



# Guidelines for Developing and Maintaining a Formulary

By EDSP in Collaboration  
with DFID and WHO







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(Final Draft)

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*Emergency Drugs Supply Project of TheNetwork for Consumer Protection in Pakistan  
for  
Government of NWFP & Balochistan*

EDSP is committed towards strengthening of the drug management system in Pakistan.

First Published 30th December 2002.

1st Revision After Six months

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*Enquiries concerning printing should be sent to TheNetwork for Consumer Protection in Pakistan.*

Printed in Pakistan by  
Agha Jee Printers

Published by



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# Preface

Medicines save lives, alleviate discomfort and improve health. Despite all the benefits that they provide us, a lot of harm can be done by medicines that are of questionable value or when prescribed with negligence. A sound healthcare system requires effective screening methods to provide the clients the most cost-effective and cost-efficient drugs. Implementation of a proper formulary system and development of formulary manuals and lists is an empirical step towards this end.

This document aims to provide information on the process of development of a formulary. Important definitions concerned with development of a formulary, along with the step by step process of formulary development is explained. This document also introduces the concept of Formulary and Therapeutics Committees, which ideally should have the responsibility of developing and maintaining a formulary system in their respective districts. At the end of the document, exercises are made available for further reinforcing the information provided.

It is expected that this manual will prove to be a helpful tool that can be used by managers to upgrade drugs management in their respective settings.

# Foreword

The drug management in health sector of our country leaves much to be desired. It was realized by a group of motivated individuals that this issue needs to be addressed actively. In order to collect information on various dimensions of drug use and management, a baseline survey was carried out by EDSP, with cooperation from the Governments of Baluchistan and NWFP. Three areas, namely prescribing, storage and dispensing practices were identified as key areas that need to be improved and for which standard guidelines or operating procedures have to be developed. For this purpose, brain storming sessions were conducted and responsibilities were delegated inside and outside EDSP to collect available national and international literature on these aspects of drug management.

After collection of relevant literature, workshops to review these documents were conducted, which led to the development of initial drafts. Further workshops were conducted in which the existing drafts were thrashed out word-by-word to make these documents more practical and relevant to our country's conditions. These revised drafts were sent to different stakeholders for their expert comments. In the light of these comments, final drafts were prepared. After some minor modifications, the documents took their current final shape that is to be used in training workshops for technical personnel involved in storage, dispensing and formulary development. This document shall be revised after six months and improvements will be made, taking into consideration the experiences gained in the upcoming training workshops.

The following resources were consulted during the process:

- ◆ **Managing Drug Supply: The Selection, Procurement, Distribution And Use Of Pharmaceuticals**  
Second Edition, revised and expanded. Published 1997
- ◆ **E - drug**  
E-DRUG is the English version of SATELLIFE's electronic discussion groups on essential drugs. E-DRUG is used by health care professionals, researchers and policy makers to obtain and discuss current information on essential drugs, policy, program activities, education and training. Members also use E-DRUG to announce and learn of upcoming conferences or courses in their field.  
([www.essentialdrugs.org/edrug](http://www.essentialdrugs.org/edrug))
- ◆ **British National Formulary (BNF 44)**  
Published September 2002 by the British Medical Association and the Royal Pharmaceutical Society of Great Britain.
- ◆ **WHO model formulary 2002**  
Publisher: WHO, Published: November 1, 2002.  
The WHO Model Formulary presents formulary information of over 300 medicines included on the WHO Model List of Essential drugs, as a reference for national and institutional drugs and therapeutic communities.
- ◆ **Armed Forces Technical Instructions**  
This is a document that outlines the medical procedures' protocols for the armed forces of Pakistan
- ◆ **MSH**  
Management Sciences for Health (MSH) is a private, nonprofit educational and scientific organization working to close the gap between what is known about public health problems and what is done to solve them.  
([www.msh.org](http://www.msh.org))
- ◆ **Medical Journals(BMJ, JAMA, Lancet, NEJM,AJHP)**
- ◆ **Cochrane database**  
[www.cochrane.org](http://www.cochrane.org)
- ◆ **US Pharmacopoeia and the National Formulary (USP 26 - NF 21)**  
Book and Supplements Edition (November, 2002)  
(One main edition and two Supplements)  
USP-NF provides clear and concise standards of identity, strength, quality, and purity as well as packaging, storage, and labeling for drugs, dietary supplements, and other healthcare products.
- ◆ **American Hospital Formulary**  
A Drug Information Reference from the American Society of Health-System Pharmacists. Published: 2000, Edition: 01.
- ◆ **WHO website**  
[www.who.int](http://www.who.int)
- ◆ **NIH US**  
[www.nih.org](http://www.nih.org)

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# Acknowledgements

The document has been written with an overall view to improve the quality of care in our health systems. The preparation owes a great deal to many individuals and organizations.

The funding of the project was provided by Department for International Development (DFID) U.K Department of Health N.W.F.P and Balochistan were extremely helpful in facilitating the whole process. WHO also was closely involved throughout the process of SOP development and provided their technical input.

A number of seminars, workshops, meetings, discussions and opinion sharing sessions were conducted during the three months period. We would particularly like to express our gratitude to the Federal Minister of Health Dr Abdul Malik Kasi, Minister of Health NWFP Dr Meher Taj Roghani and Minister for Health Balochistan Mr Agha Abdul Zahir for their patronage during the whole exercise. Secretary Health Balochistan Mohammad Arshad Bhatti, Director General Health Dr Pir Jan Khawjakhail, Director Public Health Dr Mohammad Sharif Lodhi deserve a special thanks for their whole hearted support. Secretary Health NWFP Mr Arshad Mirza, Additional Secretary Health NWFP Muhammad Ishfaq Khan, and Director General Health, Brig Dr Habib-ur-Rehman were extremely helpful with their comments and feedback. We are also grateful to Country Representative WHO Dr Khalif Bile Mohamud and his team for taking keen interest in the development of SOPs. Ms Elizabeth Smith and Dr Inayat Thaver from DFID were always available for our help whenever needed. I would like to acknowledge with gratitude the role of the whole EDSP team in Islamabad, NWFP and Balochistan, without their hardwork and dedication this Herculean endeavor would not have been possible. A special mention of guidance & efforts of Dr Zafar Mirza Executive Coordinator of TheNetwork for Consumer Protection, Mr Ayyaz Kiani Deputy Executive Coordinator of TheNetwork and Mr. Khalid Saeed Director Pharmacy Services Children's Hospital Lahore, is pertinent here who were always accessible, willing to contribute and their input indeed made a difference.

We acknowledge every effort however small it may have been, towards the achievement of our ultimate goal, which is improvement in quality of health care for our people. The list attached is a re-collection of the names which took part in the process of developing of this SOP but there would be many more that may not have been included here. However, each and every endeavor is thankfully recognized by EDSP.

Dr Assad Hafeez  
Project Director  
Emergency Drugs Supply Project - NWFP & Balochistan



## Purpose

This manual provides information about the formulary system and how it functions within the Pharmacy and Therapeutics Committee (P&TC). There will be discussion about implementing and maintaining a formulary, criteria for evaluation of drugs for the formulary, and a review of drug information resources.

As many as 70 percent of all drugs on the market today are either duplicative or of questionable value. This forces the health care system to institute its own complex screening methods to provide the most effective and cost efficient drugs. This ample selection of drugs will only increase, as more drugs are produced by manufacturers and distributors in search of greater profits.

Benefits arising from the appropriate selection of drugs are numerous and well known and include improved drug therapy, decreased adverse drug reactions, improved efficiency in procurement/inventory management, and decreased overall health care cost.

## Objectives

Upon completion of this session, participants will be able to-

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

## Preparation

### Read:

- ◆ Participant's Guide
- ◆ *Managing Drug Supply*, Chapter 10, "Managing Drug Selection"
- ◆ *Managing Drug Supply*, Chapter 11, "Treatment Guidelines and Formulary Manuals"

### Further Readings:

American Society of Health System Pharmacists. *ASHP Guidelines on Formulary System Management*. ASHP 1997-98. ([www.ashp.org](http://www.ashp.org))

Management Sciences for Health. *Manual for the Development and Maintenance of Hospital Drug Formularies*. Russia Rational Pharmaceutical Management Project. 1996.

## Introduction

Formularies and formulary systems are the backbone of the Pharmacy and Therapeutics Committee. The formulary provides many benefits in providing improved patient care at decreased cost through improved selection and rational drug use. The formulary system also improves efficiency with-

in the procurement and inventory management programs. A comprehensive and active formulary system provides numerous benefits to hospitals and primary care clinics-

- ◆ Approved and efficacious drugs that all practitioners will be required to use:
  - Only the most effective and safe products will be available.
  - Available drugs will have been evaluated in a systematic manner.
  - Drugs will be chosen and approved to treat the disease states of the country.
  - Physicians will develop better experience with fewer drugs. Training will be easier as there will be fewer drugs on which to concentrate teaching activities.
  
- ◆ Drug therapy at a lower overall cost:
  - Ineffective high-cost drugs will not be available.
  - The most effective drug 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 drugs:
  - Managing and regulating the number of drugs and improving the procurement and inventory management systems will result in the ordering of fewer drugs 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 drugs.
  
  - Less money will be wasted, making it possible to be more consistent in purchasing essential drugs and increasing availability.

The P&TC and formulary system drive the entire health care system in the direction of improved cost-efficient care and patient outcomes. Every step in the formulary system will result in a more efficient system that will better utilize scarce health care resources.

## Key definitions

**Formulary List** Drugs approved for use in the health care system by authorized prescribers and it is restrictive.

**Formulary Manual** The document that describes drugs that are available for use in the. Health care setting (provides information on indications, dosage, length of treatment, interactions, precautions, contraindications, etc.)

