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This month’s cover features a work by Jasper Johns. Johns is representative of a movement that assimilated the shocking, new concepts of the mid-century art and advanced them even further, while incorporating the images and sensibility of mid-century America. Johns’ work “hit the art world like a meteor” when formally introduced in 1958, and his influence persists to the current day.

**THE ORIGINS OF POP**

The achievements of the post-World War II experimental art movements are often characterized as a consolidation and expansion of ideas formulated by pre-war pioneers. Many of the principles of light, motion, figural fantasy, and utilization of the found object evident in later modern painting were laid down in the 1920s and 1930s. The young artists of the post-war world were responsible for enlarging the vocabulary, rethinking the implications, and applying new contexts to established revolutionary concepts.

In the United States, as in Europe, abstract expressionism had become a universal artistic language by the end of WWII. A descendent of cubism and organic surrealism and in the heritage of Kandinsky, Miro, Duchamp, and Picasso, abstract expressionism surfaced in the United States after 1942. As a loosely defined phenomenon, it developed into the most powerful original movement in the history of American art. It was not so much a style as an idea centered on the spontaneous assertion of the individual; its manifestations dealt in monotone expressionistic expanses or furious painterly gestures of abstraction. It was also an overwhelming reversal of the regional, social-realist styles of painting dominant in America up until WWII.

The transition from abstract expressionism proceeded almost from its founding. The early 1950s expressionistic styles of DeKooning, Pollock, Motherwell, and Kline quickly moved away from pure abstraction. One emerging trend was the return to figuration and naturalistic fantasy. The re-introduction of subject matter figures in this new style was notable for its macabre effect, traceable to the dadaists, but even more experimental and explicitly a reaction to abstraction. By the mid-1950s, techniques emerged employing layered, fortified pigments or found objects as artists embraced figure, solid relief, and representation.

Though founded in England, pop art had its greatest impact in the United States in the early 1960s. Pop art concerned itself with the visible, tangible world—a world of objects and everyday events. It was a powerful reaction to all forms of abstraction despite its dependency on the conceptual accomplishments of abstract art. Essential to pop art’s emergence was the rejection of composition as either a representation or abstraction of nature. Rather, the painting was conceived as an entity of pure creation in itself. Pop art in America, particularly, portrayed contemporary culture and representational commercial images in an aggressive but disaffected and unromantic way that speaks to the pervasiveness of the cultural environment. This “new realism” strove to present subject matter without expressionistic or social-realist overtones. Pop art looks at the world in which we live and examines objects and images that surround us with an intensity and penetration that makes us conscious of them for the first time.

**POP REALITIES**

Combining the surreal concepts of the early twentieth century, the experimental attitude of the abstract expressionists, the acute figurative tradition of Renaissance Europe, and the modern culture of the New World, the pop artists emerged with a unique message. Jasper Johns, raised in South Carolina, conceived his vision of the style in the late 1940s at Black Mountain College, North Carolina, a center of avant-garde influence. Friction of his style was realized in the contemporary art world of New York City, the foundation of consumer culture. His paintings of familiar objects, most often in relief, are rendered with such precision and neutrality as to become objects in themselves rather than reproductions. The absolute objectivity of his composition often includes intrusive images of mysterious elements that establish the existence of the piece as a work with its own reality, despite the familiarity of its elements.

**Target with Four Faces** (29 3/4 in. x 26 in.) crosses the boundary of enlightening subjects within a refreshing new context that revives our way of seeing ourselves. Johns employed the difficult, seldom-used technique of encaustic, in which pigment is mixed with hot wax, then applied to newspaper and layered on canvas. The target is thus constructed, both visually familiar and structurally unfamiliar. Above the target, the piece incorporates four tinted plaster casts of human heads, each in its own box and blindfolded by the frame of the enclosure. The faces were cast serially from the same model, then rearranged in different poses of relaxation. The concentric target is an object visually precise and psychologically dangerous. It is a universal image that the mind already knows, and it therefore provides a platform on which the artist can explore other levels of meaning. In Target, the faces convey a sense of urgency; they are vulnerable and in jeopardy of isolation. Johns’ urgency is not lost in our times of rediscovery and resolution.


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Journal of Managed Care Pharmacy (ISSN 1083-4087) is published bimonthly by the Academy of Managed Care Pharmacy, 1650 King Street, Suite 402, Alexandria, VA 22314; 703/683-8416; 800/TAP-AMCP; 703/683-8417 (telefacsimile). Annual membership dues of AMCP are $125 for Active Members, $225 for Associate Members, $20 of which is allocated to a subscription to Journal of Managed Care Pharmacy. Periodicals Postage pending at Alexandria, VA, and additional mailing offices.

Postmaster: Send address changes to Journal of Managed Care Pharmacy, 1650 King Street, Suite 402, Alexandria, VA 22314.

Correspondence related to editorial content should be mailed to the Managing Editor at Mitchell Petersen, Inc., 1707 Osage Street, #400, Alexandria, VA 22302-2611. Annual Subscription Rates: USA, individuals/institutions-$60; Canada-$70; other countries-$80. The cost of single copies is $10. Requests to replace missing issues free of charge are honored only up to six months after date of issue. Send requests to AMCP headquarters.

Advertising for Journal of Managed Care Pharmacy is accepted in accordance with the advertising policy of the Academy of Managed Care Pharmacy. For additional information, contact the Advertising Representative at the address above shown.

Instructions for authors are published in the first issue for each volume. Contact the Editor for more information.

All articles published represent the opinions of the authors and do not reflect the official policy of the Academy of Managed Care Pharmacy or the authors' institutions unless so specified.

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Tinkering with the structural elements of drug benefits programs is not uncommon. However, when changes are made and implemented based on research that is conducted in isolation of its impact on other components of the system, there is a real potential for problems. The result could be the adoption of policies that do not have the desired effect of maintaining quality of care and achieving efficiency in the use of resources. Conducting studies without considering externalities associated with the drug benefits program, such as patient outcomes and impact on other services, makes it nearly impossible to determine if a policy is either fiscally or financially sound. Accordingly, the study results do not allow us to adequately judge the program's value, only other than to determine the short-term net fiscal impact on a line item budget.

Short-term savings or cost avoidance can be reversed by externalities associated with the selection of a specific drug therapy mandated by the prior authorization program. As treatments become more potent, both in terms of safety and efficacy, and the costs per unmeasured outcome increase, the potential impact of externalities increases. The rate of increase of both these variables has been accelerating and has evolved to the point where it is inappropriate to assume equal medical outcomes and cost effectiveness. Conducting analyses with limited information may have an intuitive appeal, but the discussion of these limitations should be explicit.

Neither the allure of basing decisions on less comprehensive investigations nor the undeniable difficulty of detecting and measuring the impact of unintended therapeutic outcomes obviates the need to address these issues in a study's methodology or, at a minimum, in the discussion of results.

Prior authorization is one area in which inadequate or incomplete research could cause serious problems. The rationale for prior authorization programs is that standard medical therapies generally are applicable to all patients, and certain drugs should be given only to patients who cannot take standard therapy because of extenuating circumstances, or who have experienced treatment failures with standard therapy. Prior authorization programs assume that quality of care will be assured across treatment alternatives. In many instances, the programs focus not on quality but on drug costs.

In some prior authorization programs, it is difficult to determine whether cost, utilization, or both are the driving force behind the construction of the drug list. For example, patients' access to an entire class of drugs or to a specific drug may be restricted by prior authorization programs. Minor tranquilizers and antidepressants can be designated as drugs on the prior authorization list to reduce costs or to encourage their appropriate use. The program also could restrict their use because of the prevailing negative attitudes about psychological disorders and the need to employ drug therapy in their resolution.

While the evaluation of these types of policy changes and a discussion of their implications appear straightforward, policy research is fraught with difficulties, and causality is difficult to establish. Also, not addressing issues such as medical outcomes and the effects on other resource utilization patterns fails to measure externalities associated with policy changes. Unmeasured externalities endanger the public's health, and their costs can be substantial.

Externalities are benefits and consequences that occur beyond the direct, finite outcome of a particular therapeutic intervention. For instance, it has been shown that constraints in expenditures for prescription drugs has been associated with increases in expenditures for long-term care. In the case of evaluative research comparing alternative drug therapies, it is known that differences in clinical effectiveness can increase resource utilization and the total costs of managing an illness. Even in those cases where therapeutic outcomes are essentially the same, the costs of managing side effects can offset lower acquisition costs. Only where outcomes are identical for all relevant alternatives would externalities be equivalent.

Using inadequate, biased, or isolated studies to tinker with a drug benefits program is unacceptable. Those involved with developing and reviewing drug benefits programs must be aware of the pitfalls of such a practice. As managed care pharmacists, we need to ensure that our studies meet the highest standards of objectivity and ethics. Only by working together can we keep poor studies or good studies applied improperly from making their way into our policies and programs.

Robert Freeman, Ph.D.
Looking Back, Glancing Ahead: State and Federal Legislative Fronts

Last year, Congress debated controversial health care legislation and looked at several laws affecting pharmacy and other aspects of patient care. However, all of this debate and study resulted primarily in unresolved issues that will continue to generate arguments and action during 1997.

Managed care pharmacy and other health care professionals will be keeping a careful eye on the 105th Congress as members take a renewed look at issues such as entitlement reform. There was lots of talk and some action on the restructuring of Medicaid and Medicare and other issues in the last Congress, but little made it into the books. There will be more talk in this session, but will there be more action?

1996: LOTS OF TALK, LESS ACTION

During 1996, there was lots of activity. But campaigning and other election year activities seemed to prevent any real action from taking place. One of the few instances of decisive action was a plan for restructuring Medicaid as a block grant program, which passed both houses of Congress last year but was vetoed by President Clinton. The

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veto was welcomed by many, including pharmacist organizations, who were concerned that under such a program, federal standards for pharmacy reimbursement would be eliminated. There also was concern that tight funds would cause states to limit or eliminate prescription drug benefits.

At the same time, Congress hotly debated a variety of cost-cutting proposals for Medicare but failed to pass any. Generally speaking, these proposals would have permitted delivery of Medicare benefits by private managed care organizations using capitated payments. Organizations representing pharmacists were concerned about potential reimbursement levels under these proposals, and a possible focus on drug distribution rather than pharmaceutical care services.

OTHER ISSUES: DEBATE BUT NO ACTION

There was substantial bipartisan support for proposals to reform the mission, structure, and operations of the U.S. Food and Drug Administration (FDA). Major FDA reform legislation was introduced and continually amended throughout the 104th Congress. The original focus of the FDA reform bill was an effort to streamline the approval process for new medications. However, additional issues were attached to the bill throughout the session, including a provision allowing manufacturers to offer providers information about off-label uses of medications under certain conditions. Another provision specifically preserved the right of pharmacists to retain compounding privileges within pharmacy walls. It became clear during the last two weeks before Congress adjourned that the final compromise proposal on FDA reform would not pass.

Another issue before the 104th Congress was the need for confidentiality and privacy of medical records. The Medical Records Confidentiality Act, introduced by Sen. Bennett (R-UT) gave patients authority to inspect health information about themselves, required health providers to protect the confidentiality of medical records, and established federal health information privacy protection standards. Similar bills were introduced in the House. However, the legislation did not progress in either place.

Despite the stall, managed care pharmacists should watch this issue carefully in the coming months. Such legislation potentially could be used to limit managed care providers’ access to electronically-transmitted prescription information. In June, AMCP released a position paper that said, “The use of electronic prescriptions benefits patients, prescribers and pharmacists. It’s the patient, however, who benefits most by being assured of an error-free prescription for which payment already has been authorized under a prescription benefit plan...Electronic data is consistent, legible, accessible, and easily stored and analyzed. It decreases prescribing errors caused by illegible handwriting, misspelling, and the use of inappropriate abbreviations...Electronic prescriptions also help in the area of formulary administration, which managed care organizations use for improving patient outcomes and decreasing patient drug costs.”

While no specific action was taken on any patient confidentiality bills, the issue was addressed indirectly in the Health Insurance Portability and Accountability Act (informally known as the Kennedy-Kassebaum Bill), which was enacted in August. It provided for the development of standards for privacy protection for health information, including regulations to assure the confidentiality and integrity of medical records.

The Safe Medications for the Elderly Act was introduced by Rep. Pallone (D-NJ) in 1996. This legislation is expected to receive some attention from the 105th Congress. It would reimburse pharmacists for providing specified pharmaceutical care services, or "cognitive services," to beneficiaries under Medicare Part B. Covered services include a consultation with a patient that achieves improved drug regimen compliance; a consultation with a physician that results in initiation or discontinuation of drug therapy or change in drug regimen or dosage; and administration of influenza, pneumococcal, and hepatitis B vaccines. Improved compliance must be proven and documented.

MEDGUIDE: TO CHANGE OR NOT TO CHANGE?

In August 1995, the FDA proposed a rule, known as MedGuide, mandating the development of standardized FDA-approved leaflets to be given to patients whenever they received new prescription drugs. Essentially every pharmacy organization and the pharmaceutical industry expressed concern that focusing too much effort on these could take attention away from more effective methods of patient education. AMCP issued a position statement saying, “The content of printed drug information is currently determined by those pharmacists who purchase and distribute prescription drugs. The detail of the information supplied is tailored to the needs of the pharmacy’s patient population and community practice. If the federal government determined the content of a patient drug information insert, it would interfere with the professional judgment of the pharmacist in giving information to patients with whom he or she is familiar...[MedGuide] would displace the existing system which has not been determined to be inadequate.”

As a result of concerns expressed about MedGuide, compromise legisla-

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tion was enacted in August 1996. This delayed the proposed FDA MedGuide regulations and required FDA to consider private sector initiatives for alternative written and oral communications. The stated goal of the compromise language is to ensure that 75% of people who receive new prescriptions will receive written information by the year 2000, and 95% by 2006.

In response to the legislation, the Department of Health and Human Services (HHS) asked an outside party to convene a special steering committee comprised of consumers and representatives from national pharmacy organizations, medical groups, voluntary health care organizations, patient-information database companies, and the pharmaceutical industry to draft a private-sector alternative to MedGuide aimed at giving more useful prescription information to consumers.

The 34-member committee spent weeks working on a compromise plan, which was submitted to HHS Secretary Donna Shalala in December. In January, she announced acceptance of the plan, meaning the government will not intervene for now in private-sector efforts to give consumers more useful prescription information. Pharmacy organizations and others are expected to take new initiatives in this area. Meanwhile, FDA will continue to do surveys to measure how frequently consumers report getting useful information, and launch new surveys to gauge the quality of the information being provided.

STATES CONSIDER HEALTH CARE ISSUES

In addition to federal legislation, increasing activity at the state level has the potential to dramatically reshape the health care environment. For example, during 1996, 15 states considered bills on drug pricing that would require pharmaceutical manufacturers to offer the same terms to all nonretail buyers. Legislation to this effect passed in Maine in 1996. As of mid-February 1997, Mississippi had introduced a bill requiring drug manufacturers to offer the same discounts to all classes of purchasers (HB1275). Observers plan to watch the following states for possible developments on this front: Pennsylvania, Connecticut, North Carolina, South Carolina, Kentucky, Louisiana, Ohio, Maryland, Minnesota, Montana, New Mexico, and Oregon.

Many states also have considered "any willing provider" legislation that requires health plans to accept any provider willing to meet the standard contracting terms and conditions of the health care network. Wisconsin passed "any willing pharmacy" legislation in 1989. At present, 24 states have enacted some form of this legislation, with 11 states passing laws that only apply to pharmacy.

Since federal Medicaid reform has stalled, many states have applied for waivers from the Health Care Financing Administration (HCFA) so they can implement their own Medicaid managed care systems. At present, 10 states have received and implemented Section 1115 Medicaid waivers (which permit five-year demonstration projects), six have received approval and are awaiting implementation, more than 12 have applications pending for the waivers, and several more are now drafting their applications. Key issues are whether pharmacy services will be covered through managed care or carved out and not covered under the capitated payments system.

Elsewhere, in Oregon voters last year considered a ballot initiative that would have banned capitated payments for health care providers. The measure failed at the ballot box. And eight states considered some form of payment to pharmacists for cognitive services, with legislation passing in six states. New Jersey, Oklahoma, and West Virginia passed laws requiring insurers to reimburse registered pharmacists for providing diabetes self-management services. Meanwhile, Mississippi passed a law authorizing Medicaid reimbursement for additional pharmacist services including monitoring the initiation of drug therapy, changes in the form or dosage of outpatient medications, and administration of vaccines.

In addition, the National Association of Boards of Pharmacy (NABP) approved model rules on electronic transmission of prescriptions in Spring 1996, that prohibit access by pharmacy benefit managers during transmission of any prescription from prescriber to provider. These model rules probably will encourage individual states and state pharmacy boards to enact this restrictive legislation.

State executive agencies, as well as state legislatures, are considering measures that could substantially affect pharmacists and other health care professionals. For example, the Texas Department of Insurance and the California Department of Corporations are both considering action to limit the use of closed formularies.

NEW CONGRESS TO REFORM MEDICARE AND REVISIT CONTESTED ISSUES

While it is impossible to predict the exact course of the 105th Congress, it is clear that certain major issues will be considered early in the legislative process. Medicare reform is certain to head the 1997 legislative agenda, since under current projections the Part A Trust Fund will become insolvent by the year 2001. The debate over Medicare is likely to include long-term structural issues as well as short-term cost-cutting, including substantial cuts in Medicare payments to HMOs, cuts that would probably force plans to cut back their offers of prescription benefits to seniors. Medicaid reform will be on the table again. And FDA reform, since it came so close to passage last year, will likely be refought early in the 105th Congress.

Another issue with significant poten-
FEATURE: Looking Back, Glancing Ahead: State and Federal Legislative Fronts

tial impact on all health care providers is the continuing debate over privacy and confidentiality of medical records. One expected proposal will reframe confidentiality legislation to allow health professionals continued access to the patient medical information they need, and also allow them to implement appropriate safeguards to preserve confidentiality of records.

In addition to these broad issues, which have implications for the entire field of health care, we also can expect continuing debate on more focused issues of special concern to managed care pharmacists, including legislation to reimburse pharmacists for providing cognitive pharmaceutical care services to Medicare patients.

On the state front, formularies are likely to receive some attention, especially after the March 1996 publication of the controversial Susan Horn study. The study, which found a correlation among restrictive formularies, higher health care costs, and greater use of medical services, has sparked a debate over closed formularies. But although the study has come under criticism from many sources, states are likely to debate the formulary issue in a variety of forums. As of mid-February 1997, Georgia, Ohio, and Tennessee had introduced managed care consumer protection bills that would undermine formularies by requiring plans to cover all FDA-approved drugs. In Virginia, the legislature this year is considering a bill that would ban therapeutic substitution where any financial incentive is involved.

Because of increasing activity on the state level on a wide range of health care issues, many professional associations are expanding their level of staff and member volunteer commitment to monitor actions of state legislatures and agencies. These efforts promise to keep everyone involved in health care, including managed care pharmacy, busy in the coming months.

Key Contacts in the 105th Congress

- In both houses of Congress, key committees play a major role in drafting legislation related to health care and pharmaceutical issues. In the House of Representatives, these committees include the Ways and Means Committee, which deals with Medicare, health plans, and health insurance issues; and the Commerce Committee, which also deals with health insurance, Medicare, and public health agencies such as the Food and Drug Administration. On occasion, the House Appropriations Committee also plays an important role because it is responsible for funding the FDA, the National Institutes of Health (NIH), and other discretionary health programs.

- In the Senate, the Finance Committee, which is one of the most powerful committees in Congress, has broad responsibility for Medicare, Medicaid, and health-related tax issues. The Senate Labor and Human Resources Committee has jurisdiction over public health service programs, FDA, and NIH.

- The 105th Congress convened January 7. While some key committees dealing with pharmaceutical issues still have the same chair, others will have new leaders. As we go to press, the expected roster is:

- Senate Finance Committee

  Chair: Senator William V. Roth, Jr. (R-DE)
  Subcommittee on Health: Chaired by Sen. Phil Gramm (R-TX)
  Last session this committee had a Medicare, Long-Term Care, and Health Insurance Subcommittee, which was chaired by Sen. Dole (R-KS), who has retired from the Senate. Sen. Phil Gramm (R-TX) is the likely chair for this session.

- Senate Labor and Human Resources Committee

  Chair: Sen. Jim Jeffords (R-VT)
  Subcommittee on Aging: Chaired by Sen. Judd Gregg (R-NH)

- Senate Appropriations Committee

  Chair: Sen. Ted Stevens (R-AK)
  Subcommittee on Labor, Health and Human Services And Education: Chaired by Sen. Arlen Specter (R-PA)

- House Ways and Means Committee

  Chair: Rep. Bill Archer (R-TX)
  Subcommittee on Health: Chaired by Rep. Bill Thomas (R-CA)

- House Commerce Committee

  Chair: Rep. Thomas J. Bilicki, Jr. (R-IL)
  Subcommittee on Health and Environment: Chaired by Rep. Michael Barsky (R-FL)
Managed Care Pharmacy: Leading Pharmaceutical Care Integration Forward

Before pharmacists can implement pharmaceutical care, they must re-define their role in health care and demonstrate that they can improve outcomes cost-effectively.

The enormous power of the trillion-dollar health care market has dramatically modified organizational, financial, and legal structures in recent years. These changes are evidenced most notably in emerging integrated health care systems that combine primary, specialty, and hospital services. Within the next decade, integrated systems will deliver care to 80%-90% of the insured American population.1

According to a 1995 report issued by the Pew Health Professions Commission, the “new world” of health care will present difficult realities for many health professionals and great opportunities for others.1 The commission has predicted, for example, a surplus of 40,000 pharmacists as the dispensing function for drugs becomes further automated and centralized.

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The commission intended to help health professionals survive this period of transformation and thrive in the emerging health care culture. In addition to offering recommendations for all health professionals, the commission identified such harsh realities as these:

- Independent community pharmacies have declined sharply in number (from 32,079 in 1990 to 23,067 in 1995), as have total retail outlets (from 58,756 to 52,345).
- Insurers, health systems, and pharmacy benefits management (PBM) companies are consolidating, both to achieve integration and to maximize their purchasing power.
- Hospitals have from 25% to 45% excess capacity because admissions, average length of stay, and billings are decreasing, while costs are increasing.

This report was a reality check for everyone and leaders must now articulate the new reality. Because there is little unity in the pharmacy profession, progress is going to be difficult and frustrating. Community pharmacy may already be part of integrated health care, and home health care may be part of the integrated health care continuum. All of this vernacular is beginning to change dramatically, yet the various disciplines of pharmacy continue to act like singular entities.

To make progress in the current health care environment, all segments and disciplines of pharmacy must contribute. This is consistent with two significant market forces: continence and the continuum of care. Continuance means not forcing patients to have their care interrupted by having to move to different models (i.e., HMO, PPO, IPA). Continuum of care refers to a spectrum from acute to chronic care. A related concept, continuity of care, implies that all elements should work together. Specifically, this means that community, hospital, home care, long-term care, and managed care pharmacy need to be communicating and collaborating with each other.

Because health care delivery is moving toward a more integrated approach, such an approach is needed in pharmacy as well. The challenge is to think of pharmacy as a health care profession in which the environments, segments, disciplines, and associations are immutably linked and integrated.

In this new reality, survival of the pharmacy profession depends on high quality leadership ability, consultative and clinical services, and resourcefulness in data aggregation and analysis. A common pathway beckons the most capable in the profession: the implementation of pharmaceutical care all along the health care continuum.

**TAKING A LEADERSHIP ROLE**

Pharmacists in every practice setting are undergoing intensive self-evaluation and developing strategies and collaborative relationships with other health care professionals to realize a new ideal known as pharmaceutical care. Efforts are shifting toward delivering the appropriate quantity and quality of direct patient care to achieve optimal outcomes from therapeutic interventions.

In broad terms, pharmaceutical care includes the evaluation of a patient's medication needs, development of a therapeutic plan with defined outcomes, interaction and communication of information about the plan, dispensing and distribution of medications, and monitoring and adjustment of the treatment plan for desired outcomes. Pharmaceutical care involves other people besides pharmacists. It must be a collaborative, integrated process that includes the consumer, the prescriber, the pharmacist, and other health care professionals.

Nevertheless, pharmacists should assume a pivotal role. "If we don't develop the capacity to deliver pharmaceutical care, I think we are significantly challenged as a profession, and we will miss a major opportunity," says John A. Gans, Pharm.D., executive vice president of the American Pharmaceutical Association (APhA).2

Managed care pharmacists are in a unique position to see this opportunity clearly because they are most involved with the payors of health care, including the pharmacy benefit.

