

Technology Assessment and the Drug Use Process

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This activity is designed for pharmacists, physicians, physician assistants, nurses, and other healthcare team members, payers for health services, and healthcare executives.

OBJECTIVES

Upon completion of this activity, the participant should be able to:

1. Describe the rationale behind, the development of, and the advantages arising from the formulary process, and discuss the health professionals involved in the creation of formularies.
2. Describe the impact of new drug development and technology on the drug use process.
3. Discuss the functions of the pharmacy and therapeutics committee.
4. Describe the impact of consumers on the drug use process.

CONTINUING EDUCATION CREDIT

This course has been approved for a total of two (2) contact hours of continuing education credit (0.2 CEUs) by the University of Tennessee College of Pharmacy. The University of Tennessee College of Pharmacy is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. ACPE Program Number: 064-000-99-202-H-04. This course expires on February 28, 2002.

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Technological advances and economic factors are driving continual changes in the health-care environment. Technological advances are evident in increasingly sophisticated surgery (cardiac, eye, organ transplant, etc), radiographic procedures, and advanced drug therapy. Overall growth in the healthcare industry is also continuing despite an increasing number of mergers among hospitals, health maintenance organizations (HMOs), physician medical practices, and home care providers, which in 1996 included 970 transactions (a 55% increase from 1995).¹ This growth will likely continue for the next several decades as the baby boomers age.

The world of pharmaceuticals and drug therapy in the 1990s continues to increase in complexity. Technological advances, such as new drugs, drug delivery systems, diagnostic devices, automation, and/or computerization, have a significant impact on the healthcare system and specifically the drug use process. There are now several hundred new drugs in the FDA drug pipeline. Indeed, there are 187 medicines and vaccines in development for use in children and 158 pharmaceuticals in development for geriatric patients.² The number of new drugs approved by the FDA could easily reach 600 in the decade of the 1990s. The number and types of new chemical entities and dosage forms (biotechnology drugs, drug delivery systems, drug combinations, and more generic pharmaceuticals) point out the need for comprehensive evaluative systems and processes for health professionals and patients who participate in the drug use process.

This article will discuss some of the tools used by pharmacists, physicians, and other caregivers to evaluate and manage the drug use process, notably the formulary system, and will detail the role of technology assessment in this process.

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The Medication Formulary Process

Medication formularies and the concept of a formulary system have been utilized for decades in healthcare facilities, particularly hospitals, to assist physicians and pharmacists with information on available medications. The systematic, objective review, selection, and ultimate use of therapeutic agents in patients continues to have considerable merit.³ Formulary management is made challenging, however, in the face of escalating drug costs and the introduction of new medical technology. The primary challenge is to make available the necessary variety of pharmaceutical products to meet the needs of different patient populations while maintaining fiscal stability within a defined budget.

While there has been some debate in recent years challenging the utility of formularies,⁴⁻⁶ the formulary continues to be a major tool to assist with clinical utilization and cost control of the drug use process. In fact, successful experiences with formularies in hospitals have yielded clinically relevant and cost-effective drug regimens for patients. This has created greater acceptance and use of formularies in other healthcare settings such as HMOs, pharmacy benefit management groups (PBMs), and integrated systems.⁷⁻¹⁰ Although pharmacy benefit management groups have traditionally functioned as claims processors for third-party health insurance programs related to prescription medication benefits, PBMs have in recent years more rigorously embraced the formulary concept and the attending utilization review process. In some progressive PBMs, drug therapy guidelines are being developed and implemented. One report indicates that projected formulary use in HMOs by the end of 1998 will be 90%.¹¹ Deciding which drugs to put on formulary is a key consideration, and is most often the task of the pharmacy and therapeutics (P&T) committee.

Structure and Function of the Pharmacy and Therapeutics Committee

Members of the P&T committee (also called the formulary or medication use committee) are generally appointed or assigned by an institution's administration and medical staff. Appointment is based on a health professional's drug therapy expertise, which ensures that medications are selected and used safely. Economic expertise is also a consideration, as the cost-effective use of drugs is vitally important. The committee is often comprised of physicians, pharmacists, a nurse, an administrator

of the facility, and a risk manager, and should be structured to meet the goal of providing appropriate cost-effective drug therapy and monitoring outcomes.

