be reached, voting by show of hands will be held. All MTC members will have a vote. The majority will be half of the total number of members (including absent) plus 1. • Decisions from MTC will take the form of recommendations to the management. Management will have to endorse and either implement or grant MTC the authority to implement.
Reports and communication	The chairperson with the secretary will be responsible for reporting to the health facility Administrator/Director, and the secretariat will be responsible for sharing minutes and reports with the relevant MOH department. It is recommended to adopt a summarized format for reporting to the director (attached).

Performance monitoring and evaluation	Communication with the other staff of the health facility will happen through memos, information sheets, and feedback meetings. The MTC will compile an annual self-assessment according to the MOH standard format and share it with the health facility Administrator/Director and the relevant MOH department. The health facility Administrator/ Director will include MTC performance as a performance indicator in the health facility's annual report. The relevant MOH department will be responsible for technically supervise and assess MTC performance.
Code of contact, conflict of interest, confidentiality, transparency	MTC members will uphold their respective professional Code of Conduct in conducting MTC business. Members will ensure there is no conflict of interest by signing a declaration (format attached) and commit to transparency (within the health facility and MOH system) and confidentiality (in relation with structures and individuals outside the health facility) in conducting MTC business. Any influence or undue relationship with the pharmaceutical industry should be avoided, and selection and procurement decisions will be bound to confidentiality within the health facility. Communications with the rest of the health facility must occur through approved channels (memos, feedback meetings).
Resources and finances	MTC is a standing committee of the health facility; therefore, funds for MTC routine operations should come from the health facility budget. When possible, donors/IP/MOH may support refreshments, stationery and communication costs, training and workshops or any other activity deemed necessary for MTC business. Service as MTC members is part and parcel of the professional tasks as a health worker and should not routinely attract additional remuneration.

Annex 1.3: Approval of Terms of Reference of the health facility Medicines and Therapeutics Committee

The terms of reference of the MTC were duly adopted at the meeting of the MTC on the..... (day) of.....(month).....(year)

Signed by:

.....

MTC Chairperson Date

Approved by:

.....

Health Facility Administrator/Director Date

Witnessed by:

.....

Secretariat Date

Annex 1.3: Approval of Terms of Reference of the health facility Medicines and Therapeutics Committee

The terms of reference of the MTC were duly adopted at the meeting of the MTC on the..... (day) of.....(month).....(year)

Signed by:

.....

MTC Chairperson Date

Approved by:

.....

Health Facility Administrator/Director Date

Witnessed by:

.....

Secretariat Date

Annex 1.4: EXAMPLE OF A DECLARATION OF INTEREST FORM

Name..... Position.....

Have you, or anyone in your family, any financial or other interest in any pharmaceutical manufacturer or supplier, and which may constitute a real, potential or apparent conflict of interest?

Please tick

Have you had, during the past 4 years, any employment or other professional relationship with any organization that is a pharmaceutical manufacturer or supplier or represent such organization?

Please tick

If you answered "yes" to either question, please give details in the space below:

Name of MTC:
Date of meeting:
List of attendees;
Apologies
1. Resolutions
2. Actions implemented (findings, corrective interventions developed, and results)
3. Unresolved matters that need input, consultation or further discussion
4. ADR reporting and product quality issues
5. Top expenditure items (from ABC analysis)
6. Report of expired medicines
7. Interventions undertaken to support appropriate medicines use

NB: Please include a copy of the MTC meeting minutes with this report. Please submit this report to the Director and the Appropriate Medicines Use Unit- Department of Pharmaceuticals and Natural Medicines, MoH

Annex 1.6: Template work plan for Medicines and Therapeutics Committees and example

Work plan Template

Area	Activity	Resources	Responsible persons	Timeline/ period	Expected output/ outcome
MTC operations (meetings, trainings…)					
Surveys/ reports					
Interventions/ actions					

Example of a work plan for Medicines and Therapeutics Committees

Area	Activity	Resources needed	Responsible persons	Timeline	Expected output/ outcome
MT operations	Adopting the terms of reference (TOR) Appointment of MTC members	Stationery Refreshments MTC manual	Chairperson MTC	By October 2025	Approved terms of reference (TOR) List of appointed MTC members
	Conduct MTC meetings	Stationery refreshments Communication costs	Secretary	Bi-monthly	Meetings held as per work plan
	Conduct sub-committee meetings	As above	Sub-committees' heads	As needed	Meetings held as per plan
	Conduct trainings of MTC members	Transport and accommodation costs refreshments	Secretary and chairperson (to liaise with MOH and IPs)	As needed	At least half of MTC members trained
Surveys/ reports	Write quarterly medicines and supplies expiry reports	Staff time Stationery Refreshments	Chair, supply chain/logistics subcommittee	End of each quarter	Report compiled and discussed
	Write quarterly medicines and supplies availability reports	Staff time Stationery Refreshments	Chair, supply chain/logistics subcommittee	End of each quarter	Report compiled and discussed
	Write bimonthly reports on medicines and supplies ABC and VEN analysis	Staff time Computer Refreshments	Chair, supply chain/logistics subcommittee	beginning of each order cycle	Bimonthly ABC VEN analysis presented and discussed in MTC
	Artemisinin Combination Therapy (ACT) medicines use evaluation (MUE) in OPD	Staff time Stationery Refreshments	representative of OPD (or any OPD staff) and record officer	End of June End of December 2025	Survey undertaken and discussed for root cause analysis
	Ceftriaxone tracking and MUE	Staff time Stationery	Head of clinical services and of nursing	March 2018	Survey undertaken and discussed for root cause analysis
	Prescription audit on surgical prophylaxis in Cesarean section	Staff time Stationery	Senior midwife and obstetrician	June 2025	Survey undertaken and discussed for root cause analysis

Interven-tions/ actions	Revision Institutional Medicine List	Staff time Stationery	Head of pharmacy and chairperson	October 2025	Revised list approved by director
	IP pharmacy implementation	Room, shelving	Head of pharmacy	December 2025	IP pharmacy functional
	Procurement plan	Staff time Stationery	Head of pharmacy/ store	March 2025	Plan approved by …
	Policy on donations	Staff time Stationery	Senior dispenser (to liaise with MOH)	June 2025	Policy officially adopted
	Malaria intervention in OPD/IP	Staff time Stationery	As per emerging findings	June 2026	Intervention planned and started (as per findings from surveys)

Annex 3.1 Definitions in Pharmacovigilance

Term	Definition
Adverse Drug Reaction (ADR)	A response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.
Adverse event	Any unpleasant medical occurrence that may present during drug treatment with a medicine, but which does not necessarily have a causal relationship with this treatment.
Adverse event following immunization (AEFI)	Any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.
Counterfeit	Medicine that is deliberately or fraudulently mislabeled with respect to source or identity. Counterfeit products may include products with the correct ingredients or those with the wrong ingredients, those without active ingredients, or those with fake packaging.
Drug interaction	An event where one drug or any other chemical substance alters the pharmacological effect of another drug.
Drug or medicine	A pharmaceutical product, used in or on the human body for the prevention, diagnosis or treatment of disease, or for the modification of physiological function.
Drug resistance	Reduction in the effectiveness of a medication when used at the recommended therapeutic doses. It occurs mostly with anti-microbial agents whereby microbes tend to survive even in the presence of a drug that would normally kill them or inhibit their growth.
Medication error	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.
Quality Defects	These are attributes of a medicinal product which may affect the quality, safety and/or efficacy of the product, and/or which are not in line with the approved Product Authorization.
Serious Adverse Drug Reaction	Any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistence of significant disability or incapacity, or is a congenital anomaly/birth defect.
Side effect	Any unintended effect of a pharmaceutical product occurring at doses normally used in man, which is related to the pharmacological properties of the drug.
Substandard medicine	A genuine, authorized medical product that fails to meet the quality specifications acceptable as per national standards. Therefore, their composition or ingredients may not meet specifications; and consequently, they may be dangerous to the patient.
Therapeutic failure	Therapeutic failure is failure to accomplish goals of treatment resulting from inadequate or inappropriate drug therapy and not related to natural progression of the disease.
Unexpected Adverse Drug	ADR whose nature or severity isn't consistent with the applicable product information.
Vaccine	A biological preparation that improves immunity to a particular disease.