In a growing number of managed care organizations (MCOs), senior pharmacy administrators are intimately involved in identifying needs, wants, and concerns with respect to pharmacy benefit design components, through their interaction with payors. The primary focus of payors has traditionally been to reduce or at least slow the growth of their health care expenditures. Because the pharmacy benefit is carved out so well, this contributes to the perpetuation of the unit cost reduction mentality. However, considerable pharmaceutical costs have already been eliminated from the system, so that continued reduction of unit cost is less likely. In addition, employers are demanding greater value for all health care services and are looking for innovative ways to reduce or slow the growth of overall health care costs, not just the cost of pharmaceuticals.

While unit cost management responsibilities of managed care pharmacy continue to be important, many managed care pharmacy leaders are beginning to realize that their organizations' ability to contribute to the management of overall outcomes will soon be a key driver of their ability to maintain or grow their market share of pharmacy plan members. The successful contribu-
tion to outcomes management of pharmaceutical care programs is highly dependent on the capabilities and willingness of pharmacy practitioners to participate effectively in these programs.

To help increase participation, managed care pharmacists need to take a leadership role within their organizations and the profession as a whole. Managed care pharmacists have many skills that make them valuable in designing, developing, and assisting the various pharmacy disciplines in implementing the pharmaceutical care components of disease management programs.

Managed care pharmacists also bring a diverse background of technological, clinical, and management experience that can be brought to bear to assist the pharmacy profession in implementing pharmaceutical care by:

▲ integrating pharmacy and other health care data;
▲ quantifying value, measuring results, and educating payors; and
▲ improving communication between the different disciplines and managed care.

INTEGRATING PHARMACY AND OTHER HEALTH CARE DATA

Current electronic links in health care delivery are used mostly for claims processing, but they are also the key to managing pharmacy networks. Creation of a prescription drug database is one of the goals of MCOs (Figure 1).

In addition, a pharmacy data information highway needs to be in place to integrate prescriptions from various locations. MCOs need to build this information highway to capture data quickly and accurately from various providers, corporations, and geographic areas. Once this database exists, financial and clinical reporting and retrospective drug utilization evaluation can take place. Access to pharmacy data allows a managed care company to devise programs that contribute to more appropriate drug use, which can lower other health care costs. For instance, hospital admissions, doctor visits, and specialty referrals may decrease, and fewer lab tests may be ordered.

The prescription drug database can also be integrated with medical and hospital claims and ancillary service data (Figure 2).

Once medical and pharmacy data become integrated, MCOs are better able to do pharmacoeconomic research, including outcomes measurement, determination of best practices, and development of treatment guidelines. This is how the value of pharmaceuticals can be demonstrated objectively. Data used in this manner have relevance in formulary decision making and in the monitoring of prescription costs and physician prescribing practices. The data also can be used to justify the pharmacy budget. For example, data may show that using a more expensive medication results in better compliance and fewer hospitalizations.

The ideal system has a central drug database that can be used by all pharmacy disciplines (community, mail service, hospital, long-term care, and home care) to submit and retrieve data on-line in real time (Figure 3). As health professionals embrace the use of electronic databases, the process will become more interactive.

Once the system is in place, software applications should be used to identify patients who would benefit from pharmaceutical care. These are patients with certain diseases and patterns

Continued on page 145

FIGURE 1: Pharmacy Database Integration

FIGURE 2: Integration of Pharmacy and Medical Information Databases
of hospitalization and overuse (or underuse) of other health care services. Whenever developing or utilizing a patient health care database, it is critical to preserve the confidentiality of this information and restrict the access to this data to appropriate individuals.

QUANTIFYING VALUE, MEASURING RESULTS, AND EDUCATING PAYORS

From a managed health care perspective, the goal of pharmaceutical care is to improve patient outcomes by maximizing the effectiveness of pharmacy providers in delivering managed integrated health care. Pharmacists must demonstrate not only that they can improve patient outcomes but that they can also do so more cost-effectively than other health care providers. Every pharmacy dollar spent should be justified and add value to the health care system.

The provision of pharmaceutical care in the managed health care environment has three inherent challenges: (1) health care data is sparse, incomplete, and inconsistent; (2) opportunities to improve medication outcomes must be identified; and (3) patterns of drug use and outcomes need to emerge. Put simply, one cannot manage what one cannot measure. Historical information is necessary to convince providers to change their behavior; it is an educational process that can demonstrate to physicians how change can improve their practice patterns. For this purpose, especially, data capture is critical.

When dealing with pharmacists from different disciplines, MCOs have a number of strategies at their disposal to develop relationships (Table 1).

In addition, several broad guidelines may help in the design and development of pharmaceutical care programs:

- Limit participation to pharmacies that meet plan-specified performance criteria. These are usually certain community-based pharmacies (chain and independent) or a specialty pharmacy network under contract with an MCO. Determining selection criteria for these pharmacies will be difficult. One proposed method of doing so is to request or require that the pharmacies that want to participate in a "special" pharmaceutical care program submit to the managed care plan or PBM verification of enhanced pharmacist training and, equally important, "report card-like" information from interactions with their patients, which document adherence to patient counseling and DUR guidelines.

- Target no more than five diseases to make sure the organization's resources are not depleted and that success can be achieved during one fiscal year. Diseases well suited for pharmaceutical care programs include asthma, diabetes, cardiovascular disease (e.g., anticoagulation therapy), depression, and hyperlipidemia. Cancer is another area to consider in light of the high costs of oncology drugs.

- Train and evaluate participating pharmacists in the diseases selected before implementing any pharmaceutical care programs.

- Focus on selected patients. Not all patients with a given disease will benefit from pharmaceutical care.

- Identify on-line, real-time intervention opportunities and provide participating pharmacists with retrospective drug utilization data and screening tools.

- Document and present quantifiable (not theoretical) outcomes data to help demonstrate the results of the program.

IMPROVING COMMUNICATION BETWEEN DIFFERENT PHARMACY DISCIPLINES AND MANAGED CARE

Managed care pharmacy must remove barriers to communication across all practice types and increase interdependency in order to integrate pharmaceutical care within health systems. Managed care companies can use their pharmacy and therapeutics (P&T) committees to introduce pharmacy providers from the various disciplines. Inviting the pharmacy director from a key hospital and a pharmacy supervisor from a local pharmacy chain to attend a P&T committee meeting is one way to begin to remove the barriers between these two disciplines.

Additionally, some managed care plans are developing forums that allow for the effective discussion of important pharmacy benefit management issues. These forums bring the MCO and the community pharmacist together. A committee or pharmacy advisory council may include administrators, operational management coordinators, clinical program coordinators, and member services staff. Independent pharmacies participating in the network should be able to select community pharmacists to represent them in these meetings. A local pharmacy advisory council can form the cornerstone of the relationship among all the
Table 1. Strategies for Interfacing with Other Pharmacy Disciplines

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<tr>
<th>COMMUNITY PHARMACY</th>
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<tr>
<td>▲ Work with select community pharmacies to hook up electronically with hospital/home care/long-term care pharmacies to coordinate drug therapy</td>
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<tr>
<td>▲ Include community pharmacists in the development, implementation, and management of the drug formulary</td>
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<tr>
<td>▲ Work with community pharmacies to identify inappropriate drug utilization</td>
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<tr>
<td>▲ Develop educational programs in conjunction with community pharmacies to promote patient compliance</td>
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<th>HOSPITAL PHARMACY</th>
<th>INTEGRATION STRATEGIES</th>
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<tr>
<td>▲ Meet with the pharmacy director from the local hospital that handles the most admissions</td>
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<tr>
<td>▲ Evaluate the hospital’s drug formulary for collaborative opportunities</td>
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<tr>
<td>▲ Determine opportunities to provide consistent drug use between inpatient and outpatient settings</td>
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<tr>
<td>▲ Develop a pharmacy process with the hospital to ensure continuity in drug therapy when a member becomes an outpatient</td>
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<tr>
<td>▲ Install a computer terminal to allow the hospital access to patient drug profiles</td>
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<tr>
<th>HOME CARE PHARMACY</th>
<th>INTEGRATION STRATEGIES</th>
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<tr>
<td>▲ Work collaboratively with home care pharmacies to develop policies for pharmaceutical care</td>
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<tr>
<td>▲ Focus on specific home care pharmacies with the highest usage</td>
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<tr>
<td>▲ Determine which diseases can have the greatest impact on lowering overall health care costs</td>
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<tr>
<td>▲ Ask home care pharmacies to document improvements in health care outcomes</td>
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<th>LONG-TERM CARE (LTC) PHARMACY</th>
<th>INTEGRATION STRATEGIES</th>
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<tr>
<td>▲ Allow LTC pharmacies to electronically retrieve member drug profiles</td>
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<tr>
<td>▲ Work with LTC pharmacies to learn the value of drug therapy management activities in LTC that help lower overall health care costs</td>
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The parties involved in managing, implementing, and evaluating pharmaceutical care. For such a forum to be effective, the core group of members must clearly define objectives. Quality improvement issues can be evaluated once the group convenes. Examples of discussion items include member service issues such as standardized waiting times, inventory levels, purchasing and out-of-stock performance, customer relations (including a process that addresses complaints), and pharmacy benefits monitoring. The council is also the arena in which to introduce and discuss pilot projects such as those that identify patients with selected diseases in areas where pharmaceutical care programs are being developed. The only way to ensure that these projects are administered successfully on behalf of the managed care plan is through interactive customer-focused committees, such as an advisory council. In addition, benefit changes and their impact on the operational management of the pharmacies must clearly be communicated.

A team approach is necessary if the alliances formed between MCOs and community pharmacy organizations are to bring about quality, cost-effective pharmaceutical care. Why not include all major disciplines of pharmacy in such forums so they can work together on programs to improve the continuity of pharmaceutical care?

Managed care pharmacy has the most to gain from improving the quality of the pharmaceutical care continuum. Improving this continuum can be expected to improve drug utilization and outcomes which, if documented, will better meet the needs of the ultimate decision maker—the payer. Sponsoring regular forums to achieve such progress is an important leadership initiative.

HELPING REENGINEER THE PROFESSION

Another major challenge confronting the pharmacy profession is to participate in a health care solution. This challenge is driven by the belief, held by both payors and patients, that a solution truly exists. Furthermore, the Pew Commission maintains that a solution can and should be implemented.

Pharmacy is a servant to, not a leader of, this process. With a servant mentality, pharmacy can make great headway. This approach supports the notion that pharmacy should be realigned as a health care profession. It must be aligned very closely with the care givers—medicine and nursing. But before pharmacy can truly be taken seriously as a profession, it needs to get its own house in order.

To do so, all segments of pharmacy must contribute to the implementation of pharmaceutical care. Community, home care, hospital, and long-term care pharmacists must relate to one another along the continuum of care. In addition, several areas of pharmacy must be refocused to make pharmaceutical care a reality. Such changes include redesigning practice sites, enhancing pharmacists’ skills, adding new information systems, and changing reimbursement methods. The value of different practice sites also must be determined. And, perhaps most important, pharmacists need to demonstrate that they can cost-effectively improve outcomes through the provision of pharmaceutical care.
Because of ongoing changes in the health care marketplace, pharmacy as a profession must reengineer itself. The challenge is for the various pharmacy practice areas to be indistinguishable as they become aligned on a new set of core values.

These values must be centered on pharmacy’s role in ensuring the appropriate use of pharmaceuticals in all patient care settings. Managed care pharmacy can lead in the integration of pharmaceutical care by:

- educating employee benefit managers about the value of pharmaceutical care and its impact on lowering overall health care costs;
- developing pharmaceutical care programs with the assistance of the appropriate pharmacy community, and providing pharmacists with the training and tools to implement these programs;
- requiring participating pharmacists to report on skill competencies and patient/member satisfaction with pharmaceutical care services; and
- designing and implementing shared reward and reimbursement methods that motivate pharmacists to participate in pharmaceutical care and make it a reality.

The forces driving health care and the profession of pharmacy have put managed care pharmacists in a leadership position. The question is whether they will seize this opportunity to advance their profession and strengthen health care as a whole.

References

"STATE-OF-THE-ART QUALITY TRENDS: NCQA, HEDIS, AND BEYOND"

A Breakfast Seminar, held in conjunction with the AMCP Ninth Annual Meeting Saturday, May 10, 1997 New Orleans, Louisiana Hyatt Regency New Orleans 6:00 AM-8:00 AM

PROGRAM GOAL
The goal of this program is to update the managed care pharmacist regarding current trends and measures associated with achieving optimal quality of care.

TARGET AUDIENCE
This program has been designed for managed care pharmacy clinicians and managers who are interested in expanding their knowledge on the National Committee for Quality Assurance (NCQA) and the updated version of the Health Plan Employer Data and Information Set (HEDIS).

LEARNING OBJECTIVES
After attending this session, the participant should be able to:
1. Define HEDIS, and its implications and opportunities for medical directors and directors of pharmacy in managed care organizations.
2. Understand factors contributing to the heightened accountability for quality and costs of medical care.
3. List factors that should be considered in defining the methods and strategies to improve the delivery of medical care.
4. Provide a historical overview of HEDIS.
5. Identify performance categories defined in HEDIS 3.0.
6. Recognize the potential limitations of HEDIS 3.0.
7. Describe the major changes in HEDIS 3.0 relative to previous versions.

For more information or to register, contact the Registration Department at Medical Education Systems, Inc. at (215) 645-1060.

PROGRAM AGENDA

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<th>Session</th>
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<tr>
<td>6:00 AM</td>
<td>Continental Breakfast</td>
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<td>6:30 AM</td>
<td>Introduction</td>
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<td>6:30 AM</td>
<td>Craig Stark, PharmD, MBA</td>
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<td>6:30 AM</td>
<td>Proforma Pharmaceutical Consultant, Inc. North Ridge, California</td>
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<tr>
<td>6:35 AM</td>
<td>STATE-OF-THE-ART QUALITY TRENDS: NCQA, HEDIS, AND BEYOND</td>
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<tr>
<td>6:30 AM</td>
<td>Overview of HEDIS 3.0 and NCQA Accreditation</td>
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<td>6:30 AM</td>
<td>Wendy Semner, MD, PhD</td>
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<td>6:30 AM</td>
<td>NCQA Accreditation</td>
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<td>6:30 AM</td>
<td>Washington, DC</td>
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<td>7:10 AM</td>
<td>Pharmacy’s Role in Quality</td>
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<td>7:10 AM</td>
<td>Improvement: Core Studies</td>
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<td>7:10 AM</td>
<td>Michael W. Collins, MS: RPh</td>
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<td>7:10 AM</td>
<td>Community Health Plan</td>
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<td>and George Hill, RPh</td>
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<td>Blue Cross and Blue Shield of Alabama</td>
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<td>7:10 AM</td>
<td>Birmingham, Alabama</td>
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<td>7:40 AM</td>
<td>Program Summary and Conclusion</td>
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<td>7:45 AM</td>
<td>Craig Stark, PharmD, MBA</td>
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<td>7:45 AM</td>
<td>Question and Answer Session</td>
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<td>Panel Discussion</td>
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CONTINUING EDUCATION CREDIT

Medical Education Systems, Inc., Continuing Pharmaceutical Education Division, is approved by the American Council on Pharmaceutical Education (ACPE) as a provider of continuing pharmaceutical education (ACPE #777-000-97-006-L04). This program is acceptable for 1.5 hours of continuing pharmaceutical education credit (0.15 CEUs), which will be awarded free of charge via mail within 4 weeks of the program to participants who attend the program for its duration and turn in a completed evaluation form at its conclusion.

For information or to register, contact the Registration Department at Medical Education Systems, Inc. at (215) 645-1060.

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Vol. 3, No. 2 Mar/Apr 1997 JACP Journal of Managed Care Pharmacy 147
Dealing Proactively with Attacks on Managed Care

During the past year, the field of managed care has received a good deal of negative press that often emphasizes “horror stories” about potentially inadequate care. As the major trade association representing managed care organizations, the American Association of Health Plans (AHP) has learned how to deal with this atmosphere and present a more balanced view of managed care.

AHP’s Grassroots Coordinator John L. Cattelan says, “We try to educate lawmakers about the philosophy of care our member plans adhere to, that is, providing high-quality, affordable care. One positive step we've taken in this arena is to share our success stories with lawmakers. We find they really do take an interest in these stories, and they do sink in.”

His advice for managed care pharmacists: “Emphasize the quality of service you provide and its affordability. It might be valuable to try to involve senior citizens who are enrolled in a managed care plan, and would be happy to discuss the prescription coverage they get through managed care. We’re doing that in terms of other aspects of care for senior citizens, and we find they are great spokespeople.”

the right but some would say even an obligation to convey your views.” Lobbying can take many forms, including providing testimony at public hearings, mobilizing grass-roots support, supplying technical information, and building coalitions with other organizations. Although lobbyists often can be found on Capitol Hill in Washington, these days decisions in the state legislatures and executive branch agencies also have a substantial impact on health care issues. Therefore, state legislatures and federal agencies also play host to today’s lobbyists.

Technical information is extremely important. The essential thing is not only to supply technical information but to explain it in clear language that shows how the bill under consideration will affect the legislator’s district and constituents.

—Karen Fennell, R.N., M.S.

DO LOBBYISTS MAKE A DIFFERENCE?

There is no doubt that lobbyists have influence, says Hermelin. For example, he has recently spent significant energy defending the right of pharmacists to compound medications. APhA drafted legislation and won support from 142 members of Congress who cosponsored the draft bill. The organization also urged its members and state associations to write letters of support and formed alliances with many other associations. “Our bill was incorporated as a provision within the FDA reform bill that was working its way through Congress before it adjourned, and I anticipate it will be enacted during the coming session,” Hermelin says.

John Jones, R.Ph., J.D., director of contracting and compliance at Prescription Solutions in Cypress, California, a pharmacy benefits manager (PBM) owned by an HMO, has testified before committees of the California and Oregon legislatures. Recently, when the California Senate Insurance Committee and Assembly Health Committee were considering a plan for regulation of PBMs, Jones offered detailed information on how PBMs operate and the potential effects of the proposed regulations. “I explained that were it not for PBMs and the way they control utilization, the senior citizens in their districts would not have a pharmacy benefit at all, because it would be far too expensive,” he says. “In the end, the legislature was willing to forego direct regulation, and work with the Department of Corporations, which licenses HMOs, to achieve some of their goals indirectly.”

Karen Fennell, R.N., M.S., senior policy analyst for the American College of Nurse-Midwives (ACNM), a practitioner group with about 6,000 members, also sees her primary role as educating legislators about the effects of proposed actions. “Technical information is extremely important. The essential thing is not only to supply technical information but to explain it in clear language that shows how the bill under consideration will affect the legislator’s district and constituents,” she says. This is key, because legislators care most of all about the opinion of the folks at home. After all, these are the people who finally decide who will or will not be re-elected. As John L. Cattelan, grass-roots coordinator for the American Association of Health

Continued on page 154
FEATURE: Pharmaceutical Lobbyists Educate Legislators

Plans (AAHP), says, "Surveys have shown that lawmakers would rather hear from their constituents than anyone else. They know that the issues that impact the voters also impact them as lawmakers."

This means that one of the most important roles lobbying plays in any professional association is preparing members to speak effectively with their own representatives. Last March, for example, when the American Society of Consultant Pharmacists (ASCP) held its Annual Conference on Legislative and Regulatory Affairs in Washington, D.C., it prepared information packets and set up appointments for society members with their representatives on Capitol Hill. Julie Scott, government affairs assistant, who has been coordinating ASCP's state-level grass-roots activities, adds, "We currently have 14 state chapters, and we've been working to set up a contact system so we can identify members who have specific contacts and relationships with state and federal legislators and their staff. In many ways these 'key contacts' become the eyes and ears of ASCP. Many of them serve on policy committees and subcommittees in their respective states. Through this active grassroots base, we are able to rapidly execute letters, faxes, and phone calls on our most crucial issues."

ASCP also emphasizes that Washington-based lobbyists must maintain regular contact with legislators and staff. Leigh Davitian, J.D., director of government affairs, says, "The most critical part of lobbying is face-to-face interaction on a regular basis. Our philosophy is 'out of sight, out of mind,' so we try to meet with legislators and staff on a weekly basis."

Should lobbyists speak to legislators or to their staff? "If I need to speak to a member, I usually can," Hermelin says. "But members of Congress have limited time, and much of the detailed work gets done by the staff, so it's important that they be fully cognizant of the issues." It is important not to understand the role of Congressional staffers. These are the people who do the research and draft the actual legislation. Representatives count strongly on their staff for information and input on various topics. "If it's a technical issue or if there are many different positions that need to be clarified, it's always best to talk to the staff," notes Hermelin.

DO PACS PACK A PUNCH?

The 1980s saw a huge growth of political action committees (PACs) in Washington, many of them funded with millions of dollars and administered by slick, high-power professionals. Today, thousands of organizations, including associations of all sizes, have PACs.

ASCP has a PAC that is fairly typical. It has a board of trustees that decides which candidates to support, and the PAC funds are used to make contributions to those candidates. During 1996, the ASCP-PAC focused on members of major committees affecting health care legislation and made bipartisan contributions to about 20 candidates. Funds are usually raised through dinners or other events with tickets ranging from $500 to $1,000. "When we attend these fundraisers, we look for an opportunity to meet and speak with the representative and key legislative staff. Our goal is to engage in a conversation and briefly discuss important issues, and then follow up with a personal visit to the office," Davitian says. "These fundraisers are an excellent opportunity to build relationships; many times that initial contact allows us to eventually hold meetings with a representative to discuss policy issues."

Clearly, the sheer number of active PACs suggests that many people see them as powerful tools. But is a PAC necessary to influence opinions? Many groups say no. For example, ACNM also has been able to influence legislative decisions even though it has no PAC money to distribute. "In a Congress-

al district, just 10 to 15 letters can make a world of difference, particularly when they come from consumers who are concerned about an issue. We've found that sort of strategy to be very successful," Fennell says. "In addition, this sort of work can't be done alone. I rely heavily on coalitions and build many different partnerships."

LOBBying INTO THE 21ST CENTURY

During the next few years, we can expect to see continuing efforts to improve the United States health care system step by step. In this environment, increasingly sophisticated efforts to educate legislators about the precise effects of proposed actions will be essential.

"The state legislatures and Congress without question will be taking actions that affect pharmacists' livelihoods and profession," Hermelin predicts. "Managed care pharmacists need to learn about the issues Congress and the states are addressing and become politically active, either individually or working in affiliation with others through state and national associations. You absolutely cannot ignore the role that government plays if you are in the health professions today."
Looking Back: Failed Health Care Reform Put Managed Care on the Map

While President Clinton's health care reform efforts didn't pack the punch he'd hoped for, they did act as a catalyst for change that led to the growth of managed care nationwide.

With President Clinton settled in for his second term in office, it's hard to believe that just four short years ago health care reform was the talk of Washington. Everyone, from consumers and practitioners to employers and politicians, had an interest in what reform might mean and what form it would take. But after many headlines, much debate, and heated battles on Capitol Hill and in state capitols, health care reform died with more of a whimper than a bang.

But to say that the health care reform movement was all for nothing would be untrue. In reality, even though no comprehensive legislation was passed, the reform movement resulted in some noticeable changes to the nation's health care system. And it led legislators, employers, and others to see managed care as a means of cutting costs while providing quality care.

Health care reform efforts brought concerns about the system to the forefront of public notice. Vague dissatisfaction with rising costs and issues of

JOANNE KALDY

JOANNE KALDY is Managing Editor of the Journal of Managed Care Pharmacy.

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quality turned to deep concern, as reports indicated that health care expenditures were rising at twice the rate of inflation. The media, the government, and special interest groups warned of the imminent dangers of a system out of control. As the public listened, concern among consumers grew. At the same time, however, they worried about what change would mean; consumers wanted lower costs, but without giving up choice or making other sacrifices. In fact, several studies showed that Americans generally were pleased with the health care they received. Still, the need for change was apparent.

REFORM CATAPULTS MANAGED CARE INTO SPOTLIGHT

“There is no question that managed care owes its fast development to Clinton’s health care reform,” says Robert Davis, executive director of the Maryland Health Care Coalition, a non-profit organization of Maryland-based employers, businesses, insurers, providers, and labor unions. The failed health care reform efforts were the “catalyst” that led to managed care’s rise. When the nation’s employers and others were looking for a way to provide cost-effective, quality care, Kaiser Permanente, Group Health Association, and George Washington University Health Plan—among other plans—were setting positive examples in the Washington area. Plans such as these began to gain national attention as good examples of what managed care could do. Several large corporations nationwide already were using managed care with varying levels of success, and they began to spread the word as well.

