

## Medication Management

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### Learning Objectives

After completing this chapter, readers should be able to:

1. Describe the purpose of a formulary system in managing medication use in institutions.
2. Discuss the organization and role of the pharmacy and therapeutics committee.
3. Explain how formulary management works.
4. List the principles of a sound formulary system.
5. Define key terms in formulary management.

### Key Terms and Definitions

- **Closed formulary:** A list of medications (formulary) which limits access of a practitioner to some medications. A closed formulary may limit drugs to specific physicians, patient care areas, or disease states via formulary restrictions.
- **Drug formulary:** A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and/or treatment of disease and promotion of health.
- **Drug monograph:** A written, unbiased evaluation of a specific medication. This document includes the drug name, therapeutic class, pharmacology, indications for use, summary of clinical trials, pharmacokinetics/dynamics, adverse effects, drug interactions, dosage regimens, and cost.
- **Drug therapy guidelines:** A document describing the indications, dosage regimens, duration of therapy, mode(s) of administration, monitoring parameters and special considerations for use of a specific medication or medication class.
- **Drug use evaluation (DUE):** A process used to assess the appropriateness of drug therapy by engaging in the evaluation of data on drug use in a given health care environment against predetermined criteria and standards.
  - ◆ **Diagnosis-related DUE:** A drug use evaluation completed on pa-

tients with a specific disease state or diagnosis. An example is the use of antibiotics in patients with community acquired pneumonia.

- ◆ **Prescriber-related DUE:** A drug use evaluation completed on patients managed by a specific physician or physician group. For example, selected antibiotics may be limited to infectious disease specialists or drotrecogin alfa may be limited to critical care specialists.
- ◆ **Drug-specific DUE:** A drug use evaluation completed on a drug (medication).
- **FOCUS-PDSA:** A performance improvement model used by hospitals and health-systems. It includes the performance improvement elements of measuring the output of the process and modifying the process to improve the outcome.
- **Formulary restriction:** The act of limiting the use of specific formulary medications to specific physicians based on areas of expertise (e.g., cardiology), patient disease state (e.g., acute myocardial infarction), or location (e.g., operating room).
- **Formulary system:** An ongoing process whereby a health care organization, through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.
- **Health-system board:** A committee of hospital and community members chosen to govern the affairs of hospital or health-system.
- **Medical executive committee:** A committee of the hospital medical staff that has the primary authority for activities related to self governance and for performance improvement of the professional services provided by all practitioners privileged through medical staff process.
- **Medication use review:** A performance-improvement method that focuses on evaluating and improving medication-use processes with the goal of optimal patient outcomes.
- **Nonformulary agent:** A medication that is not a part of the drug formulary. This may be due to the medication not being considered for formulary addition or the medication being considered but the P&T committee choosing not to add it.
- **Open formulary:** A list of medications (formulary) which has no limitation to access to a medication by a practitioner.
- **Order entry rules:** Logic established within the hospital information system order entry module to notify prescribers of adverse effects, drug interactions, monitoring required or other actions required.
- **Outcome assessment:** A systematic process of evaluating the appropriateness, safety and efficacy of a medication. The process involves review of patient medical records to evaluate the drug use against predetermined criteria and standards.
- **Pop-ups:** Information that appears on a computer monitor when specific actions are taken. Hospital information systems often use *rules* to determine when *pop-ups* will occur. These pop-ups may contain clinical information about medication use, potential drug interactions, recommended monitoring, etc.
- **Stop orders:** Physician orders that are automatically terminated. The P&T committee may establish *stop orders* for medications that require additional evaluation after a specific time. Examples of stop orders are antibiotic

therapy stopped after 7 days and nesiritide therapy stopped after 24 hours.

- **Therapeutic class review:** An evaluation of a group of medications with an established therapeutic class (e.g., first-generation cephalosporins). The review evaluates the indications for use, pharmacokinetics/dynamics, adverse effects, drug interactions, dosage regimens, and cost to determine similarities and differences.
- **Therapeutic equivalent:** Drug products with different chemical structures

but of the same pharmacologic or therapeutic class and usually having similar therapeutic effects and adverse-reaction profiles when administered to patients in therapeutically equivalent doses.

- **Therapeutic interchange:** Authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines or protocols within a formulary system.



## Introduction

Medication use management describes the process used to assure the safe and effective use of drugs in a cost conscious manner. Key to medication management in the health-system environment is the formulary system. The formulary system is a mechanism for ongoing assessment of medications that are available for use. The system is managed by a committee of experts, which includes pharmacists and physicians.

This chapter will discuss the medication management system with focus on the following:

- Formulary system
- Pharmacy and therapeutics committee
- Formulary management
- Drug use evaluation
- Medication use policies
- Published formulary

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## The Formulary System

A drug formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and/or treatment of disease and promotion of health. It is often described as a list of medications routinely stocked by the health care system. The formulary was developed by hospitals in the 1950s as a management tool. It was initially used to assure that physicians had an adequate and consistent supply of medications for their day-to-day needs. A key purpose of the formulary was to discourage the use of marginally effective drugs and treatments.

Over time, the formulary has evolved beyond a simple list of medications. It is now one element of a system that includes medication use policies, a pharmacy and therapeutics committee, medication use evaluation, and formulary management. The formulary, today, can be more accurately defined as a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and/or treatment of disease and promotion of health.

Formularies are fundamental to the formulary system—defined as an ongoing process which methodically evaluates medications on an ongoing basis for inclusion or exclusion, establishes guidelines for optimal medication use, and develops policies and procedures for prescribing, dispensing, and administering medications. The formulary system is managed by the pharmacy and therapeutics committee or equivalent group—made up of an organized team of medication system experts.

There are advantages and disadvantages to a formulary system. The primary advantage is that it provides a systematic method to review scientific evidence on clinical effectiveness and cost effectiveness in drug selection decision, thus potentially improving health outcomes while reducing costs. A major disadvantage, however, is that an overly restrictive formulary system may potentially reduce the quality of care by limiting access to clinically indicated medications.



