Desert Eloquence (1994) ✿ ✿ Bo Newell

A painting within a painting is the signature of Bo Newell. Here Newell legibly discloses the austere, powerful elements of the desert while captivating his audience with a traveling herd of addax.

Because addax are one of the world’s rarest mammals, they have been introduced into areas beyond their natural Sahara Desert habitat. Newell actually observed this herd of addax on a game reserve. The addax survive on very little water and have large, wide hooves for easy travel through the desert; hunters are largely responsible for the reduction in their numbers. In Desert Eloquence, Newell casts a discerning eye on the expedition of this herd; his mixture of beauty and stark reality introduces an aphoristic, sobering view. He draws the parallel between the harsh elements and the attempted evisceration of this desert-dwelling antelope.

While Newell has been influenced by such wildlife artists as Bob Kuhn and David Shepherd, he also credits Salvador Dali, Claude Monet, and Frederick Remington for affecting his personal artistic development.

It is easy to see why Newell believes that artists are born, not converted. At the age of five, he declared his love for animals while simultaneously making his debut into the art world. He created a clay sculpture of a turkey that was exhibited at the Boston Museum of Fine Arts. During high school, his dual fascination of art and animals continued and he won two coveted awards for his wildlife creations.

In 1974, after receiving his B.F.A. in fine arts from Texas Tech University, Newell traveled to Africa. His steadfast admiration and respect for wildlife found a home there; the trip informed him with a sense of responsibility for animals that are endangered species. Subsequent trips to Africa confirmed his calling, and, today, Newell’s advocacy for wildlife conservation extends far beyond the African continent.

In 1976 Newell had his first one-man show in Houston. Its success ended his amateur status. In 1980 his work was part of an international art show in London held at the Grosvenor House Hotel. Currently, his work is exhibited by galleries throughout the United States; limited edition prints are handled by Virtual Gallery—Archetype Publishing in Los Gatos, California.

Bo Newell lives and works in Houston; his studio is a diversionary symposium. While wildlife remains at the core of Newell’s passion, he punctuates his oeuvre with landscapes of Africa, Europe, Mexico, and the southwestern United States. Newell also paints seascapes and spherical themes. Mindful of his childhood success, he continues to sculpt. Yet although he is accomplished in depicting many venues, Africa remains a special location for him personally and professionally.

For the past 10 years, though Newell’s art has continued to deal with animals from many areas of the globe, he has introduced a surreal approach. Yet he is ritualistic about authenticity, often taking hundreds of photographs to capture the movement and traits of each species.

To visit the African continent is to observe different inhabitants, territories, cultures, and wildlife. To visit the art of Bo Newell is to witness the eloquent and exotic reconciliation of art and life. ✿ ✿

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The health care community, including pharmacy, has been forced to face the issues of errors, medication errors, and fallibility. Unfortunately, the stimulus was not from within, but from a government study: the Institute of Medicine’s (IOM’s) report, To Err is Human. Building a Safer Health System. The world of health care was alerted by payors, patients, and the government that it was expected to perform like other industries that abhor even one error. Their expectation is that health care is too important to be practiced within a system that is not dedicated to perfection, and that demonstrates its disdain by delivering poor service. Health care providers have answered the IOM study not by rapidly embracing a culture of change, but by debating the accuracy of the numbers. Is health care really so different from other industries?

We are surrounded by systems that are designed to deliver accurate services every time. We expect telephones to deliver a dial tone, computers to boot up every time, and automatic teller machines to deliver the correct amount of cash. We expect waiters to give courteous and excellent service, service stations to repair a car correctly the first time, and accountants to provide error-free tax forms. Unfortunately, in the health care arena errors in service delivery happen routinely. The difference is that other industries and organizations have a policy of zero tolerance for error. They design and implement their processes to always deliver outstanding performance.

Health care is unique. Patients are complicated biological organisms with frequently unpredictable problems. The management of medical problems requires years of study and practice treating numerous patients. Patients and payors accept the inevitable consequences of individualized care and unpredictable patient problems. Yet while emphasis is placed on the clinical aspects of health care, little attention is paid to the processes of care. Are there organizations that are as complex as health care that have learned how to manage processes to deliver uncompromising service every time?

Organizations do exist that manage systems every bit as complex as health care. They employ high-risk technologies that must be operated with maximum accuracy. Errors and “bad luck” in these organizations can lead to disrupted operations, destruction of major equipment, and even death. Two researchers studied such organizations and identified the elements of their success. Health care can learn a great deal from their research.

Todd La Porte of the University of California at Berkeley studied the operations of nuclear-powered aircraft carriers, air-traffic control, large power-distribution grids, and nuclear power plants. These systems are as complex as any you can find. They cannot afford errors, bad luck, or statements of “It’s not my job,” or “It’s not my responsibility.” As a result, they have developed management systems that minimize errors (i.e., one error is too many). These systems work because of management systems that morph between traditional hierarchical systems and loosely organized structures based on collaboration. For example, La Porte studied how aircraft carriers can launch so many fighter planes, so quickly, with so few errors. He learned that while the military is still highly regimented and is the quintessential hierarchical organization, each and every member of the team has the power and the responsibility to shut down operations immediately if the circumstances warrant. Team members are continually talking to one another, sharing what they have done and what they will be doing. Youths in their early 20s are constantly trained in their very specialized jobs. Training is based on years of experience that have produced collections of best practices, defined by thick manuals of standard operating procedures, whose purpose is to extend the organization’s control over as many eventualities as possible.

How do these systems respond to dynamic situations? They train, train, and train some more. They encourage “people to work together across the system to anticipate and avoid problems, so that events that cannot be controlled in advance by following the rules are effectively dealt with on the fly.”

Kathleen Eisenhardt of Stanford University studied organizational characteristics that help companies make more effective decisions in rapidly changing environments. Eisenhardt’s organizations share common elements with health care. She found that these organizations divided jobs into highly specialized areas, emphasized constant communication and monitoring of information, and were organized around composites of centralized and decentralized styles. These systems provide examples of complex, dynamic systems that have learned to function, thrive, and minimize error through constant communication, training, and evolving procedures.

Additional examples of the commitment to zero tolerance are provided by Perot Systems, siteROCK, Applied Information Technologies, and NOCPulse. Even though these companies operate under strict military-style top-down procedures, they are committed to a zero tolerance for errors. In their world, customer security is paramount. They emphasize training, process rules (strict processes or standard operating procedures), war games (detailed planning blueprints and troubleshooting sessions), and mettle testing (interrogating managers to see...
how they handle themselves under pressure). Organizations develop processes to minimize risk once they have developed a culture of zero tolerance. Six Sigma, or 3.4 defects-per-million (i.e., the quest for zero defects), is the latest quality trend in business. The emphasis is on continuous improvement in reducing waste, inefficiency, and variability. The results are higher-quality products and services at a lower cost. Six Sigma is being implemented with spectacular results by General Electric, Lear Corporation, American Express, 3M, Toshiba, General Motors, and Ford to name just a few companies for which it is a major emphasis of competitive strategy. The hallmarks of Six Sigma are training, DMAIC (define, measure, analyze, improve, control), and commitment. For example, 3M’s quality program, PPU (process and product understanding), includes four phases: understanding the customer, understanding key quality characteristics, establishing capabilities, and improving continuously. Communicating concepts and information across 3M is the key to the program.

A blueprint for health care is provided in the elements necessary for any Six Sigma program. One of the Six Sigma training companies, Sigma Breakthrough Technologies, Inc., has summarized these elements as:

- clear need, strategy, and monetary goals for improvement;
- management that is involved;
- procedures for selecting strategic improvement projects;
- good improvement methodology;
- user-friendly software to implement the improvement methodology;
- dedicated and trained resources;
- periodic reviews by various levels of management;
- communication of need and benefits; and
- recognition, rewards, and celebration.

The lessons to be learned from these organizations are to establish a culture that is dedicated to driving error, inefficiencies, and waste out of the system; and to ensure that outstanding customer service is an expectation from which any variance is not tolerated. Health care must adopt similar philosophies, and in this cannot differ from these organizational examples.

Managed care could do worse than to commit to improving health care by changing the culture from cost containment to zero tolerance for anything short of perfection in patient care. Cost improvements will then be a consequence, rather than a goal.†

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References

Focus on Drug Utilization

Over the past decade the growth and evolution of interest in health outcomes research, especially pharmaco-economic research, has been tremendous. For those working in managed care, the interest is still exploding. The obvious reason is that we all want to find the best value for our dollar. It was this desire and the need it reflects that fueled the creation and progress of the Center for Pharmacoeconomic Studies at the University of Texas.

The center was opened seven years ago when faculty at the university decided that the best approach to studying the economics and management of pharmaceuticals and the related health outcomes was through a multidisciplinary team of researchers. Thus, the center combines the strengths of two different research groups: clinical pharmacotherapy practitioners and research specialists, and researchers whose skills lie in the methods, statistics, economics, management, and social behavioral issues related to drug use. The merging of these two research groups has been more than successful; it has been synergistic.

The center brings together researchers from different disciplines and health care sectors and encourages their collaboration with other health care providers and other academic institutions. The result is that the center’s researchers have investigated a wide variety of issues. Some examples are:

- estimating the cost of Alzheimer’s disease in a managed care setting;
- measuring the impact of direct-to-consumer prescription-drug advertising;
- measuring the impact of a nonsteroidal anti-inflammatory drug (NSAID) algorithm in managed care;
- comparing the cost-effectiveness of selective serotonin reuptake inhibitors (SSRIs), antibiotics, and other agents; and
- examining the extent to which Mexican prescription drugs enter the United States.

The center conducts clinical, economic, and policy research on how pharmaceuticals and pharmacy services affect patients’ health care outcomes. For example, a recent study by center researchers has shown that increasing the use of newer-generation antipsychotic medications within a population may lead to fewer costly inpatient hospitalizations. Another group found that using a lower dosage of a third-generation cephalosporin than usual to treat otitis media minimized costs while achieving the same outcomes.

One example of center research that has had an impact on U.S. health care policy was the study measuring the extent to which Mexican prescription drugs were entering the United States. This research was a major factor in the decision by U.S. authorities to ban importation of flunizolid. The obvious reason is that we all want to find the best value for our dollar. It was this desire and the need it reflects that fueled the creation and progress of the Center for Pharmacoeconomic Studies at the University of Texas.

Managed care plans must find ways not only to control the rising costs of pharmaceuticals, but also to ensure the correct use of drug products provided.

Making sure that the right patient gets the right dose of the right drug at the right time should be the responsibility not only of physicians but also of pharmacy benefit managers, pharmacists, and patients. Monitoring and ensuring appropriate utilization is perhaps the biggest challenge that now confronts the drug-delivery process.

These results point to future directions for center researchers. Questions to be investigated by the center’s researchers include:

- Is the right drug being given to the right patient and is it being used correctly?
- To what extent do drug therapies reduce or increase other health care costs?
- Are there less costly alternatives that do not sacrifice efficacy and quality of care?

A specific example of such current center research deals with the question, “To what extent do patients have injuries due to falls as a result of urinary incontinence?” The urge to urinate may cause
patients to hurry, be careless, stumble, and fall, thus suffering injuries. Though there is a plethora of anecdotal evidence that this does occur, objective research data are scarce. Do drug therapies for urinary incontinence reduce the incidence of falls and thus reduce the probability of fractures or other costly injuries to the elderly? In other words, are such therapies cost-effective?

Another area where center researchers are devoting more time is measuring the impact of pharmacy-based value-added services. Such services usually increase patient drug compliance and thus drug utilization and costs, but they also affect the use of other health care services. For example, consider diabetes care services provided by community pharmacists. Center researchers have shown that community pharmacists who provide high-quality diabetic counseling services reduce hemoglobin A₁c values in their patients nearly 1% over a 12-month period. In this same study, patients who were enrolled in the program reduced their overall health care costs by an average of $2,382 because of fewer hospitalizations.

Managed care plans must find ways not only to control the rising costs of pharmaceuticals, but also to ensure the correct use of drug products provided. They must measure the outcomes of the products. Researchers at the Center of Pharmacoeconomic Studies are dedicated to this goal. ♦

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C A V E A T S
Policy, legislative, and regulatory issues and trends

Getting a Quick Fix Online

Do you know that right now most consumers can purchase any prescription medication online without a prescription? That's right, any consumer with a valid credit card can purchase lifestyle-enhancing medications such as hydrocodone/acetaminophen (Vicodin), acetaminophen/codeine (Tylenol #3), or even diazepam (Valium). Gaining access to injectible testosterone and other steroids is easy. Unscrupulous entrepreneurs have even written manuals (available for purchase) that describe how to exploit the Internet for prescription medications.

How did this virtual deregulation of prescriptions occur? The problem stems from two sources: Pharmacies or entities based in other countries whose laws and regulations are less stringent than those in the United States operate freely on the Internet; and unscrupulous operators everywhere claim to diagnose conditions online without ever having met the patient. These "online pharmacies" are not pharmacies at all, because they do not conform to U.S. state and federal regulations. Most importantly, they place the consumer's health in jeopardy.

I went online and found various foreign pharmacies offering manuals for purchase in the Caribbean, Mexico, Asia, the Philippines, and many other places. I paid $29.99 to order each of these manuals. I quickly received five glossy brochures that detailed Web sites and e-mail addresses of international pharmacies offering manuals for the consumer's health in jeopardy. These "diagnosing" pharmacies have undergone a great deal of scrutiny and many lawsuits have been filed against them.

The most worrisome experience I had was with the Mexican pharmacies that I contacted via e-mail. I simply stated that I was interested in purchasing 10 flunitrazepam (Rohypnol) tablets. Rohypnol is a benzodiazepine that is commonly known as the "date-rape" drug. The e-mail response I received read, "Sorry all out, check back next week."

What about these so-called pharmacies that offer Viagra, Propecia, and Xenical without a prescription? These sites aren't difficult to locate. They claim that from an online questionnaire, they can diagnose problems and assess the need for the medication. No physical examination or prescription required. Anyone can answer these questionnaires, falsely if necessary. The message here is that the questionnaires are not reviewed; what is reviewed carefully is the customer's credit card number. Some questionnaires even have all of the correct answers pre-selected, to simplify the ordering process.

Even with regulation, enforcement is difficult. These sites can operate for a short time, then simply change URLs when they come under scrutiny. Our state and federal laws do nothing to identify and track these Web sites. While the pharmacy profession is indeed over-regulated, federal regulations and funding could help identify these operators and impose heavy penalties. Our current state board investigators do not have the training, expertise, or time for this responsibility.

Unregulated purchasing of prescription drugs online is a big problem. Why aren't we hearing more about it? That's the scary part: because consumers who frequent these sites are not willing to report them. ♦

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An Inside Look at the Benefits of a Student Pharmacy and Therapeutics (P&T) Committee Competition from the University of Illinois at Chicago

Pharmacy students across the country are faced with a dilemma. How can students enrich their understanding of the complexity of pharmacy practice beyond what is taught in the classroom? Many students obtain part-time jobs and summer internships, but often these jobs do not provide the students with the deeper hands-on experience they need. More professional development is sought, usually outside the classroom.

Five years ago, the University of Illinois at Chicago (UIC) College of Pharmacy Academy of Managed Care Pharmacy (AMCP) Student Chapter developed a Pharmacy & Therapeutics (P&T) Committee Competition to give students a “behind-the-scenes” experience of the inner workings of a P&T committee. Such a committee in many different pharmacy environments enables pharmacists to demonstrate their clinical expertise in a critical, expanded role vis-à-vis their physician colleagues. The primary mission of the P&T committee is to promote cost-effective and rational drug therapies through a formulary-management system. In doing so, the P&T committee recommends policy to medical staff and administrators about the desired therapeutic use of drugs and other health-related issues.

The P&T Committee Competition was initiated, developed, and sponsored by the AMCP student chapter and has been held annually at the UIC College of Pharmacy for five years. The competition is designed to simulate a “real world” experience outside the classroom. Past cases have addressed evaluations of:

- pharmaceutical manufacturer proposals on H₂-receptor antagonists, antihyperlipidemic products, and a disease-state management program that centered on use of the manufacturer’s osteoporosis treatment drug (1997);
- bundling a group of drugs for preferred status on a formulary (1998);
- use of selective serotonin reuptake inhibitors (SSRIs) in a specific patient population (1999);
- restricting the use of non-sedating antihistamines in a student-based health maintenance organization (HMO) (2000); and
- the use of prescription versus over-the-counter products (2001).

The goals of the P&T Competition are to:

- enhance pharmacy students’ understanding of the P&T committee decision-making process;
- further improve student professional skills through research, presentation, and discussion of case-related issues;
- augment student experience and education in formulary design and managed care pharmacy;
- provide students with an opportunity and environment to network with seasoned managed care pharmacy professionals, including alumni; and
- recruit pharmacy students to participate in a professional-organization activity.

In the competition, four students make up a team which represents the pharmacist on P&T committee. Each team must include a first-, second-, and third-year student; the fourth member can be from any pharmacy class. This structure creates an academically diverse team and exposes each student to knowledge levels and thought processes involved in varying stages of educational development. The four competition judges are selected based on various backgrounds, which may include managed care professionals, industry professionals, faculty, and/or alumni.

The primary purpose of the selection is to provide a diversity of opinions from different health care settings and professional perspectives.

Each team is presented with the same case-specific scenario, which incorporates many aspects that a “real” P&T committee might encounter. The team is asked to evaluate the case and develop a proposal to be submitted for committee consideration. The proposal must include a clinical research review, a pharmacoeconomic analysis, and an ethical-issue assessment. Within the clinical evaluation, the case information provided to the students includes the health plan’s demographics, current formulary information, percent of members with related disease states, and drug utilization by drug classes under review. In addition, the students are given the current annual expenditures per drug, the amount of drugs used by plan members, the current drug prices including any rebates, and prior physician switch rates to assist them with their pharmacoeconomic analysis. The students also are informed of the use of disease-state management programs, pharmacoeconomic software for their products, and any academic detailing. All of this information may be used to assist the students in performing an ethical analysis. The ultimate goal of the student teams in performing these analyses is to determine if the overall proposal is therapeutically valuable, economically viable, and ethically preferred.

Once the teams have researched and evaluated all of the information, they must prepare a written executive summary and a 35-minute oral presentation for the panel of judges. Each team’s write-up must include pertinent clinical data, and the economic and ethical analyses of the overall case, ending with a team decision and rationale to support the final recommendation to the P&T committee. During the first 15 minutes of the oral presentation, each team must explain the written summaries and present the rationale of its findings. During the second 15 minutes, the panel of judges asks a series of standard questions addressing the clinical, economic, and policy aspects of each team’s recommendation. The final five minutes are reserved for participant questions and feedback from the judges.

Continued next page
The winning team is chosen based on its members’ ability to think “out of the box” and extract pertinent data in order to synthesize the team’s final decision.

At the conclusion of the oral presentations, the judges select the first-place team. They use a standard judging criteria to evaluate the quality of the teams’ written and verbal presentations, problem solving and critical thinking skills, application of relevant clinical research, and overall coordinated team effort. The winning team is chosen based on its members’ ability to think “out of the box” and extract pertinent data in order to synthesize the team’s final decision. All participating students learn from each other in a team setting through research, thinking, and presentation experiences, and through constructive feedback from the judges.

The benefits to the students of participating in a P&T Committee Competition are numerous. First, the competition increases student interest in managed care environments and provides an insight into the roles and responsibilities of a managed care pharmacist. Indirectly, the competition promotes consideration of career choices toward managed care pharmacy. The students are given the opportunity to develop and refine research, analytical, and presentation skills and gain a functional understanding of the P&T committee in a managed care environment. Students learn to use pharmacoeconomic and pharmacotherapeutic evaluations to enhance future decision-making processes as they participate in making “real life” therapeutic recommendations and decisions. In summary, the P&T Competition serves to incorporate student learning into a well-rounded managed care education for student participants.

In October 2000, at the AMCP Educational Conference in San Diego, California, several members of the UIC-AMCP student chapter presented a poster titled “Learning Managed Care Concepts Outside the Classroom: A Pharmacy and Therapeutics Committee Competition.” Three chapter officers and two participants from the winning team of the fourth-annual UIC-AMCP P&T Committee Competition developed the poster. This poster-presentation opportunity increased the exposure of the P&T Competition and sparked interest from students in other leading pharmacy schools. Many students expressed interest in holding their own P&T competition at their respective AMCP student chapters.

The success of the AMCP student P&T Committee Competition led to the development of the first National P&T Committee Competition sponsored by AMCP at the Annual Meeting in Tampa, Florida, this past April. The national competition provides all AMCP student chapters with an excellent learning opportunity and increases interaction among chapters to promote professional and personal growth within the student membership.


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Traditionally, discussions of women's health were limited to conditions that are unique to women, such as contraception, fertility, and menopause. Yet very little was known about even these issues, as illustrated by an article written in 1967, which described menopause as a chronic and incapacitating deficiency disease. The definition of women's health has expanded. A menopausal woman was considered a castrate, with all the inherent physical and psychic disorders observed in patients who have undergone bilateral oophorectomy. The understanding of menopause, and of women's health in general, has grown tremendously since that time.

Because gender differences in medicine have become clear, we realize that we cannot treat males as the norm; thus, the definition of women's health has expanded. Carolyn Clancy, director of the Center for Outcomes and Effectiveness Research, U.S. Agency for Healthcare Research and Quality (AHRQ), explained:

Women's health may be defined as screening for, preventing, diagnosing, and treating conditions unique to women; conditions more prevalent or more serious in women; or conditions that have different risk factors or require different interventions for women, and thus deserve special attention.

The purpose of this article is to increase recognition of the importance of women's health issues and the role that managed care pharmacists can play in women's health care.

+++ Women's Health Issues in Managed Care

Financial Issues
The cost of care is a general issue for managed care organizations (MCOs), as well as for government agencies and many employers. An integrated database of medical and pharmacy claims reported that nearly 60% of all health plan expenditures are attributed to women and 59% of all prescription drugs are prescribed to women. Reproductive issues—menopausal symptoms, menstrual disorders, and contraceptive management—accounted for 16% of all health plan expenditures, more than cardiovascular disease, diabetes, and asthma combined.

