

# Formulary Decisions: Then and Now

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An institution's formulary is a constantly evolving entity with a myriad of considerations that must be taken into account when any agent or chemical entity is being evaluated for formulary inclusion or is under review to continue as a therapeutic option. Originally a simple list of available agents, the formulary has developed into a required part of the hospital's administrative structure and an authoritative source for cost-effective management of drug use within the institution. In recent years, closer evaluations of internal processes surrounding drugs with black-box warnings, safety protocols, and the development of programs such as the risk evaluation and mitigation strategies (REMS) have added to the costs of using some therapeutic agents. Whether it is regulatory agencies levying fines for inappropriate use of a drug, the cost of compliance with various therapeutic protocols within an institution, or the costs of adhering to the requirements of REMS, formulary choices have a much greater impact on an institution's budget now than they did in the recent past. In the future, one may also see reduced or denied payments under increasingly recognized "never events," should they be applied specifically to a given drug or class of drugs. Forward-looking pharmacists must accept the challenge of making thoughtful formulary decisions within this complex milieu that extends well beyond assessment of cost-effectiveness focused on therapeutic efficacy and acquisition costs.

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Fundamentally, the formulary represents a system governing the use of drugs and other products in a medically appropriate, safe, and cost-effective manner. The system that creates the formulary should be one that continuously updates and reevaluates policies and protocols that relate to the use of agents found on the

formulary.<sup>1</sup> Originally developed as a simple list of available therapeutic agents, the hospital formulary has become an integral part of the institution's patient care mission. This evolution has been driven by input from regulators at the national and local levels, scientific research that continuously evaluates an agent's safety and efficacy, and requirements from agencies such as the Centers for Medicare & Medicaid Services (CMS).

Beginning in the 1960s, institutional pharmacists found their roles changed by the presence of a formulary as they implemented the first generic interchanges among the drugs available in their pharmacies. Over time, reimbursements for care became tied to the presence of a formal formulary. Furthermore, a process for evaluating agents along with a formal pharmacy and therapeutics (P&T) committee became a requirement for

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accreditation by agencies such as the Joint Commission on the Accreditation of Healthcare Organizations, now known as the Joint Commission. Mounting evidence of the economic value attributable to a well-designed formulary system reinforced the cost-effectiveness of the formulary, and eventually, groups such as the Pharmaceutical Research and Manufacturers Association and the American Medical Association recognized the utility of the formulary and accepted basic tenets such as generic interchange in hospitals.

This article will provide an overview of the formulary process as it exists today and the agents of change that may affect the process in the future. The discussion will include administrative costs associated with monitoring drugs within an institution and costs associated with state and other oversight agency protocols, as well as pay-for-performance initiatives that may affect the formulary decision-making process. In addition, considerations associated with the use of drugs with black-box warnings, risk evaluation and mitigation strategies (REMS), and the evolving area of “never events” and how they may come to affect future reimbursements based on current guidelines from CMS and private payors will be discussed.

### **Impetus for Change**

In 1999, and updated in 2000, the Institute of Medicine (IOM) published results from its landmark study of medical errors and their cost to the health care system.<sup>2</sup> This study laid bare a simple fact—errors are symptomatic of system failures. Even with system improvements that significantly reduce dosing errors, such as unit-dose drugs dispensed by pharmacists replacing drug doses measured from multiple-use vials by nurses on patient wards,<sup>3</sup> preventable medical errors still resulted in annual costs estimated in 1999 of \$17 billion–\$29 billion and an estimated 98,000 deaths.<sup>2</sup> The costs were found to be not just monetary but had more intangible, but no less real, effects on a patient’s trust in the health care system, along with reduced satisfaction with care for both health care professionals and patients.<sup>2</sup> Furthermore, and perhaps most important, the IOM found that there was no financial incentive for systemic improvements of safety and quality. The IOM emphasized that it was the systems that were at fault, not individuals, and that system improvements, not punishment of individuals who commit errors, are essential to correcting

these problems. Thus, the IOM’s study was an impetus for change related to medical and medication errors across the United States health care system.

