Q & A

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

Part 2: J. Russell May, PharmD

C. Lee Ventola, MS

This article presents the second 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.

A year ago, 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 inclusion, 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 2, the author interviews J. Russell May, PharmD, Clinical Professor, Department of Clinical and Administrative Pharmacy, at the University of Georgia College of Pharmacy in Athens, Georgia. He has a practice at the Medical College of Georgia Health System in Augusta, 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. May: Communication of P&T committee decisions is key. Minutes of the meeting are distributed to all P&T committee members to share with their departments and to all pharmacists and other health care practitioners in our institution. The minutes are reviewed and approved by the medical center's Medical Executive Committee. This ensures that the organization's leadership is informed. Results are reviewed by the P&T committee with the pharmacy staff within a week of the meeting. This measure includes providing new drug monographs and any new usage guidelines or drug policies. All new guidelines and policies are also published on our Web site and are summarized in our drug information newsletter, which is widely distributed throughout the medical center.

One of the best examples of the P&T committee's role in increasing practitioners' knowledge is the *Guide to Antimicrobial Therapy*, which we publish annually. All antimicrobial guidelines are reviewed annually and updated. This process is overseen by a subcommittee of the P&T committee. The book contains evidence-based guidelines for using agents that are available on our formulary and takes our antibiogram into consideration. Also included are renal dosing tables, our intravenous-to-oral (IV-to-PO) conversion policy, and monitoring guidelines. The book is distributed to all new physician house staff during their orientation in July. It is also available on our Web site. Monitoring adherence to these guidelines and other associated medical safety issues is an ongoing part of our antimicrobial stewardship program. Outcomes are reported back to the P&T committee for information and action. Examples of medication safety and therapeutic outcomes initiatives include venous thromboembolism (VTE) prophylaxis guidelines and our weight-based IV heparin protocol.

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. May: P&T committee members are asked for disclosures when appointed. They are allowed to abstain from voting if there is a perceived conflict of interest. This has not been an issue to date since most of our votes are unanimous.

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

Dr. May: Our new formulary request form requires requestors to disclose any perceived conflicts of interest. The evaluative monograph for the drug is prepared in our Drug Information Center using published evidence only. Requestors are not invited to the P&T committee meeting at which the drug is initially discussed. If their request is turned down, the committee offers them the opportunity to review the evaluative monograph and to come to the next meeting if they disagree. This offer is seldom taken.

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

Dr. May: An attempt is made to review them annually.

The author is a Consultant Medical Writer living in New Jersey.

Accepted for publication November 2, 2009.

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

Dr. May: The Medical Staff Executive Committee approves all P&T committee decisions. This committee is made up of all medical staff department chairs, the Chief Medical Officer, the Vice President for Quality and Safety, the Epidemiology department chair, legal counsel, and the Quality Management department chair.

Formulary Management

Q. *What criteria does a medication have to meet for inclusion on a formulary?*

Dr. May: We require the drug be on the market for 12 months before we will consider adding it unless it has received a "priority" review from the FDA or we see an immediate need in our patient population.

Q. *What is the drug being considered for the formulary being compared with? Other agents in the same class that are on the formulary already? Other drugs for the same indication that aren't on the formulary but are on the market?*

Dr. May: The new drug would be compared with the agents on the formulary that currently are used in the same situation (i.e., in the same pharmacologic or therapeutic class). If the new drug is in a new pharmacologic class without any comparative agents on the formulary, we compare it with medications that have the same indication and that have been historically used to treat those patients.

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

Dr. May: We are basically looking at the incidence and severity of reported adverse drug events (ADEs) and side effects compared with the formulary agent. This must be carefully done because a new drug might not have had the benefit of being studied in a wide range of patients. Frequently the new drug looks safer initially, but after it has been on the market a while, the safety profile will more closely match that of the older drug.

For agents in a new pharmacologic class, this evaluation is more difficult. If we can delay the evaluation for one year after the drug's release, as described earlier, we can better weigh risks versus benefits. At that point, enough time has passed to have a clearer picture of the drug's adverse-reaction profile. The P&T committee also evaluates IV implications such as monitoring and administration issues as well as look-alike, sound-alike drugs.

