Contemporary Issues Affecting P&T Committees
Part 2: Beyond Managed Care

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FORMULARIES AND COMMITTEE EVOLUTION THROUGH EMERGING MANAGED SYSTEMS OF CARE

Pharmaceutical care and the number of individuals who play a large role in its delivery have made rapid strides over the years. Part 1 of this series, published in the November 2004 issue of *P&T*, described how and when pharmacy and therapeutics (P&T) committees came into being and their specific roles over the years.

With changing times, pharmaceutical care in the U.S. has also changed. The concept of managed care came into existence as a measure to control the rising costs of delivering care, including medication costs. P&T committees came into being primarily in response to a proliferation of new, and sometimes significant, drugs entering the market.

Over the years, the needs and demands of patients have become more complex. As a result, P&T committees have continued to face increased responsibilities and challenges. In Part 2 of this series, we discuss the evolving role of P&T committees.

THE EXPANDING ROLE OF P&T COMMITTEES IN TODAY'S WORLD OF MANAGED CARE

The plethora of pharmaceuticals available and the ever-increasing complexities surrounding their safe and effective use make it necessary for health care organizations to have a sound program for maximizing rational drug use. The rising number and advancing age of older adults, the higher prevalence of multiple comorbidities, and the introduction of growing numbers of new and often costly medications to the market have made the functions of P&T committees more vital.

An ongoing, significant growth in the number of American citizens reaching 65 years of age and older will occur over the next few decades; the number is projected to reach 70 million by the year 2030.[1] This rapid increase in the segment of the population that uses the largest number of prescriptions, coupled with the constantly mounting costs of pharmaceutical therapy, makes it imperative for health care organizations to develop a sound approach for evaluating new pharmaceuticals—their costs and the economic, clinical, and humanistic outcomes from their use.

In the early 1980s, managed care organizations (MCOs) adopted the use of P&T committees to create medication formularies (preferred drug lists) for the ambulatory setting. At that time, drug formularies were created primarily to designate preferred drugs based on available safety, efficacy, and cost information. Formularies were also used as leverage to obtain discounts or rebates from pharmaceutical manufacturers for these preferred drugs.

When the fee-for-service model was the primary reimbursement method for health care services, there was little incentive to control costs, especially for ambulatory patients. Patients paid cash for their prescriptions. It was only when health plans began to attach medication riders to their medical coverage that members began to see their out-of-pocket drug costs shrink to the cost of a minimal co-payment. Early formularies were considered to be "open," and there were few restrictions on coverage. Clinical efficacy and safety were the primary considerations for medications to gain formulary approval.

As the cost of prescription drugs began to rise in the middle to late 1980s, the emergence of restrictive formularies, generic substitution, and Drug Utilization Review (DUR) as a means to control pharmaceutical costs became commonplace in managed care. Today, MCOs face increasing competition in many regions, and this adds to the pressure to control costs even more. At the same time, MCOs are facing escalating demands from various government bodies and employers to have authentic quality data on the services that they provide to their members. As a result, MCOs, hospitals, and other health care organizations must control costs as well as document the delivery of high-quality care.

There has been a gradual evolution in the purpose of the P&T committee, as described in Part 1 of this series. As more and more medications are introduced, including expensive biotechnology-derived products, and as the U.S. population ages, the role of P&T committees is expected to become more multifaceted.

CHANGES IN THE MAKEUP OF P&T COMMITTEES

Every day, decisions about which drugs to accept into a health plan or onto a hospital formulary, issues surrounding their coverage, and the level of co-pays, deductibles, and co-insurance affect physicians, pharmacists, and patients. The composition of P&T committees is changing to meet their increasing demands and responsibilities. These committees were originally composed primarily of physicians and pharmacists. Today's committees utilize the assistance of numerous physician-specialists and experts and include input from various advisory subcommittees.[2] Some organizations are also adding health care ethicists, economists, and geneticists to their P&T committees (Table 1).

The role of pharmacists on P&T committees has evolved as well. Many health plans and pharmacy benefit managers (PBMs) also seek to add pharmacist-representatives from both independent and chain-store pharmacies in their net-

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works. The number of pharmacists on these committees has grown dramatically over the years; today, pharmacists make up about 30% of members on the average committee.[2]

Part of the reason for such an increase is that pharmacists have the necessary expertise and are best able to analyze and evaluate the choices and put them in the appropriate context for the committee's members. Pharmacists are also in the best position to recommend drugs to be included at the appropriate level in a tiered benefit setting. This is of critical importance, because the appropriate tier placement of the selected drug determines the amount of co-payment or co-insurance to be paid by the health plan's members. The level of co-payment or co-insurance can have a dramatic effect on the utilization mix of some drug categories.