One factor that contributes to the increased cost of medical care for women is that they visit their doctors more often than men do. Women are more likely than men to suffer health problems associated with their reproductive systems. Prenatal care and routine cervical and breast cancer screening bring women into the health care system often. Another contributing factor is that women are more susceptible than men to certain diseases, among them rheumatoid arthritis, osteoporosis, urinary incontinence, anxiety, depression, and Alzheimer's disease.

In addition, some diseases have more significant consequences in women. Among females attending family planning clinics, the prevalence of chlamydia ranges from 4%–12%. Complications of chlamydia in women are severe and frequent. Once infected, women are more susceptible to reproductive cancers and infertility.

The sheer number of women in government programs (Medicare and Medicaid) presents significant financial concerns. In 1999, 57% of the 39 million people enrolled in Medicare were women, as were 57% of Medicaid enrollees. Of the Medicare members older than 85 years, 75% were women. Medicaid is a major payer for nursing home care, three quarters of nursing home residents covered by Medicaid are women. Medicaid is also America's largest single purchaser of maternity care (prenatal, delivery, and postpartum services). In 1995, Medicaid paid for 39% of the more than 3.1 million live births in the United States.

Marketing
The phrase “women's health” is often used in marketing, especially within the managed care and employer markets, because women make 75%–90% of the health care decisions for themselves and their families. Some managed care plans have found that promoting preventive care to women increases the likelihood of their re-enrollment by as much as 28%. Employers may also benefit from promoting women's health care because women now make up 44% of the paid U.S. workforce.

Quality of Care
Some conditions that may affect a woman's
HEDIS Quality Measures Specific to Women’s Issues—
1999 National Results

<table>
<thead>
<tr>
<th>Measure</th>
<th>Results of Plans in the 10th Percentile</th>
<th>Average Health Plan Results</th>
<th>Results of Plans in the 90th Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer screening</td>
<td>64%</td>
<td>73%</td>
<td>82%</td>
</tr>
<tr>
<td>Cervical cancer screening</td>
<td>60%</td>
<td>72%</td>
<td>83%</td>
</tr>
<tr>
<td>Checkups after delivery</td>
<td>54%</td>
<td>71%</td>
<td>87%</td>
</tr>
<tr>
<td>Chlamydia screening, ages 16–20 years</td>
<td>5%</td>
<td>18.5%</td>
<td>32.6%</td>
</tr>
<tr>
<td>Chlamydia screening, ages 21–26 years</td>
<td>4.6%</td>
<td>16%</td>
<td>28%</td>
</tr>
<tr>
<td>Management of menopause counseling (composite of subscores)</td>
<td>48.7%</td>
<td>56.6%</td>
<td>63.7%</td>
</tr>
<tr>
<td>Prenatal care in the first trimester of pregnancy</td>
<td>71%</td>
<td>85%</td>
<td>95%</td>
</tr>
</tbody>
</table>

Note: HEDIS is the Health Plan Employer Data and Information Set.

Women's health care is also important to managed care pharmacy. In terms of finances only, women represent 62% of prescription drug use and 58% of total prescription costs. Approximately 70% of all prescriptions for antidepressants and anti-anxiety agents and 80% for migraine drugs are filled for women. Several other classes of medications (e.g., gastrointestinal drugs, pain medications, antihistamines) are more commonly filled for women.

In the past decade, a dramatic 75% increase in pharmaceutical industry research on areas of women's health has led to a full pipeline of drugs to help meet the special health needs of women. U.S. pharmaceutical companies are developing more than 348 new medicines directed at women's health needs of women.

Conducting more research on diseases that disproportionately afflict women, but for some gender-based research is being slowed. Little is known about how oral contraceptives and hormone replacement therapy affect the course of many diseases or the response to therapy. Additionally, women have often been excluded from or seriously underrepresented in clinical trials (e.g., major studies of coronary heart disease). Lack of understanding surely affects quality of care.

In order to remedy this disparity in research and assure that the care of women is adequate, it is necessary that women be included in the study populations of federally funded clinical research and clinical trials on medications submitted to the Food and Drug Administration (FDA). One notable trial, designed to address the gap in knowledge, is the Women's Health Initiative, which will evaluate strategies for preventing heart disease, breast cancer, colorectal carcinoma, and osteoporosis in postmenopausal women. This will be the first trial to provide disease data on hormone therapy for ethnic minority women. Through advocacy by women's organizations, federal funding has become available, particularly for breast cancer research.

The National Committee for Quality Assurance (NCQA) evaluates and reports on the quality of the nation's MCOs. One of its measures, the Health Plan Employer Data and Information Set (HEDIS), will soon account for 25% of an MCO's NCQA accreditation. HEDIS measures the following women's health indicators: chlamydia screening, management of menopause, breast cancer screening, cervical cancer screening, prenatal care in the first trimester, and check-ups after delivery (see Table 1, left). Future HEDIS measures are likely to include osteoporosis and family planning counseling.

Opportunities for Managed Care Pharmacy

Women's health care is also important to managed care pharmacy. In terms of finances only, women represent 62% of prescription drug use and 58% of total prescription costs. Approximately 70% of all prescriptions for antidepressants and anti-anxiety agents and 80% for migraine drugs are filled for women. Several other classes of medications (e.g., gastrointestinal drugs, pain medications, antihistamines) are more commonly filled for women.

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The significant opportunities to improve the care of women are illustrated by the wide variation of care in HEDIS measures, especially chlamydia screening (see Table 1). Smoking rates are declining more slowly for women, and obesity and physical inactivity are more prevalent in women than men. Recently, the Centers for Disease Control and Prevention revealed that clinicians are missing opportunities for...
heart-disease-prevention counseling. In a study of 29,273 routine office visits, women were counseled less often than men about exercise, nutrition, and weight reduction. Managed care pharmacists have an opportunity to work toward improving the care of women by educating members and providers (see Table 3, page 266).

Managed care pharmacists must recognize differences in the safety of medications between men and women. A recent report by the General Accounting Office stated that 8 out of 10 prescription drugs pulled from the U.S. market since 1997 posed greater health risks for women than for men. Four of these (Rezulin, Redux, Pondimin, and Lotronex) may have had more adverse events in women than in men because they were prescribed more often to women. The other four (Posicor, Seldane, Hismanal, and Propulsid) had more adverse events in women even though they were widely prescribed to men as well as women. Women in particular have a higher incremental risk of suffering an arrhythmia after taking these drugs, probably because the interval between heart muscle contractions is naturally longer for women than for men and because male sex hormones moderate the heart muscle’s sensitivity to these drugs.

Gender differences in efficacy may also exist. Because phenytoin is cleared more rapidly in women during the luteal phase of
The inclusion of prescription drug benefits in managed care pharmacy, including benefit design, formulary management, and clinical programs. A survey of more than 14,000 women demonstrated that the inclusion of prescription drug benefits has important ramifications for customer satisfaction.\textsuperscript{15} The survey found that 51\% of women made their health plan decision based on whether there was a prescription drug benefit and 33\% stated that their decision was based on medical and pharmacy copayment differences between health plans.

Managed care pharmacists should be able to defend the economic and health rationale for including contraceptives within the pharmacy benefit. For example, reportedly because of the increased use of contraceptives, from 1987 to 1994 the rate of unplanned pregnancies dropped 16\%, abortions declined 11\%, and unplanned births declined 22\%.\textsuperscript{16}

Express Scripts’ oral contraceptive model, based on actual use of oral contraceptives in 1996 by 1.8 million employer lives, can estimate the cost of contraceptive coverage based on the age demographics of a group’s female population. The model is based on average wholesale price (AWP), and thus does not include discounts or copayments. Overall, the cost of oral contraceptives is $0.77 per member per month or $1.48 per female member per month. Payors should also be made aware that they may already be covering some oral contraceptives to treat medically appropriate conditions such as endometriosis or dysfunctional uterine bleeding.

An analysis of contraceptive coverage is beyond the scope of this article, but one reference that does describe the cost to employers of adding all contraceptive options is available on the Alan Guttmacher Institute Web site at www.agi-usa.org/pubs/kaiser_0698.html.

Coverage of fertility medications within the pharmacy benefit is another issue that may seem to specifically affect women. Thirteen states have now mandated some form of infertility coverage, yet there are no national standardized protocols. Managed care pharmacists may be involved in designing infertility medication benefits or developing protocols for their use. For example, the expense of one of the treatments, gonadotropins, may be compounded by waste (e.g., cycles are often cancelled, patients may have remaining

gonadotropins after a cycle). Therefore, a distribution system or benefit design strategy that reduces gonadotropin waste can reduce costs. A resource that describes some issues in developing infertility treatment algorithms is an article by Glicker in Human Reproduction Update.\textsuperscript{17}

Clinical Programs
Care of chronic disease is one of the fastest-growing and costliest segments of women’s health care. Conditions that lend themselves to clinical/educational programs or multi-disciplinary guidelines in women include chronic headaches, chronic rheumatologic conditions, obesity, coronary artery disease, osteoporosis, and depression. Effective therapy adherence programs are needed for osteoporosis and hormone replacement therapies. Clinical programs that strive to improve women’s knowledge of menopausal therapies, both pharmacologic and non-pharmacologic, would also fill a gap in member education.

Formulary Management
There are at least two perspectives of how the care of women falls into formulary management. One is the need for safety and efficacy information specifically directed at women. A second is the safety and efficacy of how a medication is to be used in combination with oral contraceptives or hormone replacement therapy products.

†† Case Examples
Below we describe programs that contribute to understanding women’s health, improving the quality of care, or reducing costs of pharmaceuticals.

Accurate Health Statistics
A World Health Organization technical paper states that, first and most importantly, it is essential that the situation of women be more accurately reflected in routinely collected health statistics.\textsuperscript{18} It has been a frequent complaint that most statistics are not separated by gender. Express Scripts’ Drug Trend Report now has a chapter that describes use of medication in men and women across the lifespan.\textsuperscript{19}
One important finding was that there was a greater percentage change in cost per prescription for females (+10.96%) than for males (+7.24%) as they aged. Mean AWP per prescription increased 18.2% for women in their seventh decade of life and 20.25% for women at age 80 years of age and older. Increases in cost per prescription hit elderly females disproportionately hard.

Patient Counseling
A pharmacist-to-patient counseling program focuses on members who are most at risk for negative outcomes related to polypharmacy. Two-thirds of the members contacted are women. These services promote formulary or generic and lower-cost medicines as well as prevention of adverse drug events and interactions. Members are educated about their medications, including dosing schedules and contraindications, via letters and telephone counseling. All members are encouraged to discuss pharmacist recommendations and any additional questions with their physician. The top five interventions discussed with women are (1) calcium requirements; (2) bisphosphonates, including proper use, calcium requirement, and side effects; (3) bone-density tests for osteoporosis risk assessment; (4) incontinence/bladder control; and (5) management of menopause.

One example highlights the value of pharmacist counseling. During a phone consultation, a pharmacist noticed that the female patient that she was speaking with was having difficulty breathing and talking at the same time. The pharmacist noted two similar heart medications (metoprolol and atenolol) on the patient’s record and notified the physician immediately about the duplicate therapy. One of the medications was then discontinued.

Osteoporosis
A recent National Institutes of Health report stated that fewer than 5% of patients with osteoporotic fractures are referred for medical evaluation and treatment. This is worrisome because up to 20% of postmenopausal women with a vertebral fracture will have a second fracture within a year. A program being designed by Express Scripts will use integrated pharmacy and medical claims to target postmenopausal women diagnosed with osteoporosis or who have had a hip, vertebral, or radial fracture and have not received a medication for osteoporosis. Letters will be sent to the patients and their physicians, discussing prevention and treatment of osteoporosis, lifestyle modifications, and therapy options. Patients who start on medication will be enrolled in a compliance program. The goal is to promote evaluation and treatment of patients at risk for osteoporotic fractures.

† † Conclusion
Women’s health is a priority for many health care systems for financial, marketing, and quality-of-life reasons. Significant advances in women’s health care have been made in the past 30 years. The inclusion of women in clinical trials will continue this effort to understand gender-specific differences in medicine.

Managed care pharmacists have opportunities to improve the care of women by incorporating the information from clinical trials into their practice. They are well positioned to improve quality of care through educating providers and members.

Lastly, managed care faces the challenge of managing the potential costs presented by a vast pipeline of new drugs specifically designed for women.

References
Employee Benefits Consulting: An Essential Role for Pharmacy

By Connie Perry

Employers today face a complex assortment of health care decisions as employees clamor for expanded benefits and the cost of health care continues to grow. The pharmacy benefit, although one of the most desirable for employees, is financially a high risk for payors. The role of the pharmacy benefits consultant has grown to match employers’ needs; it now includes not only review of medication expenditures but also analysis of the overall health care plan design and increased use of clinical programs to optimize medical and prescription-drug management.

The importance of good benefits consulting can be underscored by some recent cost trends. In the early 1980s, prescription drugs accounted for about 2.3% of the U.S. health care dollar. That figure grew to 10% in the early 1990s, and to 15% by 2000. Clients outside of a managed care plan experienced higher annual increases (about 18%) than did managed care clients (approximately 16.3%). Clearly, drug-benefit management has had an impact.

During the next five years, double-digit annual increases are expected. It is commonly accepted that the cost of the prescription benefit will only be curbed if a clinical consulting approach is used when pharmacy benefits are introduced or refined. This represents an opportunity for managed care pharmacists to have considerable impact on the cost and quality of health care.

**History Is Important**

Managed care has arrived at this point as the natural consequence of its history. Managed care is a form of insurance. Until World War II (WWII), health insurance was a fringe benefit, meaning it was an optional incentive to attract and retain employees. During WWII, wages were frozen but benefits were not. Consequently, the health care benefit as a form of compensation moved from the fringe into the limelight. The government provided incentives to promote employee benefit plans, including tax laws favoring businesses that provided health insurance.

Over the next two decades, fee-for-service health care flourished, and the cost of health care was unfettered. Benefits that were once considered optional or attractive—pharmacy, dental, and vision—became highly desirable to employees, and pressure to manage insurable risk to maximize outcomes increased. By the 1960s, health care financing had become a national concern, and various methods of controlling costs were introduced.

From the inception of managed care, performance benchmarks focused on cost savings, not clinical outcomes. Plan designs assumed that providers would manage insurable risk to maximize outcomes and minimize complications at a reasonable cost. In the 1980s, pharmacy benefit management relied on controlling unit cost and unit utilization. How successfully managed care principles were applied depended on a number of factors. The initial cost containment began to level out in the 1990s.

Today, there are concerns about quality of care, member satisfaction, and breadth of coverage as well as cost. Thus, health care plans must use cost management as a foundation, use managed care principles to design benefits, use a delivery system based on quality-management principles, and comply with numerous laws. For the pharmacy benefit today, three factors are essential:

- controlling unit cost and utilization;
- sharing financial risk (and some decision making) by having members pay a nominal fee whenever they access the health care system; and
- obtaining discounts from all providers and vendors that influence drug costs.

The complexities of drug therapy, the entry of cosmetic and life-enhancing medications, new product pricing, and clinical program opportunities have all affected medication use and opened new venues for benefit management. Pharmacy-benefit consulting must give history its due, use today’s tools efficiently, and look to the future to anticipate changes on both the immediate and the distant horizons.

**Who Manages the Benefit?**

Employers have options when evaluating cost drivers in their populations. They can use a third-party administrator, their medical insurance carrier, or a pharmacy...
Employee Benefits Consulting: An Essential Role for Pharmacy

Pharmacy Cost Drivers in 2001

- Aging population
- Explosion of new drugs
- Medical guidelines specifying earlier drug interventions
- New, multidrug regimens
- New treatments for previously untreatable diseases
- Better patient compliance
- Direct-to-consumer advertising
- Price inflation

What Pharmacy Benefit Consultants Can Do

Pharmacy benefit consultants:

- Control costs by managing unit cost (price) and number of units used (quantity or utilization)
- Introduce or recommend enhancements to tools and techniques to manage the prescription benefit
- Design and implement organizational activities to influence prescriber, pharmacist, and patient behavior in such a way that the cost and use of prescription coverage is decreased

benefits management company (PBM). Regardless of which they select, employers expect recommendations based on data and reports that respond directly to the issues in ways that are easily understood and supportable.

These reports can serve as tools to educate employers on what drives costs in today’s market (see Table 1, above). Tom Lerche, health and welfare practice leader at Aon Consulting, describes the pharmacist’s role succinctly: “Our customers are self-funded employers who find that the prescription drug benefit is one of their top three problems. This is a difficult area because it is high cost, but of high value to employees. Pharmacists bring to bear clinical knowledge and skills.” He then demonstrates that disease management is a cousin to the drug benefit, and that when a consulting pharmacist is able to apply disease-management theories creatively, the customer benefits. These pharmacists are particularly helpful when employers request additional clarification on current prescription drug benefit issues.

Defining what a pharmacy benefits consultant does is difficult. Table 2, below, shows several definitions. While the general duties can be specified, how they are performed varies. Often, information about benefit management is not available because it is proprietary to the companies that own it.

In general, consultants use two techniques to manage the benefit: economic techniques (plan design) and benefit management (clinical tools). Three unique functions pharmacy consultants perform today

Drivers in 2001

- Aging population
- Explosion of new drugs
- Medical guidelines specifying earlier drug interventions
- New, multidrug regimens
- New treatments for previously untreatable diseases
- Better patient compliance
- Direct-to-consumer advertising
- Price inflation

Evaluating the Pharmacy Benefit

Evaluating the pharmacy benefit requires simultaneous analysis of the financial and clinical techniques employed.

Financial areas include member cost-sharing, the exclusion medication list, retail and mail service pricing and fees, use of generic medication, formulary analysis, and rebate/discount arrangements. Despite their designation as financial, each of these areas can be addressed better if the pharmacist’s inherent clinical insight adds perspective. For example, though the decision to change from a two-tier to a three-tier cost-share affects members, the impact can be mitigated if sound clinical judgment is used to determine where drugs are placed in the tiers.

Research has confirmed that current cost drivers in pharmacy include increased drug use by members, with a changing mix of drugs contributing approximately equally and inflation contributing less. Reasons for increased use include an aging population, new prescribing guidelines that emphasize combination therapy, a plethora of new therapeutic drug advances, increased compliance among members, and pharmaceutical company advertising (both direct-to-consumer and to providers).

Clinical program opportunities abound: retrospective, concurrent, or prospective drug-utilization review; prior-authorization protocols; provider profiling; and wellness or disease-management programs. Clearly, implementing these programs can reduce costs and minimize the need to increase member cost share.

Pharmacy consultants have learned several lessons over the decades:

- Introducing several changes at once is likely to be less successful than introducing changes gradually with ample communication to and lead-time for affected parties.
- Analysis of plan design should start with the member cost-share to ensure that it is appropriate, encourages use of generics and mail-in programs, and addresses cosmetic, life-enhancing, or discretionary drugs in a way that is fair and humane.
- Pharmacy benefits consultants should and can successfully address utilization, affecting cost significantly.
- Excluding drugs after they have been approved and have gained users creates discontent among providers and members; each new drug choice should be analyzed well before its introduction to the market.
- Formularies can promote step care, limiting inclusion only to those doses and delivery forms that are most cost-effective.

Measuring the pharmacy benefit against regional standards, reconciling employer human resource strategy and employee need, integrating clinical and financial processes, and anticipating new drugs before they enter the market place together create the best foundation for cost-effective, high-quality care.

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**TABLE 1** Pharmacy Cost Drivers in 2001

- Aging population
- Explosion of new drugs
- Medical guidelines specifying earlier drug interventions
- New, multidrug regimens
- New treatments for previously untreatable diseases
- Better patient compliance
- Direct-to-consumer advertising
- Price inflation

**TABLE 2** What Pharmacy Benefit Consultants Can Do

Pharmacy benefit consultants:

- Control costs by managing unit cost (price) and number of units used (quantity or utilization)
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Vol. 7, No. 4 July/August 2001 JMCP Journal of Managed Care Pharmacy 269
**TABLE 3 Core Performance Measures**

<table>
<thead>
<tr>
<th>Key Measure</th>
<th>Description of Measure</th>
<th>Best Practice Standard</th>
<th>Reporting Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID card production</td>
<td>Accuracy in delivery of ID cards after receipt of processable eligibility information</td>
<td>100% within 2 business days</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Reporting standards</td>
<td>Standard reports and Core Performance Measures are reported on a regular basis</td>
<td>Within 45 days of end of quarterly cycle</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Prior-authorization turnaround time</td>
<td>The response time for prior-authorization requests is reasonable</td>
<td>1 business day</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Claim-adjudication accuracy rate</td>
<td>Prescription claims are processed with accuracy</td>
<td>99% of claims are processed with 100% accuracy</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Average speed of answer</td>
<td>Average speed of answer for all calls received by PBM's customer service unit</td>
<td>100% of calls answered within 25 seconds</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Mail-service prescription turnaround time</td>
<td>Number of days for mail-service prescriptions to be delivered to members</td>
<td>95% of &quot;clean&quot; orders are mailed to members within 2 business days</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Access to claims data</td>
<td>Ability of client's benefits staff and their designee(s) to access claims data, etc., for the purpose of auditing, etc.</td>
<td>Access is granted with timely notices</td>
<td>Notice of 15 days</td>
</tr>
<tr>
<td>Member reimbursement for inaccurate dispensing</td>
<td>Each eligible person is reimbursed the cost of any inaccurately dispensed prescription drug</td>
<td>Vendor agrees with the description of measure and will also reimburse for the cost of the replacement drug</td>
<td>N/A</td>
</tr>
<tr>
<td>Call-abandonment rate</td>
<td>Percentage of calls lost due to hang-ups</td>
<td>No more than 2.5% of total calls are abandoned</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Call-resolution rate</td>
<td>Calls answered and resolved by customer service unit</td>
<td>95% of calls are resolved on first call</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Telephone busy signals</td>
<td>Minimal busy signals for members calling the customer service unit</td>
<td>No more then 3% of total calls will result in a busy signal</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Issuance of rebate check</td>
<td>Rebate check received in a timely manner</td>
<td>60 days post end of reporting quarter</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Denied/rejected claims</td>
<td>No administrative fees are charged for denied or rejected claims</td>
<td>Vendor agrees with description measure</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**The Proposal Process**

Among the pharmacy benefit consultant’s most popular projects is the request for proposal (RFP) or vendor marketing and selection process. Pam Hodge, an assistant vice president with Aon Consulting, suggests bringing in a pharmacy consultant whenever a client requests a prescription drug study. Her clients are generally interested in a long-term strategy for controlling prescription drug costs. These strategies may include plan redesign, employee education, a common formulary approach, and negotiating rebates and lower administrative costs with vendors. She has found that the expertise of a pharmacy benefits consultant can be helpful to clients in designing and executing these strategies.