Functions of the committee common to institutions, managed care organizations, PBMs, and state Medicaid programs are as follows:

- Acting on recommendations for medication formulary additions/deletions (assuring a current drug therapy armamentarium for staff and patient use)
- Monitoring adverse drug reactions (noting trends in this data and reporting significant events to the Food and Drug Administration)
- Monitoring investigational drugs (assuring patient safety and protocol compliance with new drug entities)
- Preventing and monitoring medication errors (developing reporting mechanisms and cause/effect analyses to reduce medication errors)
- Conducting drug use evaluations (monitoring the appropriateness of medication prescribing)
- Monitoring the overall effectiveness of the medication use process (reviewing all aspects including prescribing, dispensing, administration, and monitoring)
- Approving medication use policy (deciding on behalf of the organization the best drug use practices for patients and staff)
- Educating patients and staff on the safe and effective use of medications (providing inservice education to patients and staff)

In regard to the last item in particular, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is concerned that both health professionals and patients handling complex medications and dosage forms are educated on the safe and effective use of medications. JCAHO requires documentation of patient education in the patient's chart.

The JCAHO, however, no longer requires a P&T committee per se; instead, the focus is on the performance improvement process of medication use and interactions among healthcare team members. With this in mind, more medical centers are developing "process" focused committees known as "medication use committees." While similarly staffed and responsible for virtually all the same tasks as the P&T committee, including formulary development and maintenance, the medication use committee is more focused on the drug use process (prescribing, dispensing, administration, and moni-

toring) and patient outcomes. Such committees also complement other medical center performance improvement initiatives to improve process and effectiveness.

Formulary Product Selection

Formulary management is shifting from a reactive to a proactive process. New drugs undergo analysis prospectively by the P&T committee in anticipation of their release. By staying abreast of the latest medical technology and making timely formulary additions and adjustments, P&T committees provide patients with the most appropriate, current pharmaceutical care. *FTC Reports*, medical and pharmacy literature, clinical trial data newsletters, and professional meetings are among the major sources of information for drug and drug delivery systems under development.¹²

Selecting formulary products is less complicated if the acquisition cost of a medicine is the deciding factor. Effective formulary decision making, however, requires a thorough comparison of drug treatment options when differences exist in efficacy, safety, patient acceptance, or quality of life. Literature review is a key step in the decision-making process. Although clinical trial data is the most useful source of information for evaluating new agents, manufacturer information may be helpful as well. Tools such as decision analysis, cost-benefit analysis, and cost-effectiveness analysis may also aid in decision making.

The P&T committee may choose to form a panel of clinical experts to evaluate the potential role of new drugs in disease state management and establish criteria for use. Clinicians' participation in criteria development and the decision-to-use process will foster physician "buy-in" and the continued peer support essential to appropriate drug use. This is a crucial matter for physicians, who by training are very autonomous. Although collegiality and peer prescribing are influential factors on drug use, we argue that the participation of knowledgeable and respected clinical pharmacists working closely with prescribers in the approval and use process and daily aspects of patient care offers an additional powerful inducement for proper drug use.

In addition to soliciting physi-

cian buy-in, healthcare organizations have used other strategies to increase formulary compliance, some of which are summarized in Table 1.¹³ Some of these formulary compliance strategies have the disadvantage of being retrospective in nature while other strategies must be continually reinforced and/or repeated to achieve success. One of the more promising strategies that will be discussed in the technology section is computerized provider order entry in which control and flexibility are given to assist with medication prescribing.

Economic, Clinical, and Humanistic Issues Associated With Formulary Use

While formularies should be developed with drug therapy treatment as the primary focus, economic and humanistic issues clearly influence their development.

Economic Issues. Strategies used for controlling drug cost have included competitive bidding (discount contracts), patient copayments, generic and therapeutic interchange, provider education and incentives, drug use evaluation, restrictions of drug use (to specific providers or services), and clinical pathways.¹⁴⁻¹⁶ Several of these specific strategies (eg, formulary management relating to an effective drug-use evaluation program) were utilized at the University of Iowa Hospital and Clinic, which resulted in improved medication use and an annual savings of \$500,000.¹⁷

Discount and rebate contracts have provided managed care organizations and PBMs with a strong incentive in recent years to use formularies. Discount and rebate contracts create revenues for

Table 1. Formulary Compliance Strategies and Their Targets

Formulary compliance strategy	Physician	Pharmacist	Patient
Financial incentive	✓	✓	
Point of service messaging		✓	
Differential copayment incentive			✓
Academic detailing by pharmacist	✓		
Conversion to formulary program	✓		✓
Nonreimbursement for nonformulary drugs		✓	✓

care providers based on percentages of contract and formulary compliance.

