DRAFT ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System

Purpose

These guidelines outline important considerations and recommend processes for formulary system management. Pharmacist responsibilities and roles in managing the formulary system in partnership with other healthcare professionals are embedded throughout. These guidelines also provide assistance to pharmacists in the organization and operation of the pharmacy and therapeutics (P&T) committee or equivalent body, evaluation of medications for formularies, and development and implementation of strategies to optimize medication use through the formulary system. A glossary of terms is provided in Appendix A.

Formulary and formulary system

A *formulary* is a continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. 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. A *formulary system* is the ongoing process through which a healthcare organization establishes policies regarding 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.[1] Formulary systems are used in many different settings, including hospitals, acute care facilities, home care settings, and long-term-care facilities, as

well as by payers such as Medicare, Medicaid, insurance companies, and managed care organizations. Many organizations have policy statements on the use of formularies.[2-8] These guidelines focus on the use of formulary systems in hospitals and health systems, in both inpatient and outpatient settings.

Evolution of formularies

Formulary systems have evolved over time. Modern formularies began as rudimentary drug lists developed by the military in the 1940s and came into more widespread use during the 1950s. Pharmacists, in conjunction with their organizations, developed policies to dispense generic equivalent drugs when a specific brand-name drug was prescribed. In the late 1950s, the ASHP minimum standard for pharmacies in hospitals called for the implementation of a formulary system.[9]

During the 1960s, the concept of a hospital formulary continued to grow. Hospitals developed policies that authorized pharmacists to make generic interchanges in an institutional formulary system based on prior consent from physicians.[10] ASHP and the American Hospital Association (AHA) issued joint statements on the legality of formularies.[11,12] AMA and the American Pharmaceutical (later Pharmacists) Association subsequently joined with ASHP and AHA to revise the statements.[13] In 1965, two significant events occurred: (1) Medicare listed formularies as a reimbursement eligibility requirement[14] and (2) the Joint Commission on the Accreditation of Hospitals (now known as the Joint Commission) included an active P&T committee in its accreditation requirements.[15] Even with these actions, formularies were typically no more than lists of drugs stocked by the pharmacy.

By the 1980s, literature describing the clinical and economic value of well-designed formularies emerged. Evidence from the hospital setting was published first, soon followed by evidence from the ambulatory care environment.[10] This literature led to more widespread acceptance of formularies by providers, payers, and industry.[5,16]

Today, formulary systems are considered an essential tool for healthcare organizations. Formularies have grown from simple drug lists to comprehensive systems of medication-use policies intended to ensure safe, appropriate, and cost-effective use of pharmaceuticals in patient care.

P&T committee

The P&T committee is generally the medical staff committee responsible for managing the formulary system. The P&T committee provides an evaluative, educational, and advisory service to the medical staff and organizational administration in all matters pertaining to the use of medications, which may include investigational medications, in collaboration with the institution's designated investigational review board. The P&T committee should be responsible for overseeing policies and procedures related to all aspects of medication use within an institution.

The P&T committee's organization and authority should be outlined in the organization's medical staff bylaws, medical staff rules and regulations, and other organizational policies, as appropriate. The description of organization and authority becomes even more important as healthcare facilities merge into larger health systems.

Typically, P&T committee member appointments are made based on guidance from

the medical staff. Voting members include facility medical staff, other prescribers, pharmacists, nurses, and administrators. If the scope of the P&T committee includes a health system, site representation needs to be addressed to ensure equitable input from each facility. Additional supporting P&T committee members may include quality improvement managers, informaticists, and other healthcare professionals and staff who participate in the medication-use process.

The P&T committee should have the following administrative components in place to maximize meeting effectiveness:

- Charter
- Process to track attendance
- Definition of quorum
- Process to allow (or disallow) delegation of vote
- Process to appeal committee decisions
- Defined term limits for members
- Process for identifying, disclosing, and addressing conflicts of interest (COI)
- Policy and procedures
- Scope of committee responsibility (e.g., specific site or entire system; inpatient or outpatient sites; drugs, devices, and biologics)

Other responsibilities of the P&T committee include medication-use evaluation (MUE), adverse drug event monitoring and reporting, medication error prevention, medication safety, and development of clinical care plans and medication management initiatives (e.g. protocols,

restrictions, guidelines, etc.). Information about these activities is available in ASHP guidelines on the topics.[17–20]

Oversight of a formulary system and the capacity to make appropriate formulary decisions requires consideration of patient care factors and a thorough, unbiased review of the biomedical literature. Voting members should be required to provide COI statements to avoid actual or perceived interference with evidence-based decisions.[21] Some healthcare organizations exclude heathcare professionals with COIs from P&T committee membership, whereas others allow participation in committee discussions but prohibit voting on particular items. Practitioners requesting additions or changes to the formulary should also be required to disclose financial relationships with pharmaceutical companies and other potential COIs to the P&T committee.