Selecting the best vendor to meet an employer’s needs can be challenging today. Legal, clinical, and business changes in health care have created an environment in which complex plan designs, superior account management, and performance-measurement agreements are the rule rather than the exception. This complicates the proposal process. In the past, fee or discount negotiation often gave the complete answer to an employer’s cost concerns. Today, clinical issues abound, and performance meas-
TABLE 4  Elements of a Database Audit

- Analyze manufacturer rebates and their application to client
- Identify apparent duplicate claim payments
- Identify prescribing/utilization patterns within specific therapeutic categories
- Analyze formulary alternatives used and the formulary-conversion process
- Identify generic fill rate
- Validate eligibility updating and procedures for terminations and additions
- Validate claim-system edits for plan limitations, maximums, and prescription preauthorizations
- Analyze for possible fraudulent, drug abuse, or misuse-related claims
- Validate pharmacy reimbursement rates and accuracy of claim payments
- Evaluate impact of retail versus mail reimbursement formulas (if applicable)

ures must be incorporated to address customer service concerns. In addition, member access to services must be considered.

One state-government manager commented after working with a pharmacy benefits consultant to develop an RFP for a 100,000-member program: “Any organization that is going through the painful task of looking at prescription drugs is bombarded with information from lobbyists, vendors, and other interested parties. They all have an interest in the outcome. Having a pharmacy benefits consultant helps us direct our energies appropriately.”

Table 3, page 270, describes some current performance measures that define the employer, provider, and consumer expectations of acceptable service. Too often the community pharmacist is swamped with problems when new identification cards should have been mailed but were not, the physician is frustrated with prior approval delays, or the member’s prescription arrives after several doses have been missed. Incorporating performance measures into contracts improves the quality of service by clarifying tasks, time frames, appropriate measures, and reporting frequencies. Performance, however, must be measured with both the client’s or business environment’s perspective and accepted or pending mitigating factors in mind.

Vendor Audits

Vendor audits ensure quality service. They determine the effectiveness of vendor performance and compliance with contracts.

Audits are necessary because benefits managers and pharmacy directors may not always have the capability or documentation to verify certain aspects of service. For example, rebate amounts are based on volume of product sold; an audit can determine if the rebate was appropriate to the volume sold. Also, key performance measures can be audited to ensure that they are being met. In short, almost anything—financial or clinical—can be audited.

Table 4, above, describes the basic elements of an audit. Audits generally rely on review of databases. Once the audit is conducted, the pharmacy consultant must report findings and make recommendations for corrective actions. These recommendations may include changes to the PBM agreement or benefit plan. The report must also document any variances in terms of billing errors or overpayments and describe trends or specific areas where new processes can prevent future problems.

†† Implications for Managed Care Pharmacists

Pharmacists working with health care plans should work with the plan’s marketing department to ensure that employers understand the pharmacy-management programs used. Meeting face-to-face with employers is an excellent way to facilitate accurate communication.

As pharmacy benefits grow in importance, there will be more opportunity in the benefit-consulting field. Pharmacists with managed care experience, gained from employment with either a health plan or a PBM, will be ideal candidates for these positions. In this way, the effect of managed care on health care will continue to expand.

References

This paper reports on the Academy of Managed Care Pharmacy’s (AMCP’s) suggested process for pharmaceutical manufacturers to submit a uniform, evidence-based dossier for each product submitted for formulary approval.

The process requires that manufacturers provide clinical and economic evidence and an economic model that projects the potential economic consequences and impact of product coverage on health outcomes. This formulary-submission process is designed to achieve two main goals: (1) improve the timeliness, scope, quality, and relevance of information provided to pharmacy and therapeutics (P&T) committees; and (2) streamline the process of acquiring data and reviewing products for health plan staff pharmacists. In time, it is hoped, this process will lead to progressive improvements in the quality of formulary submissions and, at a minimum, provide P&T committees with evidence that previously was often unavailable.

KEYWORDS: Economic model, formulary, health outcomes, P&T Committee

J Managed Care Pharm 2001: 272-82

AMCP has designed a companion Format for Formulary Submissions so that manufacturers will submit evidence of clinical and economic benefit in a standard format to health plans, pharmacy benefit management firms, hospitals, and other organizations so that they can make objective evaluations of pharmaceuticals for coverage or reimbursement. These data will enable P&T committees to consider a wider array of information in their decisions about products to include on a health plan’s formulary.

The process is intended to foster a meaningful partnership between the manufacturer and the health plan and to elicit rational decisions about product adoptions based on clinical, economic, and other outcomes data should be the foundation of a sound formulary system. These precepts were affirmed by the new guidance, “Principles of a Sound Drug Formulary System,” endorsed by the AMCP, American Society of Health-System Pharmacists, American Medical Association, Department of Veterans Affairs, National Business Coalition on Health, and United States Pharmacopeia.1
**Formulary Submission Checklist**

A COMPLETED FORMULARY SUBMISSION CHECKLIST SHOULD ACCOMPANY EACH SUBMISSION, WITH A BRIEF EXPLANATION FOR ALL MISSING DATA.

<table>
<thead>
<tr>
<th>SUBMISSION PROCESS</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you met with [PLAN NAME] staff to review the submission process?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you agreed upon a submission date with [PLAN NAME]?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you requested summary data to identify baseline characteristics of the plan population?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you included an explanation for any missing data? (Check yes if not applicable)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT INFORMATION</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has a product description been provided?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a list of approved indications been provided?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the place of this product in therapy for each indication been included?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have copies of treatment guidelines been provided?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have the intermediate and final outcomes of therapy been listed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you listed any coprescribed drugs by indication?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you identified the comparator drugs by indication?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SUPPORTING CLINICAL INFORMATION</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you identified all relevant clinical and other experimental studies for the product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you identified all relevant clinical and other experimental studies for comparator products?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are copies of all studies identified included in the submission package?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you provided a spreadsheet summary of all studies identified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do the outcomes need to be translated into effectiveness terms?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have these translations been included in the submission?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you included all relevant noneperimental studies for the product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you included all relevant noneperimental studies for comparator products?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you provided a spreadsheet summary of all noneperimental studies for the product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do the outcomes in noneperimental studies need to be translated into effectiveness terms?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have these translations been included in the submission?</td>
<td></td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>SUPPORTING ECONOMIC INFORMATION</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you identified all relevant pharmacoeconomic (PE) studies?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you justified the relevance of these PE studies for this population?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you provided a spreadsheet summary of these PE studies, detailing their relevance?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you developed a therapy intervention framework for each indication?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you confirmed the therapy intervention framework with the health plan?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you identified the characteristics of patients to be switched to this product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you identified the characteristics that would exclude patients from using the product?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Continued next page
Guidelines and Drug Coverage Decisions

For most health plans, the formulary has become the foundation for the entire drug benefit program. Successful management of a drug formulary often hinges on the integrity of the criteria and evidence used to make approval or removal decisions. Unfortunately, adequate data often are not readily available; unpublished studies and information on unapproved indications are difficult to obtain; manufacturers do not routinely supply data addressing quality-of-life and economic outcomes; and the time required for clinical pharmacists to assemble, critically evaluate, and summarize data for the P&T committee is excessive.

To minimize these problems, formulary guidelines may be used. Guidelines support the selection of a rational drug formulary by (1) standardizing the information required from the manufacturer; (2) formalizing the importance of a drug's impact on both the health plan and its enrolled patient population; and (3) making the assumptions and evidence influencing formulary choices explicit, transparent, and relevant.

AMCP's format is consistent with an international trend toward evidence-based health care decision making. Perhaps the most prominent effort is that of the National Institute for Clinical Excellence (NICE; www.nice.org.uk) in the United Kingdom, where the National Health Service (NHS) chartered NICE to provide guidance for England and Wales on the appropriate use of selected technologies, including drugs, based on evidence of their social value and impact on health budgets. In turn, NICE guidelines detail the

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**TABLE 1** Formulary Submission Checklist (continued)

<table>
<thead>
<tr>
<th>Section</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on economic impact that can be customized to the population of the specific health plan. This paper reviews the AMCP Format for Formulary Submissions and details the formulary submission dossier. The template is published on the AMCP Web site at <a href="http://www.amcp.org">www.amcp.org</a> for public use.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guidelines and Drug Coverage Decisions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For most health plans, the formulary has become the foundation for the entire drug benefit program. Successful management of a drug formulary often hinges on the integrity of the criteria and evidence used to make approval or removal decisions. Unfortunately, adequate data often are not readily available; unpublished studies and information on unapproved indications are difficult to obtain; manufacturers do not routinely supply data addressing quality-of-life and economic outcomes; and the time required for clinical pharmacists to assemble, critically evaluate, and summarize data for the P&amp;T committee is excessive.</td>
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<td>To minimize these problems, formulary guidelines may be used. Guidelines support the selection of a rational drug formulary by (1) standardizing the information required from the manufacturer; (2) formalizing the importance of a drug's impact on both the health plan and its enrolled patient population; and (3) making the assumptions and evidence influencing formulary choices explicit, transparent, and relevant.</td>
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<td>AMCP's format is consistent with an international trend toward evidence-based health care decision making. Perhaps the most prominent effort is that of the National Institute for Clinical Excellence (NICE; <a href="http://www.nice.org.uk">www.nice.org.uk</a>) in the United Kingdom, where the National Health Service (NHS) chartered NICE to provide guidance for England and Wales on the appropriate use of selected technologies, including drugs, based on evidence of their social value and impact on health budgets. In turn, NICE guidelines detail the</td>
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content of requests for clinical and economic evaluations of selected technologies from manufacturers. These data are independently reviewed and used in the NHS appraisal process. Guidelines not unlike AMCP's have now been issued in a growing number of other European countries and by the Canadian Coordinating Office of Health Technology and the Australian Pharmacy Benefit Advisory Committee, which in the early 1990s was the first authority to issue “pharmacoeconomic” guidelines.1,5

In the United States the promulgation of health economic guidelines for formulary submissions has been led by Regence BlueShield in Seattle in the private sector and in the public sector by the Centers for Disease Control and Prevention and the United States Public Health Service, with some academician contributing.6–10 Evidence-based decision making about pharmaceuticals is increasingly embedded in the process of numerous other health-related entities, including the United States Medicare Coverage Advisory Committee (MCAC), the Blue Cross Blue Shield Technology Evaluation Center (TEC), and the new Blue Cross Blue Shield RxIntelligence group. They are sending a clear message to producers and sponsors of health care technologies that decisions will increasingly be made on evidence of value.

Unfortunately, early evidence from Australia suggests that the quality of vendor submissions can vary substantially; however, the Australian authorities continue endorse the process as helpful in formulary decision making.11 The AMCP guidelines promote practices that enhance the use of consistent submissions and reduce the perceived threats to credibility noted with current practices.12 In the past, standard formulary kits supplied limited clinical information and no economic data. These kits failed to communicate the value of pharmaceuticals and were at best of limited use to health plans. By considering total cost and health impact, the new AMCP guidelines should be able to move managed care away from the pharmacy silo-budgeting approach typical of formulary decisions.

The AMCP guidelines offer both a process and a template. Although economic considerations receive substantial attention, they are subordinate to clinical benefit, notably safety and efficacy. However, because the state of practice in economic evaluations is just evolving, more detailed guidance is needed in this area. Submission of information in the recommended format does not guarantee product approval, but it is a necessary first step in rational drug selection within constrained budgets.

†† Overview

The Food and Drug Administration (FDA) requires, within certain limits, that information provided to health professionals (including health plans) be supported by evidence detailed on the product label. Health economic and outcomes data (including computer simulation models) can be supplied in accordance with section 114(a) of the Food and Drug Modernization Act of 1997.13 Manufacturers cannot routinely make some information, especially comprehensive economic evaluation data, available to health plans without an explicit request.

The AMCP guidelines will constitute a request for all available information on products that allows the manufacturer to provide broader information than would be available without it, such as projections of effectiveness from efficacy data, including long-term outcomes and other “off-label” unapproved usages. Health plans could also get retrospective database studies, health economics information, and other outcomes data.

In general, the AMCP guidelines do not restrict formulary submission dossiers to a specific set of information, study

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Product Description</th>
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<tbody>
<tr>
<td>• Generic name, brand name, and therapeutic class of the product</td>
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<tr>
<td>• All dosage forms, including strengths and package sizes</td>
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<tr>
<td>• NDCs for all formulations</td>
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<tr>
<td>• Copy of the official product labeling and literature</td>
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<td>• Cost per unit size (AWP and plan contract price, if available)</td>
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<tr>
<td>• DPS/AHFS drug classification</td>
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<tr>
<td>• FDA-approved and other studied indications</td>
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<tr>
<td>• Pharmacology</td>
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<td>• Pharmacokinetics</td>
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<td>• Contraindications</td>
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<td>• Warnings/precautions</td>
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<td>• Adverse effects</td>
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<tr>
<td>• Interactions (drug/drug, drug/food, drug/disease) and suggestions for avoiding them</td>
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<tr>
<td>• Availability, dosing, and administration</td>
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<tr>
<td>• Coprescribed or concomitant therapies, including dosages</td>
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<tr>
<td>• Comparison with the pharmacokinetic/pharmacologic profile of other agents in the therapeutic area</td>
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Notes: AHFS is American Hospital Formulary Service; AWP is average wholesale price; DPS is department of pharmacy services; FDA is Food and Drug Administration; NDC is National Drug Code.

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>Disease Description</th>
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<tr>
<td>• Epidemiology and risk factors</td>
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<tr>
<td>• Pathophysiology</td>
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<tr>
<td>• Clinical presentation</td>
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<tr>
<td>• Approaches to treatment—principal options/practice patterns</td>
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<tr>
<td>• Description of alternative treatment options (both drug and non-drug)</td>
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<tr>
<td>• Place of the proposed therapy in treatment (e.g., first line)</td>
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<tr>
<td>• Expected outcomes of therapy</td>
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<tr>
<td>• Other key assumptions and their rationale</td>
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</table>

...
research design, or format. Rather, the guidelines are intended to delineate what information the health plan needs. Manufacturers are encouraged to supply all available data on clinical and economic benefit, rather than just the clinical trials used to support licensing or those used in promotional materials. Consequently, it is recommended that the manufacturer collaborate early in the process with the health plan’s representatives (see Section 5.4: Agenda for Presubmission Meeting).

**Recommended Process**

The recommended steps for the formulary submission process are:

**Step 1.** At least six months before submission, a letter (Notice of Intention to Submit) should be sent to notify the health plan’s pharmacy director or formulary manager of the manufacturer’s intent to submit a product for formulary consideration. This letter should include the anticipated timelines for the submission, allowing the health plan to schedule a review and assign the submission to a subcommittee.

**Step 2.** The manufacturer should schedule a presubmission meeting with representatives of the health plan to review the format’s requirements and to identify any data needed to establish a baseline for assessing product impact. This meeting should also address how to capture these data (see Section 5.4: Agenda for Presubmission Meeting).

**Step 3.** At least two months before the P&T committee meets, copies of the submission should be provided to the health plan’s designee. It should be accompanied by an executive summary, a completed checklist (see Table 1, page 273), and justification for any incomplete or missing data.

**Step 4.** Once the dossier has been received, the health plan’s designee will review the submission and may ask the manufacturer to submit additional information to complete the dossier.

**Step 5.** At least two weeks before the P&T committee meets, the health plan should inform the manufacturer in writing as to whether the dossier is considered complete and whether it will be abstracted for the committee’s consideration. If it is not considered complete or useful, the dossier will be returned to the manufacturer with an explanation of why it was not submitted.

**Step 6.** At the P&T committee meeting, the health plan’s designee will summarize the manufacturer’s dossier, present the principal arguments for and against listing the product on the formulary, and describe any conditions that apply.

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**Table 4** Study Summaries

- Name of the clinical trial or study, location, and study date
- Trial design, randomization, and blinding procedures, research questions,* type of economic study,* study perspective*
- Washout, inclusion, and exclusion criteria
- Sample characteristics (demographics, size, disease severity, comorbidities), treated population (actual or assumed)*
- Patient follow-up procedures (e.g., if an intention-to-treat design was used, were drop-outs followed?), treatment period*
- Treatment and dosage regimens, treatment framework,* resource utilization classification,* unit costs*
- Clinical outcome measures; outcomes evaluated*
- Other outcome measures (e.g., quality of life), principal findings*
- Statistical significance of outcomes and power calculations
- Validation of outcomes instrument (if applicable)
- Compliance behavior
- Generalizability of the population treated, relevance to health plan’s enrolled population being treated*
- Publication citations/references used
- Limitations of study design

Note: Items with asterisks are necessary for economic studies.

**Table 5** Information to be Included in the Analytical Model

- Disease or condition, its natural history, clinical course, and outcomes
- Primary treatment options and the treatment process (clinical pathway) for each option. If the health plan employs a treatment guideline for this condition, follow this framework. Alternative clinical pathways presented by the manufacturer also may be considered.
- Proportion and characteristics of patients being treated by each clinical pathway
- Product and other medical resources used to support each clinical pathway
- Costs of product and other medical resources consumed within each clinical pathway
- Outcomes of therapy for each clinical pathway, including expected proportion of treatment failures and mean or median time to failure, if known. These outcomes can be broadly and uniquely defined by the manufacturer and can be modeled from other data sources. The manufacturer should address the relevance of the selected outcomes measure and generate both baseline and projected outcomes and impact assessments.
- Incremental cost and outcome analyses, presented in either cost/consequences tables or as cost-effectiveness ratios, and total costs
- Results tables that provide outcomes in raw form (e.g., total events avoided) and prevalence of disease (events avoided/1,000 patients)
TABLE 6 Terms and Definitions

**Care Pathways:** A general method of using predetermined, time-staged, evidence-based actions for managing the care of patients who have clearly defined diagnoses or require certain procedures. Ideally, care pathways should apply to managing patients moving among a managed health care system’s multiple levels of care and practice settings. Other terms for care pathways include clinical care plans, clinical pathways, critical pathways, care guides, and care maps.

**Cost and Outcome Modeling:** A quantitative modeling method used to estimate the impact of formulary changes on (1) potential health outcomes and (2) total costs of drug and medical care in a population. One possible use of cost and outcome modeling, for example, is to extrapolate trial-based efficacy data into effectiveness and cost-effectiveness end points; cost and outcomes impact data from models can then be used to assess the health and overall fiscal consequences of formulary changes. Estimating effects of a new product on the total costs and outcomes of care for health plan members is preferable.

**Dossier:** A detailed report for each product submitted by the manufacturer for consideration that contains (1) clinical and economic data from published and unpublished studies and (2) a disease-based economic model to project effect introducing the product would have on health and economically across the entire health plan system.

**Effectiveness:** The actual effects of treatment by the drug under real life conditions (e.g., patients forgetting to take their doses, physicians prescribing doses higher than those recommended, uncontrolled side effects). Head-to-head effectiveness studies with similar medications are preferable.

**Efficacy:** The potential effects of using the drug for treatment under optimal circumstances (e.g., patients taking all doses at the right times, physicians prescribing correct doses, side effects appropriately managed). Efficacy studies are typically the foundation of new drug submissions to the Food and Drug Administration. Active comparator trials evaluating efficacy are preferred to placebo comparisons.

**Formulary:** A continually updated list of medications, related products, and information representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and treatment of disease and the promotion of health.

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

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**Step 7.** The manufacturer is informed in writing of the committee’s decisions about listing the product on the formulary and any recommendations for restricting access. If the product is denied or restricted, the health plan should provide a detailed rationale, with guidance for reconsideration or appeal.

**†† Health Plan Role**
The health plan must provide health plan-specific data to support the manufacturer putting together the formulary submission. The specific data that will be used should be agreed upon during the presubmission meeting. If the health plan cannot provide the necessary data on which to build the impact model, it should agree to accept a model that uses data from other sources (e.g., national, regional, another health system).

To assess the complexities of the outcomes data provided by the manufacturer, a health plan may use the guidelines for authors and peer reviewers published in the British Medical Journal, which provides a checklist to health plans for evaluating economic and outcomes models.14

**†† The Manufacturer’s Role**
After soliciting data from the health plan, the manufacturer integrates into a clear, concise, and comprehensive document published and unpublished data evaluating the efficacy, safety, economic impact, and other medical outcomes associated with the use of the product. If data are unavailable or incomplete, the manufacturer is advised to explain why, and state when they will be provided. The manufacturer should reveal the identities of the authors of the submission document and all primary economic evaluations. The exchange of information will be improved if the manufacturer specifies a person who can answer questions and give health plan reviewers additional information. The manufacturer forwards the completed dossier to the formulary manager at the health plan.

**†† The Formulary Submission**
The formulary submission dossier includes the following sections:
- Section 1: Product Information
- Section 2: Supporting Clinical and Economic Information
- Section 3: Impact Model Report
- Section 4: Clinical Value and Overall Cost
- Section 5: Supporting Information: Bibliography, Checklist, and Appendices

A detailed description of the content of each of these sections, with suggested maximum page lengths, follows.
Section 1: Product Information

Section 1.1: Product Description (10 pages maximum). In this section, the new product should be compared with other agents commonly used to treat the condition, whether or not these products are currently on the health plan’s formulary. The product description consists of information that traditionally has been incorporated in a product monograph (see Table 2, page 275). It should include a detailed discussion of the FDA-approved indications, the date approval was granted (or is expected to be granted), and any data on off-label use. The section should also discuss comparative products or services that the proposed product is expected to replace (including nonexperimental data to supplement them). The section should also discuss comparative products or services that the proposed product is expected to replace (including nonexperimental data to supplement them).