### Key Point . . .

The formulary has evolved beyond a list of medications to a system that manages the drug use process.

### . . . So what?

Standard definitions of formularies refer to them as static compilations of recommended medications in a pharmacy. In truth, they are really dynamic entities that consist of a constantly changing medication list, policies and procedures for managing that list, and tools used to encourage appropriate use of medications on that list—e.g., therapeutic substitution, drug utilization review).

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## The Pharmacy and Therapeutics Committee

The pharmacy and therapeutics committee (P&T committee) has oversight for medication management in the health-system. Specific regulatory or accrediting bodies may confirm this accountability. To be effective, the committee must have the support of the individual members as well as the health-system and medical staff as a whole.

### Organization

The committee is generally a policy recommending body to the medical staff through the **medical executive committee**—a group of the hospital medical staff in charge of institutional governance and performance. The committee is responsible to the medical staff as a whole, and its recommendations are subject to approval by the organized medical staff as well as the routine administrative approval process. More recently, in some organizations, the P&T committee has reported directly to a non-medical staff advisory committee of hospital and community members called a **health-system board** rather than a local medical executive committee.

Because drug products and medical literature are continually changing, meetings should occur at least four to six times per year. Generally, monthly meetings are needed to keep the meeting time to 60–90 minutes.

Subcommittees or task forces have been established to facilitate meeting efficiency. Examples of subcommittees include medication safety, drug review panels, and medication use review. The medication safety task force may be charged with review of adverse drug events and medication errors, their trending, and development of plans for preven-

tion of future events. Drug review panels may be focused on a particular specialty such as cardiology or infectious disease and review drug products and guidelines in their area of specialty. The medication use review task force may monitor one or more medications use reviews, evaluate the data and development plans to optimize specific drug use. Figure 4-1 illustrates how these subcommittees relate to the organizational structure of the P&T committee.

It is important to establish rules for a quorum to make certain that key stakeholders are represented at meetings. Such rules may establish a minimum number of members that must be present to conduct a meeting or a minimum number of member types that must be present to conduct a meeting. For example, a committee with 15 members might be required to have at least five members present of which two must be physicians and one must be a pharmacist before a quorum has been established.

### Committee Membership

P&T committee membership should include pharmacists, nurses, physicians, administrators, risk or quality improvement managers, and others as appropriate. These members are selected with the guidance of the medical staff. Medication management is a multidisciplinary process. Committee

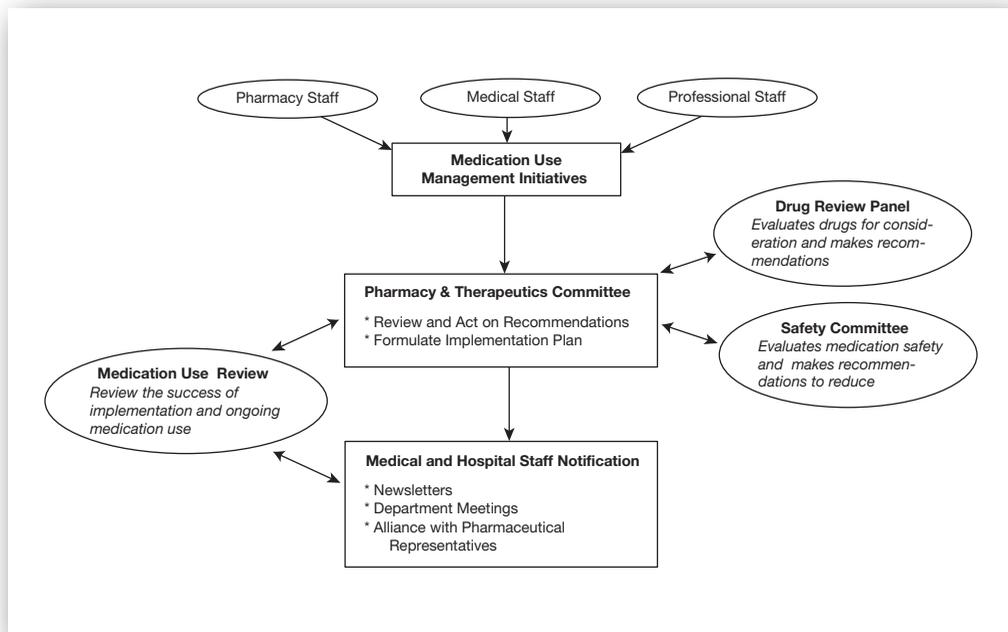
#### Key Point . . .

Medication management is a multidisciplinary process.

#### . . . So what?

Even though it is called the *Pharmacy and Therapeutics* committee, representation on the committee often includes physicians, nurses, and respiratory therapists given their roles within the medication use process. The collective efforts of all of the disciplines is needed to achieve optimal health outcomes.

**Figure 4-1.** Formulary management process.



membership should include nonphysician members such as nurses, respiratory therapists, and other health care professionals. While the voting members of the P&T committee in many hospitals remains the physician members only, this is changing as the committee membership is evolving.

### **Responsibilities**

The committee performs the following functions:

- Establishes and maintains the formulary system.
- Selects medications for formulary inclusion by considering the relative clinical, quality of life, safety, and pharmacoeconomic outcomes. Decisions should be balanced to all of the above. Decisions should include consideration of continuity of care (e.g., local health plan formularies).
- Evaluates medication use and related outcomes.
- Prevents and monitors adverse drug reactions and medications errors.
- Evaluates or develops and promotes use of drug therapy guidelines.
- Develops policies and procedures for handling medications to include their procurement, prescribing, distribution, and administration.
- Educates health professionals to the optimal use of medications.

### ***Formulary System Maintenance***

The committee develops a list of medications for use in the organization. They may also develop guidelines for the optimal use of the medications and/or for specific disease management. They review the medication list and guidelines on a regular basis to assure that it is current and meets the needs of the medical staff and patients.