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

## Formulary management principles

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

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

## Maintaining a formulary

The formulary maintenance process is dependent on two key components, additions/deletions of drugs and therapeutic drug class reviews. Additions and deletions should be handled following specific policies and procedures developed for the P&TC. A transparent methodology must be developed for these important decisions concerning addition or deletion of a drug. See the next section for recommended criteria for adding drugs to the formulary. (Evaluating drugs for formulary)

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

In order to maintain the formulary, regularly scheduled meetings must be established and attended by committee members. Ideally, the committee

would meet, at least once every four months. Longer meeting intervals will necessitate too many agenda items and make it very difficult to accomplish the necessary activities.

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 agenda will be prepared by secretary of committee (pharmacist).

Typically, an effective committee will provide the following at each session:

- ◆ Action on newly requested drugs and deletions (Addition of a new drug should lead to the deletion of a similar drug on the formulary in most cases.)
- ◆ Systematic review of therapeutic groups/classes by a competent physicians and pharmacists
- ◆ Review of programs to identify and resolve drug use problems

Without this review process, the formulary may become a collection of older drugs that may not reflect the most effective products available. It is the P&TC's responsibility to see that review is accomplished on a regular basis.

## Process for selection of a new drug

Selection of drugs for the formulary should follow carefully considered Policies and procedures for determining the most useful drugs. These policies should be followed routinely and accurately each time an evaluation is needed. The following process is recommended for selection of new drugs:

1. A request for addition or deletion of a drug to the formulary, which can be made only by a physician or pharmacist, is made through completion of a Request for Addition/Deletion form. Information needed from the physician or pharmacist includes-
  - ◆ List of specific pharmacological actions of the drug
  - ◆ Information on why the drug is superior to current formulary drugs
  - ◆ Specific literature support for use
  - ◆ Background on any financial support received from the supplier or other organization
2. Obtain drug information resources. These should include primary literature, international newsletters, standard treatment guidelines, textbooks, and Internet sources. All sources of information must be credible and unbiased.
3. Perform the evaluation using established criteria.
4. Write the drug information monograph. The drug monograph should include details about the drug obtained from several information sources. At a minimum, the monograph should include-:
  - Pharmacology

- Pharmacokinetic
  - Efficacy compared to placebo and other drugs Clinical trial analysis
  - Adverse drug reactions
  - Drug interactions
  - Cost comparison
  - Sources of supply (to ensure availability)
5. Develop formulary recommendations. After a thorough research of the literature, the P&TC should formulate recommendations concerning the drugs on the evidence-based drug information. Recommendations should include dosage forms and strengths that will be purchased. If a specific manufacturer or supplier is necessary because of bio-availability problems, then this should be addressed in these recommendations. Specific guidelines for administration or use should also - be placed in these formulary recommendations.
  6. Obtain expert opinions and recommendations. These should be obtained from knowledgeable and respected physicians and pharmacists. Opinions should complement the information provided in a drug information search. (P&TC)
  7. Make a formulary decision (at the P&TC meeting). Information should be presented to the P&TC at a regularly scheduled meeting. The P&TC must vote on the recommendations as presented by the individual who performed the drug evaluation.
  8. Disseminate the results of the evaluation and P&TC's recommendations. Results of the P&TC actions and recommendations must be disseminated to the health care staff in the form of meeting minutes, newsletters, or department meetings.

## Criteria for selection of drugs

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

- ◆ Disease patterns of the country, area, province
- ◆ Efficacy, relative efficacy, effectiveness
- ◆ Safety
- ◆ Quality
- ◆ Cost
- ◆ Drugs that are well known
- ◆ Health system personnel and equipment available to manage the drug
- ◆ Financial resources available

## Disease Patterns

The morbidity of the region needs to be assessed carefully before adding or deleting any drugs. Formulary drugs 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 drugs for the medical conditions listed in the guideline.

## Efficacy

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

Information that accompanies a new drug, including the package insert, drug company literature, and advertisements, may not always provide unbiased information for evaluating the drug in question. A comprehensive review of journal articles, especially randomized controlled trials, will provide the best unbiased information. Reviewing information in texts and international newsletters 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 drug requires close attention to established information on the drug as well as current post marketing surveillance (provided by the manufacturer or drug regulatory agency) of the drug's safety record. Drugs with excellent safety records are necessary for the formulary, but are not always possible to obtain. A careful assessment of risk-benefit will be necessary for all drugs before they are added to the formulary.

The cost of treating adverse drug reactions is very high, both in monetary terms and in lowered patient quality of care. Every effort must be made to evaluate a drug's safety record and its potential for adverse reactions.

## Quality

The quality of a drug that is requested for the formulary is very important. Poor-quality drugs 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 drug to the formulary it is necessary to 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 drug contains no contaminants.
- ◆ Potency- The drug 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.
- ◆ Bio-availability- Bio-availability refers to the speed and completeness with which a drug administered in a specific form enters the blood stream; different manufacturers of the same drug may have different bio-availability.
- ◆ Stability- A drug product must retain its properties within specified limits in order to be useful.

The purpose of a quality assurance program for hospitals and clinics is to ensure that every drug 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 P&TC.

Ensuring quality of a product is twofold:

1. *Obtaining* quality products that are safe and effective through structured selection and procurement methods
2. *Maintaining* quality products through the appropriate storage, distribution., monitoring, and prescribing methods

A comprehensive drug quality assurance program requires procurement, pharmacy, warehousing departments, and the P&TC 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.

## Cost

The cost of a drug in relation to its benefits is a very important consideration with any new drug. A drug with questionable benefits at a high cost would have an unfavorable cost-benefit ratio. However, a new antihypertensive drug with good comparative efficacy, decreased incidence of adverse drug reactions, and a lower overall cost than current drugs on the formulary would represent an excellent cost-benefit relationship. This drug would therefore have a favorable status for being added to the formulary.

However, when a new drug with equal efficacy and possibly fewer adverse side effects at a higher cost is requested, the decision becomes more com-

plicated.

## Drugs That Are Well Known

Ideally, drugs 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 is not possible for all drugs added to the formulary, but it should be one of the basic parameters to consider when adding a drug.

## Availability of Appropriate Personnel

It is important to have available health care personnel who have the experience, training, and credentials necessary to utilize these drugs. Any drug, no matter how effective and safe, must be measured against the personnel who will actually be using the drug. A system of layered prescribing authority is useful when the health care system has practitioners with different levels of experience and qualifications.

## Availability of Financial Resources

The health care system must have at its disposal a sufficient amount of money to actually purchase and maintain the drug for an indefinite amount of time. A thorough cost analysis is therefore necessary before the drug is actually accepted for the formulary. If the resources are not available for the consistent procurement of a new drug, then it should not be accepted. "Intermittent purchase of a drug that the system cannot afford only serves to foster poor medical services with little or no continuity of care.

## Non formulary drugs

Most formulary systems are designed as an "open" system. The open system allows for the introduction of non formulary drugs on a limited basis, usually for a single patient use. A closed system reflects the P&TC's choice to exclude all non-formulary drugs from being available in any form.

Non-formulary drugs are necessary, in limited amounts, for patients who require specialized treatments or patients who have been stabilized on drugs from practitioners outside of the health care system.

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

- ◆ Limiting the number of non-formulary drugs
- ◆ Limiting access to appropriate prescribers
- ◆ Reviewing frequently

Policies and procedures on how these drugs will be purchased are necessary and close follow-up of all non-formulary drugs by the P&TC is war-

ranted in order to limit their use.

## Restricted drug use

Restricted drugs include those products that fill a particular need by a specialty within the health system. These drugs need to be defined by the P&TC in order to limit their use. Some examples of restricted drugs and their applicability include-

- ◆ Certain antibiotics for infectious diseases
- ◆ Antipsychotic drugs for use by mental health professionals
- ◆ Antineoplastic products for use by physicians with specialized knowledge of these drugs

The use of restricted drugs requires that there be close monitoring and evaluation of these drugs. Monitoring of restricted drugs should include determining that appropriate patients are receiving the drugs and that authorized medical staff is prescribing and providing follow-up for patients on these medications.

## International nonproprietary drug names

The use of international nonproprietary drug names (generic names) is encouraged for all listings in the formulary, evaluation monographs, and all other communications about drugs. This international nonproprietary name is the drug's official name, regardless of who manufactures or markets it.

Formulary systems that utilize 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 more trade names for each drug entity, there will be only one. The system will also enhance any therapeutic or generic substitution programs that may exist.

## Information resources for evaluating

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

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

- ◆ Primary literature
  - Includes journal articles and unpublished studies that may be obtained from journals and services that provide the entire article.
  - Represents the most complete information about a subject because all the data discussed in the article are available to the reader
  - Disadvantages include that the reader must have skills to evaluate the article and the amount of time necessary to actually read and analyze

- ◆ Secondary literature
  - Includes indexing and abstracting services that provide abbreviated reviews of articles
  - Usually published in newsletters, CD-ROM databases, and online services
  - Advantages include readily accessible and easy-to-read information
  - Disadvantage is the long time period between publication and the republication in the newsletter or abstracting service
- ◆ Tertiary sources
  - Include published textbooks, which can be an excellent source of information if reputable and current sources are used.
  - Advantages include readily accessible information and short time in reading and assimilating the information
  - Disadvantages include 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.

