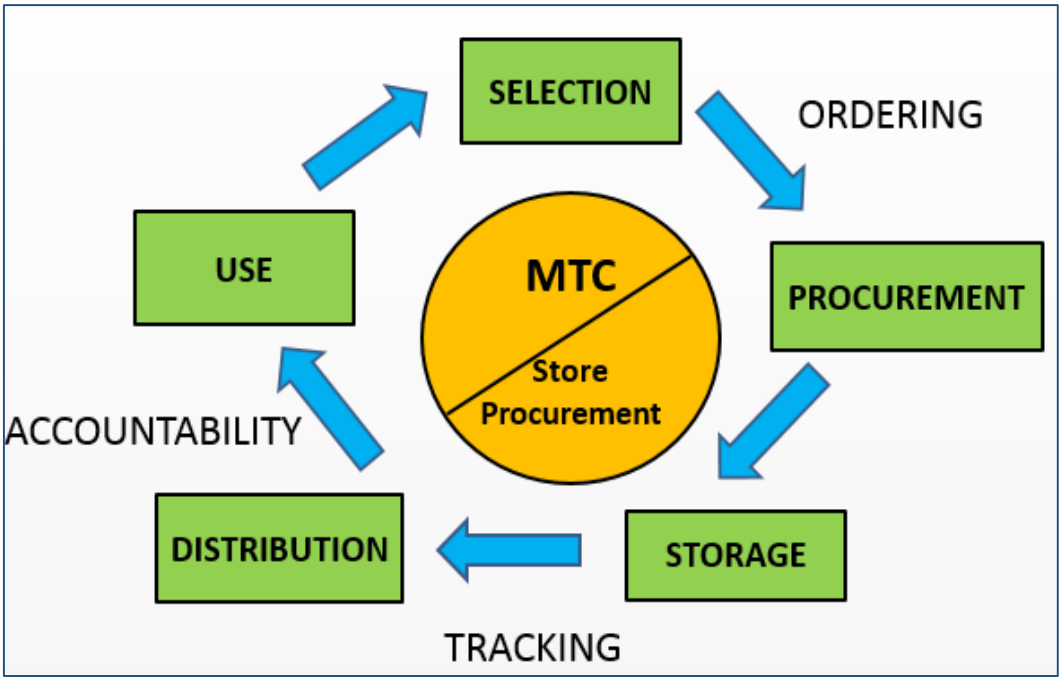
THE REPUBLIC OF UGANDA

MEDICINE AND THERAPEUTICS COMMITTEES MANUAL



Pharmacy Department

Ministry of Health

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Foreword

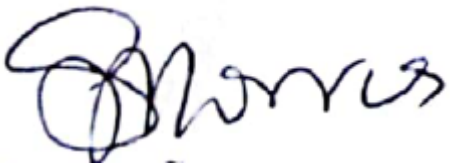
Uganda has made significant strides in improving access to health services for its population. Efficient utilization of resources and delivery of quality health services are essential to meet the goals of universal health coverage.

The Pharmaceutical Sector Strategic Plan 2015-2020 recognizes the establishment of a functional national appropriate medicines use program as one of the strategies to ensure maximum therapeutic benefits from medicines through scientific sound and cost-effective use by prescribers, dispensers and consumers.

The appropriate medicines use program identifies the establishment of functional Medicine and Therapeutics Committees (MTC), as an operational arm of Improvement structures in the area of efficient management and use of medicines and health supplies. MTCs are key in providing scientific sound and cost-effective evidence that guides intervention to support improvement in appropriate medicine use.

This Manual, accompanied by a structured training curriculum for operationalization of MTCs at health facility level, provides practical guidance for quality improvement efforts in the area of therapeutics, addressing both the logistical and clinical aspects of medicines management. Better management and utilization of medicines will also contribute to efficiency, and ensure that resources are optimally utilized for the maximum benefit of the population.

I commend the efforts of all the health workers who actively participated in the development of this manual, and thank all the stakeholders who provided input and support under the coordination and leadership of Pharmacy Department. I encourage all health facilities and partners, in the private and public sectors to implement this intervention.



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Acronyms

ACT	Artesimisin-combination treatment
ADR	Advert Drug Reaction
AMC	Average Monthly Consumption
AMR	Anti Microbial Resistance
AMU	Appropriate Medicine Use
AMS	Anti Microbial Stewardship
ART	Anti Retroviral Treatment
ATC	Anatomical Therapeutic Classification
BS	Blood Slide
CME	Continuous Medical Education
CQI	Continuous Quality Improvement
DDD	Daily Defined Dose
DHIS2	District Health Information System
DTC	Drug and Therapeutic Committee
EMHS(LU)	Essential Medicines and Health Supply (List of Uganda)
EML	Essential Medicine List
FGD	Focus Group Discussion
HMIS	Health Management Information System
IMCI	Integrated Management of Childhood Illnesses
IML	Institutional Medicine List
INRUD	International Network for Rational Drug Use
IP	In Patients
IPC	Infection Prevention and Control
IV	Intra Venous
JMS	Joint Medical Store
MAUL	Medical Access Uganda Limited
M&E	Monitoring and Evaluation
MCH	Maternal and Child Health
MOH	Ministry of Health
MOS	Month Of Stock
MTC	Medicine and Therapeutics Committee
MUE	Medicine Use Evaluation
NAP	National Action Plan
NDA	National Drug Authority
NMS	National Medical Stores
OPD	Out Patient Department
NPC	National Pharmacovigilance Center
OTC	Over the Counter
PDSA	Plan Do Study ACt
PGD	Practical Guidelines for Dispensing
PID	Pelvic Inflammatory Disease
PPS	Point Prevalence Surveys

PV	Pharmacovigilance
PUD	Peptic Ulcer Disease
QI	Quality Improvement
RDT	Rapid Diagnostic Test
RRH	Regional Referral Hospital
RTI	Respiratory Tract Infection
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SP	Sulphadoxine-Pyrimethamine
SPARS	Supervision Performance Assessment Recognition Strategy
STG	Standard Treatment Guideline
STI	Sexually Transmitted Diseases
TB	Tuberculosis
TOR	Terms of Reference
UHSC	Uganda Health Supply Chain
VEN	Vital Essential Necessary
URTI	Upper Respiratory Tract Infection
USAID	United States Agency for International Development
UTI	Urinary Tract Infection
WHO	World Health Organization

Introduction

This manual has been developed over the course of a year, during a pilot intervention to revitalize the Medicine and Therapeutics Committees of seven regional referral hospitals in Uganda. It is based on international literature - mainly existing WHO guidelines - but has been adapted to the local setting, enriched with new topics and examples drawn from the practical experiences. Where appropriate, the content is cross-referenced with the local policies and regulations. The process was led by the Appropriate Medicine Use unit of the Pharmacy Department, with support from the USAID-funded Uganda Health Supply Chain project.

The result is, we hope, a very user-friendly and beneficial manual, to be used as a training base and also a practical guide for hospital MTC to implement their mandate. As much as possible we have provided tools and blueprints built more from experiences of the participating hospitals and the examples presented are real.

The introductory chapters of the manual provide an overview of the roles and responsibilities, composition and mode of operations of a hospital Medicine and Therapeutics Committee, and presents as well a performance assessment framework. A blueprint for the Terms of reference is included as an annex. The principles of quality improvement and appropriate medicine use are summarized in the subsequent two chapters, to provide some theoretical background. The following chapters present, in a practical way, the formulary process, the investigations which can be used to identify and assess medicine use problems, and the intervention strategies which can be adopted to address them. A chapter on supply chain aspects has been added, where MTC are introduced to the most important tasks and reports in the area of medicine logistics. A brief chapter on quality and safety follows, since pharmacovigilance activities fall within the scope of MTC mandate. Last but not least, a chapter on antimicrobial stewardship has been added, since the MTC represents the ideal platform for the implementation of such activities at hospital level.

The Medicine and Therapeutics Committees of Lira, Moroto, Naguru, Arua, Soroti, Mbarara and Masaka were the testing ground where these guidelines were developed and their contribution to the development of this manual is greatly acknowledged and appreciated.

The Manual is accompanied by a training package, with a training schedule, PowerPoint presentations and exercises structured in 4/5 short trainings, to be delivered over a 12-15 months' period with support supervision in between trainings. The material is available to be used, with authorization from the Pharmacy Department Ministry of Health.

Any request and feedback will be welcome and highly appreciated at ugandaclinicalguidelines@gmail.com.

Appropriate Medicines Use Unit
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1 Medicine and Therapeutics Committees: an overview

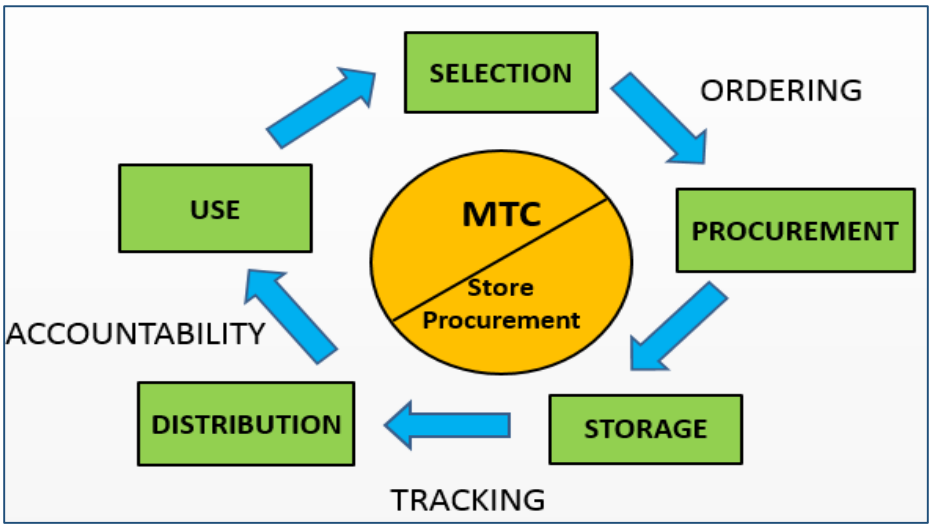
1.1 Introduction

The Medicine and Therapeutics Committee (MTC) is a committee designated to ensure the safe, effective and efficient management and use of medicines and health supplies in the health facility.
It ensures that:

- Medicines and supplies are used appropriately and with maximum benefit for the patient/ community
- Pharmaceutical products are safe and of adequate quality and quantity
- Resources are used efficiently and cost effectively

Scope of MTC
The medicine management cycle consists of a sequence of steps as shown in Figure 1.1 below:

- Selection of the products
- Ordering and procurement
- Storage, distribution and tracking
- Use and accountability.



- *Figure 1.1 Scope of action for MTC in the medicine management cycle*

The MTC has a direct role in the components of selection, use and accountability, but it also has an advisory and monitoring role on the more "logistical" steps of the cycle, which are the direct responsibility of the stores, pharmacy and procurement departments.

In summary, the roles of the MTC are:

1. Evaluating and improving the clinical use of medicines and supplies (the "use" component)
2. Developing and/or monitoring policies and procedures for management and use of medicines and health supplies (the logistical functions)

3. Developing and managing an institutional medicine list (the “selection” component).

1.2 Function and benefits of MTC

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

ROLE	FUNCTION
Evaluating and improving the clinical use of medicines	• Formulate, implement and monitor policies and guidelines for appropriate use of medicines and supplies in the health facilities. • Develop, implement and monitor the use of standard treatment guidelines • Identify medicine use problems (prescriptions, administration, availability, etc) • Conduct effective interventions to improve medicine use (educational, managerial, regulatory and financial programs) • Conduct pharmacovigilance activities: medication errors, adverse drug reactions, treatment failures and causes, drug quality issues • 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 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 or adopt/adapt and monitor policies and procedures e.g: ○ Pharmaceutical promotion ○ Medicine donations ○ Selection, quantification, procurement planning, storage, distribution and re-distribution, accountability systems ○ Prescription, dispensing, administration of medicines e.g. restrictions and permissions for different cadres ○ Expiries and disposal of pharmaceutical products
Developing and managing an institutional medicine list	• Develop criteria for inclusion and exclusion of essential medicines and health supplies onto the institutional medicines list (IML) • Develop institutional medicines list (IML) • Develop a facility-based antibiogram to guide antibiotic selection

1.2.1 Benefits of MTC

A functional and active MTC will have several benefits:

- Availability of effective, safe, high-quality, and cost-effective pharmaceuticals
- Reduction of medicine use problems, leading to improved medicine use
- Prevention and improved management of antimicrobial resistance
- Improved staff and patient knowledge
- Decreased Adverse Drug Reactions and medication errors
- Improved medicine procurement and inventory management
- Improved management and control of pharmaceutical and health supplies expenditures

All this will contribute, in the end, to better quality of services and more cost effective and efficient use of resources.

1.3 Structure, Organization and Functioning of MTC

In order for the MTC to function, it should have a multidisciplinary, transparent approach, technical competence and an official mandate. It is essential to define and document:

- The official mandate – MTCs will not work without senior administrative support
- 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

A blueprint for Terms of reference for a health facility medicine and therapeutics committee is presented in Annex 1.

1.3.1 Principles in setting up the MTC

In order to ensure that that the committee functions effectively, it is fundamental to have very motivated key members and strong and visible support from the administration/top management of the health facility. The following principles should be followed when setting up the MTC:

- **Technical competency:** members will need to bring their expertise and skills in the committee and contribute in a constructive manner to the work of the committee
- **Multidisciplinary approach** sensitive to the local situation: the committee should have a wide representation of cadres and departments (clinicians, nurses, pharmacy/logistics and procurement, administration, laboratory, records/statisticians etc.)

- **Transparency and commitment to good service**
  - MTC has to be active, and make sound decisions in a transparent way

- MTC work has to 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**
  - Delegation of activities (e.g., research studies, investigations, data collection and analysis) to subcommittees.
  - Meetings with clear agenda, for discussions and decision making.

1.3.2 Composition of the MTC

The MTC is usually made up of professionals from all the areas involved in health care:

- Medical and clinical staff, representatives of the major specialties
- Pharmacist/pharmacy technicians (the secretary to the committee)
- Nursing personnel
- Records officers/statistician
- Laboratory staff
- Store in charge
- Administration representatives.

This mix of personnel would provide the all-round input from the diverse segments of the health care facility. Each MTC has the liberty to choose whether to include a community person or co-opt them in the committee or in sub-committees as and when needed. The committee should choose the chairperson. Ideally, a well-known and respected senior clinician will provide leadership to the committee. The store and pharmacy in-charge must be members, with the head of pharmacy as the secretary and the pharmacy department as the secretariat. It is advisable to appoint a deputy chairman and deputy secretary within the committee. Chairperson, secretary and their deputies will form an **executive committee** to handle administrative tasks.

While generally guidelines indicate head of departments as the most suitable candidates, this will depend on the local situation: the most important criteria is a technically competent and motivated person with an official mandate. A head of department may select another staff to represent the department. The recommended number of members is 12 to 15; however, this can be adjusted to allow adequate representation and at the same time keep the number manageable. Additional staff can be co-opted in case of specific issues, or included in sub-committees.

MTC members are required to sign a declaration of interest, to make sure they do not have any conflict of interest which could affect MTC work (*see annex 1.1*).

1.3.3 Subcommittees

The MTC often works through subcommittees, which can be:
Standing (permanent) committees: Recommended standing committees are antimicrobial stewardship and pharmacovigilance sub-committees. Facilities can also decide to form a supply chain sub-committee.
Ad hoc committees, created to address specific issues for a period of time.

Based on the need, interest and competencies, some committees can be permanent or not e.g. an MTC may choose to have a standing surveys committee, or create a temporary group to address a specific issue such as implementing a specific intervention or task.

1.3.4 MTC position within the facility

MTC should be established at all health care levels with the purpose of promoting appropriate medicine use, and thereby ensuring that end-users receive maximum therapeutic benefits from medicines through scientifically sound and cost effective use by prescribers, dispensers and users. The MTC is part and parcel of the continuous quality improvement interventions taking place in the facilities, and works in collaboration with the other committees (e.g. infection control committee) to improve quality of health services (*more details in Chapter 2*).

1.4 Mode of operation of Medicines and Therapeutics Committees

One of the commonly cited obstacles to effective implementation of MTCs is the lack of clear "instructions" and guidelines, especially in situations where the committee has to be established (or functionalized) from scratch. This section gives practical advice, also based on the experience of the health facility MTCs that have participated in pilot interventions to revitalize MTCs at regional referral hospitals. These can be emulated in the national referral hospital, district hospitals and lower health facilities.

There are 3 important principles underlying effective MTC work:

Leadership: only a strong leadership by the secretariat will ensure that problems are addressed, and solutions are developed and implemented. Decisions have to be taken, tasks assigned and followed up at the subsequent meetings. Effective management of meetings means that discussions have to 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 periodically to discuss issues and take decisions, but most of the work will take place outside the meetings: individuals or groups (sub-committees) will be tasked to identify and investigate issues, prepare reports, and design and implement interventions. The MTC meeting is the plenary forum to brainstorm, present, report, discuss, analyse, take decisions and follow up, but members should be ready to commit some extra time to implement the decisions taken. The organization of sub committees allows division of work among members and hence make 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.

1.4.1 Effective meetings

In the table below find some 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 walk out with) - Formulate an agenda, in consultation with the chairperson, specifying agenda items, person responsible and time allocation for each item - Communicate date and venue in advance (at least 1 week) - Organize equipment and refreshments - 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 overview of the objectives of the meeting - Receive feedback from all subcommittees - Direct and keep 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 way forward for each item, record decisions and give assignments as necessary - Make conclusions and action points at the end of the meeting - Review and adapt minutes of the preceding meeting. Chairperson and secretary should sign.
AFTER	**Document and Follow Up** - Write and circulate minutes within 72 hours after the meeting, highlighting 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.

1.4.2 Decision making and implementation in MTC work

The MTC will discuss and take decisions, by consensus or voting. Decisions will take the form of recommendations to management/administration who will endorse and allow MTC to proceed and/or support implementation, for example:
MTC can formulate policies and guidelines, and administration will officially endorse
MTC decides to undertake a survey, or organize a CME: management has to be informed and approve
MTC decides to introduce a restriction on antibiotic prescribing: administration has to approve and issue a circular.

The MTC reports and is accountable to the administration/top management of the health facility. In addition, the MTC, through the health facility in-charge/director, also reports to the relevant departments in the Ministry of Health (Appropriate Medicine Use unit in Pharmacy Department and to the Quality Assurance), which are responsible for technical support and supervision. A blueprint template for reporting, which can be used for the hospital administration and for the MOH relevant departments, is presented in **Annex 2**.

1.5 Work-planning and performance monitoring

A fully established MTC should be able to formulate annual work plans, detailing both routine activities and specific issues to be addressed. MTC should draw a budget and submit 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 see **Annex 3** for guidance. Examples of MTC activities are presented in the table below.

Routine activities	Ad hoc activities
- Review 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 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.)

Many times the MTC will find itself addressing emerging issues, but it is worthy to have a plan on the routine activities and on the specific issues the MTC wants to address in a certain period. Most likely it won't be possible to address all the problems at once, the MTC will have to prioritize and plan sensibly: 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.

1.5.1 Performance Assessment of MTC

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 indicators have been divided into three groups:
Input and process (activity) indicators: describe the resources (financial, human, material) and the activities performed.
Output indicators: describe the immediate "products" of the activities.
Outcome indicators: describe a change in the situation as consequence of the intervention.
Impact indicators are not considered, since they refer to the ultimate goals of health care (improve the health of the population) and are very difficult to assess in relation to a single intervention.

It is important to note that while input, process and outputs indicators are useful to monitor if an MTC is "active" 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.

The table below shows an example of performance assessment indicators:

PROCESS/INPUT INDICATORS		
Area	**Indicator**	**Description**
MTC structure	Official appointment	MTC has officially appointed members
	Terms of reference	MTC has clear terms of reference
	MTC guidelines	The necessary guidelines are available: - MTC guidelines - National standard treatment guidelines - Essential medicine and health supplies list - Pharmacovigilance guidelines - Antimicrobial stewardship guidelines
	MTC subcommittees	MTC has a pharmacovigilance subcommittee (or focal person), antimicrobial stewardship subcommittee, etc
MTC Operations	Work-plan and budget	MTC has a work plan and a budget included in the hospital workplan
	Meetings	Number of MTC meetings conducted Minutes available
	Meeting attendance	Percentage meeting attendance
	Other activities	Trainings (attended, organized) Surveys conducted , staff meetings

OUTPUT INDICATORS		
Area	**Indicator**	**Description**
Selection *(see chapter 4)*	Institutional medicines and supplies list	- Facility has an approved list of medicines and health supplies (with VEN classification & prescriber levels) approved by MTC and director - Clear criteria for adding and deleting products from IML
	Institutional list review	Institutional medicines list reviewed (annually)
Policies and procedures *(see chapter 7)*	Policies or procedures developed, reviewed or adapted	Number and type of policies reviewed or developed e.g. - Management of donations - Regulation of pharmaceutical promotion - In-patient pharmacy - Tracking of medicines and supplies
Medicine use problems *(see chapter 3, 5 and 6)*	Problem identification and investigations	Medicine use or management issues identified, surveys and investigations conducted for example: - over use of injectable medicines and antibiotics in OPD - poor recording of administered medicines in wards - overstock of certain items
		ADR reports and medicine quality issues sent to NDA
	Interventions	Interventions implemented to address problems e.g: - CMEs, Supervision and mentoring - Restrictions (withdrawal of injectables from OPD) - Re-organization of services (introduction of RDT in OPD, introduction new forms and procedures…)
Supply chain *(see chapter 7)*	Procurement	Annual procurement plan approved by MTC
	Logistics reports	Reports produced and discussed: - ABC analysis (annually) - Availability, stock outs, expiries, stock status, consumption reports (quarterly)

OUTCOME INDICATORS		
Area	**Indicator**	**Description**
Adherence to STGs *(see chapter 5)*	General prescription practices	% adherence to general OPD prescription indicators - WHO standard prescribing indicators (see chapter 5)
	Adherence to STGs	Adherence to STG for specific conditions (e.g. URTI, diarrhoea, uncomplicated malaria, UTI, hypertension)
		Changes adherence to prescription practices targeted by specific interventions (as per problem identified)
Stock Manage-ment *(chapter 7)*	Drug Expiry	Quantities, type and value of expired commodities/amount spent (cumulative for the year)
	Stock outs and availability	% stock out/availability of tracer medicines over a selected period. These tracer medicines can be decided by the MTC depending on the local needs of the facility
	Consumptions	Changes in consumptions as per targeted interventions

1.5.2 Practical tips

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 be easily analysed and addressed
- Share your work to ensure transparent decision-making: e.g. after identifying and analysing 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 and report back to the MTCs, in implementation phase distribute tasks and responsibilities

1.5.3 Challenges to MTC operations

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

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 organization	• Discuss with management purpose and benefit of MTC
Confusion on roles and responsibilities	• Clarify with members role and responsibilities using MOH guidelines, formulate and disseminate clear Terms of Reference
Limited awareness on medicine use problems and possible 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 health facility work plan and budget • Lobby for support from Implementing partners
Lack of follow-up support from central level (ministry of health or senior authority)	• Ask for support from MOH but also 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

CHALLENGE	SUGGESTIONS
Over-reliance on pharmacy to implement	• Divide tasks and responsibilities according to competences and time
Heavy workload	• Address few issues at a time, keeping into account other engagement of the MTC members. Involve students, interns where possible, ask for support from Implementing Partners
High staff turnover of trained MTC members	• Keep a library of MTC guidelines to be used to induce members • Share knowledge after training
Some issues beyond the control of MTC members (or even of the health facility itself)	• Address issues which can solved within the powers of the MTC. Lobby for others and ask for support but do not concentrate on problems beyond MTC reach

References

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

Annex 1.1: Model Terms of Reference for Medicine and Therapeutics Committee

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. Its responsibilities will be: - 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 and 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 though 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 management and use of medicines and health supplies - Regulate and monitor availability, tracking and accountability of pharmaceuticals within the health facility - Analyse, monitor and regulate and 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
Composition	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 - 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 ex-officio member and the secretary of the committee except otherwise recommended by the chairman. Head of store is as well 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 (transferral, retirement, 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 - Behaviour detrimental to aims and objectives of the committee (e.g. conflict of interest). The chairperson, supported by elected members, will investigate any wrong doing 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 - 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: o Setting agenda in collaboration with the secretariat o Call the meetings as per agreed schedule o Chair and moderate the meeting, guide decision making o Review and endorse minutes and MTC reports o Report to health facility Administrator/Director o Facilitate and monitor 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: o Organizing meetings (sending invitations at least 1 week in advance and reminder 2 days before, preparing materials, arrange for logistics etc.) o Setting agenda in collaboration with chairperson o 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. o Follow up implementation of actions by the persons/subcommittees responsible and informing the chairperson of progress and challenges o 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, by attending 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). Sub committees will be chaired by an MTC member, as by decision of the plenary. Other subcommittees can be formed ad hoc, on temporary or permanent basis, by deliberation recorded in 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	Frequency of meetings will be at least bi-monthly, according to an annual schedule included in the health facility annual work plan. Emergency meetings can be called by the executive committee. Invitation should be sent at least one week before, and agenda and material should be shared at least 3 days before the meeting. Appointed members are expected to attend in person, substitutions are not acceptable. Apologies have to 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. 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 chairman with the secretary will be responsible for reporting to the health facility Administrator/Director, and the secretariat will be responsible to share minutes and reports with the relevant MOH department. It is recommended to adopt a summarized format for reporting to the director (attached).

	Communication with the other staff of the health facility will happen through memos, information sheets and feedback meetings.
Performance monitoring and evaluation	The MTC will compile an annual self-assessment according to a 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 annual report. The relevant MOH department will be responsible to 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. In particular, 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 has to occur through approved channels (memos, feedback meetings).
Resources and finances	Funds from MTC routine operations will come from the health facility budget. When possible, donors/IP/MOH may support refreshments, stationery and communication costs, trainings 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.

APPROVAL OF TERMS OF REFERENCE OF THE HEALTH FACILITY MTC

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

EXAMPLE OF A DECLARATION OF INTEREST FORM (from "Drug and Therapeutic Committees-a practical guide. WHO 2003)

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 ☐ Yes ☐ No

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 ☐ Yes ☐ No

If you answered "yes" to either questions, please give details in the space below.

Type of interest, for example patents, shares, employment, association, payment*Name of commercial entity Belongs to you, your family or work unit? Current interest? Or year that interest ceased

**amounts do not have to be declared*

Is there anything else that could affect, or be perceived to affect, your objectivity or independence in carrying out your duties in the MTC?

_____

_____

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances.

_____ _____

Signature Date

Annex 1.2: Reporting Template for MTC Meetings

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. Red flags in facility pharmacy (e.g. human resource implications, stock availability)
5. ADR reporting and product quality issues
6. Top expenditure items (from ABC analysis)
7. Report of expired medicines
8. 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- Pharmacy Department, MOH*

Annex 1.3: Blueprint work plan for MTC and example of a filled work plan

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

Area	Activity	Resources needed	Responsible persons	Timeline	Expected output/outcome
MTC operations	TOR/appointment	Stationery	Chairman MTC	By October 17	Approved TOR and appointment for MTC
	MTC meetings	Stationery refreshments Communication costs	Secretary	Bi-monthly	Meetings held as per work plan
	Subcommittee meetings	As above	Sub committees heads	As needed	Meetings held as per plan
	Trainings	Transport and accommodation costs	Secretary and chairman (to liaise with MOH and IPs)		At least half of MTC members trained
Surveys/ reports	Bi-Annual expiry report	Staff time Stationery	Head of pharmacy	July 2017 January 2018	Report compiled and discussed
	Bi annual availability report	Staff time Stationery	Head of pharmacy	July 2017 January 2018	Report compiled and discussed
	ABC and VEN analysis	Staff time Computer	Head of store, Head of pharmacy	August 2017	Annual ABC VEN analysis presented and discussed in MTC
	ACT MUE in OPD	Staff time Stationery	representative of OPD (or any OPD staff) and record officer	December 2017	Survey undertaken and discussed for root cause analysis
	Artesunate 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 2018	Survey undertaken and discussed for root cause analysis
Interventions /actions	Revision Institutional Medicine List	Staff time Stationery	Head of pharmacy and chairman	October 2017	Revised list approved by director
	IP pharmacy implementation	Room, shelving	Head of pharmacy	December 2017	IP pharmacy functional
	Procurement plan	Staff time Stationery	Head of pharmacy/store	March 2018	Plan approved by …
	Policy on donations	Staff time Stationery	Senior dispenser (to liaise with MOH)	June 2018	Policy officially adopted
	Malaria intervention in OPD/IP	Staff time Stationery	As per emerging findings	June 2018	Intervention planned and started (as per findings from surveys)

2 Quality Improvement for Pharmaceuticals

2.1 Introduction

The *National Health Sector Quality Improvement (QI) framework and Strategic Plan 2015/16 – 2019/20* identifies the MTC as a Work Improvement Teams (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 and 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*".

2.2 Quality in Health Care

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 in fact the part of quality assurance dealing with the use of pharmaceuticals, and follows the standard steps, as shown below.

