

An Interview Series with Members of the ASHP Expert Panel on Formulary Management

Part 3: Sabrina W. Cole, PharmD

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This article presents the third in a series of three interviews that *P&T* conducted with several members of the American Society of Health-System Pharmacists (ASHP) Expert Panel on Formulary Management.

In 2008, ASHP convened this panel of experts to develop revised guidelines for P&T committee and formulary management to replace the previous guidance issued in 1991.¹ These revised guidelines include recommendations concerning the review and evaluation of drugs for formulary in-

clusion, pharmacoeconomic assessments, therapeutic interchange, medication-use evaluations (MUEs), management of drug shortages, and many other important topics.

In this series, ASHP experts discuss P&T committee and formulary management guidelines in their respective institutions as well as other observations and insights. In Part 3, the author interviews Sabrina Cole, PharmD, Clinical Specialist, Drug Information, at the Grady Health System in Atlanta, Georgia.

P&T COMMITTEE AND FORMULARY ADMINISTRATION

P&T Committee Management

Q. *P&T committees are said to increase practitioners' knowledge about drugs and improve safety and therapeutic outcomes. In what way do they accomplish these goals?*

Dr. Cole: P&T committees are successful in accomplishing the goal of increasing knowledge about drug therapy, safety concerns, and improved therapeutic outcomes, since the composition of the committee is multidisciplinary and members have regular discussions related to drug therapy. The scope of the P&T committee's responsibility includes all aspects of drug therapy, prescribing, dispensing, administration, and monitoring; therefore, all disciplines are required to consider risk points in each step of the process. In addition, all drugs requested for formulary consideration are evaluated based on safety, efficacy, and the potential for medication errors. They are also candidates for a six-month utilization review if added to the formulary.

Q. *Conflicts of interest may interfere with a P&T committee member's ability to make evidence-based decisions. How does your organization prevent conflicts of interest? Are people with disclosed conflicts of interest allowed to participate on the P&T committee?*

Dr. Cole: Each member of the P&T committee completes a conflict of interest form annually; however, if a conflict of interest exists for a member, he or she is still allowed to serve on the committee.

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Q. *How does your organization deal with potential conflicts of interest with regard to practitioner requests?*

Dr. Cole: Grady Health System is a teaching hospital, so only attending/faculty physicians are allowed to request medications to be added to the formulary. In addition, their chief of service must cosign the request, indicating endorsement, and a conflict-of-interest disclosure is required of the requestor.

Q. *How often do you review and revise P&T committee policies?*

Dr. Cole: P&T policies are all reviewed biennially and revised on an as-needed basis.

Q. *What is the composition of your medical staff leadership? Who has final approval on the P&T committee's policy decisions?*

Dr. Cole: The medical executive committee, which is responsible for the approval of the decisions made by the P&T committee, is composed of the chiefs of service for all service lines and the executive administration. Nursing is also represented on the medical executive committee.

Formulary Management

Q. *What criteria does a medication have to meet in order to be included on the formulary?*

Dr. Cole: We apply several criteria to new formulary applications, including: an established need in relation to the diseases and conditions treated by our practitioners, therapeutic effectiveness, pharmacokinetic properties, similarity to other formulary medications, cost-effectiveness, and safety. We also request that a medication be on the market for a minimum of one year to allow for clinical experience and the manifestation of adverse drug reactions before it is introduced into our organization. However, if a medication is a novel treatment, this one-year guideline is waived.

Q & A: ASHP Interview with Dr. Cole

Q. *What safety criteria are used to evaluate medications?*

Dr. Cole: All new medications that undergo formulary review are evaluated for safety based on published reports of adverse drug reactions (ADRs) from clinical trials and postmarketing surveillance. If there are any internal safety reports, those would also be presented to the P&T committee.