Section 1.2: Place of the Product in Therapy (3 pages maximum per disease). This section provides the disease context: to assess the impact of the new product effectively, the clinical condition being treated and the role of the product in its treatment must be well understood. Although the manufacturer is responsible for determining the relevant treatment options for comparison, the determination should be made with guidance from the health plan during the presubmission meeting. The manufacturer should include information about the disease, characteristics of patients treated for the condition, and the relevant treatment options for comparison, the determination should be made with guidance from the health plan during the presubmission meeting. The manufacturer should include information about the disease, characteristics of patients treated for the condition, a brief summary of the literature for each topic, and the information identified in Table 3, page 275, and when feasible should attempt to generalize these findings to the health plan’s population. This section should also address the implications of any differences between the literature and the health plan’s practice patterns and patient population. If more than one disease is addressed, each separate condition should be described, with results of studies presented in tabular form.

Section 2: Supporting Clinical and Economic Information

This section summarizes published and unpublished clinical safety, efficacy, and economic evaluations. Studies should be summarized in a clear, concise format; presenting data from multiple studies in tabular form is strongly encouraged. Table 4, page 276, lists items that should be summarized for each study.

Section 2.1: Presenting Clinical Study Results (1 page maximum per study). The manufacturer should summarize each clinical trial and is encouraged to provide any head-to-head clinical studies between the proposed product and the principal comparators, with no more than five trials from each of the following categories:

- safety and efficacy trials;
- prospective effectiveness (e.g., large sample) trials;
- trials examining noneconomic end points, such as health status and quality-of-life measures (previous validation and reliability studies of the instruments used should be referenced); and
- retrospective studies.

Summaries of principal trial results of key comparator products, while desirable, are not required. Review articles and meta-analyses, with particular emphasis on inclusion and exclusion criteria and main outcome measures, also may be summarized. For each study, the section should describe important study findings and comment on their implications for the health plan’s patient population.

Information from all known studies on the product should be summarized in a spreadsheet. The spreadsheet should incorporate citation, if published; sample size; end points; study dates; treatments; results; design; inclusion/exclusion criteria; statistical significance; and study limitations.

Section 2.2: Clinical and Disease Management Intervention Strategies (3 pages maximum). This section should summarize any studies or reports that evaluate the impact of the product being...
proposed as part of a disease or care management intervention strategy, with particular attention to variables that have proven to be problematic for the health plan.

Section 2.3: Economic Evaluation Supporting Data (1 page maximum per study). Economic evaluations may include prospective cost-efficacy and cost-effectiveness studies, cross-sectional or retrospective economic evaluations, review articles, and meta-analyses. This section may include studies with a variety of analytic designs, such as prospective studies piggy-backed onto pivotal clinical trials or naturalistic comparative, retrospective, or modeling studies. Since this portion of the document is to be a comprehensive assessment of available evidence, the number of studies is not to be restricted by methodological standards. However, the health plan will judge the merit of individual studies based on published standards for conducting and reporting them.6, 8, 9, 15–22

Section 3: Impact Model Report (15 pages maximum)

Section 3.1: Model Overview. Properly constructed pharmacoeconomic models can combine estimates of treatment effectiveness, resources consumed (i.e., costs) by each treatment process, and the uncertainty of these estimates for predicting systemwide consequences of formulary changes. Such models can support decisions about adding a new product to the formulary, help define its specific role in the environment of a given health plan, and help create benchmarks against which the product’s future performance can be measured. To minimize the potential for bias in economic evaluation, manufacturers should follow generally accepted rules of scientific conduct.23, 24

The type of analytic model described in this section is a precondition for the health plan to evaluate how the new product, if adopted, is likely to affect costs and clinical and humanistic outcomes for the plan’s enrolled population. Even though the specific formats may vary, each should incorporate a comprehensive, disease-based analytical model tailored to the plan (or that can be modified) and incorporating all the items listed in Table 5 (see page 276).21 The manufacturer also should separate volume of resources used and unit costs for each resource, perform sensitivity analyses on pivotal estimates and assumptions, consult with the health plan early in model development to ensure the incorporation of appropriate comparator products and end points, and present the following information in tabular form:

<table>
<thead>
<tr>
<th>TABLE 8</th>
<th>Manufacturer Responsibilities for the Presubmission Meeting</th>
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<tbody>
<tr>
<td>• List of intended indications</td>
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<tr>
<td>• Summary of all studies to be included in the formulary submission, including:</td>
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<tr>
<td>† Clinical trials (experimental and nonexperimental)</td>
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<tr>
<td>† Outcomes studies</td>
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<tr>
<td>† Meta-analyses</td>
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<tr>
<td>† Retrospective studies</td>
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<tr>
<td>† Pharmacoeconomic models</td>
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<tr>
<td>• A general description of how cost and outcomes impact assessments will be developed, including:</td>
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<tr>
<td>† List of data sources (studies, databases, etc.)</td>
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<tr>
<td>† Discussion of the conversion of efficacy to effectiveness for both drug and comparators</td>
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<tr>
<td>† Approach to modeling the environment of the health plan</td>
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<tr>
<td>† Assumptions</td>
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<tr>
<td>† Suggested approach for determining patient characteristics for switching</td>
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<tr>
<td>• Summary of studies expected to be completed within one to three years</td>
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<tr>
<td>• A completed submission checklist</td>
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be less familiar with pharmacoeconomic techniques, information should ideally be presented in terms familiar to the average health plan administrator (events/1,000 patients, per member per month [PMPM] cost, etc.).

The model should be based on the clinical trial and economic data, as modified by realistic expectations of the plan, practice patterns within the plan, and the patient population enrolled. For the model to be realistic, the manufacturer may need either to obtain information from the health plan or, if these data are not available, to provide best estimates and a supporting rationale. The manufacturer is encouraged to contact the formulary manager early in model development to find out what data are available. Other information sources include randomized controlled trials, retrospective analyses, case-control studies, cross-sectional surveys, case reports, and expert opinion.

The model’s time frame is a critical element. For chronic illnesses, both a one-year and a longer period should be adopted, as appropriate for the clinical problem and its resolution. For the longer period, determining a final health outcome is recommended. For acute illnesses, shorter periods may be appropriate. However, the overall effect on the health plan should be presented on a yearly basis.

The model should consider recommendations published by the Panel on Cost-Effectiveness in Health and Medicine convened by the U.S. Public Health Service.27 Although no standard approach is proposed, good modeling practices should always be followed.28
Section 3.2: Clinical Trials: Claims for Safety and Efficacy (10 pages maximum). The primary considerations for adding a product to a formulary are how safe and effective the product will be for the plan's eligible population. Although clinical trials typically focus on efficacy, the outcomes for modeling purposes must be translated to effectiveness (see Table 6, page 277). The best quantitative estimates of effectiveness are required, with uncertainty handled analytically via sensitivity analysis. If these data are not available, manufacturers should give their best estimate of the expected effectiveness outcomes in usual practice. Translating claims from an efficacy to an effectiveness context also should be considered when (1) the model's treatment period extends beyond the clinical trial; (2) outcomes supported by the trial are intermediate or surrogate; or (3) compliance, dosing, comorbid conditions, and the population of interest (e.g., children, elderly) are expected to differ from the efficacy trial data.

Poor compliance, especially for chronic conditions, can undermine claims that are based exclusively on clinical trials. All claims made for new products (whether in therapeutic or economic terms) should clearly state assumptions about patient compliance. It is recommended that manufacturers document anticipated compliance patterns from populations similar to the plan's treatment population, if available. Additional clinical trial data issues include establishing a trial's external validity and controlling for provider and patient behavioral characteristics.

Section 3.3: Incidence and Prevalence Impact Assessments. An analytic model should reflect a prevalence rather than an incidence framework for chronic diseases. The prevalence framework represents the patterns of treatment experienced by the health plan over a specified time (e.g., a 12-month period), irrespective of the disease state reached by individual members. Incidence analysis, however, can be an acceptable modeling perspective for some acute diseases.

Outcomes should be differentiated by incidence and prevalence. Typically, in incidence analysis, a cohort of patients is tracked from start of therapy to an intermediate or final outcome. The manufacturer should translate such point-estimate impact claims into prevalence-based claims, if possible, to clarify how the outcomes are achieved and how they are distributed within the treated population. If this is not possible, the manufacturer should work with the health plan to estimate the net effect of treatment across the entire patient population.

Section 3.4: Optimizing Patient Care. The impact assessment should start by assessing resource utilization and associated medical costs at baseline for the designated therapy area, using data aggregated from service claims. This will allow the manufacturer to describe treatment options, determine patterns of resource utilization, and determine imputed costs for pharmacy and medical claims.

Treatment-pattern models should characterize the health plan's population and reflect best practices as promulgated by task forces, learned societies, or government agencies. If these utilization patterns differ from actual practice, the actual treatment patterns also should be modeled. It is desirable for the model to depict both scenarios when actual and best practices seem to differ.

Evidence for care-pathway effects on patient outcomes, resource utilization, costs, and therapy options should be provided, as available, (1) under the evidence supporting clinical and pharmacoeconomic claims, and (2) under the model assumptions chosen for the impact assessment. Direct evidence of health outcomes often may not be available, however; the health plan and the manufacturer must agree on which approach or assumptions will be acceptable. All assumptions should be justified as consistent with the prevalence framework of the analysis. These assumptions may be justified using known characteristics of patient population, epidemiological profiles and clinical trials, meta-analyses, literature reviews, and expert panels.

When a product is to be used to treat more than one disease, its effect should be modeled in each therapeutic area. Because of the complexity of constructing a model that simultaneously addresses several therapeutic areas, a separate model for each condition is recommended.

Section 3.5: Presentation of Model Results. Results of the model should be presented as follows:
1. Estimates must include the cost of any additional resources associated with implementing the therapy (e.g., disease management).
2. Costs should be presented as total net costs of introducing the new product.
3. Based on discussions between the plan and the manufacturer, the submission should include recommendations about the use of medical and pharmacy data to monitor costs and patient outcomes and validate claims.
4. Effects should be estimated for the first three budget periods after product launch.

Section 3.6: Exceptions. In some situations, a model developed for another health plan may eliminate the need for a new model. To be acceptable, the existing model should follow the framework described in this document and must demonstrate the systemwide impact of introducing the product to the health plan's formulary. The manufacturer must justify the adequacy of pre-existing substitutes.

Section 4: Clinical Value and Overall Cost (2 pages maximum)

This section of the formulary submission dossier is the principal opportunity for a manufacturer to communicate the value of its product to the health plan. The manufacturer should briefly summarize the information presented, state the expected per unit product cost, and estimate the health plan's expenditures.
for the product. Based on this information, the company should then articulate the value argument to justify expenditures on this product in terms of its anticipated effects on health-related quality of life and the economic consequences for the health plan and its members. Through this process, product value is redefined as both parties move beyond simple cost containment to optimize drug utilization given limited resources.

Section 5: Supporting Information

Section 5.1: References Contained in Dossiers. Submissions should list and provide copies of all clinical and pharmacoeconomic references used in previous sections and of information sources from which estimates were drawn for use in the economic evaluation. Referenced articles can be attached as appendices.

Section 5.2: Spreadsheet Models (Media). In addition to the written report, the manufacturer should provide a transparent, unlocked electronic copy of the model without the graphical interface on a 3.5-inch disk as an Excel workbook, ASCII tab-delimited file, or an alternative format agreed upon by the health plan and the manufacturer. The model should be transparent to allow plan staff to investigate assumptions and calculations, and to perform independent sensitivity analyses by varying individual parameters. This model will be retained by the health plan for internal analyses; it will not be released to any other party without the manufacturer’s permission.

Section 5.3: Data and Information from the Health Plan. Specific data elements will vary from plan to plan and model to model.

Section 5.4: Agenda For Presubmission Meeting. The presubmission meeting should take place at least four to six months before the actual date of the formulary review to allow time for the manufacturer to compile the necessary data. The proposed agenda can serve as a discussion guide to ensure that all relevant topics are raised (see Table 7, page 278). At this meeting, the manufacturer should provide a copy and be prepared to discuss all of the items listed in Table 8, page 279.

† † Conclusion

All clinical decisions should be based on the best available evidence at the time of decision making; the formulary decision process is a particularly opportune time for systematic review of the body of evidence for pharmaceuticals. The most important evidence needed for informed decision making is clinical efficacy; its source is the traditional clinical literature. However, as numerous authors, scientific bodies, and authorities around the world have come to believe, clinical efficacy evidence is necessary but not sufficient to guide optimal clinical care. Clinical efficacy alone cannot determine the value for money to be spent. The AMCP format is a modest effort to help P&T committees improve the decision process. It envisions a collaborative effort between the health plan that must decide whether to make a drug available as a benefit to its patient population and the manufacturer of the drug.

Performed appropriately, the process should reward manufacturers of high-value drugs by providing a vehicle for the systematic presentation of value for money. This is an opportunity that manufacturers have wanted for a number of years. Similarly, doctors want their patients to have access to effective drug products. Furthermore, all parties who pay for care, including patients, employers, and taxpayers, want access to cost-effective products. Health plans, caught in the middle, need mechanisms to help assure that they receive optimal value for money spent. These guidelines are intended to accomplish this objective; they are consistent with many other guidelines being implemented worldwide.

The ultimate goal of this process is optimal patient care, taking into account the reality of constrained budgets. The AMCP Format for Formulary Submissions offers a clear, shared vision of the formulary process and information requirements that facilitate partnership between the managed care plan and the product manufacturer. The format describes the minimum information required to support a comprehensive assessment of a product. With increased use of this format, the quality of submissions is expected to improve over time; at a minimum, they will give pharmacists data that were often unavailable in the past.

References


Driving Market Share in an Integrated Health System without Therapeutic Interchange

by Joseph F. Fischer, Robert M. Mowers, David J. Ormerod, and Ellen S. Burriss

It is rare for a new drug, in a major therapeutic class, to be released at a significantly lower acquisition cost compared to the existing drugs in that class. In March 1999 we targeted the use of the selective serotonin reuptake inhibitors (SSRI) for review; in July 1998 citalopram (Celexa) had become the fourth SSRI marketed in the United States. The average wholesale price (AWP) for citalopram was significantly less than the other SSRI drugs available, especially fluoxetine (Prozac).

The managed care team at the UC Davis Medical Group (UCDMG) set out to treat depression more cost-effectively by increasing the use of citalopram and decreasing the use of fluoxetine. The goal was to save at least $100,000 per year on SSRI prescriptions. In the first quarter of 1999 citalopram made up 3% of the SSRIs prescribed at UCDMG but 9% of the SSRI market in the United States. (Market share is defined here as the number of prescriptions for each individual SSRI divided by the total number of SSRI prescriptions, expressed as a percent.)

A review of the literature established that citalopram was an effective SSRI with a side-effect profile comparable to the other drugs in its class; it was comparable to the other SSRIs in overdose and safer than tricyclic antidepressants. Since the AWP for citalopram was lower than the other SSRI drugs, patients could get a state-of-the-art SSRI as first-line therapy, physicians could use an SSRI as first-line therapy, and managed care would be providing, based on our analysis of the literature, the most cost-effective drug in the class.

UCDMG is composed of 12 off-campus medical clinics and several outpatient clinics on the hospital grounds. The clinics are staffed by 40 family-practice physicians and 34 internal medicine physicians. UCDMG has 90,000 managed care patients under contract with several large health maintenance organizations. Our three major insurers added citalopram to their formularies.

The authors reviewed the data on the effectiveness, side effects, and costs associated with SSRI antidepressants with the chair of the department of psychiatry and the medical director for managed care. The managed care team was commissioned to implement an effort to move market share at UCDMG to citalopram. The team consists of the medical director, the nurse manager, and two managed care pharmacists. Rather than increasing the presence of drug manufacturer representatives, internal detailing was used because it has more credibility with our providers. It would also allow the managed care pharma-

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cists to respond to drug information being provided to the physicians from other sources, such as the pharmaceutical industry.

Because of the nature of depression, it would not have been appropriate to ask physicians to do a therapeutic interchange, switching patients off their current SSRI if it was working. We therefore developed the following message to deliver to our physicians:

- Citalopram is an antidepressant that is as effective as the other SSRI agents.
- Citalopram has an adverse-event profile similar to the other SSRI agents.
- Citalopram costs less than the other SSRI agents.
- Fluoxetine is the least cost-effective antidepressant at UCDMG, especially at doses greater than 20 mg.
- Citalopram should be considered for all new patients who are candidates for an SSRI and for patients who have not achieved optimum therapeutic benefit from their current SSRI.

This message was delivered by as many methods as possible. The main pathway was at the monthly utilization management (UM) meetings at each clinic site. The managed care team already participated in these meetings. At each meeting, pharmacists comment on the treatment of depression. Initial discussions focused on the effectiveness and safety of citalopram in comparison to the other agents. The managed care medical director was present at these meetings to lend full support to the program. The medical director thanked the providers for their help in this area and shared cost-savings data with them.

To reinforce this message, the managed care pharmacists prepared a clinical synopsis of citalopram and the treatment of depression. At least quarterly, the pharmacist e-mails all the clinic providers drug-information sheets related to managed care and pharmacoeconomics. The citalopram sheet detailed the basic pharmacology and toxicology of the drug and gave a synopsis of the clinical trials and cost comparisons.

Because of Joint Commission on Accreditation of Healthcare Organizations (JCAHO) restrictions on storage and dispensing of samples, most of the UCDMG clinics have chosen not to sample. The manufacturer gave trial script vouchers for citalopram to the managed care pharmacists, who distributed them at the UM site meetings at least every other month. The initiative is monitored through pharmacy claims data for the three largest health maintenance organizations (HMOs) contracting with UCDMG. Plans H, P, and W all cover citalopram. Plans H and W cover all four of the available SSRIs; plan P covers only citalopram and paroxetine. The brochure also contained information on cost for the most common antidepressants and a grid showing which drugs the local HMOs' formularies covered.

Updates on the success of this project and cost savings are presented to the medical group at the UM site meetings at least every other month. The initiative is monitored through pharmacy claims data for the three largest health maintenance organizations (HMOs) contracting with UCDMG. Plans H, P, and W all cover citalopram. Plans H and W cover all four of the available SSRIs; plan P covers only citalopram and paroxetine. On plan P, fluoxetine and sertraline require prior approval (PA).

The market share percentage report represents the average market share for the quarter.

**Results**

By March 1999 citalopram had been available for nine months. The usage by UCDMG physicians was 2% for plan H, 3% for plan P, and 1% for plan W. Since the initiative began in March 1999 there has been an almost linear increase in the market share for citalopram (see Figure 1, page 285). By the 2nd quarter of 2000, it had reached 21% (plan H), 26% (plan P), and 14% (plan W).

All quarterly mean market-share percentages were compared for significance using chi-square analysis with appropriate p values reported. The increase in the percent market share was statistically significant (p < 0.01) by the start of the third quarter of 1999 for all three plans. The national market share of this drug, its manufacturer reports, is currently 14% (August 2001).
Driving Market Share in an Integrated Health System without Therapeutic Interchange

Plan P, with its more restrictive formulary, had the highest increase. However, the difference between plan P and plan H was not statistically significant.

Table 1, above, shows SSRI market shares for the second quarter of 2000 for each SSRI and for new prescriptions only. The percent of new prescriptions for citalopram was 32% (plan P) and 27% (plan H). The increase in mean market share of new prescriptions for citalopram compared to its total market share was statistically significant for the two plans for which data on new prescriptions were available (plan H; \( p < 0.01 \), plan P; \( p = 0.05 \)).

Table 2, left, shows that market share for fluoxetine decreased by 10% from the first quarter 1999 to the second quarter of 2000. The difference was significant for all plans (\( p < 0.01 \)). The market shares for paroxetine and sertraline were not significantly altered.

Limitations
Pharmacy claims data were only available from 3 of the 10 managed care companies doing business with UCDMC. Two of the companies are large HMOs while the third is a small company (fewer than 50,000 lives). Not all of the managed care companies for which UCDMC has pharmacy risk cover citalopram. UCDMC has no control over formulary selection at these companies.

Conclusion
The managed care team achieved both its objectives. First, market share for citalopram increased significantly. In March 1999, citalopram use at UCDMG was 7%–8% below the national average; currently, it exceeds the national average by 6%. Second, the use of fluoxetine has decreased. It is possible to move market share in both a positive and negative direction without therapeutic interchange.

Analysis of new prescriptions for SSRIs written in the second quarter of 2000 (Table 1) indicates the market share for citalopram continues to increase. The percent of new prescriptions for citalopram was significantly higher than its market share for all (new and refill) prescriptions. Since this program does not involve therapeutic interchange, new prescriptions are an important indicator of market trends. While this is not a perfect indicator, it does give an indication of initial therapy. (Some new prescriptions will be the result of continuing therapy where refills have expired.)

Plan W was the slowest to respond. This is the only plan to have California Medi-Cal Managed Care (MCMC) members. They account for 61% of the membership of just over 13,000. Analysis of this subgroup of Plan W patients is shown in Table 3, page 286.

The MCMC section of Plan W had a market share for citalopram of only 8% by the end of the first quarter of 2000, while its commercial plan members had citalopram utilization of 18%. Of the MCMC patients, 30%–50% have contracted physician groups as their primary care providers. Because these groups are not part of the integrated health system and do not have regularly scheduled meetings with the managed care team, the team only had access to about 50% of those who provide care to MCMC patients.
MCMC patients function as an internal control group. The importance of the managed care team repeatedly reinforcing the initiative is reflected in the increased use of citalopram in the commercial versus the MCMC patients. Based on a comparison of the market share for the MCMC group versus the average market share for all the commercial plans the estimated yearly cost saving is $126,000, or 8% of total SSRI ingredient cost. This is a conservative estimate, as the managed care team did have contact with the providers of care for about 50% of the MCMC patients, which undoubtedly affected the use of citalopram.