	QUALITY ASSURANCE	APPROPRIATE MEDICINES MANAGEMENT AND USE
Defining quality	Setting standards, procedures, regulations	Standard Treatment Guidelines, Essential Medicine List, Medicine Management policies and guideline
Measuring quality	Quantifying current level of performance and compliance with expected standards, in order 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 medicines

2.2.1 How to begin: set standards and implement 5S

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

The second step, before embarking in more complex and time consuming work, should be to follow the 5 S quality method. The 5S methodology (from Japan) 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:

5 S	Definition
SORT	Eliminate all unnecessary tools, parts, equipment, keeping only essential items, neatly organized in easily accessible places.
SET	Set in order to flow: arrange the work, the workers, the equipment, the parts, the steps of a process, 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, 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 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 WORK FLOW!

2.2.2 Continuous Quality Improvement

The next step is the real core of the process: continuous quality improvement (CQI), a long term continuous approach based on a system (not individual) 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 who takes responsibility for quality improvement in a determined area of care, (e.g., the MTC, the infection control committee, the ART QI committee). While some committees are recommended at central level, the overall QI committee will be responsible for identifying areas which needs to be addressed.

The improvement cycle involves 4 steps:

Identify the problem: according to priority criteria like magnitude (number of people affected) , severity of consequences, economical costs…but also on the possibility of addressing it: choose an issue which is within your reach, for example, the 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 allow you to monitor change when interventions are put in place.

Analyse the problem further and investigate the determinants/causes): Focus on system issues – why the problem exists (e.g. lack of staff? Of knowledge? Of 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.

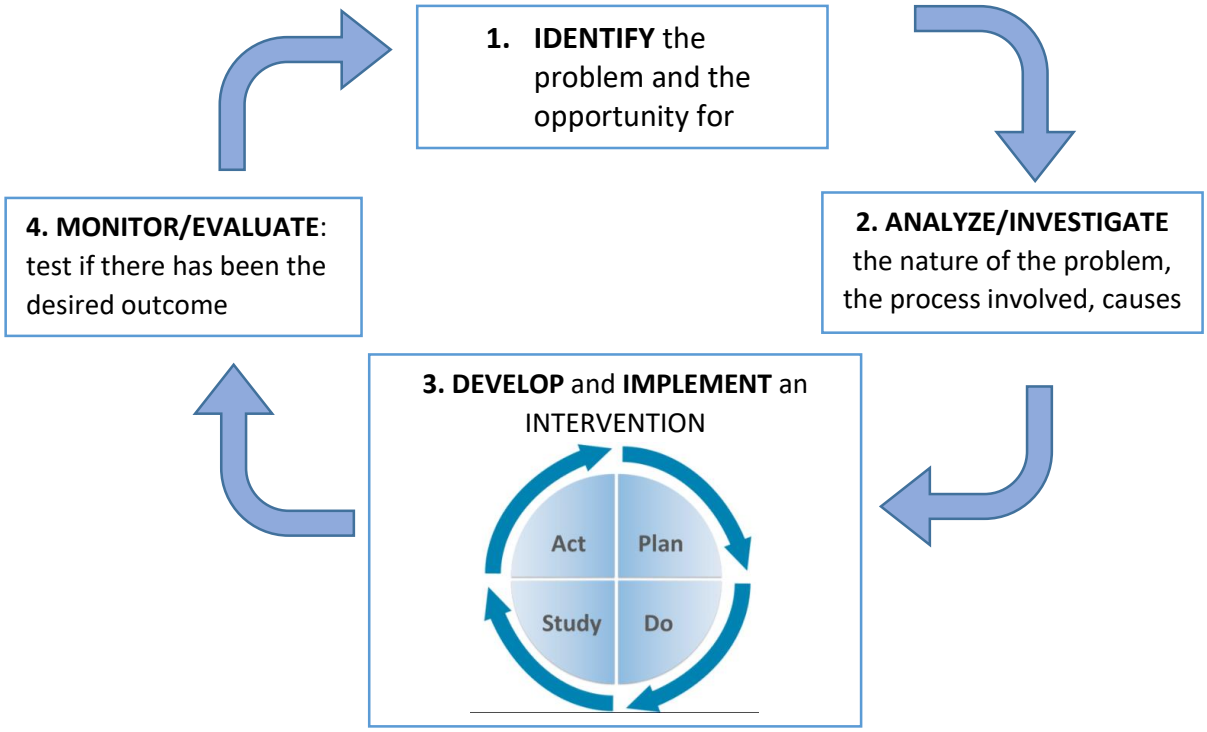
> More often, problems are caused by a complex combination of factors, not by an individual making a mistake. Root causes have to be investigated and understood in order to develop effective interventions!!

Design and implement an intervention): This entails reflecting on the root causes identified and plan how to address at least some of them. You may need to try different approaches and see which one is obtaining 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 larger scale, and include the change into the mainstream, making sure that the new approach becomes a 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 backwards!

Fig 2.1 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 a number of 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.

2.3 Quality Improvement Tools

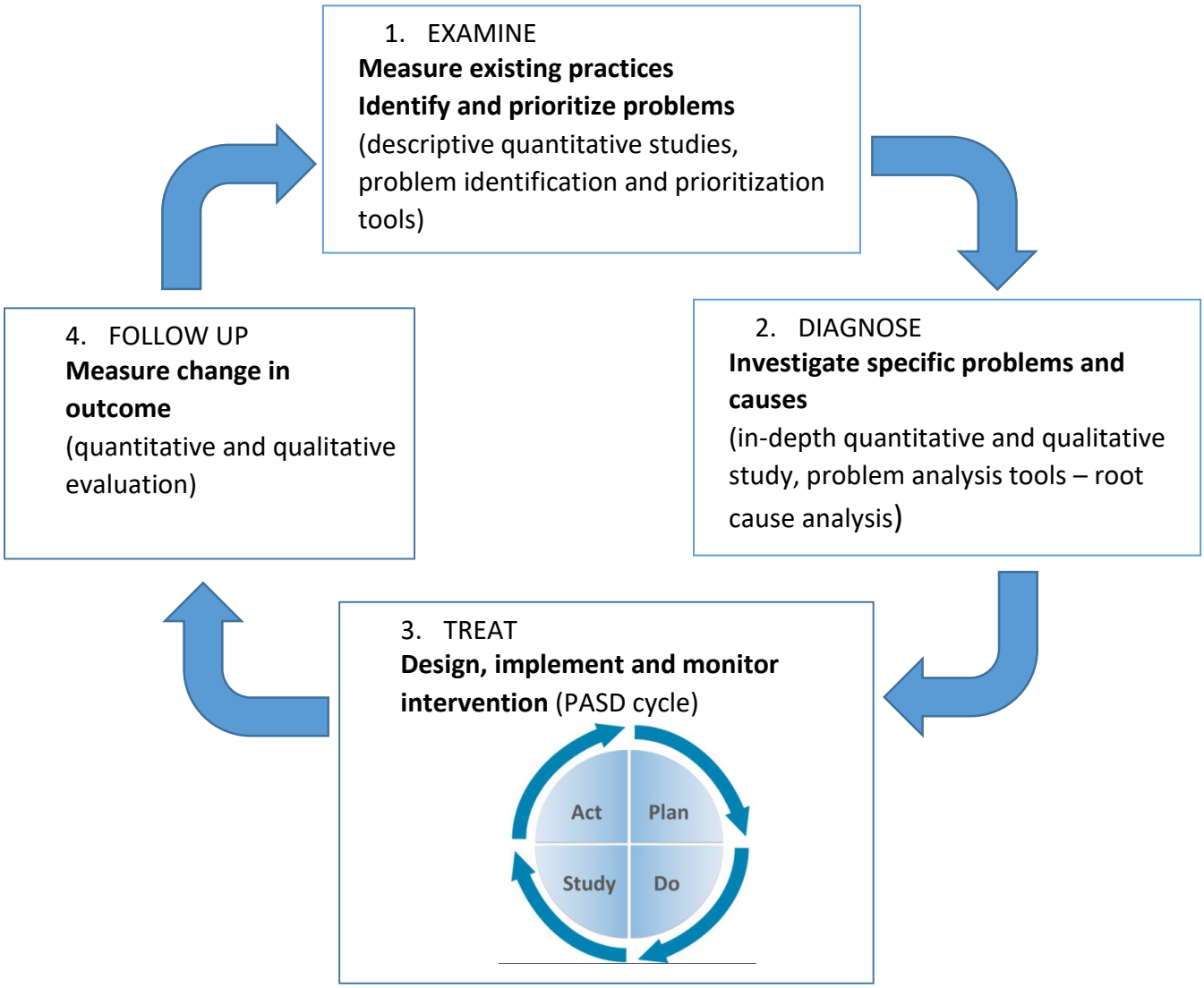
There are many QI tools and methodologies, which can be used at the different stages of the CQI process. They are presented here briefly and in the following chapters, their application to the area of appropriate medicine management and use will be demonstrated.
The table below shows a summary of different methods of identifying and analysing problems, to identify the root causes and see the relationships between the different factors, and to formulate possible solutions and interventions.

Method	Description	Used for	Example
Brain-storming	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. though 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 there is 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 categorised into OPD and IP issues, general or disease specific issues… The causes of treating without testing can be grouped into: staff, supply, knowledge, service organizational issues…
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 for each criteria. Total scores are calculated and issues are prioritized by the scores.	Problem prioritization Intervention design and Implement-ation	In prioritization of problems, there can be impact on morbidity/mortality, economic impact, quality of care etc. Intervention chosen is based on feasibility, affordability, degree of impact, acceptability etc
Method	**Description**	**Used for**	**Example**

Cause-Effect diagram/ Fishbone Diagram/ Problem tree	Technique used to discover the possible causes of a problem, often using data generated from a 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 e.t.c.
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 result from lab Why does it take too long to get the results? Etc…
FLOW CHARTS	Way of analysing a problem by breaking it down in steps, in order to be able to analyse each one of them and identify bottlenecks, inefficiencies, and causes	Problem analysis	What is the process of care for an OPD patient with fever?
PDSA cycle Plan-Do-Study-Act 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 implement-ation	How can we change that practice? Does this work?

2.4 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 similar to 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 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:



In the following paragraphs the single steps are 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 5**.

2.4.1 Step 1. Examine: Measure, Identify, Prioritize

A problem is regarded as a difference between the actual situation and the desired situation. Obviously in order to define this difference we need to know what the ideal (desired) situation is, that is the STANDARD. As said before, 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, therapeutic category, ABC-VEN analysis and VEN classification)
- Drug use surveys (OPD drug indicator surveys, hospital antibiotic use survey)

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

In order to select and develop strategies to improve medicine management and use in the health facility, it is important that the problems listed are prioritised 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.

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 problem? 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 shading 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 prioritised 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 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.

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.

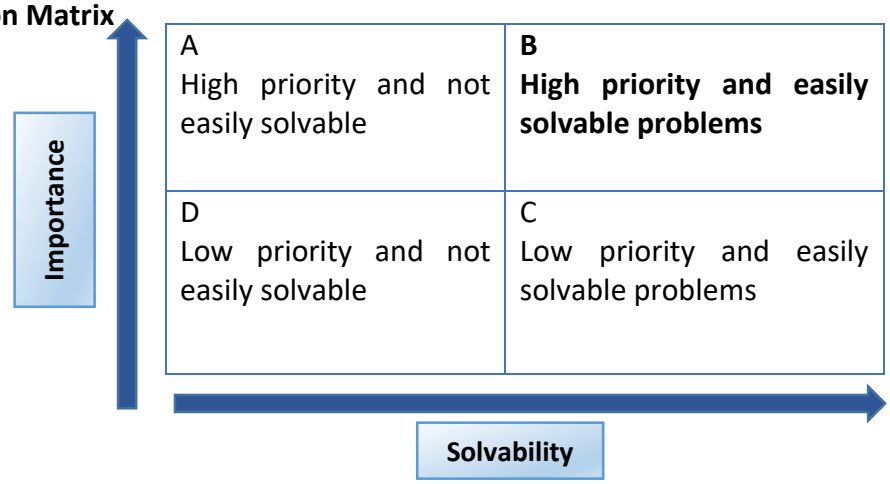
2. Ranking the problems: For each criterion you rank the problems, assigning a rank from higher number (most important) to lower number (least important). The difference with rating is that you can only assign a rank once so results are more clear-cutting. This method leads to a much livelier discussion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

Ranking	Treatment of malaria without testing	Low adherence to guidelines in hypertension treatment	Overuse antibiotics in OPD
Scale of the problem	3	1	2
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. **Prioritisation matrix:** Another simple way of prioritising problems is by use of the matrix (*see figure below*). The identified problems are discussed and categorised based on importance of problem and solvability. The problems falling in **box B** would then be considered first to tackle.

Prioritisation Matrix



2.4.2 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 OPD department
- Prescription surveys on the most common infective diagnosis in 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 by a problem solving team. It is used to centre and 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.

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.

> **VERY IMPORTANT:** Investigating a problem is not a mistake-finding and blame-apportioning exercise. The task is to find explanations in order to design solutions.

It is important to dig into a problem enough to understand which factors are involved, how internal and external factors interact, which ones can be modified, and those which will be difficult or impossible to change. The process of determining a root cause also helps us to describe the problem in detail by finding out how different stakeholders view the problem.

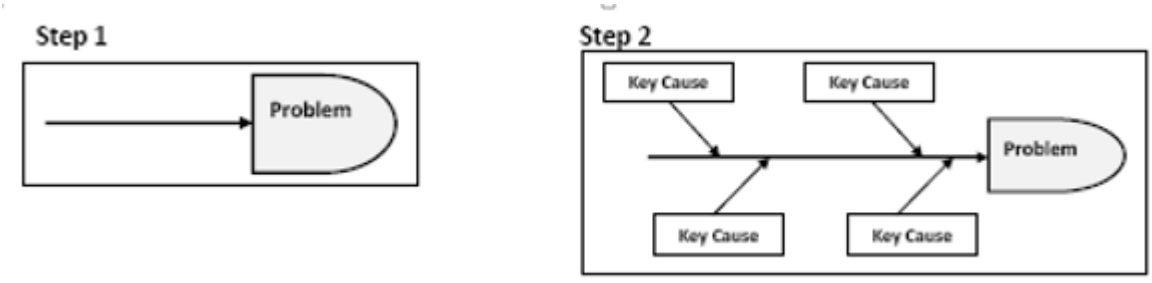
Techniques for root cause analysis

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.

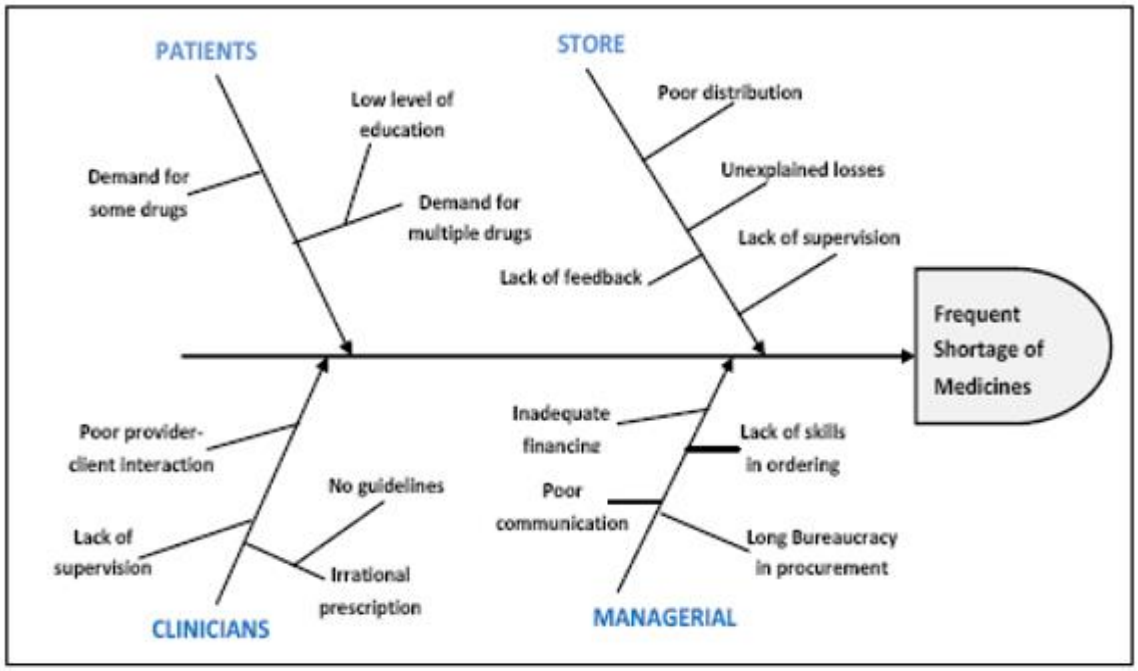
The "5 Whys" technique: This technique involves asking the question "why" 5 times, while listing down the reasons given by different stakeholders. Then to each answer, the "why" is asked again until a root cause is reached. It helps to determine the relationship between different root causes of a problem. 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.
An example for the "The quality improvement methods: a manual for health workers in Uganda" is shown below.

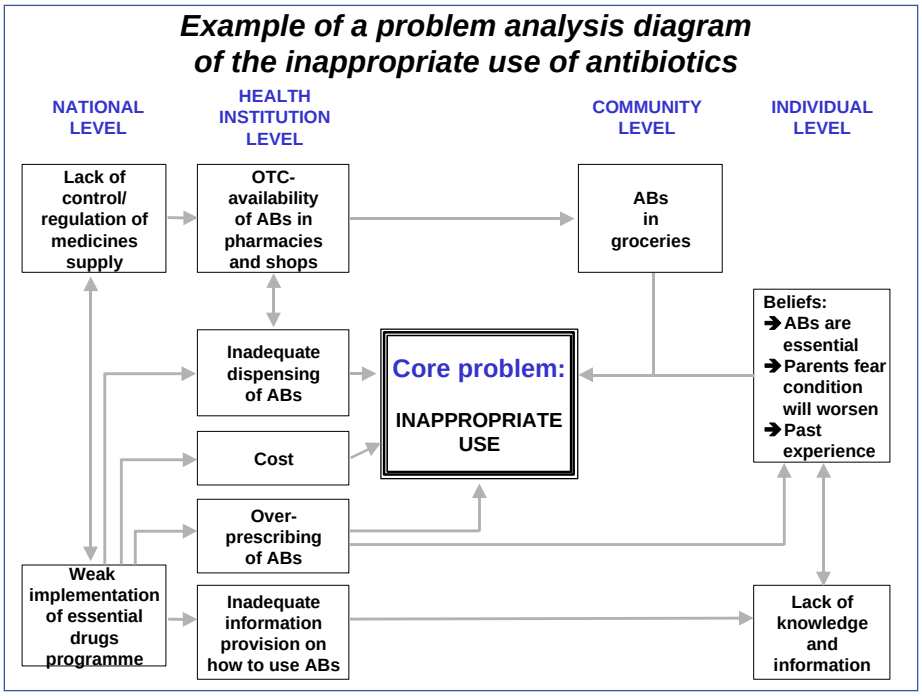


Step 3



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 below as an example.



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 change?

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.

2.4.3 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 behaviours 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 what training will they need?
- **Plan Do Study Act cycle:** conduct pilot tests to determine the acceptability and effectiveness of an intervention, analyse 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 6**.

2.4.4 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 those 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

3 Appropriate Medicines Use

3.1 Definition and Principles

Pharmaceuticals take up to 40-60% of health care budgets. Medically inappropriate, ineffective and economically inefficient use of pharmaceuticals is commonly observed in health care 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 use of medicines (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 issue of AMU in the health facilities and will cover:

- Definition, examples, causes, consequences of inappropriate use
- Core strategies to promote appropriate medicines use
- Essential medicines concept
- Standard treatment guidelines

3.1.1 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.

Appropriate use of medicines requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (WHO 1985).

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 diagnosis:*** defining a patient’s problems correctly is important or else it would set off a cascade of inappropriate use
- ***Right medicine:*** prescribing cost-effective, safe and affordable medicines. The issue of costs has to 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 patient:*** selecting appropriate medicines for age, sex, dosage, administration route and duration, no contraindications, acceptability to the patient
- ***Appropriate patient information*****:** patients are provided with relevant, accurate, important and clear information regarding their conditions and their prescribed medication(s), including how and when to take, importance of adherence, side effects and possible toxicity
- ***Appropriate evaluation.*** The anticipated and unexpected effects of medications are appropriately monitored and interpreted.

3.1.2 Examples of Inappropriate Use

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

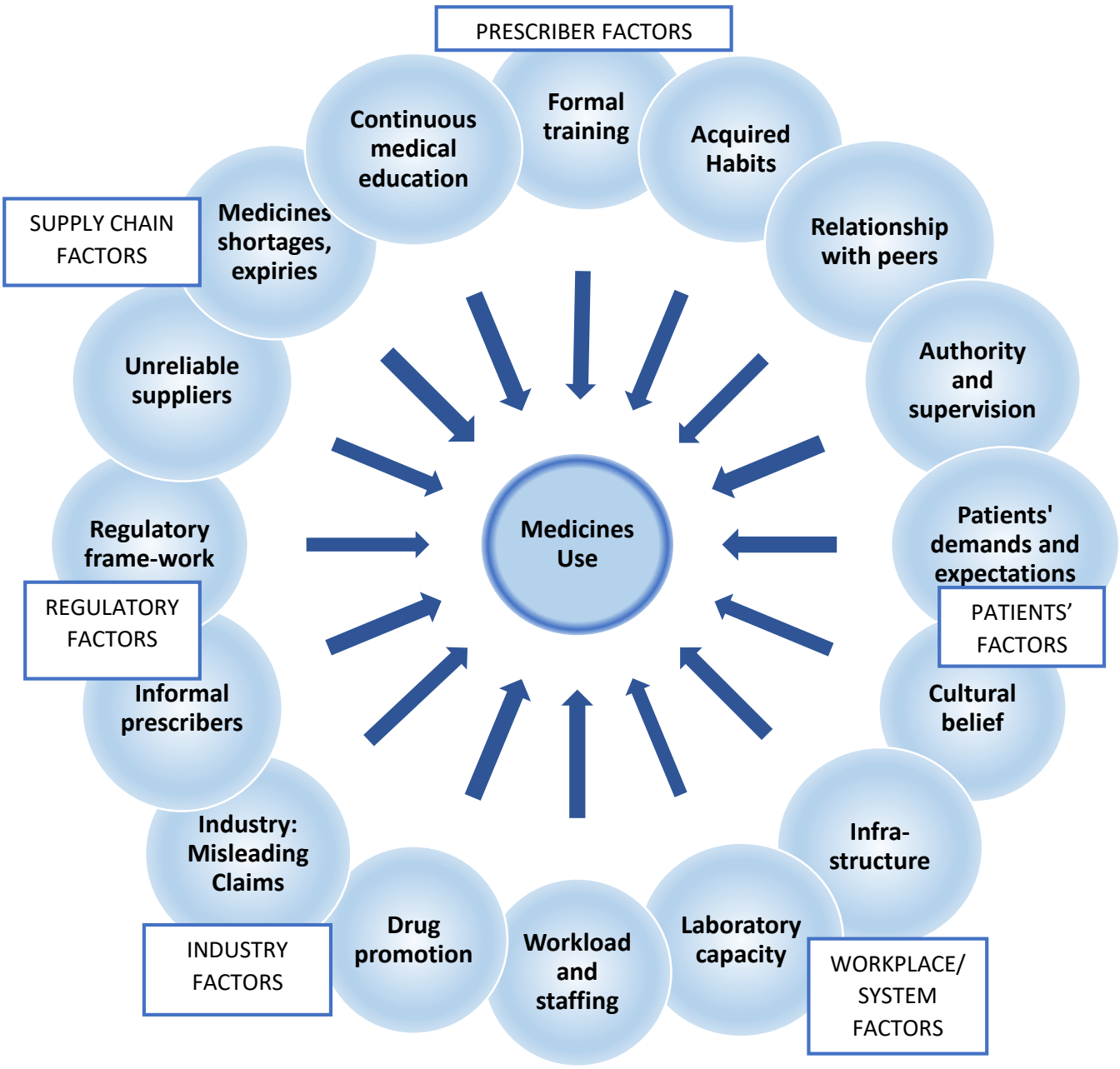
- The use of medicines when no medicine therapy is required e.g. use of antibiotics for viral infections
- The use of the wrong medicine for a specific condition e.g. treatment of simple non-bloody diarrhoea with antibiotics
- The use of medicines with doubtful or unproven efficacy e.g. use of multivitamins without evidence of deficiencies
- The use of medicines of uncertain safety status e.g. unlabelled medicines
- The use of unnecessarily expensive medicines, 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.

3.1.3 Factors That Influence Appropriate Medicine Use

A wide range of factors cause problems in medicine use. These factors differ in importance from problem to problem and from setting to setting. Before trying to correct any problem in medicine use, it is helpful to identify which factors are most important in causing the problem at hand. Unless the proposed intervention targets the appropriate causes of the problem, it is unlikely to be successful.

The major forces can be categorized as those deriving from patients, prescribers, the workplace, the supply system including industry influences, social and cultural influences, regulation, medicine information and misinformation, and combinations of these factors.

Figure 3.1: Some factors influencing appropriate medicine use



3.1.4 The Impact of Inappropriate Medicines Use

The impacts of this irrational use of medicines can be seen in many ways:
Reduction in the quality of medicine therapy leading to increased morbidity and mortality
Wastage of resources leading to stock outs, reduced availability of other vital medicines and increased costs
Increased risk of unwanted effects such as adverse medicine reactions and the emergence of medicine resistance, e.g., malaria or multidrug resistant tuberculosis
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.
Irrational use of medicines can also compromise the trust in the health system.

IMPORTANT TO NOTE: Medicine use is the end of the therapeutic 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 frequently lowers cost.

3.2 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 therapeutic benefits from medicines through their scientifically sound and cost-effective use by prescribers, dispensers and consumers.

Table 1.1: Core strategies for improving 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 list
4. Establishment of drug and therapeutics committees (also called Medicine and Therapeutics Committees) in districts and hospitals
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
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 Pharmacy Department 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.

3.3 Standard Treatment Guidelines

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.

Standard Treatment Guidelines provide the “standards” used to assess appropriateness of medicine use and are therefore at the core of any work in appropriate medicine use.

3.3.1 Potential benefits of standard treatment guidelines

STGs promote high quality of care across the health system by:
Linking scientific evidence to clinical practice
Promoting appropriate use of resources
Guiding procurement/supply of pharmaceuticals
Guiding training
Promoting standards of care

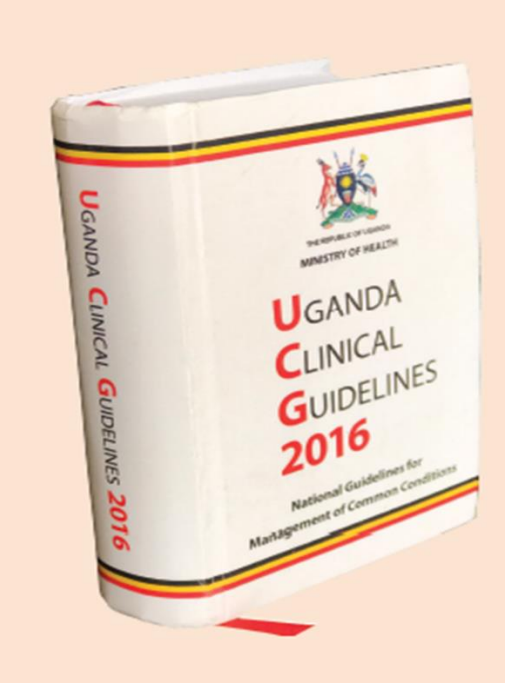
Table 1.2: Benefits of standard treatment guidelines for different stakeholders

For health officials/practitioners	For Managers
- Evidence based guidance - Improved diagnostic accuracy - Effective and safe therapy - Standardised information for patients - Support evidence/protection/defence against malpractice - Comprehensive guidelines inclusive of special programs	- Tools to measure, monitor and improve performance and quality of care - Standardised basis for quantifying, ordering and procuring supplies - Basis for health workers training - Tool to enhance efficiency/appropriate use of resources
For supply management staff	**For Patients**
- Identifies which medicines should be available for the most commonly treated problems - Facilitates pre-packaging of course-of-therapy quantities of commonly prescribed items	- 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

3.3.2 Uganda Clinical Guidelines

Uganda has had five editions of national standard treatment guidelines published in 1993, 2003, 2010, 2012 and 2016 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 when needed.

In both the 2012 and 2016 editions, the UCG was harmonized with the Essential Medicines List to ensure that all medicines recommended in the UCG are in the EML, which in turn ensures that they are procured and availed at the health facilities.

Getting the diagnosis correct is a very important first step in appropriate patient management, and therefore the UCG 2016 in addition is harmonized with "**laboratory test menu"**, which indicates the tests available at the different levels of care.

3.3.3 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 is generally entrusted with the academic specialists (experts) for each given therapeutic 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/implementability*** for our setting and the level of care within the Ugandan health care system: the selected alternative has to be affordable, implementable (the conditions for its implementation have to 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 particular in the area of medicine use.

