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RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning, and in promoting the appropriate use of health commodities in the public and private sectors.

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Developed in Collaboration with the
World Health Organization
Geneva, Switzerland
### ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
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<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
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<tr>
<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
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<tr>
<td>EML</td>
<td>essential medicines list</td>
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<tr>
<td>INN</td>
<td>international nonproprietary name</td>
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<tr>
<td>NSAID</td>
<td>nonsteroidal anti-inflammatory drug</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>USD</td>
<td>U.S. dollar</td>
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<tr>
<td>VA</td>
<td>visual aid</td>
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<td>WHO</td>
<td>World Health Organization</td>
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SESSION 2. DEVELOPING AND MAINTAINING A FORMULARY

Purpose and Content

Session 2 provides information about the formulary system and how it functions within the Drug and Therapeutics Committee (DTC). There will be discussion about implementing and maintaining a formulary, a description of criteria for evaluating medicines for the formulary, and a review of pharmaceutical information resources.

As many as 50 percent of all medicines on the market today are either duplicative or of questionable value, so the health care system is forced to institute its own complex screening methods to provide the most efficacious, safe, and cost-effective medicines. The problem of an over-selection of medicines will only increase as more medicines are produced by manufacturers and distributors in search of greater profits.

Benefits arising from the appropriate selection of medicines are numerous and include improved drug therapy, decreased adverse drug reactions (ADRs), improved efficiency in procurement and inventory management, and decreased overall health care cost.

Objectives

After attending this session, participants will be able to—

- Define the formulary system concept
- Understand basic formulary management principles
- Describe the benefits of an effective formulary system
- Identify criteria used for selection of medicines
- Describe basic pharmaceutical information resources for evaluating medicines

Preparation and Materials

Read—

- Participants’ Guide
- Managing Drug Supply, Chapter 10, “Managing Drug Selection”
- Managing Drug Supply, Chapter 11, “Treatment Guidelines and Formulary Manuals”

Further Readings


**Key Definitions**

**Formulary**—A list of medicines approved for use in the health care system by authorized prescribers

**Formulary manual**—The document that describes medicines that are available for use in the hospital and clinics (provides information on indications, dosage, length of treatment, interactions, precautions, and contraindications)

**Formulary system**—The system of periodically evaluating and selecting medicines for the formulary, maintaining the formulary, and providing information in a suitable manual or list

**Introduction**

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence and evidence of efficacy, safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.¹

Formularies or essential medicines and formulary systems are the backbone of the DTC. The formulary provides many benefits in providing improved patient care at decreased cost through improved selection and rational medicine use. The formulary system also improves efficiency within the procurement and inventory management programs.

A comprehensive and active formulary system provides numerous benefits to hospitals and primary care clinics, including the following—

- Approved and efficacious medicines that all practitioners will be required to use.
  - Only the most effective and safest products will be available.
  - Available medicines will have been evaluated in a systematic manner.
  - Medicines will be chosen and approved to treat the disease states of the region or country.

Physicians will develop better experience with fewer medicines. Training will be easier because there will be fewer medicines on which to concentrate teaching activities.

- Drug therapy at a lower overall cost
  - Ineffective, high-cost medicines will not be available.
  - The most effective medicines will be available to treat common health problems, resulting in fewer visits, improved outcomes, and subsequently lower costs.
  - Inventory cost will be reduced.

- Consistent supply of medicines
  - Managing and regulating the number of medicines and improving the procurement and inventory management systems will lead to fewer medicines being ordered in larger quantities.
  - These actions will enhance price competition and economies of scale with regard to quality assurance, procurement, storage, distribution, and dispensing, and will subsequently lead to improved availability of medicines.
  - Less money will be wasted, making it possible to be more consistent in purchasing essential medicines and increasing availability.

The DTC and formulary system drive the entire health care system in the direction of improved patient outcomes at reduced costs. Every step in the formulary system will result in a more efficient system that will better utilize scarce health care resources.