According to two studies,[3,4] an increase in patient cost sharing resulted in reduced drug-utilization rates. In the first study, the authors concluded that after the introduction of prescription drug cost sharing, the use of essential medications decreased by about 9% in elderly patients and the use of less essential agents dropped by approximately 15%. In the second study, an increase in patient co-payments was associated with fewer prescriptions dispensed per visit. With increasing cost sharing, members are more likely to take a more active role with their prescribing physician in determining which prescriptions they receive when choices between therapeutically similar agents need to be made.

One key issue that will profoundly affect the future structure of P&T committees will be the growth in the availability and importance of outcomes studies in the evaluation of medications to be added to or subtracted from their formularies. P&T committees rely heavily on the pharmaceutical industry for these studies. Today, despite the need for outcomes studies, they are not as readily available as they should be, partly because pharmaceutical companies do not have an endless budget with which to perform these studies. Further, in this highly competitive market, they have not had the luxury of time to invest in such studies. That said, the growing emphasis on the need for outcomes data would result in the greater availability of such studies over time.

Another key factor to be considered in the role and structure of future P&T committees is the inclusion of a pharmacy benefit for Medicare beneficiaries. The Medicare Moderniza-

Table I **Trends in the Responsibilities of P&T Committees**

Attribute or Task	Description
Composition and size	• The P&T committee should be composed of the following voting members, at a minimum: physicians, pharmacists, nurses, administrators, quality assurance personnel, and others as needed. • Experts (nonmembers) should be invited as needed to contribute their unique or specialized knowledge, skill, or experience. • Size is determined by the scope of services provided.
Chair and secretary	• The chairperson is appointed from among the physician staff. • A pharmacist is designated as secretary.
Meeting schedule	• The committee meets regularly, at least six times per year and more often if necessary.
Agenda and minutes	• Beforehand, an agenda that includes pertinent reading materials should be distributed to committee members, who should be given sufficient time to prepare for the meeting. • The secretary should prepare the minutes of the meeting, and they should be maintained in a permanent record. The minutes of the previous meeting should be distributed with the current agenda.
Committee recommendations	• Committee recommendations should be presented to the medical staff, or its designee, for review and comment or adoption.
Formal liaison	• A liaison should be maintained with other organizational committees that are concerned with medication use.
Communication	• All actions recommended by the committee should be routinely communicated to the appropriate health care personnel.
Ensuring credibility	• The organization and operation of the committee should ensure that recommendations are objective and credible. A conflict-of-interest policy should be established. • The committee should stay current with respect to setting standards and to professional organizations' changes to guidelines and policies.

Adapted from the American Society of Hospital Pharmacists. ASHP statement on the pharmacy and therapeutics committee. *Am J Hosp Pharmacy* 1992;49:2008–2009.

tion Act (MMA) of 2003 states that these pharmacy benefits are to be handled by private PBMs that use formularies and other utilization-management tools to control costs and optimize resources (Table 2).

Table 2 **Current Structures and Functions of P&T Committees**

Attribute	Description
Size and composition	• Average of 19 members; dominated by physicians (average, 12 members)
Committee meetings	• Average about one meeting per month, between 60 and 90 minutes in duration
P&T subcommittees	• Most P&T committees are supported by several subcommittees that review a specific medication class and make recommendations to them
Committee activities	• Formulary management • Drug-use policy-making • Drug-use monitoring

Data from Nair KV, Coombs JH, Ascione FJ. *P&T* 2000;25(10):516–528.[5]

USE OF PHARMACOECONOMIC DATA

The growing prominence of drug therapies in health care and their rapidly rising costs have led to a dramatic rise in the use of health outcomes data for therapeutics and formulary decisions. The expanded use of cost-effectiveness data, analyses of health outcomes, and various pharmacoeconomic (PE) models have become commonplace in today's world of rising costs and increased utilization. For a medication to be considered effective—and at the same time to be less expensive to use than other drugs available in the therapeutic class—numerous cost comparisons are required along with health outcomes studies.

