

# **Drug and Therapeutics Committee Training Course**

## **Session 1: Drug and Therapeutics Committee— Overview**

Participant's Guide

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## **PURPOSE AND CONTENT**

The Drug and Therapeutics Committee (DTC) is the cornerstone of a health care organization's drug use and distribution program. This committee has many different functions that will contribute significantly to the goal of providing rational drug use. This session provides an overview of the role and functions of a DTC and describes all aspects of this important committee.

This training series is intended for practitioners who serve on a Drug and Therapeutics Committee. The emphasis of this session and of the entire training series is on the technical aspects of a DTC, including drug selection for the formulary, management of drug expenditures, and identifying/resolving drug use problems. Participants are referred to other sources for information on the implementation of a new DTC. The World Health Organization's forthcoming manual "Drug and Therapeutics Committees—A Practical Guide to Structure and Functions" will be a valuable resource.

## **Objectives**

After attending this session, participants will be able to—

- Understand the role of the Drug and Therapeutics Committee
- Understand the functions of a DTC, including advisory responsibilities, formulary management, developing drug distribution policies, promoting rational drug use, and providing quality assurance programs
- Understand the structure and organization of the committee and its relationship to other hospital committees
- Discuss the importance of the DTC in promoting rational drug use
- Describe the importance of the committee in managing antimicrobial use and decreasing the emergence of antimicrobial resistance

## **Preparation and Materials**

- Read Participant's Guide.

## **Further Readings**

American Society of Hospital Pharmacists. “ASHP statement on the Pharmacy and Therapeutics Committee.” *Am J Hosp Pharm* 1992;49:648–52.

Management Sciences for Health. *Managing Drug Supply*. Second Edition. West Hartford, CT: Kumarian Press. 1997: Part III Section A and Part IV Section A Chapter 38.

Management Sciences for Health (MSH). *Manual for the Development and Maintenance of Hospital Drug Formularies*. Arlington, VA: MSH. April 1996.

## INTRODUCTION TO THE DRUG AND THERAPEUTICS COMMITTEE

A health care organization's Drug and Therapeutics Committee has numerous responsibilities that, when performed successfully, will have a very positive impact on the health care system. The overall value of the DTC is not easily measured, but most authorities agree that it is one of the more important components in a comprehensive health care system. Some of the important benefits of a functioning DTC are—

- Selection of effective, safe, high-quality, and cost-effective pharmaceuticals for the formulary
- Control and management of drug expenditures
- Improved rational drug use, including antimicrobial utilization
- Improved drug procurement and inventory management
- Increased staff and patient education levels on matters related to drug use
- Decreased adverse drug reactions and medication errors

Many countries will spend 30 to 40 percent of their health care budgets on drugs and much of that money is wasted on irrational drug use and inefficiencies in procurement of drugs. Other serious problems that health care organizations face are the overuse of antibiotics, increasing antimicrobial resistance, increasing adverse drug reactions, and considerably higher costs associated with drug use. DTCs can provide the leadership and structure to select appropriate drugs for the formulary, promote rational drug use, and help reduce drug costs to acceptable levels.

## KEY DEFINITIONS

**Drug and Therapeutics Committee (DTC)**—The committee that evaluates the clinical use of drugs, develops policies for managing drug use and administration, and manages the formulary system\*

**Formulary Committee**—The committee dedicated to selecting, developing, and maintaining a list of approved drugs for the hospital or clinic

**Formulary**—The document that describes drugs that are approved for use in the hospital, clinic, or health care system

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\* American Society of Hospital Pharmacists. "ASHP statement on the Pharmacy and Therapeutics Committee." *Am J Hosp Pharm* 1992;49:648–52.

**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

## **ROLE OF THE DRUG AND THERAPEUTICS COMMITTEE**

The role of the DTC is to optimize rational drug use by evaluating the clinical use of drugs, developing the policies for managing drug use and drug administration, and managing the formulary system. The DTC has the responsibility to promote rational drug use through education of professional staff, patients, and their families. The committee has broad responsibilities in determining what drugs will be available, at what cost, and how they will be used.