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

Dr. May: The P&T committee's drug evaluation document describes pharmacology (including mechanism of action) and indications and clinical efficacy (what medical evidence exists that demonstrates efficacy). This is always done in a comparative manner if possible. There are also sections on pharmacokinetics, adverse drug reactions (ADRs), dosing and administration, budget analysis, summary of advantages and disadvantages, recommendations, and references.

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

Dr. May: Documents from external sources are reviewed only after our own literature search is performed and our monograph is developed. External documents could serve as an addendum to our monograph if deemed credible. Expert opinion documents are evaluated for the level of evidence they use and the credibility of authors.

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. May: We purchase medications based on our group-purchasing organization policies. These policies include established guidelines for the selection of generic drug vendors.

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. May: Our general rule is that if the agent has a National Drug Code (NDC) number, it is handled by the pharmacy. Therefore, it would be reviewed by the P&T committee. Herbals and supplements are handled on a case-by-case basis. If there is sufficient published evidence to support that a particular need is not being met by a formulary agent, we would review the product.

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. May: We have a mechanism for obtaining non-formulary drugs. Some selected non-formulary items may even be stocked in the pharmacy in limited supply. Most drugs that fit into this situation can be predicted. Our definition of a formulary includes the phrase "meets the usual patient care needs." There will always be unusual needs. Another option is to follow our "use of patient's own meds" policy, under which a pharmacist identifies the medication and labels it with instructions for the nurse to administer.

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

Dr. May: If a requested drug is in the same pharmacologic class as agents already on the formulary, a class review is prepared with emphasis on the new drug. If the drug can totally replace a current formulary agent, the older agent is removed.

An annual review of drug usage is also performed to detect formulary items that are no longer prescribed. These may be removed if deemed appropriate. Medications are also deleted if new safety concerns suggest that the drug might be more harmful to the patient than originally thought.

Evidence-Based Evaluations in Formulary Management

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

Dr. May: Clinical trials are critiqued with standard drug literature evaluation techniques that look at the study's goals and objectives, methodology, statistical analysis, results, and conclusions. We provide close scrutiny in examining the study's primary and secondary endpoints. We also evaluate study design, statistical flaws, and whether the authors interpreted the data appropriately in order to determine how well the conclusions are supported by the results.

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

Dr. May: The Drug Information Center Coordinator writes or supervises the development of the monograph for the requested drug. Postgraduate Year One (PGY-1) pharmacy residents may assist in this process. Literature searches are also performed in the Drug Information Center. Information from the manufacturer may also be considered if deemed appropriate. Occasionally, the requestor will also provide published evidence. This material, like any other, is reviewed using basic drug literature evaluation techniques.

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

Dr. May: Information from the manufacturer generally puts the drug in the most positive light. Many times it is accurate and unbiased; however, we always subject it to close scrutiny. The materials from the requestor often comes from the manufacturer. The bottom line is that all information that we use is individually assessed by applying drug literature evaluation principles.

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

Dr. May: We use drug literature evaluation principles to assess the material. Sometimes the material from the manufacturer is useful. If the only evidence that is available is "data on file with the manufacturer," it is very difficult to evaluate the data More weight is given to published evidence. The manufacturer's information can be used to identify what the company feels are the advantages over formulary agents, which helps us focus on what evidence we are searching for. We can see whether the advantages claimed have also been shown in the literature.

Q. *Are observational studies—for example, case–control and cohort studies, case reports, and consensus opinions—ever utilized to make decisions?*

Dr. May: We try to use the best evidence available. Sometimes the best that is available includes the type of studies you have listed. The monograph we prepare clearly states the level of evidence that was used.

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

Dr. May: Evaluating "outcomes" can be difficult because there are several types of outcomes that could be measured: humanistic (functional status, quality of life), clinical (many ways to define), and economic (cost-effectiveness being just one). Each individual study must be evaluated on its own merits. Most often, we are evaluating clinical outcomes. In all cases, the criteria I previously described regarding the evaluation of clinical evidence still apply.