3.4 Essential Medicines

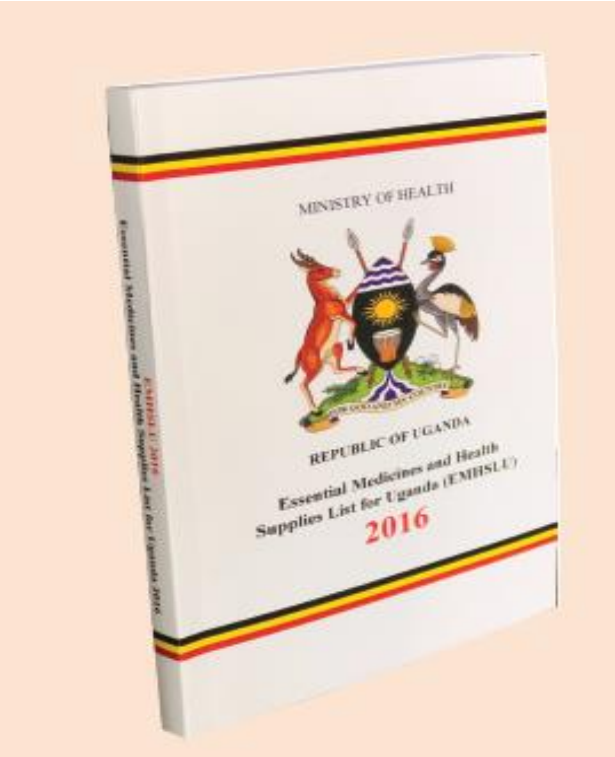
Essential medicines are those that satisfy the priority health care needs of the population. They therefore must be available at all times, in adequate amounts and in the appropriate dosage forms, (WHO 2002).

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:

- Majority of health problems can be treated with a small number of medicines.
- In practice, health professionals routinely use fewer than 200 medicines. Training and clinical experience should focus on the proper use of these few medicines.

Benefits of the Essential Medicines Concept
- Better therapy as clinicians become knowledgeable with an adequate number of medicines - Procurement and distribution is 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

3.4.1 Uganda Essential Medicines List



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

From 2012 the EML 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) and assure availability of all supplies needed to deliver optimal care at health facilities.

Both the 2012 and the 2016 editions of the EMHSLU are harmonized with the clinical guidelines (UCG), to ensure that all the medicines recommended in the UCG are listed on the EML. In addition, the EML 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 EML 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 dose-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

3.4.2 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 prioritise 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 first 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, must be available always
- **E: Essential** drugs are effective against less severe but nevertheless significant forms of illness but are not absolutely vital to providing basic health care;
- **N: Necessary** (or sometimes called **non-essential**) drugs are used for minor or self-limited illnesses, are of questionable efficacy, or have a comparatively high cost for a marginal therapeutic advantage.

3.4.3 Institutional Medicines List (IML)

The EMHSLU of Uganda is developed at central level, and it contains a wide range of medicines/formulations, (approximately 600 preparations). Not all these are required at all facilities, and therefore it is expected that hospitals each develop 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, eases monitoring of stock, fosters adherence to treatment guidelines and eases training of health workers.

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

- Morbidity patterns of the hospitals 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

3.5 Medicines Information: Practical Guidelines for Dispensing

In order to use medicines appropriately, health care 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 pressurize prescribers into prescribing expensive or unnecessary medicines that are outside of the essential medicines list.

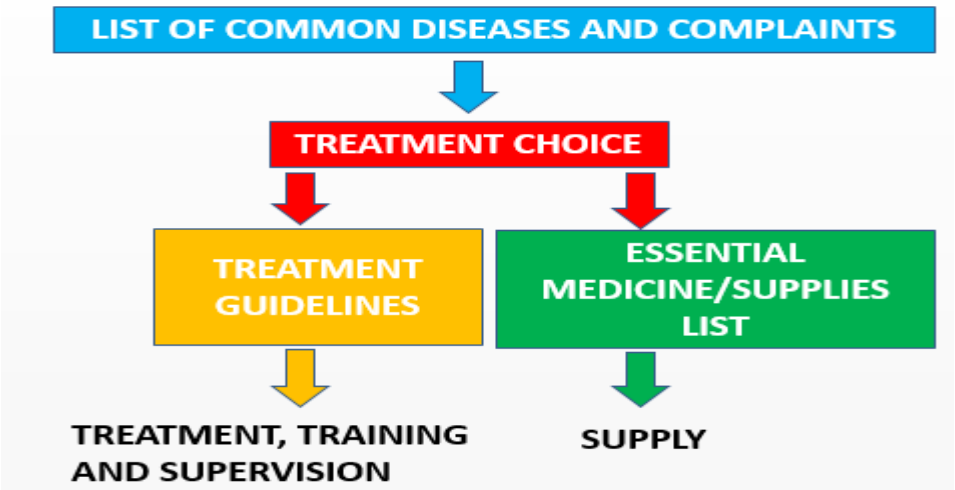
The MOH Pharmacy Department has developed and distributed two medicines information reference books, the "***Practical Guidelines for Dispensing (PGD) for lower level (2014) and higher level health facilities (2015)***". These provide information and instructions about the medicines in the Uganda essential medicines 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.

3.6 Development of clinical guidelines and essential medicines lists

Clinical guidelines and essential medicines and supplies 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 on a continuous basis from MTC, provide important information about arising needs and issues and acceptability and feasibility of options.



4 Institutional Medicine List

4.1 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 health care needs of the majority of the patients. At national level in Uganda 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 centres,** containing information on the medicines in the Essential Medicines and Health Supplies List of Uganda, and to the National formulary, which is under development, and should contain 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 list **Institutional Medicine List** (IML) should be developed and maintained based on recommended treatments from standard treatment guidelines, using explicit medicine selection criteria that have been agreed 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 3**.

4.1.1 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. Quality of care will be further improved if medicine selection is based on evidence-based treatment guidelines.

4.2 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 5***) can give inputs to this process.
- Availability of a reliable supplier (in 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.

4.2.1 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 facility level may be the department which can use the specific product or the cadre which is allowed to prescribe it. For example, a hospital may choose to restrict prescription of certain injectables to in-patients, or restrict prescription of specific antibiotics to consultants or certain medicines to specialist cadres. An example is provided below.

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

Table 4.1: model for Institutional Medicine List

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.

4.2.2 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 4.1** 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 at 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 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 medicine of choice for the condition identified • Avoid duplications, both therapeutic and pharmaceutical (dosage forms) • Use explicit selection criteria, based on prove efficacy, safety, quality and cost • Use evidence-based information whenever possible • Be consistent with national Essential Medicine List and Standard Treatment Guidelines • Consider requests for addition of new products only when made by health care 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 of 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.

4.3 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.

In order to efficiently maintain an IML, the MTC should:

- inform, educate and involve prescribers in the development of the IML
- review and take action on all non-formulary medicine use; action may include adding the medicine to the formulary, educating the prescriber about the non-formulary status of the medicines or banning use of the medicine 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.

Annex 4.1: Template for application form for addition or deletion of a product in IML/EML

Applicant name	Title	Department
Signature	Date	
Name/strength and formulation of product		
Is the product in the updated Essential Medicine and Health Supply List of Uganda?		
If not, is the product in the updated WHO Essential Medicine List?		
If not, what is the document of reference?		
Proposed indication for use		
Pharmacological properties (mode of action, contraindication, side effects, interactions)		
Are there standard prescribing guidelines (if yes, attach)		
Are there restriction for prescribing? If yes, specify		
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.		
Does it replace any other treatment?		
What is the cost of the product and per course of treatment?		
Specify the VEN classification of the item added/ deleted		
Estimated number of patients needing that medicine per year and estimated total expenditure per year		

(Adapted from Drug and Therapeutics Committees - a practical guide, WHO, 2008)

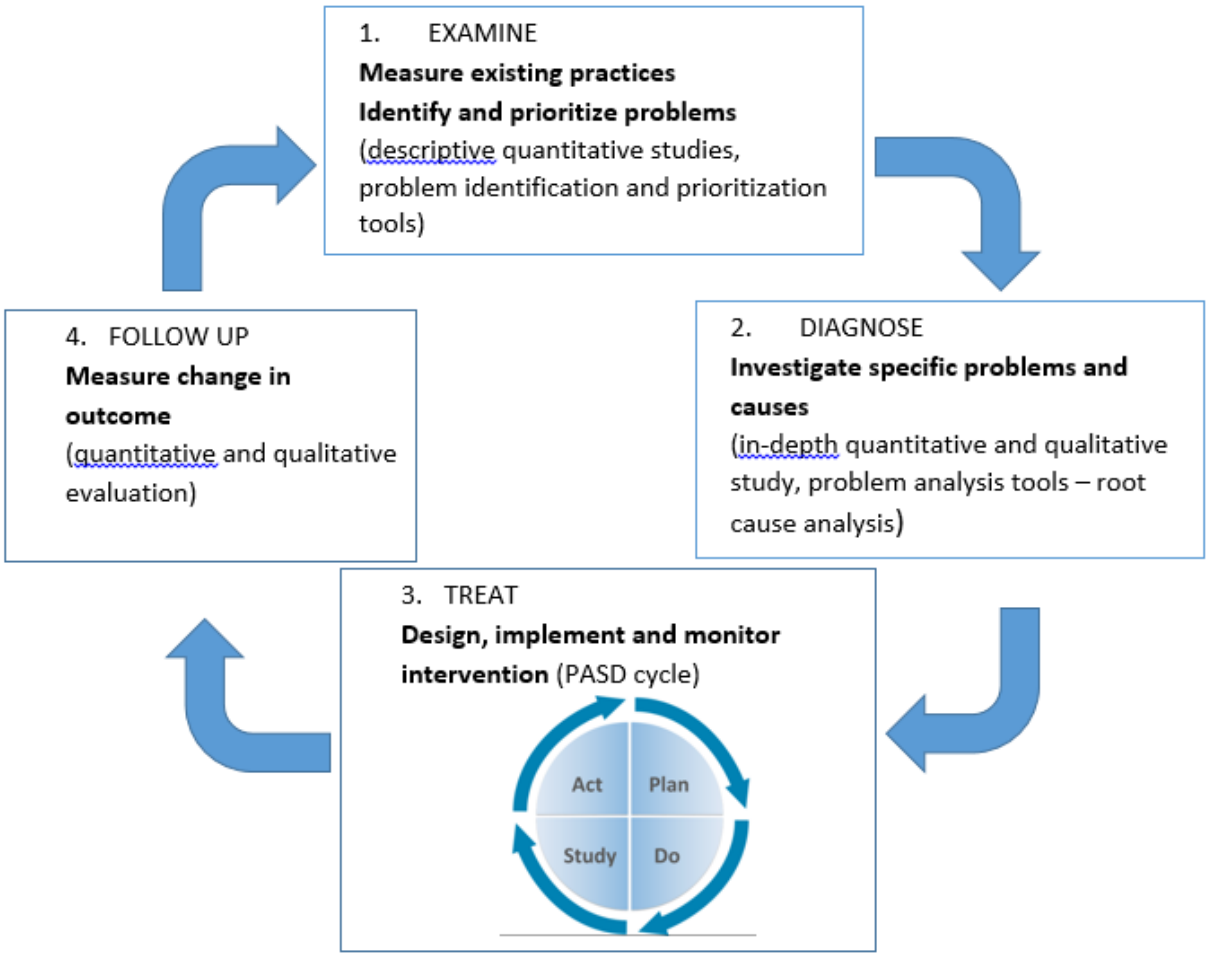
5 How to Investigate Medicine Use Problems

5.1 Introduction

The first steps in addressing inappropriate use of medicine and supplies are to **Identify, Measure** and **Investigate** problems, followed by the development and implementation of **Intervention** and the **Monitoring and Evaluation** of the result. This cycle mirrors exactly what is described in the general CQI approach in **chapter 2**.

Medicine use problems may be difficult to detect on a day-to-day basis, except a few obvious ones, and so specific methodologies 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.

Figure 5.1: Steps in addressing a medicine problem



Medicines use investigation methods can be broadly categorised into two groups as shown below:

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 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 in following flow of a certain commodity and reconciling amounts from ordering, to delivery from 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, they are addressed in **chapter 7**.

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.

5.1.1 Challenges in data collection

Most of the methods described in these chapters require data collection activities from facility documents: stock cards, invoices, patients’ registers, dispensing logs, patients’ files.
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 the improvement in documentation is one of the quality improvement interventions that will emerge as necessary.

5.2 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 facility level or at department level. Generally aggregate analysis is done on medicines but it should also be done on laboratory items and health supplies, 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 most money spent?
- Which are the most expensive items?
- What are the most expensive therapeutic categories?
- What is the percentage of 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 less expensive?
- Does items consumptions match expected consumptions according to morbidity records?

5.2.1 ABC analysis

ABC analysis is the breakdown of the consumption of medicines and supplies and their cost for a certain period of time (commonly one year), in order 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 consumptions of items not reflecting 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 who 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 the table below:

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 large-volume and/or 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 the majority 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 book and invoices) or obtained from 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 level. 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 e.t.c).

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 analysing.
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.

No	Medicine	VEN	Unit cost	Quantity consumed (a specified period)	Total cost	
1	Amoxicillin 250 mg 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 in order 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

No	Medicine	VEN	Unit cost	Quantity consumed	Total cost	% of total cost	
1	Amoxicillin 250 mg 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 item.

No	Medicine	VEN	Unit cost	Quantity consumed	Total cost	% of total costs	Cumulative % of costs
2	Paracetamol 500 mg 1000 tab	E	4,000	25	100,000	***40%***	***40%***
1	Amoxicillin 250 mg 1000	V	5,000	17	85,000	***34%***	***34% + 40% =74%***
3	Nifedipine R 20 mg 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 next 15-20% of the budget
- C: those accounting for the remaining 5-10% of the budget.

	Medicine	**Unit cost**	**Quantity consumed**	**Total cost**	**% of total costs**	**Cumulative % of costs**
A	Paracetamol 500 mg 1000 tab	4,000	25	100,000	***40%***	***40%***
	Amoxicillin 250 mg 1000	5,000	17	85,000	***34%***	***34% + 40% =74%***
B	Nifedipine R 20 mg 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:

- What are we spending our money on?
- Do we spend significant money on N (necessary/non-essential) items? Or on items with cheaper alternatives?
- Could some items be over-consumed?
- 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 which have the potential for more cost-saving and impact.

Sources of data

Ideally, the ABC analysis is conducted using consumption data, which are the quantities issued from the central 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 have been filled correctly for a sufficient period of time, the program should be able to give the ABC report automatically – provided that the report settings are correct.
- If your data are manual, consumption data for a certain period can be got from the stock book, or stock cards, and entered into 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 weighed 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 more or less 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 analyse projected consumptions and verify your choices, and make adjustments 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 supplies.

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 the consumption, causing an underestimation. If an item has been out of stock for 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 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 on the medicine budget they are often not considered. There are different solutions to this: give a market value and include them 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 worthy to look into their use and make sure they are used optimally. Examples in the Ugandan setting are antimalarials, HIV, TB and reproductive health commodities, that are which 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 the class A are shown. The total number of medicines in the ABC was 245. 23 items (10%) are responsible of 80% of the total medicine expenditure, and the first 3 items alone represent almost a third of the medicine budget!

	Description	QTY	VEN	TOTAL COST	% of total cost	CUM %
1	Sodium Chloride/Normal Saline 0.9% Infusion24 bags	1,067	V	30,422,304	12%	12%
2	Ceftriaxone Sodium 1g Powder For Inj. Vial 1	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/1ml Injection 100 amp	124	V	2,545,296	1%	80%

Several observations can be done about 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 analysing 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 in 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 9***)

- Anaesthetic 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?

Example 2: ABC analysis of Hospital B

	Description	VEN	Issued Qty	UNIT PRICE	TOTAL COST	%	CUM %
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% Mouth Wash; 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; 60 mL [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 quite 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.

Example 3: ABC analysis of Hospital C

	Description	VEN	Issued Qty	UNIT PRICE	TOTAL COST	%	CUM %
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 items are gloves! Actually, the complete ABC shows that 2/3 of the expenditures is on supplies and only 1/3 on medicines. Analysing and improving use of supplies is therefore VERY IMPORTANT to overall cost-savings on the pharmaceutics budget.

5.2.2 The VEN analysis

In the context of limited resources, it is very important to learn to prioritise 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 which 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 nevertheless 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 prioritise items during procurement and verify that purchases are done according to correct priority criteria: vital items have first 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 anyway 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 more 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 2016 have already 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 which are not really essential at HC3 level may be vital at regional referral level because of availability of different or specialised skills, diagnostic possibilities, or because that specific region has a high morbidity of a particular disease.

Step 2: Analyse 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 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 again the ABC analysis of example 1 Hospital A above (see *full ABC in Annex 5.1*). 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. BUT 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 we sum up the percentages, and we end up with the following results:

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**!

5.2.3 Therapeutic Category Analysis

The therapeutic category analysis evaluates medicines by therapeutic group (i.e., antibiotics, anti-hypertensives, anaesthetics 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 highest consumption and expenditures
- Cross-check consumptions with morbidity patterns.

Practical instructions for performing a therapeutic category analysis

Step 1 to 5: As for 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 which 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 together 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 sulphate 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 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 pointers to inappropriate use (e.g. high consumption of second line anti-hypertensives). Remember to compare the costs of items within a therapeutic category using the average daily dose.

For example, in order 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 analyse the consumption on medicines based on a standardized daily dose. It is mostly used for monitor and comparison purposes, especially of antibiotics, and it will be explained in **Chapter 9**.

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 is presented below.

Class/category	% of budget	Class/category	% of budget
Anaesthetics	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%**

Anaesthetics 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).

5.3 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.

5.3.1 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 question: **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 below.

Category	Example
Prescribing indicators	1. Average number of medicines per encounter 2. % of medicines prescribed by generic name 3. % of encounters with an antibiotic prescribed 4. % of encounters with an injection prescribed 5. % of medicines prescribed which are from the EML or formulary list
Patient care indicators	1. Average consultation time 2. Average dispensing times 3. % of medicines actually dispensed 4. % of medicines that are adequately labelled 5. % of patients who know how to take their medicines
Facility indicators	1. Availability of essential medicine list 2. Availability of key set of indicator medicines 3. Availability of standard treatment guideline (STG)

Additional drug use indicators

Additional indicators have been developed but they are more difficult to define, measure and to collect, and are therefore are less standardized:

Category of indicator	Example
Complementary indicators	1. % of patients treated without medicines 2. Average medicine costs per encounter 3. % of medicine cost spent on antibiotics 4. % of medicine cost spent on injections 5. % of prescriptions in accordance with STG 6. % of patients satisfied with care provided 7. % 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). Patients' 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 specialised 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 analysing the prescription practices of its own 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)
- Are some brand name and abbreviations to be counted as generic (e.g. aspirin, Coartem, ACT, PCM, SP)?
- 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 months January to March 2016.
- 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 (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 analyse the data using the attached form and formulas (see next page for tables an examples). Per are no pre-set absolute thresholds or standards for the value of the indicators, since they depend on a number of 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 OF RAW DATA COLLECTION FOR DRUG USE INDICATORS SURVEY (PRESCRIBING INDICATORS). EXAMPLES FROM ACTUAL DATA

OPD No	Initials of pt	Age	Sex	Diagnosis (write all diagnoses if more than one is on the prescription)	Treatment (copy original prescription as it is written, including dose duration etc)
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	Prednisolone 5 mg TDS 5/7 Calcium lactate 1 tab OD 2/52 Hifenac 50 mg TDS 5/7

TABLE FOR DRUG PRESCRIBING INDICATOR SURVEY DATA COLLECTION

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						
7						
8						
9						
10						
11						
12						
……..						
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** % of medicines being antibiotics **=(C/A)*100**	% PATIENTS RECEIVING 1 OR MORE INJECTIONS **=(H/F)*100** % of medicines being injections **=(D/A)*100**	% OF MEDICINES NOT IN THE UCG **=(E/A)*100**	% DIAGNOSIS RECORDING **=(I/F)*100**

Example 1: Drug indicator survey results in Uganda

The table 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 3 months	110 over 3 months	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
    a. Hospital 3 has a higher number of medicines per patient (WHO standard is 2.5-3).
2. % of medicines prescribed by generic name:
    a. Excellent in hospital 2, but unsatisfactory in hospital 1 and 3. Ideally, medicines should always be prescribed by generic name.
    b. % patients receiving Antibiotics: over prescription in all the 3 hospitals. An acceptable range 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 to use injectable medicines at OPD level so injection use should be carefully scrutinized.
4. % 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) which may need to be further investigated.

Patient care indicators

These indicators are very useful to assess the quality of dispensing, which is as well 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.

The following table 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 are undergone the training for Medicine Management Supervisors will have good knowledge on the methods.

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 actually dispensed	Compare number of medicine actually dispensed by the number of medicines prescribed. Since the current dispensing log only record dispensed medicines, this information can be extracted from patient's forms only. Or, retrospectively, by comparing data from OPD register and dispensing log.
Percentage of medicines adequately labelled	Percentage of medicine packages adequately labelled (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

5.3.2 Antimicrobial Use Indicators

This is a more recent and more complex set of indicators presented at the last International Conference for Improving Use of Medicines in 2011. They focus on antibiotic use at 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 life-saving 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,
- Last but not least, 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 similar to 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 Module (***See Chapter 9***).

5.3.3 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 in order to detect eventual inappropriate practices which can potentially cause adverse effects including therapeutic failure. From the point of view of safety and pharmacovigilance, these are called ***medication errors*** (***see chapter 8***).

Investigations in administration and dispensing can be conducted through:

- Chart review (paper or electronic)
- Direct observation

In both cases, standards of practice have to 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 depends 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* conducted an investigation on 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 5.2**

5.4 In-Depth Investigations of Medicine Use Problems

The following methods allow to investigate the **nature and reasons of 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 of 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 stock outs 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).

5.4.1 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 to 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 outcome 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, 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 have to 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, 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 analysed: **minimum 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.

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 also has a quite straightforward and standardized management protocol, especially uncomplicated malaria in OPD.

The criteria for an ACT Medicine Use Evaluation in OPD would then be:

	Criteria	Indicator	Standard
1	Patients who receive ACT should have been diagnosed malaria	% of cases receiving ACT with diagnosis of malaria in OPD register	100%
2	Patients who receives 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 receives ACT should have a positive test for malaria	% patients who received ACT with positive malaria tests	95%
4	Patients with single diagnosis of malaria should not get antibiotics	% single malaria receiving antibiotics	0%

The sampling frame would be samples 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 below.

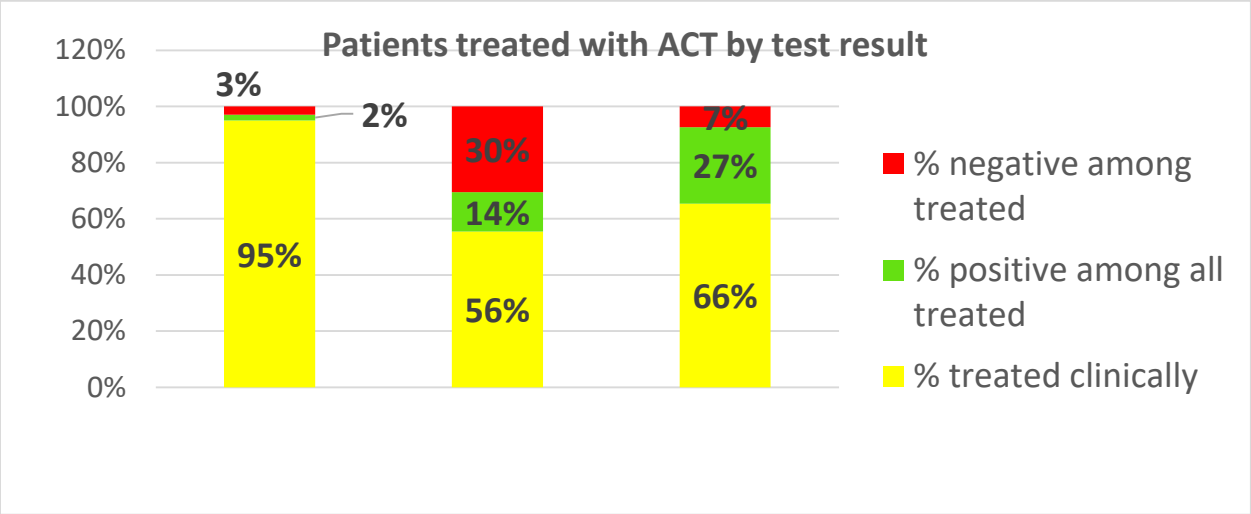
No	Initials or name	OPD No	Date	Age	Sex	Test (RDT or B/S or none)	Result (POS or NEG or Not Applicable)	Diagnosis (copy exactly as written in OPD Register)	Anti-malarial treat given	Antibiotic Treatment (name of Ab prescribed)
1										
2										

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

	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 patient 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 single diagnosis of malaria and given antibiotics	7	14%

Here is the graph 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.



If instead of a MUE, a **malaria prescription audit** was done, the sampling frame would be "all patients diagnosed malaria", from the diagnosis column in OPD register.
The data collection tool would be the same, but the summary table and indicators could look like the following:

	Description	No	%
1	Total number of patients diagnosed 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 patient 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

The table below reports the data collected retrospectively from the OPD register for a UTI 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.

No.	NAME OF PATIENT	AGE / SEX	NEW DIAGNOSIS	DRUGS / TREATMENT
1	MS	10M	UTI	Cipro/metro/pcm
2	IJB	60M	UTI + Keloids	Nitro/pcm/ampicillin
3	MR	7M	UTI	Cipro/metro/pcm
4	NR	11/12 M	UTI	Cipro/pcm/zinc
5	MS	4M	UTI	Flagyl/Cipro
6	LG	29M	UTI	Cipro/metro/pcm
7	SM	1M	UTI	IV Cef/pcm
8	MR	16M	UTI	Cipro/amoxyl/metro/pcm
9	MK	9M	UTI	Nitro/pcm
10	JF	12M	UTI	Cipro/metro/pcm
11	KE	30M	UTI	Metro/pcm
12	LJ	17M	UTI	Doxy/Cipro/metro/pcm
13	NB	14F	UTI	Cipro/metro/pcm
14	MM	16F	UTI	Cipro/metro/pcm
15	NA	24F	UTI	Cipro/metro/inj. Diclo
16	FM	22F	UTI	Doxy/metro/Cipro
17	NM	19F	UTI	Cipro/metro/pcm
18	NM	47F	UTI/cystitis	Metro/Cipro/pcm
19	NM	45F	UTI/PID	Doxy/Cipro/metro/pcm
20	NM	40F	UTI/PID	Metro/Cipro/pcm
21	NR	21F	UTI	Metro/cefixime/pcm
22	NC	30F	UTI/Enteritis	Metro/Cipro/pcm/zinc
23	NK	20F	UTI	Cipro/metro/pcm
24	NJ	29F	UTI	Cipro/metro/albendazole
25	NK	54F	UTI	Cipro/doxy/metro/brufen
26	OM	38F	UTI	Metro/doxy
27	NJ	69F	UTI	Cipro/metro
28	NP	26F	UTI/cystitis	Nitro/bisacodyl
29	NC	26F	UTI	Cipro/metro/pcm
30	NM	15F	UTI	Metro/pcm

The standard guidelines for UTI treatment (UCG 2016) are presented 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.

7.2 UROLOGICAL DISEASES

7.2.1 Acute Cystitis

ICD10 CODE: N30

An infection/inflammation involving the bladder, a part of the lower urinary tract. It is a common manifestation of uncomplicated UTI (Urinary Tract Infection) in non-pregnant women.

Uncomplicated cystitis is less common in men and needs to be differentiated from prostatitis and urethritis (sexually transmitted).

Cause

- Bacterial infection, usually gram negative (from intestinal flora) e.g. *Escherichia coli*

Clinical features

- Dysuria (pain and difficulty in passing urine)
- Urgency of passing urine, frequent passing of small amounts of urine
- Suprapubic pain and tenderness
- Pyuria/haematuria (pus/blood in the urine making it cloudy)
- Foul smelling urine
- There may be retention of urine in severe infection

Investigations

- Midstream urine: urine analysis for protein, blood, leucocytes, nitrates, sediment
- Culture and sensitivity (if resistant/repeated infections)

Diagnostic criteria

Symptoms ± leucocytes and/ or nitrates at urine analysis

Differential diagnosis

- Women: vaginitis
- Men: urethritis (in young sexually active patients), prostatitis (fever, chills, malaise, perineal pain, confusion, in older men)

Note: Asymptomatic bacteriuria or pyuria (leucocytes in urine) does not need treatment except in risk groups such as pregnant women, patients undergoing urological interventions and post kidney transplant patients

Management

TREATMENT	LOC
Uncomplicated UTI (cystitis) in non-pregnant women ▶ Ensure high fluid intake ***First line agents:*** ▶ **Nitrofurantoin** 100 mg every 12 hours (every 6 hours if severe) for 5-7 days *Child:* 3 mg/kg/day every 6 hours for 7 days ***Second line agents*** ▶ **Ciprofloxacin** 500 mg every 12 hours for 3-7 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	

Prevention

- Improved personal/genital hygiene
- Pass urine after coitus
- Drink plenty of fluids

Observations

- Only 3 patients (10%) received nitrofurantoin (the first line treatment as per UCG 2016), in one case with associated ampicillin.
- 1 patient received ceftriaxone alone, 1 received cefixime alone, 2 received metronidazole alone, the rest were treated with ciprofloxacin +/- metronidazole +/- doxycycline.

