Formulary Evaluation Using a Class Review Approach
Experience and Results From an Academic Medical Center

Emily L. Persson, PharmD, BCPS; Katherine S. Miller, PharmD, BCPS; Jennifer A. Nieman, PharmD, BCPS; Angela P. Sgourakis, PharmD; and Shawn R. Akkerman, PharmD

Key words: hospital formularies, Joint Commission, pharmacy and therapeutics (P&T) committee, formulary management

ABSTRACT
Developing and maintaining a drug formulary is an essential process that allows hospitals to meet mandatory standards, such as those defined by The Joint Commission, while ensuring that drugs are being used in a safe, appropriate, and cost-effective manner. In this article, we describe our strategy for an annual formulary review, the first year’s results of its implementation, and its ongoing development at an academic medical center.

Our strategy for reviewing the formulary was based on two main components—a scheduled class review (CR) process and a continuous safety-review process. After the first year of implementation, the pharmacy and therapeutics (P&T) committee reviewed 17 drug classes. The CR and safety review processes led to three formulary additions, 15 deletions, five new therapeutic interchanges, and six drug-safety issues requiring action. Cost-savings opportunities also resulted from using lower-priced generic medications and alternative product formulations.

Institutional strategies to address the annual formulary review requirements can be accomplished via several methods, including the drug CR process. This process should be routinely evaluated and modified with the potential to provide additional institutional drug use evaluation benefits and to incorporate efficiencies as needed.

INTRODUCTION
Creating and maintaining a drug formulary allows hospitals to meet requirements such as those defined by The Joint Commission while ensuring that medications are being used safely, appropriately, and cost-effectively. In 2004, The Joint Commission introduced medication management (MM) standards (specifically MM 02.01.01), which mandated that accredited hospitals maintain a formulary. The formulary had to include a drug’s strengths and dosages, and it had to be “reviewed at least annually, based on emerging safety and efficacy information.”

The Joint Commission has not clearly defined the criteria for meeting this performance standard, and guidelines for a standardized approach are limited in the primary literature.

One publication that included responses to questions about the 2004 MM standards, provided by a Joint Commission reviewer, indicated that there were no defined criteria for the timing of this review, whether the process would be continuous or completed at one time, and whether the individuals completing this review could include subcommittees or pharmacy staff members reporting directly to a P&T committee. According to the Joint Commission reviewer, strategies involving only reviews of and responses to bulletins and alerts, provided by resources such as the FDA and the Institute for Safe Medication Practices, would not be adequate to meet the annual formulary review standard.

This article describes the strategy for completing an annual formulary review, our first year’s results following its implementation, and its ongoing development at our institution.

OUR INSTITUTION
The Nebraska Medical Center’s core campus is a licensed 624-bed, not-for-profit academic medical center and a partner of the University of Nebraska Medical Center. The medical center is part of a health care enterprise comprising the main campus hospital and clinics, university physician clinics, Bellevue Medical Center, and four outpatient infusion centers.

Within the pharmacy division, the Pharmacy Relations & Clinical Decision Support (PRCDS) group consists of 4.5 full-time equivalent pharmacist coordinators, four part-time pharmacist interns (approximately one full-time), and up to one rotating pharmacy student and/or resident per month. The pharmacist coordinators are the primary providers of objective drug information for The Nebraska Medical Center’s health care enterprise. These coordinators have the broad responsibilities for the analysis, development, and reporting of evidence-based medication evaluations, drug-use policies, and quality and cost improvements related to medication use within the organization.

Formulary reviews, policies, and protocols are brought to the medical staff’s P&T committee monthly for discussion and voting. The formulary review process is accomplished primarily by individual drug class review and single-agent reviews via a formulary addition request.

DEVELOPING AND MODIFYING THE FORMULARY REVIEW STRATEGY
Given the breadth and scope of The Nebraska Medical Center’s formulary, we considered a yearly review of individual drug classes by the American Hospital Formulary System (AHFS) designation to be the best approach for meeting the

Disclosure: The authors report that they have no financial or commercial relationships in regard to this article.

Dr. Persson, Dr. Miller, Dr. Sgourakis, and Dr. Akkerman are Drug Policy Coordinators, and Dr. Nieman is Lead Drug Policy Coordinator, in Pharmacy Relations & Clinical Decision Support at The Nebraska Medical Center–Drug Information Center, in Omaha, Nebraska.