Q. *What information is included in your drug evaluation document? Does it include off-label uses and comparative-effectiveness data?*

Dr. Cole: The formulary monograph for a drug we are reviewing includes the following information: therapeutic indications, critical analysis of clinical studies, bioavailability and pharmacokinetics, dosage and administration, adverse effects and toxicities, therapeutic comparisons with other drugs or treatment regimens, a potential for medication errors, and a cost comparison of a standard treatment regimen with currently used medications versus the new agents. Off-label uses are included in the monograph if the formulary application specifically states this as an intended use within our organization.

Q. *Do formulary status recommendations from external drug information services or expert groups have an influence on P&T committee decisions?*

Dr. Cole: Yes. While our P&T committee asks that routine requests not be accompanied by a formal recommendation, oftentimes internal expert panels are employed to make recommendations regarding the formulary status of a therapeutic class or individual agent. In addition, we have an antimicrobial subcommittee that evaluates all requests for antimicrobial agents and makes recommendations to the P&T committee. These recommendations are generally accepted.

Q. *What review process, if any, does your institution require for generic drugs that have been deemed bioequivalent by the FDA? Are they reviewed for safety concerns (for example, look-alike, sound-alike issues)? How about those that have a narrow therapeutic range?*

Dr. Cole: Generic medications do not need specific approval as long as they are deemed therapeutically equivalent to formulary medications according to the FDA's *Orange Book*.

Q. *The ASHP guidelines state that the P&T committee should interpret the term "medication" broadly to include "alternative remedies," including herbals and supplements, nonprescription drugs, blood derivatives, contrast media, and other diagnostic and treatment agents. Does your organization include such "alternative remedies" on the formulary?*

Dr. Cole: The inclusion of alternative remedies on the Grady Formulary is product-specific. There are certain blood derivatives that are the responsibility of the blood bank; however, the P&T committee is responsible for reviewing contrast media, vitamin supplements, and nonprescription drugs to be

placed on the formulary. Our organization does not currently review herbal products for formulary inclusion, nor does the pharmacy have these products available.

Q. *How does your institution handle formulary exceptions that are medically necessary for patients who have unique needs that might not be satisfied by formulary medications?*

Dr. Cole: We have a nonformulary process in place for the following situations:

- if the patient has a documented therapeutic failure with the formulary options
- if the patient has a documented adverse effect with the formulary options
- if there is no appropriate therapeutic equivalent on the formulary
- if a patient is stabilized on a nonformulary medication prior to admission and a change in the medication would jeopardize his or her status

We also utilize the nonformulary process in our outpatient pharmacies when a patient's prescription drug coverage differs from the Grady Formulary.

Q. *What criteria are applied to decide to delete a medication from the formulary?*

Dr. Cole: We consider medications for formulary deletion if there has been low utilization, significant safety concerns (as evidenced by ADR reports), or a significant potential for medication errors, or if the drug has been the source of a medication error or manufacturer discontinuation.

Q. *In what way is purchasing information used to make additions or deletions to the formulary?*

Dr. Cole: We screen formulary products through use of our purchasing data. If our records show that we have not purchased a product recently, we will verify with utilization data to determine whether the product should be deleted from the formulary.

Evidence-Based Evaluations in Formulary Management

Q. *How are clinical trials evaluated and critiqued?*

Dr. Cole: Two to three clinical trials are selected for inclusion in the formulary monograph. Each study is evaluated by a clinical pharmacist and critiqued by a systematic evaluation of the study's objective, methods, statistical analyses, results, and conclusions.

Q. *Who generally provides the information to evaluate medications that are being considered for formulary inclusion?*

Dr. Cole: The Drug Information Service is responsible for preparing unbiased evaluations of medications requested for formulary addition. The staff participating in this process

Q & A: ASHP Interview with Dr. Cole

includes the drug information specialist, PGY-1 (postgraduate year one) pharmacy residents, P4 (fourth-year) pharmacy students, and clinical pharmacists also provide targeted support.

