

Do Formularies Enhance Patient Safety?

THE "PRO" SIDE

Pharmacists and others have been debating the value of formularies for many years,¹ but recently the context has changed somewhat. Whereas the debate used to focus on whether formularies improved therapeutic outcomes and reduced costs,^{2,3} the emphasis has now shifted to whether they improve medication safety or, conversely, place patients at greater risk of medication-related adverse events.^{4,5} The recent debate has been fuelled by reports suggesting that the outpatient prescription drug benefit formularies used by large health maintenance organizations in the United States may place some patients, particularly the elderly, at greater risk for adverse drug events.^{6,7} The involvement of the pharmaceutical industry in the ownership and management of pharmacy benefit management companies in the United States and the questionable substitution practices used by some of those companies have raised further questions about the impact of formularies on medication safety.⁸ The question now being posed is "Do hospital formularies have a positive impact on medication safety?" The answer to that question is a clear "It depends". However, when the question "Depends on what?" is answered, it becomes evident that properly designed hospital formulary systems serve as an important part of a hospital's strategies for optimizing both the efficacy and the safety of institutional drug therapy.

Depends on What?

To begin with, the safety potential of a formulary depends on whether the formulary is part of a comprehensive "formulary system". Webster's dictionary defines a "system" as "a complex unity formed of many often diverse parts serving a common purpose". So, if a hospital wants its formulary system to fulfill a medication safety role, the stated purpose of the system must include medication safety, as well as better clinical outcomes and lower drug costs. In fact, in a sound drug formulary system, cost factors should come into play only after the safety and efficacy of a drug have been evaluated.⁹ Key components of a formulary system designed to address safety would include the following⁹:

- evidence-based formulary decisions that employ a comprehensive, scientifically objective review of the efficacy and safety of the drug
- a comparison, against alternative drug therapies, of the type and frequency of side effects, drug interactions, and potential for medication error (such as those caused by confusing product names or labels)
- the likely impact of a drug product on patient adherence
- tools and systems that are targeted to ensure the safe use of formulary drugs (e.g., up-to-date IV drug manuals for

nursing staff that address the safe and appropriate use of all injectable formulary products and integration of the formulary into computerized prescriber order entry systems)

- drug-use evaluation to ensure that drugs are used in a manner consistent with any criteria or restrictions that have been placed on their use
- monitoring, reporting, and analysis of adverse outcomes of drug therapy (adverse drug reactions and medication errors)

Flowing from these principles are a number of questions that we might all want to ask about our own formulary systems. Does the hospital use structured tools for grading the evidence on which formulary decisions are made¹⁰ and for assessing potential safety issues associated with requests for new formulary drugs?¹¹ Does the hospital have a Medication Safety Subcommittee as part of its Pharmacy and Therapeutics Committee structure? Does the Medication Safety Subcommittee use information from the monitoring of adverse events to advise the Formulary Subcommittee and the main Pharmacy and Therapeutics Committee about formulary decisions? Are those safety considerations also built into the contracting process used by the hospital?

With respect to the second bullet point above, the safety potential of a formulary system also depends on the health care setting and structures within which the formulary system is developed and used.⁸ The setting-related factors that optimize the possibility that formularies will achieve their full potential include the following:

- the existence of an active and motivated Pharmacy and Therapeutics Committee that
 - includes physicians, pharmacists, and other health care providers who practise within the setting
 - is subject to organizational policies that address conflict of interest and ensure that formulary decisions are based solely on efficacy, safety, and cost
 - meets frequently enough to make the decisions required to maintain a formulary system that will meet the needs of the organization's patients
 - is prepared to guide prescribing practices through the use of established options for achieving safe and effective drug use within the hospital setting (e.g., limit on the number of options in any given therapeutic class so that physicians and other hospital staff will develop greater familiarity with the drugs they use, use of restricted and unrestricted formulary approvals, appropriate access to nonformulary drugs when justified for safety reasons)
 - is supported by organizational resources for monitoring the appropriateness and safety of drugs used within the organization
- the ability of the hospital to closely monitor patients who are subject to certain types of formulary decisions, such



as therapeutic interchange (which may be much more difficult to achieve for outpatients than it is for inpatients)

Show Me the Evidence, My Love

The evidence that formulary systems improve medication safety is largely empirical, based on the observations of those who have experienced the positive outcomes of a well-designed formulary system. In the author's own practice setting, the formulary system has driven many medication safety initiatives: restrictions on the availability of concentrated electrolytes, controls on insulin usage, standardization of infusion concentrations for many high-alert drugs, and labelling requirements for high-alert drugs, among many more. The formulary system, managed through the Pharmacy and Therapeutics Committee and acting under the authority of the medical staff, has the power to determine which drugs are available in the hospital, what safety standards those products must satisfy, how the drugs are prepared and administered, and what monitoring must take place when a drug is being used. The obvious question for the cynics is what other hospital mechanisms would they propose to address the ever-present safety issues related to the use of drugs?