Managing the formulary system

Health systems should develop, maintain, and implement a formulary management process. Decisions on the management of a formulary system should be founded on the evidence-based clinical, ethical, legal, social, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care.[22-24] The process must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals, as well representatives with expertise in finance, law, and informatics. This evidence-based process should not be based solely on economic factors. The formulary system should be standardized within integrated health systems when standardization leads to improved patient outcomes and safety.

Management of a formulary system is a significant component of a healthcare organization's ongoing medication-use policy development process. A comprehensive, well-maintained formulary is tailored to the organization's patient care needs, policy framework, and medication-use systems while ensuring alignment with medication management standards of accrediting organizations.[25] A well-managed formulary system ensures a close relationship among the organization's medication-use policies, the therapies offered by the organization, and the medications routinely stocked in the pharmacy. A formulary also identifies those medications that are most medically appropriate and cost-effective to best serve the health interests of the health system's patient population. The P&T committee should interpret the term *medication* broadly in the context of care delivery to include alternative remedies (herbals and supplements), nonprescription drugs, blood derivatives, contrast media, and other diagnostic and treatment agents.[25]

The formulary system should review and approve all policies related to the medication-use process; all medication-use policies, regardless of their origination, should flow through the P&T committee. The organization's medical staff leadership (i.e., the body to which the P&T committee reports) should complete the final policy approval. Policy review and revision should occur as new information becomes available and at regularly established intervals (e.g., annually). The organization should have medication-use policies that address the following:

- How medications are requested for addition to or deletion from the formulary.
- How medications are reviewed for addition to or deletion from the formulary, including who performs the reviews.
- The process for developing, implementing, and monitoring medication-use guidelines.

- Methods for ensuring the safe prescribing, distribution, administration, and monitoring of medications.
- Methods for selection of suitable manufacturers for specific medications (the pharmacy department is 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).[26]
- The process for using nonformulary agents within the hospital and health system.
- The process for managing drug product shortages.
- The process for developing an organization or health system-specific MUE plan.
- Policies regarding specific medication-use processes (e.g., procurement, prescribing, distribution, administration, monitoring).
- The process for disseminating medication-use policies and how users will be educated regarding the process.
- Implementation of P&T committee decisions into the electronic health record (EHR).

A formal process to review medication-use policies should be in place. This process may include the use of expert panels or subcommittees of the P&T committee. Expert panels or subcommittees should serve in an advisory role to the P&T committee, and their membership should include recognized experts in their areas of practice. The P&T committee may also find subcommittees that address specific therapeutic areas to be beneficial (e.g., antimicrobial, oncology therapy, cardiovascular, adverse drug reaction, pharmacogenomics, or biotechnology subcommittees). Panels and subcommittees are helpful in applying clinical

study results to specific patient populations and developing recommended strategies for the safe and effective use of medications. Subcommittee and panel members can help educate groups of physicians, who ultimately drive prescribing behaviors, about significant formulary changes. User groups, representing those primarily affected by the policy, may also be helpful.

The P&T committee should have formal interactions (i.e., communication lines) with other committees whose functions may affect the medication-use process. These committees would include those responsible for developing tools to facilitate medication use (e.g., forms or order set review committee, computerized prescriber order entry committee), those concerned with safety or performance improvement (e.g., quality improvement or patient safety committees), those involved in developing patient care policies (e.g., medical and nursing committees), those involved with investigational medications (e.g., investigational review boards), and other committees whose actions may affect medication use (e.g., nutrition, equipment and supply, or finance committees). Recommendations from other committees, subcommittees of P&T, expert panels, and others should be submitted to the P&T committee for review. P&T committee decisions on recommendations should be communicated to the recommending group in a timely fashion.

