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

Part 1: Linda S. Tyler, PharmD

C. Lee Ventola, MS

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A year ago, ASHP convened this panel of experts to develop updated guidelines for P&T committee and formulary management to replace previous guidance issued in 1991. These updated guidelines include recommendations concerning the review and evaluation of drugs for formulary inclusion, pharmacoeconomic assessments, therapeutic interchange, medical-use evaluations (MUEs), management of drug shortages, and many other important topics.

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Q & A

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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 things?

Dr. Tyler: The P&T committee is responsible for determining what gets admitted to the formulary as well as any guidelines and therapeutic procedures for the medications. We review drug monographs and make decisions determining whether the drug works, is efficacious, is safe, and applies to our patients. Then we make a decision about whether any special safeguards are necessary to use this drug, such as if there are any drug interactions or side effects. We work with practitioners on how to use the drugs better, and that really serves to boost practitioners’ knowledge about that drug.

We also review our adverse events and drug reactions, so that does a great job of educating people on safety issues. And we think not only about the drugs but also about how we deliver medications and how we can do that better. So that whole process really does help to boost everyone’s knowledge about a new drug both on and outside the committee.

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. Tyler: We feel that disclosure annually by individuals supports our process. We ask our P&T committee members to declare whether or not they have any conflicts of interest. The disclosures are shared with the committee but are also reviewed by a separate committee. Some members may have relationships with industry, such as serving on advisory boards, receiving research funding, or receiving speaker honoraria, but they would be asked to not participate in a vote involving those companies. However, if members have even more significant conflicts, they might not be able to serve on the committee.

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

Dr. Tyler: When a practitioner makes a request, he or she is required to divulge any conflicts of interest. We’ve recently strengthened our policies whereby the P&T committee will not take a request if we don’t have a conflict-of-interest statement. We’ve also had to clearly state in our minutes that a conflict-of-interest statement was received from the practitioner and that all of them have been declared. If a practitioner has conflicts of interest, the P&T committee has to evaluate them.

Our HIV drugs are a perfect example. We wouldn’t want anybody besides our infectious-disease practitioners to request these drugs. However, these physicians do research for many of the companies that are developing new HIV drugs. Clearly, they have relationships with industry that have been declared, but they are also truly the experts. So that’s when we balance both the declared and perceived conflicts of interests with what’s reasonable and practical.

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

Dr. Tyler: We review every policy at least every three years. Our P&T committee meets monthly. We have about 40 to 50 policies and 60 to 70 guidelines. Some policies need revising.
Q & A: ASHP Interview with Dr. Tyler, Part I

more frequently, but others just need to be reviewed periodically.

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

Dr. Tyler: Policies passed by the P&T committee go to the medical board for final approval. The medical board has physician representatives from all the departments plus the Chief Executive Officer and the Chief Nursing Officer.

Formulary Management

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

Dr. Tyler: When the P&T committee reviews a medication, we are looking to determine if it’s efficacious and safe and, once those two determinations are made, whether or not it applies to our patients. After those decisions are made, we do a cost analysis in terms of how we are going to handle the costs and how they compare with other drugs.

Q. What safety criteria are used to evaluate medications?

Dr. Tyler: I don’t know that we have formal criteria, but we do have an organized process. We look at the adverse effects, drug safety monitoring, drug interactions, and any dosing issues, such as a narrow therapeutic window. We then think about how we have to prepare the drug, how it is packaged, and how it is stored as well as special facility issues. We’re also looking at whether we have any sound-alike, look-alike problems, if there are any issues with preparation, and whether there will be questions about how the drug should be administered.

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

Dr. Tyler: Our drug evaluation document includes information such as an introduction, indications, a disease overview, pharmacology, pharmacokinetics, an evidence table, and a review of the clinical trials. It also includes a discussion of all the clinical studies, adverse effects, drug interactions, dosing and administration (which includes drug preparation procedure and dosing information), and renal and organ function. We’ll then have a section called “Critical Issues,” which would mention critical safety issues, whether there is a lack of data for the drug, drug interactions, and special pharmacokinetic considerations, such as a longer half-life that might require less frequent dosing. We try to pick the three or four points that are most important in clinically evaluating the drug to include in the Critical Issues section.