### **Role of the Pharmacy and Therapeutics Committee**

Although hospital formulary committees are distinctive to their parent organizations, they do have many common features. Not always appreciated by some is that P&T committees are a function of the medical staff and not of the pharmacy.<sup>1</sup> The composition of the committee varies from institution to institution and may comprise any mix of specialties including physicians, nurses, pharmacists, hospital administrators, quality improvement managers, and any other member of the health care delivery team as guided by the medical staff. The P&T committee is responsible for the evaluative process for all drugs—old or new—and for developing and overseeing drug-related institutional policies and procedures. Decisions of the P&T committee are recommendations that are subject to the administrative approval process of the medical staff.

The P&T committee sits at the center of a number of user-driven committees and subcommittees made up of those responsible for implementing and administering the formulary and its components. These committees may be standing committees with regular meetings and an established organizational structure, or they may be ad hoc committees established and dissolved to suit specific needs of the institution. Often broken down into broad categories such as oncology or antimicrobial users and committees responsible for order set reviews, patient safety, and patient care policies, these subcommittees provide the medical staff and other hospital personnel avenues for input to the formulary process. Integral to the creation and presentation of drug review documents that underlie every P&T committee formulary decision are pharmacists and their expert review of the available data on agents under consideration.

Decision making will always hinge on the safety and efficacy of the drug or class of drugs under consideration. As stated in the formulary management guidelines published by the American Society of Health-System Pharmacists (ASHP) in 2008, “Consideration of patient care and unbiased reviews of the biomedical literature are the cornerstone principles of formulary decision-making.”<sup>1</sup> Evidence-based reviews

founded on an independent review of applicable literature, expert opinion where appropriate, and established internal data and benchmarking programs can result in improved patient care and cost-effective use of accepted agents. Whereas patient safety and a drug's efficacy are always of paramount consideration, other factors may be taken into account when considering agents of similar efficacy and utility.

It has been recognized that the cost of a drug does not just consist of the acquisition cost, but other costs are included that increase the economic burden of managing a given disease state to society as a whole, in addition to the individual and a particular health care system.<sup>4</sup> For example, therapeutic drug monitoring costs as well as costs associated with adverse drug events are factors that should be considered by P&T committees as part of their evaluative process. In addition, there are costs associated with institutional dissemination of educational materials (e.g., newsletters, clinical guidelines) and education (e.g., one-on-one, group) as strategies for influencing physician prescribing behaviors.<sup>5</sup> Auditing and generation of reports designed to apprise physicians as to their prescribing patterns compared with their peers or accepted standards (e.g., management of coronary artery disease) are other costs related to drug use within an institution.<sup>5</sup> Finally, consideration of pay-for-performance initiatives and compliance with quality improvement mandates are of growing importance to P&T committees in the present and future relative to evaluating the overall cost of drug therapy.<sup>6</sup>

### Evolution of the Formulary Decision Process

Formularies are dynamic by their very nature. After-market evaluations of an approved agent's efficacy, therapeutic profile, and frequency and severity of adverse events are continually appearing in the literature. As our understanding of an agent's positive and negative attributes changes, new agents become available on the market, and brand-name drugs become available as generic drugs, formularies must evolve to reflect the very best decisions relative to patient therapy and safety, as well as cost-effectiveness.