As the market share for citalopram increases while fluoxetine decreases, cost savings will continue. Savings from this program will continue until generic fluoxetine costs less than citalopram. Generic fluoxetine is scheduled to become available in September 2001.

This process should work for any large integrated health system, provided that a mechanism is in place to educate providers and monitor the movement of market share. The managed care team identified the following factors as important for the success of this initiative: (1) the providers must be at risk for all or part of the pharmacy cost; (2) the medical director must give active support to the project; (3) individual clinics and providers must be regularly informed about their role in the success of this project; and (4) the message must be repeated and reinforced often.

References
An Investigation of Allergic Rhinitis, Asthma, and Medication Use in a Privately Insured Population

RESULTS: Asthma was more prevalent in the overall population. In addition, the rate of allergic rhinitis in the asthmatic population (44%) was much higher than the rate of allergic rhinitis in the overall population (11%). On average, patients with both conditions had approximately 30% more asthma prescriptions (10.9) than did those with asthma alone (8.4). Likewise, patients with both conditions also had approximately 31% more allergic rhinitis prescriptions (4.62) than did those with allergic rhinitis alone (3.52).

CONCLUSION: The increase in medication use by people with both asthma and allergic rhinitis lends support to the idea that nasal inflammation is a marker for increasing dysfunction of the entire respiratory tract. Given the increased prevalence of these diseases, effective aggressive treatment would benefit a large segment of the population. As the link between allergic rhinitis and asthma continues to be established, it is probable that treatments for one condition could alleviate the coexisting condition.

KEYWORDS: Allergic rhinitis, asthma, drug therapy, disease prevalence, retrospective claims data

REFERENCES

matics had both forms of the condition.

Some studies have suggested that appropriate treatment of allergic rhinitis may alleviate symptoms of asthma. Pharmacotherapy for allergic rhinitis may increase airway caliber and decrease bronchial hypertension. For example, Grant et al. found that asthma symptoms improved in allergic rhinitis patients treated with an antihistamine in comparison to patients who did not receive treatment. In their examination of the effects of intranasal corticosteroids in patients with chronic perennial allergic rhinitis and mild asthma, Henriksen and Wenzel found that four weeks of therapy significantly reduced both rhinitis and asthma symptoms. Welsh et al. found that allergic rhinitis patients receiving intranasal corticosteroids also experienced improved lower airway symptoms attributed to asthma. Watson and colleagues found that intranasal corticosteroids therapy reduced both rhinitis and asthma symptoms even though less than 2% of the drug was deposited in the lower airways.

The purpose of this study is to provide further evidence that a link exists between asthma and allergic rhinitis. First, we compared the prevalence of allergic rhinitis and asthma in the MarketScan population to each disease population (all asthmatics and all persons with allergic rhinitis) to determine whether either condition is more prevalent in those individuals already suffering from the other condition. Second, we compared condition-specific medication use for people having allergic rhinitis only or asthma only to those with both conditions. If asthma and allergic rhinitis are related, it may be that persons with both conditions have more complex upper and lower airway involvement and thus need to use more medications to successfully manage their symptoms.

++ Study Methods

Data

The analytical file used in this study was constructed from the 1994 and 1995 MarketScan Private Pay Fee-for-Service databases. These files contain data on more than four million covered lives per year. Indemnity type insurance as well as noncapitated managed care plans are represented. Included in these databases are diagnosis, procedure, provider, benefit plan, and payment information from medical claims for nearly 200 large, self-insured employers located throughout the United States. (Plan-specific benefits information was available for only a subset of individuals in this study and so was not incorporated in the analyses.) Data from employees and their dependents are included. Outpatient prescription drug data—National Drug Code (NDC), copayment, deductible, total payment, and other elements—are available for roughly one million members per year.

Study Population and Analytical Variables

To construct the study sample, we first identified patients with allergic rhinitis or asthma in the 1994 MarketScan file. A patient was considered to have allergic rhinitis if they had a diagnosis of allergic rhinitis (477.x) or two or more nonsedating antihistamine prescriptions or two or more nasal inhaled steroid prescriptions during the year. Asthma patients were identified by an asthma diagnosis (493.x) and the presence of at least one beta-agonist prescription, or in the absence of an asthma diagnosis, by two or more beta-agonist prescriptions during the year. (International Classification of Diseases, 9th Revision, Clinical Modification [ICD-9-CM] codes used to identify asthma and allergic rhinitis are available upon request.) To arrive at our final study population, we excluded persons who were under 12 or over 60 years of age, who did not have prescription drug data in 1994 and 1995, and who were not continuously enrolled in 1995. Note that continuous enrollment was identified using the MarketScan enrollment file, and a claims-based proxy. For those who did not have enrollment data, we checked to see if they had any service claims during the first and last quarters of 1995. If this criterion was met, we assumed that the patient was continuously enrolled. Patients with a diagnosis of chronic obstructive pulmonary disease also were excluded.

For each patient in the sample, we constructed a count of the number of prescription drug claims during 1995 for various asthma and allergy medications. For allergy treatment, we grouped prescriptions into two categories, nonsedating antihistamines (NSA) or nasal inhaled steroids (NIS). Medications examined for the treatment of asthma were beta-agonists, inhaled steroids, oral steroids, theophylline, and cromolyn. Sedating antihistamines were excluded because many are sold over-the-counter and thus would not be represented by pharmacy claims.

Methods

Using the definitions noted above, we calculated overall prevalence rates for asthma and allergic rhinitis in the 1994 MarketScan database. The initial prevalence rates were calculated on the entire 1994 database and were not limited to those persons who were continuously enrolled. After applying the exclusion criteria to the analytic file, we compared the percentage of patients in each of the three mutually exclusive subsamples by age grouping and gender type. To determine whether differences exist along these dimensions between the three groups, associated F-tests of significance were calculated. Mean medication use was then examined. The overall mean number of asthma drug claims for patients with asthma alone was compared to the mean numbers of such claims in those with both conditions. We also compared the overall mean number of allergic rhinitis drug claims for patients with allergic rhinitis alone to the mean numbers of such medications in those with both conditions. These calculations examined whether there were differences in the mean number of claims by drug type (beta-agonists, inhaled steroids, oral steroids, theophylline, or...
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Results

Prevalence Rates
Approximately 2.5% of the overall MarketScan population had asthma in 1994. Asthma was more prevalent in the allergic rhinitis population (10%) than in the general population. In addition, the rate of allergic rhinitis in the asthmatic population (44%) was much higher than the rate of allergic rhinitis in the overall population (11%). After limiting the sample to only those persons who were continuously enrolled in 1995, the final study population consisted of 54,171 individuals: 5,525 with both allergic rhinitis and asthma, 42,686 with allergic rhinitis alone, and 5,960 with asthma alone.

Table 1, this page, presents the numbers and percentages of patients in each subgroup in the final study population by age category and gender. An ANOVA procedure revealed that the age composition of patients differed significantly among the three study groups ($p<.001$). Those with both asthma and allergic rhinitis clustered in the middle-age groups, with 53.2% between 35 and 54 years in age; the age distribution was similar among those with allergic rhinitis alone. Asthmatics, however, were divided relatively evenly across all age groups. The distribution of gender was also statistically different across the three subsamples ($p<.001$), although in all cases women comprised the majority of the samples.

Medication Use
Tables 2, page 290, and 3, page 290, present the average number of claims for asthma and allergic rhinitis medications by drug type. Table 2 compares the mean number of asthma medications for patients with asthma alone and for those with both asthma and rhinitis. The mean number of asthma-medication claims was significantly higher for those with both conditions than for those in the asthma-only category. This finding was consistent for men and women across all age groups. Of the 5,525 patients with both asthma and rhinitis, 93% had at least two asthma prescriptions; of the 5,960 people with asthma alone, 91% filled at least two prescriptions for asthma drugs. Overall, those with both conditions had approximately 30% more prescriptions for asthma medications during 1995 than persons with asthma alone.

Although there were statistically significant differences in the types of asthma medications between people with asthma alone and those with both conditions, the mean number of claims appears to be similar. As explained above, the identification criteria for asthma included at least one prescription for beta-agonists; thus, every participant had at least one asthma medication.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Descriptive Statistics for Age Groups and Gender, by Illness Category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Asthma Only</td>
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<tr>
<td><strong>Age Group</strong></td>
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<tr>
<td>12-17</td>
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<tr>
<td>18-34</td>
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<tr>
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<td>55-60</td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
<td>2,475</td>
</tr>
<tr>
<td>Female</td>
<td>3,445</td>
</tr>
<tr>
<td>Not reported</td>
<td>40</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,960</td>
</tr>
</tbody>
</table>

*p values were calculated using an F-test from the ANOVA procedure.

cromolyn for asthma, and NSA or NIS for allergic rhinitis) across the groups of patients with one of the conditions versus the group with both conditions. Pair-wise comparisons of means were tested with t-tests.
An Investigation of Allergic Rhinitis, Asthma, and Medication Use in a Privately Insured Population

drug claim. Therefore, the fact that in 1995 the greatest number of average claims was found among the beta-agonists, at 5.4 claims per asthma/rhinitis patient versus 5.1 claims per asthmatic, is not unexpected. The second largest category of prescriptions was inhaled steroids, prescribed at an average of two claims per asthma/rhinitis patient compared to one claim per asthmatic. Inhaled steroids are intended through regular use to decrease symptom frequency for patients with chronic asthma. Both inhaled steroids and cromolyn are intended for long-term control of mild, persistent asthma. Both groups of study participants filled less than one prescription claim for cromolyn per year on average. They also had less than one claim on average for oral steroids, which are indicated for more severe and persistent asthma. There were more claims for theophylline, a bronchodilator used for long-term asthma control. On average, patients with both asthma and rhinitis had 1.4 prescription claims during the study period, while patients with asthma alone had 1.3 theophylline claims.

Table 3 presents the mean number of allergic rhinitis medications by asthma status. Patients with asthma alone or with both conditions had approximately 31% more allergic rhinitis prescriptions on average than the rhinitis-only patients. Of the 5,525 asthmatics having rhinitis, 84% submitted at least one claim for an allergy drug and 75% submitted two or more claims. The proportion with one claim was slightly smaller among people with rhinitis alone, about 80%. In total, asthma and allergic rhinitis patients had an average of 4.6 prescriptions for allergic rhinitis in 1995 versus 3.5 prescriptions on average for the rhinitis-only patients. People having both asthma and allergic rhinitis also had significantly more NSA and NIS prescriptions than did patients with rhinitis alone.

**Discussion**

This study provides further evidence of the substantial link between allergic rhinitis and asthma. The high prevalence of allergic rhinitis among asthmatics observed in these data is consistent with results from recent studies, and the rate of asthma among persons with allergic rhinitis was notably higher than in the general population. These findings lend support to the view that certain upper and lower airway conditions considered to be separate diseases should be understood instead as different points on a continuum of airway inflammation.

Because incidence and prevalence rates for both diseases have been increasing, effective treatment for both diseases would benefit a large segment of the population. As the link between allergic rhinitis and asthma continues to be established, it is probable that treatments for one condition could alleviate the coexisting condition.

The prevalence of allergic rhinitis (10.7%) in our insured population falls within the 9%–20% rates previously reported for the U.S. population as a whole. The prevalence rate of asthma (2.5%) is lower, however, than the 4%–6% rate estimated for the U.S. population. The disparity in asthma rates has several potential causes. Asthma prevalence varies by age, race and ethnicity, family income, urbanization, and birth weight, among other characteristics. Our data represent employees of large firms and their dependents, a group that is wealthier than average and more likely to be older, white, and urban than the general population. In addition, rising asthma prevalence during the 1990s suggests that estimates from 1994–1995 will be lower than those from more recent years.

In this study, patients with both asthma and allergic rhinitis appear to have a significantly greater number of prescription
drug claims for asthma and allergy medications on average than do those with only one of the conditions. Similarly, Halpern found that patients with symptomatic rhinitis had more asthma medications, especially more inhaled and supplemental corticosteroids, than did the general population. As postulated by Corren, the increase in the use of asthma medications in patients with co-occurring conditions may indicate that these patients have increased asthma severity. This study reveals, however, that patients with both conditions also have higher utilization of allergic rhinitis medications, lending support to Corren's alternative explanation that nasal inflammation is a marker for increasing dysfunction of the entire respiratory tract.

Because we did not adjust the claims for the number of days supply per prescription and cannot verify that patients adhered to their treatment regimens, however, it is important to interpret these data with caution.

Medications that can be purchased without a prescription are often used in the treatment of allergic rhinitis. Individuals with this condition who use only over-the-counter medications cannot be identified in the MarketScan database if they did not have a doctor's visit for their allergies. As a result, there may be individuals in the asthma-only subsample who have allergic rhinitis who were not identified for this study.

References
Collaborating with Community Pharmacists to Improve the Quality of Diabetes Care in an IPA-model HMO

OBJECTIVE: To assess the ability of community pharmacists to identify managed care patients with diabetes who are not achieving therapeutic goals.

SETTING: A network of independent community pharmacists in West Virginia and southeastern Ohio in collaboration with The Health Plan of the Upper Ohio Valley.

METHODS: Pharmacists conducted assessments of patients’ glycemic control (HbA₁c), blood pressure (BP), lipid levels (total cholesterol, low-density lipoprotein [LDL], high-density lipoprotein [HDL], triglycerides), and body mass index (BMI). The therapeutic goals were: HbA₁c less than 7%, BP lower than 130/85 mmHg, total cholesterol under 200 mg/dl, LDL less than 100 mg/dl, HDL higher than 45 mg/dl, triglycerides under 200 mg/dl, and BMI lower than 30. These indices were measured during scheduled appointments in the pharmacy by pharmacists who had completed a certificate program in diabetes care. Reports on each patient’s status, along with recommendations, were sent to the patient’s physician.

RESULTS: Fifty-four persons were enrolled in the pharmacist program and complete clinical data were obtained for 47 patients. The following percentages of patients were identified as not achieving the therapeutic goal for a particular measure: HbA₁c: 63.9%, BP: 56.3%, total cholesterol: 38.3%, LDL: 69.8%, HDL: 76.5%, triglycerides: 57.4%, BMI: 61.9%. Patients who were not reaching the therapeutic target were referred to their physicians for additional evaluation.

CONCLUSION: Pharmacists can identify a substantial number of persons with diabetes who are not achieving the goals for HbA₁c, blood pressure, lipids, and weight. This approach can facilitate the continuous assessment and improvement of care for managed care enrollees with diabetes.

KEYWORDS: Diabetes, quality improvement

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by David P. Nau, Joshua D. Blevins, and Stephen E. Neal

The treatment of persons with diabetes is often expensive and inadequate. In 1992, 14.2% of direct health care expenditures was used to treat patients with diabetes who make up less than 5% of the population.¹ This represents an average annual expenditure on medical care for persons with diabetes of $9,493, compared to $2,604 for patients in general. Many of these costs are associated with the management of the complications of diabetes, such as myocardial infarction or end-stage renal disease (ESRD).² The cost of treating an acute myocardial infarction in a person with Type-2 diabetes is estimated at $27,630, while ESRD costs have been estimated at $53,659 per year.³

The American Diabetes Association (ADA) estimates that the complications of diabetes could be reduced dramatically if patients maintained adequate control of their diabetes. Results from the Diabetes Control and Complications Trial (DCCT) suggest that intensive treatment and monitoring could reduce the risk of retinopathy (76%), nephropathy (50%), neuropathy (60%), dyslipidemia (34%), and cardiovascular disease (41%).⁴

To decrease the risk of diabetes complications, the ADA recommends that patients receive annual assessments of lipids and microalbumin, and that glycosylated hemoglobin (HbA₁c) be measured two to four times per year, depending upon the patient’s glycemic control.⁵ Numerous studies have shown that these assessments frequently are not done. A recent study of Medicare claims from three states found that only 16% of Medicare recipients with diabetes received at least one HbA₁c test over the course of one year, 46% saw an ophthalmologist, and 55% were screened for high cholesterol.⁶ Managed care organizations tend to fare better than fee-for-service providers, but are far from meeting the ADA guidelines. A large health maintenance organization (HMO) in California reported that HbA₁c tests were done for 44% of its patients with diabetes and United HealthCare Corporation recently reported rates of about 60% for HbA₁c testing in its enrollees.⁷ ⁸

As part of the Health Plan Employer Data and Information Set (HEDIS) 2000, the National Committee for Quality Assurance (NCQA) requires managed care organizations (MCOs) to track key indicators of the quality of care for persons with diabetes. The frequency of glycosylated hemoglobin and lipid tests for this population are such indicators. MCOs strive to implement mechanisms to continuously improve their performance in monitoring the care provided to their members with diabetes. Pharmacists could potentially increase the number of persons who receive these tests by conducting the assessments in the pharmacy.
Increasingly, health care organizations are using pharmacists or nurses to assist in the monitoring and management of patients with diabetes. The Veterans Affairs (VA) Medical Center in Pittsburgh found that persons with Type-2 diabetes who were enrolled in its pharmacist-based program experienced significant improvements in glycemic control within six months. After adjusting for the costs of the program, they estimated that net savings to the VA Medical Center for 15 of their most severely ill patients was more than $103,000 per year. In 1997, Fincham and Lofholm suggested that community pharmacists could reduce health expenditures for diabetes by $4,295 per patient. A network of community pharmacists saved the city of Asheville, North Carolina, more than $900 per patient per year on diabetes care, while a pharmacy in Virginia documented significant improvements in their patients’ glycemic control after enrollment in a diabetes care program.

Practice Innovation

The Ohio Valley Pharmacist Care Network (OVPCN) is a group of independent community pharmacists located in the northern panhandle of West Virginia and southeastern Ohio. This network was formed in 1998 with the goal of establishing common pharmaceutical care programs to meet the needs of patients, physicians, and payors in the region. At the time of this publication, the membership of OVPCN consisted of thirteen pharmacists at seven pharmacies.

Representatives of OVPCN met with the Director of Pharmacy and Director of Quality Improvement at The Health Plan of the Upper Ohio Valley to identify the needs of this independent practice association (IPA)-model HMO. In addition, faculty from West Virginia University (WVU) School of Pharmacy were asked to help identify opportunities for quality improvement and to develop training programs for the pharmacists. A collaborative effort was initiated to assess and improve the quality of diabetes care for the HMO’s enrollees.

The goals of the collaborative effort were to:

• increase the percentage of patients with HbA1c lower than 8% (ideally lower than 7%);
• increase the percentage of patients with low-density lipoprotein (LDL) cholesterol less than 130 mg/dl (ideally less than 100 mg/dl);
• increase the percentage of patients whose blood pressure is lower than 130/85 mmHg;
• decrease diabetes-related ER visits, hospitalizations, and unscheduled physician visits;
• increase treatment guideline adherence (regular eye exams, foot exams, immunizations, microalbumin, HbA1c, fasting blood glucose [FBG], lipids, blood pressure [BP], weight);
• enhance health-related quality of life; and
• optimize the flow of information between patient, pharmacist, and physician.

Standardized diabetes care services were established at the network pharmacies to ensure the consistency of The Health Plan member benefits. Equipment such as the Bayer Diagnostics DCA2000+ and the Cholestech LDX Analyzer were purchased by each pharmacy to facilitate the collection of data at each site. The services consist of an initial assessment and education program, as well as follow-up visits with the patients. These services are provided through scheduled appointments that last between 30 and 60 minutes. The initial assessment of the patients includes the following:

• collection of baseline data: weight, blood pressure, blood glucose, lipid panel, HbA1c;
• assessment of guideline adherence: primary care physician (PCP) visit, eye/foot exams, immunizations;
• review of medication regimen and patient adherence to regimen; and
• patient education (three sessions of one hour each).

The documentation and recommendations are forwarded to the patient’s primary care physician.

Follow-up visits are scheduled every three months and generally last less than 30 minutes. The pharmacists collect monitoring data (weight, BP, blood glucose); perform a lipid panel and microalbumin testing on an annual basis; perform HbA1c testing every three to six months based on HbA1c levels; assess guideline compliance (PCP visit, eye/foot exam, immunizations); re-evaluate medication regimen and patient adherence; re-educate patient if necessary; and forward documentation to the PCP.

Additionally, the pharmacists agreed to work with the WVU faculty to develop a continuous-quality-improvement process for the care they provided. This entails monthly meetings to discuss cases, as well as periodic reviews of the pharmacists’ documentation by the WVU faculty. Feedback is provided by the faculty to both the pharmacists and The Health Plan.

The Health Plan agreed to compensate the pharmacists for diabetes services provided that the pharmacists:

• were registered pharmacists;
• completed an approved certification program in diabetes-related pharmaceutical care from a national organization (APhA, NIPCO, or AADE Comprehensive Review Program);
• completed the WVU certificate program in Pharmaceutical Care for Persons with Diabetes;
• possessed and were trained in the proper use of DCA2000+ (HbA1c), Cholestech LDX or equivalent (lipid profiles), blood pressure monitoring equipment, and glucose meters;
• obtained Clinical Laboratory Improvement Act waivers for all equipment requiring this waiver;
• demonstrated competence in using the OVPCN diabetes education materials;
• had a private area in which to meet with patients; and
• maintained appropriate patient care records.

Methods

Study Population

Adults over 18 years of age with Type-2 diabetes were eligible for...
inclusion. It was anticipated that the majority of participants would be members of The Health Plan of the Upper Ohio Valley because this HMO is paying for the educational component of the pharmacists' services. However, the assessments were available to all patients with Type-2 diabetes who attended the OVPCN pharmacies. The pharmacists solicited the involvement of their current patients and also accepted referrals from physicians. Nearly all health plan patients who were offered the opportunity to participate chose to enroll in the pharmacy-based program (54 out of 60 enrolled).