## **FUNCTIONS OF THE DRUG AND THERAPEUTICS COMMITTEE**

The functions of a DTC are numerous and may be only partially performed by many committees. The most important functions are—

- Advising medical, administrative, and pharmacy departments on drug related issues
- Developing drug policies and procedures
- Evaluating and selecting drugs for the formulary and providing for its periodic revision
- Assessing drug use to identify potential problems
- Promoting and conducting effective interventions to improve drug use (including educational, managerial, and regulatory methods)
- Managing adverse drug reactions
- Managing medication errors

### **Advising Medical Staff, Administration, and Pharmacy**

The DTC is a valuable asset to the medical staff, administration, pharmacy, and other departments within the health care organization. The committee provides advisory services to these departments on all aspects of drug selection, use, and distribution. Typically, the DTC provides recommendations and advice, while the executive or medical staff committee takes action on these recommendations and implements approved decisions.

There are many other departments and services that would benefit from the DTC and its advisory services. These include the nursing department, public health, Infection Control Committee, vaccination programs, and private health care sector drug management programs.

## **Developing Drug Policies**

The DTC is responsible for developing drug policies in the health care organization. These policies are necessary to adequately control important aspects of drug selection, purchase, distribution, use, and administration. The DTC is the logical choice for doing this, since its members have the most experience and training in drug therapy and distribution. Policies and procedures are generally the first order of business in the committee, as they will provide the foundation for other functions that evolve from the committee. Besides general policies about drug use, the following specific policies should be in place:

- Addition of new drugs
- Nonformulary drugs
- Restricted drugs
- Investigational drugs
- Generic substitution and therapeutic interchange
- Automatic stop orders
- Structured order forms and guidelines
- Standard treatment guidelines, critical pathways, and treatment algorithms
- Drug representative and promotional literature

The development of comprehensive policies and procedures are critical to the success of the DTC. These policies will provide the framework for implementing improvements in drug selection and use.

## **Evaluating and Selecting Drugs for the Formulary**

One of the most important functions of the DTC is the evaluation and selection of drugs for the health care organization's formulary. Evaluating drugs and consequently approving or rejecting them requires significant expertise and commitment from the committee.

The evaluation of drugs will require a rigorous approach that looks at documented efficacy, safety, quality, and cost of all drugs requested for the formulary. There is also a need for a system of periodic review of drugs on the formulary as the information base about drugs is constantly changing. These changes may be reflected in new indications, information about efficacy, safety, and comparative information with other drugs. The cost of a drug, whether it is a new drug or a generic that has been on the formulary for many years, may change frequently and requires frequent evaluation. Consistent decision making is necessary in the selection of drugs and involves—

- Evidenced-based medicine
- Consideration of local context
- Transparent evaluation process

The evaluation of drugs for the formulary includes the review of generic drugs and other therapeutic equivalents so the most cost-effective formulary for the hospital and primary care clinic can be established.

The evaluation process should include review of the primary drug literature (especially randomized controlled trials), published standard treatment guidelines, pharmaco-economic studies, review articles, and reliable textbooks.

## **Assessing Drug Use to Identify Problems**

The DTC should assess the quality of care (related to drug use) in a consistent, ongoing fashion. This component is an important and frequently overlooked responsibility of the committee. Time and attention here will have significant return in the long term with improved quality of drug therapy, improved patient outcomes, and decreased drug cost. There are several drug management areas that need to be assessed to identify drug use problems—

- Drug procurement and availability
- Drug distribution
- Drug prescribing
- Administration/use
- Adverse drug reaction reports
- Medication error reports
- Antimicrobial resistance surveillance reports

There are many different methods to assess quality of care, including the following that will be discussed in this training series: ABC/VEN analysis, aggregate data analysis, health care indicator methodologies, and drug use evaluation.

## **Promoting Effective Interventions to Improve Drug Use**

Irrational drug use is a common problem present in all health care systems worldwide. This irrational use contributes to poor patient outcomes and wastes valuable resources. Promoting and implementing effective interventions are necessary to ensure rational drug use. Important interventions to improve drug use are as follows:

- Educational
  - Educational programs for the professional staff
  - Educational programs for patients and their families

- Managerial
  - Development of standard treatment guidelines
  - Drug use evaluation
  - Clinical pharmacy programs
  - Structured order forms
  - Automatic stop orders
- Regulatory
  - Drug registration
  - Professional licensing

## Managing Adverse Drug Reactions

The committee must address the issue of adverse drug reactions (ADRs) to medications on a regular basis. ADRs are a serious problem with increasing incidence, as more drugs become available and more people become exposed to them. In the United States, a recent review of prospective studies showed that hospitalized patients in 1994 had 2.2 million adverse drug reactions (6.7 percent incidence) and 106,000 fatalities.\* Other studies have shown that hospital admissions resulting from adverse drug reactions account for three to seven percent of all admissions. These statistics are just astounding. They become more significant when you consider that the statistics in these studies do not include errors of administration, which would only increase the total incidence of morbidity and mortality. The Lazerou et al. study has received criticism from a number of authorities concerning the meta-analysis methodology, but the study still indicates at the very least that there is a significant problem in adverse drug reactions in the United States.