The conclusion is that adherence to UCG 2016 guideline 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 UTI, and on the differentiation between UTI and STIs. It is also important to investigate the reasons for the observed practices, e.g, was the first line 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 criteria 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 below.

No	Initials	Age/ sex	Weight (Kg)	Admission diagnosis	Discharge diagnosis	Artesunate prescript-tion (mg, doses and frequency)	Number of doses given from administra-tion 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	Penumo-nia	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 analysed 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 many data are missing from the charts or records, a prospective/observation study may need to be done.

5.4.2 Qualitative methods

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

Understanding the causes of the problem is fundamental to design and implement an intervention to change it. Prescribing behaviour is complex and is affected but 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:

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 behaviour or a group of patients to assess 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 behaviour.
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 a number of 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, behaviours. For example, assessing level of knowledge on a certain topic among health workers
Structured observation	This method is usually used to assess the interaction prescriber/patient and requires an independent observer recording data on a predefined tool. It allows to record what happens versus what it is stated to happen, but it has its limitations (e.g., an observer may be biased and observed person may change his/her behaviour 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 is beyond the scope of this manual, also because appropriate design and implementation of these studies may require an expertise which is not routinely available at 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: After finding out that in OPD the testing rate of 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.

ANOTHER EXAMPLE: 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 behaviours: 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 last, 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 behaviours in OPD.

5.4.3 Root Cause Analysis

The principles and methods for conducting a root cause analysis have been presented in Chapter **2**. 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 behavioural 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:

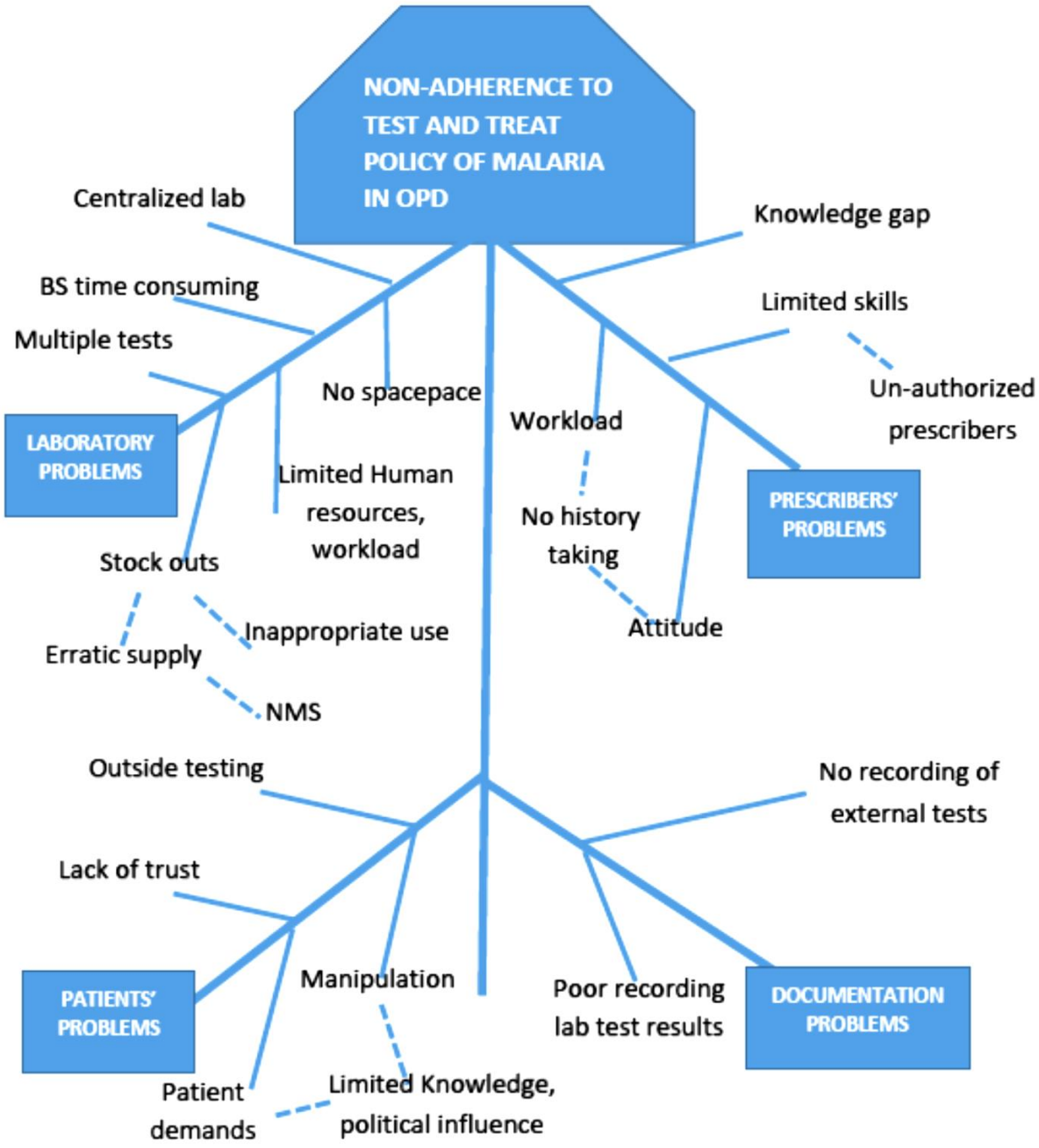
- The fish head is the problem: the lack of adherence to the test and treat policy of malaria in OPD (as may be found with the ACT MUE described above).
- The big spines represents the categories of problems: prescriber, laboratory, patient and documentation problems. Categories can be pre-defined or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



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Annex 5.1: ABC and ATC Analysis Example

ABC ANALYSIS EXAMPLE 1

No	Description	VE	UNI	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%**

No	Description	VE	UNI	PRICE	QTY	TOTAL	%	CUM
53	Glibenclamide 5mg tablet	V	100	2,643	220	**581,497**	**0%**	**94%**
54	Furosemide 20mg/2ml inj im/slow iv/ivinf	V	100	19,899	29	**577,085**	**0%**	**94%**
55	Cis-atracurium injection 2mg/ml 10ml vial	E	5	282,960	2	**565,920**	**0%**	**94%**
56	Cefotaxime sodium powder for injection 1gm vial	*E*	*1*	11,165	50	**558,253**	**0%**	**94%**
57	Chloramphenicol sodium succinate 1g injection	V	50	56,900	9	**512,100**	**0%**	**95%**
58	Anti d immunoglobulin 300mcg/ml	V	1	170,373	3	**511,119**	**0%**	**95%**
59	Dapsone 100mg tablet	V	100	49,279	10	**492,786**	**0%**	**95%**
60	Amoxicillin dispersable tablets 250mg	V	100	6,480	75	**486,000**	**0%**	**95%**
61	Nitrous oxide gas	E	1	1,620,0	0	**486,000**	**0%**	**95%**
62	Fentanyl citrate injection 50mcg/ml 2ml amp	E	10	23,898	20	**477,960**	**0%**	**96%**
63	Haloperidol tablets 10mg	V		15,893	30	**476,793**	**0%**	**96%**
64	Tobramycin eye drops 0.3%, 5ml dropper bottle	*E*	*1*	11,794	40	**471,744**	**0%**	**96%**
65	Atropine 1% eye drops 10ml	N	1	10,436	45	**469,632**	**0%**	**96%**
66	Ranitidine 25mg/2ml inj	E	100	32,133	15	**465,930**	**0%**	**96%**
67	Predinisolone 5mg tablet	V	100	24,307	19	**461,835**	**0%**	**96%**
68	Hydralazine injection 20mg/ml	V	5	103,100	4	**412,399**	**0%**	**97%**
69	Clotrimazole 1% topical cream	V	1	747	550	**410,955**	**0%**	**97%**
70	Phenobarbital 200mg/2ml injection	E	10	130,680	3	**392,040**	**0%**	**97%**
71	Betamethasone sodium phosphate 0.1% eye drops	E	1	864	430	**371,520**	**0%**	**97%**
72	Diazepam 10mg/2ml inj im/slow iv/iv infusion	V	100	30,378	12	**364,531**	**0%**	**97%**
73	Quinine sulphate 300mg tablet	E	100	179,089	2	**358,177**	**0%**	**97%**
74	Polyvidone-iodine 10% solution, bottle 200ml	E	1	3,499	100	**349,920**	**0%**	**98%**
75	Darrows solution (half strength),500ml infusion vial	V	24	31,104	11	**342,144**	**0%**	**98%**
76	Hydrogen peroxide 6% solution 200ml	E	1	1,069	311	**332,521**	**0%**	**98%**
77	Penicillin, benzathine benzyl 2.4mu/1.44g ampoule	V	10	7,554	42	**317,272**	**0%**	**98%**
78	Tramadol injection 100mg/2ml ampoule	E	5	4,825	63	**303,948**	**0%**	**98%**
79	Gentamycin 0.3% eye/ear drop	E	1	433	581	**251,312**	**0%**	**98%**
80	Anti-snake bite sera polyvalent 10 ml	*E*	*10*	2,367,7	0	**236,770**	**0%**	**98%**
81	Doxycycline 100mg caps	V	100	4,428	50	**221,400**	**0%**	**98%**
82	Meropenem inj 500mg vial	E	1	11,007	20	**220,147**	**0%**	**98%**
83	Metoclopramide 10mg/2ml injection	E	100	14,845	14	**207,832**	**0%**	**98%**
84	Potassium chloride 10% vial	E	1	20,252	10	**202,517**	**0%**	**99%**
85	Labetalol 5mg/ml 20ml vial	E	1	38,880	5	**194,400**	**0%**	**99%**
86	Sodium valproate 500mg tabs	V	100	36,228	5	**181,141**	**0%**	**99%**
87	Clotrimazole 100mg pessary	V	6	736	240	**176,743**	**0%**	**99%**
88	Piperacillin -tazobactam 4.5g inj	E	1	11,783	15	**176,739**	**0%**	**99%**
89	Phenytoin sodium 50mg/ml injection 5ml	V	1	4,130	40	**165,204**	**0%**	**99%**
90	Diclofenac sodium 50mg enteric coated tablet	E	100	1,021	160	**163,347**	**0%**	**99%**
91	Omeprazole 20mg capsules	E	100	3,024	50	**151,200**	**0%**	**99%**
92	Enoxaparin 40mg/0.4ml,0.4ml vol,pre-filled syring	E	2	30,240	5	**151,200**	**0%**	**99%**
93	Atropine 1mg/1ml inj iv/im	V	100	13,280	11	**146,083**	**0%**	**99%**
94	Charcoal activated 250mg tablet	E	100	7,806	18	**140,510**	**0%**	**99%**
95	Haloperidol 5mg/1ml injection	*V*	*5*	17,451	8	**139,605**	**0%**	**99%**
96	Pyridoxine 25mg tablets	E	100	6,076	22	**133,661**	**0%**	**99%**
97	Carbimazole 5mg tablets	V	100	31,671	4	**126,684**	**0%**	**99%**
98	Bendrofluazide 5mg tablet	E	100	25,128	5	**125,642**	**0%**	**99%**
99	Fluoxetine cap 20mg	V	100	3,780	32	**120,960**	**0%**	**99%**
100	Penicillin. Benzyl 1mu/600mg inj (pfr) im	V	10	2,318	44	**101,975**	**0%**	**99%**
101	Sodium valproate 200mg tablets	*V*	*40*	16,264	6	**97,584**	**0%**	**99%**
102	Allopurinol 100mg tablets	E	25	11,839	8	**94,708**	**0%**	**99%**
103	Haloperidol tablets 5mg	E	100	18,878	5	**94,392**	**0%**	**100%**
104	Heparin injection 5000iu/ml, 5ml vial	V	1	12,887	7	**90,212**	**0%**	**100%**
105	Hydroxyurea 500mg capsule	V	100	172,328	1	**86,164**	**0%**	**100%**
106	Mannitol 20% 100ml infusion	E	1	5,043	17	**85,726**	**0%**	**100%**
107	Chloramphenicol 5% ear drops 10ml.	E	1	713	110	**78,484**	**0%**	**100%**
108	Codeine phosphate 30mg tablets	E	100	24,001	3	**72,004**	**0%**	**100%**

No	Description	VE	UNI	PRICE	QTY	TOTAL	%	CUM
109	Amethocaine (tetracaine) hydrochloride eye drops	*N*	*1*	6,528	10	**65,280**	**0%**	**100%**
110	Neostigmine 0.5mg/ml ampoule	N	10	64,800	1	**64,800**	**0%**	**100%**
111	Diazepam 5 mg tablet	V	100	12,853	5	**64,265**	**0%**	**100%**
112	Benzhexol 2mg tablet	V	100	6,196	10	**61,958**	**0%**	**100%**
113	Chlorpromazine 100mg tablet	V	100	29,275	2	**58,551**	**0%**	**100%**
114	Cetrizine tablet 10mg	N	100	2,268	25	**56,700**	**0%**	**100%**
115	Salbutamol 4mg tablet	E	100	6,206	9	**55,851**	**0%**	**100%**
116	Chloramphenicol 0.5% eye drops 10ml	V	1	432	120	**51,840**	**0%**	**100%**
117	Calcium lactate 300mg tablets	N	100	10,148	5	**50,741**	**0%**	**100%**
118	Furosemide 40mg tablet	E	100	11,260	4	**45,041**	**0%**	**100%**
119	Vitamin b complex tablet	*E*	*100*	3,370	11	**37,066**	**0%**	**100%**
120	Fluphenazine 25mg/ml injection	*E*	*10*	18,127	2	**36,253**	**0%**	**100%**
121	Promethazine injection 25mg/ml 2ml amp	E	10	1,997	15	**29,958**	**0%**	**100%**
122	Bisacodyl 5mg tablets	E	100	1,836	15	**27,540**	**0%**	**100%**
123	Aminophylline 250mg/10ml inj. Slow iv infusion	E	1	284	85	**24,104**	**0%**	**100%**
124	Loperamide cap 2mg	*N*	*100*	2,740	7	**19,178**	**0%**	**100%**
125	Hyoscine butyl bromide 20mg/ml injection	*N*	*1*	1,510	10	**15,105**	**0%**	**100%**
126	Clomiphene citrate 50mg tablets	*N*	*10*	7,359	2	**14,718**	**0%**	**100%**
127	Silver sulfadiazine 1% cream 500g	*V*	*1*	5,712	2	**11,424**	**0%**	**100%**
128	Ketoconazole 200mg tablet	*N*	*100*	8,471	1	**8,471**	**0%**	**100%**
129	Warfarin 5mg tablets	*V*	*28*	5,731	1	**5,731**	**0%**	**100%**
130	Artemether 20mg+lumefantrine 120mg (strip of 6	V	30	0	0	**0**	**0%**	**100%**
131	Artemether 20mg+lumefantrine 120mg (strip of 12	V	30	0	24	**0**	**0%**	**100%**
132	Artemether 20mg+lumefantrine 120mg (strip of 18	V	30	0	0	**0**	**0%**	**100%**
133	Artemether 20mg+lumefantrine 120mg (strip of 24	V	30	0	462	**0**	**0%**	**100%**
134	Misoprostol 200mcg tablets	V	100	0	49	**0**	**0%**	**100%**
135	Morphine sol 5mg/5ml bottle	V	1	0	172	**0**	**0%**	**100%**
136	Artesunate injection 60mg vial	V	1	0	6,20	**0**	**0%**	**100%**
137	Medroxyprogesterone acetate 150mg/ml w/syringe	V	200	0	1	**0**	**0%**	**100%**
138	Levonorgestrel 0.75 mg	V	2	0	100	**0**	**0%**	**100%**
139	Ethinylestradiol0.03+levonorgestrel0 .15mg 3cycles	E	1	0	200	**0**	**0%**	**100%**
140	Etonogestrel 68mg implant (implanon)	E	1	0	30	**0**	**0%**	**100%**
141	Levonorgestrel 0.03mg tab 3 cycles	E	1	0	100	**0**	**0%**	**100%**
	Total					**262,216,9**		

ATC ANALYSIS EXAMPLE 1

DESCRIPTION	VEN	CAT	QTY	TOTAL COST	%
Bupivacaine hcl 0.5% in dextrose 8.0% inj solution, 4ml ampoule,	V	Anaesth	96	12,317,184	5%
Isoflurane 250ml inhalation	V	Anaesth	81	9,688,505	4%
Suxamethonium chloride 100mg/2ml injection	V	Anaesth	32	6,225,777	2%
Halothane inhalation 250ml	V	Anaesth	45	4,590,098	2%
Lidocaine hcl 2% injection	V	Anaesth	1925	4,536,359	2%
Midazolam 5mg/ml injection 3ml ampoule	E	Anaesth	58	4,196,880	2%
Ephedrine 30mg/ml 1 ml ampoule	E	Anaesth	75	2,912,592	1%
Ketamine 500mg/10ml injection iv/im	V	Anaesth	83	1,018,017	0%
Cis-atracurium injection 2mg/ml 10ml vial	E	Anaesth	2	565,920	0%
Nitrous oxide gas	E	Anaesth	0.3	486,000	0%
Fentanyl citrate injection 50mcg/ml 2ml amp	E	Anaesth	20	477,960	0%
Atropine 1mg/1ml inj iv/im	V	Anaesth	11	146,083	0%
Epinephrine (adrenaline) 1mg/ml inj iv/im/sc	V	Anti all	12	1,058,725	0%
Cetrizine tablet 10mg	N	Anti all	25	56,700	0%
Ceftriaxone sodium 1g powder for inj.vial	V	Anti-	25800	27,923,340	11%
Metronidazole 500mg/100ml infusion	V	Anti-	17300	15,606,676	6%
Amoxicillin 250mg capsule	V	Anti-	325	14,040,000	5%
Metronidazole 200mg tablet	V	Anti-	464	5,754,755	2%
Ampicillin 500mg powder for reconstitution iv/im/infusion	V	Anti-	139	5,679,534	2%
Ciprofloxacin 500mg tablet	V	Anti-	210	1,965,195	1%

DESCRIPTION	VEN	CAT	QTY	TOTAL COST	%
Bupivacaine hcl 0.5% in dextrose 8.0% inj solution, 4ml ampoule,	V	Anaesth	96	12,317,184	5%
Griseofulvin 500mg tablet	N	Anti-	80	1,760,939	1%
Tetracycline 1% eye ointment 3.5g tube	V	Anti-	1440	1,623,629	1%
Gentamycin 80mg/2ml inj iv/im	V	Anti-	97	1,290,511	0%
Mebendazole 100mg tablets	E	Anti-	78	774,318	0%
Cotrimoxazole 480mg tablet	V	Anti-	22	662,238	0%
Cefotaxime sodium powder for injection 1gm vial	E	Anti-	50	558,253	0%
Chloramphenicol sodium succinate 1g injection	V	Anti-	9	512,100	0%
Dapsone 100mg tablet	V	Anti-	10	492,786	0%
Amoxicillin dispersable tablets 250mg	V	Anti-	75	486,000	0%
Quinine sulphate 300mg tablet	E	Anti-	2	358,177	0%
Penicillin, benzathine benzyl 2.4mu/1.44g ampoule	V	Anti-	42	317,272	0%
Doxycycline 100mg caps	V	Anti-	50	221,400	0%
Meropenem inj 500mg vial	E	Anti-	20	220,147	0%
Clotrimazole 100mg pessary	V	Anti-	240	176,743	0%
Piperacillin -tazobactam 4.5g inj	E	Anti-	15	176,739	0%
Penicillin. Benzyl 1mu/600mg inj (pfr) im	V	Anti-	44	101,975	0%
Ketoconazole 200mg tablet	N	Anti-	1	8,471	0%
Artemether 20mg+lumefantrine 120mg (strip of 6 tabs)	V	Anti-	0		0%
Artemether 20mg+lumefantrine 120mg (strip of 12 tabs)	V	Anti-	24		0%
Artemether 20mg+lumefantrine 120mg (strip of 18 tabs)	V	Anti-	0		0%
Artemether 20mg+lumefantrine 120mg (strip of 24 tabs)	V	Anti-	462		0%
Artesunate injection 60mg vial	V	Anti-	6200		0%
Ferrous sulphate/fumarate 150-200 mg+folic acid 0.25 -0.4mg tab	V	Blood	490	8,289,056	3%
Vitamin k1 (phytomenadione) 10mg/ml inj im	E	Blood	930	1,084,864	0%
Folic acid 5mg tablet	N	Blood	45	656,100	0%
Enoxaparin 40mg/0.4ml,0.4ml vol,pre-filled syringe	E	Blood	5	51,200	0%
Pyridoxine 25mg tablets	E	Blood	22	133,661	0%
Heparin injection 5000iu/ml, 5ml vial	V	Blood	7	90,212	0%
Hydroxyurea 500mg capsule	V	Blood	0.5	86,164	0%
Warfarin 5mg tablets	V	Blood	1	5,731	0%
Nifedipine retard 20mg tablet	E	Cardiov	610	1,347,661	1%
Amlodipine 5mg tablets	E	Cardiov	200	691,200	0%
Furosemide 20mg/2ml inj im/slow iv/ivinf	V	Cardiov	29	577,085	0%
Hydralazine injection 20mg/ml	V	Cardiov	4	412,399	0%
Labetalol 5mg/ml 20ml vial	E	Cardiov	5	194,400	0%
Bendrofluazide 5mg tablet	E	Cardiov	5	125,642	0%
Furosemide 40mg tablet	E	Cardiov	4	45,041	0%
Clotrimazole 1% topical cream	V	Dermat	550	410,955	0%
Silver sulfadiazine 1% cream 500g	V	Dermat	2	11,424	0%
Polyvidone-iodine 10% solution, bottle 200ml	E	Disinf	100	349,920	0%
Hydrogen peroxide 6% solution 200ml	E	Disinf	311	332,521	0%
Insulin mixtard human 100iu/ml	V	Endocr	420	6,004,030	2%
Hydrocortisone sodium phosphate 100mg injection	V	Endocr	29	1,948,893	1%
Insulin soluble, neutral, human 100iu/ml inj sc	V	Endocr	130	1,763,386	1%
Dexamethasone 4mg/ml 1ml,2ml ampoule	E	Endocr	18	1,339,173	1%
Metformin hcl 500mg tablet	V	Endocr	405	1,245,646	0%
Insulin isophane human 100iu/ml inj sc	V	Endocr	75	995,099	0%
Glibenclamide 5mg tablet	V	Endocr	220	581,497	0%
Predinisolone 5mg tablet	V	Endocr	19	461,835	0%
Carbimazole 5mg tablets	V	Endocr	4	126,684	0%
Allopurinol 100mg tablets	E	Endocr	8	94,708	0%
Clomiphene citrate 50mg tablets	N	Endocr	2	14,718	0%
Co-packaged ors and zinc tablets	V	Gastro-	3288	6,329,729	2%
Ranitidine 25mg/2ml inj	E	Gastro-	14.5	465,930	0%
Metoclopramide 10mg/2ml injection	E	Gastro-	14	207,832	0%
Omeprazole 20mg capsules	E	Gastro-	50	151,200	0%
Charcoal activated 250mg tablet	E	Gastro-	18	140,510	0%
Bisacodyl 5mg tablets	E	Gastro-	15	27,540	0%
Loperamide cap 2mg	N	Gastro-	7	19,178	0%
Hyoscine butyl bromide 20mg/ml injection	N	Gastro-	10	15,105	0%
Rabies vaccine + solvent 0.5ml inj 1 dose	V	Immunol	220	5,747,986	2%
Diazepam 2.5mg suppositories	V	Mental	80	1,449,260	1%
Amitriptyline 25mg tablet	V	Mental	50	777,600	0%

DESCRIPTION	VEN	CAT	QTY	TOTAL COST	%
Bupivacaine hcl 0.5% in dextrose 8.0% inj solution, 4ml ampoule,	V	Anaesth	96	12,317,184	5%
Trifluoperazine 5mg tablet	E	Mental	7	640,103	0%
Haloperidol tablets 10mg	V	Mental	30	476,793	0%
Phenobarbital 200mg/2ml injection	E	Mental	3	392,040	0%
Diazepam 10mg/2ml inj im/slow iv/iv infusion	V	Mental	12	364,531	0%
Sodium valproate 500mg tabs	V	Mental	5	181,141	0%
Phenytoin sodium 50mg/ml injection 5ml	V	Mental	40	165,204	0%
Haloperidol 5mg/1ml injection	V	Mental	8	139,605	0%
Fluoxetine cap 20mg	V	Mental	32	120,960	0%
Sodium valproate 200mg tablets	V	Mental	6	97,584	0%
Haloperidol tablets 5mg	E	Mental	5	94,392	0%
Diazepam 5 mg tablet	V	Mental	5	64,265	0%
Benzhexol 2mg tablet	V	Mental	10	61,958	0%
Chlorpromazine 100mg tablet	V	Mental	2	58,551	0%
Fluphenazine 25mg/ml injection	E	Mental	2	36,253	0%
Promethazine injection 25mg/ml 2ml amp	E	Mental	15	29,958	0%
Neostigmine 0.5mg/ml ampoule	N	Muscle	1	64,800	0%
Magnesium sulphate 50% 5ml inj	V	Obstet	840	4,855,990	2%
Oxytocin 10iu/1ml injection	E	Obstet	124	2,545,296	1%
Pyrimethamine 25mg+sulfadoxine 500mg tablet	V	Obstet	8	864,000	0%
Anti d immunoglobulin 300mcg/ml	V	Obstet	3	511,119	0%
Misoprostol 200mcg tablets	V	Obstet	49		0%
Medroxyprogesterone acetate 150mg/ml w/syringe	V	Obstet	1		0%
Levonorgestrel 0.75 mg	V	Obstet	100		0%
Ethinylestradiol0.03+levonorgestrel0 .15mg 3cycles	E	Obstet	200		0%
Etonogestrel 68mg implant (implanon)	E	Obstet	30		0%
Levonorgestrel 0.03mg tab 3 cycles	E	Obstet	100		0%
Betamethasone+neomycin 0.1%+0.5% eye drops 10ml	E	Ophtal	1210	1,110,780	0%
Timolol maleate 0.5% eyedrops in 5ml	N	Ophtal	113	1,037,340	0%
Tobramycin+dexamethasone eye drops; 0.3%+0.1%, 5ml dropper	N	Ophtal	58	655,078	0%
Tobramycin eye drops 0.3%, 5ml dropper bottle	E	Ophtal	40	471,744	0%
Atropine 1% eye drops 10ml	N	Ophtal	45	469,632	0%
Betamethasone sodium phosphate 0.1% eye drops 10ml	E	Ophtal	430	371,520	0%
Gentamycin 0.3% eye/ear drop	E	Ophtal	581	251,312	0%
Chloramphenicol 5% ear drops 10ml.	E	Ophtal	110	78,484	0%
Amethocaine (tetracaine) hydrochloride eye drops 0.5%, 0.5ml dose	N	Ophtal	10	65,280	0%
Chloramphenicol 0.5% eye drops 10ml	V	Ophtal	120	51,840	0%
Paracetamol 500mg tablets	E	Pain-k	787	9,774,540	4%
Paracetamol 125mg suppositories	E	Pain-k	436	2,135,201	1%
Diclofenac sodium 75mg/3ml injection	V	Pain-k	77	989,700	0%
Pethidine 100mg/2ml inj iv/im/sc	V	Pain-k	32	820,072	0%
Tramadol injection 100mg/2ml ampoule	E	Pain-k	63	303,948	0%
Diclofenac sodium 50mg enteric coated tablet	E	Pain-k	160	163,347	0%
Codeine phosphate 30mg tablets	E	Pain-k	3	72,004	0%
Morphine sol 5mg/5ml bottle	V	Pain-k	172		0%
Anti-snake bite sera polyvalent 10 ml	E	Poison	0.1	236,770	0%
Salbutamol nebuliser 5mg/2.5ml vial	N	Respir	91	2,516,978	1%
Salbutamol 4mg tablet	E	Respir	9	55,851	0%
Aminophylline 250mg/10ml inj. Slow iv infusion	E	Respir	85	24,104	0%
Sodium chloride/normal saline 0.9% infusion	V	Solutions	1067	30,422,304	12%
Sodium (ringers) lactate compound infusion	E	Solutions	415	10,756,800	4%
Glucose (dextrose) 5% infusion 500ml	V	Solutions	211	7,520,040	3%
Water for injection 10ml	V	Solutions	428	3,697,920	1%
Glucose 50% injection 100ml	V	Solutions	1200	1,790,844	1%
Darrows solution (half strength),500ml infusion vial	V	Solutions	11	342,144	0%
Potassium chloride 10% vial	E	Solutions	10	202,517	0%
Mannitol 20% 100ml infusion	E	Solutions	17	85,726	0%
Calcium lactate 300mg tablets	N	Vit/min	5	50,741	0%
Vitamin b complex tablet	E	Vit/min	11	37,066	0%
TOTAL				**262,216,943**	

Annex 5.2: 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) 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 in itself. 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. Parenteral
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 and dispensing.