People began to get the message and started to look at managed care as “a way to solve problems relating to cost-effectiveness and quality,” says Pam Kalen, executive director of the Managed Health Care Association, a Washington, D.C.-based coalition of employer purchasers whose members are involved in the quality accountability movement.

However, while health care reform brought attention to the issues and to managed care, it was the private sector that put ideas into action. According to Kalen, “The concept of managed care fit in well with the demographics of the nation,” providing quality care at lower costs in urban and suburban America. Employers saw managed care as a viable way to reduce costs; they liked the fact that managed health care was a buyer’s market. If an employer wasn’t satisfied with one company, there were always others vying for his or her business.

From an entrepreneurial standpoint, the health insurance industry was positioned to lead the managed care charge. The industry had the connections, the money, and the marketing experience to take managed care into communities throughout the country.

While managed care owes much of its growth to the health care reform efforts of the early ’90s, its future will depend on how the industry handles current and future challenges and on legislative activities that will shape the overall future of health care. So, what’s ahead?

“All the forces were good” for the advent of managed care, says Davis. And managed care did become increasingly popular. In 1993, 22% of the nation’s employers offered HMO plans to employees; today about 30% of employers have HMOs. Also experiencing impressive growth, preferred provider organizations (PPOs) were offered by 24% of employers in 1993 and 43% in 1996. Meanwhile, traditional indemnity plans are on the downside, going from 57% in 1993 to only 30% in 1996. Enrollment of employees for managed care plans also went up, with the largest increase in point-of-service plans (7% in 1993 to 19% in 1996).

States jumped on the managed care bandwagon; during the mid ’90s, several states applied for Medicaid waivers to implement managed care pilot programs for their Medicaid populations.

As managed care became more prevalent, it also underwent increased scrutiny by the press and the public. “Horror stories” about patients who were denied procedures or given improper care began to surface. Some of the bad press could be attributed to growing pains. As Davis indicated, when enrollment in managed care plans was only 5%-10%, there naturally were fewer negative stories. Davis and others also suspect that some such stories likely were generated by practitioners who felt they had a lot to lose from managed care’s successes. Nonetheless, employers generally encouraged managed care because they saw immediate results (i.e., lower costs). By now, too, employers had become more savvy about health care plans, and were skeptical about much of what they heard and read. Increasingly, employers see themselves as having a role in health care management and, as John Fortin, a principal with Foster Higgins in Atlanta, Georgia, notes, “They are more educated than ever before. They are dying to get their hands on drug and medical data.”

Health care reform surely contributed to employers’ involvement. However, the heightened attention reform efforts received also contributed to a growing number of educated consumers who wanted more say in their own health care. “Reform efforts, especially the press coverage, raised awareness of health care and especially managed care,” says Carol Cronin, senior vice president of Health Pages. Health care reform resulted in managed care becoming “a household word,” notes Fortin, adding that more people now understand terms such as “utilization” and “HMO.”

Continued on page 163 ▼
LOOKING AHEAD: WALKING UPHILL

While managed care owes much of its growth to the health care reform efforts of the early '90s, its future will depend on how the industry handles current and future challenges and on legislative activities that will shape the overall future of health care. So, what's ahead?

"Managed care will have another long, hard year," Davis predicts, pointing to pending legislation that may change the way managed care functions. For example, there is a bill that would give patients the right to see practitioners outside their network without penalty. Also, "any-willing-provider" bills are popping up in several states. "If these types of bills pass," Davis says, "we'll see a dismantling of the system, including the components that have brought costs down. There is a tendency for consumers and providers to seek legislative redress for the aspects of managed care they don't like, and employers are caught in the middle." In the meantime, Davis feels that while some tampering with the system is to be expected, too much could "take us back to where we started." To help managed care get a handle on upcoming challenges, it needs to do a better job of public relations than it has in the past.

Fortin says that "bigger" is the buzzword of the future for managed care and health care in general. "We're seeing lots of consolidation. And this trend, which started in the pharmaceutical industry, will spread throughout health care. We'll see mergers, mergers, and more mergers," he says, "of hospitals, physician groups, and HMOs." According to Fortin, managed care and its consumers are driving this trend. "People love access," and consolidation means greater access.

Fortin also predicts that managed care's growth will continue. "We'll see more people moving into managed care—not just HMOs, but PPOs and others." One important challenge facing managed care will be its handling of Medicare risk contracts, Fortin says, which will bring a growing number of elderly Medicare patients into managed care. "Medicare risk HMOs are increasing exponentially," he notes, adding that, "the growing numbers of elderly patients this will bring into the system will change life for HMOs and present a challenge for them to manage. This will be interesting to watch."

It's evident that there is a place for pharmacists in managed care, and many have embraced the system and found a home in it. They have expanded their role to provide total pharmaceutical care, going beyond traditional activities to involvement in education and research activities, development of drug formulary, drug benefit, and other programs, and involvement in disease management activities and development of quality assurance tools such as critical pathways and clinical practice guidelines.

Cronin predicts a trend toward smaller networks as managed care heads into the 21st century. "Over time, wide open managed care networks may not be available," she suggests, and there will be a trend toward smaller networks.

IMPACT ON PHARMACISTS AND OTHER PROVIDERS

Clearly, health care reform and the growth of managed care had a strong impact on pharmacists and other providers. Many "mom and pop" drug stores either were sold or went out of business, and small private practices became more difficult to sustain. A number of practitioners have fought the managed care trend; some have succeeded, others have not.

It's evident that there is a place for pharmacists in managed care, and many have embraced the system and found a home in it. They have expanded their role to provide total pharmaceutical care, going beyond traditional activities to involvement in education and research activities, development of drug formulary, drug benefit, and other programs, and involvement in disease management activities and development of quality assurance tools such as critical pathways and clinical practice guidelines.

Managed care owes much to the health care reform movement, but its future and the future of pharmacists and others practicing in this environment will depend on how challenges are managed and obstacles are anticipated and overcome.

Vol. 3, No. 2  Mar/Apr 1997  JMC Journal of Managed Care Pharmacy  163
Consultant Pharmacy and Managed Care: A Partnership for the Future

Traditionally, managed care and consultant pharmacy have paid little attention to each other. But changes in the health care marketplace and new demographic trends are prompting these groups to take a second look at how they might form symbiotic relationships that also benefit patients.

Until recently, few in the health care industry would have predicted that managed care would have a significant impact on the delivery of care in long-term care (LTC) facilities such as nursing homes. After all, managed care had traditionally provided care for young, relatively healthy, working individuals and their families, not for the chronically ill.

But that's changing. Increasingly, individuals with chronic health problems, from the elderly to patients with AIDS, are receiving more of their care through some form of managed health delivery system. As more managed care plans assume the risks of caring for these individuals, they need to adopt new, specialized medical management techniques to help them refine and improve the way they deliver care to these and other special patient populations, both to improve patient outcomes and reduce costs.

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CAROL SARDINHA is AMCP Director of Communications, Alexandria, VA. Copyright © 1997, Academy of Managed Care Pharmacy, Inc. All rights reserved.
Likewise, many facilities that once relied exclusively on fee-for-service are starting to rethink their position. Nursing homes, subacute care facilities, and other institutions are finding that the rules of reimbursement are rapidly changing, putting them at greater financial risk. In response, they must find ways to become more efficient and proactive in caring for the chronically ill in order to identify and avert potential complications in these patients, which can lead to additional costly medical care.

Increasingly, managed care organizations and long-term care facilities are turning to consultant pharmacists (traditionally called long-term care pharmacists) for their expertise in managing the medication needs of the chronically ill, the elderly, and other special patient populations. This article presents the views of four experts on what's driving this trend and of what relationship the future is likely to hold for the managed care and consultant pharmacist.

**MEDICAID: A DRIVING FORCE**

The move by states to enroll more of their Medicaid populations into managed care could be the impetus for bridging the gap between managed care and consultant pharmacists, says Ralph Kalies, R.Ph., Ph.D., president of KDS Corporation, Konsult Research Associates, and PBM Plus, all based in Oshkosh, Wisconsin. As more states move toward capitating their Medicaid programs, "that will require more interaction between consultant pharmacists and managed care," predicts Kalies, who also is president of the American Society of Consultant Pharmacists (ASCP).

Because consultant pharmacists traditionally have worked in nursing homes and other facilities where they have access to patient medical charts on a regular basis, "they bring a lot to the table" when trying to build relationships with managed care, Kalies says.

Consultant pharmacists, like some managed care pharmacists, are used to looking at total patient data, not just pharmacy data, he observes. That advantage, combined with the growing automation of dispensing functions, "puts pharmacy in a position to be an adjunct to the provision of patient care."

Kalies, whose company, PBM Plus, provides LTC pharmacy networks and services in addition to more traditional PBM (pharmacy benefit management) services, says managed care plans are just starting to ask his firm questions about incorporating consultant pharmacy services into their programs. Most plans are still only at the investigation stage, says Kalies, who sees the need to "educate managed care plans about the differences in treating someone who is 30 years old and plays tennis four times a week, compared with someone who is 80 years old with six disease states."

Kalies shares the views of many of his pharmacy colleagues in managed care when he says that health systems must move away from the "silo" mentality. Spending more, not less, on appropriate pharmacy services, he says, will ultimately lower overall health costs, particularly the costs of caring for the elderly or those with chronic health problems.

"Something major is going to happen, and it's just around the corner," he predicts. The challenge for consultant pharmacists and managed care plans will be to implement the data and information systems necessary to demonstrate how pharmacist interventions reduce overall costs. Consultant pharmacists also need to focus more on getting involved with patients early on to detect and prevent adverse events that can lead to serious medical complications, rather than "wait to have a major [drug] event and then conduct an event-driven [drug] review."

Although Kalies generally is optimistic about the future role of consultant pharmacy in managed care, he points to some storm clouds on the horizon. Discussions in Washington about cutting Medicare reimbursement to HMOs could prompt many plans to walk away from caring for the elderly. Only if incentives remain will managed care be willing to take on the risks of caring for this population, he says.

**BARRIERS TO PARTNERSHIPS REMAIN**

PBMs increasingly are willing to partner with consultant pharmacists, but there are still significant barriers to overcome, says managed care consultant Cathie Hegg, R.Ph., M.S., president of Hegg & Associates, a managed care consulting firm. Many PBMs are considering forming partnerships with consultant pharmacists to more effectively provide a continuum of care, from the acute to the LTC setting, Hegg says. Some PBMs also are becoming involved in activities where consultant pharmacists can lend their expertise, including developing senior drug formularies, enhanced on-line DUR messaging targeted at seniors, treatment guidelines and algorithms, and formalized programs to address LTC management, she says.

However, many PBMs are still shy- ing away from this area because they do not yet know how to adequately assess the costs and risks of dealing with the LTC patient population, Hegg adds. There are also other barriers. For example, the PBM may have different drugs on its geriatric formulary than the treating facility has on its formulary. In those cases, it may be unclear which drug the patient should receive when he or she is transferred from one level of care to another, or which party (the PBM or the facility where the patient is treated) should get rebates for the drug.

In spite of these obstacles, discussions on possible PBM-consultant pharmacist partnerships are underway, Hegg says. Several PBMs and HMOs report
SPOTLIGHT: Consultant Pharmacy and Managed Care: A Partnership for the Future

ASCP BOOKLETS ADDRESS LTC PHARMACY BENEFITS

The American Society of Consultant Pharmacists (ASCP), Alexandria, VA, has two booklets available that offer guidance for developing a managed, long-term care pharmacy benefit. Pharmacy Services in Long-Term Care: A Guide for Managed Care Plans, is a 10-page guide that outlines strategies and principles for managed care organizations to consider as they develop the pharmacy component of long-term care benefit plans. It features:

- detailed guidelines for managed care plans to use in structuring pharmacy benefits and protocols;
- analysis of innovative managed long-term care programs in Arizona and Minnesota, as well as limited capitation initiatives in other states, and
- an overview of essential consultant pharmacist services, including drug regimen review, utilization management activities, in-service training, continuous quality improvement, and interdisciplinary care planning.

The booklet is a companion piece to another ASCP publication, A Model Long-Term Care Pharmacy Benefit, which details the components of an effective long-term care pharmacy benefit plan and the value of long-term care pharmacists in containing costs and improving the quality of patient care. To order copies of the publications, call ASCP customer service at 800/355-2727, or visit their web site at www.ascp.com.

having been approached by consultant pharmacists interested in forming shared-risk/capitation arrangements. This trend is likely to continue as more facilities that typically employ these pharmacists move away from traditional per diem payments. Hegge's advice to consultant pharmacists is to be proactive: Contact PBMs and HMOs about such partnerships or risk-sharing arrangements before the PBMs and HMOs set up their own programs and pricing policies.

NEW MARKETS, NEW APPROACHES

Much of this movement toward embracing consultant pharmacy expertise is rooted in managed care's desire to find new ways to better manage patient outcomes and lower treatment costs. "What we are seeing is that managed care organizations with high levels of sophistication are recognizing the need to utilize the expertise of the long-term care pharmacist in providing care for the new markets they are serving," says Brian Kahan, chief executive officer of Comp-Script in Boca Raton, Florida, which provides pharmacy services to the LTC and subacute care industries.

Kahan's company has advised managed care organizations that seek to identify LTC and other facilities that meet their needs from both a quality (standards) and cost perspective, and organizations that seek to find out more about successfully managing and caring for higher-risk populations. Kahan echoes other experts who stress the importance of clearly recognizing the differences in intensity of services required for the elderly or chronically ill and those for the average managed care enrollee.

For example, a typical managed care plan might have practice guidelines in place that stress the importance of using a step-therapy approach when prescribing medication, Kahan says. Practitioners are encouraged to prescribe the least expensive medication for a patient with a particular condition, and if it does not work, to move on to the next least expensive or more potent drug, until the desired outcome is achieved. In a normal population of patients, this poses little if any risk to patients, he says. But in a chronically ill or elderly person whose health already may be seriously compromised, such an approach may be dangerous. With antibiotics, for example, "if you don't get it right the first time, the patient may deteriorate," Kahan says.

"We recognize that every geriatric patient we serve is unique, and that anything less than having a long-term care pharmacist evaluate that patient causes the payor to pay more down the road because of inappropriate selection of drug therapy," says Kahan, who also serves as chairman of the board of directors of ASCP.

Kahan also is optimistic that the need for consultant pharmacy services by managed care organizations will continue to grow as managed care comes under increasing political pressure to cover the more chronically ill and as more retirees and pensioners receive some of their health benefits through managed health care systems.

FEE-FOR-SERVICE: A FOSSIL FROM A BYGONE ERA

Over the next five years, in order to survive, LTC facilities will need to have a good grasp of managed care and how it works, predicts Maude Babington, Pharm. D., vice president of consulting for Pharmacy Corporation of America (PCA), Tampa, Florida, the nation's second-largest LTC pharmacy services company. That understanding includes getting a handle on capitation and capitation arrangements, as fee-for-service eventually will "go by the wayside," she says.

This trend will most likely be further fueled by the consolidation in the LTC market, Babington says. As more of
the large LTC companies buy up smaller mom-and-pop operations, these LTC facilities will seek to expand both vertically and horizontally. A company may seek to integrate many different types of facilities—nursing homes, assisted living facilities, subacute care facilities, and home care companies—in order to provide a continuum of care model attractive to managed care. Some facilities and small chains already are starting to experiment with capitation in order to market to managed care. These facilities might send a request for proposals to pharmacies and pharmacists in the region that would be willing to assume some of the risk, Babington says.

The long-term care field is changing in other ways to meet the emerging demands of managed care. LTC pharmacists in particular are becoming more proactive in managing and coordinating care to avert medical problems, rather than simply recommending changes in therapy on a retrospective basis. “That’s a real big change,” Babington says.

One of the things PCA is doing to prepare for the changes ahead is to become more involved in the disease management area, she says. The company is rolling out several pilot disease management programs within its facilities to address a number of high-cost care areas, including peptic ulcer disease, depression, anti-coagulation management, and diabetes. Physicians and other caregivers will be educated in following appropriate treatment guidelines and algorithms, some of which will be based on guidelines already crafted by the American Medical Directors Association, the association of nursing-home medical directors. Clinical pharmacists also will be involved in the development of the guidelines, she says.

NEW ALLIES FOR THE NEXT PHASE

Clearly, momentum is building for radical changes in how the health care delivery system manages and coordinates the care of the growing number of chronically ill patients who require medical services, both now and in the future. As more providers and health systems begin to take steps to address this growing demand, they’ll need to form innovative and constructive new partnerships to come up with feasible options for enhancing patient outcomes while controlling costs. Consultant pharmacists and managed care systems may very well become new allies as we enter the next phase of managed care’s growth.
Outpatient Treatment of Uncomplicated Deep Vein Thrombosis: An Overview of Program Development

Amy Santoro, Pharm.D.

Those who provide health care in managed care environments continually are challenged by the need to control costs while maintaining high standards of quality. One trend that has resulted in significant cost savings is the increased use of ambulatory care in lieu of hospitalization. In fact, many illnesses and events that formerly resulted in lengthy hospitalizations now are being treated entirely or partially on an outpatient basis. This shift, while resulting in cost-effective care, has presented new challenges for health care professionals and administrators in ambulatory care settings.

Among these challenges is the need to maintain high-quality health care and patient safety as increasingly serious medical conditions are treated outside the hospital setting. From an administrative perspective, this involves coordination of more complicated treatment regimens on an outpatient basis.

Acute deep vein thrombosis (DVT) is an example of a medical condition that traditionally has necessitated hospitalization for treatment. Standard initial therapy for DVT has included a five- to seven-day course of intravenous heparin, with the dose being adjusted based on the activated partial thromboplastin time (aPTT).\(^1\) More recently, low molecular weight heparins (LMWHs) have been investigated for the treatment of this condition. Two recent clinical trials have explored the possible effectiveness of treating DVT with LMWHs on an ambulatory basis.\(^1,2\)

This new approach for the treatment of DVT may provide an opportunity for managed care plans to realize significant cost savings by decreasing the length of or avoiding hospitalizations for many patients with this condition.

However, there are many clinical, administrative, and logistical factors that must be considered before attempting to establish a program for the outpatient treatment of DVT. Specifics will vary depending on the type and structure of the managed care organization considering such a program. In any setting, however, pharmacists can play a key role in program development and implementation.

LOW MOLECULAR WEIGHT HEPARIN

LMWHs are fragments of standard heparin that have several properties differentiating them from their parent compound. These properties include longer plasma half-lives, increased bioavailability after subcutaneous administration, and less interpatient variability in anticoagulant response to a given (weight-adjusted) dose.\(^2\) These advantages allow LMWHs to be given subcutaneously once or twice a day without laboratory monitoring of the aPTT. The availability of LMWHs thus may provide an opportunity to shift the treatment of DVT from intravenous infusions of standard heparin given in the hospital to subcutaneous injections of LMWH administered at home. The two recent trials addressing this possibility were controlled, randomized studies comparing intravenous standard heparin administered in the hospital to subcutaneous LMWH administered primarily at home for the treatment of acute, uncomplicated proximal DVT.\(^2\) Outcome events, including recurrent symptomatic thromboembolism and major bleeding, were low in each study and did not differ significantly between study groups. In both trials, the researchers concluded that many patients can be treated safely and effectively for acute, uncomplicated DVT on an ambulatory basis.

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BACKGROUND RESEARCH

Once a potential new treatment approach has been identified, further research is necessary to determine whether it represents an opportunity within a specific managed care organization. This research may take various forms, including communication with pharmaceutical companies, gathering data from other health care organizations, and conducting a detailed search and analysis of the available medical literature.

A good starting point is a thorough review and critique of the clinical trials that have investigated this therapy. This should include an analysis of the inclusion and exclusion criteria used in the trials, in order to determine whether the population served by the managed care organization is similar to the population studied. Analyzing the specific methods used in the trials can help ascertain whether a similar protocol is practical within the organizational structure of one's own health system. In addition, a general review and critique of the literature and the validity of the conclusions can help verify that decisions are being based on sound, well-designed medical research.

A more complete literature search for information on the treatment being considered is also wise. In this case, additional articles describing the use of LMWHs for the treatment of acute DVT are available and merit review. Because outpatient DVT treatment programs use LMWHs for an unapproved indication, it is particularly important to confirm that the treatment is well-documented in the medical literature to be safe and effective. In addition to evaluating the published literature, communication with pharmaceutical companies can be a valuable method of obtaining information. Manufacturers may be willing to provide the results of literature searches, as well as share some of their own unpublished data. This may include clinical information from studies they have conducted and practical information such as stability data (in case the protocol calls for the drug to be repackaged). Finally, health care facilities that have established protocols similar to the one under consideration can provide useful information.

Once a program is deemed practical and worthwhile, planning the actual protocol can begin. The next step is to organize a team and develop a plan for implementation of the program itself.

ORGANIZATION OF A PROGRAM DEVELOPMENT TEAM

A multidisciplinary team should be organized to develop the specific details of the program. One potential method for accomplishing this is to present the idea to the organization's Pharmacy and Therapeutics Committee or other appropriate group. This allows for a formal discussion of the proposal and the identification of individuals who are interested in becoming more involved. To best assess the clinical, financial, and operational aspects of the proposal, the team should be composed of both administrators and clinicians.

Economic Considerations

Before a new treatment approach is implemented, it is important to consider its potential financial impact on the managed care organization. The team members who are assigned this task may be health care administrators with a background in business or finance, drug information specialists with a sound knowledge of pharmacoeconomics, or others with the necessary skills.

There are several factors to consider when evaluating the potential financial impact of a program for the outpatient treatment of DVT. One is to estimate the number of patients who would likely be treated in the program, keeping in mind that only a fraction of patients with DVT will be candidates for outpatient treatment. The published clinical trials should be reviewed, noting the percentage of patients who met the inclusion and exclusion criteria. This information can then be combined with specific data from the organization, such as patient demographics, statistics on the incidence of DVT in their patient population, and average lengths of hospital stay for those patients admitted for DVT treatment. Another factor to consider is the estimated costs of increased utilization of ambulatory care resources, which may include clinic visits, drug dispensing costs, the use of a home health care agency, and telephone follow-up.

Pharmaceutical Considerations

In addition to clinical and economic factors, practical issues regarding drug preparation, storage, and administration also merit consideration. For instance, LMWHs currently are packaged in syringes containing single prophylactic doses. Because doses for the treatment of an established DVT are higher, repackaging the drug is necessary in order to provide a convenient means of administering the medication. Therefore, information must be obtained regarding the product's stability and compatibility with other syringes.

A pharmacist or other team member with a sound knowledge of pharmaceutics and the preparation and storage of parenteral medications should be assigned to evaluate the available pharmaceutical data. With this information, decisions can be made regarding the most practical methods for preparing, storing, and dispensing the medication. If the managed care organization has the appropriate equipment for sterile preparation and storage of the product, dispensing may be done directly from the health care facility. Contracting with a home infusion company for these services is another option. Of course, these decisions must be based on sound and reliable data to ensure patient safety.

Protocol Development

Once the members of the program development team have completed their individual research, the team should reconvene to decide how to proceed with the program. If the group decides to move forward, development of the protocol itself is the next step. This should be a multidisciplinary task, involving members of the program development team and outside experts. One or two team members should be placed in charge of
MANAGING CARE: Outpatient Treatment of Uncomplicated DVT

coordinating the program and drafting the written protocol itself.

Both logistical and clinical factors must be considered when developing the specific details of the program. Logistical considerations include determining how patients presenting to affiliated hospital emergency rooms with acute DVT will be referred to the outpatient treatment program. Also, the overall coordination of the patients’ care while they are being treated needs to be planned, including how the drug will be dispensed and administered, who will be in charge of patient monitoring, how many follow-up visits and phone calls will be necessary, and who patients should contact if problems or questions arise.

Clinical factors that must also be taken into account include determining the inclusion and exclusion criteria for participation in the program, deciding what diagnostic and laboratory tests should be conducted when patients begin treatment, determining schedules for concurrent warfarin administration, follow-up examinations, and laboratory tests. These decisions should be based on the methods used in the clinical trials, as well as on the clinical experience of those developing the protocol.