- ◆ Primary resources
  - *British Medical Journal*
  - *Lancet*
  - *New England Journal of Medicine*
  - *Journal of the American Medical Association*
  - *Annals of Internal Medicine*
  - *American Journal of Health-System Pharmacy (AJHP)*
- ◆ Secondary resources
  - *Medical Letter*
  - *Australian Prescriber*
  - *Journal-Watch*
  - MEDLINE and EMBASE abstracts
  - Cochrane Library abstracts and evaluations
  - International Pharmaceutical Abstracts
- ◆ Tertiary resources
  - *Martindale: The Extra Pharmacopoeia*
  - *British National Formulary*
  - *United States Pharmacopoeia Dispensing Information (USP DI) Drug Information for the Health Care Professional*
  - *American Hospital Formulary Service (AHFS)*
  - *Facts and Comparison*
- ◆ Internet resources
  - MEDLINE-www.nlm.nih.gov
  - World Health Organization (WHO)-www.who.int
  - Centers for Disease Control and Prevention (CDC)-www.cdc.gov

- National Institutes of Health (NIH)-[www.nih.gov](http://www.nih.gov)
- Food and Drug Administration (FDA)-[www.fda.gov](http://www.fda.gov)
- Cochrane Collaboration-[www.cochrane.org](http://www.cochrane.org)
- Agency for Healthcare Research and Quality (AHRQ)-  
[www.aq.gov](http://www.aq.gov)

Ideally, the hospital health facility will have a drug information center to handle requests concerning adding drugs 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 less than unbiased information and this must be screened before use. Many articles and documents may appear to provide usable information, but frequently the information presented has a particular bias for the company's product.

It is worth taking note of the phenomenal changes that are occurring in the drug information resources on the Internet. Although this communication method may not be available to pharmacists or physicians in many parts of the country, it is something to establish if at all possible. The information sources on the Internet are virtually endless. The quality of drug 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.

The following are the stages for formulary development

# Stage I. Administrative

## Step 1. Introduce the Concept and Obtain Support

The desire to implement a formulary system may arise from either operation- or administration-level personnel.

Regardless of where this desire arises, successful implementation requires support from both the medical staff and administrators. To obtain necessary support, vital background information is needed, such as:

- ◆ yearly drug budget
- ◆ drug budget as a percent of hospital budget
- ◆ total number of drug products routinely used
- ◆ the value of expired drugs during the last year
- ◆ names of the top ten drugs arranged by value
- ◆ incidence of adverse drug reactions
- ◆ number of deaths attributable to drug misadventures
- ◆ a list of drugs used in the facility that are banned in the country of manufacture
- ◆ examples of drug duplication

This information should be used in meetings and presentations tailored to the targeted professionals. Administrators will be more interested in how formulary systems can reduce the hospital drug budget, while clinical information will be of more interest to physicians. Regardless of the audience, presentations should result in familiarization with the benefits of formulary systems, and with the scope of work ahead.

A mandate in a government health plan facilitates formulary system implementation. An appropriate audience for gaining such support includes health administrators at central and local governments, senior prescribers, healthcare providers, and local government authorities.

At the facility level, physicians must accept the need for restricting drug use, and be willing to change prescribing habits. Those responsible for drug procurement must agree to buy only drugs on the formulary list.

After the hospital administration decides to implement a formulary system the decision should be properly documented and incorporated as hospital policy.

## Step 2. Establish a Pharmacy and Therapeutics Committee

The main objectives of the Pharmacy and Therapeutics Committee are the development and implementation of professional policies on drug selection, evaluation, procurement, safe use, and drug information in a given health facility. The committee also assists in the formulation of education programs designed to meet the needs of the professional staff for current and complete knowledge of matters related to drugs and drug practices.

Specific functions of the committee include:

- ◆ to develop the criteria for evaluating drugs for inclusion on the hospital formulary
- ◆ to serve in an advisory capacity to the medical staff and administration in all matters pertaining to drug use
- ◆ to aid in providing optimal drug therapy to all patients through the development of standard treatment guidelines
- ◆ to objectively evaluate clinical data regarding new drugs proposed for use in the health facility
- ◆ to prevent unnecessary duplication of drugs
- ◆ to develop the list of drugs accepted for procurement and use in the hospital
- ◆ to recommend and approve additions and deletions from the formulary
- ◆ to establish and plan suitable educational programs for professional staff on pertinent matters relating to drugs and their use
- ◆ to review reported adverse reactions to drugs administered
- ◆ to conduct ongoing drug use evaluation programs
- ◆ to design and develop a drug formulary manual and other drug information activities, such as newsletters

The decision to launch a Pharmacy and Therapeutics Committee is made by the administrative head of the facility (MS) who, together with the first deputy, appoints members of the Committee. Normally, the Pharmacy and Therapeutics Committee is composed of seven to eleven voting members (odd number):

- ◆ The Chair - Administrative head of the facility
- ◆ The Secretary - pharmacist
- ◆ Heads of main clinical hospital departments/specialists
- ◆ Head of the nursing services

When specific drugs are being considered, the committee may invite other specialists to participate in meetings as needed. These ad hoc members do not have voting privileges. Decisions on inclusion or deletion of drugs are made by consensus or if required by majority voting.

In order to eliminate bias in drug selection, committee members may not have any business relationships with pharmaceutical distributors or manufacturers.

All the health care providers should have regular CME in clinical pharmacology for effective implementation of the formulary system.

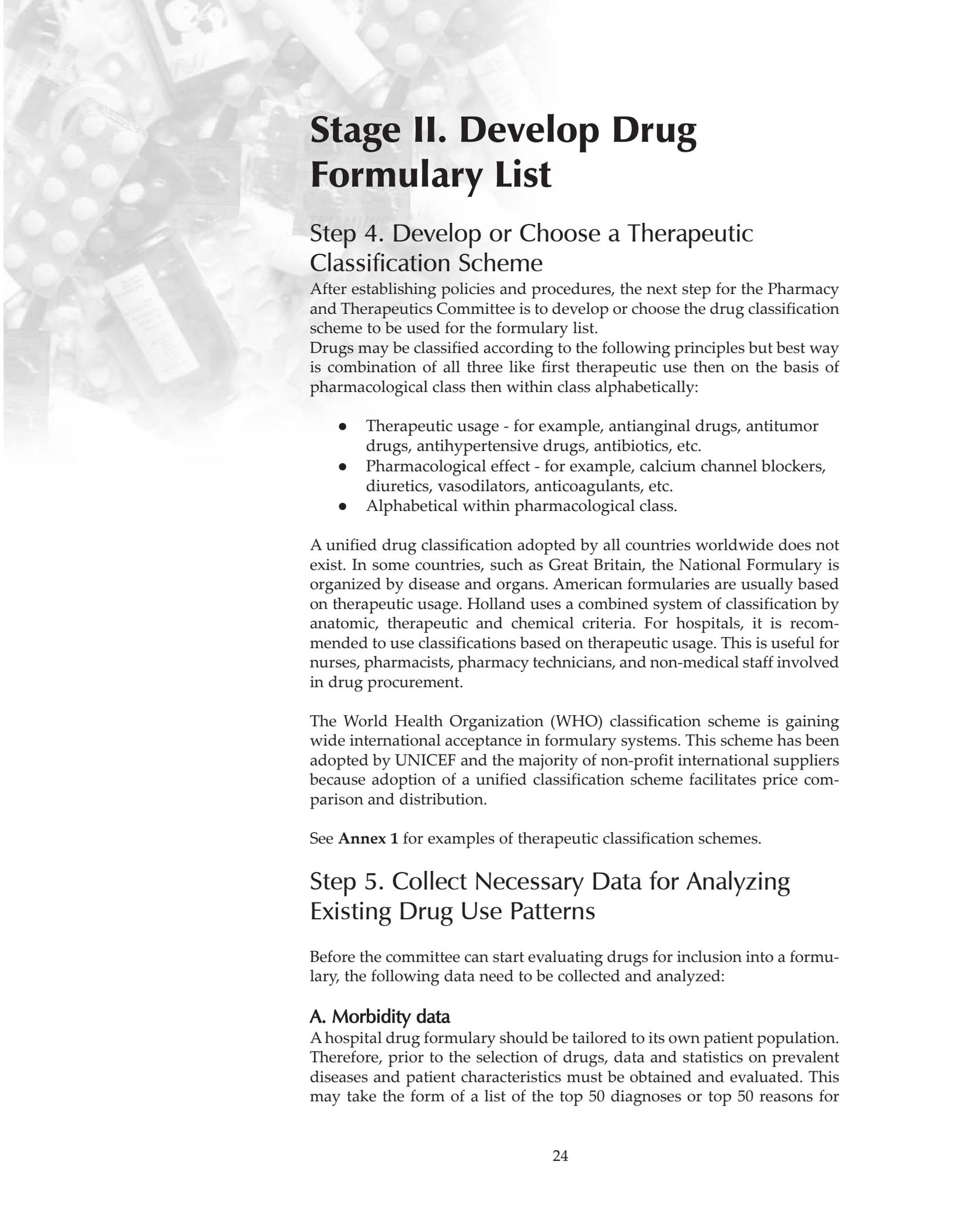
### Step 3. Develop Policies and Procedures

Developing policies and procedures is imperative to the work ahead. These should be approved by the Chief Physician or Chief Administrator in the organization, so that the Pharmacy and Therapeutics Committee is empowered to make and implement decisions, and request compliance from the medical staff. Additionally, the policies and procedures serve as a tool to create organization, structure and planning of workload. The poli-

cies and procedures should cover the following areas:

- ◆ Criteria of formulary drug selection
- ◆ Additions to and deletions from the formulary
- ◆ Prescribing requirements
- ◆ Non-formulary drug use
- ◆ Adverse drug reaction monitoring
- ◆ Drug usage evaluation
- ◆ Investigational drug use
- ◆ Sales representatives' guidelines
- ◆ Rules governing the Pharmacy and Therapeutics Committee

Examples of hospital Pharmacy and Therapeutics Committee policies are given in Annex 1.



# Stage II. Develop Drug Formulary List

## Step 4. Develop or Choose a Therapeutic Classification Scheme

After establishing policies and procedures, the next step for the Pharmacy and Therapeutics Committee is to develop or choose the drug classification scheme to be used for the formulary list.

Drugs may be classified according to the following principles but best way is combination of all three like first therapeutic use then on the basis of pharmacological class then within class alphabetically:

- Therapeutic usage - for example, antianginal drugs, antitumor drugs, antihypertensive drugs, antibiotics, etc.
- Pharmacological effect - for example, calcium channel blockers, diuretics, vasodilators, anticoagulants, etc.
- Alphabetical within pharmacological class.