**Formulary Management Principles**

The formulary is a periodically revised list of medicines that reflects the current judgment of the medical staff. The formulary system utilizes the medical and pharmacy staff to evaluate, appraise, and select from among the numerous available medicines those products that are the most efficacious, safest, of adequate quality, and available at a reasonable price. When completed, the formulary should conform to the following principles—

- Medicines should be selected based on the needs of the community; they should treat the locally identified diseases and conditions.
- Medicines selected for the formulary are “medicines of choice.”
• The formulary list should have a limited number of medicines, only those necessary to provide for the needs of the hospital or clinic; duplication of agents that have therapeutic equivalence should not occur.

• International nonproprietary names (INN) (i.e., generic names) should be used.

• Combination (fixed-dose) products should be used only in specific proven conditions (e.g., to treat tuberculosis).

• Medicines need to be selected based on explicit criteria that include proven efficacy, safety, quality, and cost.

• The formulary must be consistent with any national or regional formulary or approved standard treatment guidelines.

• Medicines should be restricted to appropriate practitioners.

Maintaining a Formulary System

The formulary maintenance process is dependent on two key components: (a) additions and deletions of medicines, and (b) therapeutic medicine class reviews. Additions and deletions should be handled following specific policies and procedures developed for the DTC. A transparent methodology must be developed for these important decisions concerning addition or deletion of a medicine. See the next section (“Process for Selecting New Medicines”) for recommended criteria for adding medicines to the formulary.

Routine medicine class reviews are important to maintain the formulary. The medicine class review involves the evaluation of a complete section of medicines (e.g., cephalosporin antibiotics). This review would evaluate current medicines on the formulary in a systematic manner so that the entire formulary is reviewed over a two- to three-year period. This task is difficult, but it will provide the necessary review and analysis of formulary medicines that is so important in a medical discipline that is changing rapidly. Any new medicines that would offer an advantage over the current selections would be evaluated and considered for the formulary. Medicines that are no longer used or lack sufficient evidence of efficacy, safety, and quality should be recommended for deletion. Medicines that no longer meet the criteria for being cost-effective should be evaluated and deleted when an acceptable alternative is identified.

To maintain the formulary, regularly scheduled meetings must be established and attended by committee members. Ideally, the committee would meet monthly or, at the very least, every four months. Longer meeting intervals will necessitate too many agenda items and make accomplishing the necessary activities difficult.

Each meeting should have an agenda, one that describes exactly what will be addressed during the meeting. Minutes are taken and reviewed at the next scheduled meeting.
Typically, an effective DTC will provide the following at each session—

- Action on newly requested medicines and deletions (in most cases the addition of a new medicine should lead to the deletion of a similar medicine on the formulary)
- Systematic review of therapeutic groups or classes by a competent physician or pharmacist
- Review of activities to identify and resolve medicine use problems

Without this review process, the formulary may become a collection of older medicines that may not reflect the most effective products available. It is the DTC’s responsibility to see that review is accomplished regularly.

**Process for Selecting New Medicines**

Selecting medicines for the formulary should follow carefully considered policies and procedures for determining the most useful medicines. These policies should be followed routinely and accurately each time an evaluation is needed.

1. A request for addition of a medicine to the formulary, which can be made only by a physician or pharmacist, is done by completing a “Request for Addition/Deletion” form. Information needed from the physician or pharmacist includes—

   - List of specific pharmacological actions of the medicine
   - Information on why the medicine is superior to current formulary medicines
   - Specific literature support for use
   - Background on any financial support received from the supplier or other organization

2. Medicine information resources are obtained, including primary literature, international newsletters, standard treatment guidelines, textbooks, and Internet sources. All sources of information must be credible and unbiased.

3. The evaluation is performed using established criteria (see “Selection Criteria for New Medicines” below).

4. The medication information monograph is written. The medication monograph should include details about the medicine obtained from several information sources. At a minimum, the monograph should include—

   - Pharmacology
   - Pharmacokinetics
   - Efficacy compared to placebo and other medicines
   - Clinical trial analysis
   - ADRs
• Medicine interactions
• Cost comparison
• Sources of supply (to ensure availability)

5. Formulary recommendations are developed. After a thorough research of the literature, the DTC should formulate recommendations concerning the medicines on evidence-based information. Recommendations should include dosage forms and strengths that will be purchased. If a specific manufacturer or supplier is necessary because of bioavailability problems, then this issue should be addressed in these recommendations. Specific guidelines for administration or use should also be placed in these formulary recommendations.