Effective formulary management is made difficult when operating under a flat-line budget, which places a cap on pharmacy expenditures. Although the rate of growth of these expenditures can be controlled, it cannot be capped. Not only do flat-line budgets fail to account for inflationary increases in pharmaceutical costs, but they also critically limit the funding of new drug entities. With today's focus on outpatient management of health conditions that previously required hospitalization, the acuity level of the inpatient population has increased. As a result, more complex and more intravenous drug therapy is required to provide optimal treatment to hospitalized patients. Providing the most appropriate pharmaceutical care may be significantly hindered by budgetary constraints. Flat-line budgets may be employed under the assumption that they will control drug costs by promoting the use of alternative, cost-beneficial agents. However, attempting to manage drug expenditures within the confines of a finite budget may lead to the withholding of more expensive but perhaps more effective treatment for patients.

Optimally, funds saved in other areas of the institution as a result of more appropriate but possibly more expensive drug therapy must be returned, at least in portion, to the pharmacy drug budget. For example, some drug therapy treatments and regimens accelerate the discharge of patients and this decrease in length of stay results in substantial cost savings to the institution. Also, drug regimens may alleviate the need for surgical or other invasive and costly procedures. When hospital stay is reduced and/or drug therapy is utilized in lieu of costly procedures, consideration should be given to shifting or reallocating monetary resources to increasing the drug therapy budget. If this is not done, failure to meet the drug therapy and pharmaceutical care needs of all patients is unlikely.

Particular challenges are posed by integrated healthcare systems where patients are treated on a capitated basis and the acquisition cost of medications is not the only factor in the cost equation. As patients move through various levels of care (ie, acute, home, ambulatory care, etc) the need exists to continually review and document the relationships among drug use, costs, and outcomes in patients.

A final economic consideration is the expectation that 40 individual drugs with combined sales of \$16 billion per year (25% of the industry's US rev-

enue) will go "off patent" by the end of 2002.¹⁸ This expected event will clearly increase competition among generic manufacturers while accelerating the trend toward developing modified pharmaceuticals with extended release, causing manufacturers to seek approval for new indications and shift products from prescription only to nonprescription or over-the-counter (OTC) status. Noteworthy among the drug classes changing from prescription to OTC status are gastric acid-reducers, nonsteroidal anti-inflammatory drugs, and antifungal agents. From 1976 to 1996, more than 63 drugs were approved by the FDA to switch from prescription to OTC status; approximately 70 more are expected to switch over the next 5 years.^{19,20} Since patient use of OTC medications focuses on self-care, preventive care, and wellness, health plans will become increasingly interested in the economic and appropriate role of OTCs in patient care.

Clinical Issues. The formulary committee's prime responsibilities include managing the clinical issues, assuring rational drug therapy, and the provision of safe and effective medications for the patient population. Complex technology assessment issues and the use of biotechnology products make this task increasingly difficult. The number of new products and technologies coming to market and the increased cost of both make it obvious that the drug use process has become more complex. The issue of medication safety is also of prime concern to the public as well as to the healthcare provider.

Humanistic Issues. Until the 1990s, humanistic issues such as patient satisfaction and quality of life were not discussed in any great depth by formulary committees because it was not considered their responsibility. These are now major issues for managed care organizations, which must maintain patient enrollment, and pharmacy benefits managers, which must maintain enrollment of MCOs. They are also issues for the Medicaid program and other institutions as well. As the marketplace becomes more diverse and competitive and consumers become more selective regarding providers and care, it is imperative that the process can accommodate patient needs. As we evaluate new technologies and drugs for the future, economic, clinical efficacy, and humanistic issues must be addressed. For instance, if a patient requests the impotence product Viagra® and the P&T committee denies that request through the formulary process, what impact does this have on patient enrollment and satisfaction? These are very nebulous issues in some cases; however, the science of

dealing with humanistic issues such as quality of life and patient satisfaction are very real.

A tool such as the Economic, Clinical, Humanistic Outcomes (ECHO) Model (Figure) can aid in the formulary process. This model is used to assist healthcare providers in planning, conducting, and evaluating pharmaceutical products and services from a multidimensional perspective in an effort to enhance patient satisfaction, increase quality of life, and reduce healthcare cost.²¹ The model depicts the value of a pharmaceutical product or service as a combination of traditional clinical based outcomes and more contemporary measures of economic efficiency and quality.²²

Specific objectives of the ECHO Model are to:

- Provide a theoretical framework for identifying, collecting and using outcomes data to assess the value of pharmaceutical treatment alternatives
- Propose causal relationships between disease, health-related outcomes, and decisions about medical interventions
- Consider potential trade-offs among economic, clinical, and humanistic variables in optimizing the allocation of healthcare resources
- Identify and rank patient populations for treatment alternatives of interest
- Assess the relative value of the competing alternatives
- Provide a mechanism for stimulating discussions

between healthcare providers, administrators, and researchers²²

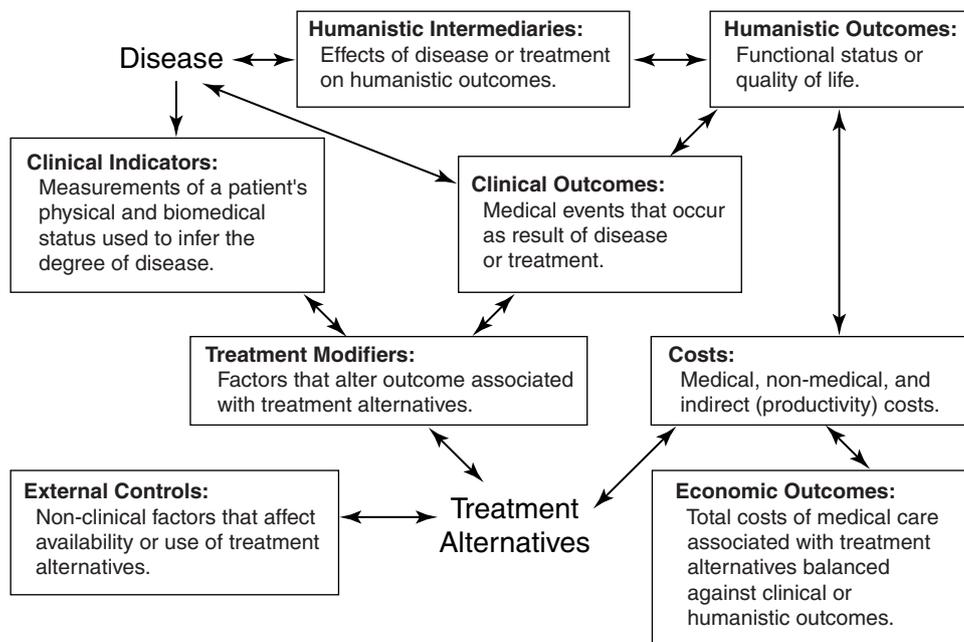
Patients have also become more informed and knowledgeable about their disease state and drug therapy. This can include the patient's participation with practitioners in considering the selection and benefits of a particular drug therapy, which should be weighed against predicted side effects of alternative medications. Additionally, since most medications are self-administered, the patient is the ultimate determinant of medication compliance.

Impact of Drug Development and Technology on the Drug Use Process

New Drugs and Drug Delivery Systems in Development. The utmost responsibility of healthcare professionals is to provide patients with the best pharmaceutical care available. This requires continuous assessment of new and existing pharmaceutical and medical technology in an effort to identify the most appropriate and cost-effective treatment modalities. This process has historically been driven by prescribers and industry representatives, but the current practice of aggressive, direct-to-consumer advertising by manufacturers has shifted the marketing landscape.

A constant flow of new technology is being intro-

Figure.



duced to the healthcare community. Many new pharmaceuticals are associated with unprecedented research, development, and marketing costs. It is not uncommon for a product to cost \$1000-\$3000 per dose (eg, tissue plasminogen activator, abcixamab). In addition to pharmaceuticals, the quality and cost effectiveness of drug delivery systems and administration devices must also be assessed. This is not an easy task since some products are associated with considerable costs and risks but may offer benefit to a small number of patients. Examples of drug delivery systems that often incur additional costs but are generally assumed to improve outcomes by enhancing compliance or reducing adverse events are osmotic pumps, liposomal encapsulation, and transdermal patches.²³ Currently available drug administration devices such as mechanical, gravity-driven, and electro-mechanical pumps are also part of the economic equation that must be considered in the total economic impact.²³ This frequent introduction of high cost drugs and drug delivery systems places greater emphasis on developing cost-effective formularies.¹²

Technology Assessment Related to Drug Use Process. Medical technology assessment is the process by which drugs, procedures, techniques, and equipment are evaluated to form conclusions about their value and make recommendations about their acquisition and utilization.²⁴ Among the tools available for technology assessment are randomized controlled trials, consensus panels, meta-analysis, and outcomes assessment. Assessment is difficult when evidence is lacking or inconsistent or when decision makers disagree on the method of assessment. Cost, potential adverse effects, ethical issues, and the number of patients who may benefit from a particular technology also factor into the decision-making process. After a new technology is deemed valuable and acquired by a healthcare institution, it should be periodically reevaluated for its cost effectiveness and quality.