As P&T committees have evolved, the amount of information that the members need to take into account in order to make sound decisions about their formulary drug selections has also simultaneously increased. Besides available outcomes studies and surrogate measures of long-term health and economic outcomes, P&T committees must consider the impact that a given agent may have on patient compliance and adherence, the potential for medical errors, the effect on prescribing behaviors, and the published results of clinical trials. Methods such as disease-based economic models, which can help determine the potential impact on clinical and economic consequences following the introduction of a particular product into a formulary, should be devised.[6]

Odedina et al. noted that 86% of surveyed pharmacist-members of P&T committees in Florida hospitals stated that PE data were used in their formulary evaluations all the time or very often.[7] The survey also showed that approximately 70% of the participants' hospitals had someone with pharmacoeconomic skills on staff and that 4% of the hospitals consulted outside experts in this field.[7]

THE VALUE OF CLINICAL EFFECTIVENESS DATA FOR FORMULARY DECISION-MAKING

Assessment of both cost and outcomes of a particular product becomes a critical task for P&T committee members during the decision-making process. Various measures are available for evaluating the costs of medications and their use.

One such measure, the DUR, is a formal, stepwise approach that evaluates the clinical appropriateness and patterns of use, adverse drug events (ADEs), and acquisition costs. DURs identify whether current patterns of prescribing, dispensing, and using drug therapy are consistent with accepted criteria and standards. If therapy is determined to be inconsistent with the agreed-upon criteria and standards, then specific actions may be needed to address this problem. Figure 1 illustrates the DUR process.[8]

Even though DURs are useful for evaluating costs and drug usage patterns, they have inherent limitations. They incorporate patient care outcomes, provider preferences, provider-prescribing behaviors and habits, and their current knowledge of therapeutic choices in an inconsistent manner. DURs and other traditional approaches to determining medication inclusion and use base their results on incomplete or possibly inaccurate data and often focus on the unit cost of drugs rather than on total therapy costs and medical care savings.

After examining data from six state Medicaid programs, Hennessy et al. concluded that DUR programs did not improve patient health or reduce the rate of prescription errors.[9]

Lichtig et al. developed a new integrated approach, called the Clinical Effectiveness Initiative (CEI), which uses the readily available administrative databases of hospitals.[10] The CEI is used to evaluate the overall cost of treating patients, which includes laboratory, medical, and surgical supplies; intensive care; and all other department expenditures in addition to the pharmacy expenses.

Clinical Effectiveness Resource Management (CERM), an output of CEI and a method that we developed, was designed to assess available therapeutic options and newer therapies for comparison with existing ones.[11] This approach uses the financial information obtained from a hospital's Medicare cost report, the UB-92 Claim Form, and other administrative data to compare the costs and patient outcomes of existing alternatives. Such an approach allows a hospital to allocate its limited resources appropriately and to direct them to areas in which they see the potential for financial improvement and better health outcomes for patients.

Because there has been a proliferation of new and expensive medications into the market, a population that is living longer with more diseases, the advent of direct-to-consumer marketing by the pharmaceutical manufacturers, and rising drug costs, devising ways to tackle these issues has become extremely important. There has been a raging debate as to how these new costly medications have contributed to rising overall health care expenses. The new drugs are definitely expensive, but some of them provide distinct advantages in terms of

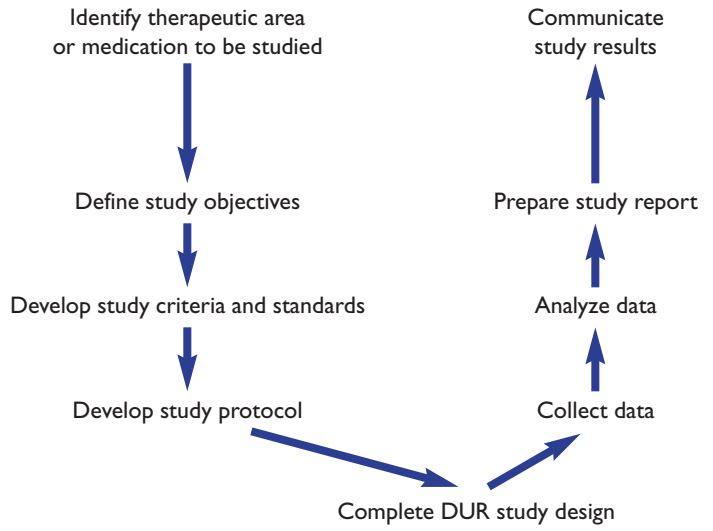

Figure 1 Process of a Drug Utilization Review (DUR) Study. (Adapted from Drug Utilization Review: A Canadian Process and Methodology for Studies of Community-Based Drug Therapy; 2001. Available at: www.canadapharma.org.[8])

reduced side effects and better patient outcomes than less expensive, older alternatives.