The DTC should have a plan to address the problems of adverse drug reactions including regular monitoring, assessment, reporting, and prevention.

Newly released drugs can be particularly bothersome because of lack of knowledge and inadequate clinical experience associated with them. The current trend to “fast track” pharmaceuticals into distribution is also increasing the incidence of adverse side effects, as these new drugs may not have been adequately tested prior to release by regulating authorities. Older drugs may produce just as many side effects, but their effects are largely known and can be anticipated and prevented in many instances.

## Managing Medication Errors

Medication errors may occur in the prescription of a drug, in the preparation and dispensing by a pharmacist, in the preparation and administration by a nurse, and when a patient takes the drug. This is a pervasive problem that occurs with all persons who handle medications. The cause of errors are numerous and include lack of knowledge, fatigued employees, careless work attitudes,

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\* Lazarou, J, Pomeranz, BH and Corey, PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA* 1998 Apr 15;279(15):1200–5.

poor procedures for drug distribution, and mental mistakes. Errors will occur no matter how ideal a health care setting may be. Therefore, it is incumbent on the DTC to provide the mechanism to monitor, assess, and prevent medication errors.

## **ETHICAL CONCERNS OF THE DTC**

The committee needs to operate in a manner that ensures transparency and avoids conflicts of interest with manufacturers and distributors of drugs or medical supplies. In order for the committee to maintain objectivity and credibility, it is necessary that a strict ethics policy be provided and rigorously enforced. There can be no relationships with the pharmaceutical companies other than a purely professional one that encourages the flow of unbiased information about their drug products.

## **DTC STRUCTURE AND ORGANIZATION**

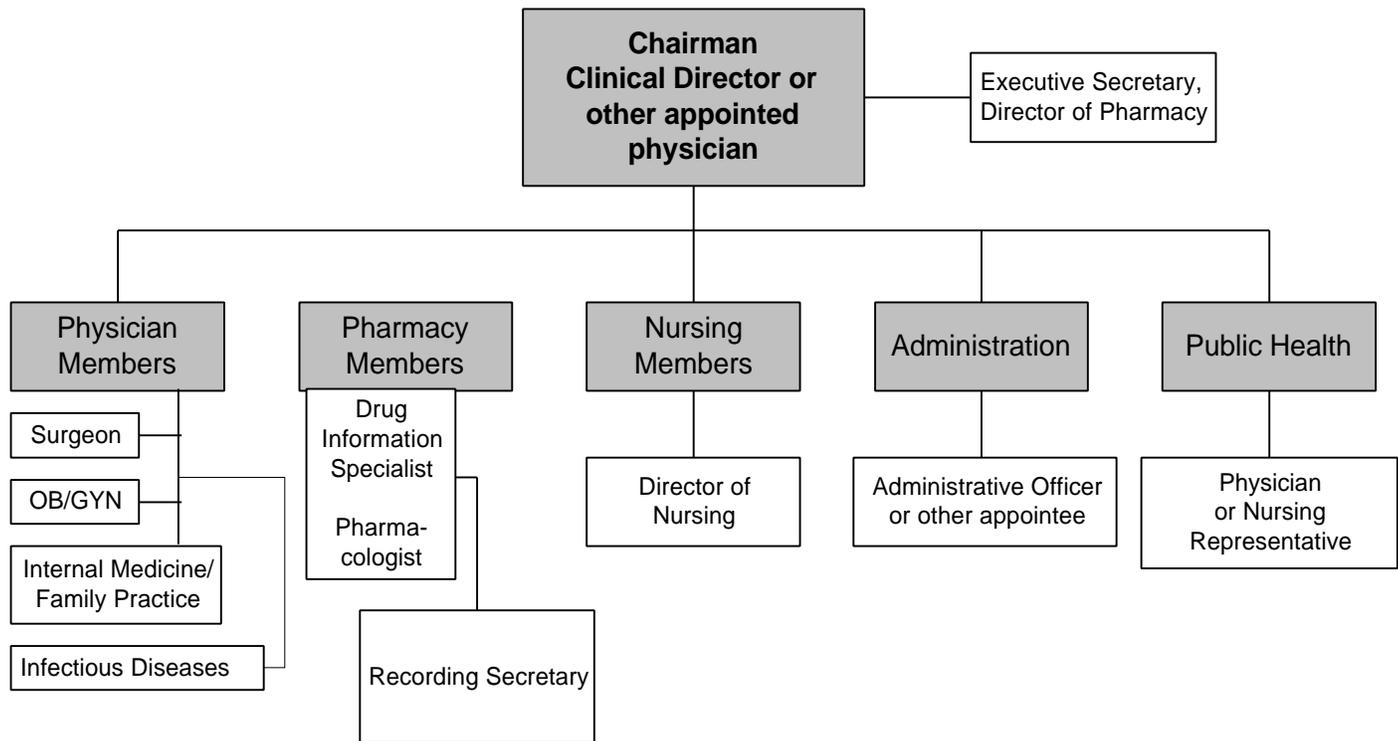
The DTC is usually made up of health care professionals from the medical staff, medical staff specialists, pharmacists, nursing personnel, and representatives from administration. Although this mix of personnel would provide the most input from diverse segments of the health care organization, there is no single method that would dictate who is on this committee. Since the committee regulates to a large extent what physicians will be prescribing and how pharmacists are involved with drug therapy and logistics, it is obvious that these professionals will need a significant voice on the committee.