Clinical Data Collection
The clinical data are collected and recorded by the pharmacists as part of their standard care program during 1999 and 2000. The HbA₁c levels are determined by analyzing blood samples in the Bayer DCA2000+ machine; these tests can be performed in the pharmacy by trained personnel. The HbA₁c reagent cartridge requires only one microliter of blood from a fingerstick and takes only five minutes to obtain results.

The lipid profile is conducted through the use of the Cholestech LDX analyzer using a fingerstick sample of blood. This test provides estimates of the total cholesterol, HDL, LDL, and triglyceride and glucose levels. All samples were drawn from patients in a fasting state.

The pharmacists also monitor the patients' blood pressure at each visit. Two blood pressure readings were taken with the patient in the sitting position over the course of the assessment visit. The mean of the two blood pressures was used for analyses.

The body mass index (BMI) for each patient was estimated using the height and weight in the following formula: (pounds × 703)/(inches × inches). Thus, a 200-pound, 72-inch person would have a BMI of (200 × 703)/(72 × 72) = 27.1. All measurements were obtained in the pharmacy.

**Results**

Patient Characteristics
The pharmacists enrolled 54 patients in the clinical program, of which 32 (59%) were female. The average age of the participants was approximately 60 years (range: 35–81 years).

Clinical Assessment
Usable clinical data were obtained for 47 patients. The baseline assessment revealed that a considerable number of persons were not “at goal” for the clinical indicators (see Table 1, this page). For HbA₁c, 63.9% of persons had not reached the desired goal of HbA₁c lower than 7%, and 36.2% were above 8%.

Blood pressure was also elevated for about half of the patients, with only 44.7% reaching the ADA recommended target of 130/85 mmHg. Approximately 15% of patients could be categorized as having Stage 2 or 3 hypertension.

Lipid levels also were not ideal for many of the patients.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Percentage of Patients Not Achieving Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA₁c</td>
<td></td>
</tr>
<tr>
<td>7–8%</td>
<td>27.7%</td>
</tr>
<tr>
<td>&gt;8%</td>
<td>36.2%</td>
</tr>
<tr>
<td>Total above goal</td>
<td>63.9%</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td></td>
</tr>
<tr>
<td>Stage 1 hypertension</td>
<td>31.9%</td>
</tr>
<tr>
<td>Stage 2 hypertension</td>
<td>8.5%</td>
</tr>
<tr>
<td>Stage 3 hypertension</td>
<td>6.4%</td>
</tr>
<tr>
<td>Total</td>
<td>46.8%</td>
</tr>
<tr>
<td>Lipids</td>
<td></td>
</tr>
<tr>
<td>Total cholesterol &gt;200</td>
<td>38.3%</td>
</tr>
<tr>
<td>LDL &gt;100</td>
<td>69.8%</td>
</tr>
<tr>
<td>HDL &lt;45</td>
<td>76.5%</td>
</tr>
<tr>
<td>Triglycerides &gt;200</td>
<td>57.4%</td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td></td>
</tr>
<tr>
<td>25–30</td>
<td>23.8%</td>
</tr>
<tr>
<td>&gt;30</td>
<td>61.9%</td>
</tr>
</tbody>
</table>

Almost seven out of ten (69.8%) patients had LDL levels above the recommended target of 100 mg/dl, and 57.4% of patients had LDL levels greater than 130 mg/dl, putting them in the high-risk level for coronary heart disease.

HDL levels were also elevated in a substantial number of patients. Over three-fourths (76.5%) of patients had HDL levels below the target of 45 mg/dl, and 40.4% of patients had HDL levels below 35 mg/dl, which places them in the high-risk level for coronary heart disease. Total cholesterol was elevated in 38.3% of patients, while triglyceride levels were above 200 mg/dl in 57.4% of patients. Fourteen percent of patients had triglyceride levels above 400 mg/dl.

Approximately 85.7% of persons were above the ideal BMI of 25, and nearly 62% were obese (BMI over 30).

**Discussion**

For persons with diabetes, glycemic control is an important
predictor of micro- and macrovascular complications. Additionally, blood pressure and lipid levels are important markers for cardiovascular mortality in persons with diabetes. The ADA recommends frequent monitoring of HbA1c, blood pressure, and lipids to help ensure that patients are maintaining control of their condition. Regular eye, foot, and renal screenings are also recommended.

In this study, a novel approach was used to identify persons with diabetes who were not reaching the recommended therapeutic goals for HbA1c, lipids, and blood pressure, as well as to identify those who might benefit from weight-management programs. Community pharmacists collected information on their patients with diabetes, and sent reports to each patient's physician. The pharmacists were able to identify a substantial number of persons who were not reaching the desired endpoints of therapy (see Table 1), and recommend adjustments to the drug regimen when appropriate. The patients and many of the physicians were quite appreciative of the pharmacists' efforts.

Achieving control of diabetes is challenging. Behavioral changes in diet, exercise, and medication use are difficult to maintain, and patients often experience decline in their glycemic control over time. Consequently, close monitoring is essential, and a supportive pharmacist can be a great help in maintaining control of the diabetes and other health indicators. Pharmaceutical care espouses a closer relationship among patient, pharmacist, and physician. It is essential that all three participants in this relationship understand the goals for disease control, that they agree on a plan for monitoring, and that information flows smoothly among the participants to continually enhance the patient's health outcomes.

Pharmacists are in an excellent position not only to provide information about drug therapy, but also to assess the patient's progress toward therapeutic goals. In this study, pharmacists identified 36.2% of their patients as having an HbA1c above 8%. The ADA suggests that an HbA1c above 8% should prompt additional action by providers to enhance the patient's glycemic control. The pharmacists notified the physicians that these patients were not "at goal" and suggested specific therapeutic options when requested. Although the long-term impact of these recommendations could not be assessed at this time, identifying the patients in need of additional help prevented more than one-third of the patients from "slipping through the cracks" and having their uncontrolled diabetes go undetected.

Many patients with Type-2 diabetes also have hypertension and/or dyslipidemia and often suffer complications such as heart attack or stroke. Thus, it is important to monitor blood pressure and lipid levels in these patients. The pharmacists in this network identified over half (55.3%) of the patients as having blood pressure readings that were consistent with Stage 2 or Stage 3 hypertension. Thus, at least 15% and perhaps as many as 55% of the patients could benefit from additional intervention.

The pharmacists also found that 57.4% of patients were within the high-risk category for coronary heart disease as predicted by LDL over 130 mg/dl. The LDL level is an important indicator of risk for cardiovascular mortality. Many patients (76.5%) had HDL levels below the recommended target, and 57.4% had elevated triglycerides. This seems consistent with the finding that 85.7% of patients were above their ideal body weight and about 62% of patients were considered obese. Clearly, many of the patients enrolled in the pharmacy-based program were in need of help in reducing their risk of macrovascular complications.

Pharmacists' involvement with diabetes care is not a new concept. An increasing number of certified diabetes educators are pharmacists, and several studies have demonstrated the impact of a pharmacist's care on diabetes outcomes. However, very few community pharmacists have conducted assessments of their patients with diabetes in a manner as comprehensive as the program described here. In addition to examining blood glucose meter readings, weight, and blood pressure, the pharmacists in this network obtained equipment to collect HbA1c and lipid levels within the pharmacy. Performing these tests while the patient was in the pharmacy allowed the pharmacist to give the patient immediate feedback on their disease control, and facilitated more timely modifications of drug therapy. Rather than the pharmacist waiting for the physician to order the test, and then hoping that the patient would go to the laboratory and that the physician would share the data and make appropriate changes in drug therapy, the pharmacist could more proactively identify problem areas and make informed, specific recommendations for drug therapy enhancement.

Having the pharmacist collect and report this information can be in the best interest of physicians and health plans. If physicians can rely on the pharmacist to coordinate the education and monitoring functions for diabetes care, then the physicians may be able to save time and be more efficient in providing care to their patients with diabetes. The pharmacist can perform the key monitoring tests recommended by the ADA and provide reports directly to the physician, along with recommendations for drug therapy modification. Additionally, the pharmacist can ensure that the patients are seeing their physicians on a regular basis and can promote positive health behaviors (e.g., regular eye and dental exams, flu shots, smoking cessation). By enhancing the frequency of regular exams and monitoring tests, a pharmacist can assist health plans in improving their diabetes indicator scores for HEDIS. Although an individual pharmacy may have little impact on the overall HEDIS score of a health plan, a network of pharmacies may be able to produce a measurable difference.

As a result of this project, The Health Plan is working with OVPCCN to develop a multi-disciplinary diabetes education program that will be integrated with the monitoring component of the pharmacists' services. In this model, the pharmacists help not only...
to monitor the patient’s clinical progress, but also to ensure that the patient is attending the education classes and adhering to diet, exercise, and medication recommendations.

The costs of implementing the diabetes care program within the OVPCN were substantial. Pharmacist spent $5,000–$7,000 at each store to acquire the equipment, supplies, and training necessary to provide this service. Although this is not an insurmountable barrier to implementation, the compensation levels to the pharmacist by the health plan should be adjusted to offset these costs within an acceptable time frame. The pharmacists were able to offset some of these costs through small grants from pharmaceutical manufacturers and foundations; however, contracts with third-party payors are currently the primary source of revenue.

Paying pharmacists to identify patients with suboptimal glycemic control or undetected hypertension or dyslipidemia may be quite cost-effective for managed care plans. A recent study demonstrated that patients with poor glycemic control (HbA1c over 10%) were hospitalized with complications of diabetes at a far greater rate than those with fair (HbA1c 8%–10%) or good (HbA1c lower than 8%) glycemic control. The average inpatient charges over three years for a patient with good control was $970, versus $3,040 per person for patients with poor control. Another recent study found that improving glycemic control in managed care patients can reduce average total expenditures by $685–$950 per year within the first four years of improvement. These cost reductions are achieved not only through preventing the complications of diabetes, but also through the immediate impact on patients’ functional ability. If a pharmacist were paid only $250 per patient, per year, to identify persons with diabetes who were failing to meet their treatment goals, helping just a few patients to achieve better control of their diabetes would offset the costs of the pharmacist-care program. Consequently, it appears that community pharmacists can produce savings to third-party payors and patients that clearly exceed the typical pharmacist compensation.

**Limitations**

The percentage of persons who did not reach the therapeutic goal was based upon the total number of those who agreed to participate in the pharmacist-based program. It is not clear whether the persons enrolled in this monitoring program were different from the general population of persons with diabetes. Because very few persons declined participation in the program, the study population is believed to be fairly consistent with the general population of managed care enrollees with diabetes.

**Conclusions**

Community pharmacists can play an important role in diabetes care by identifying patients who are not achieving their therapeutic goals, and by working with physicians to make drug therapy modifications. Through identifying patients not “at goal,” the pharmacists have the opportunity to prevent the development of diabetes-related complications and reduce total health care expenditures. Implementing a diabetes-monitoring program may require a significant investment by a pharmacist; however, this service should be of great value to patients, physicians, and third-party payors.

**References**

Prior Authorization Programs: A Critical Review of the Literature

OBJECTIVE: Though prior authorization (PA) programs are widely used in the managed care pharmacy environment, some stakeholders question whether these programs are effective. The objective of this article is to critically examine the effect of PA programs on health-related outcomes.

DATA SOURCES: A computer-aided search of the literature was conducted using several online databases to find studies that have evaluated PA programs. Other sources of information used were reference lists, authors of previous studies, and meeting abstracts.

STUDY SELECTION: In order for a study to be included in our analysis, it had to (1) appear in the peer-reviewed literature and (2) investigate the effects of a PA program on specified drugs. We excluded papers that studied the effectiveness of formulary systems, of which PA may be a component.

DATA EXTRACTION: From each study evaluated, we extracted data related to the study design and to the effect of the PA program on economic, clinical, and humanistic outcomes.

DATA SYNTHESIS: Six studies met our criteria. Overall, PA programs appear to be effective at reducing drug-related costs. There is some evidence that they reduce non-drug-related costs but little evidence that they have a positive impact on clinical or humanistic outcomes. None of the studies had a randomized, controlled design; most of the studies had severe methodological limitations.

CONCLUSION: Rigorously designed studies are urgently needed in order to evaluate the effects of PA on health-related outcomes.

KEYWORDS: Prior authorization, special authorization, drug cost containment, pharmacy benefit management, prescribing restrictions

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appropriately prescribe drugs.\textsuperscript{8} Thirty-six percent (29 of 44) said that in the past they have chosen not to prescribe a product primarily because of its limited-use status, even though the physician felt the patient might benefit from the drug.\textsuperscript{8}

Community pharmacists also complain about the administrative burden of PA programs; a recent study showed that, on average, a supermarket chain pharmacy spent 2.15 minutes and an independent pharmacy spent 2.97 minutes just on rejection resolution for each prescription that required PA.\textsuperscript{9} Last year, the North Carolina Board of Pharmacy passed special regulations to help reduce community pharmacists’ burdens of dealing with third-party payor administrative policies such as PA.\textsuperscript{10}

Perhaps the greatest controversy over the use of PA is the unintended effect of other prescribing restrictions such as restrictive formularies and benefit caps. One of the first studies to document unintended effects was a 1985 study of a closed formulary for drugs used in treating peptic ulcer disease for the West Virginia Medicaid program. After a formulary policy change, outpatient drug expenditures were reduced by 78.9\%, but monthly physician payments increased 3.1\% and monthly inpatient hospital costs increased 23.6\%.\textsuperscript{11} A 1991 study found that drug use decreased but nursing home admissions increased after a three-prescription limit per patient per month was implemented in the New Hampshire Medicaid program.\textsuperscript{12}

A controversial 1996 study by Horn and colleagues further added to the literature on the unintended effects of prescribing restrictions by concluding that health maintenance organizations (HMOs) with more-restrictive drug formularies had higher overall utilization and costs of health care resources.\textsuperscript{13} There has been considerable debate over the methodology of the Horn study in particular and over prescribing restrictions in general, including several editorials in this journal.\textsuperscript{14}

Since PA programs are common in the managed care pharmacy environment, and because of the questions about these programs stimulated by previous studies, we considered it urgent to examine the effectiveness of PA programs. The objective of this article is to review the peer-reviewed literature on PA programs and to assess their effects on economic, clinical, and humanistic outcomes of health care.

**Methods**

**Data Sources**

A computer-aided search of the medical and pharmacy literature in English was conducted in spring 2001, using Medline, International Pharmaceutical Abstracts (IPA), Health Star, and Ecolit. Keywords such as prior authorization, prescribing restrictions, prior approval, special authorization, cost containment, exception drug status, and restrictive formularies were used in the search. Other studies on PA were found in managed care textbooks, references, and reading materials previously collected by the lead author. We attempted to contact authors of published studies on PA and researchers on PA in search of studies that were not identified by our computer-aided search. We reviewed abstracts from recent educational conferences and annual meetings of the Academy of Managed Care Pharmacy (AMCP) and annual meetings of the Canadian Association of Population Therapeutics (CAPT), but a study had to be published in complete form in order to be included in our final analysis.

**Study Selection**

In order for a study to be included in our analysis, it had to (1) appear in the peer-reviewed literature, and (2) investigate the effects of a PA program on specified drugs. We excluded papers that studied the effectiveness of formulary systems, of which prior authorization may be a component, as it would be impossible to distinguish the effect of the PA program from the effect of the formulary itself.

**Data Extraction**

From each study evaluated, we extracted data related to the study design and the effect of the PA programs on health-related outcomes. In the critique of each study, each author of this article independently used a standardized data collection form based on the ECHO (economic, clinical, and humanistic outcomes) model proposed by Kozma, Reeder, and Schulz as our framework for evaluation.\textsuperscript{15} More specifically, for all studies we critically evaluated the methodology, study sample, outcomes measures, drugs studied, and economic (both drug costs and other health expenditures), clinical (both drug-related and non-drug-related), and humanistic outcomes (satisfaction and HRQoL).

**Results**

Six studies met our criteria for review.\textsuperscript{5, 16–20} The study design, study sample, outcomes measures, and drugs in the PA programs are contained in Table 1, page 299.

Because no study had a randomized, controlled experimental design, all studies had significant threats to validity. The study by Smalley and colleagues had the most rigorous experimental design.\textsuperscript{17} Four of the six studies had no control group.\textsuperscript{5, 10–20} One study did not use a baseline measurement period before the PA program was set up, and only one study had a follow-up period of more than one year to measure the long-term effects of the PA program.\textsuperscript{18, 17}

Four of the six studies used a state Medicaid program for the study sample.\textsuperscript{5, 16–18} The other studies used an urban teaching hospital and secondary data from a national survey.\textsuperscript{18, 20} None of the studies was multi-center. The intended unit of analysis was often hard to determine; indeed, three of the studies did not specify the exact number of patients considered.\textsuperscript{5, 18, 19}

Outcome measures also varied considerably. One study measured simply the cost and utilization of the PA drugs.\textsuperscript{18} Only one study included clinical outcome measures.\textsuperscript{19} Four of the studies looked at a single drug class (nonsteroidal anti-inflamm-
### TABLE 1  Summary of Reviewed Studies on Prior Authorization Programs

<table>
<thead>
<tr>
<th>Article</th>
<th>Study Design</th>
<th>Study Sample</th>
<th>Outcome Measures</th>
<th>Drugs Studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kotzan, McMillan, Jankel, and Foster, 1993&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Time-series analysis that included data up to one year before policy change and up to seven months after</td>
<td>80,064 continuously eligible recipients in the State of Georgia Medicaid program</td>
<td>Cost and utilization of NSAIDs, other anti-arthritis agents, non-narcotic analgesics, physician claims, and other medical services (exact kinds not specified)</td>
<td>NSAIDs (except those available in generic form)</td>
</tr>
<tr>
<td>Smalley, Griffin, Fought et al., 1995&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Baseline year before policy change and the two-year period after policy change; interrupted time-series analysis with a control analysis</td>
<td>Two separate study groups: (1) enrollees at any time during the three-year period in the Tennessee Medicaid program (495,821 in baseline year to 547,403 in year 3), and (2) enrollees with uninterrupted enrollment for all three years who were regular users of NSAIDs (3,174 regular users of nongenerics and 1,849 regular users of generics)</td>
<td>Cost and utilization of NSAIDs, other analgesic or antiinflammatory drugs, psychotropic drugs, outpatient services, and inpatient admissions for management of pain or inflammation</td>
<td>NSAIDs (except those available in generic form)</td>
</tr>
<tr>
<td>Kotzan, Perri, and Martin, 1996&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Cross-sectional, equivalent control group; comparison of two groups for a three-month period</td>
<td>All prescription claims processed for the State of Georgia Medicaid program for Jan–Mar 1994 (2,957,850 prescriptions, including 71,187 for PA drugs), and cash prescriptions (6,347,617 total, including 357,546 for PA drugs) from approximately 1,100 Georgia pharmacies</td>
<td>Cost and utilization of 46 drugs; market-share analysis</td>
<td>46 drugs that were part of the Georgia Medicaid program and also represented in private-payment markets</td>
</tr>
<tr>
<td>Phillips and Larson, 1997&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Baseline (12–24 months, depending on the drug studied) before policy change and the 12-month period after the policy change; no control group. Operational performance based on two weeks of data</td>
<td>Iowa Medicaid enrollees for whom a prescription requiring PA was filled during the study period (approximately 250,000 enrollees; no number for patients for whom a PA prescription was filled)</td>
<td>Cost and utilization of 16 drugs; also administrative outcomes, such as approval rates and program response times</td>
<td>16 categories of individual medications</td>
</tr>
<tr>
<td>White, Atmar, Wilson et al., 1997&lt;sup&gt;5&lt;/sup&gt;</td>
<td>Baseline (July–Dec) six-month period before policy change and a six-month period (July–Dec) six months after the policy change; no control group</td>
<td>Patients in a 575-bed urban teaching hospital during the study period who received an antimicrobial agent (exact number of patients or prescriptions filled is not provided, though the total number of patient-days per month in the hospital decreased from 14,694 to 13,738)</td>
<td>Cost of parenteral antimicrobials, antimicrobial susceptibility patterns, gram-negative bacteremia survival rates, time from initial blood culture to receipt of an appropriate antibiotic, inpatient and ICU length-of-stay</td>
<td>Six intravenous antibiotics initially, plus two other antibiotics added over the next six months</td>
</tr>
<tr>
<td>Feldman, Fleischer, and Chen, 1999&lt;sup&gt;6&lt;/sup&gt;</td>
<td>Retrospective cross-sectional study of data from the National Ambulatory Medical Care Survey; sensitivity analyses were performed to determine whether a PA age of 25 is cost-effective</td>
<td>A cost and utilization model was created from previously published data (the National Ambulatory Medical Care Survey), normalized to 100,000 covered lives</td>
<td>Cost and utilization of topical tretinoin; costs of administering a PA program to an insurer were also considered</td>
<td>Topical tretinoin</td>
</tr>
</tbody>
</table>

Notes: NSAID is nonsteroidal anti-inflammatory drug. PA is prior authorization. ICU is intensive-care unit.
<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Kotzan, McMillan, Jankel, and Foster, 1993</td>
<td>NSAIDs: monthly reduction in costs of about 54% from baseline to policy implementation period ($3,018,308 estimated savings over seven months); monthly non-narcotic analgesic use increased about 37% ($193,540 over first seven months); no other significant changes</td>
<td>No significant changes in physician claims or other categories of medical services (exact categories not specified); administrative costs of the program were not measured</td>
<td>No measured</td>
<td>No measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
<tr>
<td>Smalley, Griffin, Fought et al., 1995</td>
<td>All enrollees: Annual expenditures of NSAIDs decreased by 53% during the two years after the start of the policy ($12,800,000 estimated savings over two years); no other significant changes; regular nongeneric NSAID users: a relative decrease in expenditures of 64% compared to generic NSAID users; no other significant changes</td>
<td>All enrollees: no significant changes Regular nongeneric NSAID users: no significant changes where sample size permitted analysis Administrative costs to the Medicaid program: $75,000 for one year</td>
<td>No measured</td>
<td>No measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
<tr>
<td>Kotzan, Perri, and Martin, 1996</td>
<td>Total estimated drug costs savings attributable to the Georgia Medicaid PA program for all 46 drugs: $8–$20 million annually</td>
<td>Effects on non-drug costs were not measured Administrative costs to the Medicaid program: About $1 million</td>
<td>No measured</td>
<td>No measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
<tr>
<td>Phillips and Larson, 1997</td>
<td>Net savings (gross drug savings minus administrative costs) for four drug categories (anti-arthritics, benzodiazepines, antihistamines, and antiulcer drugs) estimated to be $2.51 million–$3.83 million</td>
<td>Effects on non-drug costs were not measured Administrative costs to the Medicaid program for four categories of drugs totaled $162,000</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Satisfaction not directly measured, though response times and approval rates were</td>
<td>Not measured</td>
</tr>
<tr>
<td>White, Atmar, Wilson et al., 1997</td>
<td>Expenditures for all parenteral antimicrobials decreased by $431,548 (32%) for the six-month period in 1994 as compared to 1993 (this included an increase in expenditures for some antimicrobials not included in the PA program)</td>
<td>No significant change in inpatient or ICU length of stay Administrative costs to the hospital: less than $150,000 per year (estimated)</td>
<td>Increased susceptibility to isolates in ICUs and inpatient units but not outpatient sites; time to receipt of appropriate antibiotics unchanged</td>
<td>No significant change in survival rates in patients with gram-negative bacteremia</td>
<td>Satisfaction not directly measured, though response times and approval rates were</td>
<td>Not measured</td>
</tr>
<tr>
<td>Feldman, Fleischer, and Chen, 1999</td>
<td>Assuming a topical tretinoin unit cost per prescription of $28 and a unit expense of $10 for performing a single PA, the total cost per 100,000 covered lives is estimated to be $23,226 for a PA age of 25 and $22,685 for a PA age of 35. The tretinoin cost with no PA program is $23,800. Effects on non-drug costs were not measured.</td>
<td></td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
</tbody>
</table>

Notes: NSAID is nonsteroidal anti-inflammatory drug. PA is prior authorization. ICU is intensive-care unit. HRQoL is health-related quality of life.
matory drugs [NSAIDs] in two, intravenous antibiotics in one, topical tretinoin in one), while the two others evaluated several drug classes.