Q. *Is the information generally appropriate—in other words, thorough, accurate, and unbiased?*

Dr. Cole: All reviews are unbiased and as thorough as possible. Since the Drug Information Service performs the drug evaluation, it is evidence-based and unbiased.

Q. *How is information provided by pharmaceutical manufacturers utilized by your P&T committee, since its objectivity may be in question?*

Dr. Cole: We do not utilize information provided by pharmaceutical manufacturers in our evaluations.

Q. *Are observational studies (case-control and cohort studies, case reports, and consensus opinions) ever utilized to make decisions?*

Dr. Cole: We prefer to evaluate head-to-head, randomized controlled trials; however, if these studies are lacking in the published literature, we may also need to utilize observational studies to evaluate outcomes.

Q. *What criteria are considered when improved patient care outcomes are evaluated?*

Dr. Cole: Again, we prefer head-to-head clinical trials when evaluating patient care outcomes for new medications. These give us an evidence-based assessment of the expected outcomes in our patient population.

Q. *Do you use internal data, prescribing, and outcomes information in making formulary decisions?*

Dr. Cole: Yes. As mentioned, we rely on purchasing information and utilization data to make additions to or deletions from the formulary. In addition, we perform medication-use evaluations (MUEs), which also assist us in making changes to our formulary with respect to additions and deletions, as well as changes to order forms and medication-use guidelines.

Pharmacoeconomic Assessments in Formulary Management

Q. *What criteria are employed to demonstrate cost effectiveness?*

Dr. Cole: Medications that are requested for formulary inclusion are compared with similar formulary agents with respect to acquisition cost, as well as other cost comparisons, based on the anticipated utilization by the requesting physician.

Q. *Does your P&T committee conduct pharmacoeconomic or cost-minimization evaluation * when considering a drug for the formulary?*

Dr. Cole: Although the P&T committee considers these factors in making formulary decisions, we do not perform pharmacoeconomic or cost-minimization evaluations for every formulary request.

Q. *Does your P&T committee consider a cost-effectiveness analysis? ***

Dr. Cole: No.

Q. *Does your P&T committee conduct cost-utility evaluations? ****

Dr. Cole: No.

Q. *Does your P&T committee use decision analysis models that incorporate local data when published pharmacoeconomic data are limited or unavailable?*

Dr. Cole: No.

Q. *Does your committee use pharmacoeconomic analyses that are published in the medical literature or provided in the manufacturer's formulary dossier? Is there any concern that assumptions made in these studies are too simplistic and therefore might not be valid in your particular institution?*

Dr. Cole: No. We take into consideration that while this information is helpful, it is often not a reflection of our organization.

Formulary Drug Reviews

Q. *At what intervals are reviews of an entire therapeutic class of drugs conducted? What sort of information is utilized to review a therapeutic class? For what reasons might a therapeutic class be removed from a formulary? What changes in restrictions or guidelines might be instituted for a drug class?*

Dr. Cole: Therapeutic class reviews are not routinely conducted at our organization. When necessary, a therapeutic class review is performed, which includes comparative information on the following: indications, published evidence, warnings/precautions, adverse effects, available dosage forms and strengths, dosage and administration, and cost. A therapeutic class may be removed from the formulary if the committee feels that the safety risks of the class outweigh any potential benefit. For example, the COX-2 inhibitors were removed from

* Cost-minimization studies consider both medication and other expenses, including administration, monitoring, prolonged hospital stays, laboratory test monitoring, and costs to patients and health care providers.

** A cost-effectiveness analysis considers the incremental difference in investment necessary to produce an improvement in clinical outcome. It is infrequently used for formulary decision making because it is complex and relies on strong evidence or data.

*** A cost-utility evaluation evaluates the incremental investment necessary to produce a change in quality-of-life adjusted clinical outcome (e.g., cost per quality-adjusted year of life gained for one medication compared to another). This type of evaluation is subject to the same concerns as a cost-effectiveness evaluation.