### ***Medication Selection and Review***

The committee should have established methods for medication selection and review. A written medication review is prepared from available literature. The review should be unbiased, as should the discussion of the review. Meeting participants (committee members and guests) should be required to discuss any conflict of interests prior to discussion of the drug or drug class. Medication selection criteria should include medication efficacy, safety, and cost.

- Is it a duplication of an existing formulary agent? If so, is it more effective? Safer? Less costly?
- How should it be used?
- When should it be used?
- Who should use it?
- Are there any other special concerns?

Barriers to optimal formulary decisions may include physician experience with the drug under consideration, physician preference for other agents, detailing by pharmaceutical company representatives, and unpublished or anecdotal studies and reports. Selection criteria should be such to minimize the effect of the aforementioned barriers.

### ***Medication Use Evaluation***

Medication use evaluation (MUE) is the method for evaluating and improving medication-use processes with the goal of optimal patient outcomes. The P&T committee should establish a regular process for reviewing how medications are used in the health-system (i.e., medication use evaluation). Medications may be considered for review based

on their use, safety, cost or a combination of factors. For example, antibiotics represent a high use item; overuse of a particular antibiotic may place patients at risk for the development of resistant infections; and some antibiotics may also be costly. Establishment of specific criteria for use, review for compliance to the criteria, and routine review of the data is the foundation of the medication use process. Key to the process is timely data to review, action plan development, and follow-up.

### ***Medication Safety Evaluation***

Medication safety is evaluated through adverse drug reaction reports and medication error reports. Such reports may be local (i.e., from the health-system) or global (i.e., literature, press releases). The impact of such reports should be considered relative to the health-system population, resources, and alternatives. A report of increased bleeding in patients over the age of 65 may not be critical in a pediatric hospital. However, reports of infusion rate reactions may require changes in nursing procedures in drug administration. Such reports should be used in considering whether a drug should be added to the formulary, retained on the formulary, or deleted from the formulary.

### ***Drug Therapy Guidelines***

**Drug therapy guidelines** are a listing of the indications, dosage regimens, duration of therapy, mode(s) of administration, monitoring parameters and special considerations for use of a specific medication or medication class. In a hospital or health-system, these guidelines are developed with the oversight of practitioners with expertise in the use of a specific medication or management of a disease state. The guidelines are often put into practice via a pre-printed physician order sheet placed in the patient chart or computerized order set.

The development of drug therapy guidelines is often the result of a medication use review or medication safety evaluation. A review of this data may indicate that the drug is not being used in an optimal manner with regard to patient selection, dosage, frequency, route, length of therapy, or a combination. The development and implementation of drug therapy guidelines may foster the safe, efficacious and cost effective use of selected drug products. Education of the professional and medical staff to these guidelines is critical to their success. Just as important is a method for routine review of the guidelines to assure they are current.

### ***Policy and Procedure Development***

The P&T committee is responsible for medication use in the hospital. This includes the development of guidelines on historically pharmacy related topics of medication procurement, selection, and distribution. In addition, they are responsible for the medication administration process. This may include determining what medications are administered in specific locations for the hospital (i.e., intensive care unit) or under specific conditions (i.e., by chemotherapy certified nurse). Finally, they define the formulary management process, specifically, guidelines for the evaluation of medications by the P&T committee, frequency of such review, maintenance of the medication list, et cetera.

### ***Education***

The P&T committee must communicate its actions to health-system staff and physicians. A newsletter is often employed to communicate these decisions. The newsletter may also include clinical information on drugs added to the formulary, drug therapy guidelines developed, and medication safety information available. The success of a newsletter may be limited by the format and content. The newsletter should be visually pleas-

ing, easy to follow, and succinct. Optimally, it should be limited to two to four pages in length. The audience for the newsletter is generally broad and includes physicians, nurses, pharmacists, and other health care professionals. Other methods to communicate and educate others to P&T committee actions are presentation at medical staff department meetings, nursing unit staff meetings, and pharmacy staff meetings and electronic messaging through email or the health-system website. The P&T committee may also assist in the development of programs to educate health care professionals or patients regarding medications.

### **Regulatory and Accrediting Bodies**

Regulatory and accrediting bodies may require a P&T committee and define its membership and responsibilities. Regulatory bodies requiring such activity include the State Department of Health or Board of Pharmacy; this varies by state. Accrediting bodies requiring this activity include The Joint Commission, the American Osteopathic Association (AOA), and Commission on Accreditation of Rehabilitation Facilities (CARF). The facility type will define the accrediting body; each has a slightly different interpretation of the term *formulary*. Regulations and accreditation standards are dynamic and require vigilance by the pharmacy to assure compliance.

### **Pharmacist Role**

Pharmacists are essential to the formulary management process. Often pharmacists will guide the P&T committee activities to assure optimal medication management. The pharmacist responsibilities may include the following:

- Establish P&T committee meeting agenda.
- Analyze and disseminate scientific, clinical, and health economic information regarding a medication or therapeutic class for review by the P&T committee.
- Conduct drug use evaluation and analyze data.
- Record and archive P&T committee actions.
- Follow-up with research when necessary.
- Communicate P&T committee decisions to other health care professionals such as pharmacy staff, medical staff, and patient care staff.

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## **Formulary Management**

The formulary is the foundation of the formulary system. In its simplest form, the formulary is a list of medications available for use at a hospital or health-system. This list includes the dosage forms, strengths and package sizes of each of the medications on it. Diligent management of this list has both patient care and financial implications. Patient care considerations include medication efficacy and safety. Financial considerations are the cost of the drug as well as the costs associated with stocking the medication such as shelf space, drug outdates, and handling.

Formularies can be categorized by their access to medications as *open* or *closed*. An open formulary has no limitation to access to a medication. **Open formularies** are generally large. A **closed formulary** is a limited list of medications. A closed formulary may limit drugs to specific physicians, patient care areas, or disease states via *formulary restrictions*.