Annex 3.2: Adverse Reaction Report/Adverse Event Following Immunization Form

1.0 Type of Report

Initial ☐ Follow up ☐ | Serious ☐ Not Serious ☐ | Drug ☐ Vaccine ☐

2.0 Patients Information

Patient ID/initials: _____ Gender: Male ☐ Female ☐ Weight (kg)_____ Pregnancy status Yes ☐ No ☐ N/A ☐ If No, LNMP_____

Full address_____ Telephone Number _____

Date of birth :_ _/ _ _/_ _ (dd/mm/yyyy) OR *Age at onset:*_____ Medical History _____

3.0 Vaccine (s) Information

Vaccine						*Diluent (if applicable)*			
Name of vaccine	Date of vaccination	Time of vaccination	Dose (1st, 2nd, 3rd etc)	Batch/Lot Number	Expiry date	Name of diluent	Batch/Lot Number	Expiry date	Date and time of reconstitution

4.0 Medical Product Details (List of all medicines used in the last 3 months-including herbal medicine)

Generic Name	Brand name	Batch no	Route, Dose and frequency	Date started	Date stopped	Indication	Tick suspected medicine

5.0 Brief description of the ADR/AEFI and any treatment given

5.1 Description of the AEFIs*(for vaccines)*

Severe local reaction > 3 days ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Generalized urticaria (hives) ☐ Injection site abscess ☐ High fever ≥ 38°C ☐

Other (specify) _____

P.T.O

Date of ADR/AEFI onset: _ _/_ _/_ _ _ _ Time of onset: _____ Date ADR/AEFI stopped: _ _/_ _/_ _ _ _

6.0 Relevant Laboratory test results

6.1 Reason for seriousness

Prolonged hospitalization ☐ Congenital anomaly ☐ Disability ☐ Death ☐ Life threatening ☐

6.2 Action taken

Drug withdrawn ☐ Dose increased ☐ Dose reduced ☐ Dose not changed ☐ Not applicable ☐ Unknown ☐

6.3 Outcome

Recovered ☐ Recovering ☐ Continuing ☐ Recovered with sequelae ☐ Not recovered ☐ Death ☐ Unknown ☐

6.4 Causality of the ADR/AEFI

Certain ☐ Probable/ Likely ☐ Possible ☐ Unlikely ☐ Unclassifiable ☐

7.0 Reporter details

Name of reporter:	Email Address /Contact: Designation:	Date of reporting
Institution/Health facility:		District:

7.1 Administrative details

Report title:	Form ID number:	Date received:

SUSPECTED ADR/AEFI REPORTING FORM

Note: Reporters and patients identity are held in strict confidence by NDA and protected to the fullest extent of the law

Guidance on reporting

Brief description of the ADR/AEFI and any treatment given (cont'd)

What to Report

Report all adverse drug reactions/events suspected both serious and those that are not serious
Report any adverse reaction or AEFIs even if you are not certain the product caused the event.

When to Report

For serious ADRs within 24-48 hrs.' of notification
For AEFIs report immediately you are notified
For non-serious events as soon as possible but not later than 15 days.

Who Is to Report

- All Healthcare Providers should report as part of their professional responsibility any suspected adverse drug reactions and AEFIs.

Where to Report

- Reports should be sent to the National Drug Authority
- Reports can also be sent to the national AEFI committee

How to Report

- Fill in the sections that apply to your report
- Start date of administration for the suspected drug and the date when the suspected reaction occurred.

Detection of ADR/ AEFIs in a Patient

Follow the following steps

- Take proper history and conduct proper examination of the patient.
- Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised.
- Verify that the onset of the suspected ADR was after the drug was taken, not before and discuss carefully the observation made by the patient.
- Determine the time interval between the beginning of drug treatment and the onset of the event.
- Evaluate the suspected ADR after discontinuing the drugs or reducing the dose and monitor the patient's status (De- challenge).
  If appropriate, restart the drug treatment and monitor recurrence of any adverse events (Re- challenge).
- Analyze the alternative causes (other than the drug) that could on their own have caused the reaction.
- Use relevant up-to date literature and personal experience as a health professional on drugs and their ADRs and verify if there are previous conclusive reports on this reaction.

Please note that submission of a report doesn't imply that the health worker or the product caused or contributed to the adverse event.

WHO-UMC causality assessment scale

Causality Term	Assessment
Certain	• Event of laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically *(i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon)* • Rechallenge satisfactory, if necessary.
Probable	• Event or laboratory test abnormality, with reasonable time relationship to drug intake. • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required.
Possible / likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drugs withdrawal lacking or unclear.
Unlikely	• Event or laboratory tests abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations.
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper, assessment needed or • Additional data under examination.
Not assessable / unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because of insufficient or contradictory information • Data cannot be supplemented or verified.

Confidentiality

All information pertaining to the reported event should at all times be treated in confidence and protected from an authorized access transmission of use.

Market Product complain form

	National Drug Authority Plot No. 19 Rumee Towers Lumumba Avenue, Kampala, Uganda. email: ndaug@nda.or.ug; website: www.nda.or.ug +256-791415555; Uganda National Drug Authority	The Republic of Uganda Ministry of Health
	Market Complaint Report Form – Part 1	Page 1 of 1
Complaint Number *(To be inserted by NDA)*	**Date complaint received at NDA** *(To be inserted by NDA)*	

1.0	**LOGGING IN OF THE COMPLAINT** *(To be completed by client/customer/stakeholder/interested party/anybody)*	
1.1	**Name of complainant**	**1.2 Designation / Occupation**
1.3	**Name of institution:**	
1.4	**Location address:**	
1.5	**Tel. No.:**	**Email address:**
1.6	**Type of Complaint:** *(Check whichever is applicable by double clicking on the box)* **Drug Product Complaint** ☐ **Complaint about NDA** ☐ **Other** ☐ *(Please Specify)*	
1.7	**Nature of product complaint** *(Check whichever is applicable)* Quality ☐ Suspected Counterfeit ☐ Efficacy ☐ Expired ☐ Labelling ☐ Packaging ☐ Other ☐ *(Please Specify)*:_____	
1.8	**Product Category** (Check whichever is applicable) Drug ☐ Herbal Medicine ☐ Sundries ☐ Medical Device ☐ Other ☐ *(Please Specify)*	
1.9	**Product Details** *(Please fill whichever applies)*	
	Name of Product:	Batch/Lot No:
	Manufacturing Date: / Expiry date:	Dosage Form:
	Name of manufacturer: Address:	
1.10	**Name & Address where product was obtained or bought**	
1.11	**Description of the complaint** *a) Provide as much information as possible about the complaint and attach any available relevant information.* *b) Continue to the back of this page if you need more space.* *c) If complaint is about a product, provide a sample of the product or send a photograph on the WhatsApp number shown above.*	
1.12	**Complaint Delivered to NDA Offices via** *(Check whichever is applicable)* Hand ☐ Email ☐ Telephone ☐ WhatsApp ☐ NDA Staff ☐ Feedback box ☐	
1.13	**Have you logged a complaint about this issue before:** YES ☐ NO ☐	
1.14	**If YES, when?**	