Q & A: ASHP Interview with Dr. Cole

the formulary in July 2003 because of the significant safety concerns associated with these agents.

Q. *Do you establish dates to reassess the effect of a formulary decision on the quality or cost of care? How much later after the inclusion of a drug on formulary are decisions reassessed?*

Dr. Cole: Yes. The P&T committee may require the requesting physician to report on compliance with formulary restrictions and criteria within 6 months of the decision.

Q. *Do you have a process in place for expedited review of a new drug, indication, or re-evaluation of a previous formulary decision because of safety or other concerns? Specifically, when might this process be employed?*

Dr. Cole: Yes. Typically, a standard request for a formulary addition will be reviewed by the P&T committee within three months of being received. If there is a need for expedited consideration of a new request, it will be reviewed at the next meeting of the committee.

Q. *For what reasons would an expedited review of a drug by the P&T committee take place?*

Dr. Cole: An expedited review may take place if a medication is requested for formulary addition and there is no therapeutic alternative that exists. An expedited review may also take place if significant cost savings have been associated with the use of a drug that has been submitted for formulary inclusion.

Q. *Does your P&T committee automatically review drugs that become available in new dosage forms?*

Dr. Cole: No.

Q. *Then what is the process for making a new dosage form available in your hospital? Is the pharmacy solely responsible for decision-making in this regard?*

Dr. Cole: A physician may identify the need for a new dosage form and request it as a line extension. Otherwise, we, in the pharmacy, usually identify that an additional dosage form is needed or should be evaluated when we have been receiving nonformulary requests for it.

MANAGEMENT STRATEGIES FOR DRUG USE

Patient Safety Measures

Q. *What safety mechanisms do you have in place to ensure safe prescribing, distribution, administration, and monitoring of medications?*

Dr. Cole: We employ the use of standardized order forms for a variety of patient orders (e.g., chemotherapy, heparin, community-acquired pneumonia) to encourage safe prescribing. We also avoid a list of prohibited abbreviations to minimize con-

fusion or misinterpretation. We dispense approximately 90% of our medications from automated dispensing cabinets, which helps to minimize medication errors. We use smart pumps to ensure safe administration of intravenously infused medications.

Q. *What procedures are in place to prevent medication errors?*

Dr. Cole: We utilize order-writing guidelines, smart pumps, automated dispensing cabinets, and tall-man lettering in the pharmacy. These are all methods to prevent medication errors within our institution.

Q. *What sort of risk evaluation is conducted for high-risk medications or major system changes (such as new equipment)?*

Dr. Cole: All drugs that are considered for formulary addition are evaluated for medication error potential.

Q. *How often are medication event data reviewed and by what process?*

Dr. Cole: Medication errors and ADRs are reviewed daily by our medication safety officer, who is a pharmacist.

Q. *Does your institution use bar-coding or other fail-safe techniques to prevent medication events?*

Dr. Cole: We are in the process of implementing bar-coding technology.

Q. *How does your organization review externally available information regarding patient safety or adverse reaction reports issued by other organizations to identify ways to prevent medication events?*

Dr. Cole: Our pharmacy administration regularly reviews Institute for Safe Medication Practices (ISMP) reports to raise awareness of the potential for medication errors and to identify whether our processes need to be modified.

Q. *Are there any other medication safety resources that are reviewed to identify potential issues that might be addressed by your organization, such as MedWatch, FDA Patient Safety News, or the U.S. Pharmacopeia Patient Safety Program?*

Dr. Cole: We review all of those publications for potential medication safety issues.

Therapeutic Interchange

Q. *How do you identify opportunities for therapeutic interchange?*

Dr. Cole: We use therapeutic interchange to support our formulary. Therapeutic interchange guidelines are developed by members of the pharmacy staff and are approved by key physicians and, finally, by the P&T committee.