**Formulary restrictions** (i.e., limits on institutional drug use) do not necessarily translate to optimal medication management. For example, limitation of an antibiotic to

a *restricted* status may result in shifting to a different antibiotic. While sometimes this change is desirable, that may not always be the case. The *new agent of choice* may be more expensive or less safe than the *restricted* agent. Careful consideration of the impact of the formulary product selection and/or restriction is critical to the process. Some authors have suggested that restricting formularies has resulted in increased health care costs by increasing utilization of physician visits and hospitalizations.<sup>1,2</sup> While this data has been criticized, it is important to note the impact of formulary decisions in total health care costs.<sup>3</sup> The Institute of Medicine (IOM) evaluated the Veterans Administration (VA) *National Formulary* impact on health care costs in six closed or *preferred* class of drugs.<sup>4</sup> The IOM concluded that the VA National Formulary was cost saving, probably generating savings of \$100 million over 2 years and did not appear to have any effect on hospital admissions for selected heart or ulcer related conditions.

Drug product selection should be based on individual chemical entities. The Food and Drug Administration (FDA) defines the equivalence of individual chemical entities or generic equivalents. A list of such equivalents can be found in the Approved Drug Products with Therapeutic Equivalence Evaluation commonly known as the *Orange Book*. Policies for the use and dispensing of generically equivalent products should be set forth in the formulary system policy.

Many health systems have also established *therapeutic equivalents* and *therapeutic interchange* programs. **Therapeutic equivalents** are drug products with different chemical structure but are of the same pharmacologic and/or therapeutic class and are expected to have similar therapeutic effects and adverse effects. Examples of therapeutic equivalents include first generation cephalosporins and histamine-2 blockers. **Therapeutic interchange** is the authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines. Establishment of therapeutic equivalents extends beyond the chemical entity. It must include the dosage strength, dose frequency, and route of administration for the interchange. Examples of therapeutic interchanges are listed in Table 4-1.

The P&T committee should establish guidelines for generic substitution and therapeutic interchange. Such guidelines should include the following:

- The pharmacist is responsible for selecting generically equivalent products in concert with FDA regulations.
- Prescribers may specify a specific brand if clinically justified. The decision should be based on pharmacologic and/or therapeutic considerations relative to the patient.



### Key Point . . .

Formulary restrictions do not necessarily translate to optimal medication management.

### . . . So what?

Formulary restrictions often have unintended consequences. For example, strict limitations on the number of antibiotics used within a hospital may allow microbes a better chance of adapting to these few medications and developing antibiotic resistance in comparison to an institution with no restrictions on antibiotic use. The key is to carefully consider the potential impact of formulary restrictions prior to implementation and to monitor the actual impact after implementation.

Table 4-1.

**Therapeutic Interchange Equivalence by Therapeutic Class**

Therapeutic Class	Generic Name	Dosage	Dosage Frequency	Route
First generation	Cefazolin	1 g	Every 8 hr	IV
Cephalosporins	Cephalothin	1 g	Every 6 hr	IV
	Cephapirin	1 g	Every 6 hr	IV
H2 blockers	Cimetidine	300 mg	Every 6 hr	IV
	Ranitidine	50 mg	Every 8 hr	IV
	Famotidine	20 mg	Every 12 hr	IV

- The P&T committee determines therapeutic equivalents and how they are processed.

The pharmacist is responsible for the quality, quantity, and source of all medications, chemical, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients. Such products should meet the standards of the United States Pharmacopeia and the Food and Drug Administration.

Formulary maintenance is the ongoing process of assuring relative safety and efficacy of agents available for use in the health-system. Processes used in formulary maintenance include the following:

- New product evaluation
- Therapeutic class review
- Formulary changes (rationale for retaining or deleting an agent from the formulary)
- Nonformulary drug use review

**New Product Evaluation**

Pharmacists have the opportunity to assume a leadership role in the selection of agents to the formulary. The evaluation of an agent should consider the indications for use, pharmacokinetics, safety, and cost. Considerations to drug storage, mode of administration, special considerations, and drug-dispensing issues should also be included in the evaluation. Development of a standard format for new drug evaluations is useful in facilitating P&T committee discussions. Standard elements include the following:

- *generic name*—List officially approved name of all chemical entities in the drug product.
- *trade name*—List common trade name(s) of the drug product.
- *therapeutic or pharmacologic class*—State the pharmaceutical or therapeutic class to which the agent belongs. Similar agents within the class may be listed.
- *pharmacology*—Describe the mechanism of action and related pharmacologic effects of the drug. If the mechanism is unknown, state this.
- *pharmacokinetics*—Describe how the drug is handled by the body. Include onset of effect, serum half-life, metabolic considerations, and route of excretion as appropriate.
- *indications for use*—State the indications approved for use by the Food and Drug Administration. Include any additional uses under investigation.
- *clinical studies*—Briefly describe clinical study data supporting the indications for use. This review should be an unbiased, comparative review of studies, which identifies

strengths and weaknesses as appropriate. Study description should include information about the patient populations, inclusion and exclusion criteria, study design and protocol, statistical analysis, outcomes, and conclusions.

- *adverse effects/warnings*—List adverse effects associated with the drug and the frequency of occurrence. Describe methods to reduce or treat adverse effects. Discuss the risks and benefits of this drug therapy. Also, list any special precautions such as drug use in pregnancy and excretion of the drug into breast milk.
- *drug interactions*—List drug-drug and drug-food interactions associated with this agent, significance of these interactions, and methods for prevention.
- *dosage range*—List a dosage range for different routes of administration and indications for the drug. Include special dosing considerations for renal disease, age, and hepatic function.
- *dosage form and cost*—List the dosage form and strengths proposed for formulary addition. Include the cost of each dosage form and strength. A table listing comparable agents may be useful in determining the value of a formulary addition or modification.
- *summary*—Summarize the information provided in a single paragraph.
- *recommendation*—State the recommendation and rationale for the recommendation. Recommended actions may include formulary addition, formulary restriction, formulary deletion, or do not add to formulary.
- *references*—List references used. Reference materials useful in preparation of the formulary monograph should be unbiased and current. Peer-reviewed primary literature is optimal whenever possible. Other resources include textbooks such as *American Hospital Formulary Service Drug Information* and *Drug Facts and Comparisons*. Electronic databases such as DrugDex ([www.micromedex.com](http://www.micromedex.com)), Medline ([www.ncbi.nlm.nih.gov/entrez/query.fcgi?](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?)), and National Guideline Clearinghouse ([www.guideline.gov](http://www.guideline.gov)) are often useful.