Finally, the role of pharmaceutical company representatives and medical science liaisons in a healthcare organization should be carefully considered. Organizational guidelines should define appropriate relationships and interactions with such individuals. At a minimum, these guidelines should address the provision of pharmaceutical samples, indirect or direct funding support, and educational programming regarding formulary and nonformulary medications. Applications for formulary additions should be initiated and completed

independently by the requesting healthcare provider and not by an industry representative or vendor. Refer to ASHP's Guidelines on Pharmacists' Relationships with Industry for more information on appropriate interactions with industry.[27]

Evaluating medications for inclusion in the formulary

The P&T committee should use a structured, evidence-based process in the evaluation of medications for formulary consideration. The P&T committee should be provided with information that reflects a thorough, accurate, and unbiased review and analysis of the evidence available in the scientific literature. The evaluation process should encourage objective consideration of clinical and care delivery information, facilitate communication, foster positive patient outcomes, and support safe and effective medication ordering, dispensing, administration, and monitoring. Decisions made by the P&T committee should support improved patient care outcomes across the continuum of care.

Evidence-based evaluation. Inclusion of a medication on a health system's formulary should reflect that an evidence-based evaluation of the relative merits and risks of the medication has been performed and that the institution's P&T committee, with input from appropriate experts, has determined that the medication is appropriate for routine use in the management of the patient population at that institution (see Appendix B for a description of the four major types of reviews used in such evaluations).

Evidence-based medicine is a systematic approach to the evaluation of biomedical literature and application to clinical practice and should be applied to formulary decision-making for medication product selection.[23] Evidence-based decision-making standardizes and

improves the quality of patient care and promotes cost-effective prescribing.[23,24] To practice evidence-based medicine, practitioners must be proficient in retrieving, evaluating, and applying the biomedical literature to clinical practice.

Evidence-based decision-making incorporates the systematic approach to reviewing, evaluating, and applying the biomedical literature to guide formulary decisions. Various types and strengths of evidence (e.g., meta-analyses, randomized clinical trials, case reports, association consensus statements) may be useful in the decision-making process. Although different types of evidence are available for application, those with stronger evidence should be used to drive formulary decisions (e.g., meta-analyses, randomized controlled trials). Other types of evidence have a role in the decision-making process, however, and may be appropriate when stronger evidence is not available. Observational studies (i.e., case–control and cohort studies), case reports, and consensus opinions may be valuable even when stronger evidence is available. Some organizations find it useful to grade evidence when evaluating formulary requests; several tools are available for this purpose.[28–32]

Published evidence and expert opinion are not the only resources available to aid in the formulary decision-making process. Internal data and prescribing and outcomes information may be helpful in formulary decision-making. When published data are not available, it may be appropriate to incorporate expert opinion into the review process. Experts in practice areas sometimes have access to unpublished data or reports that may offer insight into difficult formulary decisions.

The formulary decision-making process should be guided by an independent review of evidence published in the biomedical literature, application of expert opinion, and use of

internal data and benchmarking programs. If a P&T committee uses dossiers prepared by pharmaceutical manufacturers, it should do so with the utmost caution, since the objectivity of these documents may be challenged.

Information used in the formulary decision-making process should be provided to the P&T committee in a written document with a standard format (e.g., a drug monograph, drug review, drug-evaluation document).[33] All information provided in the drug-evaluation document should be referenced to the evidence or identified as a conclusion supported by evidence. Any areas of consensus recommendations or opinion should be clearly identified.

Formulary status recommendations (e.g., from drug information services or expert groups) may be included in the drug-evaluation document. In some organizations, recommendations are not provided in the written document in order to promote an unbiased discussion by the P&T committee. Recommendations should consider the formulary status (addition or rejection) of a medication, as well as the need for restrictions, educational efforts, or policies and procedures to ensure safe and appropriate use within the health system.

Pharmacoeconomic assessments. Rigorous pharmacoeconomic evaluations can and should be conducted in some cases when reviewing new medications. These evaluations should explicitly state the perspective of the analysis (e.g., patient, healthcare provider, payer) and should include consideration of all costs and consequences relevant to that perspective. When new medications being considered are found to be therapeutically equivalent to existing alternatives (i.e., having equivalent efficacy and safety), then the cost-minimization approach is appropriate. In these circumstances, it is important to consider costs associated with the medication and non-medication-related costs (e.g., costs of administration, monitoring,

241 prolonged hospital stay, and laboratory test monitoring; costs to patients and providers).