Note: This form is also available online at: https://www.nda.or.ug/?ddownload=5172

Annex 4.1: 6-month availability/stock out report and stock status for tracer items

Item	Unit	Period in days	Days out of stock (from stock card)	Stock out rate (% of days items stocked out)	Days product available	Availability (% time item available)	AMC	Stock at hand (in units)	Months of stock at hand
A	B	C	D	E=(D/C) *100	F= C- D	G=F/C *100	H	I	J=I/H
ACT 100/20 mg	24 x 30	180	0	0%	180	100%	198	1889	9.5
Artesunate inj	Vial	180	21	12%	159	88%	2400	6300	2.6
mRDT	test	180	0	0%	180	100%	12	671	57.1
Amoxicillin 250	tin of 1000	180	61	34%	119	66%	107	169	1.6
Ceftriaxone 1 gr inj	vial	180	64	36%	116	64%	2618	5900	2.3
Oxytocin injection	amp	180	0	0%	180	100%	6	146	23.1

Here is the explanation of the table above:

Columns A and B: name and unit of the product. The list of items is chosen based on the items that the MTC considers a key priority for their facility, based on national-level interests, or even just the "A" medicines from ABC analysis (See Chapter 5). A computerized inventory system would be able to produce such a report for all the items, but it may not be necessary to know the availability/ stock out rates and available stock for every single product.

Column C: period considered (in days). It could be a standard 3-6-12-month period (90, 180, 365 days) or any other chosen period of interest. Of course, an electronic store management system will offer a wider choice of manipulation of data.

Column D: days out of stock. In pharmaceutical management, this usually refers to the days in which the STORE was out of stock, even though some departments may still have some stock.

Column E: % days the product was out of stock. If the stock-out rate is 0%, it means the items have always been available.

Column F: days the product was available. This is calculated as: total days considered minus days out of stock

Column G: % time product was available, that is (days available/total days) X 100. If a product is available 100% of the time, it means it was never out of stock. If availability is 50%, it means half of the time it was out of stock.

Column H: Average Monthly Consumption (AMC). This is calculated typically based on the consumption of the previous 3 months corrected for stock-outs (see next paragraph) – but longer periods can be used.

Column I: Current stock at hand in units (vials, or tins): This is what is physically available in the store obtained after a physical count or what is written on the stock card as present in the store can be used.

Column J: Months of Stock (MoS): This is obtained by dividing your current stock at hand by the average monthly consumption and gives you an indication of how long your current stock will last – assuming a stable consumption rate. Be sure to use the same unit as the stock at hand.

Examples of stock report for 3 hospitals for a selected number of vital items is presented below

Item	Unit	HOSPITAL 1		HOSPITAL 2		HOSPITAL 3	
		Availability (% time item available)	Stock at hand Dec24 in MoS	Availability (% time item available)	Stock at hand Dec24 in MoS	Availability (% time item available)	Stock at hand Dec24 in MoS
ACT 100/20 mg	24x 30	100	3.7	100	15.3	100	21.6
Artesunate inj	Vial	100	9.1	87	2.6	80	30.6
ORS with zinc	sachet	100	3.6	100	missing data	52	1.1
mRDT	test	100	1	100	57.1	98	8.8
Amoxicillin 250	tin of 1000	100	9.5	63	1.6	79	0.6
Ceftriaxone 1 gr inj	vial	100	9.1	61	2.3	93	3.4
Oxytocin injection	amp	100	3.7	100	23.1	88	3.5
Bendrofluazide 5 mg	tin of 1000	100	15.3	100	58.1	Data not available	Data not available
Nifedipine 20 mg tab	pack of 100	100	30.7	70	1.8	61	0.6
Metformin 500 mg tab	Pack of 100	100	4.5	100	3.2	47	0.7
Glibenclamide 5 mg tab	Pack of 100	100	18.8	100	6	28	0.2
Insulin Mixtard	Vial	100	0	38	0.4	84	1.1
Insulin short acting	vial	100	Data not available	70	7.7	Data not available	Data not available
Gentamycin inj	pack of 100	100	12.2	67	1.1	77	6.9
Dextrose 5%	Pack of 24	Data not available	Data not available	100	1.9	84	2.8
Normal Saline	Pack of 24	Data not available	Data not available	100	2.6	92	2.3
Ampicillin 500mg inj	Pack of 10	100	9.2	72	1.5	84	2.1
GLOVES 7.5	50 Pairs box	100	8.9	73	1.2	86	2.9

Comments:

- Hospital 1 has 100% availability for all commodities assessed (except IV fluids because stock cards were not updated). Several commodities are overstocked, including antibiotics and medicines for Non-Communicable Diseases (NCD). Only insulin Mixtard is out of stock at the period of reporting and mRDT is understocked.
- Hospital 2 has suboptimal availability of antibiotics – with corresponding low stocks, and of insulin Mixtard, gloves, and nifedipine, but it is overstocked with mRDT, ACT, bendrofluazide, and oxytocin.
- Hospital 3 has sub-optimal availability (and corresponding understocking) of NCD commodities, and ORS. It is overstocked with malaria commodities.
- All three 3 hospitals have problems with insulin Mixtard while generally, malaria commodities tend to be overstocked.

Based on such reports, the MTC can investigate further the reasons for under and overstocking (unfulfilled orders, changes in consumptions, misuse, change in patients' load or in protocols, etc.) and take corrective action for example by:

- Redistributing overstocked items at risk of expiry
- Reviewing orders for understocked commodities
- Adjusting consumptions if inappropriate use is the cause.

Stock Management Audit

SECTION A: HEALTH FACILITY DETAILS

Date of Visit

yyyy-mm-dd

region

- ◯ Acholi
- ◯ Ankole
- ◯ Bugisu
- ◯ Bukedi
- ◯ Bunyoro
- ◯ Busoga
- ◯ Kampala
- ◯ Karamoja
- ◯ Kigezi
- ◯ Lango
- ◯ North Central
- ◯ South Central
- ◯ Teso
- ◯ Tooro
- ◯ West Nile

district

subcounty

facility

Level of Care

- ◯ Hospital
- ◯ HC IV
- ◯ HC III
- ◯ HC II
- ◯ Clinic
- ◯ N/RRH

Ownership

- ◯ Government
- ◯ PNFP
- ◯ PFP

Warehouse

- ☐ National Medical Stores
- ☐ Joint Medical Stores
- ☐ Medical Access Uganda Limited (MAUL)

SECTION B: STOCK MANAGEMENT

basket

- ◯ ARV
- ◯ EMHS
- ◯ LAB
- ◯ RMNCAH
- ◯ TB

commodity

Is the item available?

- ◯ Yes
- ◯ No
- ◯ N/A

Is there any expired quantity of this item in stock?

- ◯ Yes
- ◯ No
- ◯ N/A

Is the stock card/ledger book available?