Q & A: ASHP Interview with Dr. Cole

Q. *What authorization and notification policies are in place to notify prescribers, patients, pharmacists, nurses, and other health care professionals when a therapeutic interchange occurs?*

Dr. Cole: Our therapeutic interchange policies allow the pharmacists to interchange medications in accordance with the approved protocol without having to contact the prescriber. Health care providers are notified of the interchange only through documentation in the patient's medical record.

Guided-Use Strategies

Q. *What sorts of considerations are included in established-use criteria?*

Dr. Cole: We utilize clinical pathways or established-use criteria that are developed by multidisciplinary committees. We also utilize guided-use strategies for preprinted order forms and drug shortages.

Q. *What sorts of drugs on formulary are limited to specially trained individuals?*

Dr. Cole: Medications with significant safety concerns (e.g., chemotherapy) are restricted according to level of prescriber (e.g., faculty) and/or by service (e.g., oncology). Also, medications that present a significant cost impact to the organization may be restricted for use only by faculty physicians to ensure appropriate utilization.

Q. *Do you have drugs on the formulary that are restricted to being used in a specific location because of the availability of equipment?*

Dr. Cole: Yes, we restrict certain medications to be administered only in the intensive-care unit if greater monitoring capabilities are necessary.

Q. *Do you have drugs that need to be approved by a medical director, or some other designee, before they are used? Why do they need approval?*

Dr. Cole: Nonformulary medications require the approval of a physician, usually a chief of service, authorized to prescribe them. This serves to ensure limited nonformulary use.

Clinical Practice Guidelines

Q. *Does your P&T committee establish clinical practice guidelines?*

Dr. Cole: Our P&T committee has established certain clinical practice guidelines in the form of restriction criteria. For example, antibacterials are restricted per established criteria, primarily to ensure appropriate utilization.

Q. *Do you use clinical practice guidelines that are developed and disseminated by national and international organizations or are they developed locally?*

Dr. Cole: Our guidelines may reflect recommendations by national organizations; however, they are developed and approved within the organization by internal thought leaders in the respective disciplines.

Instituting Medication-Use Policies

Q. *How are medication-use policies implemented and communicated in your organization? Are they conveyed through order forms, in-service education, grand rounds, conversations between pharmacist and physicians, staff meetings, e-mails, newsletters, mailings, or pharmacy or institutional Web sites?*

Dr. Cole: Medication-use policies are distributed in a variety of ways. Some policies are printed on physician order forms. Mass communications are also distributed by the Drug Information Service to all prescribers following the monthly P&T committee meeting. However, perhaps the best method of education is direct pharmacist-to-physician communication.

Q. *Does your institution employ pilot projects for new medication-use policies?*

Dr. Cole: Yes. Prior to a complete roll-out for new medication-related policies in our hospital, pilot projects are done with a few areas or services to identify any problems or barriers to the use of the new policy, guideline, or order form. Given this experience, we can modify the process to be more efficient before implementing the project throughout the organization.

Medication-Use Evaluation

Q. *What sort of MUE activities does your institution conduct, and how is the P&T committee involved?*

Dr. Cole: MUEs are conducted when necessary, depending on the specific needs of the organization. In addition, pharmacy residents are responsible for conducting several MUEs annually, based on topics submitted by the clinical pharmacy staff. The results of these quality-improvement projects are reported to the P&T committee or a subcommittee if appropriate.

Q. *Does your institution use electronic medical records to conduct MUE activities?*

Dr. Cole: Our institution is in the process of implementing an electronic medical record.

Q. *When a MUE is conducted, is an individual drug or the entire process of care for a disease state evaluated?*

Dr. Cole: The type of evaluation we conduct depends on the topic in question. We may evaluate the entire medication-use cycle or just one aspect of it, the use of medications in a specific therapeutics class, or an individual drug.