Accepted for publication January 28, 2013.
Formulary Evaluation Using a Class Review Approach

Table 1 Focus Areas for Drug Class Reviews

<table>
<thead>
<tr>
<th>Therapeutic Interchange (TI)</th>
<th>Utilization of Formulary Agents</th>
<th>Utilization of Non-formulary Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Do any of the current TIs require an update?</td>
<td>• Are there any medications that are infrequently used and could be requested for deletion from the formulary</td>
<td>• Are any non-formulary medications approved more than 30 times in a 6-month period?</td>
</tr>
<tr>
<td>• Can any new TIs be established?</td>
<td>• Are there any drugs that appear to have a very high or unanticipated volume of use?</td>
<td>• Is a more in-depth review needed for any of the high-use non-formulary medications?</td>
</tr>
<tr>
<td>• Is our current agent of choice in the TI the most cost-effective agent for our institution?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Commission’s annual formulary review requirement for our institution. The AHFS drug classification is well known, and the classification scheme is easily accessible. We excluded drug classes from the class review (CR) process if there were no formulary medications within the class or if drugs included in the class were not considered “therapeutic” (e.g., diagnostic agents, devices, disinfectants, and pharmaceutical aids). We prioritized the specific CRs based on the drug’s use in the acute-care setting and developed a standard CR document template and rotating annual review schedule for the CRs.

The first CRs, which we modeled after the pharmacy benefits manager (PBM) process, were in-depth compilations of agents in the pipeline, including the efficacy, safety, uniqueness, utilization, and the cost of each current drug in each class. Seven CRs were performed in this manner.

After several CRs were completed, the PRCDS coordinators re-evaluated and modified the CR process. The CR format proved to be too lengthy and time-consuming for the interns and pharmacists to complete. As a result, the primary aims of the CR process were shifted and streamlined to focus on analyses of therapeutic interchanges and on the use of formulary and non-formulary drugs, as our recommendations and modifications were derived mostly from these sections.

The safety alerts were acted on before the CR was completed and were therefore redundant and outdated when the CRs were presented to the P&T committee. The review of medication safety alerts and problems was removed from the formal CR process. This review is now conducted regularly, with appropriate action taken when necessary.

Overall, the length and degree of depth of the CR were adjusted to make it feasible to complete all reviews within a year. The CR format is now simpler to manage and easier to present to the P&T committee. The format consists of four sections:

- current drugs in the class
- drug utilization
- requests for formulary additions or deletions
- recommendations

STRATEGY FOR THE FORMULARY REVIEW

Class Review Process

Each drug class is scheduled for an annual review and is assigned to an individual pharmacist-intern and a PRCDS pharmacist. The assigned intern organizes all medications in the AHFS class within the standard CR format, making notations concerning formulary status and any related policies or protocols. Drug-utilization data are extracted from billing reports and non-formulary utilization reports. Cost information is collected from our distributor’s database. The CR document is then sent to the pharmacist for review.

The pharmacist reviews the class with respect to the focus areas of therapeutic interchanges, the use of formulary drugs, and the use of non-formulary drugs. For each category, efficacy, safety, uniqueness, and cost are addressed via the questions listed in Table 1.

Under the direction of the pharmacist, the interns complete any therapeutic interchanges needing to be updated, modified, or developed. The pharmacist then consults with other pharmacists, physicians, or clinicians who have expertise in the class of interest for their input and recommendations. The pharmacist then presents the therapeutic interchange to the P&T committee for approval.

Utilization reports that show a higher- or lower-than-anticipated use for formulary or non-formulary agents are reviewed in greater depth by the PRCDS pharmacists to determine whether further action is needed. The pharmacist can make a request to add or delete a drug, educate the pharmacy or medical staff about appropriate medication use, or develop a policy or protocol. Traditional medication use evaluations (MUEs) are completed when necessary.

After the PRCDS pharmacist completes the review and determines that action is necessary, the pharmacist consults with colleagues and other health care experts and providers before developing and implementing formulary or policy changes. Formal changes are submitted to the P&T committee for approval.