In preparing the drug monograph, it is important to understand the P&T committee needs. Some committees desire a detailed analysis of the points listed above, whereas others prefer an abbreviated monograph. Critical elements to both are efficacy, safety, and cost. To assist the P&T committee membership, use of tables and comparative data within a therapeutic class or indication is useful. Knowing the cost of an agent is meaningless if the cost of comparator agents is unknown. The recommendation put forth by the pharmacist should be concise, include the rationale for the decision, any possible formulary dele-



#### Key Point . . .

Conditional approval allows the P&T committee to further assess the use and safety of the product before *final* formulary addition.

#### . . . So what?

A “wait and see” attitude often serves a P&T committee well when deciding to add a new drug. Many new drugs on the market can have insufficient evidence of safety because they only need to be tested on a limited number of patients prior to FDA approval. In addition, utilization patterns for the new drugs by physicians will also be unclear. Unexpected widespread adoption of a very expensive medication can bust the pharmacy drug budget. Conditional approval can help things from getting out of hand.

tions that might result by adding this agent, guidelines for use when appropriate, and consideration for future review. Some health systems add new agents to the formulary for a limited or *trial* period such as 3 or 6 months. This conditional approval allows the P&T committee to further assess the use and safety of the product before *final* formulary addition.

### **Therapeutic Class Review**

The regular review of drug classes by the P&T committee is useful in assuring that optimal drug therapeutic options are available. Therapeutic class reviews should not be so broad or all inclusive so as to not be meaningful. The review of antimicrobials may be too broad whereas the review of quinolone antibiotics may prove to be more useful. The committee may set forth criteria for these reviews. Such criteria might include new medical information, adverse event profiles, purchase or use data and cost. Some P&T committees conduct a therapeutic class review with each consideration for formulary addition. The objective is to have the optimal agents within a therapeutic class in terms of efficacy, safety, and cost. The end result of a therapeutic class review may be formulary modifications (i.e., additions or deletions), implementation of a drug use review or the development of therapeutic guidelines.

### **Formulary Changes**

A process to continually update the formulary must be established. Such a process should include a method for making additions and deletions to the formulary. This process typically involves the submission of a request for formulary addition or deletion from the pharmacy or medical staff. This request may be written or verbal. Requests generally require specific information.

- Agent to be considered for addition or deletion.
- Rationale for request. This should include the impact on the cost and quality of patient care.
- Alternative agents currently on the formulary.

Some organizations require or permit the requesting individual to attend the P&T committee to support their request.

### **Nonformulary Drug Review**

The objective of a formulary is to have the most efficacious, safe, and cost effective agents available for routine use in the health-system. On occasion, unique patient needs may require the use of a **nonformulary** agent. To prevent the erosion of the formulary system by overuse of nonformulary agents, a process for the management of nonformulary agents should be in place. Such a process should include a policy for the use of nonformulary drugs, procedure for procurement of nonformulary drugs, and regular review of nonformulary drug use by the P&T committee. The policy for use of nonformulary drugs should include pharmacist contact with the prescribing physician to offer alternatives. It may also include the completion of a nonformulary request form by the prescribing physician or authorization by the P&T committee chair prior to dispensing. The procedure for drug procurement should be well-defined and communicated to the pharmacy, medical, and nursing staff so that expectations are appropriately understood. Such a procedure may indicate up to a 24-hour delivery time for nonformulary medications. It may also permit the use of a patient's own medications in concert with other

hospital policies. The ongoing assessment of nonformulary drug use by the P&T committee is an important part in managing the medication process. Critical information for the committee to consider includes the agent used, formulary alternatives, number of times used in previous 6–12 months, patient safety, and cost impact. Understanding this information will allow the committee to determine an action plan. Such actions may include reconsideration of an agent for formulary addition, development of guidelines for use of a drug within a therapeutic class or disease state, or individual physician intervention.

A national survey of hospital pharmacy practice was conducted in 2007.<sup>9</sup> The authors described the various formulary techniques used in their hospitals (those aforementioned in this chapter). They noted the decline of all but two of these techniques: therapeutic interchange and nonformulary medication management. The use of clinical practice or drug therapy guidelines has become a key tool in managing drug use in the health-system.

A new and evolving method of formulary management has resulted from automating the medication prescribing process. Computerized prescriber order entry facilitates the implementation and compliance with drug therapy guidelines. Formulary management oversight includes the establishment and/or review of **order entry rules**. Such rules may include weight based dosing, required laboratory tests, and allergy checks. In addition, the responses (**pop-ups**) to the rules may be determined by the P&T committee through the formulary management process. Review of this information will be a key element in managing and monitoring medication use throughout the health-system.

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## Drug Use Evaluation

Drug use evaluation (DUE) is a systematic process used to assess the appropriateness of drug therapy by engaging in the evaluation of data on drug use in a given health care environment against predetermined criteria and standards. Medication use evaluation (MUE) encompasses the goals and objectives of DUE in its broadest application, with an emphasis on improving patient outcomes. Use of *MUE* rather than *DUE* emphasizes the need for a more multifaceted approach to improving medication use.

Medication use or drug use evaluation programs were first established in the 1980s. They provide an ongoing, structured, organized approach to ensure that drugs are used appropriately. More recently, the term *outcome assessment* has been used to describe such programs. The desired endpoint is the same—safe, efficacious drug therapy.



### Key Point . . .

Medication use evaluation (MUE) encompasses the goals and objectives of DUE in its broadest application, with an emphasis on improving patient outcomes.