If there are comparative effectiveness data, they are also included in the drug evaluation document. If we are preparing the document for a drug that has off-label uses, we will approach the practitioner and say, “We know there are off-label uses for this drug; are you requesting it for an off-label use?” We always put off-label uses in the monograph, but to what degree we do varies. What determines that is how often the physician is going to use it that way and how much evidence there is. Sometimes the drug is requested to be put on formulary specifically because of an off-label use. In that case, we are going to make sure that all related data are well covered.

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

Dr. Tyler: We do evaluate that type of information, but we’re not relying on recommendations from external groups, since we do our own extensive research internally.

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 issues, for example, look-alike, sound-alike concerns? How about those that have a narrow therapeutic range?

Dr. Tyler: If a generic drug is AB-rated, we don’t review it in the P&T committee. If we have concerns or safety issues concerning a generic drug within the pharmacy, we take care of it within the pharmacy. Sometimes Drug Information Services (DIS) will say, “We have a sound-alike, look-alike situation with a new generic drug”; then we’ll make a decision about the drug internally in the pharmacy.

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

Dr. Tyler: If we are asked to stock those types of products in the pharmacy because someone wants to use an alternative product on a regular basis, that person would need to go through the same formulary request process as would be necessary for any other drug. We don’t get a lot of those requests, because at this time, there really isn’t much evidence or clinical data for most alternative remedies. Reviewing alternative remedies is a little bit different, but we have to consider the same things, such as: Do we need to handle this drug differently? Are there any special safety issues?

We had a request for some herbal supplements years ago, and we decided we needed to review them in a P&T committee meeting, because if we are going to use it in our organization, then we need standardized clinical data. Some topical creams are also used as a barrier for wound healing. It’s kind of interesting, because the FDA considers these to be medical devices, so it is difficult for the P&T committee, because, as is true for most medical devices, there isn’t much evidence to look at. But we use the same process for alternative remedies that we’ve set up to look at drugs.

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?
**Q&A: ASHP Interview with Dr. Tyler, Part 1**

**Dr. Tyler:** We deal with formulary exceptions all the time in our hospital. A physician can request a non-formulary drug. The pharmacist will discuss whether there are formulary alternatives, but many times there are patient-specific reasons for the non-formulary request. The P&T committee reviews all non-formulary use. If the use is expected to be consistent, we will ask the requestor if he or she would like to request it for formulary.

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

**Dr. Tyler:** I don’t know that we have criteria *per se*, but we frequently do review the medications that are on formulary. Oftentimes when we add a new drug to formulary, we certainly review all the drugs in the class and delete drugs if we don’t use them. We also consider deleting drugs based on emerging safety data.

**Evidence-Based Evaluations in Formulary Management**

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

**Dr. Tyler:** Clinical trials are mapped out on an “evidence table.” Putting together the evidence table is a really good tool for evaluating the articles and comparing studies with each other. To prepare an evidence table, you map out the studies using the author, the treatments, the study design, the key results of the study, and any adverse reactions that have occurred, as well as other key information. This process puts the elements of the study into table form using structured vocabulary. We then write a paragraph about each study that includes important points in the table that we want to highlight.

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

**Dr. Tyler:** DIS evaluates the available information about the medication and prepares the drug monograph. DIS prepares the agenda for the P&T committee and any other materials that are useful for the committee.

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

**Dr. Tyler:** Yes, and the quality of the information that DIS prepares is excellent. We have a standard process; when we are working on a drug review, we call the company and say, “We have a request for your drug to go on formulary. Is there any information you’d like to provide to us?” We ask the company to send us any published or unpublished information that it would like us to consider. We review everything the companies send us, but in the meantime, DIS is doing a thorough literature search. Oftentimes, we also evaluate the detailed FDA statistical review on the drug.

We grade all the evidence we have collected. We don’t discard or discount unpublished data from the company, but if the data are unpublished, they receive a low strength of evidence grade. We’ll state in the P&T committee meeting that the only data available are unpublished data from the company. We feel that for any drug, the evidence speaks for itself.

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

**Dr. Tyler:** Are they part of the decision-making process? Yes. Are they utilized to make decisions? This is where we have to look at the information in context to decide whether we want to use it or not. We grade the evidence when we review new drugs. Randomized clinical trials are assigned a grade one; unblinded experimental trials are a grade two; observational trials would be a grade three; and case reports and consensus opinions would be a grade four. So because we consider the data to be a lower strength of evidence, we won’t use case reports or consensus opinions unless there are no other data. If controlled trials are available, we also would have a tendency to not use observational data. When new drugs come to market, it is very rare that there are a lot of case–control or cohort studies. They may be available after the drug has been on the market for a while but usually not for a brand-new drug.