A unified drug classification adopted by all countries worldwide does not exist. In some countries, such as Great Britain, the National Formulary is organized by disease and organs. American formularies are usually based on therapeutic usage. Holland uses a combined system of classification by anatomic, therapeutic and chemical criteria. For hospitals, it is recommended to use classifications based on therapeutic usage. This is useful for nurses, pharmacists, pharmacy technicians, and non-medical staff involved in drug procurement.

The World Health Organization (WHO) classification scheme is gaining wide international acceptance in formulary systems. This scheme has been adopted by UNICEF and the majority of non-profit international suppliers because adoption of a unified classification scheme facilitates price comparison and distribution.

See **Annex 1** for examples of therapeutic classification schemes.

## Step 5. Collect Necessary Data for Analyzing Existing Drug Use Patterns

Before the committee can start evaluating drugs for inclusion into a formulary, the following data need to be collected and analyzed:

### A. Morbidity data

A hospital drug formulary should be tailored to its own patient population. Therefore, prior to the selection of drugs, data and statistics on prevalent diseases and patient characteristics must be obtained and evaluated. This may take the form of a list of the top 50 diagnoses or top 50 reasons for

admission. This list of diagnoses or reasons for admissions needs to be compiled from admission data for an adequate time frame, e.g., one year. The exact information available will depend on statistics kept by the hospital.

### **B. Drug information available**

The Pharmacy / Formulary and Therapeutics Committee (P&TC) cannot properly select drugs for inclusion into the formulary without reliable and unbiased information. The use of drugs of questionable efficacy can be prevented or reduced by providing unbiased drug information.

Typical examples of biased drug information are drug company brochures, the *Physician's Desk Reference*, and Vidal. Unbiased drug information reference materials are based on studies and clinical trials from different sources, not with the intent to promote a product but to provide the users of the product with relevant data. Examples include *The United States Pharmacopeia Drug Information for Health Professionals*, and *The American Hospital Formulary Service Handbook*.) ([www.ashp.org](http://www.ashp.org))

Hospitals implementing formulary systems must, therefore, evaluate currently available references. If necessary, one or more of the above mentioned unbiased sources of drug information should be obtained from National Drug Information Centre.

### **C. List of all drugs purchased and used by the health facility during the last year**

The pharmacy or drug procurement department should provide the Pharmacy / Formulary and Therapeutics Committee with a list of all drugs that have been purchased during the last fiscal year, calendar year, or previous 12 months. Data from one year is desirable because of seasonal variations in drug use, but a shorter time period can be used if necessary. For the analysis that follows, the following information is needed: drug name, strength, dosage form, cost to facility, and quantity used over a given time period.

## **Step 6. Analyze Morbidity and Drug Utilization Patterns**

### **Analyze morbidity data**

This is a necessary step for the committee to understand if the therapeutic needs of patients are being met, and whether drugs are purchased and used rationally. Accurate morbidity data is required to perform the analyses.

1. Rank order the morbidity data obtained in the previous step (ideally, the top 50 diagnoses) by the number of cases for each disease or condition. This information will be valuable when deciding which group of drugs should be analyzed first.
2. Calculate the percent that each of the top 50 diseases represents in the

overall morbidity. Disregard diseases that typically do not require drug therapy. For example, myopia may constitute around 20% of patient visits for nervous and sensory disorders in outpatient settings, but usually requires only a simple eye exam and fitting for eyeglasses.

3. Using the information on drug purchases, choose the drugs (and their costs) that were used to treat the top 50 diseases, and calculate the percent of their value (by disease) to the overall health facility drug budget.
4. Compare the lists compiled in steps 2 and 3 above to get an idea if drug use appears to be rational according to the morbidity in the facility. For example, the morbidity data at a hospital may indicate that infectious and parasitic diseases accounted for 8.0% of outpatient, and 5.4% of inpatient visits, while only 3.14% of purchased drugs (by value) were appropriate therapy for these conditions. Similarly, while "psychological disorders" represented 7.5% of outpatient, and 6.5% of inpatient visits at this hospital, no antipsychotic or antidepressant drugs were among the top drugs purchased (by value), despite the fact that these drugs tend to be expensive. Priority should be given to the drugs based on disease pattern in specific reason.

These figures suggest that infectious/parasitic diseases and psychological disorders may have been under-treated using pharmacotherapy at this hospital.

Once areas of concern with treatment of disease groups have been identified, it is necessary to identify the specific drugs that represent the greatest portion of the drug budget. This is done through ABC and VEN analyses.

### **Conduct ABC and VEN analyses**

ABC analysis is a method by which drugs are divided according to their annual usage (unit cost times annual consumption), into Class A items (10 - 20% of the items, which account for 70-80% of the funds spent), Class B items (with intermediate usage rates) and Class C items (the vast majority of items with low individual usage, the total of which accounts for less than 25% of the funds spent). ABC analysis can be used to give priority to Class A items in making drug selection and procurement decisions.

VEN analysis is a system of setting priorities for drug selection and purchasing in which drugs are classified according to their health impact: Vital, Essential and Non-essential drugs:

**Vital drugs:** Drugs that are potentially life-saving (vaccines), or which have significant withdrawal side-effects such that a regular supply is mandatory (e.g., propranolol, steroids)

**Essential drugs:** Drugs that are effective against less severe, but nevertheless significant forms of illness

**Non-essential drugs:** Drugs for minor or self-limited illnesses, drugs that

are of questionable efficacy, and drugs that have a high cost for a marginal therapeutic advantage

**Using both systems** provides the Pharmacy / Formulary and Therapeutics Committee with important data that will facilitate decision making on which drugs can be eliminated from use, which drugs need to be incorporated into the formulary, and which drugs are being over- or under-utilized.

If desired, a more detailed classification can be done.

For example, rather than Vital, Essential or Non-essential designations, the following may be used:

**Ethiothrope Therapy** - therapy directed at elimination of disease cause

**Pathogenic Therapy** - therapy directed at elimination or suppression of disease development mechanisms

**Symptomatic Therapy** - therapy directed at elimination or decrease of certain disease manifestations

**Replacement Therapy** - is held with the insufficiency of natural biologically active substances

**Preventive Therapy** - is held for disease prevention

## Step 7. Conduct Drug Class Reviews and Create a Draft Formulary List

This step is the most important one in the formulary development process because it is here that the list of drugs to be used in the hospital is created. The drug class review will have impacts that are both therapeutic and economic in nature. Therapeutic aspects include the improvement of patient care through discontinuation of use of drug products that are less safe and/or efficacious. In addition, the results from this step will have an impact on the cost of therapy, and can provide the basis for economic improvements for the hospital budget.

It is, therefore, important to carefully plan and carryout drug class reviews, and to allow adequate time to conduct them thoroughly. A committee at a large hospital may need to review thousands of drugs, and can expect the process to take up to one year.

At this step in the process, the committee must decide how the formulary list will be developed, by choosing one of these options:

- A. The selection process may begin with the assumption that all drugs currently in use in the hospital constitute the hospital formulary list. During the course of the review process, drugs are deleted, and in some cases, new drugs are added. This is the most commonly chosen approach.
- B. The formulary may be developed one drug class at a time during the review process. After reviewing the first class of drugs, the formulary contains only the drugs selected for that class. Restricted procurement and prescribing may be immediately implemented only for those drugs. As other classes are reviewed, drugs are added to the formula-

ry.

The information obtained in the ABC/VEN analysis can be used to develop a schedule for drug reviews. For example, if the analysis shows that 30% of the drug budget is used for procurement of antibiotics, the committee may decide to start with this class of drugs. Drug classes that have been known to be problematic in the past should also be given high priority in the process. It may not be possible to create a complete time line for review until the first few reviews have been conducted and the committee can more accurately estimate time requirements. Ultimately, the schedule will be determined by the ability of the committee to prepare reviews, and the number of drugs to be reviewed.

At the time the schedule is created, committee members should be assigned to prepare review presentations of one or more drug classes. If expertise from outside the committee is needed, the chairperson should recruit required specialists. The committee members, or other specified experts, may choose to form a working group to assist in the process. Working groups allow for input from a greater number of physicians. During the review process, it may be reasonable to hold 6-monthly meetings, and review one class of drugs at each meeting.

In general, underlying questions for evaluating a drug for formulary admission are:

- Is there a justifiable need for this drug?
- Is this need met by some other agent already in use?
- Can this need be met in a safer and more efficacious manner by other agents in the formulary?
- Has the drug received adequate clinical evaluation?
- Does the use of the drug justify its expense and associated costs?

For each agent a thorough and objective evaluation must be made to ascertain that the agents in each class are being selected rationally. For agents that are the only product in a therapeutic class it should be determined that they are a cost effective form of therapy and appropriate for promoted indications.

### **Therapeutic aspects of the drug class review**

Because the drug class review will have direct clinical impact it is recommended that a short evaluation monograph be prepared. Listed below is information that is typically included in such a monograph:

- Proposed designation according to the therapeutic classification scheme.
- Generic name - The officially approved name, and, if a combination product, all active ingredients by generic name.
- Brand name(s) - This can be important for multi-source products all brand name may be included if possible.
- Product source(s) - The name and address of the manufacturer(s) for this product.