Table 2, page 300, contains the economic, clinical, and humanistic outcomes that were measured in these studies. We distinguished between drug and non-drug outcomes in both the economic and clinical outcome categories and between patient satisfaction and HRQoL humanistic outcomes.

All six studies documented drug cost savings from the PA programs. We had initially hoped to conduct a meta-analysis to better summarize the amount of drug cost savings from PA programs, but inconsistencies in the descriptions of the study samples and outcomes made it impossible to calculate an effect size. It is interesting, though, that the two studies that focused on a PA program for NSAIDs found similar drug cost savings (approximately 54% in Kotzan et al. and 53% in Smalley et al.). Some studies failed to distinguish between cost savings resulting from lower overall drug product cost (switch to generic or less expensive drug) or from lower drug utilization.

Of the three studies that measured the effect of the PA program on non-drug costs, none found a significant increase in costs elsewhere in the health care system. Five of the six studies calculated the administrative costs of operating the PA program, although they did not provide thorough descriptions of how these costs were measured, what they included, and costs to stakeholders outside of the direct organization of interest (e.g., community pharmacists, physicians, etc.). One study concluded that the administrative costs of the PA program outweighed the reduction in drug costs for a majority of age groups considered.

Only the study by White and colleagues measured how the PA program affected clinical outcomes. None of the studies measured how PA programs affected satisfaction (patient, pharmacist, physician, nurse, or other) or HRQoL, two primary humanistic outcomes.

†† Discussion

Our critical analysis of the literature indicates that although PA programs are common, their outcomes have not been adequately evaluated. PA is not alone, however; evaluation of administrative policies and programs in health care and in pharmacy benefit management today is rarely adequate. Still, the scarcity of quality evaluations of the outcomes of PA programs should be of concern to patients, health care professionals, administrators, and others who work in managed care pharmacy since these programs are widely used. Little has changed since 1993, when Kotzan, McMillan, Jankel, and Foster lamented: “The long-term impact of PA programs has not been documented. If the drug programs are devised solely on the basis of economic consideration without regard for medical consequences, then it is likely that more expensive services will replace those expensive drugs removed from the formulary.”

Why is there a lack of rigorous evaluations of PA programs?

Ray has reflected on the general problem of inadequate health policy evaluations and concluded that a primary barrier is politics; conducting a randomized, controlled trial is an admission of uncertainty. The persons or organizations involved in PA programs may have a vested interest in the success of their programs. Moreover, expensive randomized controlled trials may not be practical for many organizations, although repeated time-series analyses, such as the one conducted by Smalley and colleagues, may be possible.

One can understand the reluctance to measure humanistic outcomes of PA programs, such as satisfaction, given that PA is an administrative policy. Still, measuring what happens to patients who are denied a PA request would be valuable. Fortunately, some MCOs are now trying to improve physician and patient satisfaction with PA programs, some by automating the PA process to eliminate paperwork or pharmacist intervention. Finally, another barrier to quality evaluations is that some organizations may have difficulty in separating the outcomes of a PA program from those of the total formulary-management system.

Why is there a need for more PA program evaluations that measure all three types of health-related outcomes? The principal reason is to determine how PA programs affect clinical and humanistic outcomes. Proof that PA programs improve patient outcomes would more strongly support their use. If they affect patient outcomes negatively, all stakeholders should reassess their use. Failure to measure the clinical outcomes of PA programs is of special concern: Our literature search found no published studies, and just one presentation abstract, that measured clinical outcomes outside the hospital.

Secondly, evaluation of programs and policies is a key part of a continuous quality improvement (CQI) philosophy, where benchmarks are determined and an attempt made to improve performance to exceed those benchmarks. As Phillips and Larson acknowledge, currently there are not even PA program benchmarks for such basic outcomes as processing times, approval rates, and administrative costs. Standard principles for PA programs could be helpful, perhaps like those recently developed for drug-formulary systems by AMCP and other organizations. Setting, and reporting on, standards should lead to increased accountability and transparency for PA programs. The accountability that must clearly become a priority for each stakeholder involved in putting such programs in place should include continual monitoring to determine if the program’s mandate is being achieved.

The burden of proof whether PA programs improve patient outcomes should be on those who have programs in place, even if this is a difficult process. As Hepler says, “It may be painful to be objective about our own sacred cows.” Program evaluation is especially urgent given that many policies that regulate access to and utilization of pharmaceuticals can have unintended neg-
ative outcomes. PA programs that direct prescribers to follow evidence-based clinical practice should, in theory, lead to positive clinical and HRQOL outcomes. Yet, as at least two of the studies we reviewed acknowledged, because these outcomes were not measured, we cannot be certain whether PA programs have a positive or a negative effect on these outcomes. Given these important but still unanswered questions, now would appear to be an opportune time for evaluation of all policies that restrict prescribing, including PA.

** Limitations **

In any analysis of critical literature, some may differ with the inclusion/exclusion criteria or identify studies that have been omitted. We tried to minimize these problems by making our initial search as broad as possible through the use of multiple literature-retrieval methods and by making our criteria fairly conservative. As with any literature review, we are limited by inherent publication biases to publish only statistically significant results. Finally, we did intend to conduct a meta-analysis, but this proved impossible given the inconsistency in the description of the study samples and outcomes.

** Conclusion **

From a critical review of the literature, PA programs appear to reduce drug-related costs. There is some evidence that they may also reduce non-drug-related costs, but little evidence that they improve clinical or humanistic outcomes. Most existing studies have severe methodological limitations. There has been not one randomized controlled study to better establish the relationship of PA programs to these health-related outcomes. Resources for thorough program evaluations may be scarce, but an unformed acceptance of PA programs without consideration of their effects on health outcomes may be suboptimal at best, and dangerous at worst.

** References **


Evaluating Asthma Medication Use Before and After an Acute Asthma-related Event

OBJECTIVE: Pharmacy and medical claims data have often been used as a source of data on the asthma population in managed care settings. However, there are very few data on patterns of drug utilization surrounding an acute event. This is a report of an observational pilot study that evaluated utilization patterns in asthma treatment before and after an acute event.

DESIGN: The study was performed by evaluating pharmacy and medical claims data submitted between January 1, 1994, and September 30, 1995, in a 275,000-member preferred provider organization (PPO) in the mid-Atlantic region; 83 patients met the inclusion and exclusion criteria.

RESULTS: Evaluating the data using the McNemar test revealed a statistically significant greater number of patients using short-acting beta-agonists after an acute event who did not use them before the event compared to the number of patients who changed in the reverse (i.e., patients who used short-acting beta-agonists before an acute event but not after) (p<0.05). The number of patients who used inhaled anti-inflammatory medications, however, did not change significantly. In addition, the proportion of patients using the short-acting beta-agonists or anti-inflammatory agents was highest immediately after the acute event.

CONCLUSION: Our findings suggest that an acute event only partially affects adherence to recommended therapy. Efforts must be made to increase and maintain the use of important long-term anti-inflammatory asthma medications. This analysis may help lay the foundation for larger studies focusing on utilization patterns and compliance around an acute event for a variety of disease states.

KEYWORDS: Acute event, adherence, asthma, claims data, compliance, utilization

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cated for long-term prevention of bronchospasm, including nighttime symptoms. The leukotriene modifiers are the newest class of long-term control medications. Zafirlukast and montelukast are leukotriene receptor antagonists, while zileuton is a 5-lipoxygenase inhibitor.

The national guidelines emphasize the importance of patient education, especially on adherence to therapy. It is estimated, however, that adherence to therapy in both the pediatric and the adult asthma populations is only about 50%. Nonadherence to a prescribed therapeutic program is one of the factors suspected of contributing to asthma morbidity and mortality in all populations.

Pharmacy and medical claims data have often been used to study the asthma population in the managed care setting because these large databases can be used to identify specific patient populations (e.g., high risk), monitor appropriateness of care, and evaluate utilization patterns. Prescription usage has been used to infer patient compliance with therapy as well as to observe prescribing patterns of physicians. Although this type of analysis has its limitations, it can provide a broad picture of the utilization patterns of a population and suggest problem areas that may require special attention.

An area that has not yet been extensively explored is clinical management and patient behavior immediately before and after an acute event such as an emergency room visit or hospitalization. An acute event might influence patients to become more aware of their condition as well as more compliant with medication therapy. From the provider's perspective, the acute event could provide a "teachable moment," an opportunity to educate patients on an appropriate therapy. This article describes utilization of relevant prescriptions before and after an acute asthma-related event (hospitalization or ER visit) in an effort to determine patterns in patient compliance and physician prescribing.

+++ Study Methodology

This retrospective observational pilot study consists of an analysis of pharmacy claims for short-acting beta-agonists and inhaled anti-inflammatory agents and of medical claims submitted between January 1, 1994, and September 30, 1995, in a 275,000-member preferred provider organization (PPO) in the mid-Atlantic region. Asthmatics were identified from the International Classification of Diseases, Ninth Revision (ICD-9-CM) diagnostic codes on the medical claims. Members between the ages of 1 and 60 years with at least one encounter for a primary or secondary diagnosis code for asthma (ICD-9 codes of 493–493.99) were identified as "asthmatic." Members with only one acute asthma-related event (ER visit or hospitalization) occurring between July 1, 1994, and March 31, 1995, were included for analysis to ensure that sufficient medical-claim-free periods and pharmacy data were available for analysis before and after the acute event.

Acute events were defined as (1) a hospitalization caused by asthma (primary ICD-9 code of 493–493.99) or (2) an asthma-related ER visit (primary ICD-9 code of 493–493.99 and Current Procedural Terminology (CPT) codes of 99281, 99282, 99283, 99284, 99285, or 99288). The study population was also limited by including only those who had a continuous pharmacy benefit. It was assumed that patients were continuously enrolled with a pharmacy benefit throughout the study period if they had pharmacy claims submitted in the first (January–March 1994) and last (July–September 1995) quarters of the study. Patients were excluded if they had a diagnosis of cystic fibrosis (ICD-9 codes of 277–277.99) or chronic obstructive pulmonary disease (ICD-9 codes of 491–492.99).

Once the study cohort was identified, the medical and pharmacy claims were integrated to create a profile for each patient. The acute event was considered to be "time zero" and the pharmacy data surrounding the acute event was incorporated into a time line. The period before "time zero" was divided into 90-day pre-acute event periods and the time period after "time zero" was divided into 90-day post-acute event periods. The profiles were then evaluated for trends in utilization of short-acting beta-agonists and inhaled anti-inflammatory medications before and after "time zero."

### TABLE 1 Pre-event Short-Acting Beta-Agonist Use by Post-event Short-Acting Beta-Agonist Use

<table>
<thead>
<tr>
<th>Frequency/Percent</th>
<th>No</th>
<th>Yes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-event No</td>
<td>3</td>
<td>21</td>
<td>24/28.92%</td>
</tr>
<tr>
<td>Pre-event Yes</td>
<td>9</td>
<td>50</td>
<td>59/1.08%</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>71</td>
<td>83/100.00%</td>
</tr>
</tbody>
</table>

Pre-event "yes" — Patient had prescription filled for short-acting beta-agonist in the pre-event period

Pre-event "no" — Patient did not have prescription filled for short-acting beta-agonist in the pre-event period

Post-event "yes" — Patient had prescription filled for short-acting beta-agonist in the post-event period

Post-event "no" — Patient did not have prescription filled for short-acting beta-agonist in the post-event period.

McNemar test of significant changes reveals a statistically significant change ($p<0.05$) in that a greater number of patients changed from not using short-acting beta-agonists in the pre-event period to using them in the post-event period ($n=21$) than the number of patients who changed from using the short-acting beta-agonists in the pre-event period to not using them in the post-event period ($n=9$).
The McNemar test for significant changes found a statistically significant greater number of patients using short-acting beta-agonists in the post-acute event period compared to those who did the reverse (i.e., patients who used short-acting beta-agonists pre-acute event but not post-acute event) \( p<0.05 \). In the calculation, the number of patients who have a "no" response pre-acute event and a "yes" response post-acute event are compared to the number of patients who have a "yes" response pre-event and a "no" post-event. Table 1 represents the patients who changed their usage of short-acting beta-agonists. A statistically significant result was obtained \( p<0.05 \) comparing the 21 patients in the upper right cell to the 9 patients in the lower left cell of the 2 x 2 table.

The number of patients using inhaled anti-inflammatory agents, however, did not change significantly between the pre-acute event period and the post-acute event period \( (p=n.s.) \) (Table 2). A closer look at the cross-tab analysis of the inhaled anti-inflammatory medications (Table 2) reveals that 47 of the 83 patients were not on any inhaled anti-inflammatory medication before or after the acute event; 7 were on an inhaled anti-inflammatory medication before but not after; 14 were on an inhaled anti-inflammatory medication after but not before; and only 15 were on an inhaled anti-inflammatory medication before and after the acute event.

In total, only 29 out of 83 patients (35%) were on an inhaled anti-inflammatory medication after an acute asthma-related ER visit or hospitalization.

In a separate analysis, the proportion of patients using short-acting beta-agonists or inhaled anti-inflammatory medications was determined for each time period (see Figure 1, page 306). The proportion of patients using a short-acting beta-agonist or an inhaled anti-inflammatory medication was highest during post-acute event period one (70% of patients [58] received short-acting beta-agonists and 28% [23] received inhaled anti-inflammatory medications). Figure 1 depicts the overall use of asthma medications in the periods surrounding an acute event. As expected, more patients used asthma-related medications in the 90 days after the acute event, but that number declined with time.

**Discussion**

Nonadherence with recommended therapy has been documented as a contributing factor in asthma morbidity and mortality.\(^9\) A study that evaluated five urban teaching hospital emergency departments evaluated the correlates of compliance with follow-up appointments and prescription filling after an emergency department visit.\(^8\) Of the 1,386 patients interviewed, only 45% (408 patients) recalled being advised to take a medication and 12% (50) reported that they did not obtain the medications. In a 1997 study by Ordonez et al., children aged 3 to 15 years admitted to an Australian hospital with an acute asthma attack were evaluated to identify factors that might prevent future hospital admissions.

**Results**

Of the approximately 8,000 members with a primary or secondary diagnosis code of asthma, 83 met the inclusion and exclusion criteria. Acute exacerbations of asthma led to ER visits for 56% of these patients and hospitalizations for 42%. Hospitalizations include patients who were initially admitted to the ER.

A greater number of patients (86%) received a prescription for short-acting beta-agonists after an acute event than before (71%).

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Pre-event Inhaled Anti-inflammatory Use by Post-event Inhaled Anti-inflammatory Use</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Post-event</td>
</tr>
<tr>
<td>Frequency/Percent</td>
<td>No</td>
</tr>
<tr>
<td>Pre-event</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>7/8.43%</td>
</tr>
<tr>
<td>Total</td>
<td>54/65.06%</td>
</tr>
</tbody>
</table>

Pre-event "yes" — Patient had prescription filled for inhaled anti-inflammatories in the pre-event period.

Pre-event "no" — Patient did not have prescription filled for inhaled anti-inflammatory in the pre-event period.

Post-event "yes" — Patient had prescription filled for inhaled anti-inflammatory in the post-event period.

Post-event "no" — Patient did not have prescription filled for inhaled anti-inflammatory in the post-event period.

McNemar test of significant changes reveals no statistically significant change in the number of patients using inhaled anti-inflammatory comparing the pre-event period to the post-event period \( (p=n.s.) \).
admissions. This study found evidence of inadequate preventive treatment as well as poor compliance within the 12 months prior to an acute asthma attack.

There is also evidence that many physicians do not adhere to existing guidelines for the emergency management of asthma. For example, in a 1997 Canadian study, a cross-sectional survey determined that many Canadian emergency physicians did not follow published recommendations for the care of patients with acute asthma. This was especially true with regard to the aggressive use of beta-2-agonists and the use of corticosteroids.

Testing our assumption that an acute event would lead to more optimal therapy and better patient compliance, our results showed that this was only partially true, in that the only asthma medications whose use significantly increased after the acute event were short-acting beta-2-agonists. Although more patients did receive inhaled anti-inflammatory medications after the acute event, the number was not statistically significant. This result may indicate either poor patient compliance or physician failure to prescribe these important long-term therapies.

Our results show that the number of patients receiving short-acting beta-agonists steadily increases as time nears the acute event, with 42 of 83 patients receiving inhaled short-acting beta-agonists during the 90 days beforehand (Figure 1). This may be an indication that patients were relying on the short-acting beta-agonists to obtain quick relief of their worsening symptoms.

The proportion of patients using both the short-acting beta-agonists and the inhaled anti-inflammatory medications was highest during the 90 days after the event. This suggests some support for the hypothesis that an acute event leads to more optimal treatment. However, as time passed, the use of anti-inflammatory agents decreased.

Finally, the low proportion of patients receiving inhaled anti-inflammatory medications throughout the periods before and after the acute event suggests either low patient compliance or physician failure to prescribe these long-term controller medications.

**Limitations**

This study used medical and pharmacy claims data for the purpose of observing utilization trends in a broad population. Although informative, administrative claims data have several limitations:

- The accuracy can be disputed. Accuracy of both medical and pharmacy claims relies on how well the data are entered (e.g., the ICD-9-CM and CPT diagnostic coding).
• Use of prescription claims only assures that the medication was dispensed, not that the patient is actually taking the med-
ications or using them correctly.
• Likewise, we cannot distinguish between patient noncompli-
ance and physician failure to prescribe when a medication is not dispensed.
• Claims data does not take into account the use of samples.
• Additionally, claims data does not provide the clinical infor-
mation required to assess the severity of an illness.
• Also, because of the exclusion criteria, we studied only those
patients with one acute event during the study period. It is
possible that these patients were not moderate-severe asth-
masics who required anti-inflammatory medications but mild-intermittent asthmatics who only required the “as need-
ed” use of short-acting beta-agonists.

This pilot study specifically evaluated the short-acting beta-
agonists, inhaled corticosteroids, inhaled cromolyn, and inhaled nedocromil. The use of other asthma medications, including theo-
phylline, ipratropium, oral corticosteroids, salmeterol, and leukotriene modifiers (which were not Food and Drug Administration-approved or available during the study period), was likely to have affected utilization of the short-acting beta-agonists and inhaled anti-inflammatory medications. Extending this study’s methodology to all the available asthma therapies could provide a better picture of actual drug utilization in the asthmatic population.

Finally, the generalizability of this study’s conclusions is limited by the small sample size resulting from the strict inclusion criteria. A larger study population and evaluation of data for a longer period of time might provide a better picture of the trends in utilization.

† † Conclusion

Nevertheless, the study provides some valuable lessons. First, although evaluations of claims data may lack clinical detail to ren-
der definitive judgments, they can raise important issues about the quality of care.20 Claims data can be used to improve appropriate uti-
lization, target continuing medical education, help manage complex patients, identify underserved patients, and detect misprescribing as well as fraud and abuse.21,22 This study examined the pharmacy claims of a population with a condition that is highly prevalent yet difficult to control in many cases. The results suggest a lack of com-
pliance with recommended therapies and missed opportunities of education and intervention during an acute event. Finally, this evaluation can provide a framework for future initiatives that focus on patient compliance and utilization around a sentinel event, a fruitful area of research that has not been sufficiently exploited.

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A Prescription for Change: Bridges to Cross the "Quality Chasm"

The second report of the Committee on the Quality of Health Care in America, Crossing the Quality Chasm: A New Health System for the 21st Century is currently available as an advanced copy (uncorrected proofs). It expands the committee's work beyond the focus on medical and medication error in To Err Is Human: Building a Safer Health System to a larger issue: the need to improve the quality of health care. The new report outlines aims and principles for an improved design for the delivery of care.

The text emphasizes that it is written not to present specifics but to present a new perspective on the purpose, intents, interactions, and processes of health care. The authors acknowledge that it will be necessary to redesign structures and processes of organizations and of professionals and their interactions. They also acknowledge that the practices of the nation's health care system, providers, and users must change to include improvements in dissemination and application of knowledge and potential advances in care. They state that the nation's health care system, providers, and users must have access to and use information technology in practice. Changes must be made to fiscal (payment) policies to facilitate new and better options and to reward better outcomes, and health care providers must be better educated.