6. Expert opinions and recommendations should be obtained from knowledgeable and respected physicians and pharmacists. Opinions should only complement (not replace) the information provided in a medicine information search.

7. The DTC makes a formulary decision (at the DTC meeting). Information should be presented to the DTC at a regularly scheduled meeting. The DTC must vote on the recommendations as presented by the individual who performed the medicine evaluation.

8. The results of the evaluation and DTC’s recommendations and actions must be disseminated to the health care staff in the form of minutes or newsletters, or through department meetings.

**Selection Criteria for New Medicines**

Selecting medicines for the formulary is the most important function of the formulary system. The process, which is multifactorial, ultimately brings the best medicines to the health care system. The following represent major criteria to be considered when evaluating all new requests for addition to the formulary—

- Country disease patterns
- Efficacy, relative efficacy, effectiveness
- Safety
- Quality
- Cost and cost-effectiveness
- Medicines that are well known
- Health system personnel available to manage the medicine
- Financial resources available

**Disease Patterns**

The morbidity of the region needs to be assessed carefully before adding or deleting any medicines. Formulary medicines should be approved only after confirmation of actual need to treat the known diseases and medical conditions of the community. Standard treatment
guidelines must be reviewed to determine appropriate medicines for the medical conditions listed in the guideline.

**Efficacy**

Proven efficacy is one of the most important criteria in selecting new medicines for the formulary. The methods to accomplish a thorough evaluation of efficacy are presented in later sessions.

Information that accompanies a new medicine, including the package insert, pharmaceutical company literature, and advertisements, may not always provide unbiased information for evaluating the medicine in question. A comprehensive review of journal articles, especially of randomized controlled trials and from available meta-analyses, will provide the best unbiased information. Reviewing information from systematic reviews, e.g., the Cochrane Collaboration, international pharmaceutical information newsletters or bulletins, and current textbooks will provide the reviewer with additional supporting information concerning efficacy. Careful evaluation of all sources must be done to ensure that evidence of efficacy is supported by the literature and is unbiased and accurate.

**Safety**

Determining the safety of a medicine requires close attention to established information on the medicine as well as current postmarketing surveillance (provided by the manufacturer or drug regulatory agency) of the medicine’s safety record. Medicines with excellent safety records are necessary for the formulary but are not always possible to obtain. A careful risk-benefit assessment will be necessary for all medicines before they are added to the formulary.

The cost of treating ADRs is high, both in monetary terms and in lowered patient quality of care. Every effort must be made to evaluate a medicine’s safety record and its potential for adverse reactions. More information concerning safety will be presented in session 4, “Assessing and Managing Medicine Safety.”

**Quality**

The quality of a medicine that is requested for the formulary is important. Poor-quality medicines that are administered to patients may have adverse effects, including—

- Lack of therapeutic effect
- Toxic and adverse reactions
- Waste of financial resources
- Loss of credibility of the health care services

Before adding a medicine to the formulary, the DTC must determine if the following characteristics of quality can be assured by the health care system—

- Identity—Active ingredients are in the dosage form.
• Purity—The medicine contains no contaminants.

• Potency—The medicine has enough, but not too much, of the active ingredient.

• Uniformity of dosage form—The consistency, color, shape, and size of tablets, capsules, creams, and liquids do not vary from one dose to the next.

• Bioavailability—Bioavailability refers to the speed and completeness with which a medicine administered in a specific form enters the blood stream; different manufacturers of the same medicine may produce medicines with different bioavailabilities.

• Stability—A pharmaceutical product must retain its properties within specified limits to be useful.

The purpose of a quality assurance program for hospitals and clinics is to ensure that every medicine reaching a patient is safe, effective, and meets quality standards. A comprehensive quality assurance program includes both technical and managerial activities from selection to patient use. Many areas within a health care system may be involved with quality assurance, including procurement, pharmacy, medical, and nursing departments, as well as the DTC.