- Indication(s) - Ensure that all conditions to be treated are covered by formulary drugs.
- Contraindication(s) - Contraindication(s) can be a basis for non-inclusion.
- Efficacy/Pharmacology- When comparing drugs with similar indications, decisions can be made based on efficacy. It is important to include the mechanism of action and, in the case of ant infective agents, the microbiologic spectrum of activity.
- Side effect profile - Drugs with small side effect profiles are preferred. It is also important to provide some assessment of the incidence and seriousness of these side effects. If there are Significant numbers of people that had to withdraw from clinical trials due to side effects, it should be mentioned here.
- Previous problems experienced with the drug in the hospital - The formulary process can be used to eliminate drugs that have caused adverse drug reactions, or drugs frequently prescribed for non-indicated conditions.
- Administration schedules - There is a trend toward using drugs that are administered fewer times per day. For intravenous drugs, this can reduce administration costs.
- Duration of therapy - Shorter durations of therapy will reduce administration costs and can reduce length of stay.
- Routes of administration - Drugs that can be given orally are less expensive than injectables both in terms of acquisition cost and related administration costs.
- Pharmacokinetic profile - Absorption, route of elimination, ability to cross the blood-brain barrier, etc. are important facts to consider. Specific data such as volume of distribution, percent metabolized in the liver or eliminated unchanged through the kidney, and elimination half-life should be included. Information about dosing in patients with renal impairment can be included under the elimination subheading.
- Monitoring required - The hospital should have equipment, reagents, etc., needed to monitor formulary drugs. Lack of monitoring equipment in the facility may prevent inclusion on the formulary, however, the risk-benefit of using an efficacious drug without monitoring needs to be considered.
- Drug-drug and drug-food interactions - Drugs with fewer interactions are preferred.
- Availability - The procurement department should report on sources of supply and time required to obtain drugs.
- Similar agents that this drug may replace - List of all agents that are therapeutically similar and that may be eliminated from the formulary if this drug is included.
- Recommendations and critical issues - A recommendation should be made here as to whether or not this drug should be included in the formulary. Specific issues for use can also be addressed here, such as restriction to special services. Examples of possible restrictions are given in Annex 2.

### **Economic aspects of drug class review**

In the past, economic considerations in making formulary decisions dealt mainly with the acquisition cost of a drug. Increasingly, economic analysis has expanded to include costs and/or expenses associated with drugs that are not as obvious. These costs are part of the institution's overall cost related to drug therapy and need to be taken into consideration as well. This expanded horizon of evaluating costs associated with drug treatments has become especially important in this time of shrinking health care budgets and increasing health care costs. The knowledge of a drug therapy's economic impact to health care and ultimately to society has become more and more important. These considerations include the identification, measurement and comparison of all costs and consequences (both positive and negative) of pharmaceutical products. Because drug product acquisition costs are only one cost aspect to consider, medication formulary decisions must consider the full impact of medication use. Examples of such costs are given in Annex 3.

## **Step 8. Approve the Formulary List for Use in the Health Facility**

After the Pharmacy / Formulary and Therapeutics Committee has created the list of drugs to be included on the formulary, a vote is taken to officially approve the list, according to the established procedures. The formulary list is then disseminated to all physicians and pharmacists. The hospital Chief Executive / Chief Physician should issue an order of compliance with the formulary drug list. The order may be announced at a general meeting of all hospital health providers, together with the adopted policies of the Pharmacy / Formulary and Therapeutics Committee. At this time, the hospital begins to procure only products on the formulary list. Existing stocks of non-formulary drugs may be prescribed and used until the supply is depleted.

## **Step 9. Educate Hospital Personnel about Policies and Procedures on Non-Formulary Drug Use, Additions and Deletions to the Formulary, and Generic and Therapeutic Substitution**

### **Non-formulary drug use**

Normally, only formulary drugs are approved for use in a health facility. However, the therapeutic needs of a small number of patients may not be met by any drug on the hospital formulary. For such cases, the Pharmacy / Formulary and Therapeutics Committee establishes procedures for use of non-formulary drugs. Requests for use of non-formulary drugs are always made for a specific patient, using a Non-Formulary Drug Request Form, designed and approved by committee. The prescribing physician should complete the form, and forward it to the inpatient pharmacy, or the Pharmacy / Formulary and Therapeutics Committee, if there is no organized pharmacy department in the hospital. It may be appropriate for the pharmacist to discuss the use of a formulary drug with a prescribing physi-

cian. If the prescribing physician determines that a non-formulary drug is required, the hospital obtains a sufficient quantity of the non-formulary drug for that patient.

The Pharmacy / Formulary and Therapeutics Committee should review all non-formulary drug requests on a regular basis.

If the committee notes frequent requests for a particular non-formulary drug, and determines that it is superior to a formulary drug, it may vote for its addition, and deletion of the inferior formulary drug.

### **Requests for formulary addition and deletion**

Requests for addition of a drug to, or deletion of a drug from, the formulary are usually made by a staff physician, pharmacist, nurses using a Request for Addition/Deletion Form (see Annex Four for an example). Unlike non-formulary drug requests, requests for addition are not patient-specific, but rather are requested for general use. When a physician wants a drug to be added to the formulary, he or she should complete the form and forward it to the Secretary of the Pharmacy / Formulary and Therapeutics Committee. A designated specialist (Drug Information Pharmacist / Physician) on the committee conducts a literature search and prepares a written evaluation comparing the newly requested drug with formulary drugs used for the same indications. Criteria for comparison are cost, efficacy and safety. The committee then reviews the written evaluation. If the new drug is superior to an existing drug or drugs, on the formulary, or fills a gap, it will be added to the formulary. Existing inferior drugs on the formulary, not needed for use for other indications, should be deleted from the formulary.

The committee or the pharmacy department should publish a newsletter about additions in the formulary, including a brief review of the drug. It is rare for a staff physician to request that a drug be deleted from the formulary. Deletion usually occurs during periodic drug class reviews, or as a result of adverse drug reaction monitoring or Drug Use Evaluation, described later in the manual. If a physician does formally request that a drug be deleted, the committee should determine if deletion will create therapeutic gaps.

### **Generic and therapeutic substitution**

Physicians and pharmacists should have a clear understanding of both generic and therapeutic substitution:

#### **Generic substitution**

Generic substitution is defined as the substitution of bioequivalent drug products that contain the same active ingredients and are chemically identical in strength, concentration, dosage form, and route of administration to the drug product prescribed.

For example, substitution of one verapamil product for another is generic substitution, if the quantity of active ingredient, dosage form and strength are identical. Substitution of pork insulin for human insulin is not generic substitution, nor is substitution of a rapid action product for a product with prolonged action.

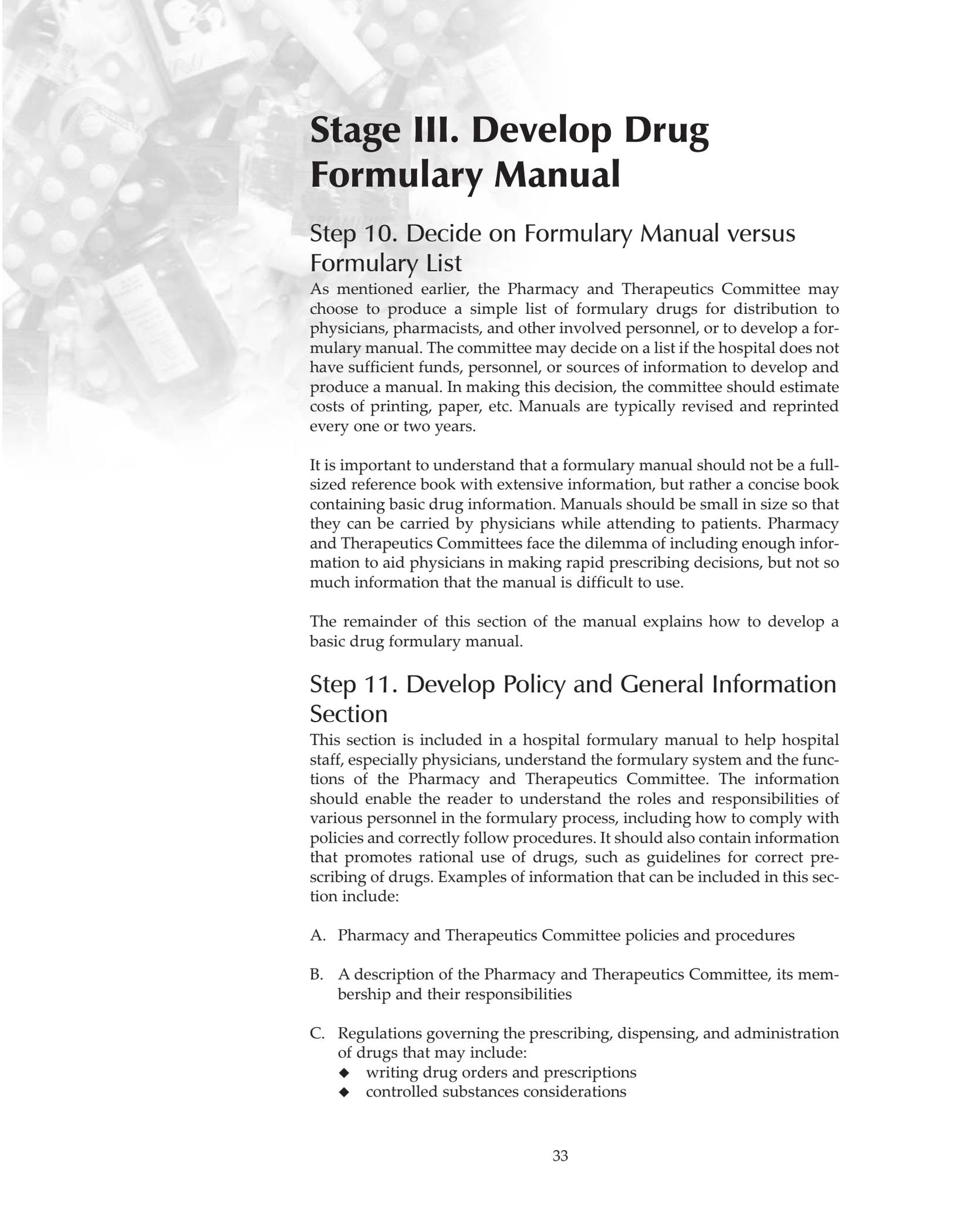
The Pharmacy and Therapeutics Committee is responsible for developing guidelines for generic substitution. In US hospitals, the pharmacy department typically makes actual decisions on generic substitution, and there are very few drugs (e.g., phenytoin and digoxin) for which use of generically produced products are not acceptable by the medical staff. In some countries, there may be more drugs for which generic substitution is prohibited by the Pharmacy / Formulary and Therapeutics Committee, due to justifiable concern for drug quality.