242 While cost-effectiveness analysis (evaluating the incremental difference in investment
243 necessary to produce an incremental difference in clinical outcome) is another potentially
244 useful analytic approach, it is not often used for formulary decision-making because of its
245 complexity and need for strong evidence or data. The academic value of this approach lies in
246 its ability to show how little (or how much) must be spent to achieve a particular margin of
247 clinical advantage when comparing an alternative that is more expensive but safer or more
248 efficacious. No standards currently exist to determine what cost is reasonable for a given
249 improvement in outcome; however, it is unreasonable to recommend alternatives of lower
250 quality simply to achieve cost savings. This approach can be used to demonstrate how a
251 decrease in clinical outcomes associated with the use of a less-expensive agent can be offset
252 by investing the savings achieved in other interventions that produce even greater total
253 benefits. When evaluating cost-effectiveness, it is important to consider the appropriate class
254 of trade of where the drug is administered.

255 Cost-utility evaluations (evaluating the incremental difference in investment necessary
256 to produce an incremental difference in quality-of-life-adjusted clinical outcome [e.g.,
257 incremental cost per quality-adjusted life years gained for one medication versus another])
258 may also be beneficial by serving to reflect patient preference in formulary decision-making.
259 However, the same concerns related to the use of cost-effectiveness evaluations apply to this
260 approach.[34–36]

261 Decision analysis models incorporating local data can be employed when published
262 pharmacoeconomic data are limited or unavailable. Probabilities for each outcome can be

extracted from the published literature or drawn from local data sources, which would provide a more relevant local perspective on outcomes. Costs associated with medications and outcomes should reflect those of the healthcare system.

Pharmacoeconomic analyses published in the medical literature or provided in the manufacturer's formulary dossier should be analyzed carefully before being included as part of the review process. Particular attention should be paid to the assumptions made in these studies. In many situations, assumptions made to simplify economic studies are not valid in particular institutions. Institution-specific costs are often different from the costs used in published studies, and local data should be used when incorporating their results into medication reviews.[37,38]

Even if a formal pharmacoeconomic evaluation is not included in a drug review document, a financial evaluation must be conducted, including consideration of site of care, non-medication-related costs and financial consequences to the pharmacy and to the organization as a whole.

Formulary exceptions. Exclusion of a medication from a formulary may affect coverage of and access to the medication. In a closed formulary system, for example, only medications listed on the formulary are covered under the patient's drug benefit. Regardless of health-system setting, the formulary system should include an exception process that provides prescribers and patients with timely access to medications that are not on the formulary but are medically necessary for the care of the patient. The underlying principle for such a process is that unique patient needs may not be satisfied by use of the formulary medications. The formulary exception process should generate information on nonformulary medication use that

will enable the P&T committee to evaluate trends in such use. Criteria for approval of nonformulary medications should be developed (e.g., allergy to or therapeutic failure of formulary alternative, condition not treatable by formulary medications).

Subformularies. Depending on state regulations, subformularies may be developed and maintained, using the same evidence-based process, to provide lists of appropriate and approved medications for furnishing by nonphysician providers or to specific patient subsets, such as Medicare patients. Health systems must follow specific rules and regulations provided under the U.S. Medicare Modernization Act of 2003 in their evaluation and inclusion of medications in a Medicare formulary for those medications to be covered.[39]

Strategies for managing medication use

Common strategies for managing medication use via the formulary include use of generic drugs, biosimilars, and specialty medications; therapeutic interchange; guided-use policies, clinical practice guidelines; and MUE.

Generic drugs. Optimizing the number of medication 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 (drugs considered bioequivalent by FDA [i.e., AB-rated drug products[40]]). The use of generic equivalents is encouraged in order to provide the best possible care at an affordable cost. Use of generic drugs that have been deemed bioequivalent by FDA does not require review or approval by the P&T committee, although a review of all new generic medications for key safety issues (e.g., look-alike, sound-alike concerns) should be conducted to prevent medication errors when possible. For some

drug categories, such as those with a narrow therapeutic range, a more thorough evaluation of the bioequivalency data and approval of experts or the P&T committee should be considered before implementing a generic substitution.

