



Republic of Zambia



**GUIDELINES FOR THE MEDICINES AND
THERAPEUTICS COMMITTEE**



European Union





**GUIDELINES FOR
THE MEDICINES AND THERAPEUTICS
COMMITTEE (MTCs)**

2017



Medicines and Therapeutics Committee

The multiplicity of medicines available and the complexities surrounding their safe and effective use make it necessary for hospitals to have an organized, sound program for maximizing rational use of medicines. The Ministry of Health recognizes the Medicines and Therapeutics Committee as the organizational keystone of the program. The Medicines and Therapeutics Committee is an advisory group of medical staff and serves as the organizational line of communication between medical staff and pharmacy department. It is the policy-recommending body to the medical staff and the administration of the hospital on matters related to the therapeutic use of medicines.

1.0 Objectives of the Medicines and Therapeutic Committee

The MTCs will serve the following objectives

- ◆ Reduce cost of Medicine treatment at all levels of care.
- ◆ Increase efficacy and efficiency of Medicine treatment or management.
- ◆ Improve Medicine treatment in accordance with acceptable current practice within the limited available resources.
- ◆ Apply the principles of evidence-based clinical practice by providing a link between research and practitioners in health care facilities.
- ◆ Improve the quality of human resource by providing Medicine information.
- ◆ Rationalize the cost care.

2.0 Purposes

The primary purposes of the Medicines and Therapeutics Committee are as specified in the following:

Advisory.

The committee recommends the adoption of, or assists in the formulation of policies regarding evaluation, selection, and therapeutic use of medicines in the hospitals.

Educational.

The committee recommends or assists in the formulation of programs designed to meet the needs of the professional staff (physicians, nurses, pharmacists and other health-care practitioners) for complete current knowledge on matters related to medicines and medicine use.

3.0 Organization and Operation

While the composition and operation of the Medicines and Therapeutics Committee may vary from hospital to hospital, the following generally will apply:

- ◆ The Medicines and Therapeutics Committee should be composed of at least a medical officer, pharmacist, nurse and administrator and other health care practitioners.
- ◆ A chairperson appointed should be a medical officer. A pharmacist is designated as secretary of the committee. The committee should have broad representation but be sufficiently small and manageable to conduct business efficiently.
- ◆ The committee should meet regularly, at least 6 times a year and more often when necessary.
- ◆ The committee should invite to its meetings persons within or outside the hospital who can contribute specialized or unique knowledge, skills and judgement.
- ◆ An agenda and supplementary materials (including minutes of the previous meeting) should be prepared by the secretary and submitted to the committee members in sufficient time before the meeting for them to properly review the material.

- ◆ Minutes of the committee meetings should be prepared by the secretary and maintained in the permanent records of the hospital.

- ◆ Recommendations of the committee shall be presented to management.

- ◆ Liaison with other hospital committees concerned with medicines use (e.g. infection control, medical audit) shall be maintained

4.0 Functions and Scope

The basic organization of the hospital and medical staff will determine the functions and scope of the Medicines and Therapeutics Committee. The functions include:

- ◆ To service in an advisory capacity to the medical staff and hospital administration in all matters pertaining to the use of medicines.
- ◆ To develop a formulary of medicines accepted for use in the hospital and provide for its constant revision. The selection of items to be included in the formulary will be based on objective evaluation of their relative therapeutic merits, safety, and cost. The committee should minimize duplication of the same basic medicine type, medicine entity, or medicine product.
- ◆ To establish programmes and activities and procedures that help ensure cost-effective medicines therapy.
- ◆ To establish or plan suitable educational programmes for the hospital's professional staff on matters related to medicines use.
- ◆ To assist pharmacy department in the development and review of policies, rules, and regulations regarding the use of medicines in the hospital.
- ◆ To evaluate, approve, or reject medicines proposed for inclusion in or deletion from the hospital Formulary.

- ◆ To participate in quality assurance activities related to the distribution, administration and use of medications.
- ◆ To collect and review adverse drug reaction reports occurring in the hospital.
- ◆ To initiate or direct (or both) medicines use review programmes and studies and review the results of such activities.
- ◆ To advise pharmacy in the implementation of effective medicines distribution and control procedures.
- ◆ To make recommendations regarding medicines to be stocked in the hospital patient care areas.
- ◆ To develop and disseminate pertinent educational materials and programmes regarding medicines to members of staff at the hospital.
- ◆ MTCs are responsible for obtaining medicine use returns in order to compare usage rates between practitioners, facilities and regions. This information will be useful in budgeting as well as in mapping treatment patterns for various diseases. They should also monitor wastage and stock control audit report.
- ◆ Monitoring and Evaluation of practices (both prescribing and dispensing practices) medicine management process and compliance to treatment guidelines. This will help design strategies and interventions to improve selection and use.

4.1 Frequency of meetings

The number and frequency of meetings of this committee depend upon the size of the hospital and volume and variety of medicines used. The committee should meet at least once per quarter, and in busier hospitals at least monthly. Notices of the meeting date and accompanying agenda should be distributed by the secretary of the committee in ample time to allow for attendance and knowledgeable participation in the discussion of the agenda items.