- ◯ Yes
- ◯ No

Is physical count done every month and PC marked in stock card (check 3 months)?

- ◯ Yes
- ◯ No

Is the card filled correct with name, strength, dosage form, AMC, special storage?

- ◯ Yes
- ◯ No

Record the balance according to stock card

.....

Count and record the quantity of medicines in stock (PC)

.....

Does stock card balance & PC agree 100%?

- ◯ Yes
- ◯ No

Is the stock book in use?

- ◯ Yes
- ◯ No

Is the stock book correctly used? (all fields filled , with entry each month for each medicine)

- ◯ Yes
- ◯ No

Record the facility calculated Average Monthly Consumption (AMC) or mark NR

Record the quantity issued in the last 3 months (from the day of survey)

Record the number of days out of stock in the last 3 months (from the day of survey)

Is the calculated AMC the same as the recorded plus or minus 10%?

◯ Yes ◯ No

Comments

SECTION C: Commodity Traceability from Store to Patients

Select Item *

◯ Artemether Lumefantrine tabs *24 ◯ Ceftriaxone injection ◯ Determine HIV Strips

» Quantity issued from store to service points in the last one month (use stock cards or eLMIS)

OPD (all clinics) *

Maternity *

Total Quantity issued from store to service points:NaN

» Quantity issued to patients in the last one month (Consumption log or eLMIS)

OPD (all clinics) *

Maternity *

Total Quantity issued to patients:NaN

Comments

VARIANCE

Variance at OPD: NaN

Variance at Maternity: NaN

Comments

Annex 8.1: Template for application form for addition or deletion of a product in IML/EML

Applicant name	Title	Department
Signature	Date	
1) Name/strength and formulation of product		
2) Is the product in the updated Essential Medicine and Health Supply List of Uganda?		
3) If not, is the product in the updated WHO Essential Medicine List?		
4) If not, what is the document of reference?		
5) Proposed indication for use		
6) Pharmacological properties (mode of action, contraindication, side effects, interactions)		
7) Are there standard prescribing guidelines (if yes, attach)		
8) Are there restrictions for prescribing? If yes, specify		
9) Explain why it is better than the current therapy (e.g. treatment for disease for which no treatment was available, or more cost-effective treatment compared to current one). Attach references.		
10) Does it replace any other treatment?		
11) What is the cost of the product and per course of treatment?		
12) Specify the VEN classification of the item added/ deleted		
13) Estimated number of patients needing that medicine per year and estimated total expenditure per year		

Annex 9.1: ABC VEN

No	Description	VEN	UNITS	PRICE	QTY	TOTAL	%	CUM
1	Sodium chloride/normal saline 0.9% infusion	V	24	28,512	1,06	30,422,30	12%	12%
2	Ceftriaxone sodium 1g powder for inj.vial	V	1	1,082	25,8	27,923,34	11%	22%
3	Metronidazole 500mg/100ml infusion	V	1	902	17,3	15,606,67	6%	28%
4	Amoxicillin 250mg capsule	V	100	43,200	325	14,040,00	5%	34%
5	Bupivacaine hcl 0.5% in dextrose 8.0% inj solution, 4ml	V	20	128,304	96	12,317,18	5%	38%
6	Sodium (ringers) lactate compound infusion	E	24	25,920	415	10,756,80	4%	42%
7	Paracetamol 500mg tablets	E	100	12,420	787	9,774,540	4%	46%
8	Isoflurane 250ml inhalation	V	1	119,611	81	9,688,505	4%	50%
9	Ferrous sulphate/fumarate 150-200 mg+folic acid 0.25	V	100	16,916	490	8,289,056	3%	53%
10	Glucose (dextrose) 5% infusion 500ml	V	24	35,640	211	7,520,040	3%	56%
11	Co-packaged ors and zinc tablets	V	1	1,925	3,28	6,329,729	2%	58%
12	Suxamethonium chloride 100mg/2ml injection	V	100	194,556	32	6,225,777	2%	61%
13	Insulin mixtard human 100iu/ml	V	1	14,295	420	6,004,030	2%	63%
14	Metronidazole 200mg tablet	V	100	12,402	464	5,754,755	2%	65%
15	Rabies vaccine + solvent 0.5ml inj 1 dose	V	1	26,127	220	5,747,986	2%	67%
16	Ampicillin 500mg powder for reconstitution	V	100	40,860	139	5,679,534	2%	69%
17	Magnesium sulphate 50% 5ml inj	V	1	5,781	840	4,855,990	2%	71%
18	Halothane inhalation 250ml	V	1	102,002	45	4,590,098	2%	73%
19	Lidocaine hcl 2% injection	V	1	2,357	1,92	4,536,359	2%	75%
20	Midazolam 5mg/ml injection 3ml ampoule	E	1	72,360	58	4,196,880	2%	76%
21	Water for injection 10ml	V	100	8,640	428	3,697,920	1%	78%
22	Ephedrine 30mg/ml 1 ml ampoule	E	10	38,835	75	2,912,592	1%	79%
23	Oxytocin 10iu/1ml injection	E	100	20,527	124	2,545,296	1%	80%
24	Salbutamol nebuliser 5mg/2.5ml vial	N	10	27,659	91	2,516,978	1%	81%
25	Paracetamol 125mg suppositories	E	5	4,897	436	2,135,201	1%	82%
26	Ciprofloxacin 500mg tablet	V	100	9,358	210	1,965,195	1%	82%

27	Hydrocortisone sodium phosphate 100mg injection	V	50	67,203	29	1,948,893	1%	83%
28	Glucose 50% injection 100ml	V	1	1,492	1,20	1,790,844	1%	84%
29	Insulin soluble, neutral, human 100iu/ml inj sc	V	1	13,565	130	1,763,386	1%	84%
30	Griseofulvin 500mg tablet	N	100	22,012	80	1,760,939	1%	85%
31	Tetracycline 1% eye ointment 3.5g tube	V	1	1,128	1,44	1,623,629	1%	86%
32	Diazepam 2.5mg suppositories	V	5	18,116	80	1,449,260	1%	86%
33	Nifedipine retard 20mg tablet	E	100	2,209	610	1,347,661	1%	87%
34	Dexamethasone 4mg/ml 1ml,2ml ampoule	E	100	74,398	18	1,339,173	1%	87%
35	Gentamycin 80mg/2ml inj iv/im	V	100	13,304	97	1,290,511	0%	88%
36	Metformin hcl 500mg tablet	V	100	3,076	405	1,245,646	0%	88%
37	Betamethasone+neomycin 0.1%+0.5% eye drops 10ml	E	1	918	1,21	1,110,780	0%	89%
38	Vitamin k1 (phytomenadione) 10mg/ml inj im	E	1	1,167	930	1,084,864	0%	89%
39	Epinephrine (adrenaline) 1mg/ml inj iv/im/sc	V	100	88,227	12	1,058,725	0%	90%
40	Timolol maleate 0.5% eyedrops in 5ml	N	1	9,180	113	1,037,340	0%	90%
41	Ketamine 500mg/10ml injection iv/im	V	5	12,265	83	1,018,017	0%	90%
42	Insulin isophane human 100iu/ml inj sc	V	1	13,268	75	995,099	0%	91%
43	Diclofenac sodium 75mg/3ml injection	V	100	12,853	77	989,700	0%	91%
44	Pyrimethamine 25mg+sulfadoxine 500mg tablet	V	100	108,000	8	864,000	0%	91%
45	Pethidine 100mg/2ml inj iv/im/sc	V	10	25,627	32	820,072	0%	92%
46	Amitriptyline 25mg tablet	V	100	15,552	50	777,600	0%	92%
47	Mebendazole 100mg tablets	E	100	9,927	78	774,318	0%	92%
48	Amlodipine 5mg tablets	E	100	3,456	200	691,200	0%	93%
49	Cotrimoxazole 480mg tablet	V	100	30,102	22	662,238	0%	93%
50	Folic acid 5mg tablet	N	100	14,580	45	656,100	0%	93%

