

Contemporary Issues Affecting P&T Committees

Part I: The Evolution

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ORIGIN OF FORMULARY SYSTEMS AND P&T COMMITTEES

The Formulary

Medication formularies should represent the objective and unbiased clinical judgment of physicians, pharmacists, and other specialists in terms of the appropriate use and selection of pharmaceuticals for the prevention and treatment of disease in patients within health care organizations. Formularies should be continually revised to reflect the current state of knowledge.

The primary objectives of a formulary are to provide the following:¹

- a list of medications available for use within the organization
- basic data about each item (e.g., generic name, strength and dosage form, usual dose, and cost)
- appropriate policies and procedures governing the use of medications
- additional information about medications (e.g., algorithms, dosing guidelines, and nomograms; abbreviations approved for prescribing; and other pertinent information such as the sodium or sugar content of various items listed)

Formularies are often called *preferred medication lists* or *preferred drug lists* (PDLs).

P&T Committees

Pharmacy and therapeutics (P&T) committees evaluate the clinical use of medications and develop policies for managing access to them and for ensuring effective drug use and administration. As a policy-recommending body to the medical and administrative staff of health care organizations, the main role of P&T committees is to maintain a limited list of medications, the formulary, that meets the needs of physicians and their patients as well as those of the health care organization.

P&T committees also strive to provide their organizations with medication choices that are more cost-effective overall when compared with alternative therapies, not simply the less expensive drugs within the class. According to "*Principles of a Sound Drug Formulary System*," P&T committees should be composed of actively practicing physicians, pharmacists, and other health care professionals.² Table 1 outlines the evolving functions of P&T committees over the past several decades.³

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The Origins

Medication formularies have existed in the U.S. since the 18th century. Some of the early formularies included the *Lititz Pharmacopoeia*, which was published in 1778 for use by the Continental forces,⁴ and *Coste's Compendium Pharmaceuticum* of 1780, which was used by the French forces during the American Revolution.⁵ Examples of other early documents included the *Pharmacopoeia of the Massachusetts Medical Society* in 1808, the *Pharmacopoeia of the New York Hospital* in 1816, and *The United States Pharmacopoeia*, which was first published and issued in 1820.^{5,6}

In 1933, W. J. Stainsby, MD, and a pharmacologist, Dr. Robert A. Hatcher from the New York Hospital, drafted the initial guiding principles of a formulary system. These principles laid the groundwork for virtually all formulary systems. They were published in 1933 in the *Journal of the American Medical Association* and in the *Journal of the American Pharmaceutical Association*.⁷ In 1936, the Minimum Standard for Hospital Pharmacies was first adopted by the American College of Surgeons.⁵

Changes in the pharmaceutical industry also had a role in the emergence of formularies. The technology used by American pharmaceutical manufacturers after World War II made significant strides, and soon new dosage forms and standardized formulations became widely available. Complementing the availability of new dosage forms and standardized formulations was a change in prescribing behaviors. Physicians began prescribing "brand-name" medications in lieu of compounded or extemporaneously prepared prescriptions.⁸ In fact, some type of compounding was required for about three-fourths of prescriptions dispensed in the 1930s. By 1970, the percentage of prescriptions that were compounded represented only 1% of all

Table 1 Trends in the Responsibilities of P&T Committees

Years	Purpose and Role
1960s	<ul style="list-style-type: none">• to ensure inventory control• to maximize rational medication use
Early 1980s	<ul style="list-style-type: none">• to identify preferred drugs• to evaluate the safety and efficacy of available medications• to minimize therapeutic duplication• to achieve cost savings
1990s	<ul style="list-style-type: none">• to continue improving processes to ensure that safe and effective pharmaceuticals are available for an organization's patients and health plan members• to control pharmacy-related costs through aggressive contracting and utilization of control mechanisms

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those dispensed.^{9,10}

The 1950s also saw a large increase in the number of new products that were introduced into the market. Improvements in technology resulted not only in the emergence of thousands of new products but also in a number of duplicate drugs reaching the market. For example, in 1952, 45 oral formulations of penicillin were being prepared by 17 manufacturers.¹¹

Duplicates such as these also served as a stimulus to standardize medication use and became the basis for medication formulary systems that were primarily hospital-based.

The Joint Commission on Accreditation of Hospitals (JCAH) provided an additional stimulus by recognizing the value of P&T committees and formularies and was promoting their adoption by hospitals as early as 1950.¹²

Early hospital formularies of the 1950s were focused primarily on product standardization, inventory control, and ensuring an adequate supply of medication.¹² Efforts by pharmacists to standardize generic products did not go unnoticed, and they were counterbalanced by powerful trade groups that supported the efforts of states to pass laws aimed at decreasing the ability of pharmacists to substitute generic medications for brand-name ones.¹¹

As the 1950s came to a close, a number of associations (e.g., the American Hospital Association, the American Medical Association, the American Pharmaceutical Association, and the American Society of Hospital Pharmacists [ASHP]) were promoting formulary policy and standards. By 1959, the ASHP issued the *Hospital Formulary Service*.⁹ By the 1960s, formularies were beginning to reflect the need to address product safety and product effectiveness.¹³

It was during the 1960s that the JCAH, now known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), required that in order to receive accreditation, hospitals had to establish P&T committees to provide guidance for the use of pharmaceuticals within their institutions. JCAHO stated that the committees' functions were the responsibility of medical staff members, who had to work in concert with the pharmacy department or service as well as with other departments, as required.