It is essential that the protocol be complete and well-designed to ensure that patients receive the complete course of therapy as well as adequate monitoring and follow-up. It may be helpful to design a flow sheet or critical pathway to clearly delineate the treatments, procedures, and tests that patients will receive throughout their course of therapy. Written educational materials for patients are also helpful. These materials should contain easy-to-understand information about the signs and symptoms of DVT, pulmonary embolism, and bleeding; details about the LMWHs and their potential adverse effects and drug interactions; and the risks and benefits of outpatient DVT treatment.

Outcomes Evaluation

Once the program has been implemented, it is important to measure patient outcomes. Patients should be monitored closely during and after completing the protocol. Any significant events, such as episodes of recurrent DVT or bleeding, should be recorded. Specific clinicians should be assigned this responsibility to ensure that adequate follow-up takes place.

In addition to clinical monitoring, administrative data such as the number of patients treated, hospitalizations avoided, and costs should be collected. Careful documentation will help to verify that the treatment has proven to be safe, effective, and practical within the managed care organization.

THE PHARMACIST’S ROLE

Pharmacists have important roles to play in the development of programs to treat DVT with LMWHs on an ambulatory basis. First of all, they must obtain, interpret, and critique the medical literature and other available information throughout the research process. They must offer objective, insightful conclusions based on this research, and not simply point to the literature that supports what the organization wants to do. This is important, as developing a treatment protocol based on insufficient, biased, or improperly collected medical data could potentially have devastating results for the patients, the practitioners, and the organization.

Pharmacists will also have significant responsibilities to fulfill once the programs have been established. They will be valuable resources for all clinicians by providing information relating to the preparation, storage, and administration of the LMWH. They can also contribute to the evaluation of patient outcomes by monitoring patients during and after completion of the protocol. In addition, pharmacists with a knowledge of pharmacoeconomic principles can evaluate the cost-effectiveness of the program once it has been implemented.

Pharmacists also are key to patient education and compliance. They should be actively involved in the development of all patient information materials. They also should be prepared to counsel patients about the medications, the treatment, the risks, and the benefits of ambulatory care over hospitalization.

CONCLUSION

The treatment of increasingly serious medical conditions is shifting from the hospital to the outpatient setting, and those who provide ambulatory care must meet the challenge of treating these conditions safely and effectively. Acute uncomplicated DVT is one example of a diagnosis that can be treated on an outpatient basis for some patients. This presents an opportunity for managed care organizations and their pharmacists to develop programs that will result in cost savings while maintaining high-quality health care. For the treatment programs to be successful, an organized approach to coordinating patient care is necessary, and a specific protocol should be developed. With proper implementation and follow-up, the program holds promise for success and paves the way for other conditions to be treated on an outpatient basis.

References

OBJECTIVE:
To define four measures of association—relative risk (RR), absolute risk reduction (ARR), relative risk reduction (RRR), and number-needed-to-treat (NNT), demonstrate the method of calculating these values, and discuss the clinical relevance of each value.

DATA SOURCES:
MEDLINE 1991 to present and bibliographies of pertinent articles.

STUDY SELECTION:
Articles designed to assess statistical data interpretation and/or discuss measures of association were evaluated.

DATA SYNTHESIS:
The RR, ARR, RRR, and NNT were calculated for the study endpoints. For the primary endpoint (nonfatal MI or death from CHD), RR=0.70; 2.26% (ARR) of the patients receiving pravastatin were spared the event; 30% (RRR) of the baseline risk was removed as a result of pravastatin therapy and 44 patients need to be treated to prevent an adverse event.

CONCLUSION:
RR, ARR, RRR, and NNT can assist the reader in determining the association between treatment and a health outcome and can be calculated from results of studies reporting dichotomous endpoints. These values can assist in the interpretation of clinical trials to determine the magnitude of benefit from therapy.

KEY WORDS: Decision making, Risk, Treatment outcome, Data interpretation, Attitude of health personnel

J Managed Care Pharm 1997; 3:179-83.

Advertisements and other sources of information present the results of clinical trials evaluating drug therapy in a variety of ways, some of which may be misleading or misinterpreted. This especially is true when health care providers are unaware of the different methods of data analysis and presentation and their significance. Clearly, pharmacists are active in decision making regarding drug utilization and should be able to accurately and appropriately assess the validity of the biomedical literature. However, studies suggest that this isn't always the case. Furthermore, health care practitioners' willingness to select a therapy option may be influenced by the manner in which trial results were presented.

The results of clinical trials are key to managed care pharmacists and other practitioners in determining the efficacy, side effect profile, and other aspects of a drug product. When this data is misleading or misinterpreted, the repercussions may be serious and widespread. Thus, health care practitioners should be well versed in the interpretation of clinical trial results prior to recommending therapy.

One technique to ascertain the clinical impact of drug therapy is to examine four measures of association: relative risk (RR), absolute risk reduction (ARR), relative risk reduction (RRR), and number-needed-to-treat (NNT). These values can assist health care practitioners in determining the association between treatment and outcome. This article will define these measurements, demonstrate the method of calculating these values, and discuss the relevance of each value.

STUDY SELECTION

The Pravastatin Primary Prevention (3P) Trial was selected as a model to demonstrate how to calculate the measures of association using endpoint adverse event data. This study was designed to evaluate the efficacy of pravastatin, an HMG-CoA reductase inhibitor, in preventing coronary
events in men with moderate hypercholesterolemia (see Table 1) and no history of myocardial infarction (MI). A total of 6,595 patients were randomized to either pravastatin 40 mg/day (N = 3,302) or placebo (N = 3,293) and followed for a total of 32,216 subject-years (an average of 4.9 years/subject). The primary endpoint of the study was the occurrence of nonfatal MI or death from coronary heart disease (CHD) as a first event; these two categories were combined. In addition, the effect of treatment on death from any cause, the incidence of nonfatal MI, and the frequency of coronary revascularization procedures were analyzed. The baseline characteristics of the patients enrolled were similar (see Table 1). Further details of the study design are described elsewhere. 

Table 1. Selected Baseline Characteristics of Randomized Patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo (N=3,293)</th>
<th>Pravastatin (N=3,302)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>55.1 ± 5.5</td>
<td>55.3 ± 5.5</td>
</tr>
<tr>
<td>Total cholesterol†</td>
<td>272 ± 22</td>
<td>272 ± 23</td>
</tr>
<tr>
<td>Low-density lipoprotein (LDL)*</td>
<td>192 ± 17</td>
<td>191 ± 17</td>
</tr>
<tr>
<td>High-density lipoprotein (LDL)*</td>
<td>164 ± 68</td>
<td>162 ± 70</td>
</tr>
<tr>
<td>Triglycerides†</td>
<td>164 ± 68</td>
<td>162 ± 70</td>
</tr>
<tr>
<td>Ex-smoker (%)</td>
<td>1,127 (34)</td>
<td>1,138 (34)</td>
</tr>
<tr>
<td>Current smoker (%)</td>
<td>1,460 (44)</td>
<td>1,445 (44)</td>
</tr>
</tbody>
</table>

*Values expressed as mean ± standard deviation.
†Units equal mg/dL.

Table 2. Format of Outcome Data According to Therapy

<table>
<thead>
<tr>
<th>Outcome*</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pravastatin</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Placebo</td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

* Example: Pravastin: Primary Preventive Trial Primary Endpoint

Since dichotomous measurements (“yes” or “no”, but not both) were collected as endpoints, these figures are used to calculate the measures of association. Table 2 shows the format in which the outcomes were arranged to perform the calculations. The 3P Trial endpoint data were entered into this table by adverse event and patient group to calculate the additional measures of association not provided by the study authors.

For instance, 174 pravastatin-treated patients and 248 placebo-treated patients experienced the primary endpoint, while 3,128 pravastatin and 3,045 placebo-treated patients did not. Thus, the corresponding cell letter for each group would be A, C, B, and D, respectively (see Table 3).

Once the outcome data was entered into Table 3, the measures of association were calculated. Relative risk (RR) is the ratio of risk of an event occurring in one group compared to another group. This value indicates the risk of the event after the experimental treatment as a percentage of the original risk. The interpretation of this calculation focuses around the whole number one (1.0). A value of < 1.0 indicates that therapy lessened the risk of developing the adverse outcome in the treatment group compared to placebo. A RR value = 1.0 denotes no difference between treatments. However, a RR value of > 1.0 indicates that therapy increased the risk of developing the adverse outcome. The formula for calculating RR from the gathered data is [A / (A + B)] / [C / (C + D)].

Table 3. Number of Patients with the Primary Endpoint Result

<table>
<thead>
<tr>
<th>Pravastin Primary Prevention Trial Primary Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Pravastatin</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
</tbody>
</table>

Absolute risk reduction (ARR) is defined as the difference in the risk of the outcome between patients who have received one therapy from those who have received another. This measure provides the percentage of patients spared the adverse outcome as a result of receiving the experimental rather than the control therapy, and changes with a change in baseline risk. The formula for calculating ARR is [C / (C + D)] - [A / (A + B)].

Relative risk reduction (RRR), a term used in clinical studies and medication advertisements, estimates the percentage of baseline risk that is removed as a result of therapy. This measure is used to compare the efficacy of treatment to the “control.” Two methods of calculating this measurement are as follows: [C / (C + D)] - [A / (A + B)] / [C / (C + D)] or simply, 1 - RR.

Number-needed-to-treat (NNT), indicates the number of patients who require treatment to prevent one event, and can provide valuable insight into the benefits of therapy. NNT can be calculated by taking the reciprocal of the ARR (1 / ARR).

DATA SYNTHESIS

Calculation examples of RR, ARR, RRR, and NNT for the primary endpoint of the 3P Trial are:

- Relative Risk: [174 / (174 + 3,128)] / [248 / (248 + 3,045)] = 0.70
- Absolute Risk Reduction: [248 / (248 + 3,045)] - [174 / (174 + 3,128)] = 2.26%
- Relative Risk Reduction: [(248 / (248 + 3,045)) - [174 / (174 + 3,128)] / [248 / (248 + 3,045)] = 0.30
  or 1 - 0.70 = 0.30
- Number-Needed-to-Treat: 1 / 0.0226 = 44
Table 4 shows the respective values for RR, ARR, RRR, and NNT according to measured adverse event endpoints of the 3P Trial.

Using the primary endpoint to explain these values in a text format, patients randomized to the pravastatin group benefited compared to placebo-treated patients (indicated by the calculated measures of association). The risk of death or nonfatal MI in the pravastatin group is approximately two-thirds of the original risk (RR = 0.70). In addition, 75 pravastatin patients were spared a nonfatal MI or death from CHD compared to placebo (ARR = 2.26%). Furthermore, approximately one-third of the baseline risk was removed as a result of pravastatin therapy (RRR = 30%), and 44 patients need to be treated for an average of 4.9 years to prevent one nonfatal MI or death from CHD (NNT = 44).

**DISCUSSION**

Measures of association (RR, ARR, RRR, NNT) can be calculated from studies designed to measure dichotomous outcomes as endpoints. Since most studies in general discuss only the relative changes (RR and RRR), additional measures can be calculated to more fully evaluate the clinical significance of the results. The definitions and implications of these measures provide a better understanding of the effect of medical intervention.

**The Influx and Impact of Aggressive Advertising**

As the economics of health care continue to be a major consideration in the delivery of patient care, payers may not be willing to pay for services and/or goods at a premium price when clinically equivalent, lower-priced alternatives are available. In response, some manufacturers compensate through more aggressive marketing techniques to maintain or increase market share. However, the medical literature has expressed some concern about pharmaceutical advertisements that present "misleading" information. In fact, one study by expert reviewers demonstrated that many pharmaceutical advertisements contained deficiencies in areas where the Food and Drug Administration (FDA) has established explicit standards of quality.6 This is of particular concern when one considers the data showing that advertisements influence clinical decisions and physician prescribing.11-13 Clearly, health care professionals need to be aware of the limitations of advertisements and promotional materials. But they also must be prepared to analyze them thoroughly and accurately.

**Deceptive Nature of Numbers**

One method of enhancing promotional materials is to display relative differences or advantages. However, "benefits" presented as relative changes can be misinterpreted due to an absent or hidden (e.g., in small-print) baseline value. For instance, RR and RRR do not reflect the baseline risk in the control population.

A simple example from everyday life illustrates the deceptive nature of relative numbers. A long-distance phone company encourages customers to sign up for their plan by claiming calls will be connected 42% faster than other long-distance companies. Based on the television commercials and direct mail materials, the offer seems attractive. However, an analysis of the data may show otherwise.

First, the consumers should determine what is the baseline time and magnitude of difference for the first company to connect the call versus the second company. If the first company takes 3.5 seconds and the second company takes six seconds, the 42% difference may not be significant. However, if the first company takes 35 minutes and the second company takes 60 minutes (still a 42% difference), there is a significant time disparity. And the cost differences could be significant. This example is comparable to some situations in medical decision making. However, the clinical implications of the risk reductions (3% to 1% versus 60% to 20%) are very different.

Consider a therapy with a 5% incidence of severe side effects that also reduces the probability of an adverse outcome from 3% to 1% (RRR = 66%). This therapy may not be desirable due to the risk-benefit ratio. However, if the therapy reduces the probability of an adverse outcome from 60% to 20% (also a RRR of 66%), it may be acceptable since, out of 100 treated patients, 40 patients would benefit and only five would experience side effects.6

**Presentation of Findings Can Influence Decisions**

Results of several studies have indicated that the manner in which research findings are presented can influence decisions. For example, physicians have been surveyed to determine their willingness to prescribe drug therapy according to vari-
ous measures of association. Although each therapy "option" was obtained from one study (but presented as ARR, NNT, or RRR), the RRR was most favorable and selected most often.1,4

Naylor et al.1 and Bucher et al.2 conducted separate, but similarly designed, studies to determine physician perception of the effectiveness of drug therapy. In the Naylor study, house staff and faculty (internal medicine and subspecialties) were included; the Bucher study focused on primary care physicians (internists and general practitioners). The physicians randomly received one of two separate questionnaires, each containing four statements enumerating the effects of therapy for three endpoint measures (fatal plus non-fatal MI, fatal MI, and total mortality) of the Helsinki Heart study.4 The first three statements were expressed as either RRR (form "A") or ARR (form "B"). The last statement on both forms was the same and expressed the effect of therapy in terms of NNT for fatal plus non-fatal MI. The physicians were asked to grade each therapy according to their perception of therapy efficacy using an 11-point scale (-5 to +5). The far left of the scale (-5) was labeled "therapy is harmful," while the opposite side of the scale (+5) was labeled "therapy is beneficial"; a zero value represented "no effect." Results demonstrated that ratings of therapeutic effectiveness were higher for the questionnaire displaying the results as relative reductions than absolute reductions (p < 0.001). Furthermore, physicians rated the effectiveness of therapy significantly higher for the endpoint represented as risk reduction (either RRR or ARR) than NNT (p < 0.001).

In addition, Forrow et al.3 conducted a study to determine if differences in presentation of research results (emphasizing relative or absolute change in outcome rates) may lead to differences in perceived treatment benefits. Physicians attending educational conferences at either a selected teaching or community hospital were surveyed; selected fellows and faculty received a questionnaire via mail. Two different questionnaires (one for hypertension and one for hypercholesterolemia) were developed, each having six brief statements summarizing information derived from published studies. Following each statement, the participants were asked how this information would affect their decision to treat their patients with this condition. Two of the six questions on each questionnaire reported the outcome of the same study in a different manner, either as RRR or ARR. Physicians were asked to rate the likelihood of starting treatment based on each statement using a seven-point scale (ranging from "definitely more likely to treat" to "definitely less likely to treat"). Results demonstrated that 46% of the physicians responded differently to the same question presented in the two different manners; of these, approximately 90% indicated a stronger desire to treat patients according to the relative, versus absolute, change in the outcome rate (p < 0.0001).

Bobbio et al.4 also surveyed general practitioners to determine whether reporting outcomes as various measures of association affected physician opinions on the treatments' usefulness. The questionnaire presented five different drug "therapies," each expressed as either RRR, ARR, NNT, percentage of event-free patients, or RRR plus relative increase in total mortality. Although each drug "therapy" appeared to be a different drug regimen, all were derived from the same outcome (change in cardiac event incidence) of the Helsinki Heart Study.4 For each therapy, physicians were asked to place an "X" along a 10-cm visual analog scale labeled "I would definitely not prescribe this drug" on the left and "I would definitely prescribe this drug" on the right. The highest response rate for agreement to prescribe the drug was for RRR (78%), while the next highest response (37%) was percentage of event-free patients (p < 0.001).

A survey of authorities responsible for establishing health care policies produced similar results. Participants were presented with two disease state scenarios: breast cancer screening and cardiac rehabilitation. Following these scenarios, four disease prevention "programs" described the effectiveness of each one. The outcome of each "program" was presented as either RRR, ARR, proportion of event-free patients, or NNT. Afterwards, the individuals were asked to rate their willingness to implement the "program" by placing an "X" along a linear scale marked from 0 ("I would not support purchasing of this service") to 10 ("I would strongly support the purchasing of this service"). The highest mean score (95% confidence interval) for both "programs" was for RRR: 79% (76-83%) and 76% (72-80%), respectively (p < 0.05). The next highest mean score was for NNT, 51% (47-55%) and 62% (58-66%). The results indicate that the method of reporting trial results influenced the policy decisions.

**Influencing Medical Therapy and Benefits**

Survey results of pharmacists and patients have demonstrated that views of medical therapy can be influenced by how potential benefits are presented. Papay et al.13 designed a questionnaire to determine if pharmacists were able to recognize different presentation styles of the same study result. The 3P Trial primary endpoint was expressed as RRR, ARR, ARR represented as "rate decreased from 7.9 to 5.5%", or NNT as though each of these were four different "therapies." After reading a brief clinical scenario, pharmacists were asked to select one of the four "therapies" that they would most likely recommend to the medical staff. Preliminary results indicated that only 6.5% of the responders were able to identify that all four "therapies" were equivalent; the highest number of responses (39%) was for ARR represented as "rate decreased from 7.9 to 5.5%.

Hux et al.16 distributed a questionnaire to patients describing the effects of the same medication displayed in three different formats: RRR, ARR, and NNT. Eighty-eight percent of the patients were willing to take the medication when presented as RRR, while the next highest response (56%) was NNT (p < 0.0001). Malenka et al.17 reported similar results — when asked to select a therapy which appeared more beneficial, patients selected the therapy results displayed as RRR most often (56.8%), compared to ARR (14.7%).
Interpreting ARR and NNT

Very few studies include ARR, while even fewer present NNT. Both values incorporate the influence of any change in baseline risk. However, neither of these two measures provide the magnitude of baseline risk. Since NNT is related to the ARR, a change in the underlying risk will cause an alteration in NNT. Furthermore, NNT is directly related to the proportion of patients in the control group that suffer an adverse event. Thus, if the risk of an adverse event doubles, only half as many patients need to be treated to prevent the same number of adverse events, and vice versa.  

A preliminary method to assist in the interpretation of NNT has been proposed by calculating a threshold NNT (T-NNT). In simple terms, the method for generating a T-NNT focuses on the concept that the net cost of treating the number of patients to prevent one adverse event equals the net value of the adverse events prevented by treating that number of patients. As with most therapies, both positive and negative consequences need to be considered in the decision to treat or not to treat. For instance, patients with elevated cholesterol can develop cardiac morbidity and/or mortality if no therapy is initiated. If therapy is initiated, the disease could regress and the patient's risk of cardiac morbidity and/or mortality may be reduced. However, the side effects and costs of treatment should be considered. Generating a T-NNT includes identifying the consequences of treating patients (e.g., side effects) versus not treating (e.g., adverse event). In addition, the associated costs (costs of treating, costs saved by preventing the adverse event, and costs of treating side effects caused by the treatment) are incorporated into the calculations. Although the calculation of the T-NNT is beyond the scope of this article, if a patient's risk of an adverse event without therapy is high and the calculated NNT is below the T-NNT, therapy should be considered, and vice versa. 

Otherwise, the decision to start therapy can be based on the patient's risk of the adverse event if left untreated versus the risk of harm from therapy (e.g., side effects) and/or costs. For example, if pravastatin produces myalgia in 3% of treated patients, the NNT to cause myalgia is 1/0.03 or 33. Thus, for every nonfatal MI or death from CHD prevented, 1.3 patients can experience myalgia. On the other hand, treating 233 patients to prevent one death due to CHD (see Table 4) can result in seven individuals developing myalgia. Despite this simple example, this approach cannot be applied to severe, episodic events. The number of adverse events per life saved (or, if the events are rare enough, the number of lives saved per adverse event) can provide a compelling picture of the trade-offs associated with the clinical intervention. 

CONCLUSION

Health care professionals need to remind themselves of the “limitations” of the medical literature and not be mislead by the presentation styles. As demonstrated by the measures of association formulas, these values can be easily calculated to provide additional data that can be used to evaluate and interpret the biomedical literature and assist in the decision making process.

Those in managed care, including managed care pharmacists, should exercise caution in evaluating review literature, studies, and other information and materials that they use in developing drug benefit programs, formularies, and other components of patient care.
As pharmacy practice has evolved, many pharmacists have found considerable success in the long-term care (LTC) environment. Initially focused on nursing home care, LTC pharmacy practice has evolved to meet the changing needs and format of this rapidly expanding and challenging continuum of care.

Long-term care is simply and most appropriately defined as care that is provided for an extended period of time. This type of care can be practiced in a variety of settings. While the traditional nursing home remains a major focus, LTC also is provided in a host of other environments, each with its own unique definition and challenges. These include assisted-living facilities, hospices, and special units (e.g., for subacute or Alzheimer's disease care).

THE ELDERLY POPULATION

The elderly population is defined as those persons 65 years of age or older. Increased life expectancies have changed the nature of the elderly population. Today's elderly—especially the "young old" aged 65-74—often are still employed, financially independent, active, and generally healthy. The LTC services provided to this segment of the elderly population typically are offered on an ambulatory basis. Many persons in the 75-84 age group—the "middle old"—are still relatively healthy and able to live independently or with limited assistance, although the likelihood of age-related illness and the subsequent need for some type of LTC is increased. The "old old"—age 85 and older—frequently are frail and...
suffer from numerous chronic illnesses of varying severity. They often require comprehensive LTC and a range of social and personal services.

The elderly population, currently numbering 34 million, has been increasing gradually over the years. However, a growth spurt is expected between 2010 and 2030 when the first of the baby boomers reach age 65. By 2030, the total number of persons aged 65 and older will reach 70 million. Meanwhile, as the elderly population grows by 75% during this period, the under-65 population will increase by only 7%.

The fastest growing segment of the elderly population currently is and will continue to be the over-85 population. In 1995, 11.6% of people in the 65-and-over age group were 85 years old or older. This percentage will grow steadily to 15.5% in 2010. In 2050, nearly one-fourth of all the elderly will be over age 85, and at least 1 in 13 Americans will be 80 or older, compared to 1 in 35 in 1990. The 100-and-older population, estimated at 76,000 in 1995, is projected to increase dramatically, reaching almost 1.5 million by 2080.

**LONG-TERM CARE AND THE ELDERLY**

Long-term care is provided to patients of all ages; however, 70% of patients in need of LTC, including care delivered in environments other than nursing home, are elderly. The rapid population growth of elderly, especially the oldest old, will have a profound impact on health care consumption, delivery, and cost. The incidence and cost of chronic conditions requiring LTC—such as hip fracture and Alzheimer's disease—are predicted to increase dramatically. By 2040, it is predicted that 840,000 hip fractures will be treated at a cost of $6 billion (in 1987 dollars), compared to 220,000 in 1987 at a cost of $1.6 billion. The number of patients with Alzheimer's disease is predicted to increase from the current 4 million to as many as 10 million in 2040, and their treatment will cost $149 billion (in 1985 dollars).

The number of elderly persons needing LTC is projected to increase to 13.8 million by 2030; 5.3 million will reside in nursing homes. Most nursing facility residents are elderly—1.3 million (90%) are age 65 and older, and 45% are over the age of 85. By 2040, there could be as many as 5.9 million nursing facility residents over the age of 65; 55% to 65% will be 85 or older.

It is important to note that 80% of the 7.1 million elderly who need LTC and assistance with activities of daily living (ADL) reside in the community—at home or in a non-institutional residence. (ADL includes personal hygiene and grooming, transfer and ambulation, toileting, eating, communication, and managing medications.) And this number is expected to grow.