In a discussion of healthcare technology assessment, Goodman²⁵ describes the 10 steps of such an assessment as follows:

1. Identify assessment topics (ie, does the item incur great costs or increase morbidity and mortality?)
2. Specify the assessment problem (ie, what is the purpose and intended audience for the assessment?)
3. Determine locus of assessment (ie, beware of biases by the person/organization conducting the assessment)

4. Retrieve available evidence (ie, conduct comprehensive literature review)
5. Collect new, primary data (as appropriate)
6. Interpret evidence
7. Synthesize and consolidate evidence
8. Formulate findings and recommendations
9. Disseminate findings and recommendations
10. Monitor impact (ie, what impact has the assessment had?)

These steps correlate reasonably well with aspects of the drug use process including formulary development and implementation, use of the literature, evaluation, and formulation of evidence-based treatment guidelines/algorithms. Additionally, the phases of the technology life cycle (eg, investigation, promotion, acceptance and utilization, decline and obsolescence) parallel closely the addition and use of a new pharmaceutical to a healthcare facility's formulary.²⁶

In addition to the larger issues of technology assessment related to the drug use process, several more immediate uses of technology can help provide care. Computer technology to control and monitor medication use is one of the most common forms of automation for pharmacy service. An increasing number of healthcare facilities have automated pharmacy systems; these have proven to be quite beneficial in both ambulatory and inpatient settings. Automation and the use of robotics in pharmacy service are used in everything from procurement and purchasing, preparation, labeling, and dispensing to medication administration. This automation uses combinations of mechanical, computerized, bar code technology, and robotic devices.

Other increasingly used technologies include hand held computers and bedside terminals with point-of-care information systems. These applications permit direct input of medication orders and charting of administered medications at the point of patient care.

In an effort to take advantage of computer technology, many healthcare facilities now generate on-line formularies in place of paper-bound formularies, which may become outdated by the time they are published. Also, electronic prescribing or healthcare provider order entry to facilitate expeditious ordering of drug therapy, laboratory tests, and radiographic procedures, etc, is becoming more common. In both acute or ambulatory care settings, medication use functions and options common to

computerized provider order entry systems include but are not limited to:

- Formulary recommendations
- Common and predefined medication order sets
- Drug use protocols and treatment guidelines
- Patient drug histories including allergies
- Prescriptions hard copies
- Automatic pharmacy service or network transmission
- Medical records update with performed transactions

Schiff and Rucker²⁷ argue strongly for increased use of computerized prescribing by clinicians. Instead of handwritten prescriptions, they advocate medication ordering be done on a computer interacting with three databases (one containing patient drug history, one of drug information references, and one containing patient-specific information such as weight, drug allergies, etc). Although conceptual, implementation, and policy barriers have prevented the development of such a system so far, developing such a system would foster more rational use of medications by prescribers and patients, point out potential drug interactions, coordinate care among team members, and assist in tracking outcomes.

Rivkin documented the results of a 6-month pilot program of electronic prescribing by 17 primary care physicians in a large health maintenance organization.²⁸ Participants were asked to identify perceived advantages and disadvantages of electronic prescribing technology. Respondents listed assistance with formulary drug selection, identification of potential drug interactions, patient satisfaction, and legible prescriptions among the advantages. Disadvantages included the need for additional computer workstations and behavioral changes necessary to adapt to the new technology.

In a larger program conducted at a single hospital, positive clinical and financial outcomes resulted from the implementation of computerized antimicrobial practice guidelines. In the study by Pestotnik et al,²⁹ antimicrobial drug usage was improved and costs reduced. Specifically, the percentage of patients having surgery who received appropriate preoperative antibiotics increased from 40% to 99.1%. Antibiotic drug costs per patient decreased from \$122.66 to \$51.90 per patient. Additionally, by using this technology, antibiotic associated adverse drug events decreased by 30%.

The Veterans Affairs Health System (VAHS) has utilized healthcare provider order entry for several years. The VAHS's new software, Computerized

Patient Record System (CPRS), which facilitates entry of clinical data at the point of care, is now being implemented. The program blends order-entry capabilities with single screen depiction of relevant patient data such as laboratory values, drug therapy, diet, progress notes, and imaging results, including electrocardiograms and magnetic resonance imaging. This system provides a more organized approach to storing, organizing, and retrieving relevant patient data. CPRS also supports such clinical activities as alerting caregivers about potential drug interactions, providing preventive health reminders, and indicating clinical practice guidelines. Other versions of computerized patient medical records are in existence or being developed.

Methods to Monitor/Contain the Drug Use Process

In addition to the technology-based oversights discussed above, several other means of drug use monitoring exist.