Ensuring quality of a product is twofold—

- **Obtaining** quality products that are safe and effective through structured selection and procurement methods

- **Maintaining** quality products through the appropriate storage, distribution, monitoring, and prescribing methods

A comprehensive medicine quality assurance program requires procurement, pharmacy, and warehousing departments and the DTC to ensure the following—

- Suppliers with acceptable quality standards are selected.

- Minimum quality standards are met or exceeded and appropriate testing of the end product is performed.

- Repackaging of supplies maintains quality.

- Storage and transportation conditions are adequate.

- Product quality concerns reported by prescribers, dispensers, and consumers are documented, investigated, and resolved.

More information on medicine quality will be presented in session 5, “Pharmaceutical Quality Assurance.”
Cost and Cost-Effectiveness

The cost of a medicine in relation to its benefits is an important consideration with any new product. A medicine with questionable efficacy or benefits at a high cost would have an unfavorable cost-effectiveness ratio. A new antihypertensive medicine with good comparative efficacy, decreased incidence of ADRs, and a lower overall cost than current medicines on the formulary, however, would represent a medicine with excellent cost-effectiveness relationship. This medicine would therefore have a favorable status for being added to the formulary. When a new medicine with equal efficacy and possibly fewer adverse side effects at a higher cost is requested, however, the decision becomes more complicated. More information on determining the cost of pharmaceuticals is presented in session 6, “Evaluating the Cost of Pharmaceuticals.”

Medicines That Are Well Known

Ideally, medicines that are selected for the formulary are ones that are well known, have been on the market for years, and have clinical experience to support their pharmacological profiles. This ideal is not attainable for all medicines added to the formulary, but it should be one of the basic parameters to consider when adding a medicine.

Availability of Appropriate Personnel

Having available health care personnel who have the experience, training, and credentials necessary to use these medicines is important. Any medicine, no matter how effective and safe, must be measured against the personnel who will actually be using it. For example, certain antiretroviral medicines should be limited to facilities where trained physicians are available to prescribe and monitor them. A system of layered prescribing authority is useful when the health care system has practitioners with different levels of experience and qualifications. Use of vancomycin, for example, should be restricted only to senior physicians and not allowed for mid-level providers; antineoplastic medicines should be limited to facilities that have oncology expertise.

Availability of Financial Resources

The health care system must have at its disposal a sufficient amount of money to actually purchase and maintain the medicine for an indefinite amount of time. A thorough cost analysis is therefore necessary before the medicine is actually accepted for the formulary. If the resources are not available for the consistent procurement of a new medicine, then it should not be accepted. Intermittent purchase of a medicine that the system cannot afford only serves to foster poor medical services with little or no continuity of care. For example, the addition of a new and expensive calcium channel blocking agent for hypertension should be questioned if financial resources are not available to consistently procure the medicine. Intermittent stocking of such a medicine would lead to poor continuity of care.
Nonformulary Medicines

Most formulary systems are designed as “open” systems. The open system allows for the introduction of nonformulary medicines on a limited basis, usually for a single patient use. A “closed” system reflects the DTC’s choice to exclude all nonformulary medicines from being available in any form.

Nonformulary medicines are usually necessary, in limited amounts, for patients who require specialized treatments or patients who have been stabilized on medicines from practitioners outside of the health care system.

Control of nonformulary medicines is important because an open system will invariably become problematic and impede the system of formulary management. Numerous nonformulary medicines will be costly, and because they may not have received the complete evaluation process, they may be less than effective or unsafe. Management of nonformulary medicines includes—

- Limiting the number of nonformulary medicines
- Limiting access to appropriate prescribers
- Keeping a register of all requests for nonformulary medicines
- Reviewing frequently and discussing at DTC meetings

Policies and procedures on how these medicines will be purchased are necessary, and close follow-up of all nonformulary medicines by the DTC is warranted to limit their use.