These changing demographics will place additional demands on the nation's health care system as needs increase and resources dwindle. Alternatives to nursing home care will be needed, and there will be increased attention to health care interventions, including pharmacotherapy, that will reduce or

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**Table 1. The Spectrum of the Long-Term Care Environment**

<table>
<thead>
<tr>
<th>Hospital-based nursing facility</th>
<th>Subacute care</th>
<th>Nursing facility</th>
<th>Psychiatric hospital</th>
<th>Intermediate care facility for the mentally retarded</th>
<th>Community-based care</th>
<th>Adult congregate living</th>
<th>Adult day care</th>
<th>Home health care</th>
<th>Community mental health center</th>
<th>Hospice</th>
<th>Senior center</th>
<th>Retirement housing</th>
<th>Correctional facility</th>
<th>Home care</th>
<th>Independent community living</th>
</tr>
</thead>
</table>

**Table 2. Terminology Describing the Community-Based Care Environment**

<table>
<thead>
<tr>
<th>Residential care facility</th>
<th>Assisted-living home</th>
<th>Board and care home</th>
<th>Chronic custodial care</th>
<th>Congregate care</th>
<th>Domiciliary care</th>
<th>Home for adults</th>
<th>Residential home</th>
<th>Rest home</th>
<th>Sheltered housing</th>
<th>Group home for the mentally retarded</th>
<th>Adult foster home</th>
<th>Community-based care facility</th>
<th>Leisure care facility</th>
<th>Retirement housing</th>
<th>Adult care facility</th>
<th>Life care—continuing care retirement community</th>
<th>Catered housing</th>
<th>Personal board and care</th>
<th>Domiciliary care</th>
<th>Sheltered care</th>
<th>Subsidized apartment building</th>
<th>Residential board and lodging facility</th>
<th>Senior apartment building</th>
<th>Personal care home</th>
</tr>
</thead>
</table>
Table 3. The Growing Long-Term Care Environment—Opportunities for Pharmacists

<table>
<thead>
<tr>
<th>Assisted Living:</th>
<th>30,000 to 40,000 assisted-living facilities care for more than one million people</th>
</tr>
</thead>
<tbody>
<tr>
<td>Board and Care:</td>
<td>32,000 licensed homes for 500,000 people</td>
</tr>
<tr>
<td>Adult Day Care:</td>
<td>10,000 adult day care centers will exist by the end of the decade</td>
</tr>
<tr>
<td>Home Health Care:</td>
<td>14,000 home health care agencies serve 6 million home-bound people</td>
</tr>
<tr>
<td>Hospice:</td>
<td>2,500 hospices serve more than 340,000 patients a year</td>
</tr>
<tr>
<td>Continuing Care Retirement Communities:</td>
<td>More than 1,000 exist now, and their number is predicted to grow to 10,000 in the future</td>
</tr>
<tr>
<td>Retirement Housing—Senior Living Communities:</td>
<td>More than 2,500 communities exist</td>
</tr>
<tr>
<td>Senior Citizen Centers:</td>
<td>As many as 12,000 senior centers serve between 5 and 8 million people a year</td>
</tr>
</tbody>
</table>

This positive trend may be due to technological advances in surgical techniques, such as cataract removal and joint replacement, that enable patients to resume normal activities on recovery. Other reasons for decreased disability in the elderly may include higher education and income levels, which long have been associated with better health. Also, many elderly people are taking steps toward maintaining a healthier lifestyle that includes eating healthier foods, smoking less, drinking less alcohol, getting more exercise, and reducing stress. While their numbers grow, older Americans are becoming more vigorous and interested in maintaining their quality of life. This population will not accept traditional nursing home care, especially if other options are available.

LONG-TERM CARE CONTINUUM: THE IMPACT ON PHARMACISTS

The growth of the older population is having a profound effect on the entire LTC environment. Many older persons who do not need nursing care per se are finding quality and affordable care in living environments that are less formal than those of nursing homes. Many alternatives to nursing home care are evolving in response to the numbers and preferences of the older population. What formerly was characterized primarily as a skilled or intermediate nursing facility is now an assortment of more than a dozen distinct LTC settings (see Table 1).

The LTC setting that is growing most rapidly generally is referred to as community-based care. The care provided in this environment allows residents to maintain maximum independence, yet affords them with necessary health care services. Community-based care is offered in a number of ways and a variety of facilities and is described by more than two dozen terms (see Table 2).

The true spectrum of LTC settings is limited only to the imagination of those who define these new care environments. It is likely that as the long-term care environment continues to develop, additional innovative environments that feature independence and an emphasis on quality of life will evolve.

While the definition and appearance of the many community-based care environments differ, they share some important common features:

- Patients living in this environment are at risk of experiencing problems with drug therapy.
- Caregivers commonly have a less sophisticated understanding of drug therapy than their counterparts working in licensed nursing facilities.
- As a rule these less formal environments do not yet have adequate pharmacy services.

These facts translate into tremendous and growing responsibilities and opportunities for pharmacists, including those in managed care (see Table 3).
EVOLUTION OF PHARMACY PRACTICE IN LONG-TERM CARE

Pharmacy practice in LTC began in the 1950s and gradually has evolved into a well-defined practice model. In the decades between World War II and the enactment of the Medicare and Medicaid programs in 1965, long-term care was state regulated. Conditions were often abysmal. There was little accounting for medication use, and social services were unavailable. During this period, state and federal funding encouraged the construction and upgrading of nursing homes. At the same time, however, requirements for pharmacy involvement were minimal or non-existent.

The enactment of the Medicare and Medicaid programs provided a means for positive change by addressing the potential for drug therapy problems. The initial requirements for participating in and receiving reimbursement from these programs specified that in nursing homes (then referred to as long-term care facilities) “the charge nurse and the prescribing physician together review monthly each patient’s medication.” In spite of this requirement, drug therapy problems continued; and shocking reports continued to relate tales of nursing home care that was unsanitary, unsafe, and compromised by misuse of medications.

Continued attention focused on drug therapy problems in nursing homes which, for regulatory purposes, were divided into two levels of care—skilled and intermediate care facilities. Skilled nursing facilities (SNF) provided 24-hour nursing care, while intermediate care facilities (ICF) provided less-intensive care.

In 1974, conditions for SNF participation in Medicare and Medicaid were strengthened to include a drug regimen review (DRR) to be performed at least monthly by a licensed pharmacist. This stipulation was part of more comprehensive standards for the supervision of pharmaceutical services. These standards included requirements for control, accountability, and proper labeling of medications and biologicals, as well as the establishment of a pharmaceutical services committee, which required the formal participation of a pharmacist.

It is important to note that this mandate for pharmacy services was not based on a long track record of pharmacists’ accomplishments in LTC. Rather, it was based on the assumption that as a discipline specializing in the proper use of medication, pharmacy would be able to solve drug therapy problems that others could not. In fact, when the pharmacist-conducted drug regimen review (DRR) was first mandated, few pharmacists had a clear idea of what this would entail. Caring for the older patient was not part of the training at most pharmacy schools. It was an entirely new frontier of practice.

Led by the example of a few innovators and visionaries, pharmacists began to define and refine the DRR process. They developed their clinical skills, sharpened their communicative abilities, and collaborated with other SNF staff to define new practice responsibilities. Pharmacists monitored drug therapy and made recommendations to physicians, who at the time were not accustomed to having anyone question their prescribing. Pharmacists involved in the early years of nursing home practice can attest to the fact that not all physicians gracefully accepted their comments. However, most physicians soon realized that pharmacists possessed unique expertise that would contribute to improved nursing home care.

Consultant Pharmacy Practice

The pharmacist’s role as a drug therapy expert and an integral member of the interdisciplinary long-term care team gradually was recognized and formalized. This was a key step in the development and formalization of an aspect of pharmacy referred to as consultant pharmacy practice.

In consultant pharmacy, the pharmacist takes on the role of problem-solver and advocate for the older patient. It does not require a particular degree or formal advanced degree training. Only a few states require additional credentials to work as a consultant pharmacist. It is open to all pharmacists who are willing to accept the challenges it offers.

Not limiting its activities simply to the required DRR, consultant pharmacy made great progress in a short time. Practitioners shared stories of their success with colleagues, published reports of their accomplishments, and continued to develop new approaches to caring for the older patient. Where no definition of DRR existed, pharmacists developed one. Where standards for nursing home pharmacy practice were lacking, pharmacists wrote them, thus assuring the continued evolution of pharmacy practice in LTC.

Table 4. Selected Pharmacist Activities in the Long-Term Care Environment

<table>
<thead>
<tr>
<th>Drug regimen review (DRR)</th>
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<tbody>
<tr>
<td>Development of innovative medication distribution systems</td>
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<tr>
<td>Resident assessment and care planning</td>
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<tr>
<td>Drug utilization or use review (DUR)</td>
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<tr>
<td>Drug use evaluation</td>
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<tr>
<td>Quality assurance activities</td>
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<tr>
<td>Continuous quality improvement (CQI)</td>
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<tr>
<td>Infection control</td>
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<tr>
<td>Formulary development</td>
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<tr>
<td>Nutritional support services</td>
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<tr>
<td>Policy and procedure development</td>
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<tr>
<td>Committee participation</td>
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<tr>
<td>Laboratory test ordering and interpretation</td>
</tr>
<tr>
<td>Therapeutic drug monitoring</td>
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<tr>
<td>Facility staff inservice education and training</td>
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<tr>
<td>Medication pass observation</td>
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<tr>
<td>Participation in state survey process</td>
</tr>
<tr>
<td>Clinical research</td>
</tr>
<tr>
<td>Pharmacoeconomic studies</td>
</tr>
<tr>
<td>Specialized clinical activities</td>
</tr>
</tbody>
</table>
Pharmacists practicing in the LTC environment provide a range of cognitive services, from the required DRR to geriatric clinical research. The extent of involvement and variety of services offered depends on the pharmacist’s motivation, formal training or experience, practice environment, relationship with other caregivers, and the availability of reimbursement for services. The efforts of the pharmacist often are well beyond the minimum standards mandated by federal regulations. Many pharmacists have become involved in highly innovative, interactive, and progressive practice activities (see Table 4).

**Pharmaceutical Care Outcomes and Consultant Pharmacy Practice**

The measurement of quality of care in nursing facilities has shifted from standardizing the process of providing care to measuring the outcome of that care. All services provided in nursing facilities and other LTC settings, including pharmacy services, will be judged by this new standard.12 No matter what services the pharmacist offers, he or she must devote constant attention to assessment, accountability, achievement of positive outcomes, and the continuous improvement of services.

<table>
<thead>
<tr>
<th>Table 5. Selected Pharmaceutical Care Services of Consultant Pharmacists 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug regimen review (DRR)</td>
</tr>
<tr>
<td>Monitoring outcomes of patient care</td>
</tr>
<tr>
<td>Identifying and resolving drug interactions</td>
</tr>
<tr>
<td>Counseling patients</td>
</tr>
<tr>
<td>Monitoring drug therapy compliance</td>
</tr>
<tr>
<td>Selecting cost-effective drugs</td>
</tr>
<tr>
<td>Using pharmacokinetic dosing</td>
</tr>
<tr>
<td>Following good formulary management practice</td>
</tr>
<tr>
<td>Conducting drug utilization or use reviews (DURs)</td>
</tr>
<tr>
<td>Educating health care professionals</td>
</tr>
<tr>
<td>Providing case management to coordinate medication use</td>
</tr>
</tbody>
</table>

Traditionally, evaluators of therapy have focused on indicators of health, primarily morbidity and mortality, as the important outcomes to measure. More recently, the definition of outcomes has broadened to include quality of life, health status, health functioning, cognitive functioning, physical functioning, and patient preferences. To satisfy these broader definitions, LTC pharmacists must continue to shift their attention from the dispensing of medications and take full responsibility for the outcomes of their professional activities and therapeutic decisions.

Pharmaceutical care is becoming the domain of all pharmacists, but it is the main focus of consultant pharmacy practice. Consultant pharmacists are well equipped to provide pharmaceutical care because many of the routine practice activities they already offer are oriented towards patient outcomes and pharmaceutical care.19 (see Table 5). Consultant pharmacists have the opportunity and responsibility to monitor outcomes and are able to make decisions about the course of care based on these observations. They need to consider how they can incorporate outcomes data into their day-to-day patient care decisions. As tools to assess quality of life become more widely available, consultant pharmacists will have additional professional opportunities to increase their activities in this area. Consultant pharmacists will work with the interdisciplinary team in a variety of environments—from hospitals to LTC to home health care—to assess health status and improved outcomes and quality of life.

**DEVELOPMENTS IN DRUG THERAPY: IMPLICATIONS FOR MANAGED CARE**

The continuing growth of the elderly population has had an effect on the long-term care environment. This effect is just a glimpse of what is yet to come. And the elderly population holds great significance for managed care.

Research in recent years has brought significant developments in the pharmacotherapy of age-related conditions. These include the introduction of new antidepressants with favorable side-effect profiles, new therapies to manage lipid disorders, drugs to treat prostatic hypertrophy, and most recently, drugs to treat Alzheimer’s dementia. Science will continue to develop drugs for these and other diseases of aging.

According to a recent survey of the U.S. pharmaceutical industry,13 more than 100 new products for diseases of aging are currently being researched (see Table 6). The availability of many of these newer agents creates a significant dilemma for managed care organizations, because long-term benefits from pharmacotherapy may require significant initial financial expenditures.

The availability of new drugs often precedes a full appreciation of whether their use by the elderly will be cost-effective. For example, although it has been demonstrated that the management of lipid abnormalities is beneficial in the adult population, it is not known whether the same benefits accrue in the elderly. Healthcare providers also question whether drug

| Table 6. Selected New Drugs in Development for Diseases of Aging |
|-----------------------------|------------------|
| Number of Drugs in Development | Disease                  |
| 20                          | Rheumatoid arthritis |
| 18                          | Respiratory/lung disorders |
| 17                          | Diabetes              |
| 15                          | Osteoporosis          |
| 14                          | Alzheimer’s disease  |
therapy should be used to manage prostatic enlargement in lieu of expensive surgery. The availability of new drugs for Alzheimer's disease adds even more confusion to the overall picture since in some patients, but not all, the use of these agents may delay nursing home admission and the expensive care that goes with it.

Managed care organizations must develop interventions including approaches to disease-based management, such as geriatric formularies, that will govern the appropriate use of these agents. The widespread use of new drugs that are not cost-effective must be avoided. However, at the same time, the appropriate use of agents that will benefit elderly patients must be encouraged. Formularies, critical pathways, and other tools used for elderly patients in managed care must be developed specifically for this population and not just adapted from those used for general patient populations. Medications and therapies that are used cost effectively with younger patients may not produce the same outcomes with elderly patients. In developing drug benefit programs, the literature as it relates specifically to the geriatric population must be considered.

**Implications for Pharmacy Practice**

Long-term care has not attracted the attention of managed care organizations in the same way that primary and acute care have, although significant exceptions exist in Minnesota, Arizona, Tennessee, and South Carolina, where programs are in place to bring managed care to LTC by combining payment for acute and LTC under a single capitated rate. As a rule, managed care organizations may shy away from the low-income, chronically ill elderly who have high health care use with costs that may be difficult to manage and predict.

The economic realities of LTC are likely to demand the attention of managed care organizations in the near future. After all, the elderly and disabled account for 70% of the nation's Medicaid expenditures, much of which is for LTC patients.

Managed care providers must realize that the expertise of pharmacists is crucial to the success of evolving LTC for many reasons: The population of the elderly, especially the frail elderly who are more likely to experience drug-related problems is growing; care is increasingly likely to be provided both by nonprofessionals and by professionals who have less than optimal knowledge of pharmacotherapy; new and expensive drugs are more available; and the need is growing for outcomes research that documents whether the new interventions in pharmacotherapy add to the quality of health care or simply increase costs.

The experience and skills that pharmacists have acquired in nursing homes have become a template for advancing pharmacy services in the rapidly growing LTC environment that exists outside of the nursing home. Inevitably, this will include LTC environments within the realm of managed care.

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**References**


9. Anon. Americans looking forward to old age, 61% want to live to 100, survey finds. Consult Pharm 1993; 8: 176


17. Porter L. What significant changes can LTC providers anticipate in the next decade? Contemp Longterm Care 1994; 17: 39-41.


CONTINUING EDUCATION: PHARMACY PRACTICE IN THE LONG-TERM CARE ENVIRONMENT

LEARNING OBJECTIVES

After completing this continuing education program, the reader should be able to:

• Define in general terms the long-term care environment.

• List at least three reasons for the growth of community-based long-term care.

• Identify at least two possible roles for pharmacists in the long-term managed care environment.

CONTINUING EDUCATION QUESTIONS

1. Which of the following terms best describes long-term care?
   a. Care that is provided for an extended period of time.
   b. Nursing home care.
   c. Care for the elderly.
   d. None of the above.

2. Which of the following are reasons for the growth of the community-based long-term care environment?
   a. The elderly population is increasingly active and vigorous.
   b. Nursing home care.
   c. Care for the elderly.
   d. None of the above.

3. Which of the following is a possible role for pharmacists in the long-term managed care environment?
   a. Helping to evaluate the cost-effectiveness of new drugs.
   b. Educating caregivers about drug therapy.
   c. Reviewing drug therapy to prevent complications.
   d. All of the above.

4. Which segment of the population is growing most rapidly (in numbers)?
   a. Children under age two.
   b. The elderly (over age 65).
   c. The “old-old” (over age 85).
   d. None of the above.

5. How many persons in the United States are 100 years old or older?
   a. 7,600.
   b. 10,000.
   c. 76,000.
   d. 760,000.

6. Approximately how many people in the United States have Alzheimer’s disease?
   a. 4,000.
   b. 40,000.
   c. 400,000.
   d. 4,000,000.

7. How often is drug regimen review required in skilled nursing facilities that participate in Medicare and Medicaid programs?
   a. Weekly.
   b. At least monthly.
   c. Semi-annually.
   d. Annually.

8. How many new products for diseases of aging are now being researched?
   a. Fewer than 20.
   b. Between 20 and 50.
   c. Between 50 and 100.
   d. More than 100.

9. Most states require a pharmacist to pass a special examination to practice as a consultant pharmacist.
   a. True.
   b. False.

10. Consultant pharmacy practice is limited to the long-term nursing facility environment.
    a. True.
    b. False.

See text of article beginning on page 189 of this issue of JMCP.

This article qualifies for 1.0 hour of continuing pharmaceutical education (0.1 CEU). The Academy of Managed Care Pharmacy is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. This is program number 233-000-91-004-H04 in AMCP’s educational offerings.
PROFICIENCY: Pharmacy Practice in the LTC Environment

DEMOGRAPHIC INFORMATION
(not for scoring)

11. In what type of setting do you work (leave blank if none of the responses below applies)?
   a. HMO.
   b. PPO.
   c. Indemnity insurance.
   d. Pharmacy benefits management.

12. Did this program achieve its educational objectives?
   a. Yes.
   b. No.

13. How many minutes did it take you to complete this program, including the quiz (fill in on answer sheet)?

14. Did this program provide relevant or practical insights into yourself or your work?
   a. Yes.
   b. No.

15. Please rate the quality of this CE article.
   a. Excellent.
   b. Good.
   c. Fair.
   d. Poor.

INSTRUCTIONS

This quiz affords 1.0 hour (0.1 CEU) of continuing pharmaceutical education in all states that recognize the American Council on Pharmaceutical Education. To receive credit, you must score at least 70% of your quiz answers correctly. To record an answer, darken the appropriate block below. Mail your completed answer sheet to: Academy of Managed Care Pharmacy, 1650 King Street, Suite 402, Alexandria, VA 22314. Assuming a score of 70% or more, a certificate of achievement will be mailed to you within 30 days. If you fail to achieve 70% on your first try, you will be allowed only one retake. The ACPE Provider Number for this lesson is 233-000-97-004-H04. This offer of continuing education credits expires March 31, 1998.

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5. □ □ □ □
11. □ A □ B □ C □ D
12. Yes □ No
13. Minutes ______________
14. □ Yes □ No
15. □ A □ B □ C □ D

Participant Identification: Please type or print

Social Security # ___________________________ Date ___________________________
For Identification Purposes Only

Name ___________________________
   Last First Middle

Company ___________________________

Address ___________________________
   Street (with Apt. No.) or P.O. Box ___________________________
   City ___________________________ State ______ Zip ______

State and Lic. No. ___________________________
   State ___________________________
   No. ___________________________

Member Type: □ Active □ Supporting Associate
   □ Student □ Nonmember

Signature ___________________________
Pharmacoeconomic Analysis of Hormone Replacement Therapy—Implications for Managed Care

Edward P. Armstrong

OBJECTIVE:
To summarize the rationale, benefits, and risks of hormone replacement therapy (HRT), assess the pharmacoeconomic analyses of HRT, emphasize its role in decision making within health systems, and identify the implications for managed care organizations.

DATA SOURCES:

STUDY SELECTION:
Articles describing the cost-minimization, cost-effectiveness, cost-utility, or cost-benefit of HRT were included.

DATA EXTRACTION:
Because of the long duration of treatment with HRT, no computer databases are available for analysis. Researchers have built models based on economic and demographic data and clinical trials. These data are reviewed and case examples are presented.

DATA SYNTHESIS:
Pharmacoeconomic data indicate that women most likely to benefit from HRT are women at risk for hip fractures (e.g., because of family history, or low bone mineral density), women having menopausal symptoms, women at increased risk for heart disease, and women having had a hysterectomy. Medical literature reveals several important implications for managed care organizations. HRT is underutilized and specific groups of women may especially benefit from this intervention. HRT should be combined with nondrug therapy. Patient compliance is critical if benefits from this chronic therapy are to be realized.

RISKS OF ESTROGEN LOSS FOLLOWING MENOPAUSE

Osteoporosis and Hip Fracture
An estimated 15-20 million Americans have osteoporosis, a gradual thinning of bone that leads to decreased bone density. The development of bone fractures is an important complication that may occur with osteoporosis. Each year, approximately 1.5 million fractures, including at least 250,000 hip fractures, occur in the U.S. because of osteoporosis. Hip fractures are estimated to cost U.S. health systems at least $8 billion annually. These fractures also have an important long-term impact on health care, as fewer than 30% of the people who suffer hip fractures are able to recover fully and resume normal physical functioning.

Because the U.S. population is aging rapidly, it is anticipated that the costs of osteoporosis-related fractures will increase. One study has estimated that the direct medical cost to U.S. health systems to manage osteoporosis fractures among U.S. white women aged 45 or older will be $45.2 billion over the next 10 years.

Multiple factors contribute to the development of
osteooporosis. The most important is estrogen deficiency after menopause.8 Following menopause, women experience decreased estrogen levels. This contributes to bone mineral loss and the development of osteoporosis. It is well established that estrogen therapy helps protect women against postmenopausal osteoporosis.9 Estrogen therapy inhibits resorption of bone and minimizes bone loss.9

In examining the relationship of menopause, estrogen deficiency, and the development of osteoporosis, it is essential to note that the loss of bone mineral is greatest within the first five years of menopause.11 An important consequence of bone mineral depletion is increased risk of bone fractures. The most common fractures are those of the vertebrae, hip, and wrist. Hip fractures are more common in elderly women (i.e., those at least 75 years of age) and have a significant mortality rate of 5% to 20% in the first year.12,13 In addition, at least half of women who suffer hip fractures also experience considerable disability. Table 1 shows what types of women are at greatest risk of developing osteoporosis.14

Increased risk is noted particularly in white and Asian women and women with a family history of fractures, low bone density, and multiple risk factors. Lifestyle factors that contribute to increased risk of fracture include low dietary calcium intake, sedentary behavior, smoking, and high caffeine or alcohol intake. A recent study also has identified risk factors for hip fractures in white women.15 This study found that women with a maternal history of hip fractures faced twice the risk of those without. Risk also was higher in women who:

- had poor contrast sensitivity;
- had a tachycardia at rest; or
- had low calcaneal bone density.

An increase in weight after age 25 was associated with a lower risk of hip fractures in these women. A previous study found that the risk of hip fractures was reduced by active exercise, a high body mass index, high parity, late age at menarche, and long menstrual cycle length.16 This study also found the lowest risk of hip fractures in women recently receiving estrogen therapy. The authors observed that the protective effect of estrogen is lost after many years when the HRT is discontinued.