When we are working on a class review, we see a lot of observational data. Statins are a good example of this, because if you just looked at the randomized clinical trials, you would not get a good feel for the rhabdomyolysis data. It is only in the observational trials that you can properly evaluate that information. So certainly, even though observational studies are considered a lower strength of evidence, they have a place in the formulary-review process. In evaluating data for a P&T committee review, you have to be an expert at using all types, recognizing the role for each, and knowing which is appropriate for each situation.

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

**Dr. Tyler:** This is a tough one. We’ve done a lot of work over the years on how to better incorporate outcomes data into our decisions; however, when a drug first comes to market, few outcomes data are available. We ask for clinicians’ input on the P&T committee’s decisions. We outline a plan to monitor the drug over time. Then, as more outcome data become available both internally and externally, we incorporate those in our decision-making process.

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

**Dr. Tyler:** When we are looking at new drugs, it is sometimes very hard to get much information on how that drug should be used. It depends on the drug. If it is a brand-new drug, first in class, it becomes challenging because there is nothing to compare it to. In this case, there are really no outcomes data and there are very limited efficacy data. The companies do some research before the drug gets approved, but it is still pretty hard to see how the drug would be used in actual practice. So it’s a bit of a tough situation. While we may want to use...
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Pharmacoeconomic Assessments in Formulary Management

Q. What criteria are employed to evaluate cost effectiveness?

Dr. Tyler: This is another tricky thing, because true cost effectiveness is dependent on outcomes. So it is difficult to measure the true cost effectiveness of a new drug without outcomes data. We don't have any "magic" criteria, if you will, about cost effectiveness. This is an area where every drug presents a different cost consideration. Likewise, true cost effectiveness involves not only the cost of the drug but other costs that are related to the use of the drug; sometimes those are also hard to determine. It's getting easier and easier to access that information, but it's still hard because of how our computers talk to each other and how the data are coded.

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

Dr. Tyler: Yes, we do a financial analysis on all drugs reviewed. We look at both the cost of the drug as well as any other costs that may be associated with using the drug. Cost-minimization analysis is probably the type of evaluation that we most commonly use.

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

Dr. Tyler: Cost effectiveness is also an evaluation that's hard to do on a new drug, because you don't always have the outcomes. We will do a cost-effectiveness analysis to make cost comparisons within a class of drugs, but it is generally performed on drugs that have been on formulary for a while.

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

Dr. Tyler: Again, it's very hard to get that kind of data, so no, not very often. We will pull internal utility data if there are concerns about how the drug was used, but we don't usually calculate cost utility.

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

Dr. Tyler: Yes, we definitely do.

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?

Dr. Tyler: Yes, if pharmacoeconomic data have been published, we will look at them. But we have found that these data are very difficult to use for exactly that reason—different assumptions are used. Four or five years ago, pharmacoeconomic data were all the rage, so the manufacturer would provide them. But while those data were interesting, they weren't really useful because they didn't consider all the drugs that are available in clinical practice. This is because in the randomized clinical trials conducted by the company, the health care providers don't have a choice of drug. However, once the drug is on the market, they have many other drugs to choose from; therefore, what they select isn't predetermined.

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. Tyler: We conduct class reviews when a new drug is requested in a class, when there are safety concerns between drugs in a class, or when there are opportunities for therapeutic interchanges or to improve clinical outcomes. DIS is also monitoring the literature for information on specific drugs. If they find significant information, we'll work with the medical staff and say that we've reviewed this specific drug and think there is an opportunity to do a therapeutic interchange or to implement 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 formulary are they reassessed?

Dr. Tyler: The P&T committee may decide that it wants to perform a reassessment at a later time. The P&T committee decides as a group whether we want to perform a reassessment

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* Cost-minimization studies consider both medication and other expenses, including administration, monitoring, prolonged hospital stay, laboratory test monitoring, and costs to patients and 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. Do you have a process in place to perform an expedited review of a new drug, indication, or a re-evaluation of a previous formulary decision because of safety or other concerns? Specifically, when might this process be employed?