4.2 The Committee's Agenda

A successful meeting depends upon preparation of an interesting agenda that is made available to the committee members reasonably far in advance of the scheduled meeting. Because of the broad scope enjoyed by this committee, many interesting subjects may, rightfully, be placed upon the agenda for discussion.

A typical agenda may consist of the following general categories:

- ◆ Minutes of the previous meetings.
- ◆ Review of the specified section of the Formulary for up-dating and deletion of products.
- ◆ New medicines that have become available e.g. change of protocols for ART.
- ◆ Review of adverse medicine reactions reported in the hospital since the last meeting
- ◆ Medicines safety in the hospital.

4.3 Policies of the Committee

In order to ensure that no misunderstanding exist amongst the membership and subsequently the medical staff, it is essential that the Committee establish policies under which it proposes to control use of medicines in the hospital. The policies should be comprehensive and reviewed regularly to ensure that they are current and relevant to practice.

Typical policy areas that need thoroughness include:

- ◆ Policy towards proposal of a new medicine for the hospital formulary; procedures for application and feedback.
- ◆ Antibiotic policy: restricting medicines into 1st line and 2nd treatments for antibiotics to achieve judicious use.
- ◆ Generic prescribing and dispensing.
- ◆ Rules and regulations governing pharmaceutical company representatives.
- ◆ In-patient and outpatient prescribing.
- ◆ Medication brought to hospital by patients.
- ◆ Automatic stop orders for medicines.
- ◆ Discharge prescriptions.

5.0 Criteria of Selection of Essential Medicines

- ◆ Epidemiology, i.e. Data to be obtained from monthly and annual returns from health centers and hospitals.
- ◆ Proven medicine efficacy. The efficacy of medicines should be internationally proven and in some cases it should be supported by data from local clinical trials where possible.
- ◆ Safety, this should be determined from international literature and where possible from local clinical trials.
- ◆ Cost effectiveness i.e. the least expensive but effective medicine treatment regimens are chosen over the more expensive ones. Ease of compliance to the dosage form and regimen should be a factor considered in the cost education.
- ◆ Pharmaceutical consideration (i.e. dose, route of administration, storage conditions). The more suitable dose regimens, appropriate routes of administration and easier to store medicines should be preferred - shelf life should be considered.

- ◆ Diagnostic capability: Medicine should be excluded from a list if its usage requires accurate diagnosis and the particular level of health care is not able to perform this either due to limited availability of expertise or lack of diagnostic tools.
- ◆ Availability of clinical management supporting equipment e.g. infusion pumps, nebulizers.

With these criteria the MTCs will produce their own Essential Medicines List for use in their health facilities at their level. The MTCs may also produce certain treatment guidelines to be followed in treating selected disease conditions that may be prevalent or problematic in their area.

6.0 Role of the MTCs in Promoting the Rational Use of Medicines

This role should be accomplished by doing the following activities:

- ◆ Collecting and disseminating medicine information: MTCs should be responsible for providing objective information to the practitioners they serve in their respective areas. They should publicize essential medicine lists and provide relevant information on these as required.
- ◆ Education and training: MTCs should organize continuing education activities and training in Medicine use and management in their respective areas.
- ◆ Prescribing and dispensing practices: Producing, guidelines, prescribing and dispensing practices in accordance with internationally acceptable standards.
- ◆ Conducting Medicine Use Research: MTCs should monitor document consumption rates, prescribing practices as well as dispensing practices and design interventions to improve them. They may also co-ordinate and carry out clinical trials to study new medicines. Clinical trials may be commissioned on older medicines to investigate bio-availability, sensitivity or other aspects. This should merge with research units and aim to increase capability to perform research.

- ◆ IEC (Information, Education and Communication) if necessary to the public or community should be developed and disseminate by MTCs.
- ◆ Recommending treatment regimens for particular areas in accordance with existing disease patterns.

7.0 Hospital Medicine Formulary Management

The hospital Medicine formulary is the cornerstone of medicines management in the hospital and it should be the principle concern of the Medicine and Therapeutic Committee.

- ◆ The formulary list should be limited to conserve resources- Remember it is usually not necessary to stock all medicines on the formulary
- ◆ Eliminate generic duplication- only one brand or label of generic medicine should be routinely stocked.
- ◆ Select medicines based on diseases and conditions treated at the facility.
- ◆ Specify medicines of choice for the formulary for common therapeutic indications. Medicines of choice should be selected by comparing efficacy, safety, toxicity, pharmacokinetics, bio-equivalence and pharmaceutical and therapeutic equivalence. Cost effectiveness should be a primary consideration by evaluating alternatives.

- ◆ Include 2nd line alternatives to Medicines of choice as needed, but minimize duplications.
- ◆ The hospital formulary should correspond with the national standard treatment guidelines that have been formally approved by the Ministry of Health.

8.0 Medicine Utilization Review

Medicine Utilization Review (MUR) is a tool to identify such common problems as inappropriate product selection, incorrect dosing, avoidable adverse medicine reactions, and errors in Medicine dispensing and administration. MUR may then be used to implement action plans for change. MUR is an ongoing, planned, systematic process for monitoring, evaluating and improving Medicine use and is an integral component of hospital efforts to ensure quality and cost- effectiveness in the use of medicines. More appropriate and more effective use of medicines ultimately results in improved patient care and more efficient use of resources.