### Cardiovascular Disease

In addition to fracture risk and osteoporosis, a second major concern is that the incidence of cardiovascular disease increases in postmenopausal women.14,17 This is especially true in women having undergone a surgical oophorectomy. It has been well established that the incidence of atherosclerosis increases after menopause.8 Various mechanisms, including a changed androgen/estrogen ratio, contribute to the changes in lipid profiles that follow estrogen loss and may contribute to the development of cardiovascular disease. These postmenopausal changes may promote the development of atherosclerosis, hypertension, and coronary artery disease.18

Because women now live longer, their years after menopause may account for approximately one-third of their total lives. Cardiovascular disease has now become the greatest killer of women.19 This is a major concern to health systems and managed care organizations. Estrogen therapy appears to reduce the risk of patients developing, and dying from, coronary artery disease.a,19

### Estrogen Loss and Acute Symptoms

Estrogen loss may lead to the well-known symptoms of menopause, including hot flashes, sweating, atrophic vaginitis, urethritis, and dyspareunia.20 Vasomotor symptoms occur in 75% of postmenopausal women, although only 30% seek medical care to reduce these symptoms.8 Insomnia may occur secondarily to the vasomotor symptoms. Most women will have hot flashes and sweating for less than one year; however, one-fourth of women will have these acute symptoms for more than five years.1 Estrogen deficiency also leads to atrophy of the vagina and urethra, thus reducing lubrication leading to dyspareunia. In addition, estrogen loss can produce a urethral syndrome including urinary urgency and frequency, urge incontinence, and dysuria. These acute symptoms obviously affect the quality of life of postmenopausal women.

### HORMONE REPLACEMENT THERAPY

Although the important risks of estrogen loss following menopause are well known, HRT continues to be an underutilized therapy.21 Within the United States, less than 30% of
eligible women receive HRT. In addition, many women with prescriptions for HRT have them filled sporadically or not at all, or stop taking their medication within the first year of treatment. Although there are no published HRT compliance rates for managed care populations, it is presumed that these concerns are real in all settings, including managed care.

**Benefits of HRT**

**Symptom Relief.** Vasomotor symptoms of menopause are treated most effectively with estrogen. Hot flashes reliably respond to HRT, often in the first cycle of treatment. Urogenital changes, such as urgency, urge incontinence, and dysuria, also respond to HRT with continued use. Conjugated estrogen of 0.3 or 0.625 mg per day, or the equivalent dose of another estrogen product, usually is quite effective. For the treatment of acute symptoms, the estrogen often can be tapered off within one year. However, therapy often is continued to reduce the risk of cardiovascular disease and osteoporosis.

**Cardiovascular Disease.** Estrogen use is associated with reductions in the incidence of and mortality from coronary heart disease. Estrogen therapy also may produce a lower incidence of strokes. There is no evidence that estrogen therapy increases the risk of venous thrombosis in postmenopausal women.

The cardioprotective effect of estrogen is likely related to its action on serum lipids and lipoprotein concentrations. Estrogen treatment produces a reduced low-density lipoprotein (LDL) cholesterol, increased high-density lipoprotein (HDL) cholesterol, reduced plasma fibrinogen levels, and/or increased fibrinolytic potential. These are the most frequently mentioned epidemiological results of estrogen therapy that lead to fewer cardiovascular complications.

**Estrogen Products**

Managed care pharmacists should keep in mind that not all estrogen products are the same. Although any estrogen product may reduce the vasomotor symptoms of menopause, various products will have different effects on lipid levels. For example, when estrogen is administered as a transdermal patch, the estrogen has a minimal effect on raising HDL cholesterol and almost no effect on lowering LDL cholesterol. The addition of a progestogen to estrogen therapy appears to lower these benefits slightly. Beyond its effect on lipids, estrogen therapy may have beneficial actions on coagulation, clot lysis, prostacyclin vasodilation, and angiotensin-converting enzyme inhibition.

Although studies that demonstrate a decline in cardiovascular complications with estrogen therapy are encouraging, some reservation in recommending universal prescribing of HRT remains. Despite the epidemiological data available, some researchers suggest the possibility of a "healthy woman effect," that is, women in cardiovascular disease studies who chose to receive HRT may have had other characteristics that could have reduced cardiovascular complications. To resolve this issue, a Women's Health Initiative study is now evaluating the effects of HRT on cardiovascular disease, fracture rates, osteoporosis, and mortality.

**Estrogen and Osteoporosis**

Estrogen unequivocally reduces fracture risk associated with osteoporosis. Estrogen clearly inhibits bone resorption and prevents bone loss and even increases bone in postmenopausal women. This study documented similar efficacy in both cyclic and continuous estrogen regimens. It is the agent of choice for the prevention of postmenopausal bone loss and is useful in the treatment of established osteoporosis.

Conjugated estrogens have been studied most, but any estrogen appears to produce this beneficial effect on bone loss. An important long-term issue for managed care organizations is that if HRT is discontinued, bone loss immediately increases at a rate similar to that observed in untreated women. Therefore, compliance with treatment such as HRT is extremely important. Patients also should ensure an adequate calcium intake, participate in a regular exercise program, avoid smoking and alcohol use, and avoid falls.

**RISKS OF HRT**

**Adverse Effects**

The return of regular monthly bleeding associated with cyclic combination HRT is an unwelcome effect for many women. It also contributes to reducing long-term compliance with HRT. Other adverse effects, including breast tenderness, edema, bloating, and dysmenorrhea occur in a minority of patients and usually are mild and self-limiting. Estrogen therapy may change the bile content and should be used with caution in women with known gallbladder disease. Women also may suffer from "menstrual migraine" and postmenopausal headaches.

**Cancer Risk**

Progestogens are added to estrogen therapy to offset the increase in endometrial hyperplasia and the risk of endometrial cancer that has been associated with unopposed estrogen use. The administration of a progestogen, such as 10 mg medroxyprogesterone per day for 12 days each month, prevents the endometrial complications. In women having undergone hysterectomies, a progestogen does not need to be included in the regimen.

The second major concern is the possible link between estrogen therapy and breast cancer. The question of whether estrogen use leads to an increased risk of breast cancer is quite controversi. Multiple studies have produced conflicting results. Contraindications to HRT include suspected or current estrogen-dependent breast cancer and undiagnosed abnormal vaginal bleeding. A history of breast cancer may not be an absolute contraindication to estrogen therapy, particularly in a patient with severe menopausal symptoms.
PHARMACOECONOMICS OF HRT

The role of HRT has generated tremendous discussion among clinicians and within health systems such as managed care organizations.10,36,44 HRT is a complex therapeutic issue because it has a range of benefits and risks. To clarify some of these issues, researchers have created a number of pharmacoeconomic models to estimate the impact of prescribing HRT for patient populations. These models are important for managed care organizations because they enable costs and outcomes to be estimated for health systems.

Pharmacoeconomic Analyses

Pharmacoeconomic evaluations consider both the beneficial and adverse consequences of therapies. With HRT, examples of benefits include resolution of vasomotor symptoms, reduction in hip fractures, and a decline in the rate of nursing home admissions following hip fractures. Examples of adverse consequences include therapy adverse effects (e.g., bothersome vaginal bleeding) and possible increased risk of breast cancer. Typically, pharmacoeconomic analyses compare two drugs and provide a cost-effectiveness ratio. However, a broader definition of pharmacoeconomics is emerging in which the costs and outcomes associated with alternative therapy treatments are included in the performance assessment of health care systems.45 Although these definitions are similar, the latter stresses that all the principal therapies for a disease should be considered and that the analysis should be done from a health system perspective to include an effectiveness evaluation.

There are four types of pharmacoeconomic analysis that are used to assess drug therapy interventions: cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis.46 Cost-minimization analysis is appropriate when treatment outcomes are equivalent and the costs of treatment regimens are compared. After outcome equivalence has been demonstrated, the analysis involves selecting the least expensive strategy.47 Unfortunately, cost-minimization analysis frequently is inappropriately called cost-effectiveness or cost-benefit analysis. True cost-effectiveness analysis determines which therapies meet a specific objective at the lowest cost.48 A common outcome objective is cost per life-year saved. Most pharmacoeconomic studies evaluating HRT utilize cost-effectiveness methodologies to determine the impact on patients' life expectancies. Cost-utility analysis is similar to cost-effectiveness analysis, but adds patient preference to the outcome measurement. Thus, rather than simply evaluating cost per life-year saved, cost-utility analysis provides cost per quality-adjusted life-year (QALY) saved.49 This is particularly important in evaluating HRT because of the adverse quality-of-life impact of hip fractures, menopausal symptoms, and treatment adverse effects. Lastly, with cost-benefit analysis, costs (inputs) and outcomes are both evaluated in monetary terms.50 This type of analysis is beneficial, although

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<th>Table 2. Pharmacoeconomics of HRT</th>
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<td>51</td>
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Table 2. Continued on following page
Table 2. Pharmacoeconomics of HRT (Continued from previous page.)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Framework</th>
<th>Treatments</th>
<th>Results</th>
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<tbody>
<tr>
<td>44</td>
<td>Decision-analytic model of perimenopausal, asymptomatic white women with uteri.</td>
<td>Three treatment groups were no treatment, 15 year estrogen-progesterone therapy for 15-years if low bone mass, and unselective, universal estrogen-progesterone therapy.</td>
<td>When quality of life is included, bone-densitometry screening was cost-effective over a range of assumptions. Universal HRT has a high incremental cost-effectiveness ratio beyond screening, without considering HRT's impact on cardiovascular disease.</td>
</tr>
<tr>
<td>45</td>
<td>Cost-effectiveness analysis to model 10 years of HRT beginning at 50 years of age.</td>
<td>Estrogen only in women with hysterectomy; estrogen plus progesterone if uterus present, estrogen only if uterus present.</td>
<td>Reduction in cardiovascular disease from HRT is likely to exceed any small increase in breast cancer risk. The cost-effectiveness of long-term prophylactic HRT in women with a hysterectomy and women with menopausal symptoms and a uterus is similar to other health care treatments.</td>
</tr>
<tr>
<td>46</td>
<td>Cost-effectiveness study to assess the risk of endometrial cancer, uterine bleeding, and gallbladder disease, and the benefits of reduction in menopausal symptoms and prevention of osteoporosis and subsequent fractures.</td>
<td>Three groups: women with menopausal symptoms treated from 50 to 60 years of age, women with osteoporosis complications within 10 years of menopause treated from 55 to 70 years of age, and asymptomatic postmenopausal women treated from 50 to 65 years of age.</td>
<td>HRT is cost-effective in menopausal women with a hysterectomy or osteoporosis. HRT is not cost-effective as a prophylactic therapy in women with a uterus and no menopausal symptoms. The effect on QALY's is larger than the impact on life expectancy.</td>
</tr>
<tr>
<td>47</td>
<td>Quality-of-life questionnaire to assess impact of menopausal symptoms.</td>
<td>Women between the ages of 45 and 60 divided into three groups; never receiving HRT, current or past HRT with mild menopausal symptoms, or current or past HRT with severe menopausal symptoms.</td>
<td>Menopausal symptoms resulted in low quality-of-life ratings. These ratings significantly improved following HRT, especially for those women with severe symptoms.</td>
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Table 2. Continued on following page.
lost productivity from reduced fractures. Indirect cost estimates (e.g., lost earnings, housekeeping services) also were included in the analysis, making this the most comprehensive study to date.

The cost-of-illness savings (present value, with a discount rate of 6%) for this group of patients during a 40-year time period would be $5.1 million. Sensitivity analyses revealed that the study results were sensitive to the compliance rate, especially in the high-risk group. For each increase of 10% in the high-risk group, there was an increased net savings of $1.9 million. The authors extrapolated their study results to the U.S. population of 50-year-old white women. They estimated that if it were possible to conduct bone density screening in 50% of these women and treat 90% of the high-risk and 70% of the mid-risk patients, the potential net savings for this population would be $27.6 million.

### Cost-Effectiveness and Cost-Utility of HRT

Several studies with different methodologies have evaluated the cost-effectiveness and cost-utility of HRT. The articles evaluating the pharmacoeconomic aspects of HRT are summarized in Table 2. Economic models have been developed to analyze HRT by including estimates of reductions in risk for hip fractures, cardiovascular mortality, and cerebrovascular disease. In addition, these models consider the possible increased risk of breast cancer and endometrial cancer (endometrial cancer risk is not increased if estrogen and progestogen are combined in women with an intact uterus). Quality-of-life estimates are included in some studies because hip fractures may significantly lower patients’ quality of life, depending on the level of disability resulting from the fracture.

Tosteson and associates have published several evaluations of HRT (included in Table 2). Their HRT decision model is quite detailed and includes the anticipated impact of HRT on fractures, nursing home admissions, heart disease mortality, breast cancer mortality, and quality of life. Table 3 lists the effectiveness and cost factors estimated within their model. To date, this is the most thorough cost-effectiveness model of HRT. Although the researchers created a complex model, it still did not consider the impact of indirect costs, the reduction in health care costs resulting from decreased rates of heart disease in women receiving HRT, or the costs of any breast cancer treatment. The researchers’ model estimated the costs and consequences of two populations: (1) 50-year-old women with an intact uterus receiving conjugated equine estrogen 0.625 mg daily plus medroxyprogesterone acetate 5-10 mg on days 1-13 monthly for 10-15 years, and (2) 50-year-old women with a previous hysterectomy receiving the same estrogen therapy (without the progestogen) for 10-15 years. The study used a Markov state-transition model and estimated the costs and consequences for women who were initially well at age 50 until their death or age 99. The model was designed to estimate the annual incidence of hip fractures and associated sequelae, placement in nursing homes, coronary heart disease deaths, and deaths from other causes.

The results of this hypothetical model indicate that the cost of HRT drugs and monitoring exceeded the cost savings resulting from fewer hip fractures and nursing home admis-

### Table 3. Characteristics of a cost-effectiveness model for HRT

<table>
<thead>
<tr>
<th>NET EFFECTIVENESS (life expectancy)</th>
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<tbody>
<tr>
<td>• Coronary heart disease mortality decreased</td>
</tr>
<tr>
<td>• Osteoporotic hip fracture mortality decreased</td>
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<tr>
<td>• Possible breast cancer mortality increased</td>
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</table>

<table>
<thead>
<tr>
<th>QUALITY-ADJUSTED LIFE EXPECTANCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Morbidity if hip fracture occurs</td>
</tr>
<tr>
<td>• Menopausal symptom relief</td>
</tr>
<tr>
<td>• Adverse effects from HRT</td>
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</tbody>
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<table>
<thead>
<tr>
<th>NET COST</th>
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<tbody>
<tr>
<td>• HRT costs (drugs and physician visits)</td>
</tr>
<tr>
<td>• Cost of long-term nursing home care saved</td>
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<tr>
<td>• Hip fracture treatment cost saved</td>
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</tbody>
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Table 2. Pharmacoeconomics of HRT (Continued from previous page)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Framework</th>
<th>Treatments</th>
<th>Results</th>
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<tbody>
<tr>
<td>50</td>
<td>Cost-effectiveness model considered relative risk of death from myocardial infarction, menopausal symptoms, and presence or absence of a uterus.</td>
<td>Comparison in women 50 years of age receiving and not receiving HRT regimens.</td>
<td>HRT following a hysterectomy is cost-effective. HRT is cost-effective in women with menopausal symptoms. Prophylactic HRT is “intermediate” in cost-effectiveness in women with an intact uterus.</td>
</tr>
<tr>
<td>53</td>
<td>Cost-effectiveness analysis of 10 years of therapy beginning at age 50. The model estimated the impact of mortality and morbidity induced or prevented by HRT, the changes in quality of life, and health care costs associated with treatment.</td>
<td>Women with intact uteri received HRT. Women following hysterectomy received estrogen only.</td>
<td>A reduction in cardiovascular disease risk from HRT will greatly overshadow any small increase in breast cancer risk. HRT use in women with menopausal symptoms and women following a hysterectomy is cost-effective.</td>
</tr>
<tr>
<td>43</td>
<td>Model of 100,000 women 50 years of age received bone density screening and treatment based on bone density.</td>
<td>90% of high risk, 70% mid-risk, and 9% of low-risk received HRT for 15 years.</td>
<td>Present value of savings (including indirect costs) is $5.1 million over 40 years in a group of 100,000 white women.</td>
</tr>
</tbody>
</table>
Table 4. Cost per quality-adjusted life-year for women with a uterus treated for 15 years

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Model Assumption</th>
<th>No Breast Cancer Risk with HRT</th>
<th>Possible Breast Cancer Risk with HRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>No menopausal symptoms and no HRT adverse effects</td>
<td>$17,900</td>
<td>$32,000</td>
<td></td>
</tr>
<tr>
<td>No menopausal symptoms and HRT adverse effects</td>
<td>$26,300</td>
<td>$70,000</td>
<td></td>
</tr>
<tr>
<td>Symptomatic and no HRT adverse effects</td>
<td>$9,700</td>
<td>$13,000</td>
<td></td>
</tr>
<tr>
<td>Symptomatic and HRT adverse effects</td>
<td>$11,600</td>
<td>$16,600</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Patient characteristics that improve the cost-outcome ratio of HRT

- Significant menopausal symptoms
- Having undergone a hysterectomy
- High risk of osteoporotic fractures (low bone density)
- Moderate risk for fractures if compliance is good
- High risk of cardiovascular disease
- Compliant with HRT regimen

Women with various characteristics. This table demonstrates that women with menopausal symptoms who do not suffer from HRT adverse effects have the lowest cost-effectiveness ratio (i.e., it is easiest to produce benefits for these patients). Women suffering from HRT adverse effects have a slightly higher cost-per-QALY ratio.

In addition to the study assumptions, there were several noteworthy limitations. For example, the researchers did not consider the use of HRT in older women, included only hip fractures (not vertebral, wrist, or limb), and did not estimate cost savings from reduced cardiovascular complications.

Each of the other pharmacoeconomic studies summarized in Table 2 used its own assumptions and methodologies. Since the studies are hypothetical models with different methods, it is difficult to compare their results and impossible to combine them in a meta-analysis. The most recent study was conducted by Daly33 whose pharmacoeconomic model was created to estimate the cost-effectiveness of HRT in hypothetical groups of patients receiving HRT (or estrogen alone in women following a hysterectomy) for 10 years beginning at age 50.

Table 5 summarizes the patient populations with the best HRT cost-outcome ratios identified from the pharmacoeconomic models. These characteristics describe patient groups for whom it is easiest to provide benefit with HRT. These characteristics are important for managed care organizations because these patients should be strongly encouraged to start and continue HRT. Although many managed care organizations have encouraged the use of HRT in general, these pharmacoeconomic models suggest that special efforts should be made to initiate and maintain HRT with these patients.

Table 6 identifies cost-outcome characteristics of HRT. The benefits of HRT are more evident in cost-utility terms (adjusting for quality of life), than in cost-effectiveness terms (from prolonged life). This is because HRT reduces disability in patients from lower frequencies of hip fractures and also minimizes vasomotor symptoms. It also demonstrates that improvements in quality of life are more significant than increases in life expectancy.

**IMPLICATIONS FOR MANAGED CARE**

Table 6. Cost-outcome characteristics of HRT

| Cost per quality-adjusted-life year (QALY) is lower than the cost per life-year saved |
| Cost per QALY is similar to the cost/QALY estimated for other health care interventions common in older patient populations |
| Cardioprotective abilities of HRT significantly contribute to its cost-effectiveness |
| Long-term therapy (≥10 years) usually is more cost-effective than short-term therapy (≤5 years) |
HRT is an underutilized therapy, and many appropriate HRT candidates remain untreated. This is a significant opportunity for managed care organizations to identify patients that are candidates for HRT. Although HRT is recommended for all women without contraindications, managed care organizations at least should identify patient groups most likely to benefit from HRT (see Table 5) and encourage them to receive therapy. The potential beneficial and adverse consequences of HRT primarily reside outside the pharmacy budget. The economic, clinical, and quality-of-life implications of osteoporosis (especially hip fractures) and the risk of heart disease affect multiple budgets within health systems. An appropriate analysis will have a health system perspective and not be limited to drug costs.

Pharmacists will play a key role in the success of HRT because patient compliance is essential for the therapy to have a lifelong benefit. Pharmacists must counsel patients about potential side effects and the importance of taking the medication on a regular basis. Compliance is necessary if patients and health systems are to obtain the beneficial clinical, economic, and quality-of-life outcomes from HRT.

Appropriate pharmacoeconomic evaluations should include all principal-treatment options. Historically, the primary drug intervention has been HRT combined with calcium and nondrug treatments. As new pharmacologic agents become available (e.g., alendronate), pharmacoeconomic analysis is needed to measure costs and outcomes in order to identify populations of patients that may benefit from combination therapy. Effectiveness analyses to determine changes in prescribing patterns and their resulting costs and outcomes are also needed.

CONCLUSION

HRT produces a beneficial effect on clinical, economic, and quality-of-life outcomes. When indirect costs are included, there is a net savings to society from prescribing HRT in high-risk patients. In addition, clinical outcomes are improved by reducing the number of hip fractures, and quality of life is improved by minimizing menopausal symptoms and avoiding disability from hip fractures. Although HRT is recommended for all patients without contraindications, pharmacoeconomic data indicate that women most likely to benefit from HRT are those at risk for hip fractures (e.g., because of family history or low bone-mineral density), those suffering menopausal symptoms, those at risk for heart disease, and those having undergone a hysterectomy. Managed care organizations should identify high-risk patients and encourage HRT use in their health systems.

Case Studies

▲ CASE #1

DT is a 52-year-old perimenopausal Asian woman in good health who is experiencing only minor hot flashes. Her mother has osteoporosis and has suffered vertebral fractures. DT is thin and tends to stay inside her home. Is DT a good candidate for HRT?

Yes. Although DT is having only minor hot flashes, she has multiple risk factors for osteoporosis and bone fractures.

▲ CASE #2

SR is a 55-year-old postmenopausal woman suffering from severe menopausal symptoms. She complains of frequent, severe hot flashes and pain with intercourse. Her parents died from myocardial infarction at the ages of 60 and 61, respectively. Is SR likely to benefit from HRT?

Yes. Although there is no family history of osteoporosis, SR likely will obtain two primary benefits from HRT: improvement in her menopausal symptoms and reduced risk of heart disease complications. Heart disease mortality reductions have been demonstrated with HRT, but researchers have not yet estimated the cost savings from lower heart disease complications. However, because she has menopausal symptoms and increased heart disease risk, there are obvious cost, as well as health, benefits to lifelong HRT therapy for this patient.
**Case Studies**

**CASE #3**

**JD is a 56-year-old woman who had a hysterectomy 11 years ago. She is otherwise healthy but complains of increasing menopausal symptoms. Is she an appropriate candidate for HRT?**

**Yes.** Pharmacoeconomic data indicate HRT is most cost-effective for women who have had a hysterectomy and are suffering from menopausal symptoms. Tosteson’s study estimated that the cost per QALY for such patients was only $5,700. These patients gain the benefit of reduced hip fractures, lower cardiovascular risk, improved menopausal symptoms, and lower drug costs (because a progestogen is not required).

**CASE #4**

**KS is a 65-year-old woman who currently is being treated for breast cancer. Her mother had osteoporosis and a hip fracture. Is KS a candidate for HRT?**

**No.** Although a family history of hip fracture is a strong HRT indication, current breast cancer is a contraindication for HRT. Other osteoporosis treatments (e.g., exercise, calcium supplementation) should be implemented without HRT. If KS is successfully treated for her cancer, it is unclear whether or not HRT would be appropriate, the issue of HRT use in women successfully cured of breast cancer is still being debated.

**CASE #5**

**EC is a moderately obese 58-year-old African-American woman. She is having minor menopausal symptoms but otherwise is in good health. Is she a candidate for HRT?**

**Yes.** The current recommendation is to treat all women without a HRT contraindication. However, from a pharmacoeconomic perspective, this patient is less likely to benefit from HRT. Because she is African-American and moderately obese, she is less likely than other risk groups to develop osteoporosis. Despite this, she would still be expected to have less bone demineralization and a reduced risk for heart disease with HRT.

**References**

Many practitioners wonder why in the world of modern medicine pharmacy students still are taught compounding of medication. Practitioners also wonder when, if ever, they will have an opportunity to apply all of the clinical knowledge they accumulate over the years. A group of pharmacists and other health care professionals got a chance to find out last summer when they participated in an eye-opening expedition to Peru with the Flying Doctors of America.

A division of Medical Mercy Missions, Inc., Flying Doctors of America is a nonprofit organization that brings volunteer medical, educational, spiritual, and economic assistance to impoverished regions around the world. The group that traveled to Peru last August consisted of two pharmacists, two physicians, an ophthalmologist, a dentist, three nurses, a chiropractor, and a physical therapist. Three college students, a marriage and family counselor, and some support personnel also participated.

