Contemporary Issues Affecting P&T Committees
Part 1: The Evolution

Sanjeev Balu, BPharm, MBA, Paul O’Connor, RPh, MBA, and F. Randy Vogenberg, RPh, PhD

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

Table 1 Trends in the Responsibilities of P&T Committees

<table>
<thead>
<tr>
<th>Years</th>
<th>Purpose and Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>1960s</td>
<td>• to ensure inventory control</td>
</tr>
<tr>
<td></td>
<td>• to maximize rational medication use</td>
</tr>
<tr>
<td>Early 1980s</td>
<td>• to identify preferred drugs</td>
</tr>
<tr>
<td></td>
<td>• to evaluate the safety and efficacy of available medications</td>
</tr>
<tr>
<td></td>
<td>• to minimize therapeutic duplication</td>
</tr>
<tr>
<td></td>
<td>• to achieve cost savings</td>
</tr>
<tr>
<td>1990s</td>
<td>• to continue improving processes to ensure that safe and effective pharmaceuticals are available for an organization’s patients and health plan members</td>
</tr>
<tr>
<td></td>
<td>• to control pharmacy-related costs through aggressive contracting and utilization of control mechanisms</td>
</tr>
</tbody>
</table>

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 Pharmacopeia, 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

Mr. Balu is a Research Fellow and doctoral student at Purdue University’s School of Pharmacy in West Lafayette, Indiana. Mr. O’Connor is Vice President and Dr. Vogenberg is Senior Vice President and National Practice Council Leader, both at Aon Consulting in Providence, Rhode Island.
Issues Affecting P&T Committees: Part 1

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.

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. 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.

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. 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. 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). 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.

### The Changing Role of P&T Committees

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.

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. 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.

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. 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. 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). 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.

### The Changing Role of P&T Committees

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.

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. 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.

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. 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. 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). 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.

### The Changing Role of P&T Committees

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.

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. 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.

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. 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. 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). 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.
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.

**REFERENCES**