51	Tobramycin+ dexamethasone eye drops; 0.3%+0.1%,	N	1	11,294	58	655,078	0%	93%
52	Trifluoperazine 5mg tablet	E	100	91,443	7	640,103	0%	94%
53	Glibenclamide 5mg tablet	V	100	2,643	220	581,497	0%	
54	Furosemide 20mg/2ml inj im/slow iv/ivinf	V	100	19,899	29	577,085	0%	
55	Cis-atracurium injection 2mg/ml 10ml vial	E	5	282,960	2	565,920	0%	
56	Cefotaxime sodium powder for injection 1gm vial	E	1	11,165	50	558,253	0%	
57	Chloramphenicol sodium succinate 1g injection	V	50	56,900	9	512,100	0%	
58	Anti d immunoglobulin 300mcg/ml	V	1	170,373	3	511,119	0%	
59	Dapsone 100mg tablet	V	100	49,279	10	492,786	0%	
60	Amoxicillin dispersable tablets 250mg	V	100	6,480	75	486,000	0%	
61	Nitrous oxide gas	E	1	1,620,0	0	486,000	0%	
62	Fentanyl citrate injection 50mcg/ml 2ml amp	E	10	23,898	20	477,960	0%	
63	Haloperidol tablets 10mg	V		15,893	30	476,793	0%	
64	Tobramycin eye drops 0.3%, 5ml dropper bottle	E	1	11,794	40	471,744	0%	
65	Atropine 1% eye drops 10ml	N	1	10,436	45	469,632	0%	
66	Ranitidine 25mg/2ml inj	E	100	32,133	15	465,930	0%	
67	Predinisolone 5mg tablet	V	100	24,307	19	461,835	0%	
68	Hydralazine injection 20mg/ml	V	5	103,100	4	412,399	0%	
69	Clotrimazole 1% topical cream	V	1	747	550	410,955	0%	
70	Phenobarbital 200mg/2ml injection	E	10	130,680	3	392,040	0%	
71	Betamethasone sodium phosphate 0.1% eye drops	E	1	864	430	371,520	0%	
72	Diazepam 10mg/2ml inj im/ slow iv/iv infusion	V	100	30,378	12	364,531	0%	
73	Quinine sulphate 300mg tablet	E	100	179,089	2	358,177	0%	
74	Polyvidone-iodine 10% solution, bottle 200ml	E	1	3,499	100	349,920	0%	
75	Darrows solution (half strength),500ml infusion vial	V	24	31,104	11	342,144	0%	

76	Hydrogen peroxide 6% solution 200ml	E	1	1,069	311	332,521	0%	
77	Penicillin, benzathine benzyl 2.4mu/1.44g ampoule	V	10	7,554	42	317,272	0%	
78	Tramadol injection 100mg/2ml ampoule	E	5	4,825	63	303,948	0%	
79	Gentamycin 0.3% eye/ear drop	E	1	433	581	251,312	0%	
80	Anti-snake bite sera polyvalent 10 ml	E	10	2,367,7	0	236,770	0%	
81	Doxycycline 100mg caps	V	100	4,428	50	221,400	0%	
82	Meropenem inj 500mg vial	E	1	11,007	20	220,147	0%	
83	Metoclopramide 10mg/2ml injection	E	100	14,845	14	207,832	0%	
84	Potassium chloride 10% vial	E	1	20,252	10	202,517	0%	
85	Labetalol 5mg/ml 20ml vial	E	1	38,880	5	194,400	0%	
86	Sodium valproate 500mg tabs	V	100	36,228	5	181,141	0%	
87	Clotrimazole 100mg pessary	V	6	736	240	176,743	0%	
88	Piperacillin -tazobactam 4.5g inj	E	1	11,783	15	176,739	0%	
89	Phenytoin sodium 50mg/ml injection 5ml	V	1	4,130	40	165,204	0%	
90	Diclofenac sodium 50mg enteric coated tablet	E	100	1,021	160	163,347	0%	
91	Omeprazole 20mg capsules	E	100	3,024	50	151,200	0%	
92	Enoxaparin 40mg/0.4ml,0.4ml vol,pre-filled syring	E	2	30,240	5	151,200	0%	
93	Atropine 1mg/1ml inj iv/im	V	100	13,280	11	146,083	0%	
94	Charcoal activated 250mg tablet	E	100	7,806	18	140,510	0%	
95	Haloperidol 5mg/1ml injection	V	5	17,451	8	139,605	0%	
96	Pyridoxine 25mg tablets	E	100	6,076	22	133,661	0%	
97	Carbimazole 5mg tablets	V	100	31,671	4	126,684	0%	
98	Bendrofluazide 5mg tablet	E	100	25,128	5	125,642	0%	
99	Fluoxetine cap 20mg	V	100	3,780	32	120,960	0%	
100	Penicillin. Benzyl 1mu/600mg inj (pfr) im	V	10	2,318	44	101,975	0%	
101	Sodium valproate 200mg tablets	V	40	16,264	6	97,584	0%	
102	Allopurinol 100mg tablets	E	25	11,839	8	94,708	0%	

103	Haloperidol tablets 5mg	E	100	18,878	5	94,392	0%	
104	Heparin injection 5000iu/ml, 5ml vial	V	1	12,887	7	90,212	0%	
105	Hydroxyurea 500mg capsule	V	100	172,328	1	86,164	0%	
106	Mannitol 20% 100ml infusion	E	1	5,043	17	85,726	0%	
107	Chloramphenicol 5% ear drops 10ml.	E	1	713	110	78,484	0%	
108	Codeine phosphate 30mg tablets	E	100	24,001	3	72,004	0%	
109	Amethocaine (tetracaine) hydrochloride eye drops	N	1	6,528	10	65,280	0%	
110	Neostigmine 0.5mg/ml ampoule	N	10	64,800	1	64,800	0%	
111	Diazepam 5 mg tablet	V	100	12,853	5	64,265	0%	
112	Benzhexol 2mg tablet	V	100	6,196	10	61,958	0%	
113	Chlorpromazine 100mg tablet	V	100	29,275	2	58,551	0%	
114	Cetrizine tablet 10mg	N	100	2,268	25	56,700	0%	
115	Salbutamol 4mg tablet	E	100	6,206	9	55,851	0%	
116	Chloramphenicol 0.5% eye drops 10ml	V	1	432	120	51,840	0%	
117	Calcium lactate 300mg tablets	N	100	10,148	5	50,741	0%	
118	Furosemide 40mg tablet	E	100	11,260	4	45,041	0%	
119	Vitamin b complex tablet	E	100	3,370	11	37,066	0%	
120	Fluphenazine 25mg/ml injection	E	10	18,127	2	36,253	0%	
121	Promethazine injection 25mg/ml 2ml amp	E	10	1,997	15	29,958	0%	
122	Bisacodyl 5mg tablets	E	100	1,836	15	27,540	0%	
123	Aminophylline 250mg/10ml inj. Slow iv infusion	E	1	284	85	24,104	0%	
124	Loperamide cap 2mg	N	100	2,740	7	19,178	0%	
125	Hyoscine butyl bromide 20mg/ml injection	N	1	1,510	10	15,105	0%	
126	Clomiphene citrate 50mg tablets	N	10	7,359	2	14,718	0%	
127	Silver sulfadiazine 1% cream 500g	V	1	5,712	2	11,424	0%	
128	Ketoconazole 200mg tablet	N	100	8,471	1	8,471	0%	
129	Warfarin 5mg tablets	V	28	5,731	1	5,731	0%	
130	Artemether 20mg+lumefantrine 120mg (strip of 6	V	30	0	0	0	0%	