Drug Utilization Evaluations. Drug utilization evaluations (DUEs) are tools to measure formulary compliance, monitor high risk-high cost therapies, identify opportunities to improve the drug use process, and ultimately enhance clinical outcomes. Properly performed DUEs ensure appropriate and cost-effective drug use and optimize treatment outcomes. The initial objective of both prospective and retrospective DUEs is to compare current drug usage with predetermined audit criteria. Once discrepancies are identified, initiating a plan of action to improve pharmacotherapy and following up on the results of this action become the goals. The JCAHO emphasizes the need to focus on patient outcomes and disease management when performing quality assurance activities,³⁰ and considers the improvement of medication use a specific performance improvement requirement. Traditional DUEs have focused on improving the use of single drug entities. Healthcare facilities should ensure that any action taken in response to initial DUE findings results in improved treatment outcomes.

Drug Class Review. Typically, a large percentage of the drug therapy budget for healthcare facilities is spent on a relatively small number of pharmaceutical products.³¹ By studying utilization trends and expenditures, critical drug classes can be identified. The P&T committee may appoint subcommittees to target specific drug categories, such as antimicrobials. After examining current drug use, the subcommittee recommends changes and establishes drug use criteria. Staff education should be under-

taken prior to criteria implementation to optimize prescriber compliance. Provision of pocket cards with prescribing guidelines, internal newsletters, or strategically placed posters with key use information are convenient methods of reminding staff of the current criteria. Once drug use criteria are in place, drug utilization reviews can be performed to evaluate criteria compliance.

Since many large drug classes often have significant therapeutic redundancy within the class, a review to select a class representative makes sense and can offer savings to the pharmaceutical budget. The VAHS recently implemented such an approach in developing a national formulary for its large number of institutions. Contractual arrangements with companies having a high use product within a class have provided major economic savings. In essence, a single product from the class is chosen through competitive bidding to be the primary agent for use. Selection frequently results in a significant price reduction. To achieve maximal economic benefit to the system, institutions often mandate the use of the final product selected. If deemed necessary, an alternative agent may also be selected. In a patient-specific situation where a nonformulary drug is deemed more appropriate, the prescriber may request purchase and use of an unavailable drug. This request is reviewed and the product obtained if approved.

Additionally, some available formulary agents may also have restricted use status. The use of such products typically requires "expert" consultation for initiation. Once initiated by the consultant or consultant service, the authorized prescriber may continue use of the product. Pharmacists are charged with orchestrating the transition to the new product(s), including patient and staff education, which is implemented in advance of the change. Clinical guidelines are then developed consistent with and in support of the use of the class representative(s). This review and selection process has been successfully completed within the VA system of hospitals for classes including proton pump inhibitors, HMG-CoA reductase inhibitors, angiotensin converting enzyme inhibitors, luteinizing hormone-releasing hormone analogues, H₂ antagonists, and β -blockers. Other drug classes currently under review include selective serotonin reuptake inhibitors, calcium antagonists, and oral quinolones. Most physicians are receptive to this approach even though it may, to an extent, remove the autonomy of the prescriber. In the experience of the authors, a selection process

based on science, hard pharmacoeconomic data, and evidence-based literature, accompanied by sound usage guidelines and a fair nonformulary approval process, minimizes opposition to class review and switching.

Treatment Algorithms. Evidence-based practice guidelines and treatment algorithms establish parameters for appropriate drug use and cost-effective disease management. Disease management should direct resources toward high yield diseases by focusing on top diagnostic related groupings.³² As with the establishment of drug use criteria, a review of the literature, staff participation (ie, expert panels) in guideline development, and education should be undertaken prior to guideline or treatment algorithm implementation. Once guidelines are in effect, prescriber compliance should be reviewed and further education should be provided if necessary. Effective guideline development should be based on clinical trial data and local expertise consensus. Again, early prescriber buy-in is critical to successful implementation.

Consumer Impact on the Drug Use Process

In this age of consumerism, healthcare and particularly medication therapy receive a great deal of focus. There has been a dramatic increase in direct-to-consumer marketing of medications (OTC, and in recent years, prescription drugs) via television, printed advertisements, or direct mailings to patients with specific chronic diseases such as arthritis, hypertension, or diabetes. Often times, prompted by the encouragement to "talk to your physician or pharmacist about..." patients will contact healthcare professionals, HMOs, or PBMs regarding availability of new pharmaceutical products.