The P&T committee should establish policies and procedures governing the dispensing of generic equivalents when branded products are ordered. These policies and procedures should include the following points:

- The pharmacist is responsible for selecting from available generic equivalents those drugs to be dispensed pursuant to a prescriber's order for a particular medication.
- The prescriber has the option, at the time of prescribing, to specify the brand or supplier of the drug to be dispensed for that particular medication order if considered clinically justified.
- The prescriber's decision should be based on pharmacologic or therapeutic considerations (or both) relative to that patient.

Biosimilars. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. Several entities have been approved as biosimilars by the FDA, and inclusion of these products on formulary should be considered as a strategy for management of the medication-use system. Biosimilars are not generically equivalent to the reference product, so the P&T committee should be involved in the decision to include these products on formulary. The implications for patients must also be considered, including coverage and reimbursement models by payers, any differences in clinical indications or activity between the reference product and the biosimilar, and contractual obligations.

Specialty medications. P&T committees should be involved in the organization's approach to managing specialty medications to ensure the pharmacy has the ability to provide medications in a timely manner, to support patient access to medications and provide continuity of care. ASHP has resources to aid in specialty pharmacy management, including the ASHP Specialty Pharmacy Resource Guide.[41] This guide provides guidance on white- and brown-bagging strategies.

Therapeutic interchange. Therapeutic interchange is the authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines, policies, or protocols within a formulary system.[1,42] Drugs appropriate for therapeutic interchange are drug products with different chemical structures that are expected to have similar therapeutic effects and safety profiles when administered to patients in therapeutically equivalent doses. Therapeutic interchange provides pharmacists with the authorization to use a formulary therapeutic alternative in place of a nonformulary medication or a nonpreferred formulary medication without having to contact the prescriber. Ideally, therapeutic interchanges are built into the EHR to allow for seamless substitution of formulary products. A process should be established for when the prescriber wishes to opt out of the interchange. Adequate educational initiatives should be undertaken to ensure that everyone affected (prescribers, patients, pharmacists, nurses, and other healthcare professionals) is notified of the therapeutic interchange.

Guided-use strategies. Medications may be added to the formulary with additional processes in place to guide the use of the medications to improve therapeutic outcomes, prevent adverse events, or reduce costs. All guidelines for use for both on- and off-label

indications should be developed using evidence-based decisions, based on the current medical literature.[43] Examples of strategies to help guide the use of medications may include the following.

Established-use criteria. Patients must meet the established criteria before the medication is dispensed. A process should be developed to cover situations in which the patient does not meet the established criteria, but the medication is nevertheless determined to be medically necessary. This strategy may also be useful when medications are in short supply.

Restricting drug use by specialty service. A specific service must approve the use of the drug before dispensing. This strategy can be used when inappropriate use or severe adverse effects may occur, and it can also be employed for antimicrobial agents when inappropriate use or overuse can result in resistant organisms and pose a danger to the general patient population or the public. Alternatively, ordering of a specific medication may be limited to a specific group of prescribers. (e.g., restricting use of chemotherapy agents to oncologists).

Designating medications for use in specific areas. Such policies can be helpful when administration of a medication requires special equipment or staff with particular skills to use the medication safely (e.g., limiting neuromuscular blockers to operating rooms and critical care areas).

Approval of medical director (or designee) before drug use. This strategy is particularly appropriate when the P&T committee has reviewed a high-cost medication and determined that the drug has little or no role in the care of patients at that organization but a prescriber would like to use the medication on a nonformulary basis. This strategy may also be used as an approval pathway for medications requested for use outside of established use criteria.

Clinical practice guidelines. Clinical practice guidelines are developed and disseminated by national and international organizations, but they can also be developed locally.

Whether the medication formulary is a reflection of existing clinical practice guidelines in a particular organization or vice versa, it is critical that the guidelines and formulary are consistent. If a specific medication is recommended by a clinical practice guideline, it should in the majority of cases be on the formulary. As formulary changes are made, agents may need to be removed from or replaced in existing guidelines. Guidelines should avoid recommending use of nonformulary medications, and they can be useful in discouraging nonformulary medication use and guiding the appropriate use of formulary products when necessary.