131	Artemether 20mg+lumefantrine 120mg (strip of 12	V	30	0	24	0	0%	
132	Artemether 20mg+lumefantrine 120mg (strip of 18	V	30	0	0	0	0%	
133	Artemether 20mg+lumefantrine 120mg (strip of 24	V	30	0	462	0	0%	
134	Misoprostol 200mcg tablets	V	100	0	49	0	0%	
135	Morphine sol 5mg/5ml bottle	V	1	0	172	0	0%	
136	Artesunate injection 60mg vial	V	1	0	6,20	0	0%	
137	Medroxyprogesterone acetate 150mg/ml w/ syringe	V	200	0	1	0	0%	
138	Levonorgestrel 0.75 mg	V	2	0	100	0	0%	
139	Ethinylestradiol0.03+ levonorgestrel0 .15mg 3cycles	E	1	0	200	0	0%	
140	Etonogestrel 68mg implant (implanon)	E	1	0	30	0	0%	
141	Levonorgestrel 0.03mg tab 3 cycles	E	1	0	100	0	0%	
	Total					**262,216,9**		

Annex 9.2: Study of Medication Administration

There are different methods of studying medicine administration including: cross-sectional study technique, direction observation, medication chart reviews and incident report reviews. All these methods are intended for detecting medication errors and for quality assurance purposes (Camilla Haw, 2007). Direct observation detects medication administration errors at a much higher rate than chat reviews or incident report reviews (Flynn EA, 2003). In addition, the observational method has been found to be valid and reliable (Dean B, 2001).

Direct Observation Method

Here, a researcher accompanies nurses preparing and administering drugs, records details of all doses administered, and compares this information with the doses prescribed. A ward/department is selected for the study activity. A dedicated personnel (preferably pharmacist) member observes medication administration of regular and prn (as required) drugs given at each of the routine drug rounds. Decide whether to observe the administration of prn drugs and depot preparations given at other times of the day (even night) outside the normal drug rounds.

Details of medications that are administered are recorded on a standard pro-forma data collection sheet (example shown below). During this exercise it has to be decided beforehand whether or not the observer should intervene if he/she witnesses a 'near miss' incident, i.e. where an error that would likely cause the patient harm is almost made. In the same vein the 'near miss' events should be counted as errors in themselves.

The observation technique appears to be acceptable to the participating nurses (Camilla Haw, 2007). The observer stands very close to the administering nurse in order to accurately record medicines administration, though some nurses may feel that being closely observed this way may make them more prone to making errors.

Participating nurses should be informed of the aims of the study, though there is a possibility of this knowledge affecting their behavior. The fact that the observation is not disguised can result in greater vigilance. An observational study conducted in a general hospital reported no evidence that the technique made nurses more or less likely to make errors (Dean B, 2001).

Chart Review Method

Studies based on chart review rely on accuracy and completeness of documentation, the absence of which may be a problem. An example of a tool adapted from international literature is presented on the next page.

What to observe

The example below is an observation tool from international literature. The report of the survey in addition to the information on the tool should include the following:

Components of Medication Administration Observation Report
A. Patient details • Total number of patients to which medication administration was observed • The diagnoses of these patients • The number of diagnoses of these patients • Ethical issues: those with inability to give informed consent with respect to medication • Incidents that are totally the patients' fault (e.g. deliberate refusal to receive medication, absentia of the patient, aggression to the administering nurse etc

B. Participants and details of medication rounds observed

- Wards/department under study
- Nurses approached and briefed
- Nurses that consent to participate in the study (%)
- Period and length of observation
- Number of medication rounds
- Number of medication rounds observed (%)

C. Details of medication administered

- Total doses administered and observed
- Oral vs. Parentera

D. Details of errors detected

- Total number of errors detected
- Errors vs. doses
- Error types
- Error grades
  - » Grade 1: Errors or omissions of doubtful or negligible importance
  - » Grade 2: Errors or omissions likely to result in minor adverse effects or worsening of the condition
  - » Grade 3: Errors or omissions likely to result in serious effects or relapse
  - » Grade 4: Errors or omissions likely to result in fatality
  - » Grade X: Un-ratable (e.g. medication was observed to be correctly administered but the nurse failed to record administration on the medication chart).

ADMINISTRATION AND DOCUMENTATION OF MEDICATIONS

CQI OBSERVATION UNIT

#	Criteria for Observation of Administration & Documentation	Yes	No	Comments
1.	Sets up medication cart			
2.	Washes or sanitizes hands prior to administration of medications			
3.	Officer present on tier with nurse			
4.	Meds prepared at time of administration in front of patient			
5.	Verifies allergies			
6.	Performs the 8 Rights			
6a.	Right Patient			
6b.	Right Medication			
6c.	Right Dose			
6d.	Right Route			
6e.	Right Time			
6f.	Right documentation: see item 9-12 below.			
6g.	Right Reason			

6h.	Right Response			
7.	Observes patient take medication at the cart (mouth check)			
8.	Nurse counsels the patient regarding medication side effects			
9.	Immediately documents the administration at the correct time on the MAR with initials as per policy			
10.	(Or) Documents the reason for not administering the medication			
11.	Refusal documented on the MAR with notification to the physician			
12.	Legibly documents initials and signature on the back of the MAR in original ink as per policy			
13.	Reconciles MAR at the end of medication process – check for medication not administered, patient not present, etc.			
14.	Cleans medication cart at the end of the med pass			
15.	Med pass started on time			
16.	Med pass ended timely			
17.	Nurse's interaction with patient appropriate			
18.	Nurse maintained focus on med administration			
19.	Incorrect medications segregated and reported to Pharmacy			
20.	Missing medications requested from Pharmacy as per policy			
21.	Medication error? If yes:			
21a.	Medication error documented on incident report			
21b.	Medication error reported to appropriate manager and provider			
22.	Potential safety issues noted (inmates crowding cart, officer not controlling situation, nurse talking with officer while preparing medications, etc.)			

(adapted with minor modifications from a tool downloaded from www.correctionalnurse.net)

Corrective Action/Comments:.....

Conducted by: ..... Acknowledged by: .....

Audit Tool for Medication Administration & Dispensing

(adapted with minor modifications from a tool downloaded from www.hse.ie/eng/about/who/qid/.../auditsupport/medication-management-.doc)

Name of facility: Objective of Audit tool:

This audit tool is to be used to retrospectively audit the processes used for medication administration anddispensing.

Methodology:

Frequency of Audit: To be agreed by the MTC

Method: This is a retrospective cross-sectional study. Sample 6 (six) patient files.

Feedback: Completed Audit Tool to be kept in the pharmacy file with a copy in the MTC file.

