One Health Region's Timid Steps to Confront the Sacred Formulary Cow

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In an earlier article in this "Focus on the Formulary" series,[1–6] I came across Neil MacKinnon's comment that "Formularies are almost as ingrained in our profession as the drugs we dispense."[2] Few would argue with that statement, but it also has a corollary — that the debate over the value and cost-effectiveness of formularies is equally ingrained within our profession.

In 1986, a provocative commentary on the formulary began with the following statement: "There has been a con job performed on institutional pharmacy — the culprits are the members of the profession itself, and the perpetuated deception is the formulary system."[7] The author challenged the arguments put forward by the proponents of formulary systems and concluded by stating that more data were needed to support the profession's continued promotion of this concept.

What has been done to rethink the formulary system, renew its vigour, and produce the data to support its value and cost-effectiveness? The continuing debate on this subject suggests that not enough has been done. Many formularies are still primarily a tool for controlling drug use, a simple list of drugs that are available for use in a particular hospital. Furthermore, there are still insufficient data to support the conclusion that formularies are effective as a tool for controlling drug use. In 1997 Hepler wrote that "perhaps most experts in the field favor formularies, but the evidence for cost-effectiveness is not clear . . . the literature shows that only half a dozen studies of the cost-effectiveness of formularies were done in U.S. health care organizations. Equal numbers were pro, con, and neutral."[8]

Recently a number of practitioners have pointed out that formularies can create drug-related problems for patients moving from one care environment to another.[1,3,9] Medications on a hospital's formulary are frequently not the same as those on the formularies of the various third-party payers in the community.[1] McLean questioned whether it is safe to substitute one drug for another, as patients move between the community and institutional settings, in the absence of the resources needed to guide patients through the formulary-mandated changes with appropriate advice and explanations.[3] Few pharmacy departments currently have the resources to effectively run such a comprehensive seamless care initiative.

So, as MacKinnon asked,[2] should we protect this sacred cow of pharmacy or should we focus on finding ways to improve the positive outcomes associated with formulary systems while minimizing their undesired consequences?

When the Winnipeg Regional Health Authority came into existence, the 9 previously independent hospitals within the region had substantial differences in their existing formularies as well as in the rules, regulations, and philosophies under which those formularies operated. The markedly different approaches to formulary management in these 9 hospitals, all designed by well-meaning pharmacists and physicians, are probably a good indication that there is no professional consensus on what constitutes a good formulary system. Few would propose that we entirely abandon the formulary system, given the operational and patient-care problems that we would face without any formulary system.[4,6,10] Perhaps, however, it is time to refocus the argument from the question of whether we should have a formulary at all to the issue of determining the characteristics of the ideal formulary. In doing so, members of the profession must focus on the reality that formulary systems must serve 2 purposes — organizational efficiency and patient welfare.[11]

In 1986, Abramowitz and Fletcher presented their views on how formulary systems of the future could fulfil both of these objectives.[12] The authors expressed their belief that cost-effectiveness and cost–benefit analyses would be applied more extensively during the formulary decision-making process and that greater coordination and standardization of inpatient and outpatient drug therapy would occur. They also suggested that although generic substitution and therapeutic interchange policies would continue to

exist, more individualization and flexibility would evolve, and drug-use control would occur more by educational mechanisms and recommended criteria for use, than by limiting drug availability.

The Winnipeg Regional Health Authority has made a number of decisions along the lines of those proposed by Abramowitz and Fletcher that we believe strike an appropriate balance between organizational efficiency and patient welfare.

- Major restrictions on drug availability and use will be applied only to agents that have a narrow therapeutic index, that are complicated to use, that are more expensive than effective alternative therapies, or that have an impact on microbial ecology.
- More flexibility and individualization will be permitted as patients move from outpatient to inpatient care:
  - Within many classes of drugs (such as angiotensin-converting enzyme inhibitors and cholesterol-lowering agents), a primary agent will be defined and promoted as the region's choice for initiating therapy and as an alternative to drugs within the same class when therapeutic interchange is possible without compromising patient care. One of the major criteria for selection of a primary agent will be its availability on formularies in the outpatient setting.
  - Other agents within the same class that are frequently prescribed in our local community setting — and that are not substantially more expensive, more toxic, or more difficult to use than the primary agent — will be classified as secondary agents. Secondary agents will be made available, with as few obstacles as possible, to patients who are admitted on these drugs if the physician feels that therapeutic substitution is not in the patient's best interest.
- Care maps and drug-use criteria, rather than nonformulary status, will become the primary tools for managing drug utilization.
- Nonformulary status will be reserved for drugs that have not yet been evaluated by the Pharmacy and Therapeutics Committee, have been rejected by the Pharmacy and Therapeutics Committee, or have been removed from the formulary. These agents will be supplied by the pharmacy only upon approval of the chair of the relevant Pharmacy and Therapeutics Subcommittee (Adult, Pediatric, or Oncology subcommittees).
- The regional practice model that is being developed for staff pharmacists will include responsibility for the drug therapy of individual patients (pharmaceutical care) and responsibility for population drug use (drug-use management). Both of these objectives will be achieved primarily through educational interventions at the interface among physician, pharmacist, and patient.

These changes are viewed by some within our region as small, timid steps in the reform of the formulary system. Others view them as radical changes that will undermine the traditional drug-utilization management role of their previous formulary system, which had been achieved largely through restrictions on drug availability. We hope to study the cost-effectiveness and patient care implications of the changes we are making to our formulary system as a way of responding to these concerns. On the other hand, would the results really make a difference? To this point in time, the profession's belief in the sacred formulary cow has had more to do with faith than with evidence.

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