Ideally, a well-known and respected physician will provide leadership for the committee, with a pharmacist as co-chair or executive secretary. These individuals should be appointed by the health care organization's administration. Figure 1 illustrates the typical organization of the DTC.

When specific drugs are being considered, the committee may invite specialists to participate in meetings as needed. These individuals do not have voting privileges. Subcommittees may be formed to carry out specific tasks, e.g., therapeutic class review of antimicrobial drugs or the development of a medication error prevention strategy.

It is very important that the DTC meet regularly, at least three to six times a year. If necessary, the committee will need to enforce mandatory attendance to accomplish the functions of the committee. Minutes are prepared for each meeting and distributed to appropriate medical, nursing, and pharmacy departments.

Figure 1. Drug and Therapeutics Committee Organization Chart



## Antimicrobial Subcommittee

Many DTCs have found it necessary to form an associated subcommittee of the DTC, one that deals solely with antimicrobials. The purpose and goal of this subcommittee is to ensure that safe, effective, cost-effective antimicrobials are made available to the health care organization. This subcommittee also dedicates itself to ensuring that antibiotics are used only when clinically indicated, at the correct doses, and for the appropriate duration of time. The subcommittee must also ensure that patients are taking these drugs correctly, as this may have a profound effect on treatment outcomes and the prevention of antimicrobial resistance.

Functions of the antimicrobial subcommittee are similar to the DTC, but with an emphasis on antimicrobial drugs. Ideally, an antimicrobial subcommittee would function as follows:

- Address issues relating to antimicrobials including correct prescribing
- Develop policies concerning use of antimicrobials for approval by the DTC and medical staff; policies should specifically include sections on methods to limit and restrict use of antimicrobials in the hospital and primary care clinics
- Assist in evaluating and selecting antimicrobials for the formulary
- Assess and monitor antimicrobial sensitivities and resistance patterns in hospitals and primary care clinics; prepare monthly reports of these activities and disseminate to appropriate departments and health care professionals