TOUCHDOWN TO A NEW WORLD

The group arrived in Lima, Peru's largest city with more than six million inhabitants. Although 70% of the country's population resides in an urban center, our ultimate destination would be the rural areas. While Peru's population is ethnically diverse, about 45% of individuals are Indian descendants of the Incas. Of course, there are many ethnic and linguistic divisions among the Indians, some of whom are fairly isolated in the Amazon jungle. About one-half of the Indian population is under age 20.

From Lima the group traveled to Cuzco, where we rested up, brushed up on our Spanish, and prepared for a trip to Chinchaypucyo where the work would begin.

DESTINATION: CHINCHAYPUCYO

Chinchaypucyo is a rural village in the Andes Mountains. Medical care in such towns is generally unavailable or, at best, unreliable. Nevertheless, the group's visit to the village began with a tour of the local hospital, which turned out to be a two-room house with a bathroom. The tiny hospital was highly regarded by the local citizens. The Flying Doctors group was met by the village Shamens, or medicine men, the traditional healers of the village. They use both ritualistic and empirical methods of treatment. In one of the few parallels to Western medicine, most Shamens in Peru specialize in some area such as bone setting or treating snake bites. It is worth noting that most Shamens practice healing only part time, making much of their livelihood from farming or other work.

After some discussion, the group decided to use the village hospital only as a dental and eye clinic. With the help of the Shamens, a rickety but adequate two-story building was chosen to set up services for pediatrics, internal medicine, chiropractic care, and a pharmacy.

Once settled, the group was greeted by the town mayor in the village square, where American and Peruvian flags waved. However, the military musical accompaniment hinted at the region's history of political unrest and violence, and reminded us that the potential for terrorist or guerrilla attacks could not be ignored.

SETTING UP THE PHARMACY

As one of the group's two pharmacists was suffering from altitude sickness, the other (the author) started organizing the pharmacy. This began with an inventory to determine exactly what medications were available and what the unit dosing process was. This was necessary as most of the medications were supplied in bottles of 1,000 pills or capsules. The Shamens were solicited to help count and place 30 tablets of each medication into plastic bags. This up-front effort turned out to be a valuable time saver, as the pharmacy ended up dispensing between 800 and 1,000 prescriptions per day.

Patients began to arrive almost immediately; unfortunately, the group's interpreters did not. Ultimately, we had only a native medical student and four local teenagers to serve as interpreters. The teenagers actually knew very little English, but at least were able to translate the local Indian dialect into Spanish.

Continued on page 212
BUSY BEGINNINGS

After a breakfast of cocoa tea and a bread-like biscuit, the group began its first full day. Two of the college students volunteered to handle “crowd control” and conduct interviews to determine the urgency of patient needs. This rudimentary “triage” system worked fairly well and turned out to be quite useful.

Following an interview, patients stood in line with a piece of paper that explained their chief complaint or illness and any other pertinent information that might be helpful to the physicians or other practitioners. The author circulated through the crowd periodically to ensure that those who most needed help received it quickly.

The pharmacy’s role included dispensing medications and counseling patients and their families on usage. Each patient who received medication was given a sheet of paper explaining what the product is used for and how to take it. Of course, these instructions were delivered in Spanish to interpreters who translated them into the local language.

CHALLENGES OF THE REGION

It became apparent early on that this was an extremely poor village, where residents have little financial or other means to obtain regular medical care. Public education in Peru, while free and compulsory for children between seven and 16 years old, was poor in this area. The only school had no running water, electricity, or bathrooms.

Unfortunately, poverty, poor education, and potential for political unrest are just a few of the problems facing the residents of Peru. The drug trade creates problems in both urban and rural areas. Peru is the world’s largest producer of the cocoa leaf, which is “exported” to other countries to make cocaine. Not only is drug trafficking rampant in rural areas, but poor villagers are afraid of losing their meager incomes and facing other more deadly consequences if they don’t cooperate with drug lords.

CHALLENGES, REALITIES OF CARE

Seeing patients at the clinic was both exciting and depressing. Clearly, these patients needed care, many of them desperately. At the same time, many Peruvians are superstitious about health care and are reluctant to use modern medical facilities; they prefer using natural remedies made of herbs and roots.

The Shamens were essential to the group’s success in the village. They worked with the medical team and helped villagers feel more comfortable and less fearful. At the same time, the group showed the medicine men how to treat such conditions as otitis media, fevers, and dehydration. In return, the medicine men showed us how they collect young eucalyptus leaves and make herbal cures for conditions such as sinus and bronchial infections. In the end, it was difficult to say who learned more from whom.

Given the limited inventory of medications available, we found the Shamens quite helpful. We learned about the ways the medicine men use eucalyptus, as well as a root from a different plant that they dry and use to induce sweating and relieve fevers.

WOMEN’S HEALTH

Many patients who visited the clinic suffered from tape worms, indigestion, conjunctivitis, and respiratory complaints. The group expected to see these types of complaints. However, the U.S. contingency was surprised at the large number of women who presented with depression, sleep disorders, and anxiety. Although the family unit is important in Peru, the life of rural women is extremely difficult and stressful.

Peruvian women in rural areas seldom work outside the home and often have as many as five or six children. The infant mortality rate is 54 per 1,000, compared to 8.5 per 1,000 in the U.S. Most rural families live simply, with few modern conveniences, and children are susceptible to many illnesses and infections. Children under the age of three are especially at risk of infection, malnutrition, and dehydration.

While we were able to treat these problems fairly easily (e.g., using boiled water, sugar, honey, and salt as an electrolyte replenishing solution), minor illnesses in a rural area can escalate into a life-threatening condition.

For women who have to deal with such personal and family stresses on a daily basis, the solutions are not easy.

SUCCESS NOW...BUT WHAT ABOUT LATER?

One particularly difficult case the group handled involved a young girl (approximately 13 years old) who came to the clinic with a severe mastoid infection. The entire left side of the girl’s neck was swollen and infected. The doctors decided to drain the infection. Since no medical drains were available, they substituted gauze to serve as a wick and drew the infected fluid out that way. The patient also received a broad-spectrum antibiotic and was instructed to return every day to have her dressing changed and to receive additional medication. After four days, she had improved significantly.

This was a true happy ending. But members of the U.S. group couldn’t help but wonder what would happen after we left. What would happen to the people treated for seizures, high blood pressure, and other illnesses? What about the people who need care beyond what we could provide? What would happen after the patients used up the medications we gave them?

Unfortunately, there are no good answers to these questions. Other groups, such as the Red Cross, will come into the village at various times. What the Flying Doctors of America did was a beginning—a small step toward a better future for the members of this village. As a group, we learned to take advantage of even the smallest opportunities to make a difference, and we hope that our efforts have some lasting effect.
OBJECTIVE:
To determine the cost-effectiveness and outcomes of a therapeutic interchange from captopril, enalapril, or lisinopril to quinapril for 36 patients with mild-to-moderate hypertension.

DESIGN:
A three-month, open-label, nonrandomized therapeutic interchange trial performed from September 1995 through July 1996.

SETTING:
University-affiliated outpatient clinics.

RESULTS:
Outcomes at minimum follow-up of three months indicated that 35 of 36 patients (97%) were successfully switched to quinapril with similar blood pressure control. Four of the 36 patients (11%) complained of a cough while on quinapril; however, these patients also experienced coughing on their previous ACE inhibitor therapy. At the same time, three other patients who had side effects on their previous ACE inhibitor therapy did not have a recurrence of side effects on quinapril. A cost savings of $4,956 per year for these 36 patients during the first year of follow-up was projected.

CONCLUSION:
Switching patients with mild-to-moderate hypertension stabilized on captopril, enalapril, or lisinopril to quinapril is cost-effective. However, therapeutic interchange programs involving other drug classes with indications in other disease states must be evaluated individually to assess their cost-effectiveness.

J Managed Care Pharm 1997; 3:219-23.

METHODS

Patients
Thirty-six patients stabilized on ACE inhibitor therapy (captopril [n=12], enalapril [n=12], and lisinopril [n=12]) for hypertension with or without a diuretic comprised the study population. Eligible patients had to be between 35 and 70 years of age. There were no restrictions with regard to gender or race. Diastolic blood pressure (BP) before starting drug therapy had to be between 90 and 110 mmHg with a systolic BP of less than 180 mmHg. Patients had to be controlled (diastolic BP<90 mmHg) on stable doses of captopril, enalapril, or lisinopril for at least three months prior to being switched to quinapril. Eligible patients were restricted to those whose diastolic BP was controlled on no more than 150 mg/day of captopril, 40 mg/day of enalapril,

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or 40 mg/day of lisinopril. There were no restrictions with regard to concomitant disease states other than end-stage renal disease, which was a reason for exclusion from the study.

### Study Design

Only four patients underwent tapered discontinuation regimens for prior ACE inhibitor therapy. Patients generally were asked to initiate quinapril the day following the discontinuation of their previous ACE inhibitor. However, in six patients, a lapse of 3-8 days without any ACE inhibitor therapy occurred because of an administrative error.

Quinapril was initiated at 10 mg/day and increased to 20 or 40 mg/day at two- to three-week intervals, depending on response and prior ACE inhibitor dose (see Table 1). Loss of BP control after the switch was defined as a rise in diastolic BP to >95 mmHg, a greater than 5 mmHg increase in diastolic BP, or a greater than 10 mmHg increase in systolic BP during quinapril therapy as compared to BP readings during the previous ACE inhibitor therapy. Patients not having adequate BP control on 40 mg/day of quinapril, or those developing dose-limited side effects on any dose of quinapril, were returned to their original ACE inhibitor. Patients with continued BP control who did not develop dose-limiting side effects were followed for a minimum of three months.

### Cost Analysis

Costs evaluated in this analysis include the comparative acquisition costs of captopril, enalapril, lisinopril, and quinapril. Acquisition costs used in this study represent the actual average cost of these drugs at six pharmacies enrolled in three local managed care plans in Omaha, Nebraska. Also included were the costs of additional clinic visits, laboratory monitoring, emergency room visits, and hospitalizations, as well as the costs of managing side effects that patients experienced following the switch to quinapril.

### Table 1. Targeted quinapril doses following conversion from other ACE inhibitors

<table>
<thead>
<tr>
<th>QUINAPRIL mg/day</th>
<th>CAPTOPRIL mg/day</th>
<th>ENALAPRIL mg/day</th>
<th>LISINOPRIL mg/day</th>
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</thead>
<tbody>
<tr>
<td>10</td>
<td>≤50</td>
<td>≤5</td>
<td>≤5</td>
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<tr>
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<td>&gt;50 to ≤100</td>
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<td>not accepted</td>
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</table>

### Table 2. Outcome of patients switched from captopril to quinapril

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<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>BP Prior to TX</th>
<th>Duration of Initial Therapy (mos)</th>
<th>Doses of Initial Therapy</th>
<th>BP on Initial Therapy</th>
<th>Side Effects on Initial Therapy</th>
<th>Final BP on Quinapril</th>
<th>Dose of Quinapril</th>
<th>Start Date on Quinapril</th>
<th>Side Effects on Quinapril</th>
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</tr>
</thead>
<tbody>
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<td>43</td>
<td>M</td>
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<td>75</td>
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<td>128/88</td>
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<tr>
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<td>51</td>
<td>F</td>
<td>162/104</td>
<td>12</td>
<td>75</td>
<td>140/90</td>
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<td>50</td>
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<tr>
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<td>cough worse on quinapril</td>
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<td>70</td>
<td>M</td>
<td>148/96</td>
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<tr>
<td>Mean ±SD</td>
<td>50.3±9.3</td>
<td>7M/5F</td>
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<td>149.2±9.0</td>
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<td>66.7±19.5</td>
<td>129.7±9.0</td>
<td>84.7±5.0</td>
<td>3 (25%)</td>
<td>128.5±8.3</td>
<td>84.7±3.6</td>
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</tbody>
</table>
Data Analysis
Comparability of demographic and baseline characteristics among baseline ACE inhibitor groups (captopril, enalapril, and lisinopril) were assessed using one-way analysis of variance for continuous variables and Pearson's chi-square for dichotomous and categorical data. Mean treatment costs among drug therapy groups were compared using one-way analysis of variance. A modified least-significance multiple range test was used for multiple comparisons. Continuous data were presented as the mean ± SD. For all analyses, a P value of <0.05 was considered statistically significant.

RESULTS
Thirty-six patients were switched from captopril (n=12), enalapril (n=12), or lisinopril (n=12) to quinapril. Outcomes are detailed in Tables 2, 3, and 4. Baseline demographics and clinical characteristics were not significantly different between the captopril, enalapril, and lisinopril groups, with the exception of the duration of initial ACE inhibitor therapy. All patients switched to quinapril were dosed on a once-a-day basis. No attempt to discontinue diuretic therapy was made in the eight patients receiving an ACE inhibitor in conjunction with a diuretic.

Thirty-five patients (97%) had continued blood pressure control and tolerated quinapril for a minimum of three months after the switch. The remaining patient, who had been controlled on enalapril 40 mg/day, experienced an increase in blood pressure after the switch to quinapril. Following the conversion, four of 36 patients (11%) complained of a cough. However, this side effect also had occurred during these patients' previous ACE inhibitor therapy. In fact, seven of 36 patients (19%) had suffered an adverse effect on their previous ACE inhibitor, while three patients who had side effects on their previous therapy had no recurrence of adverse events on quinapril.

The total cost savings resulting from the quinapril switch in these 36 patients was $4,956 ($138 per patient). See Table 5 for details. The major cost advantage of switching patients to quinapril is its lower acquisition cost compared to other ACE inhibitors. The major sources of costs associated with the switch were additional clinic visits, laboratory tests, and side-effects management. Patients switched to quinapril averaged 2.5 clinic visits through the end of follow-up. Laboratory monitoring primarily included electrolyte and renal function assessments. Emergency room visits were very few; only two patients visited the emergency room for suspected side effects, and these ultimately were determined to be unrelated to quinapril. If these non-drug-related emergency room costs were eliminated, the projected savings would be $5,441 in the first year. There were no hospitalizations during follow-up, also adding to the cost benefits.

Table 3. Outcome of patients switched from enalapril to quinapril

<table>
<thead>
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<th>Gender</th>
<th>BP Prior to TX</th>
<th>Duration of Initial Therapy (mos)</th>
<th>Doses of Initial Therapy</th>
<th>BP on Initial Therapy</th>
<th>Side Effects on Initial Therapy</th>
<th>Final BP on Quinapril</th>
<th>Dose of Quinapril</th>
<th>Start Date on Quinapril</th>
<th>Side Effects on Quinapril</th>
<th>Comments</th>
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<td>102.3±4.7</td>
<td>115.0±16.4</td>
<td>17.0±4.6</td>
<td>16.7±12.1</td>
<td>136.0±14.2</td>
<td>83.0±5.2</td>
<td>3 (25%)</td>
<td>132.0±14.2</td>
<td>84.3±8.4</td>
<td>31.7±10.3</td>
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COMPARATIVE RESEARCH: ACE INHIBITOR THERAPEUTIC INTERCHANGE

Table 4. Outcome of patients switched from lisinopril to quinapril

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Gender</th>
<th>BP Prior to TX</th>
<th>Duration of Initial Therapy (mos)</th>
<th>Doses of Initial Therapy</th>
<th>BP on Initial Therapy</th>
<th>Side Effects on Initial Therapy</th>
<th>Final BP on Quinapril</th>
<th>Dose of Quinapril</th>
<th>Start Date on Quinapril</th>
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<td>8/15/95</td>
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<tr>
<td>Mean±SD</td>
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<td>5M/7F</td>
<td>103.2±4.7</td>
<td>148.5±9.3</td>
<td>122.2±5.7</td>
<td>21.7±11.9</td>
<td>29.8±11.1</td>
<td>84.2±4.5</td>
<td>1 (8.3%)</td>
<td>128.4±10.8</td>
<td>84.2±4.1</td>
<td>30.0±10.4</td>
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</table>

DISCUSSION

ACE inhibitors, with their low incidence of overall side effects and favorable risk-benefit profile in patients with diabetes mellitus, renal dysfunction, and heart failure, are a commonly used class of drugs for the initial treatment of hypertension. However, when compared to diuretics and beta-blockers, this drug class may have a relatively high acquisition cost. Further, the availability of a large number of ACE inhibitors, the relevance of tissue ACE activity, and the absence of long-term outcomes data make product selection difficult. However, a growing number of providers are using formularies to contain prescription costs. And the tendency to choose a single preferred agent in drug classes such as ACE inhibitors makes good fiscal sense. Many managed care organizations have used therapeutic interchange or switch programs to convert patients stabilized on one drug to another product with similar efficacy but at a lower cost. These conversions typically are within, rather than across, drug classes. Although such switch programs have received widespread criticism, they continue to be used on a regular basis. Therapeutic interchange, if performed properly, can be advantageous, as the literature is beginning to show. Therapeutic interchange programs have been reported previously for cephalosporins, calcium channel blockers, H2 receptor antagonists, and selected ACE inhibitors. Two published ACE inhibitor switch programs involved conversions from enalapril to lisinopril with very similar pharmacologic profiles. In the study by McDonough et al., BP control was not established prior to or following the switch. As a result, no conclusions about dose proportionality or clinical outcomes could be reached. In the study by Lindgren-Fumaga et al., 94 of 141 patients switched between products were excluded from the study, a situation that raises concern about selection bias. Although BP control was evaluated following the switch, patients were followed for only one month. Despite these methodological concerns, both studies

Table 5. Cost analysis of ACE-inhibitor switch

<table>
<thead>
<tr>
<th>Projected Annual Costs</th>
<th>Initial ACE Inhibitor</th>
<th>Quinapril</th>
<th>Difference</th>
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<td>Acquisition Cost of ACE Inhibitor</td>
<td>$14,685</td>
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<td>$7,341</td>
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<td>Additional Anti-hypertensive Therapy</td>
<td>$432 (8 on diuretics)</td>
<td>$432 (8 on diuretics)</td>
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<tr>
<td>Laboratory Monitoring</td>
<td>$326</td>
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<tr>
<td>Clinic Visits</td>
<td>$1,210</td>
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<tr>
<td>ER Visits</td>
<td>$485</td>
<td>$485</td>
<td>$0</td>
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<tr>
<td>Hospitalizations</td>
<td>$0</td>
<td>$0</td>
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<tr>
<td>Costs of Managing Side Effects</td>
<td>$364</td>
<td>$364</td>
<td>$0</td>
</tr>
<tr>
<td>TOTALS</td>
<td>$15,117</td>
<td>$10,161</td>
<td>$4,956</td>
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concluded that cost savings could be realized by the ACE inhibitor interchange. However, the results of therapeutic interchange programs require additional study.

Limitations of this study include the lack of blinding, failure to introduce an intervening placebo baseline period, lack of a randomized crossover, and a relatively short duration of follow-up. However, while the lack of blinding may have implications with regard to the observed frequency of side effects, it should have little impact on BP outcomes. The lack of an intervening placebo baseline period and a failure to employ a randomized crossover design may ultimately have allowed the inclusion of patients who may not have had a rise in BP to pretreatment levels. Ultimately, however, the switch protocol design parallels the clinical practice of managed care organizations. The minimum three-month follow-up may have been too short to detect late onset side effects or late treatment failures with quinapril. Further follow-up is needed to identify the impact of late adverse reactions or late treatment failures.

CONCLUSION

The study reported here demonstrates that a successful therapeutic interchange with ACE inhibitors in patients with mild-to-moderate hypertension is possible. Switching patients to quinapril from captopril, enalapril, and lisinopril resulted in an excellent rate of success, few adverse outcomes, and cost savings of $138 per patient during the first year of the switch. The acquisition cost savings associated with quinapril were projected to be $7,341 for all 36 patients. This amount was reduced by the additional costs of clinic visits, laboratory monitoring, and side effects. These costs must be considered in the evaluation of switch program.
The American Pharmaceutical Association's (APhA) 1997 Concept Pharmacy Guide to Pharmaceutical Care Resource was unveiled at APhA's annual meeting in Los Angeles. The guide offers dozens of resources regarding the products and services that are available to help pharmacists get more involved in pharmaceutical care. Pharmacists can learn where to find automation and information systems, disease state management tools, pharmacy fixtures, and much more; 202/628-4410.

The International Journal of Pharmaceutical Compounding is a new journal presenting peer-reviewed articles and departments on compounding issues and research; 405/330-0094.


A Guide to Prescription Benefits is available from the Midwest Business Group of Health and ValueRx in Minneapolis, Minnesota. The book is designed to help employers and other health care purchasers gain a better understanding of the pharmacy benefit management approach, types of plan designs, formularies, and other information. Call 800/440-1486 for more information.

A new Nurses Drug Information Service is available from Facts and Comparison and features a two-volume Nurses Drug Facts Reference Set, a monthly newsletter, and a CD-ROM program. The new service is specifically aimed at giving nurses the information they need about drug information; 800/223-0554.

Effective Communication for Pharmacists presents the basics for good communication that every pharmacist should know. The book, by Norman B. Sigband, Ph.D., covers several areas to help today's pharmacists with a variety of audiences. Sigband discusses listening as the key to successful patient interaction; interactions with health care professionals and patients; patient-pharmacist consultation; writing for results; research and surveys in health care; and writing and editing in health care. The book is available for $29.95, plus $2.50 for postage and handling from Counterpoint Publications; 909/987-1831.

ASCP's Web site is up and running. At www.ascp.com, surfers can read ASCP information and publications (including online versions of its journal and newsletter); send e-mail messages or chat in online forums; get information on government initiatives and Society publications; and link directly to other pharmacy and health care Web sites.

The Virtual Human, interactive CD-ROMs for three-dimensional anatomy from Gold Standard Multimedia, will be released in March 1997. The Atlas version, for medical education and reference, will be $195, while the Studio version for medical educators, illustrators, and graphic designers will cost $1,250 (800/375-0943, ext. 25; messer.m@gsm.com).

The Bayer Quality Network is a unique cooperative educational forum for hospital, health system, and managed care professionals that serves as a resource for sharing proven principles of continuous quality improvement (888-BAYER-NET or BAYERFAX).
PHASE I/II

▲ Yukong is planning to develop its YKP10A antidepressant through Phase I. The company then expects to seek a joint venture or licensing agreement for Phase II trials. To date, the drug's major mechanisms are uncertain, although tests have indicated that D2 receptors might be involved in the compound's pharmacologic effects.

PHASE III

▲ An FDA advisory committee recommended the clearance of Ciba-Geigy's Femara (letrozole) for treating advanced breast cancer “after antiestrogen therapy in women with natural or artificially-induced postmenopausal status who are hormone receptor status positive or unknown.” The recommended initial dosage is 2.5 mg.

POSTMARKETING

▲ FDA has announced plans to withdraw its approval of Seldane (terfenadine), Seldane D (terfenadine and pseudoephedrine), and generic versions of the prescription antihistimine. FDA has determined that drugs containing terfenadine no longer are sufficiently safe since Allegra (desloratadine) now is available. The recently approved Allegra provides nearly all of terfenadine's beneficial effects but does not appear to cause a potentially fatal heart condition when taken with some other commonly prescribed medications, as is a concern with terfenadine. Following terfenadine's approval, FDA received reports of serious and sometimes fatal cardiac arrhythmias associated with terfenadine when taken with some other medications or by patients with liver disease. FDA has not yet set a date for the drug’s removal from the market.

▲ FDA has approved Rezulin (trotiglizone), the first in a new class of medications intended to attack an underlying cause of diabetes. The drug may end daily dependence on insulin injections for some diabetics. The Parke-Davis division of the Warner-Lambert Company expects to have the drug on the market by the end of March.

▲ Penderm plans to launch its retinoic acid cream Avita (tretinoin) in the third quarter of this year. Avita received FDA approval on January 14 as a topical treatment for acne.

▲ On January 17, Bristol-Myers Squibb announced a recall of one lot of norethindrone and ethinyl estradiol oral contraceptive tablets. The approximately 150,000 compacts of blister packs contain some with weeks one and four of the therapy transposed.

▲ FDA approved Forest's Monurol (fosfomycin tromethamine) late last year. The drug will be marketed with an emphasis on its status as the first one-dose antibiotic for uncomplicated urinary tract infections.

▲ Bayer's Glyset (miglitol) has received FDA approval for treatment of Type II diabetes. The drug has been approved in the European Union under the brand name Diastabol. Glyset is indicated as a diet adjunct to control hyperglycemia in patients who can't manage the condition by diet alone.