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

Dr. May: Occasionally, we will have some internal data that can drive a decision. Medication-use evaluation (MUE) summaries are used to identify areas for improvement or change. ADR and medication error reports are used to identify system improvements. For example, Exactacain (benzocaine/butamben/tetracaine), a topical anesthetic spray, replaced Cetacaine (benzocaine/tetracaine) spray when it was found that several patients developed methemoglobinemia as a result of inappropriate administration. Exactacain provided a mechanism to deliver an "exact" dose, therefore reducing the risk of this problem.

Pharmacoeconomic Assessments in Formulary Management

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

Dr. May: A budget analysis is prepared using our cost to compare the new drug's budget impact with the current formulary agent with varying changes in market share. In this analysis, the drug's dosage, route of administration, and monitoring differences are taken into account. If you are trying to evaluate comparative cost effectiveness based on published evidence, you have to try to apply the information to your specific institution and patient population. Needless to say, this can be quite difficult. Other parameters we evaluate include the new drug's effect on length of stay or initial hospitalization. For example, IV acetylcysteine was added to the formulary based on its use in the emergency department to prevent hospital admissions.

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

Dr. May: When ancillary costs can be easily calculated, such data may be used to differentiate one medication from another. However, this is frequently difficult to do.

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

Dr. May: Usable data of this type are rarely available in a credible form. Published studies in this area might not be applicable to a particular organization, which makes this information even more difficult to analyze. We are still struggling to find ways to perform this type of analysis in an institution-specific way.

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

Dr. May: To date, no.

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

Dr. May: Not at this time.

Q. *Does your P&T 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 particular institutions?*

Q. Dr. May: We have concerns about this information in an institution-specific environment. If this material is available, it is reviewed but weighted lightly unless it is compelling.

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. May: If a new drug is requested and there is already a formulary choice in the same class, a class review may be done. The same criteria are used to evaluate a drug class as an individual drug. Comparisons are made with the formulary alternative. A therapeutic class may be removed from the formulary because of major adverse effects or changes to evidence-based published guidelines.

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 a formulary are they reassessed?*

Dr. May: This is done on a case-by-case basis. If a drug is approved with specific criteria and there is a fear that it may be overused or misused—or if there is a major safety concern—then the committee may request a review in six months. We tend to re-evaluate things more often if they show up on our high-cost report, which is prepared twice a year, or if there have been any operational or safety issues identified.

Q. *Do you have a process in place for an 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. May: An expedited review may occur if a new drug got a priority review from the FDA or if evidence-based published guidelines recommend a specific therapy that is not currently available. Any time an FDA MedWatch warning comes out related to a formulary drug , the P&T committee will evaluate it to determine if it is necessary to make a change in the formulary status of that agent.

Q. *Would an expedited review occur in an emergency meeting? Or would expedited review make that issue a priority at the next scheduled P&T meeting?*

Dr. May: On rare occasions, an item would be presented for a vote between meeting dates, but I cannot recall this ever happening with a new drug request. If an FDA warning was published that we felt provided evidence that a decision was needed for patient safety, we would get a vote by e-mail. I don't recall this occurring in the past, but the mechanism is there.

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

Dr. May: No. If there is a request for it, then it may be evaluated. If there is no major cost impact, then it can be added as a line-extension item. If the drug is much more expensive in the new dosage form, it will undergo a full review to evaluate the benefits of the new dosage form.

MANAGEMENT STRATEGIES FOR DRUG USE

Patient Safety Measures

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

* 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.

medications?

Dr. May: Several years ago, the P&T committee established a Safe Medication Use Policy addressing such issues as poor handwriting, prohibited abbreviations, administration guidelines (e.g., potassium chloride, phosphate dose, concentration, and rate), standard concentrations, and a few other topics. Components of this policy are part of an ongoing MUE effort. At one point, we even distributed pens to physicians with the phrase "Write it right" on the side. This "Write it right" campaign was extremely well received and successful.