Guidelines are frequently developed to address complex or particularly expensive medication therapies. However, complicated specialty therapies that will affect the care of very few patients may not justify the time and resources necessary to develop and maintain a guideline. Guidelines may be medication specific or disease oriented and may overlap in their scope of coverage.

The development of a clinical practice guideline should begin with the synthesis of all available biomedical evidence addressing the guideline topic. In many cases, guidelines from other organizations, both national and local, can be used as a starting point for development. The subsequent consensus process, eliciting feedback and input from local stakeholders, is critical. Data from the organization should be used to make informed decisions during the consensus process. After the consensus process is completed, the guideline should be reviewed and approved by the P&T committee.

The dissemination and implementation of guidelines in the practice environment must

also be carefully executed. Communication about the availability of guidelines is necessary. Guidelines should be readily available through existing health-system platforms. If feasible, it is recommended to build the guidelines into the computer provider order entry system (e.g., through order set creation) to facilitate the appropriate care of the patient. Every guideline should include a time frame for future review and revision.

If utilization of a medication is being requested outside established health-system guidelines for appropriate use, scientific evidence to support safety and efficacy should be provided and reviewed to substantiate the request.

MUE process. MUE is a quality-improvement activity, but it can also be considered a formulary system management technique. MUEs have traditionally involved evaluating evidence-based criteria to determine the health system's compliance with established standards. Interventions could then be used to improve prescribing based on those data.

MUE can be simply informative (collecting data to guide decision-making) or used to measure the effect of interventions, such as the addition of a new agent to the formulary or the implementation of a new medication-use policy. While MUE often focuses on problem-prone, high-risk, or high-cost medications, MUE can be used to examine any aspect of medication use that is problematic to the institution conducting the evaluation. Medications recently added to the formulary should be evaluated, especially if there is the potential for inappropriate use or adverse effects. This review should occur 6–12 months after their addition to the formulary. High-cost, high-use, and problem-prone medications are also good candidates for evaluation.

A systematic plan to monitor, evaluate, and improve medication use should be established within the organization.[17] Such a plan is an accreditation requirement for many

organizations (e.g., Joint Commission[25]). The P&T committee, or its equivalent, should be involved in the MUE process.

Incorporating patient safety issues in the decision-making process

The P&T committee should systematically address medication and patient safety issues as part of its deliberations. The P&T committee should ensure that medication-use policies adequately address potential risk and safety issues. Hospital or health-system medication-event data, including near misses, should consistently be reviewed by the P&T committee, along with recommendations to prevent future events. The P&T committee should also review available information on medication or patient safety events reported by other organizations to identify ways to prevent medication events and disseminate the information to healthcare providers and, when appropriate, patients.

When evaluating a medication for inclusion on the formulary, the P&T committee and its supporting subcommittees or panels should consider adverse effects, preparation issues, sound-alike or lookalike potential, and dosing or administration issues. Proactive assessments should be conducted to identify potential safety concerns posed by use of the medication, and proposed strategies to mitigate those risks should be implemented by the P&T committee. In addition, quality improvement projects to improve the safety of specific medications or to evaluate the processes involved should be conducted and reviewed by the P&T committee. The P&T committee should champion evidence-based fail-safe techniques (e.g., bar-coding) to prevent medication events.

Resources that provide information on medication or patient safety events include the

Institute for Safe Medication Practices (www.ismp.org) and Medwatch. The Joint Commission, Institute for Healthcare Improvement, and National Center on Patient Safety provide information about conducting and examples of failure mode and effects analysis (FMEA) projects on their websites (www.jointcommission.org/, www.ihi.org/, and www.patientsafety.va.gov).

Implementation of formulary decisions into the EHR

Use of the EHR to implement, guide, and evaluate decisions made by the P&T Committee is essential. EHR technology functionality should be maximized to support drug policy and formulary management decisions. A standard process, including established expectations for timeliness, should be developed to consistently and efficiently implement these decisions into the EHR. Multi-hospital systems and integrated delivery networks that share the same EHR platform and formulary review process should centralize the coordination of implementation.[44] EHR implementation efforts should be coordinated with operational changes and education requirements identified in the decision-making process. Finally, resources and personnel available to support implementation into the EHR should interface with the P&T committee to ensure understanding and shared expectations of the EHR technology functionality. In addition, key content experts charged with evaluating and proposing drug policy and formulary management decisions should collaborate with informatics personnel on the design and validation of EHR content.