### **Therapeutic substitution**

Therapeutic substitution is defined as substitution of one drug for another of equal therapeutic value, even though they are not generically equivalent. An example of therapeutic substitution would be use of *cephradine* for *cephalexin*. In this case the drugs have the same spectrums of action, frequency of use, dosage form, strength, and route of administration. However, a Pharmacy / Formulary and Therapeutics Committee may consider drugs of different strengths to be therapeutically equivalent. For example, *cimetidine* 400 mg twice daily is frequently considered to be therapeutically equivalent to ranitidine 150 mg twice daily or *amotidine* 40 mg once daily. It should be noted that there are not officially recognized therapeutic equivalents. Decisions should be made by individual hospitals.

Therapeutic equivalence must be determined by the Pharmacy / Formulary and Therapeutics Committee of each individual hospital. Some other examples of drugs frequently considered therapeutically equivalent include:

- *furosemide* 40 mg and *ethacrynic acid* 50 mg
- *prednisolone* 5 mg and *triamcinolone* 4 mg
- *propranolol* 160 mg and *atenolol* 100 mg
- *ampicillin* 250 mg and *amoxicillin* 250 mg



# Stage III. Develop Drug Formulary Manual

## Step 10. Decide on Formulary Manual versus Formulary List

As mentioned earlier, the Pharmacy and Therapeutics Committee may choose to produce a simple list of formulary drugs for distribution to physicians, pharmacists, and other involved personnel, or to develop a formulary manual. The committee may decide on a list if the hospital does not have sufficient funds, personnel, or sources of information to develop and produce a manual. In making this decision, the committee should estimate costs of printing, paper, etc. Manuals are typically revised and reprinted every one or two years.

It is important to understand that a formulary manual should not be a full-sized reference book with extensive information, but rather a concise book containing basic drug information. Manuals should be small in size so that they can be carried by physicians while attending to patients. Pharmacy and Therapeutics Committees face the dilemma of including enough information to aid physicians in making rapid prescribing decisions, but not so much information that the manual is difficult to use.

The remainder of this section of the manual explains how to develop a basic drug formulary manual.

## Step 11. Develop Policy and General Information Section

This section is included in a hospital formulary manual to help hospital staff, especially physicians, understand the formulary system and the functions of the Pharmacy and Therapeutics Committee. The information should enable the reader to understand the roles and responsibilities of various personnel in the formulary process, including how to comply with policies and correctly follow procedures. It should also contain information that promotes rational use of drugs, such as guidelines for correct prescribing of drugs. Examples of information that can be included in this section include:

- A. Pharmacy and Therapeutics Committee policies and procedures
- B. A description of the Pharmacy and Therapeutics Committee, its membership and their responsibilities
- C. Regulations governing the prescribing, dispensing, and administration of drugs that may include:
  - ◆ writing drug orders and prescriptions
  - ◆ controlled substances considerations

- ◆ generic and therapeutic equivalency policies and procedures
  - ◆ automatic stop orders
  - ◆ investigational drug policies
  - ◆ patients' use of their own medications
  - ◆ policies on "stat" and "emergency" drug orders
  - ◆ use of emergency carts and kits
  - ◆ use of floor stock items
  - ◆ use of drug administration devices
  - ◆ rules to be followed by drug manufacturer and wholesaler representatives
  - ◆ standard drug administration times
  - ◆ adverse drug reaction and medication error reporting
- D. Pharmacy operating procedures, such as hours of service, prescription policies, pricing policies, prescription labeling and packaging practices, drug distribution procedures, handling of drug information requests, and other services of the pharmacy (e.g., patient education programs and pharmacy bulletins)
- E. Information on using the formulary, including how the formulary monographs are arranged, the information contained in each monograph, and the procedure for looking up a given drug product
- F. Reference books on drugs available in hospital library

## Step 12. Develop Drug Information Monographs for the Formulary Manual

This section is the heart of the manual, and consists of simple drug monographs for each drug in the formulary. The committee must decide on the sections to be contained in each monograph, and how much information will be included.

Monographs can be arranged in the manual in several ways:

- ◆ alphabetically by generic name, with information within the monographs on brand names;
- ◆ by therapeutic class; or
- ◆ a combination of the two systems with most drugs arranged alphabetically in a "general" section, supplemented by several "special" sections, such as ophthalmic and otic drugs, dermatologicals, and diagnostic agents, etc.

A monograph contains several sections, as decided by the committee. Examples of the most common sections are:

- ◆ Generic name
- ◆ Common brand names
- ◆ Pharmacology

- ◆ Active ingredients of combination products
- ◆ Pharmacodynamics/Pharmacokinetics
- ◆ Indications
- ◆ Contraindications
- ◆ Precautions (breast-feeding, geriatric, obstetric, etc.)
- ◆ Side effects
- ◆ Adverse drug reactions
- ◆ Drug-drug and drug-food interactions
- ◆ Stability
- ◆ Dosage forms, strengths
- ◆ Usual dose
- ◆ Monitoring
- ◆ Storage requirements
- ◆ Patient information
- ◆ Controlled substances class
- ◆ Cost information

### Step 13. Develop Special Information Section

If availability of adequate drug information is problematic in the country, the Pharmacy and Therapeutics Committee can decide to include drug information to supplement monographs.

The material in this section will vary from hospital to hospital, and should contain information not readily available from other sources. Examples of the types of items often found in the special information section are:

- A. Tables of equivalent dosages of similar drugs (e.g., corticosteroids)
- B. Standard parenteral nutrition formulas
- C. Guidelines for calculating pediatric dosages
- D. Table of the sodium content of drug products
- E. List of sugar-free drug products
- F. Contents of emergency kits
- G. Lists of dialyzable drugs
- H. Pharmacokinetic dosing and monitoring information
- I. Examples of blank and completed organizational forms (prescription forms, requests for nonformulary drugs, adverse drug reaction report forms, etc.)
- J. Tables of drug interactions, drug effects on diagnostic tests, injectable drug incompatibilities
- K. Poison control information, including telephone numbers of poison control centers
- L. Dosages, concentrations, and standard dilutions of common emergency drugs
- M. Standard vehicles and dilutions for pediatric injections
- N. Electrolyte content of large-volume parenterals
- O. Costs of drug therapy to treat various diseases
- P. Hospital-developed standard treatment guidelines
- Q. Equations to estimate creatine clearance
- R. Dosing guidelines for drugs with narrow therapeutic indexes (e.g., theophylline, digoxin, and aminoglycosides)

## Step 14. Develop Indexes to Facilitate the Use of the Manual

The manual will not be used if desired information is difficult to locate. It is not unusual for one manual to contain several types of indexes:

- ◆ **Generic - brand name cross index:** This index is arranged alphabetically, and contains both generic names, and common brand names. It is used when the reader knows a brand or generic name of a product, and wants to locate the monograph. A portion of a generic-brand name cross index might look like this:

Ophthaine: brand of proparacaine HCl, p. 114  
Ophthetic: brand of proparacaine HCl, p. 114  
Opium tincture, camphorated; synonym for paregoric, p. 103  
Paregoric, p. 103  
Proparacaine HCl, p. 114

- ◆ **Therapeutic/Pharmacologic index:** This index lists all formulary items within each therapeutic class. It is useful for ascertaining what therapeutic alternatives are on the formulary for a given class of drug. An example follows:

**11:00 Antihistamine drugs**  
Clemastine, p. 14  
Chlorpheniramine maleate, p. 14  
Diphenhydramine hydrochloride, p. 14  
Promethazine hydrochloride, p. 62

- ◆ **Indications index:** This index lists diseases alphabetically, followed by formulary drugs used to treat the disease. It is useful when a prescriber wants to know what drugs are on the formulary for a given disease or condition:

**Allergic Disorders (ophthalmic)**  
Betamethasone, p. 150  
Cromolyn Sodium, p. 194  
Dexamethasone, p. 206  
Hydrocortisone, p. 289  
Prednisolone, p. 407  
Promethazine Hydrochloride, p. 416

**Hyperlipidemia**  
Colestipol, p. 191  
Gemfibrozil, p. 273  
Lovastatin, p. 321  
Niacin, p. 366

## Step 15. Produce and Distribute the Manual

The physical appearance of a printed formulary manual has an important impact on how extensively it is used. Although elaborate and expensive artwork and materials are unnecessary, the formulary manual should be visually pleasing, easy to read, and professional in appearance. Options for production include a loose-leaf book, or a bound volume resembling a paper-back book.

Loose-leaf manuals are less expensive to produce, and can easily be updated by producing and distributing replacement pages, usually accompanied by instructions for removing and adding pages. Bound volumes have the advantage that they can be produced in pocket size and can easily be carried.

Several techniques can be used to improve the appearance and ease of use of the formulary manual such as:

- ◆ Using a different color paper for each section of the formulary
- ◆ Using an edge index
- ◆ Making the formulary pocket size
- ◆ Printing the generic name heading of each drug entry in boldface type or using some other method for making it stand out from the rest of the entry

The manual should be readily available to physicians, pharmacists and nurses, at all times. One approach is to distribute a copy of the manual to all these individuals. Another is to place a limited number of copies of the manual in patient care areas and the pharmacy department. The first approach is costly, but will result in greater use of the formulary. The latter is less expensive, but the manuals are frequently misplaced or stolen.

# Exercises

## Activities: Adding New Antimicrobials to the Formulary

### Activity 1.

The participants will break up into groups of five individuals. Each group will elect a leader who has some experience in the management of formulary systems. The group leader will report the overall findings of the group concerning this activity.