Results of the audit to be discussed with the MTC

Ward		Date of Audit	
Auditor(s) Name(s)		Auditor(s) Title (s)	
Patient Identifier (name/ number)	1.	2.	3.
	4.	5.	6.

Methodology: Record Y for Yes, if the item is found in the patient's care record. Record N for No, the item is not present or

N/A for Not applicable

Section A: Prior to the administration of medication

	Is there evidence that:	**1**	**2**	**3**	**4**	**5**	**6**
A1	The patient's full name is documented on the Prescription Sheet.						
A2	The patient's date of birth is documented on the Prescription Sheet						
A3	The patient's full address is documented on the Prescription Sheet						
A4	The patient's identification number/ chart number is documented on the Prescription Sheet						
A5	The name of the relevant prescriber is documented on the Prescription Sheet						
A6	The date of the prescriptive episode is documented on the Prescription Sheet						
A7	The relevant ward is documented on the Prescription Sheet						
	Prescriber Details						
A8	The prescription is signed by the Prescriber						
A9	The name of Prescriber is clearly stated on the prescription						
A10	The qualifications of the Prescriber are stated on the prescription						
	Prescription Details						
A11	The prescription is written on the correct Prescription Sheet						
A12	The prescription can be clearly read						
A13	The prescription is written in ink or typed						
A14	'Allergies' or 'No Known Drug Allergy' are documented as appropriate on the relevant section of the Prescription Sheet						

A15	The generic name of the medicinal product is used where relevant						
A16	The Start Date for the medication is documented						
A17	The strength/dosage is clearly documented on the Prescription Sheet						
A18	The route of administration is documented on the Prescription Sheet						
A19	The frequency of administration is documented on the Prescription Sheet						
A20	The maximum dose allowed in a 24 hour period is documented?						
A21	For Once Only/ PRN/Fixed Period Medications the duration of therapy is documented on the Prescription Sheet.						
A22	For Once Only/ PRN/Fixed Period Medications indications for the drug are documented						
A23	There is a documented date included for discontinuation of the medication or in the case of long term medication, a review date is indicated						
A24	Only standard/known abbreviations are used						
A25	A line has been drawn across the unused space on the prescription pad to prevent the fraudulent addition of extra items Repeat Prescribing						
A26	There is evidence of an appropriate assessment of the need for continued treatment with the prescribed medication						
A27	In the event of the Prescriber being involved in a cross-over of responsibilities e.g. prescribing/supplying/dispensing/ administering a medication, there is evidence that a second suitably competent person has been involved in checking the prescription						
	Total Scores for Yes						
	Total Scores for No						
	Total Scores for N/A						
	% Total = Total Scores for Yes X 100 Total = 27 (Total – N/A)						

Comments: _____

_____

_____

Section B: Administration of medication

	Is there evidence that:	1	2	3	4	5	6
B1	The 5 rights of medication were applied for the patient? 1. Right Patient						
B2	2. Right Amount						
B3	3. Right Time						
B4	4. Right Drug						
B5	5. Right Route						
B6	The practitioner administering the medication provided an accurate and contemporaneous recording of the medications administered, deliberately withheld, declined and/ or wasted						
B7	Any difficulties in the administration were documented and the prescriber was informed						
B8	If MDA (Medicines of Dependence & Abuse) Schedule 2 Drugs: The drugs were administered by two persons, at least one of which is a registered nurse						
B9	The control drug register was signed by two persons, at least one of which is a registered nurse						
B10	MDA Count is carried out at the end of each shift (at shift changeover) by two registered nurses						
B11	Any errors/ non-correlation in the MDA count are reported to nursing admin/ pharmacy						
B12	If patient brought in own MDA drugs to the unit, the type and amount were checked by two registered nurses and the MDA drugs are registered in the relevant section of the MDA book						
B13	If patient is discharged, the MDA drugs were returned to the patient and signed out of the MDA register by two persons, at least one of which is a registered nurse						
B14	If MDA drugs will not be returned to the patient the drugs were returned in a secure manner to the pharmacy						
B15	If a medication error occurred: 15. The medical practitioner, responsible for the patient's care, was informed?						
B16	16. The patient's next of kin were informed about the reaction?						
B17	17. The Line Supervisor was informed?						
B18	18. The patient was reviewed?						
B19	19. The patient's condition was monitored and vital signs recorded?						
B20	20. All actions taken were documented?						
B21	21. All the required forms were completed						
B22	If an adverse reaction occurred: 22. The medical practitioner, responsible for the patient's care, was informed?						
B23	23 The patient's relative / key worker were informed about the reaction?						

B24	24. The Line Manager was informed?						
B25	25. The patient was reviewed?						
B26	26. The patient's condition was monitored and vital signs recorded?						
B27	27. All actions taken were documented?						
B28	28. All the required forms were completed?						
B29	29 A Desk-top review/ follow up is documented						
B30	30 The adverse reaction was reported appropriately (internal and NDA)						
	Total Scores for Yes						
	Total Scores for No						
	Total Scores for N/A						
	% Total = Total Scores for Yes X 100 **Total = 30 (Total – N/A)**						

*MDA – Medicines of Dependence & Abuse

Comment: _____

_____

_____

Conclusions and Recommendations arising from the audit:	Date for completion	Responsibility

Auditor Signature: ..... Date: .....

Attendance Stakeholder Engagement

Sl. No.	First Name	Surname	Cadre	Institution
1	Winnie	Nambatya	Lecturer	Makerere University Department of Pharmacy
2	Kalidi	Rajab	Lecturer	Makerere University Department of Pharmacy
3	Bruhan	Kaggwa	Lecturer	Makerere University Department of Pharmacy
4	Edson	Munanura	Lecturer	Makerere University Department of Pharmacy
5	Rodney	Tabaruka	Principal. Pharmacist	Ministry of Health
6	Phillip	Ampaire	Senior Pharmacist	Ministry of Health
7	Daniel	Aguma	Senior Pharmacist	Ministry of Health
8	Peter	Agababingi	Monitoring and Evaluation Officer	Ministry of Health
9	Martha Grace	Ajulong	Ag Commissioner Health Services - Pharmaceuticals and Natural Medicine	Ministry of Health
10	Victor	Bewayo	Pharmacist	Arua Regional Referral Hospital
11	Chrispus	Ngabirano	Microbiologist	Kabale Regional Referral Hospital
12	Harriet	Akello	Senior Pharmacist	Ministry of Health
13	Micheal	Isabirye	Capacity Building Coordinator	Ministry of Health
14	Christopher	Amandu Harold	Senior Laboratory Technologist	Arua Regional Referral Hospital
15	James	Achol	Pharmacist	Jinja Regional Referral Hospital
16	Enock	Padere	HODM	Iganga General Hospital
17	Falisy	Lule	Senior Pharmacist	Kawempe Regional Referral Hospital
18	Joanitah	Atuhaire	Regulatory officer	National Drug Authority
19	Prossy	Atimango	Public Health Officer	Ministry of Health
20	William	Olum Pjathim	Senior Pharmacist	Jinja Regional Referral Hospital
21	Ventrine	Chelimo	Pharmacit	National Medical Stores
22	Harriet	Tino Okello	Pharmacist	Lira Regional Referral Hospital
23	Morries	Seru	Rtd. Commissioner Health Services - DPNM	Ministry of Health
24	David	Arinaitwe	Senior Pharmacist	National Medical Stores