Drug product shortages

Health systems frequently need to address drug product shortages. Drug product shortages disrupt patient care and impact all aspects of the medication-use system, including purchasing, storage, automation systems, the EHR, preparation, administration, and monitoring.

During a drug product shortage, the P&T committee plays an important role. The P&T committee needs to develop strategies to address shortages in a timely manner, including designating appropriate therapeutic alternatives, identifying strategies for mitigating use of available drug product, and establishing use restrictions. All of these strategies should be developed based on available literature and best practices. Therapeutic interchange can be useful in dealing with critical drug product shortages. The P&T committee should work collaboratively with other committees and departments, such as specific medical departments, nursing, and risk management (when necessary) to develop effective management plans for addressing shortages. Given the dynamic nature of drug shortages, it is not always possible to obtain approval from P&T committee members prior to implementation of strategies if there is a need for urgent changes. To make sure the P&T committee is aware of all changes related to drug shortages, organizations should include a drug shortage update as a regular agenda item for the P&T committee. Communication with patients and staff is crucial to effectively manage shortages.

Effective integration of these strategies into the EHR is key to successful implementation of a drug shortage plan. Various strategies exist for communication in the EHR, including placing electronic alerts on medications, blocking the ordering of medications on shortage, and facilitating the build of new medication records or order sets to guide use of alternative agents

during the time of the shortage.

More information about managing drug product shortages can be found in the ASHP Guidelines on Managing Drug Product Shortages.[45]

Implementing medication-use policies

Various tools can be used to implement medication-use policies. The policy should be integrated directly into the therapeutic decision-making processes that guide the use of a medication during order entry or incorporated into diagnosis-specific electronic treatment plan. Other specific ways of communicating information about a medication-use policy may include the use of

- Inservice education,
- Facility-approved social media,
- Grand rounds,
- Communication between pharmacists and prescribers
- Staff meetings,
- E-mail,
- Electronic newsletters,
- Prescriber detailing, and
- Pharmacy or institutional websites.

Outcome-driven projects may be beneficial in illustrating the value of a new medication-use policy and support further expansion.

Reimbursement strategies and considerations

New payment models require that P&T members are astute in their understanding of the hospital's and health system's payment policies and reimbursement strategies related to medications. A balanced approach to managing a hybrid reimbursement structure between traditional fee-for-service models and emerging value-based contracts will be required. Financing and reimbursement for medications is complex; hospitals and health systems can no longer exclusively focus on manufacturing contracts, wholesaler agreements, and inpatient reimbursement. Large health systems and integrated systems must consider implications of medication reimbursement by Medicare, Medicaid, 340B, commercial, and private payers. Prior to approval of high-cost drugs, in collaboration with the finance department, there should be a benefits investigation conducted, factoring in local payer mix, plans for financial monitoring, and payor negotiations. The organization should have a defined process and responsible department for validating reimbursement of therapy and financial outcomes over time. Site of care decisions are included in determining where a medication will be administered. Each organization should have policies on the use of medications not directly procured by the hospital pharmacy. For example, some specialty medication payer agreements circumvent traditional buy-and-bill dispensing channels and instead dispense the medication directly to the site of care for patient administration (white bagging) or to the patient, who then carries it to the site of care for administration (brown bagging).[46]

Conclusion

A formulary system is the multidisciplinary, evidence-based process employed by an

organization to select and use medications that offer the best therapeutic outcomes while minimizing potential risks and costs for patients. Organizations should employ the MUE process to continually improve how medications are used within the organization at all steps in the medication-use process. Medication use is an inherently complex process that requires constant evaluation. Organizations need to implement all necessary tools and processes to meet the goals of safe and effective medication use. Professionals involved in the medication-use process need to know and understand how the organization's medication-use policies and processes can be incorporated into their daily work to ensure medications are used appropriately and safely. Technology offers many opportunities to make those processes more effective and efficient. Communicating the actions related to medication use is a constant challenge that organizations need to address.

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Appendix A—Glossary of Terms

Cost Effectiveness Analysis: A method for assessing the gains in health relative to the costs of different health interventions.[47]

Cost Utility Analysis: A method used to determine cost in terms of utilities, especially quantity and quality of life, to compare one or multiple drugs or procedures.[48]

Electronic Health Record: A digital version of a patient's medical history that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that persons care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports.[49]

Formulary: A continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis,

prophylaxis, or treatment of disease and promotion of health.