Restricted Medicines

Restricted medicines include those products that fill a particular need by a specialty within the health system. These medicines need to be defined by the DTC to limit their use. Some examples of restricted medicines and their applicability include—

- Certain antibiotics for infectious diseases (e.g., ceftriaxone)
- Antipsychotic medicines for use by mental health professionals (e.g., use of risperidone can be restricted to psychiatrists)
- Antineoplastic products for use by physicians with specialized knowledge of these medicines

The use of restricted medicines requires close monitoring and evaluation. Monitoring of restricted medicines should include determining that appropriate patients are receiving the medicines and that authorized medical staff are prescribing and providing follow-up for patients on these medications.
International Nonproprietary Pharmaceutical Names

The use of international nonproprietary names (INNs, i.e., generic names) is encouraged for all listings in the formulary, evaluation monographs, and all other communications about medicines. The INN is the medicine’s official name, regardless of who manufactures or markets it.

Formulary systems that use the generic name system will find that it makes for a more efficient system and causes less confusion about the actual products listed. Instead of dealing with 10 to 20 (or even more) trade names for each pharmaceutical entity, there will be only one. This system will also enhance any therapeutic or generic substitution programs that may exist.

Information Resources for Evaluating New Medicines

Adequate resources to obtain information and to evaluate the efficacy, safety, quality, and cost of a medicine are essential. This section provides basic information concerning well-known medicine information sources.

Medical information sources include three categories: primary, secondary, and tertiary resources.

- **Primary resources**
  - Includes journal articles and unpublished studies that may be obtained from journals and services that provide the entire article
  - *Advantage*: represents the most complete information about a subject because all the data discussed in the article are available to the reader
  - *Disadvantage*: the reader must have skills to evaluate the article and the amount of time necessary to actually read and analyze it

- **Secondary resources**
  - Includes indexing and abstracting services that provide abbreviated reviews of articles; usually published in newsletters, CD-ROM databases, and online services
  - *Advantage*: readily accessible and easy-to-read information
  - *Disadvantage*: long period between publication and the republication in the newsletter or abstracting service

- **Tertiary resources**
  - Include published textbooks, which can be an excellent source of information if reputable and current sources are used
Advantage: readily accessible information and short time in reading and assimilating the information

Disadvantages: the lack of access to the original information sources, bias introduced by the writers of the text, and outdated information provided because of long delays in publishing a text

Representative journals and texts are listed below. There are others, but these are generally considered to be representative of excellent resources. Some journals such as New England Journal of Medicine (NEJM) and Journal of the American Medical Association (JAMA) have a policy that original research articles are available to the public at no cost six months after publication.

- Primary resources
  - British Medical Journal (BMJ)
  - Lancet
  - NEJM (JAMA)
  - Annals of Internal Medicine
  - American Journal of Health-System Pharmacy (AJHP)

- Secondary resources
  - Medical Letter
  - Australian Prescriber
  - Journal Watch
  - MEDLINE/PUBMED abstracts
  - Cochrane Library abstracts and evaluations
  - International Pharmaceutical Abstracts
  - International Society of Drug Bulletins

- Tertiary resources
  - Martindale: The Extra Pharmacopoeia
  - British National Formulary
  - United States Pharmacopeia Dispensing Information (USP DI) Drug Information for the Health Care Professional
  - American Hospital Formulary Service (AHFS)

- Internet resources
  - WHO—www.who.int
  - U.S. Centers for Disease Control and Prevention—www.cdc.gov
  - U.S. National Institutes of Health—www.nih.gov
  - U.S. Food and Drug Administration—www.fda.gov
  - Cochrane Collaboration—www.cochrane.org
  - Agency for Healthcare Research and Quality—www.ahrq.gov
  - Others—a complete list will be provided during the training course
Ideally, the hospital will have access to some kind of pharmaceutical information service to handle requests concerning the addition of new medicines to the formulary. If not, a pharmacist or a physician can provide the necessary evaluations given the time and at least some of the resources listed above. Pharmacists will find that, by using as many of the resources as possible, they will be able to provide the review in a comprehensive manner.