▲ Aphthasol (amlexanox oral paste, 5%) received FDA approval late last year for treating canker sores. It is the first prescription medication for this indication. Block Drug's Oral Health Division will begin marketing the product later this year.

▲ FDA approved Zagam (sparfloxacin) for treating community-acquired pneumonia and acute bacterial exacerbation of chronic bronchitis. The oral fluoroquinolone is recommended for dosing at two 200 mg tablets the first day and one tablet daily for nine days more: Zagam will be marketed early this year by Rhone-Poulenc Rorer.

▲ FDA has approved Organon's Orgaran (dana-paroid sodium) for preventing deep venous thrombosis that could cause pulmonary embolism in patients undergoing elective hip replacement.

▲ Late last year, FDA approved Alcon's ophthalmic antihistimine Patanol (olopatadine .1%) for temporary relief of itching eyes caused by allergic conjunctivitis. The recommended dose is one or two drops in each eye twice a day at five- to eight-hour intervals.

▲ The first non-interferon product for treating multiple sclerosis to hit the U.S. market will be launched early this year by Teva Marion Partners. Copaxone, the company says, is well tolerated without the side effects—such as flu-like complaints, fatigue, and depression—that patients may experience with other similar treatments.
AMCP LAUNCHES NEW INITIATIVES IN THE LEGISLATIVE ARENA

The Academy of Managed Care Pharmacy anticipates a surge in legislative activity that could have an adverse impact on the managed care pharmacy profession. The publication last year of a widely publicized study by researcher Dr. Susan Horn (critical of formularies), coupled with the general anti-managed care fervor that's sweeping the country, provide a ripe atmosphere for foes of managed care to influence the 1997 legislative agenda at both the state and federal levels.

A survey of AMCP members conducted last spring revealed that 82% perceived legislative tracking as an important or very important benefit AMCP should offer. In response, AMCP has taken a number of steps to help keep members up to date on legislative developments and provide them with tools to lend a more effective voice for managed care pharmacy. These initiatives include:

**LEGISLATIVE TRACKING SERVICE**

In December, AMCP contracted with an outside firm for an on-line monitoring system to track state legislation. The service allows AMCP staff to quickly search for and retrieve the latest information about the status and content of pending bills, enacted laws, regulations, and government reports, and to follow other important developments. AMCP plans to enhance the value of the service by periodically publishing state legislative updates for members.

In addition to providing quick access to a wealth of state legislative information, the service makes it possible to retrieve information on individual state legislators and their staff, including how and where to contact them and what their positions are on various pieces of health care-related legislation.

**FORMULARY FACT SHEETS, TALKING POINTS, AND POSITION STATEMENT**

In anticipation of anti-formulary initiatives at the state level, AMCP developed a set of legislative "talking points" on formularies that members can use to address concerns raised by lawmakers or their legislative staffs on this subject. AMCP prepared the talking points and received input from the American Association of Health Plans (AAHP), the nation's largest managed care industry trade group. The talking points describe formularies: what they are, how they work, and the role of P&T committees. They also discuss how formularies promote quality and cost-efficiency, explain how patients can access non-formulary drugs, and provide statistics on managed care consumers' satisfaction with access to drugs. AMCP also recently issued a revised position statement on formularies. (Members can access the talking points and the position statement via AMCP's fax-on-demand service; dial 800/964-9648 and check the table of contents.

**REPORT ON PBM/HMO RELATIONSHIPS**

AMCP submitted detailed comments to the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) regarding a government report on the relationship between PBMs and HMOs. Inspector General June Gibbs Brown had asked AMCP to review and comment on the draft report, entitled "Experiences of Health Maintenance Organizations and Pharmacy Benefit Management Companies." The OIG is scheduled to release a final report to the public in March, which would contain AMCP's comments as an appendix to the document.

The report is based on the responses of HMO administrators surveyed by the OIG, and looks at the role PBMs play in delivering pharmaceutical care to HMO clients, many of which serve Medicare and Medicaid beneficiaries.

AMCP especially thanks members of the Legislative Committee, Legislative Network, and Communications Committee for reviewing and commenting on the draft.

AMCP members can obtain a copy of AMCP's comment letter via the fax-on-demand service by dialing 800/964-9648 and requesting document #308. To obtain a full copy of the final OIG report, call 202/619-2481; ask for report #OEl-01-95-00110.

**RESPONSE TO NEW YORK PUBLIC ADVOCATE'S OFFICE**


"We believe that the report failed to present a balanced view of how pharmacists in HMOs and PBMs operate," AMCP said in the response. "Unfortunately, the report will do much to scare the public needlessly about the alleged health consequences of their prescription drug coverage, and little to educate patients about the true benefits and risks associated with their drug therapies." The report wrongly alleged that managed care systems are forcing physicians to switch patients from high-cost, quality drugs to less-expensive, inferior medications. It also criticized the use of formularies.

AMCP's response points out the report's clinical errors and provides anecdotes of patients who have had positive clinical experiences with their managed care pharmacy programs. AMCP members may access AMCP's response via the fax-on-demand service; dial 800/964-9648. To obtain a copy of the Public Advocate's Office Report, call 212/669-7200.
INTERNSHIP TAKES CLASSROOM INTO THE "REAL WORLD"

For pharmacy students, classroom lessons only go so far. "Real-world" experience is necessary to complete their education. Students seek this experience through jobs or volunteer work in a variety of settings, from retail drug stores and hospital or clinic pharmacies to human services agencies and research laboratories. However, these settings usually represent the clinical aspects of pharmacy and do not offer insight into drug development, marketing, managed care pharmacy, pharmacy association management, or other areas that aid students in their career choices and professional development. Experience in these nontraditional settings is important if a student is to gain a well-rounded education. But finding such an educational opportunity may present a challenge. This article describes one such program, a summer internship that offered insight into managed care, drug development and the pharmaceutical industry, association management, and writing and editing academic articles.

AK PHARMACY CONSULTANTS SUMMER INTERNSHIP

AK Pharmacy Consultants, a Santa Barbara, California, pharmaceutical and health care management consulting firm, initiated a four-week intensive summer internship stressing the importance of both written and interpersonal communication skills, as well as continuing education and self-motivated learning. The internship allowed for interaction with professional associations, pharmaceutical companies, home infusion services, managed care organizations, and educational program developers. The internship had three goals: (1) to provide experience in and exposure to the pharmaceutical industry, managed care organizations, pharmacy consulting services, state pharmacy associations, pharmacy-related legislation, formulary development principles, and home infusion abstract services; (2) to improve communication skills through written essays, speech presentations, and off-site rotations; and (3) to help students understand the role of pharmacy in the current market and identify the external forces that will influence the pharmacy profession's future in health care delivery.

The internship included several activities that offered insight into real-world aspects of clinical pharmacy, managed care pharmacy, and drug development. These included on-site rotations at various organizations, hands-on preparation of a marketing proposal literature abstracts, and executive summaries, as well as participation in field visits and meetings. In addition, the internship required a review of literature on managed care principles and pharmacoeconomic basics.

ON-SITE INVOLVEMENT

To observe everyday operations and gain exposure to various practice settings, the intern visited the offices of the California Pharmacists Association (CPhA), Pharmaceutical Care Network (PCN), and Integrated Pharmaceutical Services (IPS), all in Sacramento. These on-site rotations involved spending a full day at each site and provided an opportunity to experience the dynamics, mission, and operations of each organization. The intern also visited the headquarters of Amgen, a pharmaceuticals firm, to gain insight into drug development and marketing processes.

The rotation at CPhA provided exposure to the structure and mission of a state pharmaceutical association. The intern learned about association management and legislative and lobbying activities. The rotation included a brief tour of the State Capitol and a visit with one of CPhA's lobbyists.

The experiences at PCN and IPS highlighted issues in managed care pharmacy. By allowing interns to participate in customer services and claims, the rotation at PCN provided an understanding of services offered by a pharmacy benefit manager. The intern also used client-services software and learned about buying services. The rotation at IPS offered exposure to its work in formulary management, disease state management, and clinical services. The intern learned about financial aspects of formulary design, such as the need for cost analysis during drug selection processes. IPS staff also reviewed therapeutic and financial considerations of formulary design and discussed their philosophy and protocol on disease management for various patient populations.

Next, a visit to Amgen gave the intern insight into drug development and marketing. Participation in meetings and staff discussions provided information about the development of a new drug. Further, the experience offered a look at the marketing strategies that companies employ in launching a new product or service.

BACK TO AK TO HIT THE BOOKS

The intern saw the real world of managed care pharmacy, association management, and drug development and marketing. Education complete, right? Not quite. On return to AK Pharmacy Consultants, the intern was responsible for identifying and abstracting three pertinent primary-literature sources on one aspect of pharmaceutical care—home infusion services. This exercise was designed to increase the student's understanding of specialties and boost her confidence in her ability to write and edit academic articles.

The internship at AK Pharmacy Consultants picked up where the Pharm.D. education left off. It provided a well-rounded, real-world education. To prepare future health care professionals adequately, we need to anticipate the needs of the changing...
HEALTH CARE COSTS MODERATELY ON THE RISE

Total health plan cost for active and retired workers of private- and public-sector employers with 10 or more employees rose 2.5% in 1996, for a third year of low single-digit increases, according to a nationwide survey of more than 3,200 employers by benefits consultants Foster Higgins. The 11th annual survey found total health benefit costs averaged $3,915 per employee in 1996, compared with $3,821 in 1995, when costs rose 2.1%. Costs remained moderate for several reasons, including low inflation in the cost of medical goods and services, more employees enrolling in managed care plans (including retired employees), and an actual decrease in the average cost of coverage in health maintenance organizations.

TREND TOWARD MEDIC-AID MANAGED CARE CONTINUES

Six states—Colorado, Iowa, Massachusetts, Oregon, Utah, and Washington—have shifted all of their Medicaid patients into managed care. More than 75% of Medicaid patients are in managed care programs in eight states. Overall, Medicaid managed care enrollment has gone from 2.7 million in 1991 to 11.6 million in 1995, a 330% increase; enrollment went up by 51% in 1995 alone. Medicare is following a similar trend, with managed care enrollment up from 1.6 million in 1987 to 3.1 million in 1995.

DOES HEALTH FRAUD STATUTE HURT MANAGED CARE?

According to a commentary in the Winter issue of Health Affairs, James F. Blumstein claims that while health care fraud provisions in the new health insurance reform law (PL 104-191) will help expand the number of medicare and medicaid risk contractors, other provisions in the law will continue to stifle managed care and other market-based solutions to the nation’s health care problems. Blumstein observed, “Although well intended, the extremely broad interpretation of the law serves as a major potential obstacle to the continued evolution and rationalization of the health care marketplace in response to competitive market forces and pressures to contain costs.”

LABELING/PACKAGING ERRORS DOWN, FDA SAYS

FDA has reported 16 fewer product recalls involving labeling and/or packaging errors in 1996 than there were in 1995. This continues a four-year decline; 41 products were recalled in 1994 and 54 in 1993. In recent years, the agency has made a concerted effort to tighten controls over packaging and labeling, by sponsoring training seminars and mailings, investigating labeling operations during plant inspections, and following up with enforcement actions. The 1996 figures suggest that all of these activities are having the desired effect. Over-the-counter products accounted for only 17% of the recalled products in 1996; this is down from 29% in 1995.

CAMPUS: “Real World” Internship

(Continued from page 234)

pharmacy is necessary to fulfill these future needs and enable pharmacists to stay abreast of the demands placed on a changing profession.

RECIPE FOR A GOOD INTERNSHIP

An internship that enables a student to gain an understanding of all the forces contributing to the future of the profession should provide:

▲ an understanding of pharmacy’s role and influence in the global marketplace;
▲ exposure to the legislative process and law of pharmacy;
▲ an introduction to the marketing and development of new drug product lines;
▲ a better grasp of managed care concepts and issues;
▲ exposure to the concepts of pharmacoeconomics; and
▲ an overall picture of the pharmaceutical environment—past, present, and future.

Any student who wants such an opportunity can take the lead in making it happen. One only needs a willing pharmacy professional to serve as a mentor and cooperative local companies. The breadth and scope of the internship experience will depend on the student’s interests as well as the mentor’s resources and work background. With the help of professional peers, state and national pharmacy organizations, and the pharmaceutical industry, the mentor and student will be able to draw from myriad resources to tailor a program to meet the student’s needs and interests.

Morgan Bron
Doctor of Pharmacy Candidate
College of Pharmacy
University of Illinois at Chicago
Chicago, Illinois.
Caveats

To Switch or Not to Switch: That Is the Question

It seems as though every time a new medication hits the market, the reaction of many prescribers is to switch patients to the new "miracle" drug. While historically, this has been acceptable, in our current age of outcomes-based care and scrutinized budgets, such practices increasingly are being criticized. The scenario presented here is real, and the medications discussed were chosen merely as an example, not to in any way present them in an unfavorable light. They both are highly effective antipsychotic agents with favorable side effect and efficacy profiles.

The Scenario

Risperidone (Risperdal) is an atypical antipsychotic medication that has been marketed in the U.S. since 1993. Olanzapine (Zyprexa) recently was approved by the FDA and has been marketed since September 1996. Both medications are highly effective in controlling psychotic symptoms, and both appear to have very favorable side effect profiles and comparable efficacy. To date, there are no published comparisons of these two medications to indicate one is superior to the other.

However, based on available information, both risperidone and olanzapine are superior to typical, or conventional, antipsychotic medications in terms of their side effects profile, tolerability, and compliance. In fact, the most common cause of rehospitalization of schizophrenic patients is non-compliance, and typical antipsychotics are the primary offenders. Some patients describe feeling mentally clouded or "dull" when they take these medications, and this leads them to stop taking them. Fortunately, the newer atypical antipsychotic medications do not cause this effect, and compliance has been significantly better with risperidone and olanzapine. Nor do these newer agents cause dyskinesia, an unpleasant and sometimes persistent movement disorder that typical antipsychotics sometimes cause.

Clearly, it is reasonable and prudent for practitioners to consider atypical antipsychotic medications for patients if they wish to optimize compliance and minimize risks of movement disorders that occur much more frequently with older typical antipsychotic medications.

The Dilemma

The dilemma concerns what to do when a new medication becomes available and patients already are receiving one of the atypical antipsychotics. One pharmacy practice providing consultative services to a large statewide agency serving individuals with developmental disabilities and mental illness faced such a dilemma. The practice observed that a provider physician had begun switching many patients from risperidone to olanzapine. After reviewing a handful of cases and finding no clinical rationale for the changes (e.g., a patient who was responding poorly to risperidone or who had intolerable side effects), the pharmacists decided to look into the switch. It appeared to them that the practitioner changed many patients' medications based solely on information gained from journal advertisements, sales representatives, and his expectations that his patients could do better.

It is important to consider that antipsychotics are not like antibiotics; they do not cure the disease, rather, they may significantly improve the ability to function, minimize psychotic symptoms, improve quality of life, and perhaps allow patients to live in a less restrictive environment. It's difficult to argue when a practitioner says, "Jane Doe has improved somewhat on risperidone, but we think she can do better so we switched her to olanzapine." Interestingly, many patients do respond better to the new medication. But it's hard to tell how much of the improvement is due to the properties of the medication and how much is attributed to such factors as a positive attitude toward the new drug on the part of the patient, physician, and family members. Certainly, all of these factors contribute. But the question remains, should patients who are doing reasonably well on a current medication be switched to another just because they "might" do better?

From a pharmacoeconomic standpoint, the drug cost of an atypical antipsychotic is higher on a per patient per year basis than a typical antipsychotic. However, the savings attributed to reduced hospital stays, fewer side effects (and their treatment), improved compliance, and improvement in social functioning may more than justify the use of more expensive agents. However, the advantages of one newer medication over another (i.e., risperidone versus olanzapine) are much less clear.

Before making a decision to change drug therapy, practitioners should be certain the change can be justified clinically. In addition, treatment changes should be undertaken with the expectation that there will be substantial improvement, based on measurable criteria. Ethically, we should provide the best possible care, while utilizing the tools and resources available.

Conclusion

While it is important to try new agents when they become available and tempting to look for the "silver bullet," miracle, it is important to consider both the risks and benefits of the treatment change before it is implemented. This often must be done when there is little or no data to guide practitioners. This is the new frontier.

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EDITORIAL SCOPE AND POLICIES

Journal of Managed Care Pharmacy (JMCP) is dedicated to providing managed care pharmacists with the most current information they need to excel in their daily practices.

As the official journal of the Academy of Managed Care Pharmacy, JMCP is a cornerstone of membership services for one of the fastest growing associations in pharmacy. The journal is peer-reviewed, and only articles meeting high scholarly standards indicative of sound, reproducible, and valid research are accepted.

Editorial content is determined by the Editor-in-Chief with suggestions from the Editorial Advisory Board. The views and opinions expressed in JMCP do not necessarily reflect or represent official policy of the Academy or the authors' institutions unless specifically stated.

EDITORIAL CONTENT —

Journal of Managed Care Pharmacy contains three basic types of editorial material: peer-reviewed scholarly articles, news-oriented feature articles, and departments. Articles should be organized, written, and formatted for a specific part or section of the journal. Instructions for Authors are published frequently in JMCP; they always appear in the first issue of each volume.

Peer-Reviewed Articles

The heart of the journal is its peer-reviewed scholarly research, review, and report articles in five sections:

- **Comparative Research**: articles using the scientific method to compare definitively two or more alternative hypotheses.
- **Review Articles**: papers that review recent clinical, economic, or management literature and offer synthesized summaries relevant to the managed care pharmacy field.
- **Descriptive Reports**: articles describing experiences or solutions to practical problems within managed care pharmacy settings.
- **Reprise**: articles reprinted from other journals of special importance to managed care or managed care pharmacy.
- **Practitioner Update**: invited reviews of timely topics with continuing education credit (generally published in each issue).

News-Oriented Feature Articles

Feature articles highlight news and information of current interest to managed care pharmacists, pharmacy personnel, and other health care providers. Topics are selected based on advice from JMCP's Editorial Advisory Board of managed care pharmacists and administrators, educators, and industry representatives. The Spotlight section in each issue focuses on one company or organization of importance in managed care. Its history, corporate culture, and contributions to managed care pharmacy are highlighted.

Departments

Departments provide member-contributed and staff-written information of practical and immediate value to journal readers:

- **Feedback**: JMCP's letters to the editor.

**Mission Statement:**

JMCP, as the official journal of the Academy of Managed Care Pharmacy, provides applied, professional, and scientific information to advance pharmacy's contribution to patient care in managed health care systems.

- **Perspectives**: editorials by outside contributors as well as the editors.
- **Proficiency**: continuing education material for Practitioner Update articles.
- **Campus**: updates from the pharmacy education world about inclusion of managed care topics in college curricula, activities of faculty and students interested in managed care, and techniques for teaching managed care principles to pharmacy students.
- **Trends**: news articles about current events in managed care pharmacy.
- **Pipeline**: coverage of newly approved drugs and those in development.
- **Caveats**: updates from the legal and regulatory world.
- **Managing Care**: contributions from case managers about interesting situations they have seen in managed care (was titled Profiles in first four issues of JMCP).
- **Media**: updates, critiques, and information on books, software, multimedia, and other forms of current literature.
- **Events**: calendar for managed care pharmacists.
- **AMCProgress**: news and information about the Academy and the activities of its leaders, members, and staff on behalf of managed care pharmacy.

ADVERTISING POLICY —

A copy of the full advertising policy for JMCP is available from AMCP headquarters and the Advertising Representative listed on the masthead. All aspects of the advertising sales and solicitation process are completely independent of the editorial process. Advertising is interspersed throughout the editorial material other than peer-reviewed articles. Advertising is not accepted for placement opposite or near related editorial copy.

Employees of advertisers may submit articles for publication in the editorial sections of JMCP, subject to the usual peer-review process. Financial disclosure and conflict of interest statements are required when manuscripts are submitted, and these may be published at the discretion of the Editor-in-Chief if the article is printed.
INSTRUCTIONS FOR AUTHORS

As a bimonthly, scholarly, peer-reviewed journal, Journal of Managed Care Pharmacy seeks contributions from authors in the areas of managed care pharmacy practice, pharmacotherapy, research, education, economics, and other pertinent areas of pharmacy practice. Manuscripts may be in the form of comparative research, descriptive reports, clinical reviews, case studies, management studies, or pharmacoeconomic analyses.

JMCP accepts for consideration manuscripts prepared in accordance with the Uniform Requirements for the Submission of Manuscripts to Biomedical Journals.1

Mission Statement: JMCP, as the official journal of the Academy of Managed Care Pharmacy, provides applied, professional, and scientific information to advance pharmacy’s contribution to patient care in managed health care systems.

MANUSCRIPT PREPARATION

Manuscript length should generally be 10-20 typewritten pages (1500-3000 words), including tables, figures, and references. Manuscripts should include, in this order, a title page, author identification page, structured abstract of no more than 250 words, text, appendices, references, figure captions, tables, and figures. Each section should begin on a new page with one-inch margins on all sides. The entire manuscript, including references and tables, should be double-spaced.

JMCP abstracts should be structured using the following subheadings for the types of articles shown: Comparative Research ▲ Objective ▲ Design ▲ Setting ▲ Patients/Participants ▲ Interventions ▲ Main Outcome Measures ▲ Results ▲ Conclusion Review Articles ▲ Objective ▲ Data Sources ▲ Study Selection ▲ Data Extraction ▲ Data Synthesis ▲ Conclusion Descriptive Reports ▲ Objective ▲ Setting ▲ Practice Description ▲ Practice Innovation ▲ Interventions ▲ Main Outcome Measures ▲ Results ▲ Conclusion

REFERENCES

References should be prepared in the style of Index Medicus. Shown below are examples of common types of references prepared in JMCP style.

1. Standard journal article (list all authors when six or less; when seven or more, list only the first three and add et al.)
   2. No author given
   3. Journal paginated by issue
   4. Book or monograph by authors
   5. Book or monograph with editor, compiler, or chairman as author
   6. Chapter in a book
   7. Government agency publication
   8. Dissertation or thesis
   9. Paper presented at a meeting

SUBMISSION OF MANUSCRIPTS

Four complete copies of the manuscript, including photocopies of figures, should be submitted to the JMCP Editor at Mitchell Petersen, Inc., 1707 Osage St., Suite 400, Alexandria, VA 22302-2611; 703/998-4000, 703/379-4611 (fax).

In a cover letter, the corresponding author should:
 ▲ Briefly describe the importance and scope of the manuscript;
 ▲ Certify that the paper has not been accepted for publication or published previously and that it is not under consideration by any other publication;
 ▲ Suggest names of possible reviewers when appropriate; and
 ▲ Identify the nature and extent of any financial interest or affiliation that any author has with any company, product, or service discussed in the manuscript.

One of the following statements must be signed by all authors and submitted with the manuscript:

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References

EVENTS

▲ AMCP’s 9th Annual Meeting: Winning Strategies for Chronic Care
May 8-10, 1997
New Orleans, LA
Contact: Academy of Managed Care Pharmacy, 1650 King Street, Suite 402, Alexandria, VA 22314; 800/TAP-AMCP

▲ AMCP’s 1997 Educational Conference: Navigating the Changing Health Care Environment
October 30-November 2, 1997
Seattle, WA
Contact: Academy of Managed Care Pharmacy, 1650 King St., Suite 402, Alexandria, VA 22314; 800/TAP-AMCP

▲ ACCP Spring Conference
April 6-9, 1997
Contact: American College of Clinical Pharmacy, 3101 Broadway, Suite 380, Kansas City, MO 64111; 816/331-2177.

▲ Ninth Annual National Managed Health Care Congress
April 14-17, 1997
Contact: NMHCC, P.O. Box 360034, Boston, MA 02241-0634; 888/446-6422.

▲ NACDS Annual Meeting
April 26-30, 1997
Contact: National Association of Chain Drug Stores, P.O. Box 1417-D49, Alexandria, VA 22313-1480; 703/549-3001.

▲ ASHP Annual Meeting
June 1-5, 1997
Minneapolis, MN
Contact: American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD 20814; 301/657-3000.

▲ 3rd Annual Outcomes & Disease Management Conference & Exhibition
July 20-22, 1997
Contact: The Zitter Group, 90 New Montgomery, 8th Floor, San Francisco, CA 94105; 415/495-2450.

Upcoming conventions, conferences, symposia, and workshops of interest to managed care pharmacists are listed in JMCP’s Events column. Listings are placed on a space-available basis. Send notices to the managing editor at Mitchell Petersen, 1707 Osage St., Suite 400, Alexandria, VA 22302-2611.

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