Formulary System: An ongoing process whereby a healthcare organization, through its physicians, pharmacists, and other healthcare professionals, establishes policies on the use of drug products and therapies and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.[1]

Generic Substitution: The substitution of drug products that contain the same active ingredient or ingredients and are chemically identical in strength, concentration, dosage form, and route of administration to the drug product prescribed.[1]

Medication: Any prescription medications, herbal remedies, vitamins, nutraceuticals, nonprescription drugs, vaccines, or diagnostic and contrast agents used to diagnose, treat, or prevent disease and other abnormal conditions and radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, intravenous solutions (plain or with electrolytes or drugs), or any product designated by the Food and Drug Administration as a drug (including investigational drugs).[25]

Medication-Use Evaluation: A performance-improvement method that focuses on evaluating and improving medication-use processes with the goal of optimal patient outcomes.[17]

Pharmacy and Therapeutics (P&T) Committee: An advisory committee that is responsible for developing, managing, updating, and administering a formulary system.[1]

Therapeutic Alternatives: Drug products with different chemical structures but of the same pharmacologic or therapeutic class and usually have similar therapeutic effects and adverse-reaction profiles when administered to patients in therapeutically equivalent

doses.[1]

Therapeutic Interchange: Authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines or protocols within a formulary system.[1, 42]

Therapeutic Substitution: The act of dispensing a therapeutic alternative for the drug product prescribed without prior authorization of the prescriber. This is an illegal act because only the prescriber may authorize an exchange of therapeutic alternatives.[1]

APPENDIX B – Drug Evaluation Process

There are four major types of drug reviews: new drug monographs, reevaluations of previous formulary decisions, therapeutic class reviews, and expedited reviews of newly approved medications. Because of the expertise and training of pharmacists (drug information specialists in particular), pharmacists should play an integral part in the preparation and presentation of the drug review document to the P&T committee.

New drug monographs. When the Food and Drug Administration (FDA) approves a new drug for marketing that is relevant to the health system, a drug monograph should be prepared for formulary consideration by the P&T committee. New chemical entities warrant a thorough evaluation and a written drug monograph. A short (e.g., one-page) summary could be provided along with the full monograph.[33] Some organizations use an executive summary format. A new drug that is significantly similar to other available therapeutic alternatives may be presented in a more abbreviated manner (e.g., an abbreviated monograph) provided that the P&T committee or experts agree that the drug is therapeutically equivalent to agents already

593 available on the formulary.

594 ***Addenda to original monographs used to reevaluate previous formulary decisions.***
595 Formulary decisions may need to be reassessed based on relevant new information or in light
596 of newly marketed drugs or dosage forms. New data on safety, efficacy, stability, methods of
597 administration, cost, or pharmacoeconomics may warrant a reevaluation of the drug or
598 dosage strengths or formulations stocked by the health system. An addendum to the original
599 monograph summarizing the new information should be developed for evaluation by the P&T
600 committee. The P&T committee may want to establish reassessment dates at the time of
601 formulary review so that the committee can reassess the effect of a formulary decision on
602 quality or cost of care.

603 ***Therapeutic class reviews.*** Review of an entire therapeutic class of drugs should be
604 performed at regular intervals, which may be determined by the P&T committee or influenced
605 by regulatory agencies. A therapeutic class review should include all formulary and
606 nonformulary medications within the class and may include institutional utilization or
607 outcomes data and newly published information. Therapeutic class reviews may lead to
608 formulary removal of therapeutically equivalent drugs or a change in restriction or guideline
609 status for a drug.

610 ***Expedited reviews.*** A process should be available for the P&T committee to conduct an
611 expedited review of a new drug, new indication for a drug, or reevaluation of a previous
612 formulary decision. Criteria should be in place to describe when an expedited review is
613 warranted. For example, approval of a new chemical entity for a disease with no therapeutic
614 alternative may warrant an expedited review to ensure availability of the drug for patients who

need it. Likewise, a significant new safety concern may warrant an expedited review for addition of restrictions or removal from the formulary.

When approved, these guidelines will supersede the ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System dated January 28, 2008.