Dr. Tyler: Absolutely. Whenever anybody is concerned about an issue, we’ll bring it to the P&T committee right away. If there is anything that is so immediate that it can’t wait until the next meeting, we take an e-mail vote to make a decision on it. However, sometimes we’ll send out an issue to vote on by e-mail and the members will say, “No, we want to discuss this in a meeting.” I can’t think of any examples where we’ve had to do that because of a safety concern. Usually, we put a safety issue on the agenda and talk about it at the next P&T committee meeting. For example, when the safety warnings came out for droperidol, we talked about them at the very next meeting. We talked about whether anyone was concerned, what he or she was concerned about, and what additional data were needed.

One thing I think we do differently from other P&T committees is that we make a real commitment to review a drug as soon as possible when a request is made. This way, the medical staff is invested in the process if they deal with their request on an immediate basis. Also, the longer you wait to deal with a request, the more poor use occurs in the meantime. So in my opinion, the sooner you deal with the request, the sooner you have a platform in place regarding what’s appropriate with respect to utilization.

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

Dr. Tyler: Yes. Having said yes, let’s qualify that a little bit. DIS makes the decision as to whether or not a new dosage form needs to be reviewed. So clearly, if it is a different dosage form with different indications, it comes to the P&T committee. If a new dosage form is more expensive, we are going to take it back to the P&T committee for consideration. If, on the other hand, there is a 25-mg tablet on formulary and the manufacturer comes out with a 50-mg tablet that is less expensive, the P&T committee won’t have to review it. If an extended-release form becomes available, as long as it isn’t more expensive, we just go ahead and add it to formulary. If it is more expensive and there is a cost issue, it comes back to the P&T committee.

For some of the extended-release dosage forms, we want to review the pharmacokinetic data, but for most of the others, there really isn’t much of a difference in the pharmacokinetics. In that case, DIS, rather than the P&T committee, is going to review the pharmacokinetic data. For some of the new dosage forms, there really aren’t any issues. In many instances, a new dosage form is introduced by a company because of patent maneuvering more than anything else.

Q&A: ASHP Interview with Dr. Tyler, Part 1

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. Tyler: When reviewing a drug, we look at it and say, “Is this a drug for which we need to give guidance, or is this a drug for which we need hard stops in our computer system, such as an alert, to pop up?” We have a variety of safety mechanisms that we tailor toward whatever the situation is and what we have available. Some of these measures are kind of “soft,” such as when we publish a guideline and say, “Hey, this guideline is out there.” However, it may be posted more for education and therefore might be more of a soft measure. On the other hand, when you order some drugs, you need to use a preprinted order form that needs to be approved; so, this is more of a directive approach.

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

Dr. Tyler: We have a lot of procedures in place to prevent medication errors. We look at our system in general as well as some of the tools we can implement in various places. One such measure we just finished implementing is a computerized prescriber order entry (CPOE) system. So, that’s helped improve communication, order review, legibility, and order checking. As the prescribers enter the orders, there are also some checks in place in the CPOE system. The computer will certainly check drug interactions, dosing, and a notice will come up if there is a formulary interchange. So, a lot of information that used to take some time to communicate to the prescriber is taken care of, because when the prescriber enters the order, the CPOE will sound an alert.

We also have checks in other places, such as when we’re preparing medications. A good example of that is our “double-check system” in terms of how we process the orders and check calculations. That’s a process that has worked very well for us in preventing errors. Other policies focus on additional ways to keep patients safe; one policy states which people, training, and equipment need to be available to safely administer drugs. For example, when a patient needs to be in the intensive-care unit (ICU) in order to get a certain drug, we have all of those things spelled out.

We also have safety measures in place for when we receive and store the drug as well as when we dispense it. We bar-code medications when they come into our inventory system, so that also provides a way to double-check. We also bar-code a drug when we dispense it. We also use “smart pumps.” These help prevent infusion errors that might occur in drug administration. “Tall man lettering” is also used in our computer system to help flag the differences between drug names. Tall man lettering graphically accentuates different syllables, thereby creating a visually noticeable difference that prevents confusion between drug names.
Q. What sort of risk evaluation is conducted for high-risk medications or major system changes, such as new equipment?

Dr. Tyler: One thing that has been very successful for us is our use of failure mode and effects analysis (FMEA). We have used that technique on a couple of high-risk drugs such as anticoagulants. What FMEA allows us to do is to map out the whole process with flow-charting. Then we nail down each of the steps in the process and identify what problems might occur during each step. You determine how likely it is that a problem will occur and how severe the consequences are. In doing that, you then have a great map and you can say where the “high-risk areas” are and what steps can be taken to help prevent possible problems. We’ve used FMEA a couple of times with great success in order to systematically identify our high-risk steps as well as our opportunities for improvement. It is one of the major tools we use for proactively identifying risks.

