EDITORIAL

Reinventing the Pharmacy and Therapeutics Committee

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INTRODUCTION

The pharmacy and therapeutics (P&T) committee was introduced almost a century ago as a forum for discussing drug use in hospitals. Born out of the need to implement medication-management standards, the structure and function of the P&T committee have evolved over time with clinical practice, payment reforms, and the delivery of health care services. And Today, P&T committee members are challenged with complex pharmaceutical agents for an ever wider array of clinical indications—at unprecedented prices.

Those who led pharmaceutical-management programs in the past could not have anticipated the magnitude of change occurring in health care today. As value-based reimbursement and accountable-care models drive us into an era focused on cost-containment and care-management strategies, the P&T committee must evolve—in fact, reinvent—itself.

NOT SUITED FOR CHANGE

Hospital P&T committees have many responsibilities, including drug-use evaluation, adverse drug event monitoring and reporting, and approval of guidelines for medication management. The role often given the highest priority, however, is management of the formulary and the authorization and restriction of new drugs in the clinical environment. In performing these activities, the P&T committee has the overarching goal of ensuring the safe, appropriate, and cost-effective use of pharmaceuticals.⁵

It is widely believed that hospital formulary management has curbed drug expenditures. To be sure, focused pharmaceutical interventions—such as antimicrobial stewardship interventions, restricted drug-use programs (i.e., those that require pre-approval), or pharmacist interventions—have demonstrated cost savings. Yet there is, surprisingly, little evidence that the P&T committee has been effective as a cost-reduction tool. It can be argued that a P&T committee may be swayed by opinion leaders and clinician preferences as strongly as it is driven by impartial data on effectiveness and cost. A forum that can be influenced by nonobjective information is unlikely to work predictably in a value-driven environment.

Hospitals are struggling to manage pharmaceutical budgets as drug costs rise faster than overall medical-cost inflation.⁸ At the same time, hospitals are announcing major efforts to operate more efficiently.⁹ Given these forces, scrutiny of pharmaceutical management is likely to increase. Within the hospital, pharmacy as a department is largely viewed as a cost center, in isolation from other medical expenditures; for the most part, drugs have not been viewed as an integral component of the total cost of care.

With care-delivery and cost-containment models no longer evolving on separate tracks, it is time to re-evaluate the pur-

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pose, makeup, and structure of the P&T committee, as well as its responsibilities and relationships with others, inside and outside the hospital. As hospitals consolidate into larger health systems and vertical entities and as payers move toward new reimbursement methodologies, drug-utilization and management strategies also need to evolve. Formulary decisions that consider clinical pre-discharge and post-discharge outcomes have the potential to improve financial outcomes for both the hospital and the integrated entity as a whole. As currently structured in terms of makeup and responsibilities, however, the P&T committee is not ready to meet these challenges.

A CHANGING MARKETPLACE

Since the 1980s, hospital reimbursement has been based largely on fixed payments, case rates, or a *per diem* schedule. In this environment, drug expenditures are viewed as costs to the system. The exception to this is case-rate payments, in which medications have been shown to affect length of stay or to reduce the utilization of other hospital resources. ¹⁰ Isolating the impact of medications on the overall cost of care in the hospital, however, has been difficult to measure. As a result, most P&T decisions have historically been based on a product's clinical differentiation characteristics and its direct acquisition cost.

Today's emerging payment strategies are, collectively, a marker of how health care delivery must be reconsidered. Such payment methodologies as gainsharing, bundling, and value-based reimbursement, as well as a hospital's participation in accountable care organizations (ACOs) and other risk-bearing entities, 11,12 speak to the nexus of clinical and economic decision-making. All of these models are designed to align financial incentives between hospitals and physicians, and they have implications for the role of pharmaceuticals.

Although physicians are central to the process of requesting new drugs on the hospital formulary, ¹³ they have seldom been accountable for how the use of these products affects episode-of-care costs or the hospital's bottom line. Generally, this area has been beyond their scope of responsibility. The Centers for Medicare and Medicaid Services' gainsharing demonstration allows physicians to benefit from the reduction of total hospital costs. ¹⁴ Physicians can also share in the savings that result from bundling—in which hospitals define an episode of care and receive a single payment for all services provided for the episode—and from participation in ACOs. How these models will affect formulary decision-making within the hospital is not completely clear, but their reliance on financial incentives is likely to engage physicians as never before in understanding the effects of their drug choices on total costs of care.