### . . . So what?

In some respects, the differences between MUE, DUE, and outcomes assessment are arbitrary. Nevertheless, these definitions have evolved in response to a tendency for some pharmacists to only see medication use as it relates to the world of pharmacy. Therefore, compliance with formulary restrictions, pharmacy policies and procedures, and other processes are sometimes emphasized over the actual outcomes achieved by patients. Redefining terminology can refocus efforts of medication use evaluation toward achieving the goal of positive patient outcomes.

Medication use evaluation programs should be incorporated into the overall hospital performance improvement process. They should employ the performance improvement model used by the health-system. There are multiple performance improvement models. A common model used in health-systems is FOCUS-PDCA or (PDSA). The acronym is described below:

- Find process to improve
- Organize a team that knows the process
- Clarify current knowledge of the process
- Understand causes of process variation
- Select process improvement
- Plan
- Do
- Check (or Study)
- Act

Figure 4-2 illustrates a drug use evaluation using the PDCA model for antibiotic prophylaxis for surgery.

Pharmacists can take a leadership role in designing the drug use evaluation programs. The program should measure and compare the outcomes of patients who received drug therapy in concert with approved criteria versus those that did not. Selection of agents for drug use evaluation programs should be based on whether a drug is high-use, high-cost, or high-risk. Many drugs fall into more than one category: thrombolytic agents are high-cost and high-risk; select antibiotics may be high-use. Medication use criteria may be diagnosis-related, prescriber-related, or drug-specific.

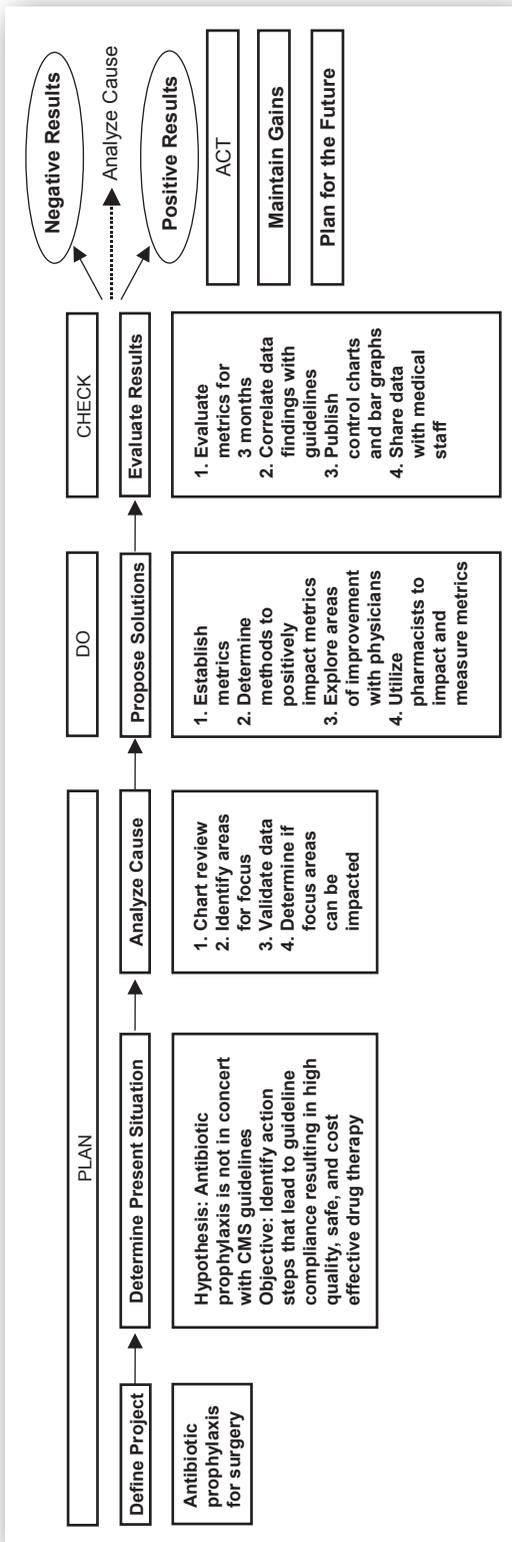
**Diagnosis-related DUE** criteria identify indications for which select drug(s) may be appropriate for a given disease state. For example, the use of selected antibiotics for community acquired pneumonia. Use of other antibiotics would fall outside the approved list and require follow-up.

**Prescriber-related DUE** criteria identify specific physicians whom the P&T committee has determined may use certain drugs. For example, selected antibiotics may be limited to infectious disease specialists or drotrecogin alfa may be limited to critical care specialists.

**Drug-specific DUE** criteria focus on specific aspects of a select drug such as the dose or dosing frequency. For example, the dosage regimen of a low molecular weight heparin might be reviewed. Dosage regimens outside the criteria would require action.

Pharmacists, working with key physicians, develop criteria for drug use evaluation. The criteria should be focused and limited. Select three to five criteria to evaluate that are meaningful and simple to collect. If possible, data should be collected during the patient visit (concurrent) rather than retrospectively (chart review). Concurrent review often is more complete. It allows the pharmacist to obtain information from the prescriber that may not have been clear in the medical record. It also provides timely information to act on. Because medical information is dynamic, the most meaningful drug use evaluations should reflect current practice patterns rather than those of 6–18 months ago. The criteria should also include a number of patients to be reviewed and the time period. For example, “20 patients each month” receiving the drug are reviewed. The drug use evalu-

**Figure 4-2.** PDCA Model: Antibiotic prophylaxis for surgery patients.



ation criteria are presented to the P&T committee for their review and endorsement prior to commencing data collection.

Technology may be used to collect or screen data. Use of information systems to identify patients for review and collate the data will facilitate the process. Hand-held computers or personal data assistants (PDAs) may be useful in the data collection process.