Despite their higher acquisition costs, many newer medications can effectively reduce the overall cost of care for patients and thus may also prove to be financially beneficial to both hospitals and managed care networks. A thrombosis management CEI is an example that focuses on a comparison of unfractionated heparin (UFH) with low-molecular-weight heparins (LMWHs), such as enoxaparin, in treating and preventing deep vein thrombosis and pulmonary embolism in hospitalized patients.

Finally, given the broader scope and complexity of drugs coming before P&T committees today, more of a multidisciplinary makeup is required to include expertise on biotechnology therapies. Expanding the P&T committee to include active participants and establishing specialist subcommittees to make specific formulary recommendations, as well as considering overall patient care implications of selected or proposed drugs, can accomplish this goal. Compared with the newer biotechnology medications, some of which cost as much as $5,000 per dose, the older injectable agents can be managed more simply within existing P&T committee structures.

David Nash, MD, MBA, recently claimed, "If a hospital hasn't made the switch to a multidisciplinary P&T committee, you have to ask what's wrong. . . . If your P&T committee is not on top of that [biotechnology products], it surely ought to be."[12]

SUMMARY

In Parts 1 and 2 of this series, we described the evolution of the roles assumed by P&T committees and the continuing challenges they face. From the focus on rational medication choices to the practice of monitoring adverse drug reactions and operating within an organization's budgetary limits, the duties of P&T committees have been continuously expanding and evolving. There is a need for P&T committee members to make a greater number of difficult choices about the medications to be included in or excluded from their formularies. These decisions become significant from the financial perspective as well as for the clinical outcomes of the patients enrolled in health care plans. Balancing costs and health outcomes is critical, and the judicious use of commonly available data is of the utmost importance.

The use of data that integrate overall costs and provide comparisons between alternative therapies gives leverage to stakeholders by allowing for more sound decision-making, thereby enabling them to more easily identify pockets of high costs and undesirable outcomes. The use of such data by P&T committee members will empower them to meet the current and emerging challenges in a sound way.

REFERENCES

1. U.S. Department of Commerce, Bureau of Census. *Projections of the Population of the United States, by Age, Sex, and Race:* 1988–2080. Washington, DC: U.S. Government Printing Office; 1989.
2. Cross M. Increased pressures change P&T committee makeup. *Managed Care*, December 2001. Available at: www.managedcaremag.com/archives/0112/0112.formularycomm.html.
3. Tamblyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. JAMA 2001;285:421–429.
4. Lurk JT, DeJong DJ, Woods TM, et al. Effects of changes in patient cost sharing and drug sample policies on prescription medication costs and utilization in a safety-net provider setting. *Am J Health Syst Pharm* 2004;61(3):267–272.
5. Nair KV, Coombs JH, Ascione FJ. Assessing the structure, activities, and functioning of P&T committees: A multisite case study. *P&T* 2000;25(10):516–528.
6. Fullerton DS, Atherly DS. Formularies, therapeutics, and outcomes: New opportunities. *Medical Care* 2004;42(4 Suppl): III39–III44.
7. Odedina FT, Sullivan J, Nash R, Clemmons CD. Use of pharmacoeconomic data in making hospital formulary decisions. *Am J Health System Pharm* 2002;59(15):1441–1444.
8. Drug Utilization Review: A Canadian Process and Methodology for Studies of Community-Based Drug Therapy. 2001. Available at: www.canadapharma.org/Media_Centre/Special_Reports/DUR Process_Oct2001.pdf.
9. Hennessy S, Bilker WB, Zhou L, et al. Retrospective Drug Utilization Review, prescribing errors, and clinical outcomes. *JAMA* 2003;290(11):1494–1499.
10. Lichtig LK, Weinberg RM, Knauf RA, Vogenberg FR. Measuring clinical effectiveness using common hospital data. *P&T* 2004; 29(5):304–313.
11. Vogenberg FR, Lichtig LK, Weinberg R, DeSantis V. Balancing physician and cost-containment demands. *Healthcare Financial Manage Assoc* 2004:66–70,72.
12. Darves B. P&T's new starting lineup. *HealthLeaders*, September 1, 2004, p 38 (36–40).