ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System

Position

American Society of Health-System Pharmacists (ASHP) believes that health systems should develop, organize, and administer a formulary system that follows the principles below in order to optimize patient care by ensuring access to clinically appropriate, safe, and cost-effective medications.

Background

A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health.[1] A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for health systems to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and cost-effective medication therapy. The formulary system is the ongoing process through which a health care organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

Pharmacy and Therapeutics Committee

To be effective, medication-use policies must have the concurrence of individuals involved in the medication-use process. Such consensus is achieved by developing medication-use policies through a properly organized and representative pharmacy and therapeutics (P&T) committee or equivalent body and ensuring that those policies are approved by the organized medical staff.

The P&T committee is composed of actively participating physicians, other prescribers, pharmacists, nurses, administrators, quality-improvement managers, and other health care professionals and staff who participate in the medication-use process. Customarily, P&T member appointments are based on guidance from the medical staff. The P&T committee should serve in an evaluative, educational, and advisory capacity to the medical staff and organizational administration in all matters that pertain to the use of medications (including investigational medications). The P&T committee is a policy-recommending body to the medical staff and the administration of the organization on matters related to the safe and therapeutic use of medications. The P&T committee is responsible to the medical staff as a whole, and its recommendations are subject to approval by the organized medical staff as well as the administrative approval process. The basic policies and procedures that govern the P&T committee's administration of the formulary system should be incorporated, as appropriate, in the health system's medical staff bylaws, medical staff rules and regulations, and other organizational policies.

The overarching purposes of the P&T committee are policy development, communication and education, and formulary management.

Policy Development

The P&T committee formulates policies regarding evaluation, selection, diagnostic and therapeutic use, and monitoring of medications and medication-associated products and devices. The P&T committee should establish and assist in programs and procedures that ensure safe and effective medication therapy (e.g., clinical care plans, treatment guidelines, critical pathways, disease management protocols). Members of the P&T committee, or their representatives from appropriate specialties (including pharmacists), should participate in or direct the development and review of such programs or procedures, which should be kept current.

The P&T committee should participate in performance improvement activities related to procurement, prescribing, dispensing, administering, monitoring, and overall use of medications. The P&T committee should advise the institution, including the pharmacy department, in the implementation of effective medication distribution and control procedures, incorporating technological advances when appropriate. The P&T committee should initiate, direct, and review the results of medication-use evaluation programs to optimize medication use and routinely monitor outcomes (economic, clinical, and humanistic) of formulary decisions. Medication-use evaluation should result in performance-improvement initiatives to improve the medication-use process.

The P&T committee should take actions to prevent, monitor, and evaluate adverse drug reactions and medication errors in the health care setting, including those occurring with biological products and vaccines. Information from these activities should be disseminated to the appropriate health care personnel for informational and educational purposes (e.g., newsletters, memoranda) and, when appropriate, to the Food and Drug Administration (FDA).

The P&T committee should establish clearly defined policies and procedures related to manufacturer sales representatives' activities within the organization.

Communication and Education

The P&T committee ensures that mechanisms are in place to communicate with health care professionals, patients, and payers about all aspects of the formulary system, including changes made to the formulary or policies and how formulary system decisions are made. The P&T committee also recommends or assists in the formulation of educational programs designed to meet the needs of professional staff, patients, families, and caregivers on matters related to medications and medication use. The P&T committee should establish or plan suitable educational programs on matters related to medication use for staff involved in the care of patients and the use of medications.

Formulary Management

Health systems should develop, organize, and administer a formulary system that follows the principles below in order to optimize patient care by ensuring access to clinically appropriate, safe, and cost-effective medications.