The ACO model, which ties reimbursement to quality-of-care metrics, compels clinical and administrative leaders to gain a systemic understanding of the effects of pharmaceutical choice beyond the walls of the hospital. Such considerations include

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the overall impact on readmissions, emergency visits, skilled and long-term care, and home health care. ¹⁵ To some degree, formulary decisions can affect short-term and long-term clinical decision-making and outcomes. Thus, the determination of a drug's total value—taking both clinical quality and cost into consideration—becomes important in evaluating a pharmaceutical product.

DIFFERENT MODELS, PARALLEL CONCERNS

David Nash has reported on the considerable variation in the structure and function of P&T committees throughout the U.S.² Most hospital-based P&T committees focus on a cost-minimization strategy for pharmaceuticals. Although clinical factors are, rightly, rated as a top factor in drug evaluations, cost was mentioned by all hospitals in one study as an important factor as well.¹⁶ These considerations included either drugacquisition costs, cost-effectiveness, or both.

By contrast, fully integrated systems and others responsible for the full continuum of care, such as the Department of Veterans Affairs (VA Health) system, have taken a more comprehensive approach toward pharmaceutical evaluations. ¹⁷ The VA, for example, emphasizes the use of cost-effectiveness data.

It is telling that hospitals face many of the same P&T challenges faced by payer organizations that focus on population-based care. Variation exists in the goals and methods of P&T committees within such organizations as commercial insurers, pharmacy benefit managers, third-party administrators for self-funded employer-sponsored plans, and state Medicaid agencies. Provider integration, the emergence of personalized medicine, and the availability of complex and costly large-molecule drugs mean that P&T committees in both hospitals and payer systems will have to strive to consider total clinical outcomes in designing cost-effective formularies.

HOW P&T COMMITTEES SHOULD EVOLVE

P&T committee members need to start with a firm understanding of where payment mechanisms are headed. This means that they must understand the hospital's role as the hub of an integrated system as well as hospital and health care system contracts and reimbursement strategies.

The needs of hospitals, health care systems, and payer organizations will force the inclusion of pharmaceutical management into the strategic and operational planning of the system. Change in the P&T committee, then, must start with a revision of its mission—allowing for consideration of pharmacy's role in the total episode of care and the impact of pharmaceuticals on value-based reimbursement strategies (Table 1). Taking a holistic view means that the P&T committee will need to vacate its responsibility as protector of the pharmacy budget and adopt a mindset of being part of an integrated team that manages episodes of illness.^{20,21}

Senior management must clearly support this new purpose of the P&T committee. Aside from organizational changes, management can support P&T committees by giving them access to the tools they will need to accomplish this new mission. Having adequate data to work from is crucial if decision-making criteria are to evolve with the needs of the marketplace. For instance, what is known about the long-term effects of a drug given in the hospital on admission or during outpatient visits and about other drug-related complications? How do these offset a drug's acquisition cost?

Finally, P&T committees will need to alter their composition to include professionals from outside the hospital, namely primary care physicians, health economics and outcomes researchers, and data analysts experienced in the continuum of care. Greater emphasis on patient engagement and compliance with medication regimens as part of chronic care management must also be part of a P&T committee's scope of accountability, thereby possibly creating a role for nurse case managers.

The lack of P&T committee member training in how to evaluate pharmacoeconomic studies has been mentioned as a barrier to more effective formulary decision-making, 4.12 but functioning effectively in the new environment will require more than just a grounding in pharmacoeconomics. It will mean having an understanding of how real-world economics affects other health care stakeholders and knowing where clinical

Table 1 How P&T Committees Can Face the Future Effectively

The role and makeup of P&T committees have always been in flux, and emerging payment models will force more change. Following are some of the ways in which hospital P&T committees must evolve to be effective agents for helping to maximize clinical and financial outcomes.

Action	Rationale
Expand mission	Evaluates pharmaceutical products in the context of total clinical and financial outcomes
Broaden multidisciplinary membership	Allows for input on effect of a product across the full continuum of care
Add data inputs	Considers a product's place in a total episode of care
Undergo pharmacoeconomic training	Is important to understand cost-effectiveness; clinical knowledge is an important contributor in any discussion of pharmacoeconomics
Evaluate impact of decisions on reimbursement strategies	New payment models require that P&T members understand hospital's role in an integrated system of health care
Improve patient engagement and compliance	Noncompliance has the potential to add costs to episodes of care

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knowledge intersects with that.

In the end, P&T committees will learn—just as other leaders in health care have been forced to learn—the meaning of having accountability for their clinical and financial decisions.

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