The main function of P&T committees was to oversee the preparation and administration of formularies.¹⁴ The "Treatment of Patients" section of JCAHO's *Accreditation Manual for Hospitals* provides guidance on the development and implementation of formularies. It states the following requirements:¹⁵

1. The formulary list should be readily available.
2. Appropriate staff within the organization, including the pharmacy department, must develop and maintain the formulary.
3. Products to be selected for inclusion on the formulary should be assessed on the basis of need, effectiveness, risk, and cost.
4. A process must be developed to address the prescribing or ordering and procuring of medications that are not on the formulary.
5. Appropriate staff members must develop, maintain, and enforce written policies and procedures for selecting, procuring, distributing, and administering medications and must also cover the safety of overall medication use.

According to the new JCAHO medication-management standards for 2004, written criteria are also required by JCAHO for adding and removing medications from an organization's formulary. JCAHO does not use the term *formulary*, however, because some of its accredited organizations do not use that term. In addition, these new standards require that health care organizations have processes to safeguard the use of drugs that are not on the organization's medication list.¹⁶

In the interest of providing the best available care to the patient, the formulary system, via the P&T committee, should be able to respond to changing practice guidelines and to individual situations by having a mechanism in place for changing the formulary on a case-by-case basis.

EMERGENCE OF MANAGED CARE AND THE CHANGING ROLE OF P&T COMMITTEES

In the 1960s, health care expenses were estimated at \$27 billion, a figure that had increased dramatically to approximately \$950 billion by 1994.¹² This huge growth in health care spending resulted in a change in the type of insurance coverage that was provided to patients. A predominant fee-for-service reimbursement model was slowly changing to a managed care setting.

From the 1970s to the mid-1990s, the number of people who were enrolled in health maintenance organizations (HMOs) increased by 970%; by 1995, it was 60 million people.¹⁷

Formularies remained almost exclusively hospital-based until the 1970s, when similar types of medication lists began to be adopted by staff and group model HMOs for ambulatory use.⁹ With the rapid growth of the managed care organizations (MCOs) in the 1980s and 1990s, and with spiraling increases in the cost of delivering medication benefits to plan members, MCOs began to use formularies as a tool to leverage discounts and rebates from drug manufacturers.

Along with MCOs, state Medicaid programs began to look to formularies (PDLs) to assist them with cost control. Even though formularies vary significantly in their composition and in the goals among organizations, they are implemented to provide guidance for safe, effective, and high-quality medication therapy as well as to control costs. Formularies define those products that are to be covered for plan members or recipients, and they determine the corresponding levels of out-of-pocket expenses, or co-payments, that members must pay to pharmacies for their prescriptions.

While continuing to assume their traditional responsibilities and functions, P&T committees grew as they became a communications link between the MCO's medical staff and the pharmacy providers.¹⁸ The main purpose of P&T committees in the era of managed care became one of controlling rising health care costs, which were considered to be one of the highest among our nation's industry costs.

With cost-control the major issue, the concept of pharmacy benefits management emerged during the 1980s, when HMOs began to use the practice of selective contracting. MCOs began to outsource the management of drug benefits to independent pharmacy benefit management firms (PBMs).¹⁹ Obtaining drug discounts from various providers, such as hospitals, became a common trend. Purchasing medications with the help of formularies helped the HMOs to obtain better discounts, thus enabling them to control rising pharmaceutical costs.

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Today, formularies are an essential part of MCOs in addition to the hospital setting. More than 54,000 P&T committee members participate in the formulary process in various health systems and MCOs throughout the U.S.²⁰

Figure 1 outlines the significant developments in the evolution of formulary systems and P&T committees.

SUMMARY

Formularies and P&T committees have come a long way since the days of the American Revolution. Many factors have contributed to the changing face of the delivery of pharmaceutical care. The early 1950s and 1960s saw the introduction of new and more effective medications by pharmaceutical manufacturers. With an increased number of medications reaching the market, problems with the use of drugs and their side effects came into the picture. Gradually, it became important to implement a check on the rational use of these drugs by patients, because with the introduction of newer medications came an increase in the number of side effects, hospitalizations, and other undesirable problems.

Adverse drug events (ADEs) have led to increased hospitalizations and have caused an increase in the costs of medical care along with, in some cases, a decline in patients' quality of life. These ADEs, which were often associated with non-rational treatment choices, underuse, or overuse of medications and with noncompliance or patients' lack of adherence to treatment regimens, gradually became a more serious issue. It then became imperative to have a mechanism by which safe, efficient, and effective ways of treating diseases could be implemented.

P&T committees, by virtue of their functions and responsibilities, became the organizational keystone in maximizing rational medication use. From the early 1970s onward, the market saw a shift in reimbursement methods from fee-

for-service to third-party insurance and managed care. Medication expenditures spiraled upward during this period, and an additional function of P&T committees came to the fore, namely that of controlling burgeoning health care costs through restricted formularies. The roles of P&T committees and formularies have thus evolved with the changing health care environment. Controlling health care costs and ensuring rational medication use are arguably the two most important responsibilities of P&T committees today.

In Part 2 of this series, to be published in next month's issue of *P&T*, we explore the expanded role of P&T committees in an ever-changing pharmaceutical care setting as well as the use of clinical effectiveness data in formulary decision-making.

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