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 <u>medication error</u> 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 <u>adverse reaction</u> 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 = <u>Total Scores for Yes</u> 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:***_____

6 How to Improve the Use of Medicines and Health Supplies

6.1 Introduction

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

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

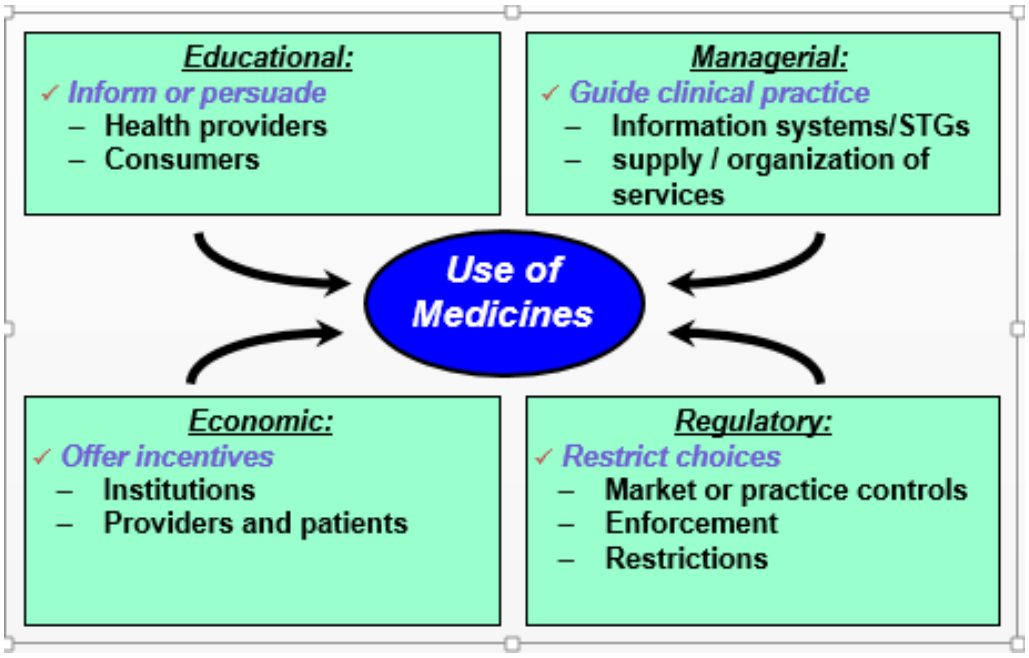
- Educational: to **inform/persuade**
- Managerial: to **guide** decisions
- Regulatory: to **restrict** decisions
- Financial/economical: to **influence** decisions through incentives (positive or negative).

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 impact, then it is better to discontinue.

This chapter will describe in detail the different types of intervention strategies, how to develop interventions and finally how to implement and evaluate the impact of interventions.

6.2 Overview of Intervention Strategies

In this section we describe the four categories of interventions to ensure appropriate medicines use: Persuasive/Educational, Managerial, Regulatory and Financial/Economical**.**



6.2.1 Educational strategies

Educational strategies aim to inform and persuade prescribers, dispensers, or patients to use medicines in a different 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 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!)

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 has to be made available!). • **Patient education** influences drug prescribing. All health workers should regularly/routinely provide patient education about 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 drug sales 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.
Printed Educational Material	• For example, 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 presents a summary of the advantages and disadvantages of the most commonly used educational strategies. These were provided by actual MTC members.

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/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

6.2.2 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.

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
Procedure and processes	• Use of structured order 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 work flows, 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.

6.2.3 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 have to be carefully thought before being used. For example, in a certain country, the prohibition to using an anti-diarrhoeal medicine resulted in an increase of prescription of antibiotics for simple diarrhoeas. 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.

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 • Restriction of medicines by level of care • Professional licensing of health care professionals • Licensing of outlets • Guidelines on handling expired or obsolete medicines
Prescribers and Dispenser regulations	• Due Licensing/registration of prescribers /dispensers • Restrictions on prescriptions by qualification (e.g. only a specialist doctor can use some medicines)
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) • Enforcement of guidelines on donations

6.2.4 Financial or Economic strategies

Financial (or economic) strategies are based on the use of incentives to promote or avoid certain behaviours ("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 behaviours ("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.

6.3 Choosing an Intervention

The choice of 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 behaviour. 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 and 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 behaviour; however, poorly thought-out incentives may lead to unexpected behaviour and the promotion of inappropriate use.
- Regulatory interventions may have unintended impacts that may be worse than the intended change.

The following factors should be considered in choosing strategies:

Factor	Description
Expected magnitude of Impact	• If intervention is successful, will it affect only a few drugs, 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 favour development and implementation of the strategy, or will they severely hinder it?
Technical feasibility	• What are the technical requirements of the strategy? Computers? 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 2***).

It is also important to involve key decision makers at intervention design stage, to allow them 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.

	Characteristics of Providers		Social Structure of Providers		Provider-Patient Interactions		Work Environment		Marketing
	Lack of Knowledge	Acquired Habits	Authority and Power	Peer Norms and Relations	Cultural Attitudes and Beliefs	Patient Demands	Medicines Availability	Work load	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 of workflow and staffing, task shifting								X	
Prioritization of vital medicines							X		

6.4 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.

6.4.1 Work plan and budget preparation

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

Area	Description
Objectives	Write what you hope to achieve, in measurable terms, from your intervention
Type of strategy	Educational, managerial, regulatory or financial? This helps to plan a suitable combination of interventions
Description of strategy	E.g: 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 to have implemented by 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 malaria cases tested from XX to XX
- Increase % of confirmed malaria cases (tested positive) from XX to XX
- (decrease number of cases of malaria without co morbidities treated with antibiotics from XX to XX)

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 result Increased accuracy of records
		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	
Managerial	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 periodically for monitoring purposes*	As above	MTC chair and secretary	Month 1	Three meetings conducted Feedback given and consensus reached on intervention	
Managerial	Decentralize testing services 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 available as per patients' load	Increased testing rate. Reduced turn-around time for lab results
		Organization of space and staff to conduct RDTs	Appropriate space/furniture	Lab in-charge Administration	Month 1	Testing point available in OPD with	

			Trained staff (lab or other) in RDT and recording			reasonable waiting time	
Educational/ Managerial:	Develop protocol or SOP for management of fever and of RDT negative malaria	Sub-committee to develop SOP for management of fever and/or management of RDT negative malaria in OPD	UCG. MOH Malaria Management Manual 2015 Stationery Refreshments Internet	Physician Head of Clinical Services	Month 1	SOP developed CME conducted SOP displayed	Decrease 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 services			
		Lamination and display of SOP	Lamination paper	Administrator			
Regulatory	Restrict ACT dispensing at pharmacy	MTC to draft a circular on dispensing ACTs at pharmacy (no ACTs without testing and prescription)		MTC chair		Circular signed by management and displayed in pharmacy	Decrease of ACT dispensed without testing
		Management to sign and disseminate to relevant stakeholders		Medical director/ administrator			
Regulatory	Regulation of authorized prescribers	Have a full list of prescribers names, specimen signatures, contacts and unit at the dispensing point	Stationery	Senior dispenser HR/Admin		List prepared and displayed	Reduction in unauthorized prescriptions
		Pharmacy dept meeting to disseminate policy		Senior dispenser			
		Communication to all staff (CME, notice board)	Stationery	MTC chair			
Educational	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	Reduced patient demand for ACTs Increased uptake of malaria tests
		Radio talks (on same topic)	Radio talk time Staff	Nursing, Health Promotion		10 radio talks conducted	

Monitoring: *monthly sample ACT MUE (20-30 cases) e.g. from last week of the month.*
Evaluation: *repeat MUE (sample of 100 patients/prescriptions) after 3 months, 6 months and at 1 year.*

6.5 Monitoring and Evaluating Interventions

It is important to evaluate interventions to assess whether they are effective or not in correcting a targeted medicines use problem. In addition, regular monitoring of processes during implementation helps to:
See that as far as possible everything goes according to plan
Find out if there are unexpected difficulties
Adjust plans if necessary.

Ideally, interventions should be initially implemented on 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 programme 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 which 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 behaviours 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 survey, semi-structured interviews, focus group discussions, direct observations.

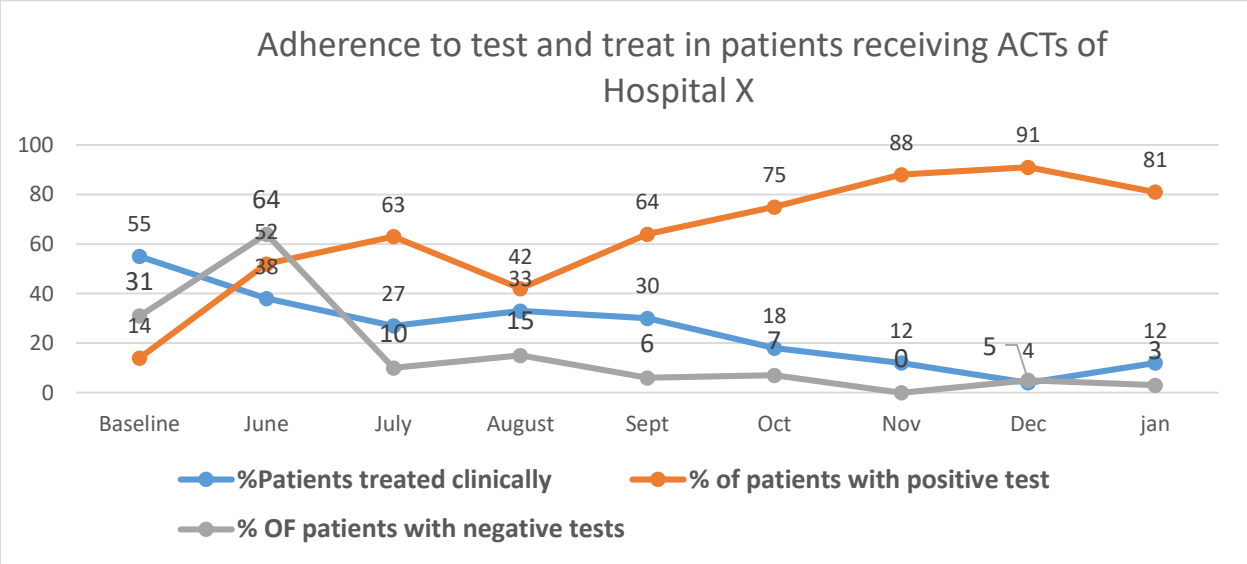
In order to evaluate if an intervention has produced the desired results, there are different approaches, simplified in the table below.

Approach	Type of study design	Description
Control vs intervention group	Randomised 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 randomised controlled trial

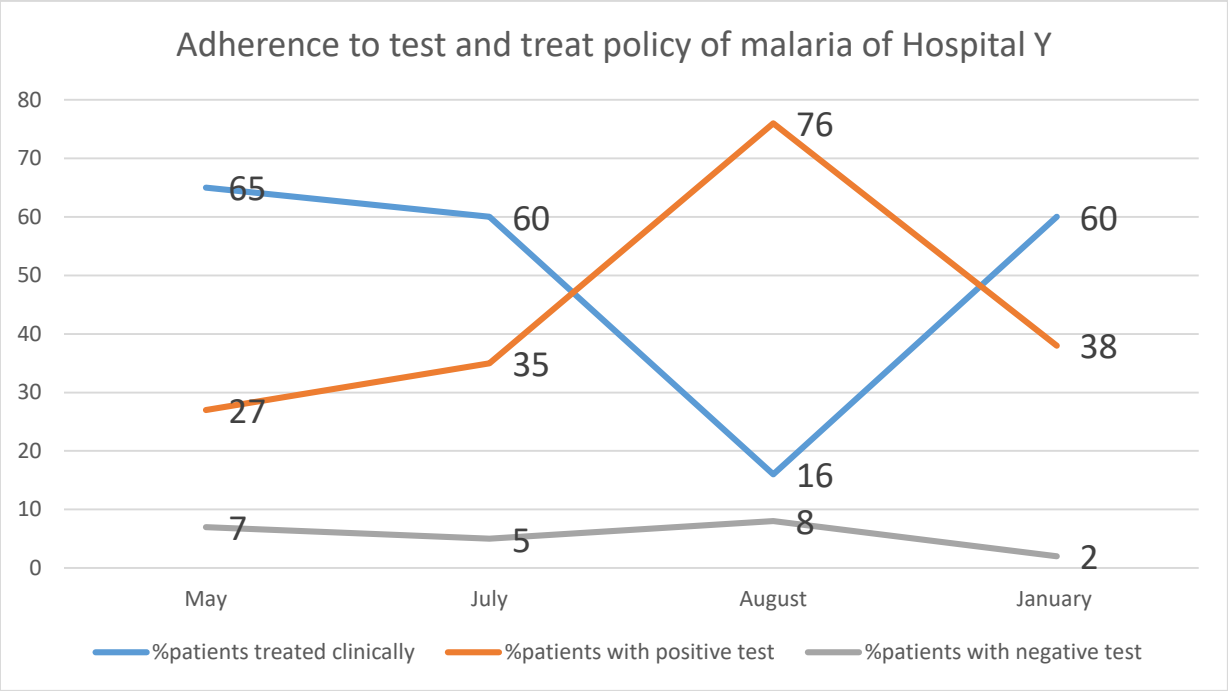
Example 1: Intervention to Correct a Medicine Use Problem in a Hospital - adherence to test and treat policy for malaria in Ugandan Hospitals

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 5, Page 84***.

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.



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!



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 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 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 has been solved, he planned no further follow-up or communication with these clinicians.

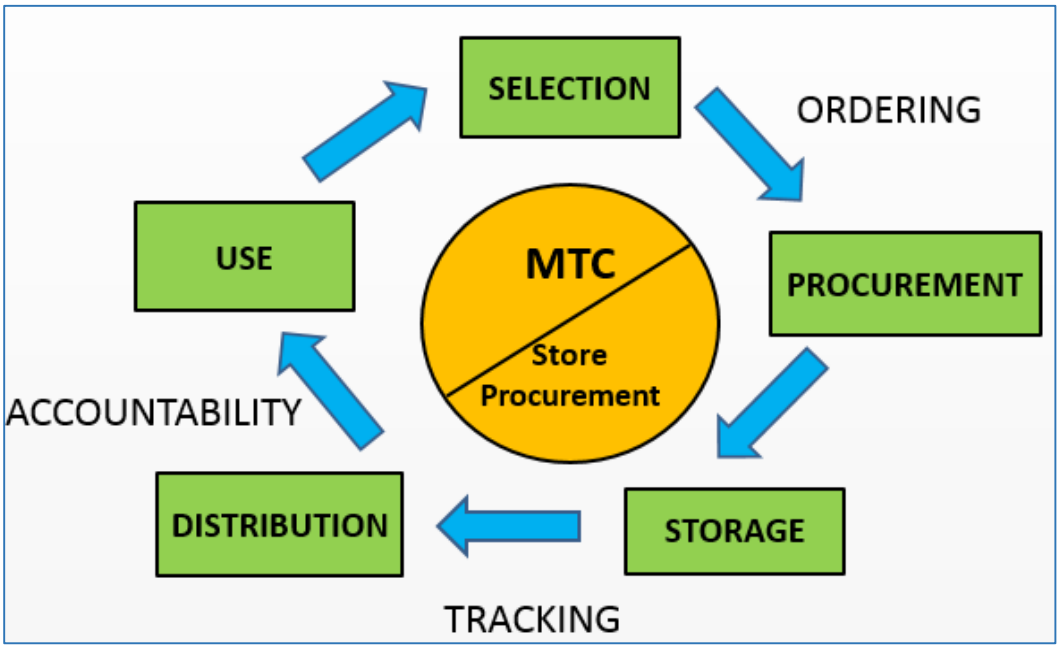
One year later, a new 10-day survey of prescription forms was conducted. Unfortunately, it was found that ceftriaxone injections have risen again to nearly their former level. In addition, the prescription forms no longer contain readable names of the prescribers.

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?

7 MTC Role in Supply Chain

7.1 Introduction

As stated in ***Chapter 1,*** the MTC has an oversight role on the supply chain section of the medicine management cycle. This involves advising and monitoring functions.



The roles of the MTC in the supply chain include:

- Develop, implement and monitor policies and procedures for management and use of medicines and health supplies
- Regulate and monitor availability, tracking and accountability of pharmaceuticals within the health facility
- Analyse, monitor and regulate expenditures on medicines to ensure cost effective use of resources
- Develop and monitor policies and procedures e.g:
    - 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 pharmaceutical products.

The day-to-day work of pharmaceutical and health supplies management is performed by the stores and pharmacy/procurement department. The MTC may create a logistics or supply chain subcommittee if deemed necessary, for instance if there are many problems or issues to address. In order 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.

The objectives of this chapter are to present 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.

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 which may be necessary to address issues. The MTC does not supposed to handle routine tasks but only:

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

This chapter provides practical orientation for MTC members to effectively oversee and support pharmaceutical management, and is complementary to ***MOH Essential Medicines and Health Supplies Manual***.

7.2 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 reports

7.2.1 Stock report: Availability/stock outs and stock status

The overall purpose of the supply chain is to avail medicines of good quality and in sufficient quantities. 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 national level availability at facility level of 41 “tracer items” (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 (at the moment of the assessment) and it is generally expressed in absolute quantities but also in “***month of stocks***”, 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.

The example in the table below can help us understand how to calculate a 6-month availability/stock out report and stock status for some 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:

Column A and B: name and unit of the product. The list of items is chosen based on the items that the MTC considers key priority for their facility, or 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 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 has 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 hands in units (vials, or tins): this is what is written on the stock card as present in the store.

Column L: Month 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.

The overall objective of the pharmacy/store department is:

To have 100% availability for all item (meaning 0% stock out rates)
To have acceptable levels of stock at hand, meaning between 2 and 4 months; not below 2 months, because there would be risk of out of stock outs, not above 4 months because there may be 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 to identify items at risk of stock outs or overstocking and take action.

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.

NOTE: 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 the situation and assess if there is need of any corrective measures within the power of the health facility when analysing availability reports. **Also to note, appropriate medicine use should ideally result in increased availability in the long run, because it usually reduces and rationalises consumptions, allowing more cost effective use of resources**.

Example 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 Dec17 in MoS	Availability (% time item available)	Stock at hand Dec17 in MoS	Availability (% time item available)	Stock at hand Dec17 in MoS
ACT 100/20 mg	24 x 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

** MoS: Months of stock

Comments:

- Hospital 1 has 100% availability for all commodities assessed (expect 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 are understocked.

- Hospital 2 has suboptimal availability of antibiotics – with corresponding low stocks, and also 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 the 3 hospitals have problems with insulin Mixtard while generally malaria commodities tend to be overstocked.

On the basis of 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.

7.2.2 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 5).

- An **ABC analysis** provides information on the quantities and value of the items the health facility has consumed in a given 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.

$$\text{Formula for AMC:} \quad \frac{\text{(quantity consumed in the period)} \times 30}{\text{(Number of days in period considered - days out of stock)}}$$

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 analyse general expenditures on pharmaceutical products (ABC analysis) or in performing specific analysis e.g. consumptions of antibiotics (**see chapter 9),** medicines for non-communicable diseases, antimalarial commodities or ART commodities.

7.2.3 Expiry reports

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

The quantities and values of expired items are therefore a good indicator on 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 which expired (***expired stock***), analyse 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 centres, 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:

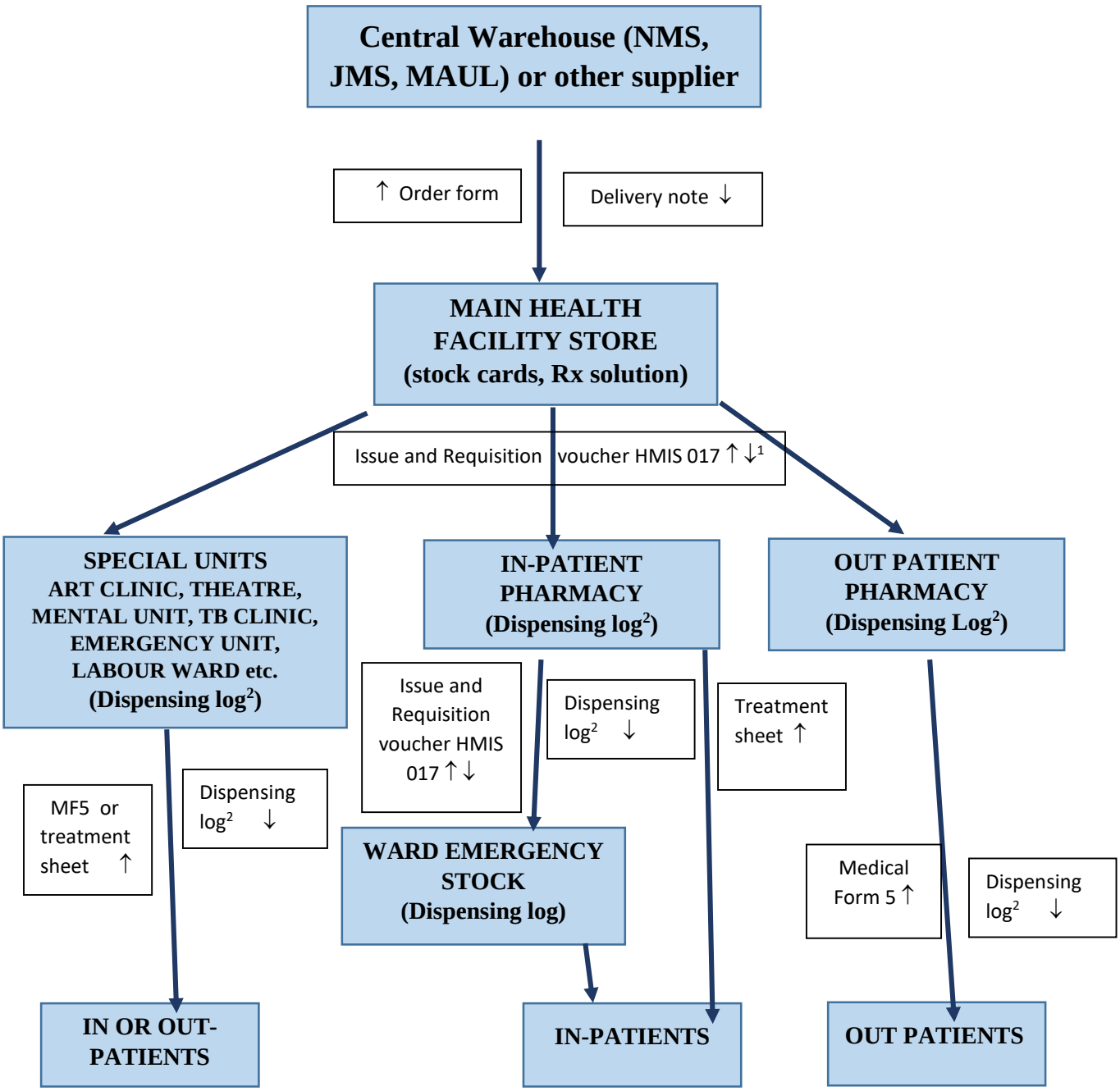
- By making sure no short expiry items are accepted from suppliers
- Items are issued in order of expiry date, and,
- Short-expiry items are re-distributed or exchanged.

7.3 Pharmaceutical flow

Uganda has national guidelines for the management of medicines and supplies, detailing how items are ordered, received and issued from store, 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 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.

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



Notes

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 store to document issues and by wards and pharmacies to requisition items)*
2. *The dispensing logs function both an internal accountability/reconciliation tool for wards and pharmacies and as a dispensing tool*

It is recommended that facilities with in-patient (IP) services dispense medicines per patient chart from the in-patient pharmacy. Exception is given for special units (emergency departments, paediatric ward, mental unit etc) who need to receive their medicines in bulk from stores, and also for emergency (life-saving) medicines which will be issued by IP pharmacy to the wards in limited quantities. In the absence of a casualty/emergency unit to attend to after-hours admissions, the wards are also allowed to keep small quantities of other essential medicines (more details in the ***Ministry of Health In-Patient Pharmacy Guidelines 2018***).

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.

7.4 Tracking and accountability

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

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

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

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

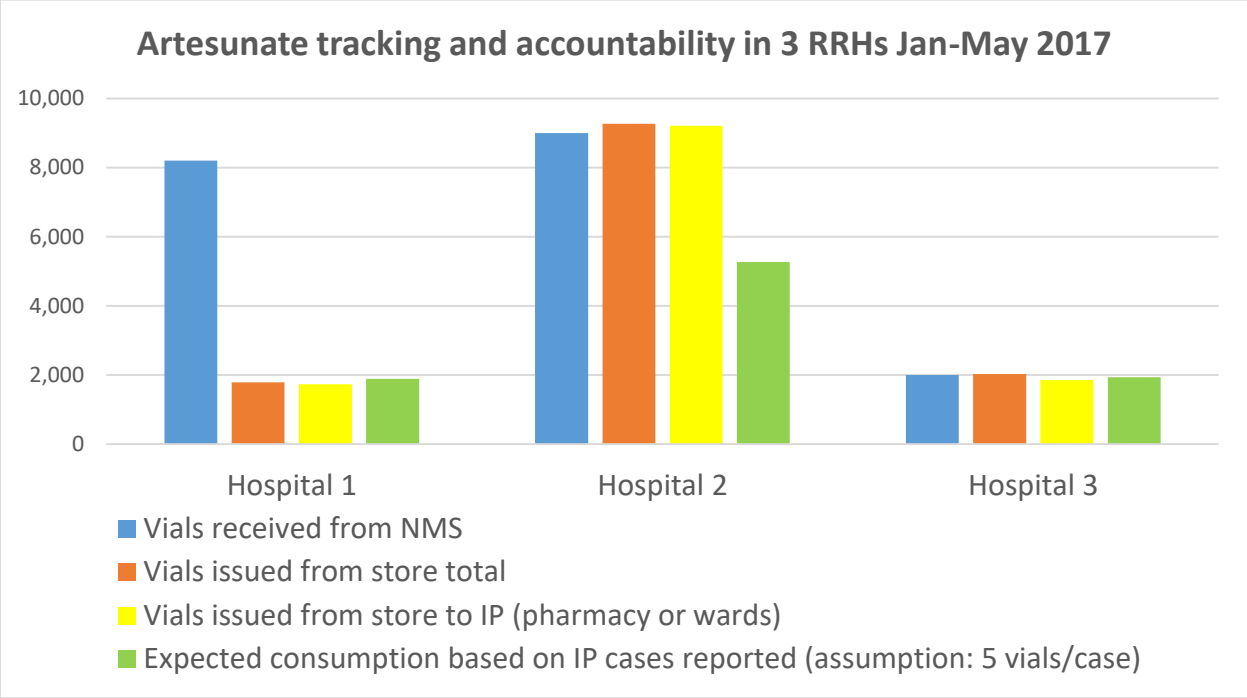
- Following administration/dispensing of each unit of product at patient's level, checking whether dispensing records march clinical records
- Comparing aggregated data of quantities consumed in a period with related clinical cases over the same period (estimating the average dose used per case). This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

Examples of tracking and accountability exercise for artesunate in three health facilities are shown in the table and graph below.

ARTESUNATE (Jan-May 2017)	Hospital 1	Hospital 2	Hospital 3
Vials received from NMS	8,200	9,000	2,000
Vials issued from store total	1,780	9,264	2,026
Vials issued from store to OPD	50 (3%)	53 (0.5%)	180 (9%)
Vials issued from store to IP (pharmacy or wards)	1,730	9,211	1,846
IP malaria cases reported (DHIS 2)	377 (79% under 5)	1,059 (50% under 5)	387 (63% under 5)
Expected consumption based on IP cases reported (assumption: 5 vials of artesunate 60 mg per case)	1,885	5,264	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 across different age groups).

***Comments*:**

In 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 combination of decreasing cases, backlog consignments being delivered and inappropriate ordering.
- The health facility therefore instituted correction measures: some pending orders were cancelled, re-distributed some quantities and hence the stock was adjusted to adequate quantities.

In 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 artesunate dispensed used to go to OPD patients!

In 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 particular special OPD clinic was ordering the artesunate needlessly, and this was stopped.