25	Isaac	Mukama	Software Developer	Jhpiego
26	Sandra	Namakula	Data Manger	Infectious Disease Institute
27	Christopher	Wagobera	Medical Officer	Kabale Regional Referral Hospital
28	Paul	Rubayinza	Lecturer	Makerere University Department of Pharmacy
29	Theophile	Tuyishimire	Pharmacist	National Medical Stores
30	Jaqueline	Nassuna	Pharmacist	National Drug Authority
31	Calvin	Chemutai	Data Analyst	Infectious Disease Institute
32	Emmanuel	Nkurunziza	Data Officer	Infectious Disease Institute
33	Hanifa	Nakwenda	GIS specialist	Infectious Disease Institute
34	Vivian	Twemanye	Senior Project Officer - Antimicrobial Consumption and Use	Infectious Disease Institute
35	Sr Josephine	Oyellla	Senior Pharmacist	St Mary's Hospital Lacor
36	Denis	Nankoola	Senior Pharmacist	Fort Portal Regional Referral Hospital
37	Zainab	Akello	Pharmacist	Gulu Regional Referral Hospital
38	Rogers	Kisame	Program Manger	Baylor Foundation Uganda
39	Moses	Mukiibi	Antimicrobial Use and Consumption Coordinator	Baylor Foundation Uganda
40	Sheila	Ampaire	Regulatory officer	National Drug Authority
41	Jakira	Ambrose	Health Product Quantification Specilist	Ministry of Health
42	Ian	Nyamitoro	Senior Health Product Management officier	Ministry of Health
43	Thomas	Ssemakadde	Laboratory Systems Coordinator	Baylor Foundation Uganda
44	Reginald Rony	Bahatungire	Ag Commissioner Health Services - Clinical Services	Ministry of Health
45	Joel Tutu	Miti	Pharmacist	Ministry of Health
46	Kenneth	Turyahabwe	Epidemiologist	Ministry of Health
47	Gerald	Manzi Mbabazizu	Senior Pharmacist	Mbarara Regional Referral Hospital

48	Carolyne	Nyamor	Public Health Specialist	Ministry of Health
49	Anita Priscilla	Murungi	Medical Officer	Ministry of Health
50	Elizabeth	Katwesigye	Infection Prevention and Control Specialist	Ministry of Health
51	Gilbert	Ayebare	Pharmacist	National Medical Stores
52	Dickens	Ahabwe	Pharmacist	National Medical Stores
53	Paul	Waiswa	Pharmacist	Mbale Regional Referral Hospital
54	Timothy	Kabonero	Senior Pharmacist	Masaka Regional Referral Hospital
55	Joshua Felix	Walakira	Technical Officer	Makerere University Department of Pharmacy
56	Jeska	Musiimenta	Graduate Research Assistant	Makerere University Department of Pharmacy
57	Shube	Bamukyaye	Graduate Research Assistant	Makerere University Department of Pharmacy
58	Shifah	Nampiima	Graduate Research Assistant	Makerere University Department of Pharmacy
59	John Paul	Waswa	Epidemiologist	Infectious Diseases Institute
60	Jennifer	Ayopo	Project Officer	Medici con l'Africa Cuamm
61	Simone	Cadorin	Project Coodinator	Medici con l'Africa Cuamm
62	Edoardo	Miotto	Project Officer	Medici con l'Africa Cuamm
63	Jane Francis	Nanteza	Senior Consultant Peadiatrician	Mubende Regional Referral Hospital
64	Patrick	Opio	Senior Pharmacist	Mubende Regional Referral Hospital
65	George	Katongole	Laboratory Technologist	Mubende Regional Referral Hospital
66	John Edwin	Mwaka	Senior Orthopedics Officer	Naguru Regional Referral Hospital
67	Helen	Kabagambe	Senior Pharmacist	Naguru Regional Referral Hospital
68	Joseph	Olore	Senior Laboratory Technician	Naguru Regional Referral Hospital
69	William	Oyang	Consultant Pediatrician	Lira Regional Referral Hospital

70	Benard	Ongora	Laboratory Technologist	Lira Regional Referral Hospital
71	Caroline	Achino	Medical Officer	Hoima Regional Referral Hospital
72	Margaret	Abigaba	Senior Pharmacist	Hoima Regional Referral Hospital
73	Emmanuel	Ntezeyaremye	Laboratory Technician	Hoima Regional Referral Hospital
74	Sophie	Nakitto	Pediatrician	Kayunga Regional Referral Hospital
75	Daniel	Kibombo	Microbiologist	Kayunga Regional Referral Hospital
76	Ismail	Ssekungu	Pharmacist	Kayunga Regional Referral Hospital
77	Francis	Oboi	Pharmacist	Soroti Regional Referral Hospital
78	Julius	Wagube	Laboratory	Soroti Regional Referral Hospital
79	Wilson	Etolu	Consultant Physician	Soroti Regional Referral Hospital
80	Anthony	Makhoba	Consultant Physician	Fortportal Regional Referral Hospital
81	Simon Peter	Seguya	Senior Pharmacist	Fortportal Regional Referral Hospital
82	Dan	Kakyakumaiso	Senior Medical Laboratory Technologist	Fortportal Regional Referral Hospital
83	Brian	Ssewankambo	Medical Laboratory Technologist	Masaka Regional Referral Hospital
84	Gonzaga	Ssenyondo	Consultant Gynecologist	Masaka Regional Referral Hospital
85	Harriet	Nambuya	Senior Consultant Peadiatrician	Jinja Regional Referral Hospital
86	Enoch	Padere	Laboratory Technologist	Jinja Regional Referral Hospital
87	Johnson	Oloya Nyeko	Medical Officer	Moroto Regional Referral Hospital
88	Stephen	Odomel	Pharmacist	Moroto Regional Referral Hospital
89	Bosco	Adranya	Senior Laboratory Technologist	Moroto Regional Referral Hospital
90	Alex	Sande	Senior Pharmacist	Mbale Regional Referral Hospital
91	Asad	Muyinda	Consultant Internal Medicine	Mbale Regional Referral Hospital

92	Dauson	Wanyibe	Senior Laboratory Technician	Mbale Regional Referral Hospital
93	Patrick	Wambuzi	Senior Dental Surgeon	Gulu Regional Referral Hospital
94	Quinto	Ogwang	Senior Laboratory Technologist	Gulu Regional Referral Hospital
95	Francis	Oriokot	Senior Consultant	Mbarara Regional Referral Hospital
96	Robert	Wagubi	Laboratory Technician	Mbarara Regional Referral Hospital
97	Tuhaise	Gamukama	Surgeon	Kabale Regional Referral Hospital
98	Patrick	Odong Olwedo	Executive Consultant	Yumbe Regional Referral Hospital
99	Boniface	Matua	Senior Pharmacist	Yumbe Regional Referral Hospital
100	Kizito	Koma	Laboratory Technologist	Yumbe Regional Referral Hospital
101	Robert	Tiondi	Consultant	Arua Regional Referral Hospital
102	Ibrahim	Asiku	Pharmacist	Arua Regional Referral Hospital

Concept, Design & Layout:
Joshua Musasizi
@smartjosh

Ministry of Health Headquarters,
Plot 6 Lourdel Road, P.O.Box 7272
Kampala, Uganda
Tel: +256-417-771330

Email: ugandaclinicalguidelines@gmail.com
Website: www.health.go.ug