Your P&TC is considering a new antibiotic for the formulary. This antibiotic is very similar to a formulary product, cefotaxime, a third-generation cephalosporin. It would be used in the emergency room for managing febrile children with the diagnosis of acute respiratory infection (ARI) or otitis media (OM) who appear toxic and are candidate for admission to the hospital. This drug is an injectable at a very high cost of Rs. 300 per dose. The physician requesting this drug states that although it is very expensive, use of the drug will decrease overall cost because hospitalizations will be decreased with appropriate use. The drug would be used by mid-level providers who staff the emergency room at night. The hospital has a very tight budget, relies on donors for a significant amount of the drug supply, and frequently runs out of medication because of poor supply management practices.

Other drugs available in the hospital for this particular medical condition include amoxicillin, cephalexin, co-trimoxazole, and chloramphenicol. .

- What criteria are necessary to evaluate this drug for addition to the formulary?
- Utilizing the criteria discussed in this session, what major concerns do you have before adding this drug to the formulary?
- What drug information resources would be used to analyze this drug for the P&TC which source would be the most useful?

### Activity 2.

The participants will break up into groups of five. Each group will select a leader who has experience with a P&TC. The group will review the activity, identify problems with the scenario, and make recommendations for evaluating the drug in question for the formulary.

You are a new member of the P&TC we for your hospital. A new antimicrobial has been requested by one of your physicians. This antimicrobial has a broad spectrum of activity that includes activity against most common gram-positive and many gram-negative bacteria. The drug is a suspension that is given four daily for 10 days.

The drug is heavily promoted, by a pharmacy company representative, for

treating many different pediatric infections. The cost is high, Rs. 120/day, but it is required (according to the requesting physician) because of a high incidence of antimicrobial resistance in the hospital. This antibiotic is typically used for children with acute otitis media, sinusitis, and bronchitis. Safety of this drug has not been fully evaluated.

Other drugs for these problems that are available on the formulary include amoxicillin, co-trimoxazole, and cephalexin. Typically the P&TC has provided very little evaluation of new drugs; a physician's recommendation was enough for approval by the committee.

- What are some important considerations when adding a drug such as this to the formulary?
- What are some obvious potential drug use problems that are depicted in this activity?
- What responsibility does the P&TC have to the health care system concerning the addition of drugs, especially antibiotics, to the formulary?
- What functions of the P&TC are needed to fully address the antibiotic request?

# Summary

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

Listed below are some key points to remember concerning the starting of a formulary system or maintaining one for years to come-

- Write detailed policies and procedures concerning the functions of the formulary system.
- Evaluate drugs carefully to obtain the best drug at a favorable cost.
- Review the formulary in a systematic manner to ensure it is current.
- Keep non formulary drugs to a minimum.
- Restrict drugs to appropriate practitioners.
- Keep on hand up-to-date drug information resources that provide unbiased comparative information.
- Enlist the support of key policymakers and influential health professionals to advocate for the P&TC-and formulary system.
- Keep the formulary process ethically correct-the P&TC 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

# **ANNEXURE**

## Annex 1: Examples of Hospital Pharmacy and Therapeutics Committee Policies:

- A. Drugs will be admitted to the formulary under a nonproprietary (generic) or official name. The combined best judgment of the medical pharmacy staff will decide whether a particular product meets the standards implied by acceptance into the formulary. Approved therapeutic equivalents may be dispensed unless otherwise indicated.
- B. When reviewing drugs for formulary decisions the following criteria shall be considered:
  - ◆ There should be a justified need for the drug.
  - ◆ There should be no other drug on the hospital formulary list that satisfies the same need.
  - ◆ Satisfactory clinical trials should be conducted at the facility, or information on such trials conducted elsewhere should be available.
  - ◆ No drug will be admitted to the formulary if its composition is secret or its therapeutic value has not been established.
  - ◆ No mixtures of two or more substances will be admitted unless the mixture presents therapeutic advantages over the single substances.
  - ◆ The cost of the drug should justify its use.
  - ◆ The drug should be readily available from suppliers.
- C. Clinical department heads shall be notified whenever a formulary drug is under consideration for deletion so that they may submit evidence for its retention.
- D. The committee may admit specified dosage forms of a drug, and not admit other dosage forms of the same drug.
- E. The Pharmacy and Therapeutics Committee will meet monthly on a regular basis or "on call" by the chair.
- F. The secretary of the committee shall notify the committee members about meetings, and carefully take minutes.

Once policies have been established, step by step procedures to implement or enforce policies should be drafted. For example, the procedure for formulary additions and deletions may be:

1. Requests for addition or deletion of a drug to the formulary can only be made by an attending physician. The request is made through completion of a Request for Addition/Deletion Form.
2. The Request for Addition/Deletion Form is sent to the Secretary of the Pharmacy and Therapeutics Committee, and, if complete, forwarded to the Drug Information Center (or drug information pharmacist, or clinical pharmacologist).
3. The Drug Information Center conducts a literature search and prepares a written evaluation comparing the newly requested drug with current formulary drugs used for the same indications. Criteria for comparison are efficacy, safety and cost.
4. The evaluation should be reviewed by the entire Pharmacy and Therapeutics Committee.
5. If the new drug is found to be superior to an existing drug on the formulary, or to be unique, it will be added to the formulary.
6. Existing drug(s) on the formulary found to be inferior, and not needed for use for other indications, will be deleted from the formulary.

### Policy on use of generic names

One of the most important policy concepts in formulary development is that drugs should be selected and listed in the formulary by generic name.

Each drug on the market has a chemical name (e.g., 6-[D(-)-a amino "-phenyl acetamide]-peni-

cillinic acid) and an international nonproprietary or generic name (e.g., ampicillin). The generic name is a drug's official name, regardless of who manufactures or markets it. A commercial, or brand trade name (e.g., Polycillin®) is often chosen by the manufacturer or distributor to facilitate recognition of the product and to differentiate it from the same drug furnished by other firms.

The use of generic names in formularies should serve to promote purchasing and prescribing by generic name. This practice has the following advantages:

- ◆ generic names are more informative than brand names and reflect their affiliation to certain therapeutic or chemical classes;
- ◆ generic prescribing facilitates product substitution, whereas prescribing by a brand name often implies filling only the prescribed brand name; and
- ◆ generic names facilitate purchasing of products from multiple suppliers, whether as brand name or as generic products. Generically produced drugs are often cheaper than products sold by brand names.

Insistence on the use of a particular brand name drug product by the committee is justified if bioavailability and bioequivalence of drug products from different manufacturers vary so significantly that they can alter the desired therapeutic effect. This mainly applies to cardiac glycosides, anticonvulsants, hormones, antiarrhythmics, anticoagulants and other drugs with a narrow therapeutic index.

When brand names drugs of prolonged action are included in the formulary list, it is critical to clearly specify them. This is another case where use of a particular brand name drug product can be justified.

## Annex 2: Examples of Possible Restrictions

1. **Diagnosis restrictions** - Identify indications that constitute acceptable uses for a formulary drug within the health-care setting. The use of toxic or potentially dangerous drugs may be justified when the risk of developing side effects is outweighed by the efficacy in specific diagnoses or medical conditions. For example, a particular colony stimulating factor might be approved for use only as an adjunct to cancer chemotherapy. Use of the drug for other indications would then fall outside the approved diagnosis criteria.
2. **Prescriber restrictions** - Identify prescribers approved to use specific formulary drugs or drug classes. Examples include limiting the use of specific injectable antibiotics to infectious diseases specialists, or restricting use of thrombolytic drugs to cardiologists or emergency room physicians.
3. **Pharmacological restrictions** - Identify approved doses, frequencies of administration, durations of therapy, or other aspects that are specific to the use of a formulary drug. Examples of evaluation monographs: cefuroxime and ceftriaxone.

### A. Cefuroxime:

- **Classification:** Second generation cephalosporin.
- **Generic names:** Cefuroxime sodium and cefuroxime axetil.
- **Brand names:** Cefuroxime sodium: Zinacef , Glaxo, Zecef Bosh. Cefuroxime axetil: Zenat , Glaxo.

**Indications:** Lower respiratory tract infections, otitis media, pharyngitis and tonsillitis, genitourinary tract infections, skin and skin structure infections, and bone and joint infections, caused by susceptible organisms.

- **Contraindications:** Hypersensitivity to cephalosporins and penicillins.
- **Precautions:** Modify dosage in patients with renal insufficiency; use with caution in patients with history of gastrointestinal disease, particularly colitis; each gram contains 2.4 mEq sodium.
- **Pharmacology:** Cefuroxime is bactericidal in action. The antibacterial activity results from inhibition of mucopeptide synthesis in the bacterial cell wall. The spectrum of activity includes staphylococci, group B streptococci, H. Influenzae (type A and B), E. Coli, Enterobacter, Salmonella, Klebsiella, Proteus mirabilis.
- **Side effects:** 1% to 10%: Thrombophlebitis, decreased hemoglobin and hematocrit, eosinophilia, transient rise in SGOT (AST)/SGPT (ALT) and alkaline phosphatase. Less than 1%: Dizziness, fever, headache, rash, nausea, vomiting, diarrhea, stomach cramps, GI bleeding, colitis, transient neutropenia and leukopenia, transient increase in liver enzymes, increase in creatinine and/or BUN, pain at the injection site, vaginitis.
- **Administration schedules and dosages:**

Neonates:	10-25 mg/kg/dose every 12 hours
Children:	Oral: Not recommended due to poor absorption <2 years: 125 mg twice daily (cefuroxime axetil) 2-12 years: 250 mg twice daily (cefuroxime axetil) IM/IV: Bone/joint infection: 50 mg/kg/dose every 8 hours Meningitis: 50-60 mg/kg/dose every 6 hours Other: 100 mg/kg/day, divided every 6 hours; max.: 6 gm/24 hours
Adults:	Oral: Not recommended due to poor absorption; 125-500 mg twice daily depending on severity of infection (cefuroxime axetil) IM/IV: 750 mg to 1.5 gm every 8 hours; max.: 6 gm per 24 hours

- **Duration of therapy:** Usual course of therapy is 7 to 10 days but should be continued for at least 48-72 hours after patient is afebrile or evidence of eradication of the infection has been obtained.
- **Pharmacokinetics:** Absorption: Following oral administration, the bioavailability of cefuroxime axetil is approximately 27% when fasting, and 52% when given with food. Cefuroxime sodium is not appreciably absorbed. Following IM administration of

cefuroxime sodium, peak plasma concentrations of the drug are attained within 15-60 minutes. Distribution: Cefuroxime is widely distributed into body tissues and fluids including the kidneys, heart, gallbladder, liver, prostatic adenoma tissue, uterine and ovarian tissue, aqueous humor, saliva, sputum, bronchial secretions, bone, bile adipose tissue, wound exudates, peritoneal fluid, ascitic fluid, synovial fluid, pericardial fluid and pleural fluid. The apparent volume of distribution of cefuroxime in healthy adults ranges from 9.3 to 15.8 L. Cefuroxime crosses the placenta and is distributed into milk. Elimination: Cefuroxime is cleared renally. The serum half-life of cefuroxime axetil ranges from 1.2 to 1.6 hours. In adults with normal renal function, the serum half life of cefuroxime sodium following IM/IV administration ranges from 1 to 2 hours. In patients with renal impairment, the serum half-life is prolonged and ranges from 1.6 to 16.1 hours.