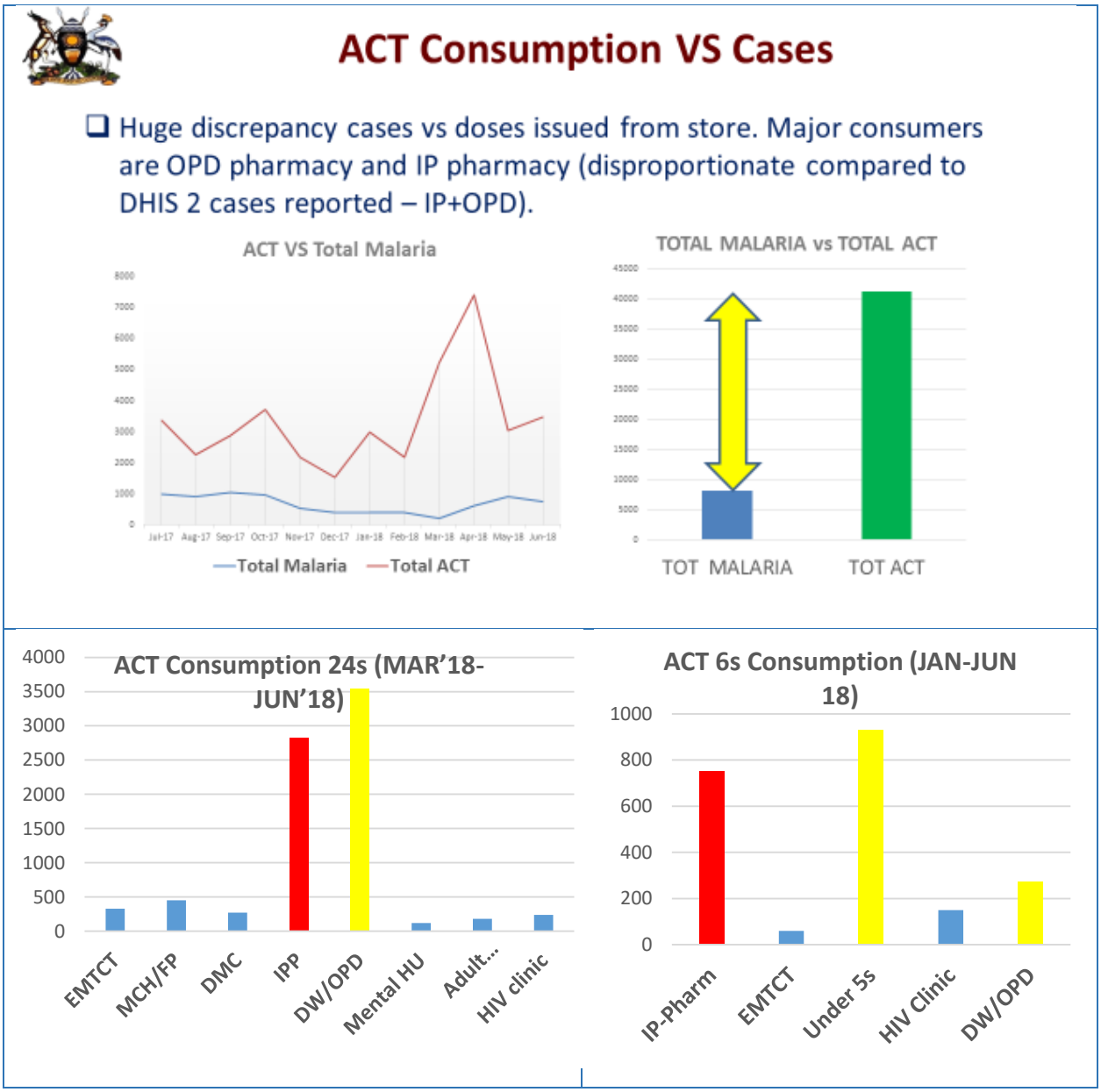
Example 2

In this second example, cases of malaria were compared with issues from store, both in the monthly trend and as aggregate data over one year.

Artesunate issues in doses (1 dose=5 vials) were compared with cases of IP malaria.

ACT issues in doses (1 dose= 17 tablets, so all pack sizes would be converted in tablets and the sum divided by 17) were compared with the number of OPD + IP malaria (since also IP malaria receive a course of oral ACT, and are not always recorded as OPD cases before being admitted).

When a discrepancy was found, the next step was to analyse issues from store in detail, to see which demander ward/department was getting what, if it reports cases, if cases balanced with consumptions, and how the tracking within the department worked. The graphs below show a summary of the results.

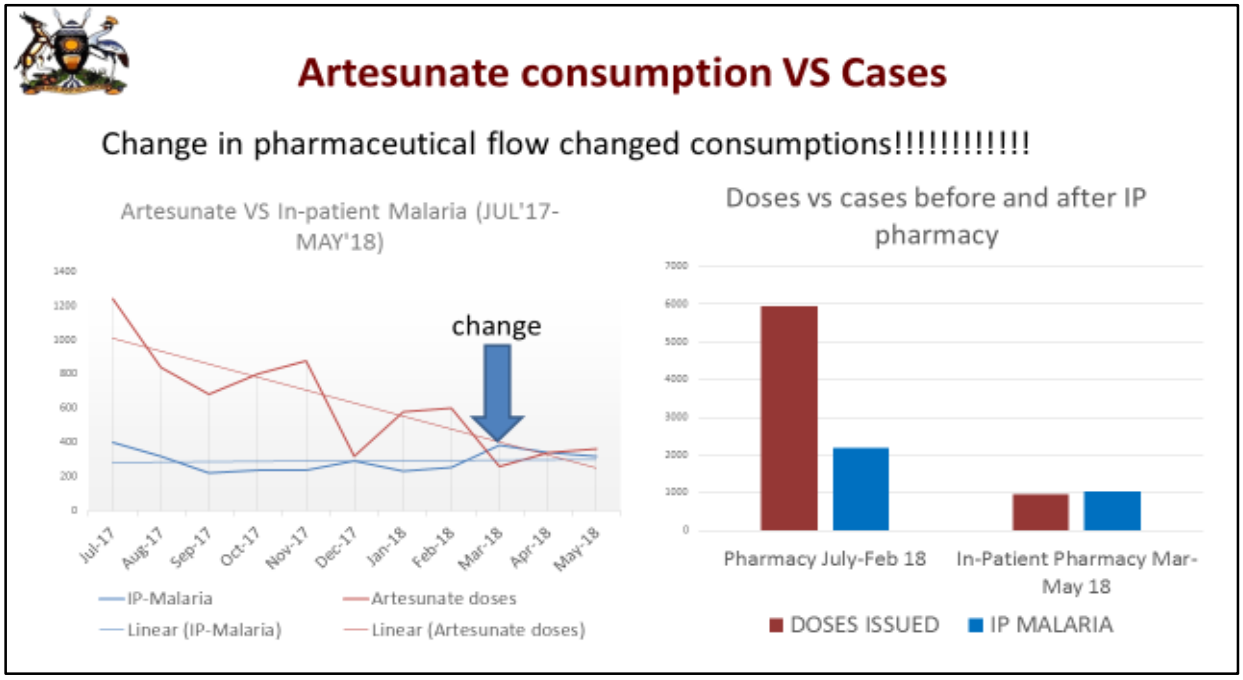


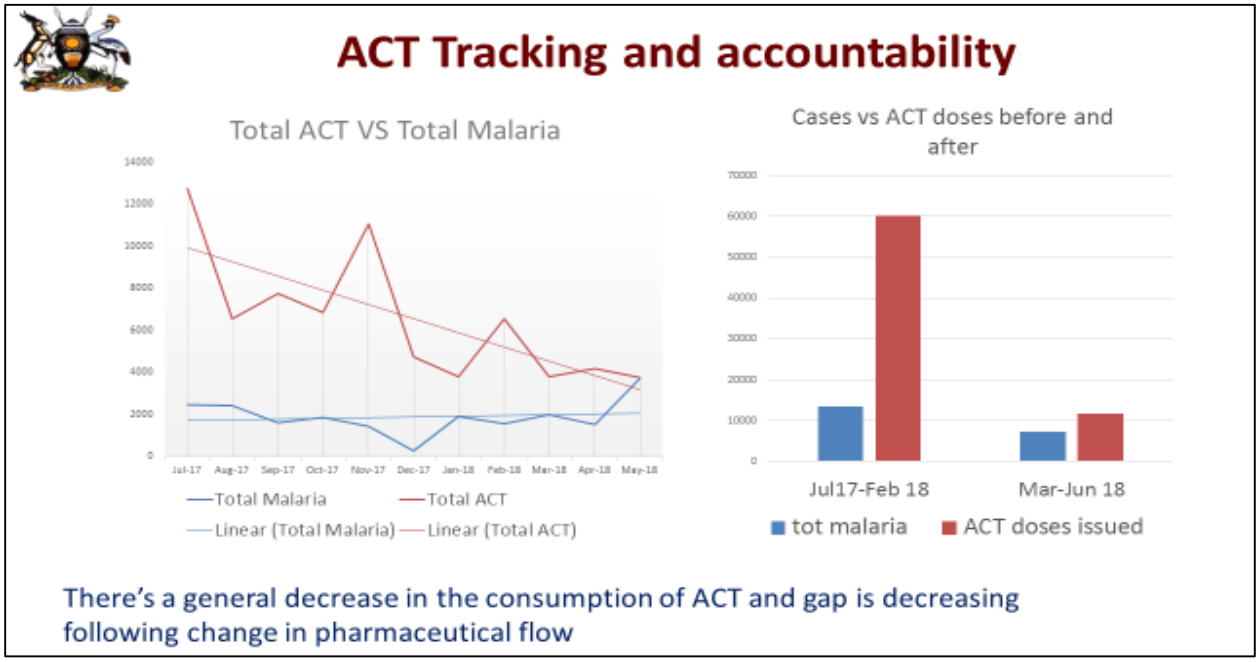
The first two graphs show a significant gap between cases and doses issued from store, both in the monthly trend and in the aggregate data. An analysis of issues from the store by department showed that the highest consumers were IP and OPD pharmacy (only the graph for ACT 24 and 6 tab are shown, but other pack sizes have a similar pattern). The next steps would be to:

- Check that all departments receiving ACT are reporting malaria cases (EMTCT, MCH, HIV clinic etc)
- Track quantities issued to IP and OPD pharmacy, quantities dispensed and number of patients
- Check accuracy of DHIS2 patient data.

Example 3

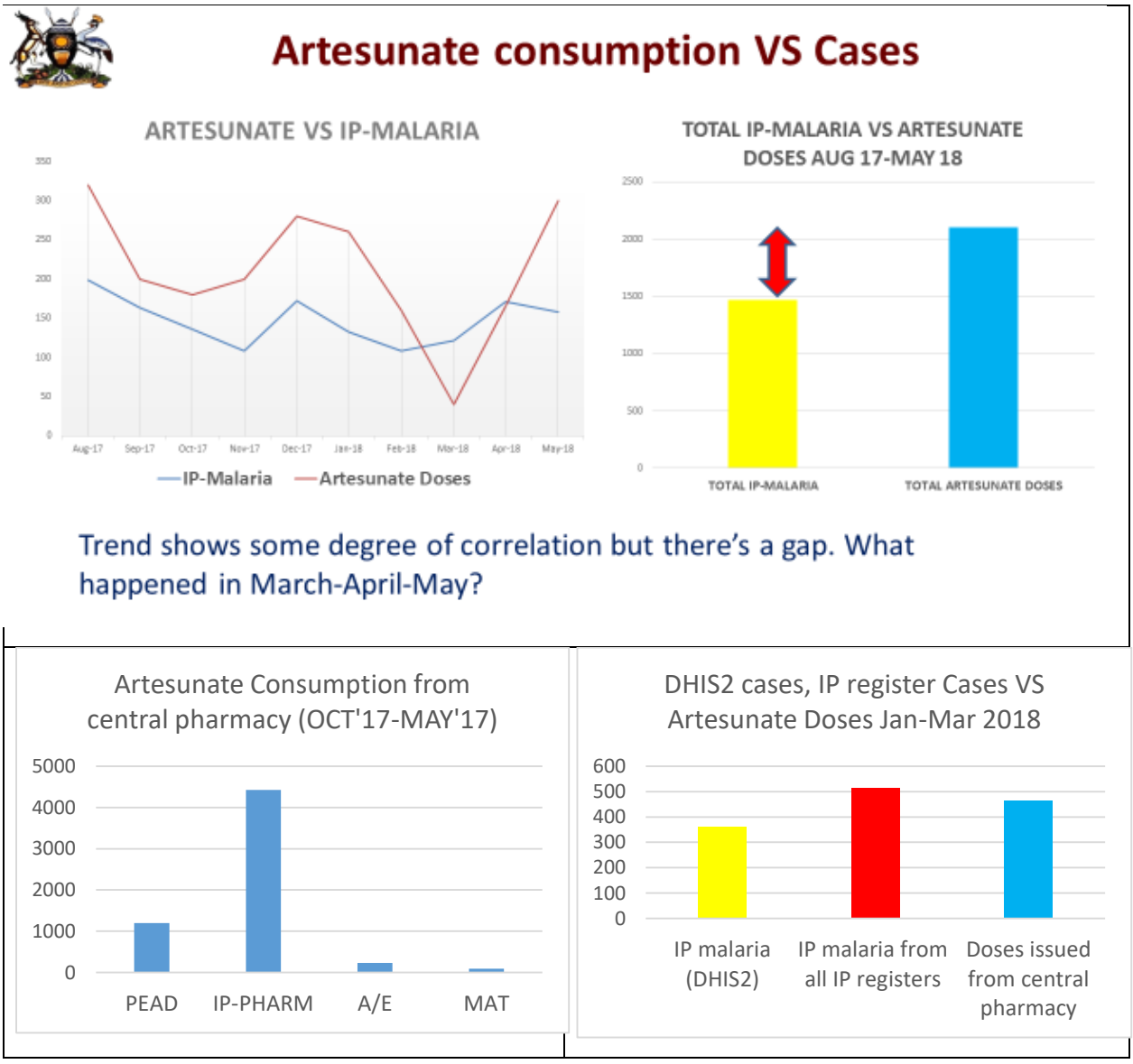
In the graphs below, consumptions of artesunate and ACT are compared with cases of malaria. Before February there is a huge discrepancy between cases reported and doses of antimalarial commodities issued. The hospital changed the pharmaceutical flow in March 2018: since then the discrepancy between doses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





Example 4

In the example below, there is 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 paediatric ward. The MTC tracked all IP malaria 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!**



Actually in several cases inaccurate or incomplete data are cause of discrepancy between reported cases and actual consumptions and often the MTC has to engage themselves in improving data quality both of pharmaceutical and clinical data.

7.5 Procurement planning and budget tracking

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

1. **Selection** is based on the Institutional Medicine List and the VEN classification.

2. **Quantification** can be estimated in different ways, but the two main methods are:
    a. **Consumption or issue method:** based on consumption 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.
    b. **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 which have only one intervention, such as TB or immunization. It should be based on accurate morbidity data and adjusted as needed.

3. **Costing**: a price has to 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 have to be done 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 is responsible of 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:

- Analyzing 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 (“budget monitoring sheet”)
  Ensuring adherence of orders to procurement plan.

Specific tools and methods to do so are described in the ***MOH Pharmaceutical Financial Management Manual***. The store/pharmacy staff is responsible for compiling and presenting this information to MTC, who then discuss and take action if necessary.

7.6 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 management of donations* (NDA and MOH).

For management of 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 drug 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 for 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, 2012
2. Pharmaceutical Financial Management Manual 2013
3. In-Patient Pharmacy Implementation Guidelines 2018

8 Quality and Safety of Medicines

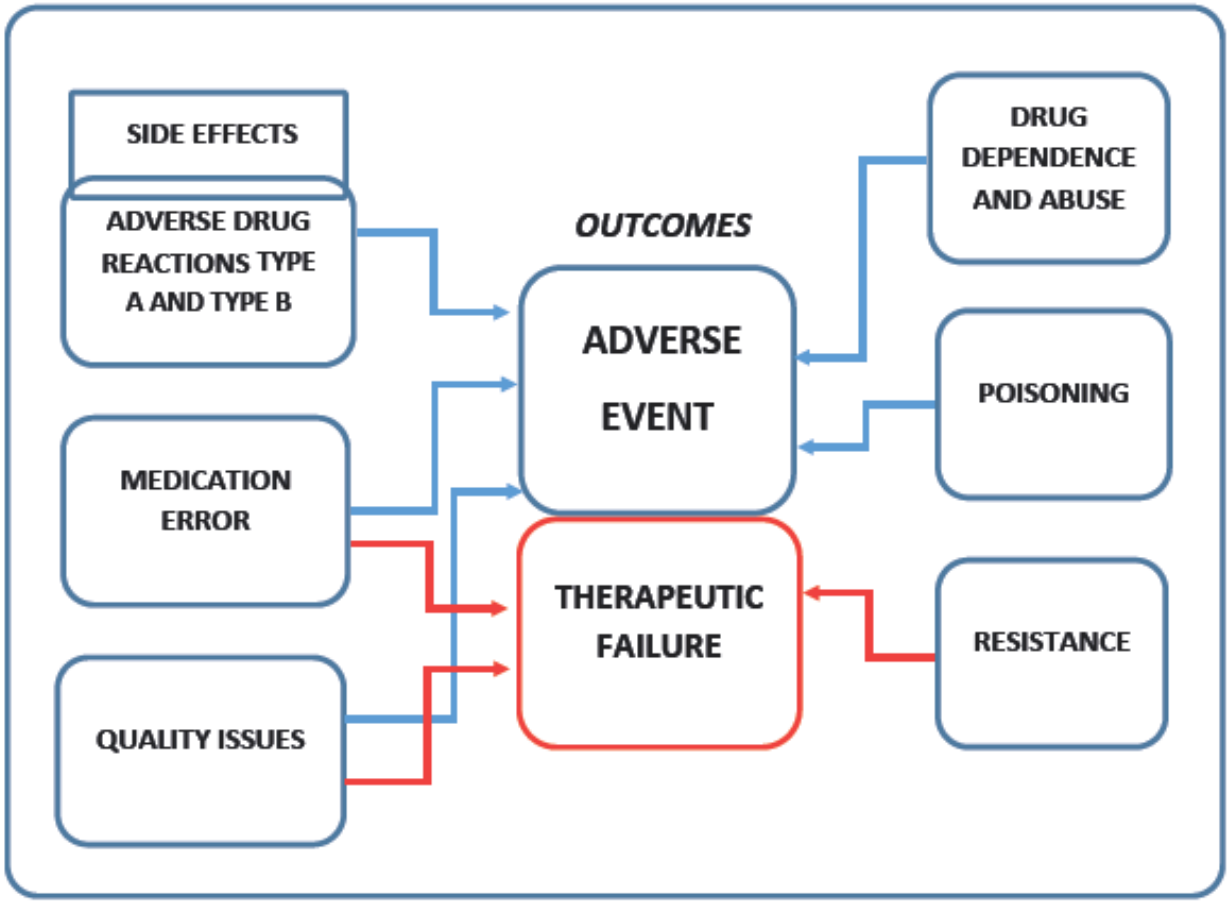
8.1 Introduction

When a medicine is prescribed, the expectation is that:

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

To achieve this, it requires the right medicine for the right patient, as clearly explained in Chapter 3: Appropriate use, but also the medicine has to be of quality, administered, dispensed, used correctly and in a manner that averts preventable adverse reaction. If any of these conditions is not observed, the consequences may be therapeutic failures and/or adverse drug events, causing poor quality of care, injury and even death, and inefficiency and waste of resources.

The figure below shows an overview of medicine related problems (from Uganda National Training Manual for Health Workers on Pharmacovigilance**,** NDA 2018).



Therefore the MTC, among its duties, is also mandated to:

- Ensure medicines are prescribed, administered and dispensed appropriately (by monitoring and addressing medication errors).
- Ensure medicine quality through good procurement, storage and distribution practices, monitoring and addressing product quality issues.
- Monitor and address adverse events, which may be caused by the medicine itself (side effects, adverse reactions) or by poor quality or by medication errors.

Unfortunately, adverse drug events are a significant cause of morbidity and mortality especially in hospitals. This is extensively documented in developed countries, while in developing countries it is less reported, though a recent review showed that in both settings a sizeable proportion of hospitalizations are related to adverse events, with most of them being preventable). In Uganda, it is estimated up to 15% of hospitalized patients are admitted with an Adverse Drug Reaction (ADR), and 20% of patients will develop an ADR. The more implicated medicines are antithrombotic, non-steroidal anti-inflammatory and cardiovascular drugs in both settings and anti-infectives (especially TB and ART medicines) in developing countries. The risk factors are older age, female gender, comorbidities and number of medications, renal impairment and heart failure, and HIV status in developing countries. Individual factors (genetic or others) often play a big role.

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 major aims of pharmacovigilance are:

a) Learn about medication related problems (mediation errors, quality issues) and create knowledge in order to enable prevention of problems and promote safe use of medicines.
b) Identify new risks (e.g. detection of previously unknown adverse drug reactions), learn more about known risks (e.g. define risk factors and underlying mechanisms, detect increase in incidence).
c) Estimate quantitative aspects of risk benefits analysis and dissemination of information needed to improve drug prescribing, use and regulation.

The process of pharmacovigilance consists in 3 steps:

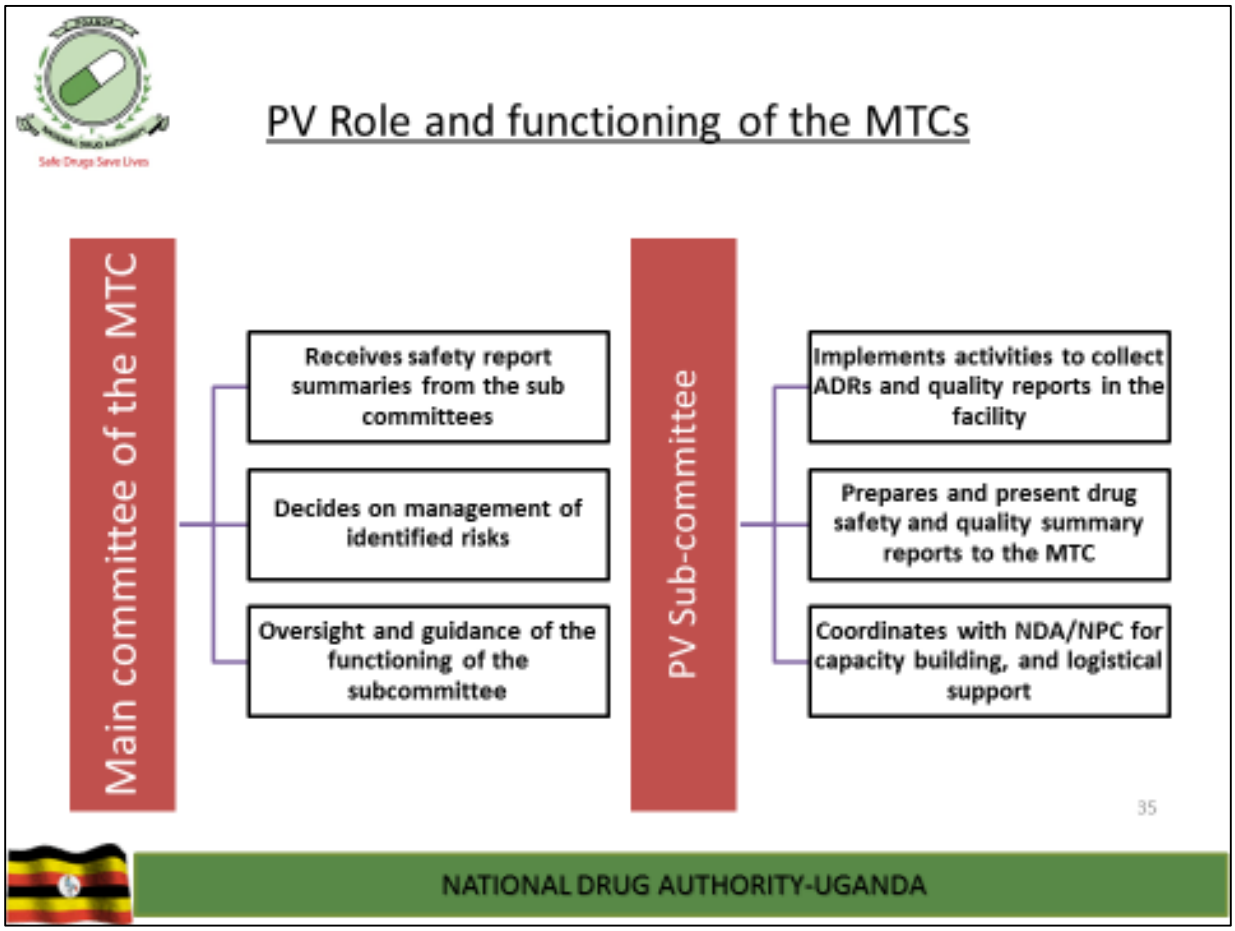
1. **Data collection:** By spontaneous reporting or specifically designed activities, that corresponding to the “identify and measure” phase of the quality improvement cycle.
2. **Causality assessment and signal management:** Investigation in order to identify if the reported event is significant and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

Pharmacovigilance activities are therefore within the scope of the MTC. Normally a focal person or a subcommittee works as the reference and coordinating point, identifying key safety issues which will then require action by the MTC.

Triggers for need of further action can be:

- Unexpected ADRs
- 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.

The figure below illustrates the role of MTC in Pharmacovigilance.



MEDICINES, DRUGS AND VACCINES

In the pharmacovigilance literature the term DRUG is still often used, rather than medicine. Even though sometimes adverse events linked to immunization are reported and handled separately at programmatic level, mechanisms and management principles are common with medicines so in this chapter VACCINES are considered as included. Key definitions in pharmacovigilance are in the annex at the end of the chapter.

8.2 Medication errors

A **medication error** is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer (WHO, 2014).

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

The table below shows the different types of medication errors.

Type of Error	Examples
Prescription errors	• Wrong diagnosis, dose, wrong drug, wrong indication, wrong frequency, 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 infusion fluid, incompatible infusion fluid • Miscalculation of required volume of infusion fluid
Administration errors	• Wrong route, wrong dose, wrong time, wrong drug, incorrect frequency, wrong patient, drug not administered • Set infusion pumps incorrectly • Non-compliance to the administration technique
Dispensing errors	• Incorrect drug, wrong patient, expired drug • Labelling errors, misinterpreted prescriptions
Monitoring errors	• Tests are not carried out at recommended frequencies

Often medication errors are linked to health systems issues such as heavy workload, poor communication, and lack of effective drug policies and procedures. "***To Err is Human***", so systems must be built to minimize errors and to protect patients from the consequences. The MTC can address these problems by making the following measures:

- Develop, implement and regularly review clear policies and procedures for drug administration e.g.:
    - Treatment charts requiring allergy notation
    - Intravenous (IV) medicine preparation and administration guidelines
    - Standardized notation for dosages and frequency
    - Clear labelling and organized storage of products (especially if vials look alike)
    - Pre-authorization and multiple checks for high-risk medicines etc.
- Conduct administration audits and dispensing studies – through chart reviews or direct observations (***see chapter 5***) to assess adherence to policies and procedures and design interventions if problems are found.
- Follow up any safety issues arising from adverse reports and,
- Address possible medication errors arising from the investigations.

Not all medication errors cause adverse events, so many may go unnoticed until a catastrophe happens so it is important to detect and prevent possible errors rather than having to later face a problem which may cost the life of a patient. This requires reporting not only of incidents, but of any medication error that is observed even if no harm has happened on that occasion. A system of voluntary reporting, blame free and not confrontational, should be established, so that appropriate investigations and action can be undertaken to prevent future damage.

Any medication error should be reported using the standard Adverse Drug Reaction report form (***see Annex 8.2***).

8.3 Quality of medicines

Quality of medicine here refers to the purity, potency, uniformity of dosage form, bioavailability and stability, and the correct labelling with respect to identity and source (manufacturer).

Quality problems can then be classified into:

- **Counterfeit (or 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 ingredient 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 cause adverse events, treatment failures, promote antimicrobial resistance, undermine confidence in efficacy of medicines and waste of resources. It is reported that in developing countries up to 30% of the medicines on sale may be counterfeit, so caution is warranted!

Quality control is the responsibility of the manufacturers and of regulatory bodies (international and national), but each health worker and the MTC have their role to play by:

- Developing, implementing, and revising policies to ensure procurement of quality products e.g. making sure medicines are procured only from reputable sources and not accepting donations from unclear sources.
- Ensuring careful visual inspection of packaging and medicines on arrival at facility, in order to look for and detect label changes or tampering, and inspect the physical characteristics of the product to detect visible anomalies.
- Ensuring proper storage and distribution of products e.g. temperature, humidity, light, respect of 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 in the appropriate way.
- Ensuring suspicions of poor quality (visual deterioration of the products, unsatisfactory therapeutic effect, adverse reactions) are followed up and reported for further investigations.

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, labelling and expiry date.
- Elicit information concerning the procurement, storage and distribution, and verify with recommended practice
- Investigate use and administration for eventual inappropriate use or medication error (e.g. we cannot claim that artesunate is not effective for severe malaria if the diagnosis is not confirmed, or that cloxacillin is not effective in treating skin infection if it is administered twice a day instead of every 6 hours).

If the above reasons for lack of therapeutic effect or adverse reaction are found unlikely, more investigations on the quality of the product may be warranted. The issue should be reported in the standard ADR report form and sent to NDA (National Drug Authority) for further investigations, but also discussed in the MTC in order to decide the appropriate course of action (e.g. suspend the use of the item involved, or carefully monitoring its use, report/return product to manufacturer etc).

While a health facility most likely not have the capacity of performing analytical tests, the users are the main source of “alerts”, and then the designated regulatory body can investigate appropriately.

8.4 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, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or it is life-threatening.

The risk factors for ADRs include: narrow therapeutic windows, polypharmacy (high risk of drug interactions), HIV infection, extremes of age, kidney and liver disease, heart failure, 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, described above, or it is linked to the chemical properties of the drugs and its interaction with the patient's physiology. The latter category is classified as in the table below:

Type of ADR	Definition
Type A reactions	• Exaggerated but otherwise known pharmacological response to the effects of the medicine given in therapeutic doses. • Can cause significant morbidity but are rarely severe. • Relatively frequent, have a dose-effect relationship and are reproducible. • Usually occur when the drug concentration in the body exceeds the recommended therapeutic window, e.g., when dose of 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, hypoglycaemia 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 is 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. • The suspected drug involved **MUST** be stopped and supportive measure 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

Steps in assessing adverse drug reaction

When a patient is taking a medicine, 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 keep a high level of suspicion.