Within the Safe Use Medication Policy, pharmacists are instructed to reject orders with violations (such as a prohibited abbreviation) and to phone the prescriber to immediately correct it. Over time, the violations became fewer and fewer; however, with new physicians in training arriving each July, we have to ramp up our efforts each summer. With the recent implementation of computerized prescriber order entry (CPOE), some of the old problems have disappeared. The P&T committee has been active in this process of approving order sets in CPOE that guide therapy to conform to evidence-based practice.

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

Dr. May: The Safe Medication Use Policy was instituted to prevent medication errors. Other measures include the use of "tall man lettering" for look-alike, sound-alike medications; required double checks for certain medications (e.g., pharmacy packaged unit-dose digoxin in pediatrics, batch-prepared pediatric injections); required nursing double checks for specific pump settings; and two identifiers for patients prior to medication administration. The P&T committee has also established a Medication Error Prevention subcommittee that actively seeks ways to reduce and prevent errors. It is made up of pharmacists, physicians, and nurses. This group meets monthly and generates an action list for the P&T committee.

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

Dr. May: Potential risks are identified in the monograph-development stage. These are weighted in the formulary decision. If we believe the benefit outweighs the risk, the medication may be added to the MUE list or may be restricted to certain indications or prescribers.

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

Dr. May: ADR summary reports are sent to the P&T committee approximately twice a year. If a significant event occurs, it may be presented at the next meeting unless specific action by the committee is required. In this case, an e-mail recommendation would be sent to P&T committee members for action.

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

Dr. May: We do not currently use bar-coding. We recently implemented CPOE in both our adult and children's hospitals, and we are investigating the use of smart pumps in order to prevent medication events.

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. May: We review reports from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the FDA and information from the University HealthSystem Consortium (UHC).

Q. *Are there any other medication safety resources that you review to identify potential issues that might be addressed by your organization, such as the Institute for Safe Medication Practices (ISMP), MedWatch, FDA Patient Safety News, or the U.S. Pharmacopeia Patient Safety Program?*

Dr. May: Yes. All of those you mention plus information gathered from our ADR reporting system, the Medication Error Prevention subcommittee, and the health care literature.

Therapeutic Interchange

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

Dr. May: If, within a class of drugs, there are choices that have essentially equivalent safety and efficacy profiles and using one agent primarily provides an economic advantage over another, then therapeutic interchange is considered. Currently, we have therapeutic interchange in place for histamine (H_2)-receptor antagonists, proton pump inhibitors, angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor antagonists, low-molecular-weight heparins, human insulins, HMG Co-A reductase inhibitors (statins), quinolones, and liposomal amphotericin.

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. May: A P&T committee protocol is in place allowing pharmacists to make the change. Upon receipt of an order for a non-formulary agent within a class with therapeutic interchange, the pharmacist enters the formulary agent into the CPOE system with a per-protocol designation and a note in the comment field about the change. By protocol, this is now an active order. The comment appears on the nurse's electronic medication administration record.

Guided-Use Strategies

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

Dr. May: Considerations for established-use criteria include indications, dosing and administration, monitoring parameters, desired safety and efficacy outcomes, and the need for approval by a specific department.

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

Dr. May: Several classes of drugs would be limited to specially trained individuals, such as anti-infectives with user-specific criteria (e.g., meropenem, linezolid); cancer chemotherapy; inhaled anesthetic agents in the operating room setting; alteplase for stroke or myocardial infarction; thymoglobulin for renal transplant patients; and epoprostenol for pulmonary hypertension.

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. May: Yes. Some examples include inhaled pentamidine, which requires a negative-pressure room; neuromuscular blockers because of the need for a ventilator; and drugs that cause conscious sedation, which require the availability of emergency equipment.

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. May: Yes. For example, high-cost, non-formulary medications and blood factor products generally need this approval by the Medical Director and/or Pharmacy Director because of their expense.