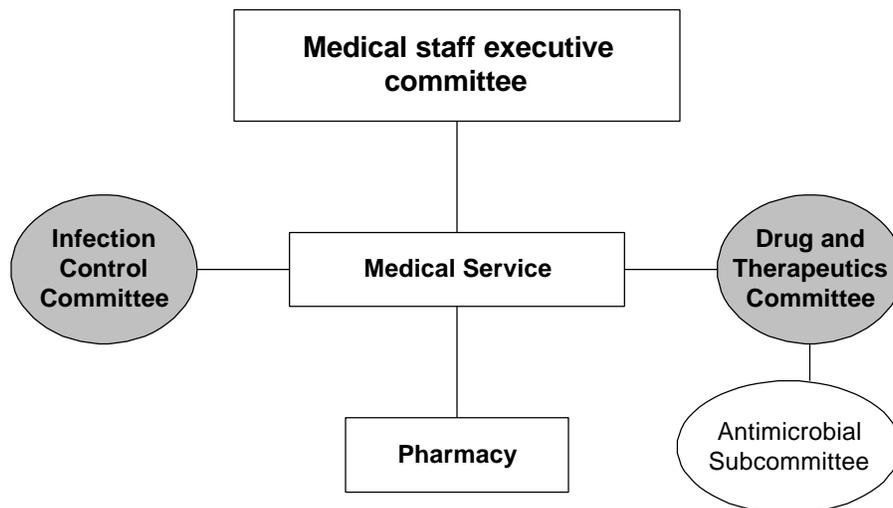
## Infection Control Committee

The Infection Control Committee is the committee that oversees the hospital's infection control, prevention, and monitoring programs. This committee operates independently of the DTC, but frequently relies on the DTC's advisory function. The committee is involved with environmental issues such as food handling, laundry handling, cleaning procedures, visitation policies, and direct patient care practices, including hand washing and immunizations. Infection Control Committees perform the following major functions:

- Obtain and manage critical bacteriological data and information, including surveillance data
- Develop and recommend policies and procedures pertaining to infection control
- Intervene directly to prevent infections
- Educate and train health care workers, patients, and nonmedical caregivers
- Recognize and investigate outbreaks of infections in the hospital and community

Figure 2 illustrates the organizational structure of these committees within the health care organization.

**Figure 2. Health Care Organization Structure**



## ACTIVITY

### Review of the Participants' DTC

In order to start our activities for this DTC training program, it would be helpful to review the kinds of programs that your DTC provides. Please take a few minutes and answer the following questions using the Drug and Therapeutics Committee Questionnaire (p. I-13). Please tear the completed form from your Participant's Guide and hand it in to the session moderator.

- Do you have a Drug and Therapeutics Committee at your hospital or clinic?
- What is the role of this committee?
- What are the major functions of the committee?
- What professional staff members are represented on the committee?
- How often does the committee meet?
- How many members does the committee have and how many typically attend meetings?
- Does your committee (or another department) routinely evaluate new requests for the formulary?
- What sources of information are utilized to evaluate drugs for the formulary or essential drugs list?
- Does your committee regularly review the formulary for availability of the most effective, safe, and cost-effective drugs?
- Does your DTC have activities to identify drug use problems? What kind of activities do you use?
- Does your DTC have programs to improve drug use problems? What are these programs?
- What is the role of pharmaceutical companies or suppliers in providing information on new drugs and promoting drugs in your institution?
- What are some major accomplishments of the committee?
- What are the major drawbacks?
- What would you like to see accomplished with your committee?

## **SUMMARY**

The Drug and Therapeutics Committee should be a dynamic, integrated, and productive organization that deals with all issues concerning drugs and drug therapy. The committee can provide leadership in promoting rational drug use.

Important functions of the committee include—

- Advising medical, administrative, and pharmacy departments
- Developing drug policies
- Evaluating and selecting drugs for the formulary and providing for its constant revision
- Assessing drug use to identify potential problems
- Promoting effective interventions to improve drug use including educational, managerial, and regulatory activities
- Managing adverse drug reactions and medication errors

**DRUG AND THERAPEUTICS COMMITTEE QUESTIONNAIRE**

DTC Question	Answer	Comments
Do you have a DTC at your hospital or clinic?		
What is the role of this committee?		
What are the major functions of the committee?		
What professional staff members are represented on the committee?		
How often does the committee meet?		
How many members does the committee have and how many typically attend meetings?		
Does your committee (or another department) routinely evaluate new requests for the formulary or essential drugs lists?		
What sources of information are utilized to evaluate drugs for the formulary?		
Does your committee regularly review the formulary for availability of the most effective, safe, and cost-effective drugs?		

**Drug and Therapeutics Committee Questionnaire (continued)**

DTC Question	Answer	Comments
Does your DTC have activities to identify drug use problems? What kind of activities do you use?		
Does your DTC have programs to improve drug use problems? What are these programs?		
What is the role of pharmaceutical companies or suppliers in providing information on new drugs and promoting drugs in your institution?		
What are some major accomplishments of the committee?		
What are major drawbacks?		
What would you like to see accomplished with your committee?		