Using information from pharmaceutical companies requires the reader to exercise some caution. These companies may provide somewhat biased information. Many articles and documents may appear to provide usable information, but frequently the information presented is positive about the company’s product.

Participants should note the phenomenal changes that are occurring in the pharmaceutical information resources on the Internet. Although this communication method may not be available to pharmacists or physicians in many parts of the world, it is something to establish if at all possible. The information sources on the Internet are virtually endless. The quality of medicine evaluation reports can improve and, with experience, the speed of providing an evaluation will also improve. The Internet can also provide very poor information, so it must be used with caution.

**Formulary Manual**

The formulary manual is the publication that brings all of the data concerning the formulary together in a manual or pamphlet. There is no set standard on how this document is arranged or what it includes, but ideally it contains both alphabetically and therapeutically arranged lists of the formulary medicines and a section on medicine usage that includes doses, contraindications, side effects, medicine interactions, and price. The manual should include a section on the medicines of choice and alternatives for treating the medical conditions of the region.

This manual is not intended to be a book that is kept on the shelf. It should be pocket-sized to allow practitioners to carry it with them at all times. The design of the manual requires that it be easy to use with appropriate indexing to facilitate location of necessary information.

The following items should be available in a comprehensive formulary manual. The DTC would have to evaluate these items and include only the most appropriate in its formulary manual.

Basic information—

- Formulary list or essential medicines list—both alphabetical and therapeutic category lists
- Brief information about each medicine (i.e., a medicine monograph)
  - Generic name
  - Dosage and strengths
  - Indications
  - Contraindications
• Precautions
• Side effects
• Dosage schedule
• Instructions and warnings
• Medicine, food, lab interactions

Miscellaneous information—

• Supplementary information for medicines
  o Price
  o Regulatory category
  o Storage guidelines
  o Patient counseling information
  o Labeling information
  o Brand names and synonyms

• Prescribing and dispensing guidelines
  o Rational prescribing techniques
  o Principles of prescription writing
  o Guidelines on quantities to be dispensed
  o Control medicine requirements
  o ADR reporting requirements
  o Dispensing guidelines
  o List of precautionary labels
  o Medicine interaction tables

• Treatment protocols
  o IV medicine administration guidelines
  o Medicines used in pregnancy and lactation
  o Medicines used in renal failure
  o Poison guidelines
  o Prescribing for the elderly

• Other components
  o Metric tables
  o ADR form
  o Product quality report form
  o Formulary request form
  o Nonformulary request forms
  o Abbreviations
  o Indexes—A comprehensive index of all items in the formulary manual is essential. Because of the complexity of this document, an index will facilitate use by practitioners and ultimately improve efficiency within the health care system.

Formulary manuals require a meticulous approach to developing and publishing the document. Like a standard treatment guideline, a formulary manual requires buy-in from opinion leaders,
administration, senior medical staff, and local professional associations. Manuals must be prepared carefully using only evidenced-based information; they must be written by experts and reviewed frequently to maintain up-to-date information.

Activity 1. Adding a New Antimicrobial to the Formulary

Your DTC is considering a new antibiotic for the formulary. This antibiotic, which we’ll call cefapime, is very similar to a formulary product, cefotaxime, a third-generation cephalosporin. It would be used in the emergency room as a single dose for treating febrile children with the diagnosis of acute respiratory infection or otitis media. This medicine is an injectable at a high cost of 2.50 U.S. dollars (USD) per dose. Although expensive, cefapime is required (according to the requesting physician) because of a high incidence of antimicrobial resistance (AMR) in the hospital to commonly used medicines. The physician also states that use of the medicine will decrease overall cost because hospitalizations of these sick children will be decreased with appropriate use. Mid-level providers who staff the emergency room at night would be the primary prescribers of this medicine. This medicine is heavily promoted by a pharmaceutical manufacturer for treating many different pediatric infections. Other medicines for these problems that are available on the formulary include amoxicillin, co-trimoxazole, and cefalexin. Typically the DTC has provided very little evaluation of a new medicine because a physician’s recommendation was enough for approval by the committee.