- **Drug interactions:** Probenecid increases serum levels of cefuroxime.

#### B. Ceftriaxone:

- **Classification:** Third generation cephalosporin.
- **Generic names:** Ceftriaxone sodium.
- **Brand names:** Rocephin , Roche. Inocef B&H
- **Indications:** Lower respiratory tract infections, skin and skin structure infections, bone and joint infections, intra-abdominal infections, urinary tract infections, meningitis, septicemia, and gonorrhea caused by susceptible organisms. It has also been used for perioperative prophylaxis.
- **Contraindications:** Hypersensitivity to cephalosporins and penicillins.
- **Precautions:** Ceftriaxone should be used with caution in patients with a history of GI diseases, particularly colitis. Since ceftriaxone can precipitate in the gallbladder, some clinicians recommend that ceftriaxone be used with caution in patients with pre-existing disease of the gallbladder, biliary tract, liver or pancreas.
- **Pharmacology:** Ceftriaxone is bactericidal in action. The antibacterial activity results from inhibition of mucopeptide synthesis in the bacterial cell wall. The spectrum of activity includes staphylococci, groups A and B streptococci, H. Influenzae, Neisseria meningitidis and Neisseria gonorrhoeae.
- **Side effects:** 1% to 10%: Eosinophilia, thrombocytosis, leukopenia, diarrhea, increased serum concentrations of AST (SGOT) and ALT (SGPT). Less than 1%: Increase in alkaline phosphatase, pruritus, fever, chills, jaundice, headache, dizziness, oral candidiasis.

#### Administration schedules and dosages: IV/IM:

Neonates:	<2000 gm: 50 mg/kg/day every 24 hours >2000 gm: 75 mg/kg/day every 24 hours
Children:	50 - 75 mg/kg/day in 1 or 2 divided doses
Adults:	1 to 2 gm every 12 to 24 hours, depending on the type and severity of the infection;max.: 4 gm per 24 hours

- **Duration of therapy:** Usual course of therapy is 7 to 10 days but should be continued for at least 48 hours after the patient is asymptomatic or evidence of eradication of the infection has been obtained.
- **Pharmacokinetics:** Absorption: Ceftriaxone is not appreciably absorbed from the GI tract and must be given parenterally. Following IM administration of ceftriaxone, peak plasma concentrations of the drug are attained 1.5 to 4 hours after the dose. Distribution: Following IM or IV administration, ceftriaxone is widely distributed into body tissues and fluids including the gallbladder, lungs, bone, bile, prostate adenoma tissue, uterine tissue, atrial appendage, sputum, tears, and pleural, peritoneal, synovial, ascitic, and blister fluids. The volume of distribution of ceftriaxone is dose dependent and ranges from 5.8 to 13.5 L in healthy adults. Ceftriaxone generally diffuses into CSF following IM or IV administration. CSF concentrations of the drug are higher in patients with inflamed meninges than in those with uninflamed meninges. Ceftriaxone crosses the placenta and is distributed into amniotic fluid. Elimination: Ceftriaxone is cleared renally and in feces via bile. The serum half-life of ceftriaxone is 5 to 9 hours in adults. Ceftriaxone is not removed by hemodialysis or peritoneal dialysis.
- **Drug interactions:** Concomitant administration of probenecid does not seem to affect the pharmacokinetics of ceftriaxone. However, in higher doses of oral probenecid (1 to 2 gm daily), probenecid may partially block biliary secretion of ceftriaxone.

## Annex 3: Examples of Costs

- Drug cost for an entire course of therapy
- Drug administration costs including costs for materials such as IV bags or bottles, solutions, syringes, etc.
- Cost of drugs that have to be co-prescribed, such as premedications, as well as medical supplies needed (examples: the cost of cimetidine as mandatory premedication for Taxol in the treatment of breast cancer; or the cost of compression stockings, a mandatory supply during enoxaparin therapy in the preventive treatment of deep venous thrombosis following hip surgery)
- Acquisition and administration costs of drugs that are needed to treat known side effects and complications (example: the cost of hydrocortisone and meperidine to treat rigors following amphotericin B administration)
- Costs related to lab tests, including monitoring equipment and reagents
- Costs related to storage if special storage conditions are required
- Probable effect on length of stay

Although it is very difficult to quantify probable effect on length of stay financially, the economic analysis should minimally include a statement of a proposed drug's probable effect on length of stay. To the extent possible these costs should be considered when making formulary decisions. Pharmacy / Formulary Committees are frequently approached by representatives of the pharmaceutical industry trying to persuade committee members to add a particular product to the formulary. It is appropriate to request sales representatives to outline total costs associated with a particular drug therapy. However, this type of cost analysis can be done by the Pharmacy / Formulary Committee itself. A multi-disciplinary make-up of the Pharmacy / Formulary Committee will enhance the accuracy of this cost analysis.

The goal of a drug formulary should not be to decrease the drug budget alone, but to decrease the overall costs needed to manage specific diseases. An example of a very basic analysis follows.

### Community acquired pneumonia

**Treatment options:** Cefotaxime 1 gm IV q8h x 7-10 days versus  
Ceftriaxone 1 gm IM q24h x 7-10 days 1

	Unit Cost (Rs)	Daily Cost (Rs)	Cost for Course (Rs)
<b>Cefotaxime 1 gm IV q8h x 7-10 days</b>			
Drug Cost	300.00	900.00	6300-9000
Medical Supply Costs			
syringe/needle	5.00	15.00	105-130
IV set	12.00	36.00	252-360
<b>Total Cost</b>			<b>6657-9510</b>
<b>Ceftriaxone 1 gm IM q24h x 7-10 days</b>			
Drug Cost	500.00	500.00	3500-5000
Medical Supply Costs			
syringe/needle	5.00	5.00	35-50
IV set			
<b>Total Cost</b>			<b>3535-5050</b>

If a Pharmacy / Formulary Committee were to consider only acquisition cost, ceftriaxone appears to be considerably more expensive than cefotaxime (Rs. 500-300 = 200 more per dose). However, when dosing frequency and the cost of supplies needed to administer the drugs are also considered, ceftriaxone is actually more cost effective to use than cefotaxime (Rs. 9510 -5050= 4460) less for a ten days treatment cost.

If the cost of the labor required to prepare doses were also considered, greater savings could be shown. However, adding labor costs to the analysis is only valid if the savings can actually be applied, such as through reduction in staff, or reassignment of a staff member from drug preparation to another task.

# Acknowledgements Annex

Dr. Nek Dad Afridi, Mr. Abid Hayat, Mr. Sabir Ali, Mr. Khurshid Ahmad Sheikh, Dr. Laeeq Ahmad, Dr. Ayoub Rose, Dr. Roohullah, Dr. Hifzurrehman, Dr. Waheed Khan, Dr. Muhammad Riaz, Dr. Muzaffar Khan Kundi, Dr. Aimal Khan, Mr. Nazar Husain, Mr. Mujtaba, Mr. Muhammad Jalil Anwar, Dr. Yousaf Parvez, Mr. Abid Hayat, Dr. Mudassir Bangash, Mr. Javed Muhammad, Mr. Saleem Khan, Mr. Abdurrashid, Mr. Bakht Karam, Dr. Muhammad Iqbal, Dr. Amanulah, Dr. Khalid Iqbal, Dr. Jalil-ur-Rehman, Dr. Sajid Shaheen, Dr. Muhammad Iqbal Afridi, Mr. Muhammad Ishfaq Khan, Brig. Dr. Habib-ur-Rehman, Brig. Dr. Farrukh Seir, Dr. Muhammad Saeed Akbar Khan, Dr. Saadullah Khan Afridi, Dr. Muhammad Iqbal, Dr. Fazal Mahmood, Dr. Khurshid Ali, Dr. Abdul Ghafoor, Dr. Shaheen Afridi, Dr. Ali Ahmad, Dr. Saeed Khan, Dr. Maqsood, Dr. Jumma Khan, Dr. Samim Khan Durrani, Prof. Nirmal Dass, Mrs. Ishrat Bukhari, Dr. Masood Noshirwani, Dr. Abdul Rahman, Dr. Ilahi Bukhsh, Dr. Allah Nawaz Bugti, D.M. Jamali, Dr. Arshad Mahmood, Mr. Jamshed Qureshi, Dr. Zaeem-ul-Haq, Mr. Azhar Hussain, Dr. Farrukh Qureshi, Mr. Shafi Mohammad Zehri, Dr. Azeem Khwajakhel, Mr. Ameer Tariq Zaman, Ms. Ishrat Bukhari, Dr. Rukhsana Bashir, Dr. Khalif Bile, Dr. Zafar Mirza.

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