Once the data has been collected, it should be compiled for review. The use of trend graphs or control charts are helpful in identifying opportunities for improvement. The result of a drug use evaluation may be validation that drug use is appropriate and safe. However, it may also indicate an opportunity for improving the way a drug is used. Once the data is collated, it may be beneficial to form a task force to develop an action plan. This task force should include key physicians, nurses, pharmacists, and other health care professional appropriate to the drug therapy under review. The task force should develop an action plan and criteria for ongoing monitoring. The action plan may include development of drug use guidelines, preprinted orders, medication order entry *rules*, professional staff education, formulary changes, or a combination of these actions. The drug use evaluation results

and action plan are presented to the P&T committee for consideration. The committee will review and endorse and/or modify the plan for implementation and follow-up. A single drug use evaluation should not continue indefinitely. Once the desired endpoint has been achieved, an ongoing review may be discontinued or conducted less frequently (e.g., once or twice a year).

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## Medication Use Policies

Medication use policies are critical in the management of medications in the health care settings. Such policies should include the following:

- Formulary management
- P&T Committee
- Medication prescribing, dispensing, and administration

### Formulary Management

Formulary policies should include information on who may use a specific agent (formulary restrictions), how a drug is added or deleted from the formulary, how a drug is stocked, and which drugs are stocked. The formulary restriction policy should specifically define how items are selected for formulary restriction, rationale for selecting approved prescribers, and a method for managing the process. A formulary policy should describe the method for drug addition and deletion as well as nonformulary drug use. A policy should describe how an agent is added to the pharmacy stock once it is added to the formulary and who gets to decide. For example, the P&T committee approves the addition of a chemical entity added and the pharmacy manager selects dosage forms, strengths, et cetera, or the P&T committee determines the chemical entity and dosage form(s) and the pharmacy manager selects the strengths or sizes to be stocked. The basic policies and procedures governing the formulary system should be incorporated in the medical staff bylaws or in the medical staff rules and regulations.

### Pharmacy and Therapeutics Committee

The policy should address the committee membership, operation, and responsibilities.

### Medication Prescribing, Dispensing, and Administration

Organizational policies on the prescribing, dispensing, and administration of pharmaceuticals are required and necessary to ensure safe medication use. Such policies should address all aspects of the medication process.

- *writing medication orders or prescriptions*—Defines practitioners that may write medication orders or prescriptions in concert with state and federal regulations. This or related policies may also include the format for order writing and unacceptable abbreviations.
- *verbal orders*—Defines who may accept a verbal order and the transcription process of such an order. This policy should address the reading back of the order to confirm its accuracy.
- *stop orders*—Defines the orders that are automatically terminated, how the prescriber is notified, if appropriate, and the method for their reinstatement. Stop orders are often established for medications that require additional evaluation after a specific time. Examples of stop orders are antibiotic therapy stopped after 7 days and nesiritide therapy stopped after 24 hours.

- *investigational drug orders*—Defines how investigational drugs are managed in the health care system. This policy should include the review process as well as the method for prescribing, dispensing, administering, and monitoring investigational agents.
- *controlled substances*—Defines the flow of controlled substances through the health care system. This policy should include approved prescribers, the ordering process from the pharmacy and the vendor, the distribution and tracking of use, discrepancy tracking and follow-up, and management of diversion.
- *generic and therapeutic substitution*—Defines how a drug is selected for generic substitution and therapeutic equivalents approved by the P&T committee. It should describe how an alternative agent may be prescribed if deemed medically necessary.
- *self-administration of medications*—Defines the conditions and process for the administration of medication by the patient in the hospital setting.
- *medication samples*—Defines the conditions and process for the use of medication samples in the hospital or clinic setting.
- *floor stock*—Defines the criteria for selecting agents for floor stock, process for modifying the stock, and the regular review of the stock by the P&T committee.
- *definition of order interpretation*—Defines the meaning of specific types of orders including sliding scale orders, range orders, as needed orders, tapering orders, and titrating orders.
- *medication administration times*—Defines specific medication administration times and rules for interpretation. This may include the definition of *stat* and related terminology.
- *adverse drug reactions*—Defines an adverse drug reaction, the reporting process, and monitoring methods.
- *medication errors*—Defines a medication error, the reporting process, and monitoring methods.
- *others*—Other topics for policy consideration include pharmaceutical representatives, pharmacy hours of service, emergency medications, and medication delivery devices.

#### Key Point . . .

Organizational policies on the prescribing, dispensing, and administration of pharmaceuticals are required and necessary to ensure safe medication use.

#### . . . So what?

Policies are developed for common, well understood problems seen in the medication use process. They are designed to ensure that the products and services provided by a pharmacy are of consistent high quality. Rather than re-inventing the wheel each time a problem occurs, clear directions are given delineating responsibilities and actions. Policies are not meant to replace professional judgment of pharmacists (e.g., I know it is a bad idea. I am just following our policy). They are meant to supplement and guide pharmacist decision making.

## Published Formulary

The published formulary should provide information on the medications approved for use, basic therapeutic information about each item, information on medication use policies and procedures, and special information about medications such as dosing guidelines, etc.

## Medication List

The key element of the published formulary is the list of medications approved for use. This section includes both entries for each medication and indexes to facilitate use.

Medication entries may be arranged alphabetically by generic name and trade (synonym) name, therapeutic class, or a combination. At a minimum, each drug entry should include the following:

- *generic name of primary active ingredient*—Combination products may be listed by generic ingredients or trade name.
- *trade or synonym name that is commonly used*—A disclaimer in the introduction to the formulary should explain that the presence or absence of a trade name does not imply that it is or is not the agent stocked by the pharmacy.
- *dosage form, strength, and size stocked by the pharmacy*
- *active ingredients (formulation) for combination products*

Additional information that may be added:

- *DEA schedule (C-II through C-V)*
- *special precautions*—Such as for im use only and protect from light.
- *pediatric or adult dosage ranges*
- *cost information*—Some health-systems have chosen not to publish actual purchase prices for confidentiality reasons but rather to list a cost scale to allow for price comparisons. Cost information is most useful when drugs are arranged within a therapeutic group or class to allow for easy comparison.