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

Dr. Tyler: We are a member of University Health Consortium (UHC), which has a product called Patient Safetynet (PSN) that we use for event reporting. As soon as a report is filed through PSN, the unit managers and the pharmacy managers are notified of the event. They can then go into the system in real time to review that event. So from that standpoint, we are reviewing events all the time.

The P&T committee also reviews all the medication event reports quarterly. In that review, we are looking at trends and patterns that emerge from these data. We also have a medication safety committee and an adverse drug reaction committee, which are subcommittees of the P&T committee. These subcommittees do a more detailed review of all events and report back to the P&T committee.

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

Dr. Tyler: We use bar-coding as a technology, but we don’t have bedside administration bar-coding. We bar-code our drugs when they come in and when we dispense them. We plan on utilizing bedside bar-coding, but with the economy the way it is, this likely won’t take place for a few years. That’s the next step of technology that we need to implement.

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

Dr. Tyler: This is one of those things that I think everyone should do because no one organization, hopefully, has enough medication events to identify problems. Ideally, you want to set up a situation in which if we can learn some things from other organizations, we should do that. One key way is to read things like the Institute for Safe Medication Practices Newsletter. This report really highlights the medication events that might occur and the opportunities for preventing them. We also look at FDA alerts, which are safety warnings issued by the FDA, and we distribute that information to our staff. From time to time, UHC will issue alerts on patient safety based on what information it’s pulling out of PSN. It’s important to keep up with safety newsletters and alerts that are coming out.

Q. Are there any other medication safety resources that you review to identify potential issues that might be addressed by your organization?

Dr. Tyler: The FDA issues “MedWatch” and “Patient Safety News,” and we review both of those. We don’t utilize the U.S. Pharmacopeia (USP) Patient Safety Program as much; we have not been involved with it.

Therapeutic Interchange

Q. How do you identify opportunities for therapeutic interchange?

Dr. Tyler: We use DIS to identify possibilities for therapeutic interchanges for the drugs we dispense in the pharmacy.

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

Dr. Tyler: We have two types of therapeutic interchanges. The first occurs when two different active ingredients are considered therapeutically equivalent and the P&T committee has approved the interchange. In this situation, the prescriber is required to be notified. When the prescriber orders a drug in CPOE, he or she will receive an alert that the drug will be interchanged to the selected formulary product. This serves as the notification.

The other type occurs when two products have the same active ingredients; however, because of formulation issues, they are not AB-rated and cannot be considered generically equivalent. In this case, the P&T committee may stipulate that the prescriber does not need to be notified of the interchange.

Guided-Use Policies

Q. What sorts of considerations are included in established-use criteria? Are these applied when medications are in short supply or in other situations?

Dr. Tyler: If we think people are going to misuse a drug, we establish guided-use criteria for the drug. Obviously, if there are cost or safety issues, those are situations in which we’d probably find these policies helpful. A good example is that for some of the antibiotics that are very expensive, guided-use criteria would be written saying not to use them for every infection—to only use them if the patient has not responded to another therapy. We also establish guided-use policies in a shortage situation. In that case, practitioners must provide notification if they’re going to prescribe a drug that is in short supply.
Q. What sorts of drugs on formulary are limited to specially trained individuals?

Dr. Tyler: We don’t have a lot of those. When I first came to University of Utah Hospital, there were so many restrictions that no one could keep track of them or remember them, so they weren’t that useful. Since then, I think we’ve cut our restrictions by half. So, compared with other hospitals, we probably have fewer restrictions, but I think we have a more effective restriction program.

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

Dr. Tyler: Yes. But rather than specifying a location, we stipulate which personnel, training, and equipment need to be available in a particular setting in order to use the drug. So if for some reason we don’t have a bed for a patient in the usual area, we can put him or her on a different unit that has the needed staff and equipment. This gives us some flexibility.

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. Tyler: Yes. Mostly, approval by the Medical Director is required for high-cost drugs, non-formulary use, or because there are restrictions on use.

Clinical Practice Guidelines

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

Dr. Tyler: Yes, we do; we have clinical practice guidelines for many things. As I mentioned, we have a lot of guidelines for antibiotic use. Some of our drug guidelines are issued just for informational purposes, and some are very directive in terms of clinical practice.