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:

1. Collect a detailed history about the patient as per standard ADR report (***Annex 8.2***). Include clinical history, comorbidities, if and how medications have been taken/administered, all medications patient has taken, risk factors, differential diagnosis.
2. Describe and document the reaction, including the time relationship, how reaction was managed, events after discontinuation, and compare with the literature.
3. 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).
4. Assess the likelihood of causality e.g. using the Naranjo algorithm below:

Question	Yes	No	Do not know
Are there previous conclusive reports on this reaction?	+1	0	0
Did the adverse event appear after the suspected drug was administered?	+2	–1	0
Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0
Did the adverse reaction reappear when the drug was re-administered?	+2	–1	0
Are there alternative causes (other than the drug) that could solely have caused the reaction?	–1	+2	0
Was the drug detected in the blood (or other fluids) in a concentration known to be toxic?	+1	0	0
Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
Was the adverse event confirmed by objective evidence?	+1	0	0
Total score			

Total score categories are defined as follows: ADR is: certain > 9; probable 5–8; possible 1–4; unlikely 0.

5. Check the medicine for possible quality issues (visual inspection, storage, expiry).
6. Assess possibility of medication error, investigating preparation and administration/dispensing procedures.
7. If possible, compare rate of ADRs between departments or with other facilities, eventually through the regulatory body, to help investigating.

All suspected adverse events should be reported using the national ADR reporting form (**annex 8.2**) to the National Pharmacovigilance Center (NPC) through the regional pharmacovigilance centers located in every regional referral hospital. Alternative methods of reporting include the NPC hotline, and the Internet portals prescribed in the NDA guidelines for detecting and reporting Adverse Drug Reactions. Internally, the pharmacovigilance sub-committee should generate and submit regular summary reports to the MTC and support it to take informed decisions.

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 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 or quality related problems including suspected contamination, questionable stability, defective components, poor packaging or labeling

Adapted from World Health Organization. Safety of medicine: a guide to detecting and reporting adverse drug reaction. Geneva: WHO: 2002

Besides reporting to NDA, the MTC action will depend on the results of the investigations:

- If a quality issue was found/suspected, it should be addressed, depending on the cause. The quality problem should be reported to NDA for quality testing and to the supplier.
- If a medication error is found, investigate and correct proceses 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), so the reporting of ADR is not only a bureaucratic requirement but an important opportunity for quality improvement.

Guidance on ADR prevention

Most ADRs can be prevented by following the basic principles of appropriate use of medicines, which is one of the main goals 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 a good knowledge of the medicine use and risks factors for adverse reactions.
- Establish, implement and monitor policies and procedures to ensure quality of medicines (procurement and storage) and to prevent medication errors.
- Educate prescribers and patients to recognize early signs of adverse events and manage 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 reaction. Geneva: WHO:2002
3. Uganda National Training Manual for Health Workers on Pharmacovigilance**,** NDA 2018

Annex 8.1. : Definitions in pharmacovigilance

Term	Definition
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.
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 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.
Unexpected Adverse Drug Reaction	ADR whose nature or severity isn't consistent with the applicable product information.
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.
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.
Counterfeit	Medicine which 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.
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.
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.
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.
Drug resistance	Reduction in 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.
Drug interaction	An event where one drug or any other chemical substance alters the pharmacological effect of another drug.
Vaccine	A biological preparation that improves immunity to a particular disease.
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.
Causal association	A cause-and-effect relationship between a causative factor and a disease with no other factors intervening in the process.

Annex 8.2: NDA Adverse Reaction report form

SUSPECTED ADVERSE DRUG REACTIONS (ADR) AND ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI) REPORTING FORM

Reports can also be submitted online via the NDA website www.nda.or.ug

A. CATEGORY (Tick whichever applies)

Report is about a	**The event is a**	**Seriousness;**
a) Drug ☐	a) suspected ADR ☐	Not serious ☐
b) Vaccine: ☐	b) AEFI ☐	Serious ☐
c) Other	c) suspected /observed inefficacy ☐	**Reason for seriousness.. Reaction resulted in**
e.g. Medical device, Medical equipment, Other biological (blood & blood products), anti-venom ☐	d) observed poor quality product ☐	a) Death ☐
Specify:……	e) medication error ☐	b) Prolongation of hospitalization ☐
	suspected counterfeit	c) Persistent Disability ☐
		d) Congenital anomaly ☐
		e) Life threatening ☐
		f) Other important medical condition ☐
		Specify ……

B. Patient Details

Patient name	Health Facility	Sex: M/F
Age (at time of onset)	District	Last menstrual period
Weight (if known) in Kg	Patient Village & Tel:	Trimester if pregnant

C. Suspected Drug (s)/ Vaccines

Generic name and Brand Name	**Batch/ lot number/ expiry date**	***Date of administration**	**Time of administration**	**Dose route frequency** For vaccines specify dose (1st, 2nd, etc.)	**Diluent name, batch number & expiry date (for vaccines)**	**Time of reconstitution (for vaccines)**	**Date stopped (for drugs)**	**Prescribed for (for drugs)**

D. Concomitant Drug(s)/Vaccines Please give information on the drug the patient has been taking in the last 3 months(include self medication and herbal preparations)

Generic name and Brand Name	**Batch/ lot number/ expiry date**	***Date of administration**	**Time of administration**	**Dose route frequency** For vaccines specify dose (1st, 2nd, etc.)	**Diluent name, batch number & expiry date (for vaccines)**	**Time of reconstitution (for vaccines)**	**Date stopped (for drugs)**	**Prescribed for (for drugs)**

E. SUSPECTED AEFI/ADR DETAILS

Please describe the reaction as observed and any treatment given to manage the reaction.

Outcome:

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

☐ Died If died, date of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Autopsy done: ☐Yes ☐No ☐Unknown

	Date (and time) reaction started	Date reaction stopped	Date of Patient notified event to health system	

Relevant laboratory	**Additional relevant information(medical history, allergies, failure of efficacy)**

F. Reporter's Details

	Name/designation	Telephone and Email Address	Date of reporting	health facility

9 Antimicrobial Stewardship (AMS)

9.1 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), antifungal (against fungi e.g. Candida), antibiotics/antibacterials (against bacteria) and antiparasitic (against parasites such e.g. P. falciparum etc).
The term **antibiotic** refers originally to natural substances produced by other microorganisms that are able to inhibit the growth/kill bacteria, but it now includes also synthetic agents with the same properties.

Antimicrobial resistance is the ability of a microorganism (like bacteria, viruses, and some parasites) to stop an antimicrobial (such as antibiotics, antivirals and antimalarials) from working against it (WHO, 2016). As a result, standard treatments become ineffective, infections persist and may spread to others. Antibiotic resistance is particularly threatening, but also resistance to antivirals (e.g. HIV) and parasites (e.g. malaria) have concerned the health community for some time.

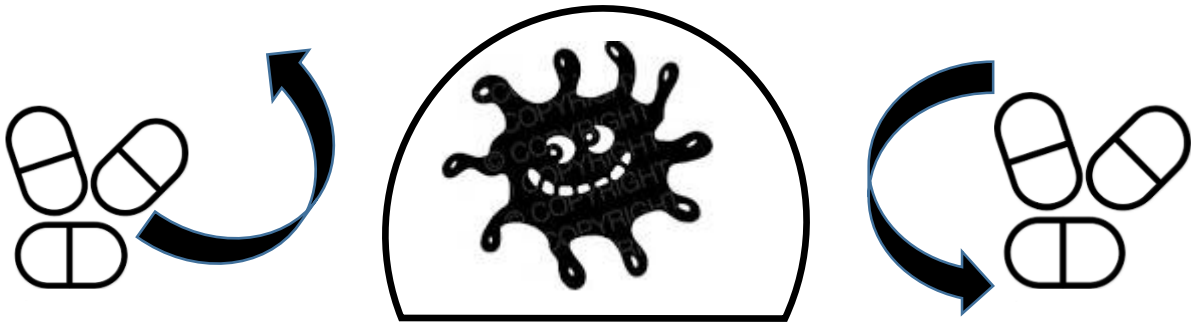


Fig 9.1: a resistant microorganism is not sensitive any more to antimicrobials

Antimicrobial resistance is a natural phenomenon: microorganisms produce antibiotics to compete with others for space and resources and can as well develop resistance mechanism in order to survive. Resistance mechanisms can be acquired through a mutation during replication (a “mistake” in duplication which confer to the bacteria the capacity to defend itself from antibiotics) or can be horizontally transmitted among bacteria, which are able to exchange strands of DNA carrying resistance genes.

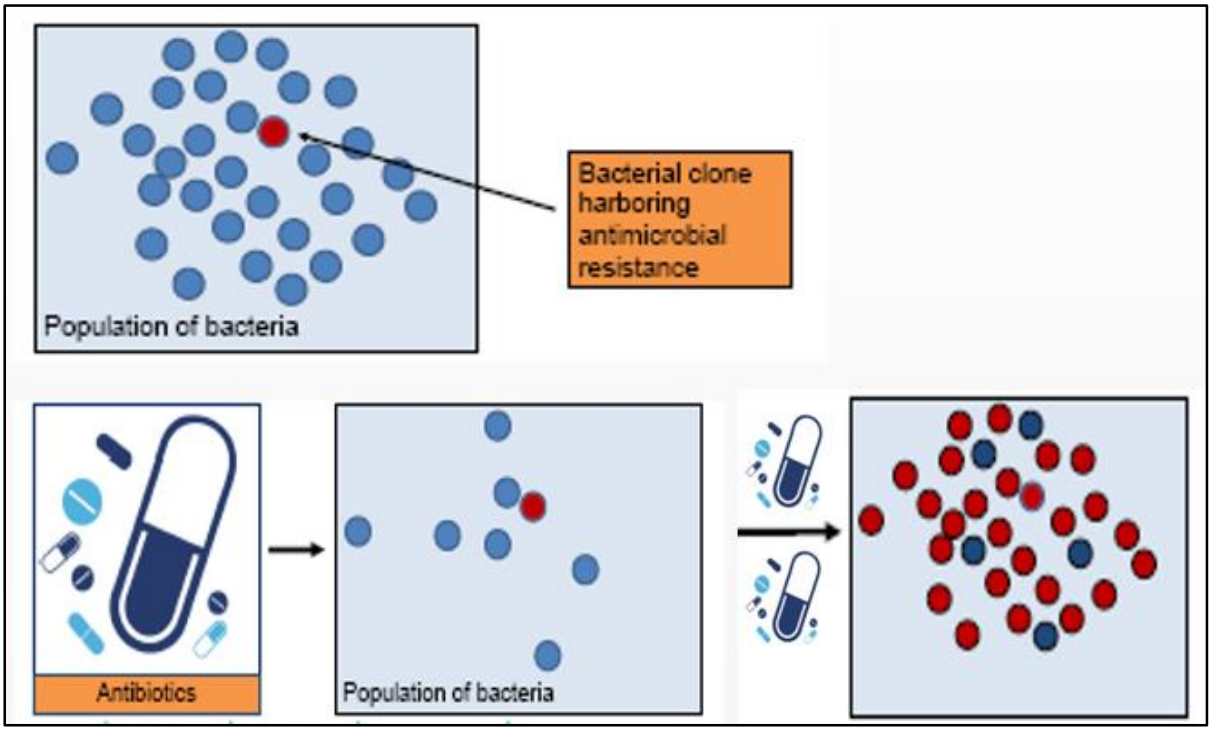
Mechanisms of resistance include:

- Decreased uptake (change in permeability of cell membrane so that antimicrobial cannot enter the cell)
- Target modification (change in the target so that the antimicrobial cannot act anymore on it)

- Inactivation (e.g. by phosphorylation or enzymatic degradation)
- Increased efflux (pumping out of the antimicrobial, so that it cannot reach sufficient concentration within the cell).

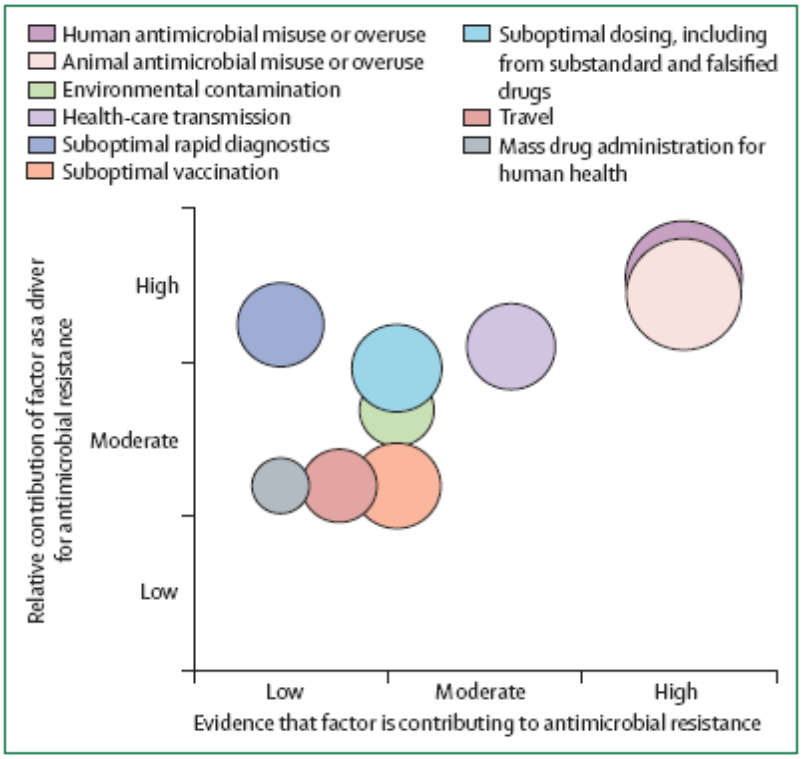
9.1.1 Drivers of antimicrobial resistance

The main driver for the emergence of antimicrobial resistance is exposure: when a population of microorganism is exposed to certain antimicrobials, there is a chance that resistant organisms are selected and, once the antimicrobials kill the sensitive ones, they resistant ones become the dominant population (**see illustration below**). This can apply to all microorganisms: bacteria, viruses, parasites and fungi.



The emergence of resistance is a therefore “natural” phenomenon related to antimicrobial use e.g. the malaria plasmodium has become resistant to chloroquine, the HIV virus is becoming increasingly resistant to antivirals, and since antibiotics were present in nature before we “discovered” them, resistance mechanisms to antibiotics are already existent in environmental bacteria.

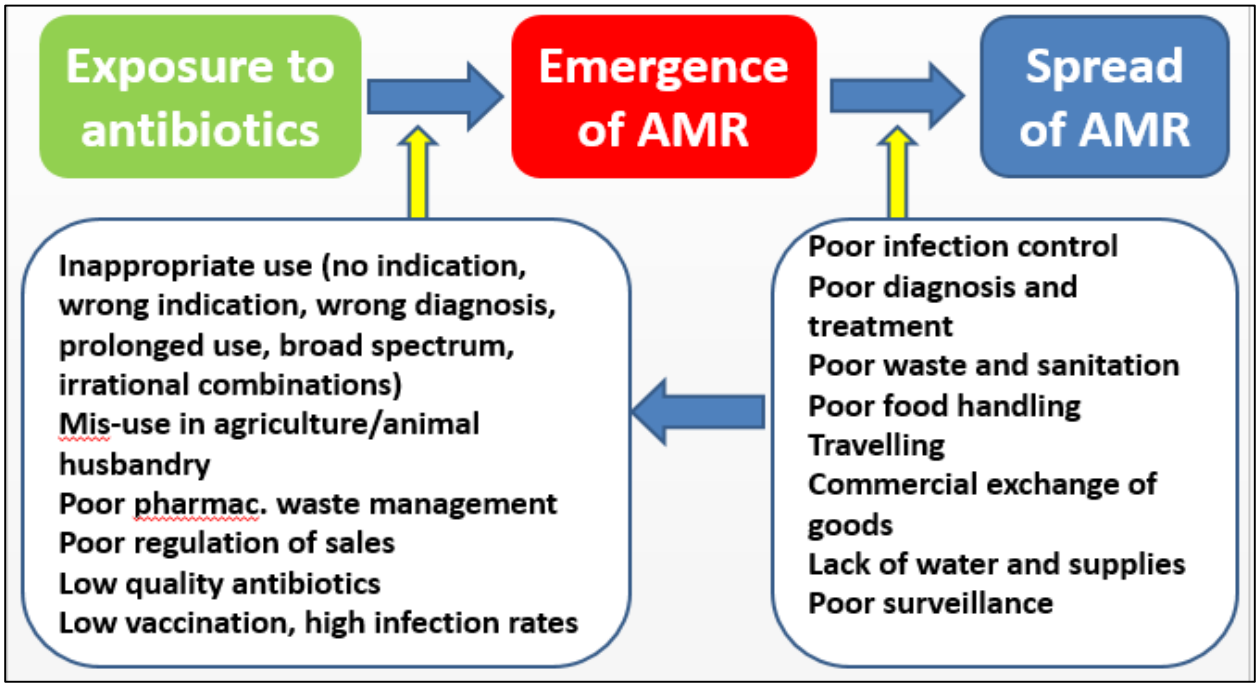
After their “discovery” though, increasing massive use of antibiotics in health care and in the veterinary and agricultural sectors has caused the progressive selection of resistant bacteria, which can subsequently spread. The graph below, from a Lancet article, depicts well the role of different factors in emergence and spread of antimicrobial resistance.



Role of modifiable drivers for antimicrobial resistance: a conceptual framework: an infographic to show the considered potential contribution of each factor. Associated relative contribution, supporting evidence and potential population affected (diameter of bubble) are shown.

From Holmes AH, Moore LSP and others. Understanding the mechanisms and drivers of antimicrobial resistance. *Lancet 2016; 387:176-187*

A brainstorming session with MTC members identified in detail a number of factors involved in emergence and spread of resistance, as shown below. To be noted, the issue of poor infection control and poor hygiene and sanitation affect both the spread and the emergence of resistance, since they cause high infection rates and therefore high use of antibiotics.

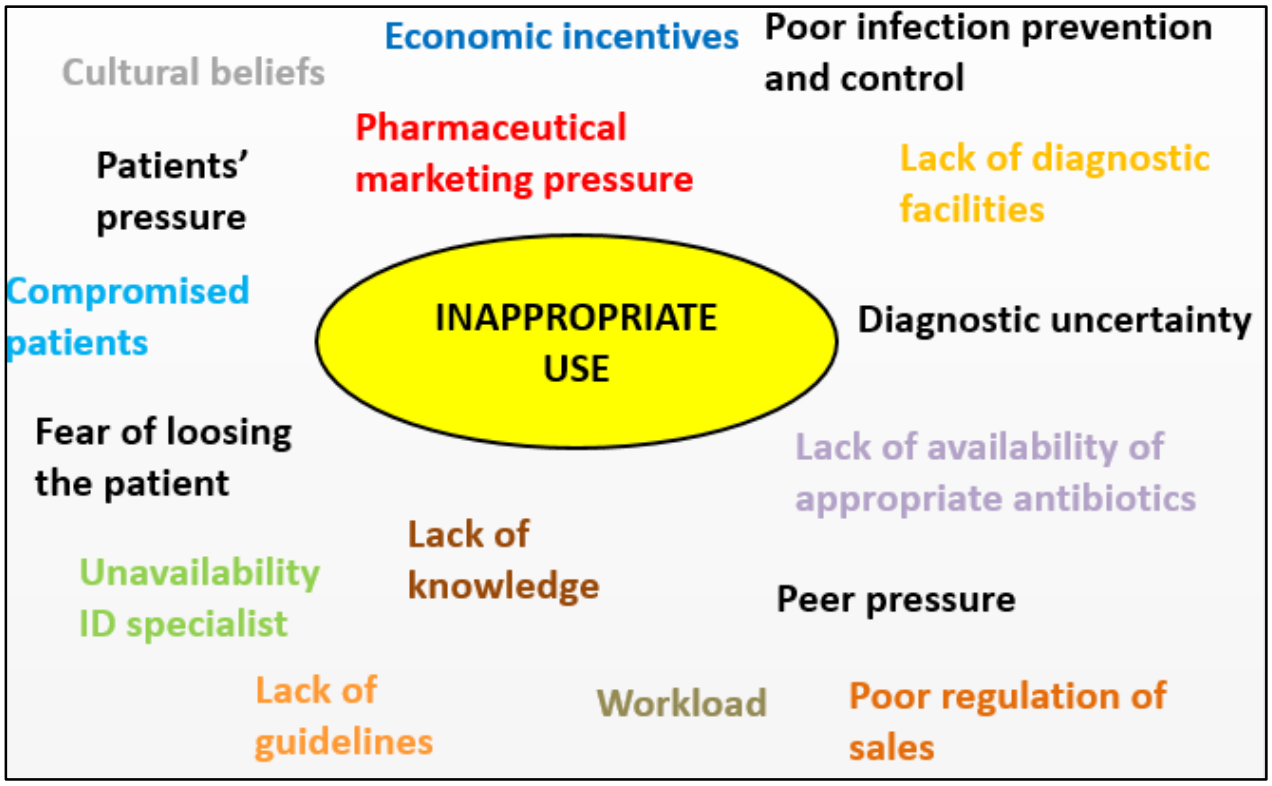


9.1.2 Inappropriate use of antimicrobials

Inappropriate use of antimicrobials, and antibiotics in particular, is of primary concern to the Medicine and Therapeutics Committee. Inappropriate use can include:

- Excessive use (when it is not necessary e.g. for viral infections or unnecessary prophylaxis)
- Incorrect use (wrong choice, wrong dose, wrong duration, wrong route, inappropriately broad spectrum, irrational combinations)
- Lack of use: while it may seem a contradiction, lack of access and use can contribute to antimicrobial resistance in various ways:
    - People may get sicker and end up needing hospitalization and stronger antibiotics
    - More people may get infected so causing more use of antibiotics
    - Access to first line narrow spectrum antibiotics can be limited, prompting use of more broad-spectrum medications, which can cause more resistance.

The possible factors involved in inappropriate use are similar to the ones described for inappropriate use in general, as shown in the figure below.



Global estimates show that up to half of antibiotics are prescribed/used inappropriately, meaning that half of the effect of antibiotic use on emergence of resistance could be avoided without affecting, and even improving, quality of care!

9.1.3 Consequences of antimicrobial resistance

Antimicrobial resistance has severe consequences both for the patients and for the community.

Consequences for the patients	Consequences for the community
• Increase in morbidity and mortality • Prolonged hospitalization • Increased risk of side effects • Increased risk of adverse events	• Increased costs • Increased transmission of resistant microorganisms • More infections, and more deaths

Health care as we know it is at risk: the spread of resistant germs will make procedures such as surgery, transplants and cancer treatments impossible, and will take us back to the "pre-antibiotic era". A report commissioned by the UK government has estimated that by 2050 AMR will kill more people than cancer!

9.1.4 AMR National Action Plan and role of MTC

In line with the resolution of the World Health Assembly in 2015, Uganda developed a national action plan (NAP) to address the threat of antimicrobial resistance. Under the guidance of WHO, 5 "pillars" have been identified as key in fighting AMR and include:

- Awareness, training and education, of both general public and professionals
- Infection prevention and control (IPC)
- Optimal access to and use of antimicrobials
- Surveillance (of resistant microorganisms, of antimicrobial use and of the environment)
- Research and innovation, to support the above.

The plan also adopts a One-Health approach, recognizing that human, animal and environmental health are deeply interconnected in various ways, of which AMR is just an example, and issues must be addressed with a global perspective. In fact, a significant percentage of antibiotics are used in the animal and agriculture sectors, and this has important consequences on human health since resistant germs can spread from animals to humans, antimicrobials are disseminated in the environment including in our food etc.

The hospital MTC has a role to play in all the 5 components of the fight against AMR:

- It is involved in sensitization, training and education of both health workers and patients
- It ensures availability and correct use of supplies and protocols for infection prevention and control (disinfectants, personal protective equipment, antibiotics for prophylaxis etc)
- It ensure optimal access and use of antimicrobials and of diagnostic supplies
- It monitors availability and use of antimicrobials and,
- Conducts operational research to improve practices and behaviors.

In addressing AMR, the MTC will work within the quality improvement structure of the facility and employ the quality improvement approach outlined in **chapter 2** by:

- Setting standards (treatment guidelines, international, national or facility based, informed as much as possible by local data)
- Examining and measuring practices for problem identification, prioritization, and investigations
- Developing and implementing interventions
- Monitoring and evaluation.

When applied to antimicrobials, the activities directed at optimizing use of antimicrobials fall under the definition of **Antimicrobial Stewardship**.

9.2 Antimicrobial stewardship

At patient's level, this term indicates "***the optimal selection, dosage and duration of antimicrobial treatment that results in the best clinical outcome for the treatment or prevention of infection, with minimal toxicity to the patient and minimal impact on subsequent resistance".***

At system level, it refers to ***"an organizational or healthcare system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness".***

The goals of antimicrobial stewardship are to:

- Improve patient outcomes (improve cure rate, decrease morbidity and mortality)
- Improve patient safety (minimize unintended consequences of antimicrobials: toxicity, adverse events)
- Reduce resistance (reduced and judicious use of antimicrobials limits the emergence and spread of resistant microorganism)
- Reduce healthcare costs - without adversely impacting quality of care.

9.2.1 Antimicrobial Stewardship Subcommittee

The goal of an Antimicrobial Stewardship (AMS) subcommittee is to assist the MTC in dealing with the management of antimicrobials, and in particular 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 patients and that, as far as possible, patients take antimicrobials correctly.

Composition of the AMS subcommittee

The committee should be composed by clinicians, pharmacists, laboratory staff and a representative from the IPC committee: it should be a small but agile team which will work within the MTC and the wider Quality Improvement framework to promote the antimicrobial stewardship agenda.

Functions of the AMS subcommittee

The functions of the AMS subcommittee are similar to those of the MTC, but with an emphasis on antimicrobial drugs as in the table below.

Functions of Antimicrobial Stewardship Subcommittee of MTC
• Advise the MTC and medical staff on all aspects of antimicrobial use and misuse. • Assist in evaluating and selecting antimicrobials for the formulary and standard treatment guidelines. • Develop policies concerning use of antimicrobials for approval by the MTC and medical staff. Policies should specifically include sections on methods to limit and restrict 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 use of effective antimicrobials of adequate quality only when clinically indicated, in the correct dose, route and for the appropriate duration. • Participate in the educational programs for health-care staff. • Collaborate with the infection control committee and laboratory departments to monitor and prevent/limit emergence and spread of resistant microorganism.

9.2.2 Setting standards: treatment guidelines and principles of antibiotic prescribing

Development of antimicrobial, and in particular antibiotic treatment guidelines presents unique challenges, since it often would require 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.

9.2.3 Role of laboratory in antimicrobial stewardship

Laboratory services have a fundamental role in the fights against AMR:

- To reduce diagnostic uncertainty and hence inappropriate/excessive use of antimicrobials
- To target antimicrobial therapy according to type of microorganism and sensitivity
- To detect and monitor emergence and spread of resistant microorganisms.

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

A number of tests can help to differentiate between a viral and bacterial disease, but at the moment, there is no cheap, easy and accurate test is widely available:

- A raised white blood cell count with neutrophilia can suggest a bacterial cause, but it is very nonspecific and many other conditions can cause raised neutrophils.
- Very elevated CRP (C-recative protein) can suggest bacterial infection, but again it can be aspecific 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 identification of the causative microorganism and in 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:

1. 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
2. They provide epidemiological data about microorganism and resistance which, if aggregated, can be used to develop a **cumulative 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 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.

CAUTION!!

While laboratory is fundamental in improving care and fighting resistance, tests should be used only when clinically indicated and results need ALWAYS to be interpreted and used with some care. For example, positive culture results can be due to a real infection, but also due to contamination of the sample (non-intended or accidental introduction of microbes from a source different from the intended) or colonization (presence of bacteria on skin and mucosal sites without causing signs and symptoms of an illness e.g. streptococcus in the throat, various bacteria in the gut, MRSA in the nose). Colonization does not require treatment with antibiotics except in specific circumstances.

More information on these topics `can be found in the video trainings listed in the references.

9.2.4 Principles of antibiotic prescribing

There are three types of prescription for antibiotics (in humans):

- **Prophylaxis:** given before exposure to prevent infection from occurring
- **Empiric therapy**: when a bacterial infection is presumed but no microbiological evidence is available
- **Definitive therapy (targeted**): given for bacterial infections when microbiological evidence is available (organism responsible of the infection and sensitivity pattern).

There are 6 basic principles of antibiotic prescribing (which can also be applied to antimicrobials in general) as shown in the table below.

Six Principles of Antibiotic Prescribing
1. Only use antibiotics for bacterial infections 2. Perform appropriate culture before antibiotics (if possible and when appropriate) 3. Source control: source of infection must be controlled e.g. draining the abscess 4. Choose an appropriate antibiotics: target the most likely pathogens for site of infection, assess likelihood of resistance, review contraindications, choose drugs with adequate target tissue penetration, aim for a single drug with adequate coverage 5. Ensure correct dose, route and duration 6. Reassess daily (consider response and further diagnostic information to decide change in treatment, de-escalation and parenteral to oral switch).

A detailed explanation of these principles is presented in the Video trainings referenced at the end of this chapter.