Increasing amounts of information continues to be available regarding medications and their use via the Internet. This information is easily accessible to health practitioners as well as consumers. With this availability of information may come potentially harmful effects to both consumers and health professionals if it is not used appropriately or if it is erroneous. There clearly need to be methods to formally evaluate health information available on the Internet.³³

Telemedicine. Telemedicine uses electronic information and communication technologies to support healthcare over long distances. The shift of telephone care to managed patient care and specifically drug therapy is growing at a fast pace. Telephone care can reduce hospital and/or clinic visits, perhaps

thereby increasing patient satisfaction. Technology related to medication use is rapidly moving from triage phone calls to physician offices for refill authorizations to direct telephone linkups to pharmacists. Patient-friendly systems have been developed by combining telephone, voice mail, and custom application software to create automated prescription refill systems and opportunities for pharmacist consultation to address patient inquiries concerning medication use. With these systems, patients enjoy the convenience of being able to request refills 24 hours per day as well as having a pharmacist available to consult. These systems also have the benefit of generating numerous statistical reports to help monitor medication use, numbers of calls received, numbers of pharmacist consultations, and a breakdown of calls and consultations on a per-day, per-hour basis.

Conclusion

Healthcare facilities and systems, including such practitioners as physicians and pharmacists, will be challenged by the rapid evolution of technology and the drug use process. Also, an exciting and related development in technology is the relationship between genes and drugs in the growing field of pharmacogenetics. Categorizing people according to their genetic makeup or genotype and matching with the most effective medications has both great potential and challenge.³⁴ Additionally, economic, clinical, and humanistic issues will continue to be considerations with medication use. However, we can expect to see medication use committees shift their focus towards assisting with medication selection for disease state management treatment algorithms and guidelines. In this regard, it has been suggested that use of such therapeutic guidelines may relegate formularies to an important yet secondary role.³⁵ The current generation of disease state management programs (including frequently used medication use guidelines) have been developed in-house by healthcare facilities. It is expected over the next several years, however, that vendors will develop and market the majority of these programs.

Experimentations with the basic formulary concept, such as "outcomes-based" formularies that look at pharmacoeconomics and quality of life issues, will continue. Clearly, other functions for formularies will be reviewed, such as tiered formularies. This option gives the patient control over the choice of brand-name and generic pharmaceuticals

and allows the patient to obtain brand-name pharmaceuticals without raising premium costs for other patients. More experience with tiered formularies is needed. This method shares financial risk with patients and may provide advantages such as being more patient friendly, eliminating time spent on authorization overrides, and providing a method for driving market share of medication use. While the utilization of medication formularies appears to be changing, their basic structures and intent—to help assure appropriate, cost-effective medication for patient use—remain intact.

Threaded throughout all this is the information and data such technologies will generate. How information on patient medication use is obtained, stored, analyzed, and distributed is changing daily. It affects how practitioners provide patient care and how patients are treated with drug therapy or self-medicate. Other questions regarding this data include:

- Who owns it?
- Who can use it?
- Who has access to it?
- Is it valid?
- Is it current?
- What can be derived from it?
- How can it be used to improve the drug use process?
- How can the data be used to better assure appropriate drug therapy outcomes in patients?
- What about commercial interests, specifically, medication use data for pharmaceutical manufacturers and pharmacy benefit management firms?

Determining answers for these questions will be difficult for healthcare facilities and practitioners. The appropriate, economical use of drug therapy will continue to challenge in the future even with the best technology assessment.

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CONTINUING PHARMACY EDUCATION

This course has been approved for a total of two (2) contact hours of continuing education credit (0.2 CEUs) by the University of Tennessee College of Pharmacy. The University of Tennessee College of Pharmacy is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. ACPE Program Number: 0640-000-99-202-H-04. This course expires February 28, 2002.

Instructions

After reading the article "Technology Assessment and the Drug Use Process," select the best answer to each of the following questions.

1. A major factor assuring growth in the healthcare industry over the next several decades is

- a) the increase in birth rate
- b) the aging baby boomers who will demand more healthcare
- c) the current elderly population
- d) the changes in demographics of immigrants

2. What 2 factors are key to driving the continual change in the healthcare environment?

- a) technological advances and patient compliance
- b) technological advances and cost of pharmaceuticals
- c) technological advances and economic factors
- d) technological advances and the baby boomers

3. The number of new drugs approved by the Food and Drug Administration could easily reach _____ in the 1990s.

- a) 200
- b) 400
- c) 600
- d) 800

4. All of the following are functions of the formulary process with the exception of:

- a) assist with clinical utilization of drugs
- b) control cost in the drug use process
- c) approve medications for use within the health-care institution
- d) credential providers of care in the healthcare institution

5. Which of the following is *not* a function of the formulary committee common to institutions, managed care organizations (MCOs), pharmacy benefit management groups (PBMs), and state Medicaid programs?

- a) acting on recommendations for medication formulary additions/deletions
- b) monitoring of adverse drug reactions
- c) setting pricing structures for medications in the institution
- d) preventing and monitoring of medication errors

6. According to Joint Commission on the Accreditation of Healthcare Organization (JCAHO) guidelines, that group is concerned that both health professionals and patients handling complex medications and dosage forms are educated on safe and effective use of medications.