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

Dr. Tyler: Both. If we’re going to establish a guideline, we identify national guidelines and see whether they fit, what works, and what’s going to work for us. We also develop them.

Instituting Medication-Use Policies

Q. How are medication-use policies implemented and communicated in your organization? Are they communicated through being printed on 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. Tyler: I would say all of the above. I think the strongest way to change medication policy is for the pharmacist to speak directly with the staff. When we have a conversation about why the policy should change and what we’re trying to do, it has such a powerful impact on patient safety and clinical outcomes. We do a lot of work with order forms, and we get a lot of feedback on them. We also do a lot of in-service education work, and sometimes we do Grand Rounds.

We have a Web site where we post information on medication-use policies. E-mails are the primary way we send out information, but the Web site is where people go if they are looking for information to help them. We also attend staff meetings to discuss new policies that we are rolling out. We don’t really distribute formal newsletters any longer. Instead, we post the information on the Web site and notify people by e-mail that the information is available.

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

Dr. Tyler: If there is a particular process we’re interested in, we’ll sometimes use a pilot project. Other times, such as when there is a change in a therapeutic interchange policy, we don’t need to.

Evaluating Medication Use

Q. What sort of medication-use evaluation (MUE) activities does your institution conduct, and how is the P&T committee involved?

Dr. Tyler: Many of the units do MUE projects. In addition, many of the departments, like the emergency medicine department for instance, may be doing MUE projects. So from that standpoint, anybody who has a project in mind or an idea on how to improve the medication system is encouraged to pursue it. The P&T committee also conducts projects and reports the data to various departments and other committees as well. So we try to distribute the information from our projects so that it can be used.

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

Dr. Tyler: Yes. We have electronic data that are available when we are conducting projects.

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

Dr. Tyler: I think the types of MUE projects that we probably think about most often involve individual medications, but we also conduct those that involve disease states. One example would be when we look at how we sedate patients in our ICU. A project like that is looking at the entire process of care. Sometimes it’s hard to look at the entire process, but sometimes that’s how we get better information—information that is going to make a difference in improving care.

Q. For what reasons are MUE projects instituted? Is the process...
Q&A: ASHP Interview with Dr. Tyler, Part 1

Dr. Tyler: We do MUEs for a lot of reasons. One of the primary purposes is because clinicians who work in that area might feel that it is an important project to do. We’ll do a project for informational reasons to assess if there’s a problem in a particular area and to see if there are any interventions we need to take. Sometimes when we do an MUE for informational reasons, we’ll find there aren’t any problems, but when there are, we’ll do an intervention and then perform another evaluation to see the impact of what we did.

Q. What sort of targeted quality improvement projects are conducted?

Dr. Tyler: We’re doing quality-improvement projects all the time. I think one of the ones that’s been very important for us is looking at the intravenous immunoglobulin (IVIG) orders. We have guidelines we use, and if a prescriber wants to use the drug outside of those guidelines, they need to talk to the Medical Director. The guidelines are formulated upon the evidence base for IVIG and dictate what we need to do when using it. So those sorts of projects are ongoing. We’re monitoring and looking for opportunities for quality improvement all the time.

Drug Shortage Management

Q. What strategies are in place at your institution to deal with drug product shortages?

Dr. Tyler: The DIS at the University of Utah Hospital specializes in drug shortage management. We have been collaborating with ASHP and Novation® to prepare the content that goes on the ASHP Web site in the event of a drug shortage. The ASHP Web site is pretty well recognized as the place to go if you want information about drug shortages. With respect to drug shortage advisories, the FDA can’t speak outside of labeling. So when a drug shortage occurs, in some instances it is very helpful if someone addresses off-label issues, for example, by providing a discussion of alternative drugs. This is one thing that we do.

We first get a notice of a shortage, oftentimes from our buyers and sometimes from the ASHP and Novation Web sites, which both include a section where shortages are reported. We then research it and look into the situation. We also contact manufacturers to see what information we can find. After we definitively determine that there is a shortage, we start preparing information. While doing that, we consider potential alternatives, strategies for managing the shortage, and restrictions. There have been over 100 shortages in the past year, and at any given time, we’re following 60 to 80 shortages.