Consider the following questions—

- What criteria are necessary to evaluate this medicine for addition to the formulary?
- Using the principles of formulary management discussed in this session, what major concerns do you have before adding this medicine to the formulary?
- What drug information resources would be used to analyze this medicine for the DTC? Which source would be the most useful?

Activity 2. Analyze the Quality of a Formulary—the Case of NSAIDs

Below is a list of nonsteroidal anti-inflammatory drugs (NSAIDS) from the formulary of a large private hospital in East Africa. Ask the participants to use the principles of formulary management learned in this session to answer the following questions about this category of medicines (possible answers are in italics below the list)—

- Do you think the listed medicines appear logical and well chosen?
- How many chemical entities are available on the formulary?
- How many NSAID medicines are necessary for a formulary?
- What medicines would you recommend be added or deleted?
What is the best method to list medicines in a formulary? Is this list easy to read and understand?

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<th>No.</th>
<th>NSAID</th>
<th>Quantity Sold (over 6 months)</th>
<th>Unit Cost (USD)</th>
<th>Total Cost (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LYSINE ACETYLSALICYLIC ACID 500 mg</td>
<td>2,026</td>
<td>0.357</td>
<td>723.54</td>
</tr>
<tr>
<td>2</td>
<td>ASPEGIC (lysine acetylsalicylic acid) 1,000 sachet ADULT</td>
<td>27</td>
<td>0.264</td>
<td>7.14</td>
</tr>
<tr>
<td>3</td>
<td>ASPEGIC 250 mg sachet INFANT (lysine acetylsalicylic acid)</td>
<td>40</td>
<td>0.126</td>
<td>5.05</td>
</tr>
<tr>
<td>4</td>
<td>ASPEGIC sachets (lysine acetylsalicylic acid) 100 mg</td>
<td>51</td>
<td>0.109</td>
<td>5.56</td>
</tr>
<tr>
<td>5</td>
<td>ASPIRIN tablets 500 mg</td>
<td>237</td>
<td>0.004</td>
<td>0.90</td>
</tr>
<tr>
<td>6</td>
<td>ASPIRIN tablets 100 mg (1)</td>
<td>1,877</td>
<td>0.002</td>
<td>2.84</td>
</tr>
<tr>
<td>7</td>
<td>ASPIRIN tablets 300 mg (1)</td>
<td>1,190</td>
<td>0.002</td>
<td>2.44</td>
</tr>
<tr>
<td>8</td>
<td>ASPIRIN tablets 80 mg</td>
<td>3,145</td>
<td>0.002</td>
<td>4.86</td>
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<tr>
<td>9</td>
<td>DICLOFENAC 100 mg SR</td>
<td>8,475</td>
<td>0.016</td>
<td>135.88</td>
</tr>
<tr>
<td>10</td>
<td>DICLOFENAC ampule ADCO 75 mg/3 ml (1)</td>
<td>7,797</td>
<td>0.061</td>
<td>477.61</td>
</tr>
<tr>
<td>11</td>
<td>DICLOFENAC gel</td>
<td>188</td>
<td>0.380</td>
<td>71.46</td>
</tr>
<tr>
<td>12</td>
<td>DICLOFENAC ointment 30 g</td>
<td>5</td>
<td>0.364</td>
<td>1.82</td>
</tr>
<tr>
<td>13</td>
<td>DICLOFENAC suppositories 100 mg</td>
<td>22,186</td>
<td>0.077</td>
<td>1,707.56</td>
</tr>
<tr>
<td>14</td>
<td>DICLOFENAC tablet 50 mg</td>
<td>23,835</td>
<td>0.006</td>
<td>133.71</td>
</tr>
<tr>
<td>15</td>
<td>IBUPROFEN syrup 100 mg/5 ml (60 ml)</td>
<td>3,080</td>
<td>0.498</td>
<td>1,533.65</td>
</tr>
<tr>
<td>16</td>
<td>IBUPROFEN tablet 200 mg (1)</td>
<td>85,197</td>
<td>0.004</td>
<td>320.16</td>
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<tr>
<td>17</td>
<td>INDOMED capsules 25 mg (1)</td>
<td>4,199</td>
<td>0.003</td>
<td>11.45</td>
</tr>
<tr>
<td>18</td>
<td>KETOPROFEN 150 mg (1)</td>
<td>128</td>
<td>0.427</td>
<td>54.69</td>
</tr>
<tr>
<td>19</td>
<td>MEFENAMIC ACID 500 mg</td>
<td>2,328</td>
<td>0.198</td>
<td>460.84</td>
</tr>
<tr>
<td>20</td>
<td>MEFENAMIC capsules 250 mg</td>
<td>37</td>
<td>0.044</td>
<td>1.61</td>
</tr>
<tr>
<td>21</td>
<td>NAPROXEN tablets 250 mg</td>
<td>252</td>
<td>0.340</td>
<td>85.63</td>
</tr>
<tr>
<td>22</td>
<td>NAPROXEN POMMADE (niflumic acid)</td>
<td>634</td>
<td>3.091</td>
<td>1,959.73</td>
</tr>
<tr>
<td>23</td>
<td>NIFLURIL (niflumic acid) capsules 250 mg (1)</td>
<td>1,537</td>
<td>0.119</td>
<td>182.52</td>
</tr>
<tr>
<td>24</td>
<td>NIFLURIL cream topical (niflumic acid)</td>
<td>649</td>
<td>2.186</td>
<td>1,419.02</td>
</tr>
<tr>
<td>25</td>
<td>NIFLURIL suppositories 700 mg (ADULT) (niflumic acid)</td>
<td>1,319</td>
<td>0.305</td>
<td>402.08</td>
</tr>
<tr>
<td>26</td>
<td>NIFLURIL suppositories (INFANT) (niflumic acid) 400 mg</td>
<td>314</td>
<td>0.258</td>
<td>81.13</td>
</tr>
<tr>
<td>27</td>
<td>NIFLURIL suppositories (INFANT) (niflumic acid) 400 mg</td>
<td>314</td>
<td>0.258</td>
<td>81.13</td>
</tr>
<tr>
<td>28</td>
<td>NIMESULIDE tablets 100 mg</td>
<td>22,260</td>
<td>0.038</td>
<td>848.67</td>
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<tr>
<td>29</td>
<td>PIROXICAM 20 mg</td>
<td>643</td>
<td>0.021</td>
<td>13.37</td>
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</tbody>
</table>
Summary