9.3 Surveillance of antimicrobial consumption and use

Collecting and analyzing data about consumption and use of antimicrobials represents the step necessary in order to measure existing practices, identify and prioritize and investigate problems, and monitor effects of interventions. Information on consumption and use can also be triangulated with information on resistance in order to analyze and monitor the relationship between use and resistance. Many of the methods already presented in the previous chapters can provide such information:

- Aggregate data methods can inform on quantities, types and cost of antibiotics consumed
- Indicator studies can provide information on OPD prescribing practices (% patients prescribed antibiotics in OPD)
- Drug administration audits can inform about how prescribed doses are administered (missing doses can cause under-dosing, and favor emergence of resistance besides causing clinical ineffectiveness)
- Medicine use evaluations and prescription audits can inform on the use of specific antimicrobials and/or prescription patterns for specific infectious syndromes.

Surveillance of antimicrobial consumption has been standardized through the adoption of a well-defined methodology which allows analysis and comparison of data at a global level: the **ATC/DDD methodology**.

9.3.1 ATC/DDD methodology

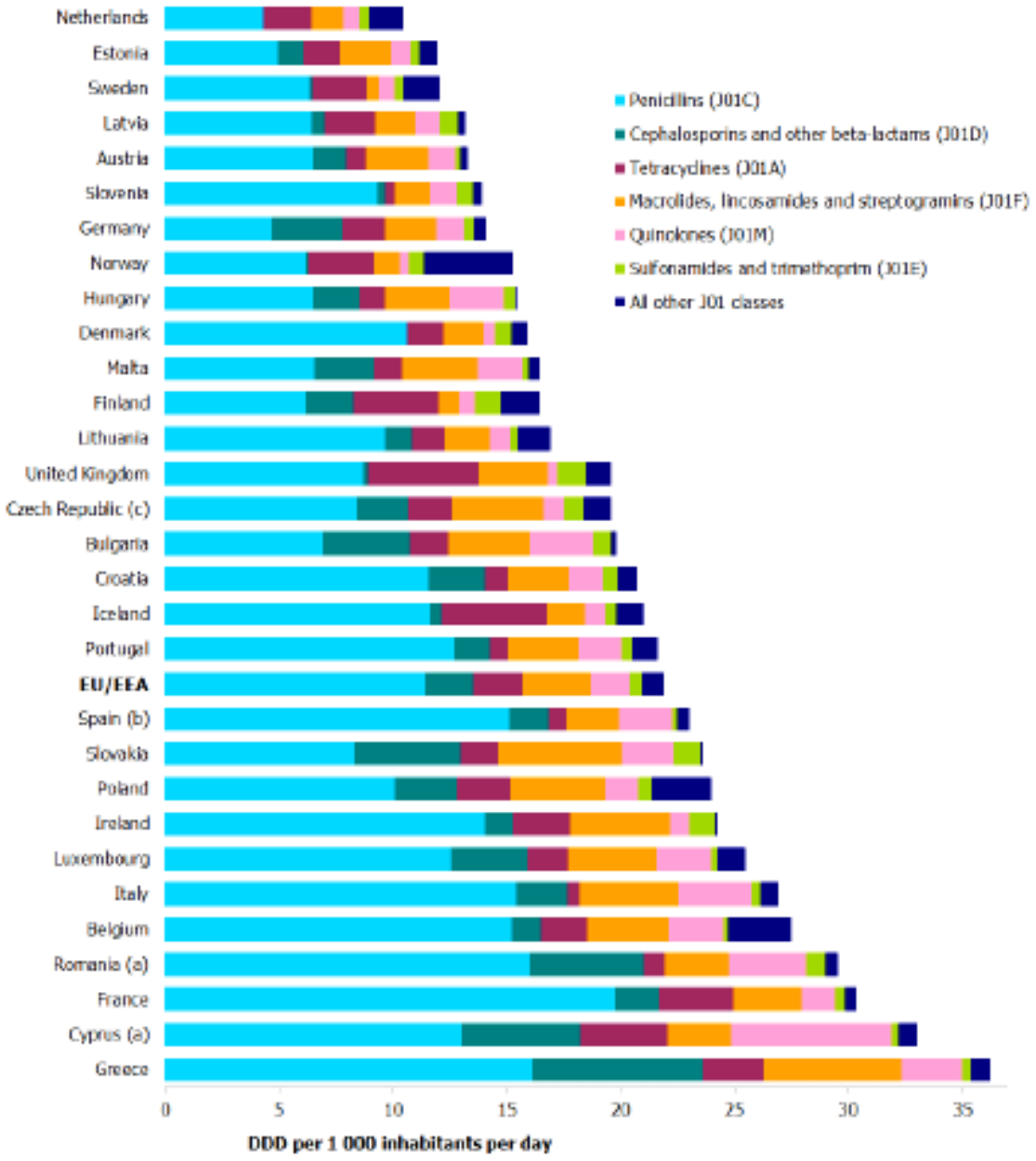
The purpose of the ATC/DDD system is to serve as a tool for medicine utilization monitoring and research in order to improve quality of medicine use: it applies to all medicines but is particularly used for antibiotics.
The ***ATC (Anatomical Therapeutical Classification)*** is a standardized classification of medicines, maintained by the WHO collaborative center in OSLO, and based on 5 levels as shown in the example below:

LEVEL	Example	
1st level, anatomical main group	J	Antiinfectives for systemic use
2nd level, therapeutic subgroup	J01	Antibacterials for systemic use
3rd level, pharmacological sub group	J01C	Beta-lactam antibacterials, penicillins
4th level, chemical subgroup	J01CA	Penicillins with extended spectrum
5th level chemical substance	J01CA04	Amoxicillin

The ***DDD, Daily Defined Dose***, is the assumed average maintenance dose per day for a drug used for its main indication in adults. The DDD is a unit of measurement and does not necessarily reflect the recommended or Prescribed Daily Dose. Therapeutic doses for individual patients and patient groups will often differ from the DDD (more information can be found in the sources listed in references at the end of the chapter).

Measurement of consumptions by **DDDs per 1000 people** (for community consumptions), or **DDDs per 100 patient days** (for hospital consumptions), allows to compare consumptions between countries, regions or even facilities. This requires comprehensive data on antibiotics consumed which may not always be available, so proxy data can be used e.g. the quantities of antibiotics imported or locally produced and passing through the National Drug Authority can give an estimate of the quantities of antibiotic consumed in the country, or the quantities issued from National Medical Store can give an estimate of the antibiotics consumed in the government health facilities. This methodology has more applications for surveillance at global, national or subnational level, even though it can be used to compare consumptions among districts or facilities.
WHO is undertaking considerable effort to introduce this methodology at global level. European countries have been monitoring consumptions for several years and an example is shown below. The difference among countries is very noticeable: Greece consumes more than double antibiotics/1000 inhabitants than Holland does!

Figure 2. Consumption of antibiotics for systemic use in the community by antibiotic group, EU/EEA countries, 2016 (at ATC group level 3, expressed as DDD per 1 000 inhabitants per day)



(a) Cyprus and Romania provided total care data (i.e. including the hospital sector).

(b) Spain provided reimbursement data (i.e. not including consumption without a prescription or other non-reimbursed courses.)

(c) Czech Republic: data from 2015

EU/EEA refers to the corresponding population-weighted mean consumption.

9.3.2 The AWaRe Classification

The 2017 edition of the WHO Model List of Essential Medicines introduced a classification of antibiotics into three classes, with examples in the table below:

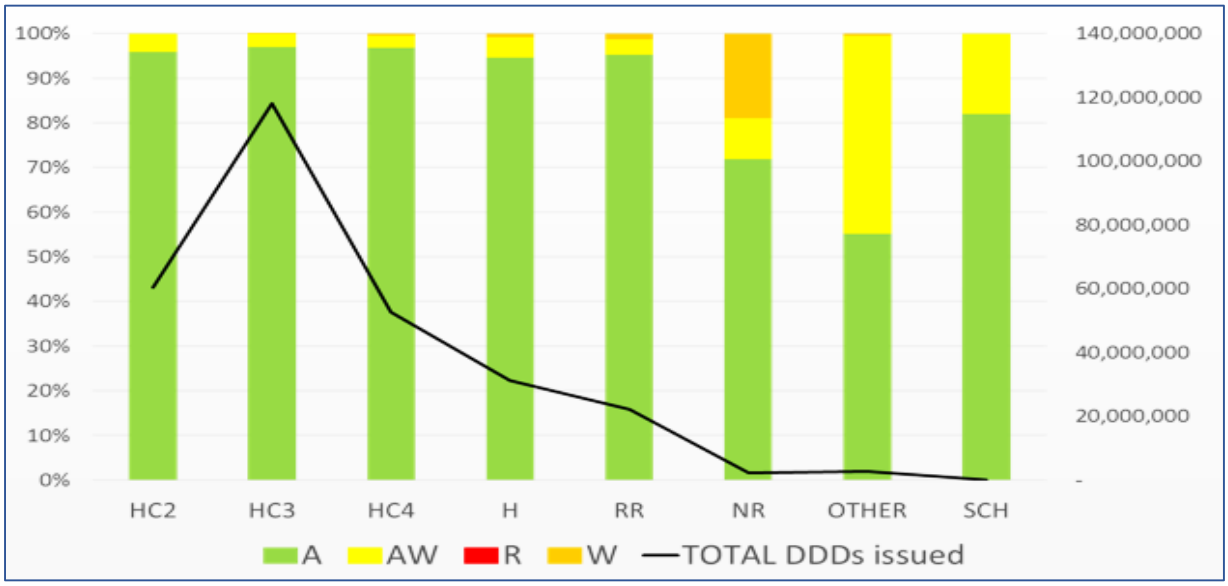
1. **Access Antibiotics:** first or second line medicines for most common clinical infective syndromes, based on comprehensive review of 21 priority infectious syndromes in children and adults, review of 5 bacterial infections in children (community acquired pneumonia, dysentery, cholera, sepsis, severe acute malnutrition), and review for antibiotics for STI (current WHO guidelines). These antibiotics should be widely available, accessible and quality-assured.
2. **Watch Antibiotics:** classes of antibiotics with a broad spectrum and a higher risk of resistance, to be used for selected indications and to be considered as a focus for stewardship. This group includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine. Some ACCESS antibiotics, like ceftriaxone and azithromycin are also in the WATCH group.
3. **Reserve Antibiotics:** "last resort" antibiotics, which should be restricted only for multi resistant infections and for targeted treatment, and should also be focus for stewardship.

ACCESS ANTIBIOTICS	WATCH ANTIBIOTICS
Amoxicillin, Amoxicillin-clavulanic	Quinolones and fluoroquinolones *(e.g. ciprofloxacine, levofloxacin,moxifloxacine, norfloxacin)*
Ampicillin, Cloxacillin	3rd generation cephalosporins - with or without beta-lactamase inhibitors *(e.g. cefixime, ceftriaxone, cefotaxime, ceftazidime)*
Phenoxymethylpenicillin	Macrolides *(e.g. azythromicin, clarithromycin, erythromycin)*
Benzathin penicillin, Benzyl penicillin	Glycopeptides *(e.g. teicoplanin, vancomycin)*
Procain penicillin	Antipseudomonal penicillins+beta lactamase inhibitors *(e.g. piperacillin-tazobactam)*
Amikacin, Gentamicin	Carbapenems *(e.g. meropenem, imipenem-cilastatin)*
Cefalexin, Cefazolin	Penems *(e.g. faropenem)*
Chloramphenicol	**RESERVE ANTIBIOTICS**
Clindamycin	Aztreonam
Doxycycline	4th generation cephalosporins *(e.g. cefepime)*
Metronidazole	5th generation cephalosporins *(e.g. ceftarolin)*
Nitrofuraintoin	Polymyxins *(e.g. polymyxin B,colistin)*
Spectinomycin	Fosfomycin (IV)
Sulphamethoxazole+trimethoprim	Oxazolidinones *(e.g. linezolid)*
Cefixime*	Tigecyclin
Cefotaxime*, Ceftriaxone*	daptomycin
Piperacillin tazobactam*	
Meropenem*	
Azithromycin* Clarithromycin*	
Ciprofloxacin*	
Vancomycin (oral)*, Vancomycin (parenteral)*	

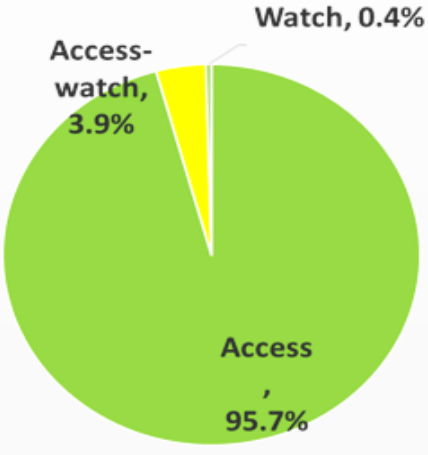
*antibiotics in both access and watch groups (*Access-Watch*)

The AWaRe classification can guide countries, facilities and prescribers in selection of antibiotics for EML and IML, guidelines development, prescription practices, design of stewardship interventions and surveillance of consumption. The graph below shows an analysis of quantities (in DDDs) of antibiotic issued by the National Medical Store for the year 2017 based on Aware and level of care: unsurprisingly, the higher the level of care, the higher the % of DDDs of WATCH antibiotics. Overall, most of the antibiotics used are of the ACCESS group (as they should be!).

Issues of antibiotics in DDDs from NMS to government facilities for the year 2017



The chart below shows the highest consumed antibiotics from NMS in the year 2017 by DDD. The most used antibiotic is cotrimoxazole, even though this most likely reflects its use for prophylaxis in HIV treatment than as treatment for common infections.



Antibiotic	AWaRe	% DDDs issued
Cotrimoxazole^	A	59.5%
Amoxicillin	A	22.2%
Metronidazole	A	8.4%
Doxycycline	A	5.1%
Ciprofloxacin	**AW**	3.1%
Azithromycin*	**AW**	0.4%
Ceftriaxone	**AW**	0.3%
Gentamycin	A	0.2%
Erythromycin	**W**	0.2%
Ampi-clox	A	0.1%
Cefuroxime	W	0.1%

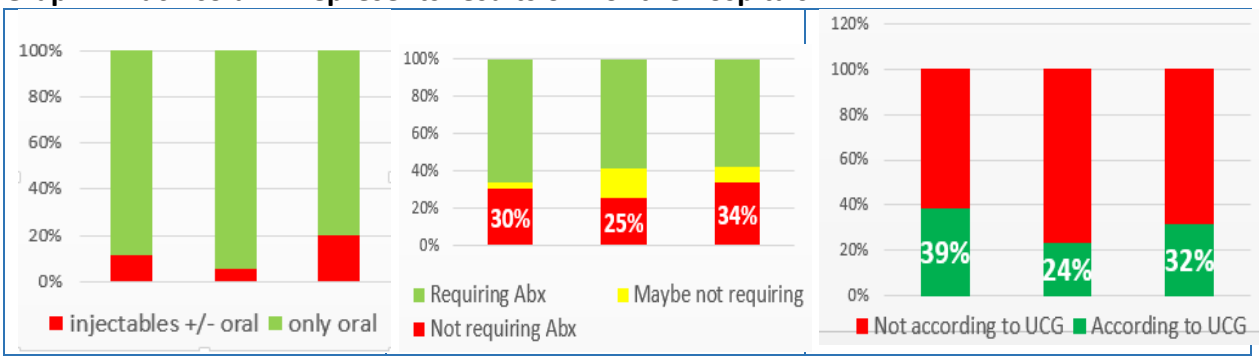
^ for HIV ***for trachoma program**

9.3.3 OPD antibiotic prescription survey

A significant amount of antibiotics are prescribed in outpatient departments. In fact, the analysis in the previous section, parenterals represented only 1% of the total DDDs issued from NMS. There is no standardized method for analysis of OPD prescribing practices, but significant information can be extracted from a sample of prescriptions and analyzed in a simple excel sheet. The sample already extracted for the Drug Indicator Survey can be used if the % of patients prescribed antibiotics is high, or a new sample can be selected using similar criteria. The number, route, type of antibiotics, type of diagnosis, need of antibiotics (based on a recorded diagnosis of infectious disease or not) and adherence to treatment guidelines can be analyzed. The data collection form is the same as for the Drug Indicator Survey (***see chapter 5***).

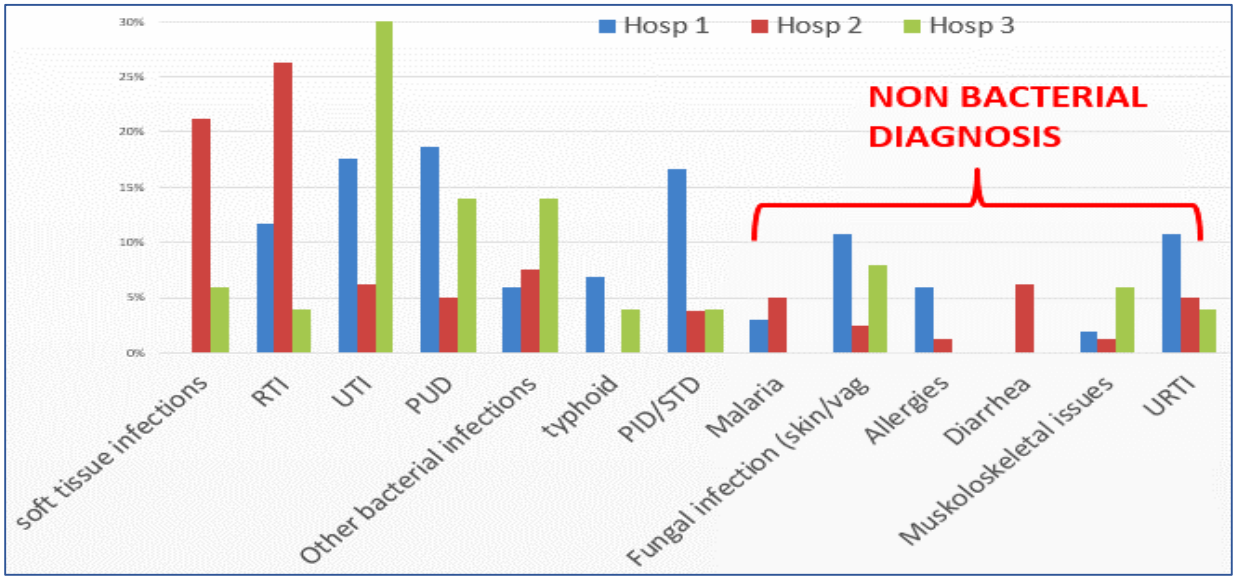
The results of OPD prescription surveys from 3 hospitals are presented in the following graphs.

Graph 1: Each column represents results of 1 of the hospitals.



In the first graph above, it is evident that less than half on treatments complied with standard guidelines, and between 25 and 34% of patients had diagnosis not requiring antibiotics.

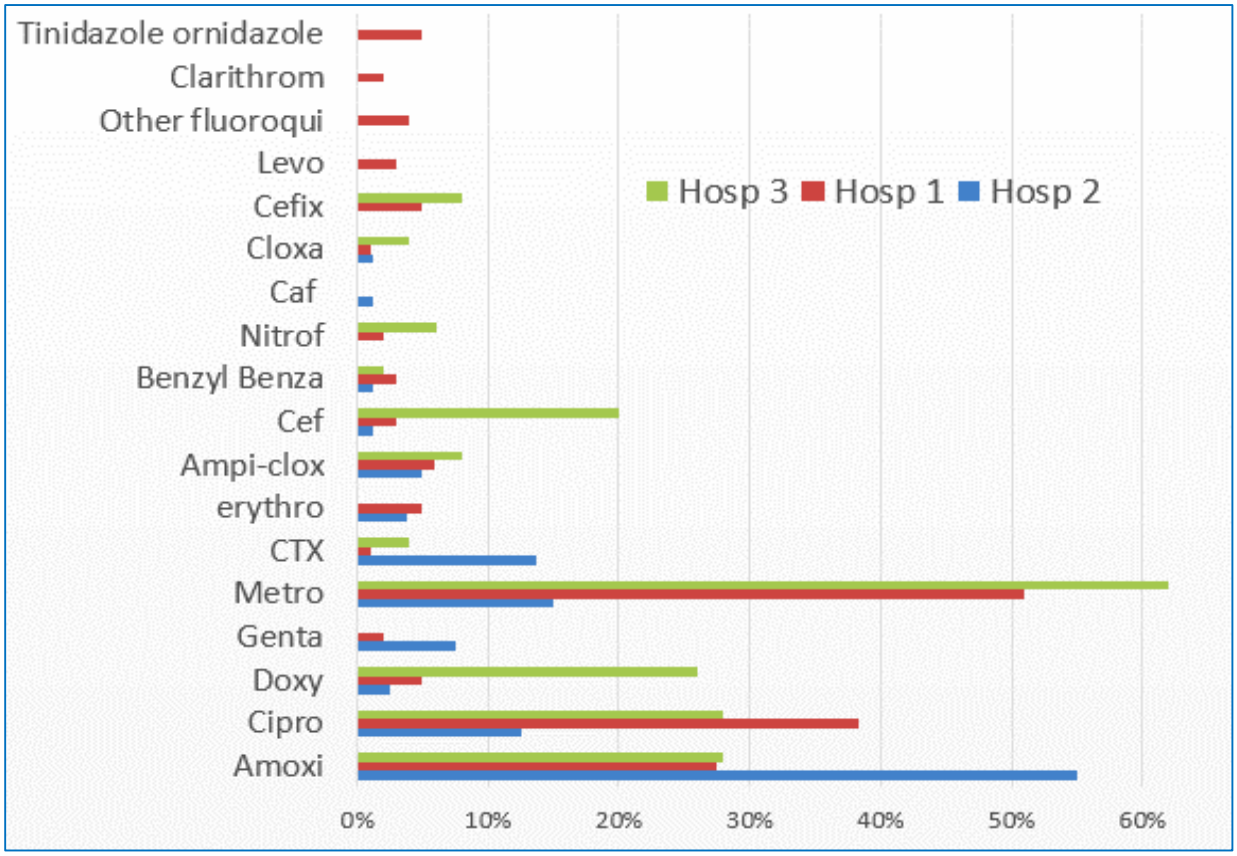
Graph 2: Types of diagnosis that were prescribed antibiotics



In graph 2 above, the analysis further shows that the type of diagnosis. Note the high numbers of diagnosis of PUD (peptic ulcer disease), UTI (urinary tract infections) and PID /STI (pelvic inflammatory disease, sexually transmitted infections) beside the expected RTI (respiratory tract infections). In addition, the diagnoses that were inappropriately prescribed antibiotics included (allergies, upper respiratory tract infections, musculoskeletal pains, fungal infections, malaria etc.).

The third graph below shows the antibiotics prescribed from survey. Note the high use of metronidazole, and a variable percentage of patients had injectable antibiotics.

Graph 3: Antibiotics that were prescribed



Further analyses

The most common diagnosis can also be analyzed in detail: the treatment of UTI in one of the hospitals is shown in the table below, and indicates a very poor adherence to guidelines, with many UTI treated with antibiotics for STIs, suggesting lack of diagnostic certainty. Further analysis could also include durations and doses. Possible courses of corrective action are discussed in the following sections.

DIAGNOSIS	SEX	TREATMENT
UTI	F	Cefixime-5days
UTI	F	CEFT-3days, Metro-5days
UTI	F	Ofloxacin + Ornidazole-5days
UTI	F	Cipro-5days, Metro-5days
UTI	F	Cipro-5days, Metro-5days
UTI/URTI	F	Nitrofurantoin-5days, Doxy, Metro-5days
UTI	M	Nitrofurantoin-5days
UTI	M	Cipro-5days
UTI	F	Metronidazole-5days, ciprofloxacin-5days
UTI	M	Amoxyl-5days
UTI	F	Cipro-5days, Metro-5days
UTI	M	CEF-STAT, Genta, Cipro-5days, Metro-5days
UTI/VVC (vulvo-vag candidiasis)	F	Ciprofloxacine-10days, Doxy-10days, Metro-5days
UTI	F	Metro-5days, Cipro-5days
UTI	F	Metro-5days, cipro-5days
UTI	F	Metro-5days, Cipro-5days

9.3.4 Point Prevalence Surveys (PPS)

Point prevalence surveys are used to assess use of antibiotics at hospital level: the parameters of interest are collected for all the patients admitted in a certain ward at a certain moment. Different standardized surveys have been developed:

- Global PPS of Consumption and Resistance (University of Antwerp, Biomeraux-fund)
- PPS of Health Care –Associated Infection and Antimicrobial Use (E CDC), and,
- British Society of Antimicrobial Chemotherapy (BSAC)
- WHO PPS (under development).

The general purpose of PPS is to provide a standardized assessment tool to be used by hospitals in inpatient departments to assess prescription practices, identify targets for quality improvement, and assess the effectiveness of Antimicrobial Stewardship interventions. The Global PPS also aimed to establish a global surveillance tool through voluntary internet-based reporting.

The PPS normally includes ***all patients present at 8 am in the morning in the ward under consideration and having received antibiotics in the previous 24 hours***. Parameters assessed are usually:

- Antimicrobial name (generic and branded)
- Route of administration (parenteral, oral, rectal),
- Indication of antimicrobial use (Community Acquired infection, Hospital Acquired Infection, Surgical prophylaxis, Medical prophylaxis)
- Diagnosis (if present in notes , and site and type of infection)
- Presence of a stop/review date
- Type of treatment: empiric vs targeted.

A simplified data collection tool modified from the on-line PPS training by BSAC is presented below. Links to more information and material are provided in the references.

Patient ID	Ward
Name of antimicrobial	Route
Unit dose	Number doses in the 24 hours
Is the reason for antimicrobial documented? (Yes or No)	Diagnosis (site of infection)
Indication • Community Acquired Infection • Hospital Acquired Infection • Surgical Prophylaxis • Medical Prophylaxis*	Complies with (local) guidance (Yes or No)
Is a stop or review date documented (Yes or No)	Number of prescribed doses documented as administered in the last 24 hours**

*Antimicrobials given to prevent infections, used in specific circumstances e.g. cotrimoxazole prophylaxis in HIV positive patients, penicillin prophylaxis in rheumatic heart disease.

** Added in consideration of the common gaps in administration and documentation in Uganda

9.3.5 Root cause analysis of antimicrobial misuse problems

As for all medicine use problems, effort has to be made to identify the drivers of the inappropriate use of antibiotics, in order to develop effective interventions. This often requires focus group discussions or interviews with various stakeholders, starting from the staff themselves. Patients should also be involved whenever possible: some prescribing practices are based on alleged patients' demands or expectations, but not always the clinicians have an accurate picture of what patients think. A very good example is the case of an outpatient department with extremely high rate of use of injectable antibiotics. A simple root cause analysis highlighted that one of major causes was: the **stock outs of oral antibiotics**!!

9.4 Stewardship interventions

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 section 3.1.3***).

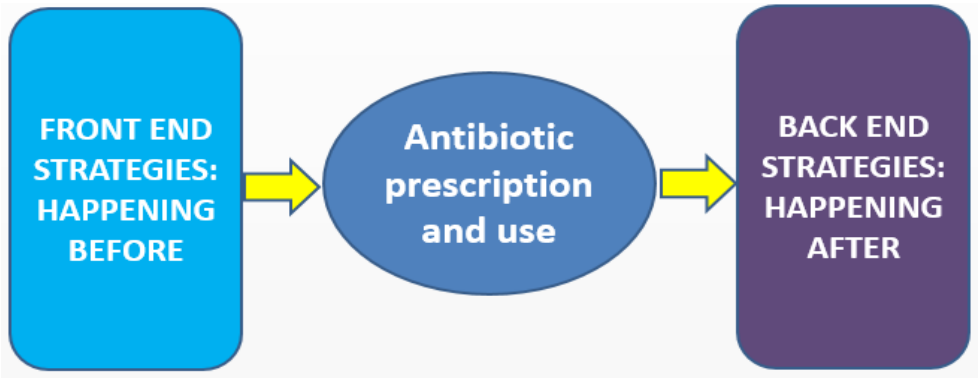
Target areas for stewardship interventions could include"

- 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 durationis 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 class": 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 already seen in **chapter 6,** 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 the illustration below:

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



Front End Strategies	Back End Strategies
- Formulary restriction - Prescription restriction (no OPD, only by specialist) - Pre-authorization - Clinical guidelines/protocols - 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 conversion - Post authorization program - Consultation with ID specialist/ microbiologist - Surveillance of consumptions - Review after laboratory results (targeted therapy) for de-escalation

A brief description of some core stewardship interventions is presented in the table below:

Intervention	Description
Formulary Restriction and Preauthorization	• 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 departments/prescribers, (***see Chapter 3***), can also be considered a simple and effective form of this strategy.
Prospective audit and feedback	• Prospective audit and feedback engages 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 are 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, 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 Center Call centers).

9.4.1 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.

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.

References

- 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
- WHO Antimicrobial Stewardship_ A competency-based approach: https://openwho.org/courses/AMR-competency *(brief and interesting videos with general topics and disease based guidelines)*
- Core Elements of Hospital Antibiotic Stewardship Programs CDC 2014
- Core Elements of Outpatient Antibiotic Stewardship CDC 2016
- E-book: Antimicrobial stewardship - from principles to practice. British Society for Antimicrobial Chemotherapy. *(e-book with cross-references with most of the available literature on AMS topics)* bsac.org.uk/antimicrobial-stewardship-from-principles-to-practice-e-book/
- 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)*