Beyond the scientific evolution of drugs, other factors also bear consideration when an agent is being evaluated for formulary inclusion. Broadly stated, external influences combined with internal cost concerns have the potential to substantially expand and complicate the P&T committee's

decision-making process. In terms of internal processes, policies and procedures must be abided by and monitored, and in some instances, compliance must be reported. Policies and procedures include but are not limited to the following: institution-specific drug usage restrictions; publication and communication of drug-specific usage criteria and monitoring methods to the medical staff; development of drug-specific pop-up warnings in institutions with computerized physician order-entry systems; drug ordering requirements (e.g., goal laboratory values and indication for the agent); maintenance of patient registries; and requirement of approval of payment before the pharmacy purchases ultra-expensive drugs. Some of these requirements grow out of external programs and mandates; for example, pay-for-performance initiatives and oversight agency quality improvement mandates, respectively, are receiving increasing attention by P&T committees relative to formulary decisions.<sup>6</sup> The pressure being brought to bear by regulatory and oversight agencies, such as the Joint Commission or state health care agencies overseeing hospitals, can significantly affect internal processes governing drug use, which agents are available on the hospital's formulary, and how and to whom specific drug use is reported and documented. It is noteworthy that these external factors can also affect the legal landscape of the formulary process and, occasionally, the pharmacist's role in it. Specific examples include consideration of drug usage for agents with U.S. Food and Drug Administration (FDA) black-box warnings and adherence to REMS (discussed below).

### Black-Box Warnings

One area where regulatory agency requirements and internal compliance requirements intersect concerns drugs with boxed warnings, commonly referred to as black-box warnings. Representing the highest FDA warning level of a drug's potential for causing serious adverse events, black-box warnings alert prescribers to these potential issues. In some instances, they also define specific management requirements for an agent's use. One example is the use of droperidol. Droperidol's package insert carries a boxed warning elucidating the potential cardiac arrhythmias associated with its use.<sup>7</sup> The proarrhythmic effects of droperidol could lead to QT-interval prolongation and/or torsade de pointes, even in patients with no known risk factors, and in some cases has resulted in

fatalities. The boxed warning also states that a 12-lead electrocardiogram (ECG) is required before any patient is prescribed droperidol therapy, and specific criteria are stated to preclude its use in certain patient populations. Failure to perform a baseline ECG recently resulted in a finding of “immediate jeopardy” and a significant fine from regulators.<sup>8</sup>

Generally, black-box warnings will apply to all members of a given drug class, such as angiotensin-converting enzyme inhibitors. Less commonly, a single member of a drug class may carry a black-box warning, whereas another member or members of the class may not carry the black-box warning or have a different black-box warning. This latter situation is found with the antiplatelet drugs clopidogrel and prasugrel. Prasugrel carries a black-box warning concerning the possibility of severe, even fatal hemorrhages associated with its use,<sup>9</sup> whereas clopidogrel’s recently announced black-box warning warns of reduced effectiveness in poor metabolizers of the drug.<sup>10</sup> With over 400 drugs or chemical entities currently bearing black-box warnings, keeping up with them, their individual requirements, and developing programs to comply with the specific black-box warnings can be a daunting task. Usually this challenge falls on the pharmacist.

### Risk Evaluation and Mitigation Strategies

First appearing in April 2008 and associated with the combination drug sumatriptan succinate–naproxen sodium, REMS have grown to encompass 81 drugs.<sup>11</sup> At their core, these strategies are intended to ensure that the benefits of prescribing a drug or chemical entity outweigh the risks associated with its use and that the risks are communicated and mitigated.<sup>12</sup> Each program or “strategy” is individualized for the agent it governs and, whereas extensive REMS relevant to the hospital-based pharmacist are the exception rather than the rule, one group of agents—erythropoiesis-stimulating agents (ESAs)—have very recently had a REMS program requirement placed on them.<sup>13</sup>

Elements of the REMS may include any combination of medication guides, patient package inserts, communication plan for health care providers, and specific requirements for anyone who prescribes, dispenses, or uses the drug.<sup>12</sup> In most cases, the REMS will only involve the provision of a medication guide intended to communicate the risks of utilizing the entity.<sup>11</sup> However, in some cases, the risks associated with

the use of an agent are deemed to be sufficient to require more extensive programs. These programs can involve not only those prescribing the drug or those taking it, but also the manufacturer and, in a few instances, the pharmacist dispensing the drug.