- a) true
- b) false

(CPE QUESTIONS CONTINUED ON FOLLOWING PAGE)

Technology Assessment and the Drug Use Process

(PLEASE PRINT CLEARLY)

Name _____

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State/ZIP _____

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Please circle your answers:

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|------------|-------------|-------------|-------------|
| 1. a b c d | 6. a b | 11. a b c d | 16. a b c d |
| 2. a b c d | 7. a b c d | 12. a b c d | 17. a b c d |
| 3. a b c d | 8. a b c d | 13. a b c d | 18. a b c d |
| 4. a b c d | 9. a b c d | 14. a b c d | 19. a b c d |
| 5. a b c d | 10. a b c d | 15. a b c d | 20. a b c d |

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...CPE QUIZ ...

(CPE Questions continued from previous page)

7. The JCAHO no longer requires a pharmacy and therapeutics committee per se; the focus is now on

- a) the credentialing of healthcare providers
- b) performance improvement process of medication use
- c) the cost of healthcare
- d) the storage, cost, distribution, and use of medications

8. New committees with such names as "Medication Use Committee" are more focused on _____ than previous committees.

- a) process and outcomes
- b) cost and medication errors
- c) credentialing and cost of medications
- d) medication errors and outcomes research

9. All of the following strategies have been used to control drug cost except

- a) competitive bidding
- b) patient copayments
- c) generic and therapeutic interchange
- d) open formularies

10. Another economic factor medication use committees will have to seriously consider in the near future is

- a) the impact of switching drugs from prescription to over-the-counter (OTC) status on patient care and the role of OTC products on the health plan's patients
- b) the increased medication error rate
- c) the increasing cost of pharmaceuticals
- d) the use of herbal remedies

11. A major incentive for MCOs and PBMs to use formularies is to take advantage of

- a) decreased medication error rates
- b) cost controls in institutions
- c) improved patient care
- d) discount and rebate contracts

12. Medication use committees must now consider in their deliberations all of the following with the exception of

- a) economic outcomes
- b) clinical outcomes
- c) humanistic outcomes
- d) research outcomes

13. The drug use process will become more complex due to

- a) the number of new drugs coming to the market
- b) the advances in technology
- c) the cost of the new drugs
- d) the number of new drugs and technologies coming to market and the cost of both

14. Which of the following are considered humanistic issues?

- a) patient satisfaction and provider credentialing
- b) patient satisfaction and quality of life
- c) quality of life and provider credentialing
- d) patient satisfaction, quality of life, and provider credentialing

(CPE QUESTIONS CONTINUED ON FOLLOWING PAGE)

CPE PROGRAM EVALUATION

The University of Tennessee College of Pharmacy would like to have your opinion. Please fill out the questionnaire below, tear off along the dotted line, and mail along with your CPE test form. We thank you for your evaluation, which is most helpful.

Please circle your answers:

My pharmacy practice setting is:	Independent	Chain	Hospital	Consultant
The objectives of the lesson were achieved:	Yes	No		
The quality of presentation of the material was:	Excellent	Good	Fair	Poor
The information presented will be useful to me in my practice.	Strongly agree	Mildly agree	Mildly disagree	Strongly disagree

How long did it take you to read the material and respond to the Continuing Education questions: (Please specify the number of hours.)

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(CPE Questions continued from previous page)

15. Humanistic issues have become more important to healthcare plans due to patients

- a) becoming more selective and the marketplace more diverse
- b) becoming more knowledgeable
- c) becoming more knowledgeable and the marketplace more diverse
- d) becoming less knowledgeable

16. The ultimate determinant of patient compliance to medication regimens is

- a) the prescriber
- b) other healthcare providers
- c) the effectiveness of the medication
- d) the patient

17. Historically, the drug use process has been driven by

- a) patients and pharmaceutical industry
- b) dispensers and prescribers
- c) prescribers and patients
- d) prescribers and industry

18. Which of the following technological factors do not impact the formulary process?

- a) drug delivery systems
- b) drug administrative devices such as mechanical, gravity-driven, and electromechanical pumps
- c) technician training programs
- d) biotechnology drugs

19. Automation and the use of robotics in pharmacy service includes all of the following with the exception of

- a) procurement/purchasing
- b) preparation, labeling, and dispensing
- c) procurement, preparation, labeling, and dispensing
- d) medication administration

20. Which of the following is considered the major reason for the increase in consumer impact on the drug use/formulary process?

- a) direct-to-consumer advertising
- b) the baby boomers
- c) primary education about health issues in the US high schools
- d) the Internet