

Formularies, Pharmacists, and Influences on the Decision-Making Process

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Since their first appearance in the 1940s as simple lists of drugs available from a hospital's pharmacy, formularies have undergone extensive changes.¹ Beginning in the 1960s with federal and regulatory agencies requiring their presence for reimbursement and accreditation, formularies and the committees that oversee them have been remade. This evolution has created an ever-changing set of parameters and options for the Pharmacy and Therapeutics (P&T) Committee to review as they make decisions on a wide variety of therapeutic agents. Pharmacists, with their expertise and knowledge of available agents, are an integral part of the flow of information that forms the foundation of the P&T committee's decisions.

Major changes have affected how the P&T committee addresses both new products in a therapeutic area and agents already on their formulary that require re-review because of emerging data and/or new regulations. Commonly, a series of subcommittees composed of physicians, nurses, administrators, and others address their respective areas of responsibility and submit their findings to the P&T committee for final decisions. Safety and efficacy will always be of the utmost importance to the process, but many other factors

can affect the committee's decision. Some of these factors include acquisition cost, the impact on a department's budget to administer and distribute a given agent, and the internal and external regulatory environments. Some of these changes have come from the rapidly changing areas of risk management and legal concerns.

As pharmacists are aware, the place of a therapeutic agent in the armamentarium of a clinician is always evolving as clinical experience brings more detailed data to refine an agent's optimal use. Less noticeable, but no less important to the process and the pharmacist, are evolutions of the systems governing their use. One example is the scrutiny by various regulatory or other entities such as third-party payers, and the administrative burden that accompanies the use of some agents. Managing the risk associated with drug therapy has become a significant part of the decision-making algorithm. These risks may be managed by placing new or strengthened warnings on established agents, or by restricting use to only very specific, specially trained personnel.

Another factor is the recent advent of risk evaluation and mitigation strategies (REMS) that have become increasingly widespread and may include onerous notification, certification, surveillance, and reporting requirements. Furthermore, payers, such as Medicare, Medicaid, and private insurance agencies, have begun addressing certain "never events" (i.e., egregious errors that should never occur) by restricting reimbursement, or in a few instances, refusing reimbursement to institutions for any costs they incur due to these events. Finally, legal and regulatory scrutiny of the formulary has increased, subjecting some institutions to potential regulatory or legal sanctions based on an agent's use.

In the first article in this supplement, I discuss

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the formulary process as it exists today and the agents of change that may affect the process in the future. This includes the significant changes to both the process itself, the agencies that are now looking more closely at the choices that are made, and some of the methods adopted to mitigate the risks associated with any therapeutic agent's use. In the second article, Dr. Jack Raber takes a closer look at the risk management aspects of pharmacy management and formulary choices, the potential legal and regulatory pitfalls, and potential methods to reduce or eliminate some of the risks. It is our hope to

provide not just pharmacists, but all health care providers and hospital administrators, with a better appreciation for the formulary process, its ongoing challenges, and insights for more effectively overseeing the safe use of drugs within the institutional setting.

Reference

1. Tyler LS, Cole SW, May JR, et al, for the American Society of Health-System Pharmacists Expert Panel on Formulary Management. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. *Am J Health Syst Pharm* 2008;65:1272-83.