The medication list should include one or more indexes. The index should assist the user in locating the medication entry by generic name. The index should include both generic and trade name entries. The trade name entry may state “see generic name, page 123.” Such an index may be incorporated into the formulary itself. If that is done, then the formulary listing should be alphabetical and include both generic and trade names. A second index type is the therapeutic index. This index arranges drugs generically by therapeutic or pharmacologic class. It is particularly useful for the prescriber that is not familiar with the formulary of a health-system and desires to prescribe a certain type of drug (i.e., ACE inhibitor).

## Medication Use Policy and Procedures

Inclusion of information on the prescribing, dispensing, and administration of medications in the published formulary provides a quick reference for health care providers. Either selected policies may be published or key information summarized in an abbreviated format. Policies for inclusion are the formulary policy, P&T committee policy, and organizational regulations regarding medication use. Information on pharmacy operating procedures may be beneficial. These would include hours of services, prescription policies, medication distribution procedures, contact information and other pharmacy services such as anticoagulation monitoring or pharmacy newsletters.

## Medication Use Guidelines

This section should detail guidelines for medication use, which are approved or endorsed by the P&T committee. Such guidelines may include preprinted orders and clinical pathways that have been developed. Examples of medication use guidelines are provided below.

- Antibiotic use guidelines
- Antibiotic use in surgical prophylaxis
- Community acquired pneumonia clinical pathway
- Weight-based heparin orders
- Potassium replacement orders
- ICU sedation guidelines
- Thrombolytic therapy guidelines for stroke
- Alcohol detoxification orders

### Special Information

The information in this section is health-system specific. It should be tailored to the needs of the professional and medical staff based on the services provided by the health-system and the pharmacy. Examples of topics to include are below.

- Nutritional products approved for use
- Equivalent dosage tables (e.g., pain medications, corticosteroids)
- Parenteral nutrition formulas
- Pediatric dosages
- Potassium content of drugs or foods
- Antidote list
- Advanced Cardiac Life Support (ACLS) or emergency medication list and dosages
- Metric conversion table
- Serum drug levels
- Standard concentrations of drugs in IV solutions
- Common equations used (e.g., ideal body weight, estimated creatinine clearance, anion gap)
- Antibiograms
- Drug dosing in renal or hepatic dysfunction
- Examples of forms that are routinely used such as nonformulary drug requests, adverse drug reaction reports

### Publishing the Formulary

The formulary must be published regularly. The medication list should be readily available to all personnel involved in the medication process. Electronic versions of the formulary may be preferable. Copies of the formulary should be made available where medications are prescribed, administered, and dispensed. Printed formularies are often revised and printed annually. A method should be established for updating the formulary between editions.

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## Summary

The pharmacist plays a critical role in the management of medication use in the health-system. As the drug expert, the pharmacist can assure safe, efficacious, and cost effective drug use through the formulary system. Ongoing formulary maintenance and routine drug use evaluations are key elements in this process. Focused consideration of medication safety in all medication related discussions optimizes formulary system management.

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## Chapter Review Questions

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1. **The following elements of the formulary system are used to manage drug costs (select all applicable).**
  - a. Therapeutic interchange
  - b. Nonformulary drug use
  - c. Generic substitution
  - d. Drug Therapy guidelines

Answer: a, c, d. Nonformulary drug use often drives up drug costs in a health-system.

2. **Once the formulary has been established, no further action is required except to add new pharmaceutical entities as they become available.**
  - a. True
  - b. False

Answer: b. False. The formulary must continually be evaluated for additions and deletions.

3. **P&T committees may have subcommittees to facilitate specific objectives. Examples of subcommittees include (select all applicable)**
  - a. Medication Safety
  - b. Antibiotic/Infectious Disease
  - c. Laboratory Testing

Answer: a, b. Laboratory testing is not under the purview of the P&T committee; but rather the pathology committee of the medical staff or health-system.

4. **When selecting a drug for formulary addition, which of the following should be considered? (select applicable)**
- Does it come in unit dose packaging?
  - Is it a duplication of an existing formulary agent?
  - How should it be used?
  - Is it safer than similar agents already on formulary?
  - Will the vendor give the health-system free samples?

Answer: b, c, d.

5. **The \_\_\_\_\_ is responsible for oversight of all medication use in the hospital.**

Answer: Pharmacy and therapeutics (P&T) committee.

6. **Therapeutic interchange is the**
- Interchange of generic equivalents
  - Interchange of chemically different drugs within the same pharmacologic or therapeutic class
  - Interchange of chemically different drugs within the same pharmacologic or therapeutic class in accordance with approved written guidelines

Answer: c. Therapeutic interchange must be approved prior to implementation.

7. **Medication use evaluation is a systematic approach to monitoring drug therapy and associated outcomes. The optimal data collection period is \_\_\_\_\_**

Answer: Concurrent or during the patient visit.

8. **The Pharmacy and Therapeutics Committee is a multi-disciplinary committee including physicians, pharmacists, and nurses.**

- True
- False

Answer: a. True. While pharmacists and nurses may not be permitted to vote, they are important members of the committee.

9. **The rationale for completing a drug use evaluation is to**
- Validate drug use is safe and appropriate.
  - Determine the most common prescribers of a specific drug.
  - Educate the nursing staff on appropriate medication administration.

Answer: a. DUE monitoring criteria often include indication for use and adverse events as well as other criteria such as dose, frequency, route of administration, etc.

10. **The pharmacist is *not* responsible for assuring the following**
- Quality, quantity and source of all medications in the health-system.
  - All medications in the health-system meet FDA and USP standards.
  - All brands of formulary agents are available for use in the health-system.

Answer: c. Formulary systems seek to reduce the number of brands of medication because offering all brands is inefficient and costly.

## Chapter Discussion Questions

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1. How do formularies influence medication use within institutions?
2. How can pharmacists take a leadership role in the formulary management?
3. What are key elements in successful and efficient operation of a Pharmacy and Therapeutics Committee?
4. How are Drug Use Guidelines incorporated into the formulary management process?