Safety Review Process

The continuous review process for medication safety involves the collection and evaluation of emerging safety information from various pharmacy media channels such as the FDA, the American Society of Health-System Pharmacists (ASHP), and Medscape. Safety alerts are compiled daily and reviewed by a PRCDS pharmacist monthly. For some alerts, further action might be required, including (but not limited to) staff education, provider notification, development of use or monitoring criteria, and a P&T committee review. Emergency situations are handled promptly when the FDA alert has been received.
RESULTS IN THE FIRST YEAR

We initiated the CR process in January 2011 and presented the first class of agents to the P&T committee for review in April 2011. Although 19 drug classes were planned for annual review between January and December 2011, 17 CRs were completed and were able to be fully reviewed by the P&T committee (Table 2). Overall, during the first year’s CR process, approximately 650 of 860 of the medical center’s formulary agents (76%) and 470 non-formulary agents were reviewed.

Other formulary modifications resulting from the CR process included the addition of three agents, the deletion of 15 agents, and the approval and implementation of five new therapeutic interchanges. One other therapeutic interchange was in development at the end of the first year.

We identified 16 formulary agents as having low-use patterns and we targeted them for further monitoring and possible consideration for deletion from the formulary. Additions to the formulary were usually considered when non-formulary use was frequent (e.g., 30 or more fulfilled non-formulary requests in a 6-month period) or when a therapeutic alternative was not already available on the formulary. A medication was evaluated for formulary deletion or inclusion in an existing or new therapeutic interchange when its use was low or when there was therapeutic duplication within its given class.

These new therapeutic interchanges, developed as a result of the CR process, are in addition to the 47 that had previously been implemented at The Nebraska Medical Center. During the CR process, we also identified opportunities for optimizing costs, including shifts to less expensive formulations and expanding the use of generic agents.

In 2011, we reviewed 83 safety alerts and took action for six alerts. These actions resulted from labeling changes for bevacizumab (Avastin, Genentech), simvastatin (Zocor, Merck) drug interactions and high-dose alerts, manufacturing changes involving combination products, and investigations into deaths possibly related to fingolimod (Gilenya, Novartis).

The safety alert actions taken were unique for each case. For example, when the indication for breast cancer was removed from the bevacizumab label, we consulted the appropriate oncology staff members to evaluate the effect of this change on our patient population. A mass e-mail communication regarding this safety alert was sent to all staff members, and bevacizumab was removed from all existing breast cancer order sets.

Other alerts resulted in policy changes, such as modifying our therapeutic interchange for statins (HMG-CoA reductase inhibitors) in response to the FDA’s recommendations for dose limitations on simvastatin to reduce the risk of muscle injury.

DISCUSSION

Although Joint Commission standard MM 02.01.01 requires that drugs designated as available for dispensing or administration be reviewed “at least annually based on emerging safety and efficacy information,” The Joint Commission provides no specific published guidance on which methods or processes are sufficient to comply with this standard. Given this limited guidance, we conducted a brief survey of University HealthSystem Consortium (UHC) institutions to inquire about their strategies for meeting the annual formulary review requirement of MM 02.01.01. We wanted to obtain a snapshot of other institutional experiences, for background purposes only, rather than conduct a focused evaluation of their practices.

More than 75% of the responding institutions indicated that they reviewed their formulary annually for safety and efficacy, primarily by drug class. Although more than 90% of respondents indicated that they had been reviewed by The Joint Commission since the MM standard was updated in 2004, none of the respondents indicated being told that they did not meet the standard. These responses were consistent with comments from a Joint Commission reviewer’s webinar and personal communication (e-mail, April 2012) indicating that other MM issues, such as medication storage and labeling, are more commonly identified for noncompliance and that noncompliance with the annual formulary review standard is rare.

So far, we have described the development and modification of the formulary review strategy used by the PRCDS group and the first year’s results following implementation. A comprehensive drug CR process was selected as the initial formulary review strategy, followed by a revised CR format, to allow a

Table 2 American Hospital Formulary System Drug Classes Included and Excluded From the Review Process At The Nebraska Medical Center