Clinical Practice Guidelines

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

Dr. May: Yes, we do so for drugs that have a potential for misuse, overuse, or high cost. Clinical guidelines may be written by clinical specialists but would require P&T committee approval prior to going to the Executive Committee for final approval.

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

Dr. May: Nationally published clinical practice guidelines can be used as a starting point but are almost always adjusted locally to accommodate our formulary alternatives, drug resistance patterns, and patient population.

Instituting Medication-Use Policies

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

Dr. May: All of the methods you have listed are used on a regular basis. All of them are necessary, as no one method can be successful alone. With the implementation of CPOE, we now have an additional way to institute guidelines or medication-use policies via this system that can guide prescribing and accompanying administration and monitoring procedures.

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

Dr. May: Yes, if needed. We tend to involve one nursing unit so that we are able to get feedback from a single nurse–manager, a unit-based pharmacist, and a finite group of physicians.

Medication-Use Evaluation

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

Dr. May: The focus is typically on high-cost, high-use, high-risk or problem-prone medications. The Drug Information Center establishes a list of potential priorities annually. These are sent to P&T committee members, key physicians, pharmacists, and nurse–managers for ranking. Based on feedback, the P&T committee sets the priorities. In addition, some non-drug-specific topics require continual evaluation such as monitoring adherence to the Safe Medication Use Policy.

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

Dr. May: Yes.

Q. *When conducting an MUE, do you evaluate the use of individual drugs or the entire process of care for a disease state?*

Dr. May: Our approach could go either way, depending on the issue. We do evaluate individual drugs through the entire medication-use process (e.g., prescribing, dispensing, administering, and monitoring). We might also look at a specific disease state to see whether our guidelines are being followed. We recently did this for community-acquired pneumonia.

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

Dr. May: The reason why a particular topic gets on the list for such an evaluation varies greatly. This could result from ADR reporting, observation of a perceived problem by a health professional, a new formulary addition that has the potential for being prescribed outside approved indications, or just an evaluation of the effectiveness of a new clinical program (e.g., a pharmacy consult service for vancomycin).

Q & A: ASHP Interview with Dr. May, Part 2

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

Dr. May: Usually we target our projects to study potential or actual problems that we have identified. We also look at projects that help address issues reported by the JCAHO.

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. May: We utilize all of those.

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

Dr. May: Generally, this is done by the pharmacy department with support from the P&T committee as needed.

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

Dr. May: Yes. Drug shortages are reported to the P&T committee and published on the pharmacy Web site as needed.

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

Dr. May: Through newsletters, e-mails, and personal communication (e.g., staff meetings, in-service programs).

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. May: As mentioned, we purchase medications based on the established guidelines for the selection of generic drug vendors specified in our group-purchasing organization policies. Prescribers do not specify the brand of generic that is purchased.

Off-Label Uses

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

Dr. May: Yes. Some examples are the use of oral acetylcysteine to prevent contrast-induced renal nephropathy and the use of IV immune globulin for myasthenia gravis. If there is sufficient evidence to support a particular use, whether or not it is FDA-approved, the P&T committee will evaluate the use for potential inclusion in the formulary.

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

Dr. May: We evaluate the establishment of standard of care at other similar institutions, the level of published evidence in the literature, and possibly expert local opinion.

Q. *What sort of evidence is required to evaluate a drug for off-label use? Who provides it?*

Dr. May: The Drug Information Center will do a literature search. For the most part, published clinical comparative trials need to exist to add a drug to the formulary. In addition, requestors are asked to provide the evidence they have. This information is compared with what was found by the Drug Information Center.

Investigational Drugs Procedure

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

Dr. May: All investigational drugs are handled through the pharmacy department's investigational drug service. Only the primary investigator can initiate therapy. The pharmacy prepares all doses and provides the nursing staff with drug information related to proper monitoring of the drug. The P&T committee approves all investigational drug policies and procedures.

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. May has been informative and useful to our readers. This series will conclude with Part 3, an interview with ASHP Expert Panel on Formulary Management member Samantha Cole, PharmD. ■