As an example, the (47-page) REMS for the endothelin receptor antagonist, ambrisentan, not only requires a medication guide that warns of the risks associated with it, but further requires any health care provider who wishes to prescribe it be specially certified by the manufacturer (and the manufacturer must maintain a roster of certified prescribers).<sup>14</sup> In addition, the prescriber must certify on a monthly basis that liver function tests have been performed and reviewed, and that female patients of childbearing age are administered a monthly pregnancy test, with the findings reported to a requesting pharmacy. For its part in the REMS program, the dispensing pharmacy must be separately certified and is required to ensure that laboratory testing has been completed by verifying with either the patient or the prescriber and to remind the prescriber of the obligation to perform the monthly tests if they have not been done.

In February 2010, the FDA announced the new REMS protocol for ESAs.<sup>13,15</sup> Already subject to a black-box warning for their association with increased risk of death and serious cardiovascular events in addition to the potential to shorten overall survival and/or increase the risk of progression of certain tumors, ESAs now require a medication guide warning of the risks outlined in the black-box warning and require the manufacturer to develop a training program for oncologists prescribing these agents. Under this program, manufacturers are required to provide training that supports informed decision making by patients and their health care providers based on the risks posed by ESA use. Furthermore, by establishing the ESA APPRISE (Assisting Providers and Cancer Patients with Risk Information for the Safe Use of ESAs) Oncology program, the REMS has a stated goal of mitigating the risk for poorer outcomes and/or decreased survival in patients with cancer. Finally, only those institutions and oncologists certified under the REMS will be able to prescribe and dispense ESAs, with oversight and monitoring of REMS compliance being the duty of the manufacturer. This means that hospitals must be certified in order to dispense ESAs, and they must ensure that only physicians who are certified to prescribe ESAs have that privilege in

the dispensing institution. The institution's program will be subject to audits from the manufacturer. Given the recent nature of the REMS issued for ESAs, protocols may or may not have been previously in place relative to the use of ESAs within individual institutions, but it is likely that the administrative duties will undoubtedly fall on the pharmacist to implement and monitor the compliance program now and in the future.

#### Never Events

A concept that has not yet been directed at any specific drugs but that has growing implications for hospital risk management is referred to as never events. After the IOM report on health care system safety of 1999,<sup>2</sup> the National Quality Forum (NQF), a not-for-profit patient advocacy agency, studied safety-related issues and published a list of so-called never events with the support of the CMS.<sup>16</sup> These events were defined as errors that should never occur and that represent serious concerns for the safety of patients and an institution's credibility.<sup>16</sup> The original list included 27 clearly identifiable and preventable safety issues that entailed serious consequences for patients should they occur.

With passage of the Deficit Reduction Act, a first step was taken in the direction of reducing or eliminating payments for never events by allowing CMS to modify its payment policies for certain hospital-acquired conditions.<sup>16</sup> Subsequent reviews have led to the expansion of the CMS list of quality measures that hospitals are required to report and a strengthening of the bond between quality care and reimbursement.<sup>17</sup> These quality measures now include 28 recognized never events, and the CMS continues to work with the NQF to improve care and eliminate never events.

In January 2009, the CMS announced its first policy eliminating all payments, including payments to physicians, for three surgical never events: wrong patient, wrong procedure, and wrong side or body part.<sup>18</sup> This change from simply disallowing payment at higher coding rates to eliminating payment for all costs associated with these egregious errors represents a small step in the attempts by CMS and other payers to improve quality of care and control spending waste. In light of the 1999 IOM report finding that an obstacle to improving safety was the lack of financial incentive to change practices,<sup>2</sup> this would appear to be a logical progression that is likely to continue.