<table>
<thead>
<tr>
<th>Class Included</th>
<th>Class Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihistamines</td>
<td>Blood derivatives</td>
</tr>
<tr>
<td>Anti-infective agents</td>
<td>Contraceptives (foams, devices)</td>
</tr>
<tr>
<td>Antineoplastic agents</td>
<td>Dental agents</td>
</tr>
<tr>
<td>Autonomic drugs</td>
<td>Medical devices</td>
</tr>
<tr>
<td>Blood formation, coagulation, and thrombosis agents</td>
<td>Diagnostic agents</td>
</tr>
<tr>
<td>Cardiovascular drugs</td>
<td>Disinfectants</td>
</tr>
<tr>
<td>Central nervous system agents</td>
<td>Enzymes</td>
</tr>
<tr>
<td>Electrolytic, caloric, and water balance</td>
<td>Gold compounds</td>
</tr>
<tr>
<td>Eye, ear, nose, and throat preparations</td>
<td>Heavy metal antagonists</td>
</tr>
<tr>
<td>Gastrointestinal drugs</td>
<td>Pharmaceutical aids</td>
</tr>
<tr>
<td>Hormones and synthetic substances</td>
<td>Vitamins</td>
</tr>
<tr>
<td>Local anesthetics</td>
<td></td>
</tr>
<tr>
<td>Miscellaneous therapeutic agents</td>
<td></td>
</tr>
<tr>
<td>Oxytocic agents</td>
<td></td>
</tr>
<tr>
<td>Radioactive agents*</td>
<td></td>
</tr>
<tr>
<td>Respiratory tract agents</td>
<td></td>
</tr>
<tr>
<td>Serums, toxoids, and vaccines</td>
<td></td>
</tr>
<tr>
<td>Skin and mucous membrane agents*</td>
<td></td>
</tr>
<tr>
<td>Smooth-muscle relaxants</td>
<td></td>
</tr>
</tbody>
</table>

*These classes had not been fully reviewed or approved by the end of 2011.
Formulary Evaluation Using a Class Review Approach

more streamlined review process. This modification produced a more efficient and productive method of formulary review and provided useful information about shifts in drug utilization, therapeutic trends, and areas for policy improvement and adoption. Further benefits from the review included savings when we identified and used lower-cost generic and product formulations.

After initiating and modifying the annual formulary review process up to this point, we found the following steps to be essential for implementing the process successfully:

• defining focused goals, roles, and scope of the review at the outset
• defining the format and specific steps for consistency in review process and reporting
• setting dates for re-evaluating the process
• defining a clear method of identifying non-formulary use
• incorporating cost and drug-utilization data into the review
• identifying the use of triggers or thresholds indicating the need for further investigation
• developing a method of identifying annual or ongoing new safety issues or therapeutic uses
• managing follow-up or tracking of CRs and developing policies or therapeutic interchanges
• incorporating reviews of requests for new formulary agents into the overall CR when possible
• evaluating drug safety continually, not annually, for timely intervention as needed

For example, it is important to design the formulary review strategy first, so that goals, data needed, reporting format, data collection, and evaluation aspects of the review process can be clearly defined. The process should be realistically achievable and tailored to institutional needs and available staffing.

Our initial drug class reviews were comprehensive and also labor-intensive. They involved thorough reviews of updated clinical literature and guidelines, FDA safety alerts, and updates of package inserts for each agent evaluated. As such, we needed to revise our process to make it more efficient. We also gained additional efficiencies when requests for new formulary agents were included in the CR process and safety was evaluated separately on an ongoing basis through daily review of FDA alerts and other media press releases.

Based on our experience to date, it is reasonable to consider future improvements to the review process that could provide additional utility and value to the overall goals for medication use and evaluation at our institution beyond conducting annual drug class reviews for Joint Commission purposes alone. Focus criteria could be developed for selected drug classes or drugs within classes (i.e., higher-cost or higher-risk agents). More detailed information may be reported for agents or classes with higher utilization (e.g., cost, usage, and the purchasing history of individual formulations and brands) or in specific institutional areas or patient populations. These more focused examinations within the CRs can be helpful in identifying opportunities for therapeutic education or substitutions, cost savings, clinical trends, or operational or safety matters. In the future, modifications to the process will need to incorporate CRs of medications in our outpatient infusion centers and clinics.

CONCLUSION

Institutional strategies to address the annual formulary review requirement in Joint Commission standard MM.02.01.01 can be accomplished by several methods, including the drug class review process developed at The Nebraska Medical Center. This process should be routinely evaluated, modified, and possibly expanded to provide additional benefits related to institutional drug use evaluation and to incorporate efficiencies as needed. Although our general strategy could be adopted by other institutions, it would be prudent for each center to consider its respective populations, staffing, practice trends, and drug-use patterns and policies in developing a formulary review process best suited for its needs and goals.

Acknowledgment: We thank our pharmacist-interns (Adam Felber, Jennifer Gallanger, Rory Sallach, and Lei Tang) for their contribution to the preparation of the class reviews and modifications to the class review process. We also thank Donald Klepser and Lori Murante for their assistance with review of the manuscript.

REFERENCES