Formulary Considerations for Botanical Products and Food Supplements

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Pharmacy and therapeutics committees countrywide continue to grapple with the thorny issue of whether botanical products and food supplements should be part of a traditional formulary system. Inherent in considering this question is the principle that the criteria for listing a drug should embody an evaluation of efficacy, safety, and cost-effectiveness. Are these criteria also reasonable for botanical products and food supplements, or should some other approach be adopted?

The use of botanical products and food supplements is becoming commonplace. The reasons for their increased use go beyond the scope of this article, but the reader is reminded that an assessment of drug therapy of any type should be comprehensive, ensuring the appropriateness of the therapy and the avoidance of toxic effects. Care must be taken to foster a relationship of trust between the patient and the pharmacist, so that the patient provides full disclosure of all therapies that he or she is taking and so that the pharmacist understands the patient's health beliefs regarding medication. The patient must be involved in the choice of therapy, and a decision to include botanical products and food supplements is indeed a patient's right.

Institutions such as Sunnybrook and Women's College Health Sciences Centre have established task forces to review the issue of botanical product and food supplement use and to define parameters for such use. In other jurisdictions, subcommittees of pharmacy and therapeutics committees have been established to evaluate and make recommendations about non-traditional therapies.[1] Clearly, such activities are necessary in institutions that embrace the philosophy of patient-focussed care, since they acknowledge the use — often the result of self-selection — of products governed by an individual's beliefs about nontraditional therapies. These subcommittees also serve the needs of the formulary system. After deliberation, the subcommittees have concluded that the evaluation of efficacy should occur in the same manner as for traditional drugs and that, first and foremost, such an evaluation should be based on well-conducted clinical trials. The problem is that, given the relative lack of good, clinically relevant research in this area, one may be forced to rely on testimonials from so-called experts. Similarly, any evaluation of safety is hampered by a lack of documented evidence that such products are safe. All parties must feel comfortable that the product in question can do no harm. The issue of cost should also be addressed in the context of a comparison with traditional drug products within the same therapeutic class. This is important, as in many jurisdictions there is an expectation that the provision of therapies in hospital is at the expense of the publicly funded system, and therefore that such therapies should be available free of charge to patients.

The choice of product deserves special consideration, irrespective of whether the institution will bear the cost. Because many of the products available to the public are not regulated according to the requirements for a traditional drug, there is some concern about their composition, purity, and consistency. The potency of a herb may depend on the soil, weather, and harvest conditions.[2] As a result, variations within a brand from year to year or from lot to lot can be as great as the variations between brands.[3] All studies to date, regardless of the herb analyzed, have reported highly variable potencies between different brands, ranging from 0% to well above 100% of label claim.[3-6] However, because of the lack of consistency in herb potency, these studies may not indicate that one brand is consistently better than another.

Consideration of addition of these agents to a formulary not only permits continuation of prior-to-admission use, but also in essence endorses the products, giving them the institution's stamp of approval and giving permission to practitioners to continue prescribing them. However, their exclusion from a formulary does not preclude pharmacists from taking an active role in determining the appropriateness of these products for a particular patient's condition. As practitioners, we should strive to seek high-quality information about the nontraditional products that patients use, to provide objective information to help patients to make well-informed decisions about these products, and to acknowledge the right of patients to choose. In addition, we have an obligation to communicate our findings about efficacy and risk assessment to other health-care providers as part of our role in helping to establish the most appropriate therapy for any given patient.

If, therefore, institutional pharmacy and therapeutics committees are to assume some leadership and responsibility for the use of botanical products and food supplements, what might a "typical" policy engender? At Sunnybrook and Women's College Health Sciences Centre, our policy, approved by the Pharmacy and Therapeutics Committee, consists of the following principles:

1. Every effort is made to encourage patients to disclose their use of botanical products and food supplements to health-care workers.
2. These products are seen to be complementary to traditional therapies and are consistent with the Sunnybrook and Women's College philosophy of patient-focussed care.
3. Requests by prescribers to use these products are subject to the same rigorous evaluation that is currently required for conventional drugs and once the products have undergone this formal evaluation, they are included as part of the formulary system. In this circumstance, the cost of these products is assumed by Sunnybrook and Women's College Health Sciences Centre. When little information is available regarding the products' efficacy but the prescriber and other health-care providers are satisfied that the products will do no harm, patients or their families assume the cost of these products.
4. For drug products deemed acceptable for formulary inclusion, drug monographs are produced and made available to all prescribers and related health-care professionals.
5. The Pharmacy and Therapeutics Committee has indicated that it would be appropriate to review these products and their use annually.

In summary, before such therapies are made widely available in our institutions, we must be convinced that they have a proven, valuable role in achieving positive patient outcomes. At this time no other approach seems reasonable.

References

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