Adoption of the NQF's list of never events is

not confined to the CMS. Several states and private insurers have adopted the NQF's list in whole or in part as a component of payment-reduction policies; in some instances, they have expanded the scope to include reporting requirements to both state agencies and, in some cases, to patients themselves. Almost as soon as NQF's list was announced, Minnesota adopted mandatory reporting of never events to the Minnesota Hospital Association.<sup>16</sup> An investigation of each event was mandated, as well as a report if corrective actions were required, to facilitate sharing of information among member institutions and improve the quality of patient care. In its first year of collecting data, the database identified 20 deaths and four serious disabilities among 99 reported events. Second-year reporting identified 106 total events, including 53 surgical and 39 patient management events, 12 deaths, and nine serious injuries.

Other states have adopted similar reporting policies directed at reducing errors and improving patient care. In 2004, New Jersey enacted a law that required reporting of these events not only to the state, but also to the patients' families.<sup>16</sup> The state of Connecticut added specific events to some of those listed by the NQF, and Illinois now requires reporting of 24 of the 28 identified never events. More states are looking at this issue and are considering adopting their own policies.

Almost inevitably, private payers began to address never events in their own ways. In 2008 two large insurers, Blue Cross and Blue Shield (BC/BS) and Aetna, adopted policies based on never events. For example, several members of the BC/BS group instituted policies akin to those of the CMS. The BC/BS of Massachusetts indicated that it would make no payments for any of the 28 NQF-defined never events, and BC/BS of Kansas adopted a no-payment position for eight of the CMS-recognized conditions and pledged to follow the CMS' lead in future revisions.<sup>19</sup> A third member of the BC/BS family, BC/BS of Texas, adopted policies relating to all of the CMS-defined and several of the NQF-defined events with the stated intention of not paying for additional costs associated with preventable medical errors.<sup>20</sup> For its part, Aetna announced a policy adopting the NQF list of never events that requires reporting of these incidents to either a designated state agency, the Joint Commission, or patient-safety advocacy groups.<sup>21</sup> The never events provision will be included in the language of new and renegotiated agreements with hospitals and also requires the institution to waive all costs

associated to these serious reportable events and apologize to the patient or the patient's family.

As stated previously, no drug-specific or drug class-specific never events currently exist. However, three events are related to pharmaceutical care and were added to the CMS list of preventable conditions in 2008: death or disability due to poor glycemic control, contaminated drugs, or medication errors.<sup>22</sup> This addition to CMS policy reinforces the CMS' ongoing efforts to improve patient care while reducing payments that result from medical errors. Although specific drugs or drug classes are not part of the CMS' or other payer's policies as of this time, they should be kept in mind in the future as payers look to further reduce costs and patient advocacy groups identify more areas where patient safety can be improved.

### Role of the Pharmacist

As the primary source responsible for providing scientific data to support formulary decisions, pharmacists are in an ideal position to address cost-containment concerns well beyond acquisition cost. In some institutions or systems, specially trained pharmacists evaluate the pharmacoeconomic impact of a drug or drug class on the institution's budget. As stated in the ASHP formulary management guidelines, even in systems where a formal pharmacoeconomic impact analysis is not performed, a financial evaluation must be a component of the process and must take into account non-drug-related elements.<sup>1</sup> The financial consequences to the pharmacy as well as the institution must be accounted for when P&T committees consider the formulary status of a drug.

### Conclusion

Pharmacists have been integrally involved with improvements to systems such as unit-dose dispensing to reduce medication errors, technologic advances such as automatic dispensing units, and, for a growing number of institutions, computerized physician order-entry systems. The essential role played by pharmacists within the traditional formulary review process and establishment of drug use policies has also undoubtedly had a major impact on medication error reduction over the years. The challenge faced by these same pharmacists will be to account for the evolving list of factors (e.g., black-box warnings, REMS, possible drug therapy never events) affecting P&T formulary

decisions in the present and future. Only then can the safe and cost-effective use of drugs within the institutional setting be ensured.

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