So we create drug shortage information for the whole country. We started doing that because we needed to produce this information for our organization. We realized that if we need it, there must be other organizations that also do. So we looked into how we could coordinate distribution of the drug shortage information instead of just doing it for ourselves.

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

Dr. Tyler: Absolutely. One of the things about shortages is that there are different types. In some instances, there may be a shortage of a particular package size. In that case, we can still order the drug but not in the package size we would usually order. So, that is a shortage issue that our buyers and pharmacists involved in the buying program would know about, but it really doesn’t impact or change the availability of the drug. Sometimes if there is a shortage, we need to order a different dosage form. In this case, more people will have to know about the shortage and why we’re ordering a different drug or a different dosage form. For example, when we have an IVIG shortage, sometimes we can get it as a powder but not a liquid, and some people prefer the liquid. So we need to let them know that we are trying hard to get the liquid but that it won’t be available for a certain period of time.

Sometimes the drug is just not available at all; in that case, we need to let people know this. This means that not only do we need to alert the pharmacists; we also need to let many of the physicians know that it’s not available. That’s when the pharmacy works with the P&T committee to determine whether we ration the drug or perhaps it’s an opportunity for therapeutic interchange. When there is a drug shortage, the P&T committee is also sometimes involved with the risk-management committee. This collaboration would occur if we feel that a patient’s inability to be treated with a particular therapy creates a risk-management issue. A good example of this is when we had to ration tetanus vaccine because of a shortage. That meant that some people were eligible to get the vaccine, but we couldn’t give it to them because of the shortage. So we worked with the risk-management committee to determine a course of action.

We work with a lot of committees. When we have a shortage of drugs that affect the crash cart, we’ll work with that team. When we have shortages that affect the emergency department, we’ll work with them. So for most of the drug shortages, we are working with the individuals in the departments that are most affected.

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

Dr. Tyler: We have quarterly summary reports that discuss currently active shortages. We also have an internal Web site, where all the shortages are posted, and we have a newsletter that goes out every month that provides notification about active shortages.

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

Dr. Tyler: Along with the routine P&T committee newsletter that comes out monthly, we also use e-mails as another way to distribute information. We try to do targeted e-mails to people who are going to be affected by the shortage, such as providers, organizational management, and so forth.
Generic Drug Use

Q. What policies and procedures govern the dispensing of generic equivalents in your institution?

Dr. Tyler: We have pharmacy department procedures for determining which generic drugs we will purchase and have available for dispensing. If a practitioner is on our staff, he or she agrees to use generic drugs. If a prescriber requests a specific brand, we will work with the prescriber to determine the reasons and whether the product we have available can be used. If the patient clinically needs a specific brand, we will special-order it.

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. Tyler: Oftentimes this is important if the patient is allergic to one of the excipients in the formulation.

Off-Label Administration

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

Dr. Tyler: I’m sure we have drugs for off-label use included on our formulary. If a physician requests a drug to use off-label and there is literature to support that use, then it is generally considered.

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

Dr. Tyler: Again, we would review the information that’s available in order to make evidence-based decisions.

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

Dr. Tyler: We do a literature search and identify information regarding the requested off-label use. Sometimes the physician making the request will provide the P&T committee with information, but we’re still going to do a literature search. It’s very rare that we would use information provided by a manufacturer, and there are restrictions on the information they can provide on off-label uses, anyway. For an off-label use, sometimes it will be in the compendia and sometimes it won’t, but we’ll look there as well.

Investigational Drugs Procedure

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

Dr. Tyler: When people are conducting a research protocol, they apply to the institutional review board. We have investigational pharmacists on that committee; that’s where a lot of the feedback on investigational drug use comes from. From a P&T committee standpoint, we don’t really review the application for investigational drug use. The P&T committee maintains an investigational drug-use policy that describes how the investigator and pharmacy department coordinate the drug storage and dispense according to study protocol.

REFERENCES


We hope that this discussion with Dr. Tyler has been informative and useful to our readers. This series will continue next with Part 2, an interview with ASHP Expert Panel on Formulary Management member J. Russell May, PharmD.

CE and CME Articles

P&T is seeking articles to be considered for continuing education (CE) and continuing medical education (CME) credit. Articles to be considered for dual accreditation should provide an overview of topics that are directly relevant to health care professionals and should address issues such as disease management, drug class reviews, strategies for coping with medication errors, and pharmacoeconomic issues. Please contact the editor if you have questions about an article’s suitability for CE/CME credit.

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