The formulary system adds an important component to the DTC and the health care system. A system of evaluating and selecting the most appropriate medicines for the formulary will bring numerous benefits. These include rational use of medicines, improved health care outcomes, improved efficiency in the procurement and inventory management systems, regular supply of essential medicines, and a significant decrease in overall health care cost.

Listed below are some key guidelines to remember to start a formulary system or maintain one for years to come—

- Write detailed policies and procedures concerning the functions of the formulary system.
- Follow formulary management principles to obtain the best medicines at a favorable cost.
  - Medicines should be selected based on the needs of the community; they should treat the diseases and conditions that have been identified locally.
  - Medicines selected for the formulary are “medicines of choice.”
  - The formulary list should have a limited number of medicines, only those necessary to provide for the needs of the hospital or clinic; duplication of agents that have therapeutic equivalence should not occur.
  - Use INN (i.e., generic names).
  - Use combination (fixed-dose) products only in specific proven conditions (e.g., to treat tuberculosis).
  - Medicines need to be selected based on explicit criteria that include proven efficacy, safety, quality, and cost.
  - The formulary must be consistent with any national or regional formulary or approved standard treatment guidelines.
- Review the formulary in a systematic manner to ensure it is current.
- Keep the number of nonformulary medicines to a minimum.
- Restrict medicines to appropriate practitioners.
- Maintain reliable resources (human, financial, references) for the evaluation of medicines.
• Keep the formulary process ethically correct—the DTC and especially the formulary system must tolerate no influence or pressure from pharmaceutical manufacturers or suppliers concerning any product that is considered for addition to or deletion from the formulary.

• Enlist support of key policy makers and influential health professionals to advocate for the DTC and the formulary system