Well-designed formulary systems, systems that incorporate medication safety as one of their primary purposes, have been endorsed in the United States by the American Society of Health-System Pharmacists, the American Medical Association, the US Pharmacopeia, the Department of Veterans Affairs, and other groups with a strong interest in patient safety.⁹ The widespread belief in the safety value of well-designed formulary systems is somewhat like believing in love. An academic argument can be made that there is no way to prove the existence of love, but those who have experienced its power know it is real.

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THE "CON" SIDE

If you are an administrative type, this question interests you for 2 reasons: first, you may be responsible for managing a formulary, and second, patient safety is the new buzzword in health administration circles. However, if you are a practising clinical pharmacist, the word "formulary" conjures up negative ideas of interrupted clinical service; as well, you feel that patient safety involves a lot of issues, but that formularies would be very low on the list of contributors and might even present a threat to patient safety.

Formularies have been the major focus of Pharmacy and Therapeutics Committees since the mid-1950s. Hospital organizations and accreditation agencies have strongly supported the formulary system and have encouraged institutions to get on the bandwagon. The idea of selecting only agents with therapeutic advantages is certainly an appealing one, scientifically to both physicians and pharmacists and economically to administrators.

Indeed, the recent focus of Pharmacy and Therapeutics Committees in teaching hospitals has been on a more sophisticated approach, namely so-called "pharmacoeconomic" evaluation, as part of the work-up on new drug requests and drug category reviews. Such reviews have sometimes shown cost savings for laboratory tests, reductions in administration times, and decreases in toxic effects. However, they are not complete.

Unfortunately, there is rarely any follow-up to see if the anticipated savings are realized. In a program that we initiated during the difficult budgetary days of the early 1990s, we were able to realize a saving of \$500 000 in our budget with several formulary ideas on injectable antibiotics and immunosuppressants.¹ For drugs that are to be used only during the hospital stay, the game of substituting and standardizing therapies can lead to possibly improved therapy and certain savings.²

However, our pharmacoeconomic evaluation was incomplete, as are most, in that there was lack of consideration of health outcomes and impact on 2 important parties: the patient and the clinical pharmacist. Now there is evidence³ that substitution of brands, let alone completely different derivatives, from a patient's prehospital regimen and in their long-term regimen at home can actually increase health care costs.



One experience stands out in my mind: I was counselling a patient about his anticoagulant therapy when, in the middle of the explanation, he asked me when they were going to start administering the drug. I replied that he had been on warfarin for several days. He begged to disagree, stating that he was so concerned that he had asked his wife to bring in his warfarin from home—which he proceeded to show me—so that he could take it while in hospital. Trying not to show my alarm, I noted that it was a different brand from what we had been administering. It became abundantly clear why we had had to decrease his hospital warfarin dose. It also became clear that no one had explained to him that there were several brands of the drug, presumably equivalent. What would have been the consequences had I not discovered this problem?

This is just one example of a brand change; I have seen several other cases in which we changed a patient's antihypertensive therapy in hospital, only to have the patient go home and resume taking the old antihypertensive; in one case, this resulted in readmission with hypotension.

In another example, a patient who was discharged on enalapril went home and started taking her family physician's previous prescription for lisinopril (nonformulary); she ended up in the emergency department with syncope and a bad fall. How many more of these incidents have occurred? Our new prescription and discharge forms should diminish the likelihood of these problems. However, we are only beginning to get an idea of the cost of incomplete continuity of care, some of which involves formulary substitution over previous therapy and failure to educate the patient about the change.

Despite concerns expressed,⁴ there are still desperately few studies on the real costs associated with formulary changes or even those just looking at the total costs to pharmacy. In most centres, this involves tagging nonformulary orders, sending a special note, delaying therapy (sometimes for 24 h or longer), involving the clinical pharmacist to chase the prescriber for the change, and a variety of telephone and written communications about all of these. Sweet and Stevenson⁵ recently studied the labour costs of substitution as well as drug costs in Michigan, finding that the costs of substitution were greater than the drug cost savings, particularly for oral agents.

The clinical pharmacist has many duties, and few pharmacists are able to finish the day without sacrificing care nor can they complete monitoring therapies for a large roster of patients, because of excess workload and other priorities. Nonformulary drug orders take up an inordinate amount of

time and lead to cancellation of many other (probably more beneficial) clinical activities. So, in addition to the actual labour costs of substitution, there are the costs of not providing care (solving drug-related problems) that would have ensued had the pharmacist not spent time on formulary issues.

Finally, there is the issue of the patient and ongoing post-discharge complications. One study⁶ documented that when patients were consulted, a formulary decision on non-sedating antihistamines was reversed. In the real world, where health outcomes are at stake, and where nonadherence and other drug-related problems abound, changing a patient's long-term medication has definite risks. We are only beginning to quantify the costs, particularly when care is not seamless (the usual situation), and to appreciate that unless such changes can be successfully communicated to the patient, we are creating an unknown risk that may cost the health care system more than any envisaged savings.

Overall, on the basis of the evidence and from a health outcome standpoint, the formulary system can be recommended only for use of in-hospital injectable products. Most other formulary standardizations present additional labour costs to the pharmacy, inappropriate clinical priorities for pharmacists, and additional risk to our patients. Let's get off the bandwagon and try to see the big picture from the vantage of our patients' health outcomes, because many of these practices are unsafe!

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