Formulary System. The P&T committee is responsible for administering the formulary system. Although the basic organization of each health care setting and its medical staff may influence the specific functions and scope of the P&T committee, key elements of a formulary system that should also be included are the evaluation of the clinical use of medications (including outcomes), the development of policies and quality assurance activities for medication use and administration, and the evaluation and monitoring of adverse drug reactions and medication errors. The formulary system shall be endorsed by the medical staff based on the recommendations of the P&T committee. The medical staff should adapt the principles of the system to fit the needs of the particular organization and affiliated institutions and ambulatory care settings. The organization, often through the pharmacy department, should make certain that all personnel involved in the care of patients and the use of medications in all health-system components are informed about the existence of the formulary system, how to access the formulary, the procedures governing its operation, any changes in those procedures, and other necessary information (e.g., changes in drug product availability). This information may be further disseminated to other interested entities (e.g., affiliated managed care organizations).

Formulary. The P&T committee develops an evidence-based formulary of medications and medication-associated products accepted for use in the organization. The committee also provides timely revision and maintenance for the formulary and promotes the rational, clinically appropriate, safe, and cost-effective use of medications via guidelines, protocols, and other mechanisms. The P&T committee, on an ongoing basis, objectively appraises, evaluates, and selects medications for addition to or deletion from the formulary. The formulary is based on the best clinical evidence available and reflects the current clinical judgment of the medical staff, pharmacists, and other health care experts. The selection of items to be included in the formulary should be based on objective evaluation of their relative economic, clinical, and humanistic outcomes. The decisions should not be based solely on economic factors. The committee should identify potential safety concerns for each medication considered for inclusion in the formulary and should ensure those safety concerns are addressed if the medication is added to the formulary or used in the health system.

The committee should minimize unnecessary duplication of the same basic drug type, drug entity, or drug product. Optimizing the number of drug entities and products available from the pharmacy can produce substantial patient care and financial benefits. These benefits are greatly increased through the use of generic equivalents (drug products considered identical or equivalent by FDA) and therapeutic equivalents (drug products differing in composition or basic drug entity that are considered to have similar pharmacologic and therapeutic activities).[2] The P&T committee must set forth policies and procedures that govern the dispensing of generics and therapeutic equivalents.

The P&T committee, when considering formulary options, should evaluate coordination issues with local health care plans and other organizations' formularies. At a minimum, appropriateness of therapeutic interchange should be evaluated for any formulary decisions that may conflict with known managed care or other health plan formularies.

The formulary should be published and updated regularly. It should also be readily available and accessible at all times, either manually or electronically, to all personnel involved in the care of patients and the use of medications. Medications should be identified in the formulary by their generic names, and prescribers should be strongly encouraged to order medications by their generic names.

The P&T committee should clearly define terminology related to formulary status of medications (e.g., formulary, nonformulary, not stocked at a given site, restricted by criteria specific to a given site), especially in multihospital organizations, and disseminate this information to health care professionals involved in the medication-use process. The P&T committee should establish a procedure for appraisal and use by the medical staff of medications not included in the formulary (i.e., nonformulary medication use).

The pharmacist shall be responsible for specifications for the quality, quantity, and source of supply of all medications, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients.

Conclusion

ASHP believes that medication-use policies should be developed and implemented in organized health-care systems to promote the rational, evidence-based, clinically appropriate, safe, and cost-effective use of medications. The P&T committee of a health system should develop, organize, and administer a formulary system that follows the principles set forth in this statement in order to optimize patient care.

References

1. Principles of a sound drug formulary system [consensus statement]. In: Hawkins B, ed. Best practices for hospital & health-system pharmacy: positions and guidance documents of ASHP. Bethesda, MD: American Society of Health-System Pharmacists; 2006:110–3.
2. U.S. Department of Health and Human Services. Electronic orange book: approved drug products with therapeutic equivalence evaluations. www.fda.gov/cder/ob/ (accessed 2008 Sep 24).

This statement was reviewed in 2012 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Approved by the ASHP Board of Directors on January 23, 2008 and by the ASHP House of Delegates on June 10, 2008. Developed through the ASHP Council on Pharmacy Practice. This statement supersedes the ASHP Statement on Pharmacy and Therapeutics Committee dated November 20, 1991, and the ASHP Statement on the Formulary System dated November 18, 1982.

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