Q. *Why are MUEs instituted? Is the process usually employed to obtain information or to measure the effect of interventions?*

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Dr. Cole: MUEs are conducted for a variety of reasons and may be performed on high-risk, high-cost, or problem-prone formulary agents. MUEs may also be completed to evaluate adherence to institution-specific guidelines or formulary restrictions or to evaluate whether the use of high-cost medications is appropriate.

Q. *What sorts of targeted quality improvement projects are conducted?*

Dr. Cole: In addition to MUEs, our medication safety officer routinely collects data to ensure compliance with organization-specific guidelines and Joint Commission standards.

Drug Shortage Management

Q. *What strategies are in place at your institution to deal with drug product shortages? Do you use strategies such as designating appropriate alternatives, rationing, use restrictions, or therapeutic interchange?*

Dr. Cole: Drug shortages are managed in a medication-specific manner. Some shortages require only an interchange (e.g., carvedilol) with a similar therapeutic alternative, whereas others require specific recommendations based on the indication (e.g., amikacin). We utilize rationing of medications that are procured based upon allocation, and we may restrict prescribing of those drugs solely to faculty or chiefs of service in order to ensure appropriate utilization.

Q. *What do you mean by "procured by allocation"?*

Dr. Cole: In times of drug shortages, manufacturers may use a process of "allocation" to distribute their product to hospitals. For example, when there is a shortage of intravenous immunoglobulin (IVIG), we get only a certain number of grams of this medication each month, which must be reserved for patients who meet our requirements for administration of IVIG when the supply is limited.

Q. *Do you work with other committees and departments to develop management plans for addressing shortages?*

Dr. Cole: The pharmacy department, primarily, manages drug shortages. When necessary, key prescribers are contacted to agree upon a suggested alternative to the medication that is on back order. In addition, some drug shortages may require a formal recommendation from the antimicrobial subcommittee or the P&T committee regarding appropriate management, depending on the nature of the shortage.

Q. *Does the P&T committee include a drug shortage update as a regular agenda item?*

Dr. Cole: Yes, for the pharmacy staff.

Q. *How are drug shortages communicated to patients and staff by the P&T committee?*

Dr. Cole: When a drug shortage occurs, e-mails are sent from the Drug Information Service to notify the professional staff.

Generic Drugs

Q. *What policies and procedures govern the dispensing of generic equivalents in your institution? Can the prescriber specify the brand or supplier of the drug?*

Dr. Cole: Our pharmacy procurement specialist, who is a pharmacist, selects the generic equivalents with input from the Drug Information Service.

Q. *If the prescriber is responsible for specifying the brand or supplier of the drug, what reasons for that choice would be considered clinically justified?*

Dr. Cole: To my knowledge, a prescriber has never made such a request.

Off-Label Uses

Q. *Do you include medications for off-label use on your formulary? Can you give examples?*

Dr. Cole: Yes. For example, acetylcysteine is used off-label for the prevention of contrast media-induced nephrotoxicity.

Q. *What sorts of risk-benefit analyses are made before putting a drug for off-label use on the formulary?*

Dr. Cole: If the requesting physician submits an application for the addition of a medication to the formulary for off-label use, we follow the same process to evaluate efficacy, safety, and cost effectiveness. Expert panels may also be used to evaluate the literature supporting the off-label use.

Investigational Drugs Procedure

Q. *What process is followed when investigational drugs are used in your institution?*

Dr. Cole: We have an investigational pharmacist who is dedicated to managing inpatient and outpatient investigational drug use. This pharmacist coordinates his role with the study investigators in accordance with the clinical protocol. Upon receipt of an order for an investigational agent, the pharmacist ensures that it is dispensed from the protocol-specific drug supply.

REFERENCE

1. Tyler LS, Cole SW, May JS, et al. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. *Am J Health Syst Pharm* 2008;65:1272-1283.

We hope that this discussion with Dr. Cole has been informative and useful to our readers. This article concludes our series of three interviews with members of the ASHP Expert Panel on Formulary Management. ■