The committee emphasizes that the report was written as a vision of what is possible and that changes must be made to the system to achieve the vision. The first report of the Committee on the Quality of Health Care in America, To Err Is Human: Building a Safer Health System, was summarized previously in this journal (J Managed Care Pharm 2001; 62-68).

The goals of this continuing education program are to inform readers about this important report and to present the committee's recommendations for building organizational support for change.

KEYWORDS: Quality, health system, health care delivery

by Linda L. Norton

The Committee on the Quality of Health Care in America was formed three years ago and was given a directive to develop a plan to make enormous improvements in health care over the next 10 years. The members of the committee have taken a multipronged approach to achieving their mission. They have:

• conducted a literature review with a focus on quality of care;
• organized workshops to improve understanding of the issues surrounding health care quality;
• identified factors that impact improvement efforts;
• considered ideas for improving accountability for quality; and
• identified research that may lead to improved quality in health care.

Throughout all these activities, the committee has been concerned with the delivery of care to individuals rather than general public health.

The work chronicles the failure of the current health care system and the problems that often make it impossible for new health-related knowledge and information to improve the quality of our health care. It details how the quality of health care can improve when technology is applied to make such information accessible and useful to clinicians and administrators.

Most of us already know that inconsistencies in health care cause the quality of health care to vary from exemplary to ineffective. We also know that more than 40 million Americans have inadequate access to care. This is often because of a lack of health insurance. We know that, at times, some if not most areas of health care can be considered poor stewards of the resources we have. The committee's report also details how fragmentation inhibits useful sharing of information and clinical communication. Overall, there has been little progress toward restructuring and improving the system even though we know that it is not operating at peak efficiency for patients, providers, or payors.

++ Prescription for Change

Given the need for improvements in our current system and the controversies surrounding the provision of health care, one large question looms: How can health care, and managed care pharmacy, be positioned for the future when we are struggling simply to meet the demands of today? The health care system, and pharmacy in particular, is facing decreased payments, inadequate staffing, more demands from the uninsured or the underinsured and a shift from more easily contained and defined episodic care for acute needs to a need for long-term continuity of care for chronic conditions. This last demand has resulted in increased reliance on med-
The quality committee has responded to today’s health care challenges with a surprising conclusion. It has announced that it is increasingly apparent that pushing harder to make the current system work cannot be the answer. The system does not and will not work on a patient-centered, timely, effective, efficient, equitable, or even safe basis for all Americans. It has proclaimed that change, a major change, in the health care system is needed. This change should include, among other things, a significant improvement in meeting the six aims set forth by the committee for a new health care system (see Table 1, page 311).

The committee has suggested a change toward care that is safer, more efficient, timely, effective, equitable, and centered on the patients who get or need care. However, to provide this level of care, the new health care system will need to overcome several challenges. It must:

• change the way care is delivered;
• use more information technology, and use it more effectively, to support both administrative and clinical efforts;
• manage patient care knowledge and skills to produce better outcomes;
• put together effective multidisciplinary care teams;
• improve coordination of patient care; and
• maximize the use of performance and outcome measures.

To help organizations meet these challenges, the committee presents basic information on principles for change that have been successful in other industries, with explanations to help guide the process of change. These five principles are summarized below. The committee also presented 10 basic rules for the health care system. These are summarized in Table 2, page 311. Finally, the committee presented 13 specific recommendations to keep the health care system focused on a positive change. These recommendations are shown in Table 3, page 312.

†† Five Principles for Change Design

It has been said that change is the only constant. Many health care practitioners would agree. Health care has already undergone a tremendous amount of change. However, health care is not the only sector in the U.S. economy that is undergoing change. Change seems to be endemic in our economy.

Take banking. Less than 20 years ago, most of our banking had to be completed at our bank branch on Monday through Thursday from 10:00 a.m. to 3:00 p.m. or on Friday between 9:00 a.m. and 6:00 p.m. Now, we can access and review accounts in the middle of night at automatic teller machines around the world or while sitting at home at our personal computers. This radical change has occurred in less than a generation. Most of us remember the days when “banker's hours” represented a schedule many of us longed for. This is no longer the case.

In engineering, architecture, and even medicinal chemistry and pharmacology, computer models are taking the place of painstakingly assembled manual models of proposed projects. In the computer models, projects can be reviewed for feasibility, fit, efficacy, or cost before any solid models are developed. Design and turnaround times can be shortened while costly mistakes are avoided.

These examples represent what could be a positive change for health care. Imagine your patients or subscribers accessing health care in the middle of the night while sitting at their personal computers. Or imagine a team of surgeons working toward a new technique through virtual surgery before any real incisions are made. Picture a patient viewing digital instructions for exercises designed by a physical therapist. Or envision a patient with questions about medications accessing a reliable site on the Internet to review side effects and interactions, and even discussing those problems online with a pharmacist. Furthermore, imagine that a pharmacist has access to a patient's entire medical record without calling a hospital, primary care provider, specialist, insurance company, or pharmacy benefit manager.

The vision suggested by the Committee on the Quality of Health Care in America would allow each of these examples to become a reality. The committee does, however, recognize that most health care institutions, providers, payors, and patients will need some help making this vision reality. To aid in that process, the committee has suggested five principles for designing the suggested changes.

The first principle is the 80/20 principle: “Design for the usual, but recognize and plan for the unusual.” The bulk of any new health care process should be dedicated to handling 80% of the work that needs to be done in that area—the predictable work. The design for this predictable work should allow simplification and standardization, with low variance from the standards of care. The contingency plan for the other 20% of the work can be developed as needed. Other applications of the 80/20 principle should be considered in designing the new system. For example, 20% of patients will likely account for 80% of the work and cost, and a high percentage of an effect may be attributed to a low number of causes.

The second principle is to design for safety. This principle has three specific components:

1. Systems should be designed to prevent errors by avoiding dependence on an individual health care provider's memory and attentiveness. Instead, designs should simplify processes using checklists, protocols, and guidelines.
2. Systems should be designed to make any errors that do occur visible before harm comes to a patient.
3. Designs should include procedures to reduce any harm that does occur. Technical support systems such as computerized protocols for antidote administration and harmless or near harmless default modes for equipment will most likely play an important role in this area.

The third principle is mass customization, which combines
the efficiency of mass production with the unique attributes that are brought by a custom consumer-driven product. A common example is the way many of us order laptop and desktop computers. All the computer components are mass-produced, but each customer can specify which components to include in a given computer. In this way, the computer can meet the individual needs of each customer.

If components are appropriately designed with the 80/20 principle in mind, the first principle can apply to mass customization also: 80% of customers or patients will select their "custom design" options from 20% of the selections. However, another idea for design is that under the right circumstances, each option should be a consideration for 80% of customers or patients. An example for managed care pharmacy that combines mass customization and the 80/20 principle could be the design of prescription copayment options. Of the menu of possibilities,

<table>
<thead>
<tr>
<th>Aim</th>
<th>Explanation</th>
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<tr>
<td>Safe</td>
<td>Should not cause injury</td>
</tr>
<tr>
<td>Effective</td>
<td>Provide evidence-based service to patients with need and avoid overuse</td>
</tr>
<tr>
<td>Patient-centered</td>
<td>Provide responsive care with courtesy</td>
</tr>
<tr>
<td>Timely</td>
<td>Reduced waiting times and delays</td>
</tr>
<tr>
<td>Efficient</td>
<td>Avoid waste</td>
</tr>
<tr>
<td>Equitable</td>
<td>Limit individual and geographic variations in care</td>
</tr>
</tbody>
</table>

### TABLE 2

**Rules for Redesigning the Health Care System**

<table>
<thead>
<tr>
<th>The Rule</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Care must be based on continuous healing relationships rather than episodic encounters. Patients should be able to access care whenever and wherever they need care. Care should not be restricted to office, urgent care, and hospital visits. Patients should have access to responsive care 24 hours a day every day of the year. Care should not be restricted or be available only at a lower level on the weekends or at night. This care would be accessible by telephone or even over the Internet, but these methods of access should augment rather than replace face-to-face visits. Many patients and clinicians will still need and want the assurance of face-to-face encounters, which provide valuable information that may be missed during &quot;virtual visits.&quot;</td>
</tr>
<tr>
<td>2</td>
<td>Customization must be based on the patient's needs and values, not the provider's. Systems should be designed to meet the most common needs, but also to respond to individual needs, choices, and requests.</td>
</tr>
<tr>
<td>3</td>
<td>Patients should be able to control their own care. When provided with the necessary health information at an appropriate and understandable level, patients should be able to employ the level of control they want to exercise over decisions that affect their health and health care. The system design must allow patients to select the level of control they desire. They should be encouraged and trained to share in the decision-making process. Some patients will opt to give the responsibility to their health care provider, and the system should accommodate that choice.</td>
</tr>
<tr>
<td>4</td>
<td>Knowledge must be shared and information must flow freely. Patients must be allowed access to their own medical information. They should also have access to the latest clinical information. Both clinicians and patients should be encouraged and trained to communicate effectively and share information.</td>
</tr>
<tr>
<td>5</td>
<td>Decisions must be based on the best evidence rather than habit or training. Clinicians should use the best scientific evidence available to reduce illogical variations in care.</td>
</tr>
<tr>
<td>6</td>
<td>Safety must be designed into the system. Patients should not be injured by the health care they receive. Systems designed to prevent error and reduce the impact of errors that do occur are key to reducing the risks to which patients are exposed.</td>
</tr>
<tr>
<td>7</td>
<td>Evidence on system performance should be readily available and the process should be transparent to patients. Information on the health care system must be available to patients. Access to such information will allow patients and their families to make decisions based on evidence rather than rumor. Information on alternative treatments and choices should include details describing system performance as it relates to safety, evidence-based medicine, and satisfaction.</td>
</tr>
<tr>
<td>8</td>
<td>The system should anticipate patients' needs. The health care system must do more than just react to demands. It should anticipate needs.</td>
</tr>
<tr>
<td>9</td>
<td>Waste in time and resources must be decreased.</td>
</tr>
<tr>
<td>10</td>
<td>Clinicians should cooperate, collaborate, and communicate. All clinicians and health care facilities should work together to ensure appropriate care and exchange of information.</td>
</tr>
</tbody>
</table>
The purpose of health care in the United States

Six major aims of health care

Monitoring and tracking the progress of change

Ten basic rules for redesigning health care

Identifying 15 priority conditions and ways to improve those conditions

The Health Care Quality Innovation Fund

Workshops to address six identified challenges

Advances in science that are useful to health care’s constituents

Information and documentation system to support health care

Payment methods that reward, not impede, quality improvement

Research to improve the connection between payments and quality goals

Summit to strategize and assess restructuring of clinical education

Research on how the regulatory and legal systems’ affect the changes needed, and how they can be modified to support the needed changes

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>The Recommendations of the Committee on the Quality of Health Care in America</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The purpose of health care in the United States</td>
</tr>
<tr>
<td>2</td>
<td>Six major aims of health care</td>
</tr>
<tr>
<td>3</td>
<td>Monitoring and tracking the progress of change</td>
</tr>
<tr>
<td>4</td>
<td>Ten basic rules for redesigning health care</td>
</tr>
<tr>
<td>5</td>
<td>Identifying 15 priority conditions and ways to improve those conditions</td>
</tr>
<tr>
<td>6</td>
<td>The Health Care Quality Innovation Fund</td>
</tr>
<tr>
<td>7</td>
<td>Workshops to address six identified challenges</td>
</tr>
<tr>
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<td>Information and documentation system to support health care</td>
</tr>
<tr>
<td>10</td>
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</tr>
<tr>
<td>11</td>
<td>Research to improve the connection between payments and quality goals</td>
</tr>
<tr>
<td>12</td>
<td>Summit to strategize and assess restructuring of clinical education</td>
</tr>
<tr>
<td>13</td>
<td>Research on how the regulatory and legal systems’ affect the changes needed, and how they can be modified to support the needed changes</td>
</tr>
</tbody>
</table>
payors/employers could choose the 20% of options that fit the specific needs of 80% of their employees.

The fourth principle is to design for continuous flow or "a batch size of one." The concept behind continuous flow is that the care process is matched to the demand and no queuing of patients or samples is necessary before processing.

There are important assumptions embedded in this principle, including the belief that the demand for service can be satisfied and that the demand is relatively constant and predictable. If the demand is believed to be beyond what may reasonably be satisfied, then a system must be designed to manage the demand. Unfortunately, one way to manage demand is to design in barriers, such as a waiting period or a queue. However, the committee believes that continuous flow and matching design and demand will result in better care by reducing missed appointments and procedures, not to mention duplication of effort on the part of both patient and the provider.

The fifth principle presented is production planning. This allows resources such as staff and equipment to be used most appropriately to meet patients' needs and to lower wastes and costs. As in mass production, the repetitive process and the natural flow of work in many aspects of health care can be defined; resources can be allocated to meet this repeating cycle. The cycle may repeat daily, weekly, or even based on the phase of the moon. Although it is possible that only those individuals most familiar with the work will recognize the cycle; a good understanding of the work will allow many of these cycles to be identified. Once the cycle is identified and confirmed, resources can be allocated to increase or decrease staff and meet the needs in each phase of the cycle.

†† Aims, Rules, and Recommendations

The committee has based much of its work on the idea that even after extensive redesign, our health care system will not be simple. Nor, even subject to rules, will it become rigid and mechanical. The committee fully expects the system to remain complex but adaptive.

Complex implies that the system will remain highly interactive and interdependent. Adaptive means that the system can change, and it will be less predictable than a mechanical system. This is in large part because at least one component of the system reacts to stimuli in a variety of ways: In general, if humans are involved, the system will be adaptive. The human component of the system introduces a fundamental lack of predictability.

In light of the belief that the 21st-century version of our health care system will remain complex and adaptive, the committee has provided a limited number of aims and rules (see Tables 1 and 2). The aims are part of the committee's vision for the results of the redesign of care. The rules can provide the guidance needed to help that vision become reality. In addition, complex adaptive systems produce amazing results from application of just a few rules.

In addition to this effect, systems like the U.S. health care system exhibit an interesting array of outcomes that are beyond the inherent adaptability of the system. These effects include nonlinear results (e.g., small changes can result in large effects), an overall lack of predictability, inherent abilities to evolve new behaviors, an intrinsic order even in the absence of a central control (acceptance of a few basic rules or concepts may account for some of this order), interdependence, and even co-evolution.

In spite of the impressive potential for positive outcomes from a complex adaptive new system—or perhaps because of the potential for the lack of predictability outcome—the committee has adopted 13 recommendations, endorsing the phrasing of the Commission on Consumer Protection and Quality in the Health Care Industry (see Table 3, page 312). The committee's recommendations should provide direction for the constituents of the health care system. The recommendations should also provide initial guidance as participants move through the process of creating new designs and changing care.

†† Application to Managed Care Pharmacy

The challenge for managed care pharmacy is how to accomplish a major change to meet the six aims of the Committee on the Quality of Health Care in America. There has clearly been some progress through the use of disease management for provider quality improvement, the requirements for pharmacoeconomic studies to support Food and Drug Administration and formulary submissions, and an emphasis on evidence-based medicine to decrease variance in patient care. However, there is a large chasm between the vision of the committee and the development of a pragmatic action plan. Formularies, preferred drug lists, differential copayments, and other managed care tools have come under significant criticism although they are attempting to apply some standards to the use of drugs. The "five principles" are directed to total system approaches that require cooperative team-oriented problem solving. Some improvements are being made in designs for safety (e.g., progress in electronic prescribing and electronic medical records), but there has been relatively little progress in mass customization and continuous flow designs. The accomplishment of these principles is dependent on health care providers coming together in teams with the goal of improving the system for patients.

What can managed care pharmacy do to achieve the goals of the committee? As the payor or payor advocate managed care pharmacy can stress the aims and principles of the committee in provider contracts. Managed care can define the "best practices" of patient-centered care and contract with those providers willing to provide evidence that they are meeting the practices or incrementally moving toward those practices. "Centers of excellence" exist in all industries including health care and demand higher prices for their efforts. These centers can be fos-
tered through preferred contracts and moving patients to these centers when appropriate. These concepts can also apply to the services desired of pharmacists, the standards of care required, and the expected outcomes. Once these issues are defined appropriate fee structures can be developed to reimburse for outcomes, and distribution systems can be designed using the processes (i.e., mass customization, batch processing) and technology required to meet safety and financial goals.

The committee has emphasized a broad philosophy for change. The aims and principles required are not different from the broad goals of managed care and managed care pharmacy. What is required of managed care pharmacy is to declare the vision, model the culture and principles, and settle for nothing less than the standards established by the committee.

† † Conclusion

As discussed in To Err is Human, many patients are injured by the health care that was intended to improve their lives. Although the United States has some of the best care available, the health care system too frequently fails to deliver on the promise of excellent care. In specifying the need for change and suggesting the most appropriate changes to be made, the Committee has presented models for change and enunciated 6 aims, 10 rules, and 13 recommendations to improve health care in the United States. All this effort is intended to be both a guide and the impetus for change in health care.

The committee’s effort presents a vision of what may be possible. No matter what course is taken, in a system as complex and adaptive as the U.S. health care system, change is inevitable. One question that arises is: Will that change be for better or worse?

As with previous changes, there will be supporters and detractors of the role that managed care medicine and managed care pharmacy will have in the new health care system. However, the committee has suggested that with the appropriate vision—focused on their six aims, adhering to their rules, and adopting their recommendations—the change as a whole will be very much for the better. †

References

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

1. Describe the 13 recommendations presented by the Committee to improve the quality of health care.
2. Outline the six aims for improvement set forth by the Committee.
3. List at least 5 of the 10 rules for health care in the 21st century.
4. Summarize five design principles used successfully in health care that can serve as patterns for redesign and change in the system.
5. Suggest an agenda for change in a managed care pharmacy setting that is based on the committee's aims, rules, and recommendations.

SELF-ASSESSMENT QUESTIONS

1. The six aims stated by the Committee on the Quality of Health Care in America should serve as a vision of what may be possible with a redesign of health care.
   a. True
   b. False

2. The six aims include specific information on all of the following except:
   a. focus of care.
   b. the use of evidence-based medicine.
   c. equitability of care.
   d. cost reduction.

3. The 10 rules for redesigning the health care system include at least one rule on safety. When considering safety, health care in the 21st century should be designed to:
   a. prevent errors.
   b. make any errors that do occur visible.
   c. reduce the risk of serious harm when an error does occur.
   d. A and B only.
   e. A, B, and C.

4. Health care in the 21st century should be based on continuous healing relationships. To achieve this, patients should have access to care:
   a. during face-to-face visits.
   b. via e-mail or through “virtual visits.”
   c. 24 hours a day every day of the year.
   d. A and C only.
   e. A, B, and C.

5. If health care is to reach its full potential for providing excellent care, knowledge must be shared between clinicians and patients. Implicit in this statement are all of the following except:
   a. Patients should have access to their medical information.
   b. Clinicians should share only the information they believe to be appropriate and patients should inform clinicians of their progress.
   c. Both patients and clinicians should have access to the latest clinical information.
   d. Both patients and clinician should be trained to communicate effectively.

6. The purpose of health care in the United States should be to decrease the impact of injury, illness, and disability and to increase the health and functioning of the people.
   a. True
   b. False

7. To provide the level of care suggested by the committee, challenges must be overcome. These include all of the following except:
   a. a change in the way health care is delivered.
   b. improved access to and use of information technology.
   c. increased reliance on measures of process and decreased reliance on measures of patient outcomes.
   d. improved coordination of patient care.
   e. A and B only.

8. A number of barriers stand in the way of innovations in health care. One of the barriers specifically addressed in the committee's recommendations is:
   a. a reduction in the current use of multidisciplinary care teams.
   b. payment methods that fail to reward innovation and may impede efforts to improve the quality of care.
   c. the use of technology to manage clinical knowledge.
   d. all of the above.

9. Based on the 80/20 principle:
   a. 80% of health care expenditures pay for patient care; the other 20% cover administrative cost.
   b. 80% of patients use their health care coverage regularly; the other 20% do not.
   c. 80% of health care resources are used for the care of 20% of the patients.
   d. none of the above.

10. Techniques that have been successfully used for the redesign of health care include all of the following except:
    a. design for safety to (1) prevent errors, (2) make errors that do occur more visible, and (3) reduce the impact of errors that do occur.
    b. design for the usual but recognize and plan for the unusual.
    c. continuous flow or “a batch size of one.”
    d. The use of patient teams to develop a plan for redesign.
INSTRUCTIONS

This test affords 1 hour (0.10 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 test answers correctly. To record an answer, darken the appropriate block below. Mail your completed answer sheet to: Academy of Managed Care Pharmacy, 100 N. Pitt Street, Suite 400, Alexandria, VA 22314. If you score 70% or more, a certificate of achievement will be mailed to you within eight weeks. 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 233-000-01-004-H04. This offer of continuing education credit expires August 31, 2002.

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  e. Other
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 insights relevant or practical for you 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

ACPE

This test affords 1 hour (0.10 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 test answers correctly. To record an answer, darken the appropriate block below. Mail your completed answer sheet to: Academy of Managed Care Pharmacy, 100 N. Pitt Street, Suite 400, Alexandria, VA 22314. If you score 70% or more, a certificate of achievement will be mailed to you within eight weeks. 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 233-000-01-004-H04. This offer of continuing education credit expires August 31, 2002.

A B C D E
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Participant Identification: Please type or print.

Social Security #: For Identification Purposes Only

Name: LAST  FIRST  MIDDLE

Company: 

Address: STREET (with Apt. No.) or P.O. Box  CITY  STATE  ZIP

State & Lic. No.: STATE  LICENSE NO.

Member Type:  

Signature: I verify by my signature above that I have completed this examination independently.

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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
The Journal of Managed Care Pharmacy contains three basic types of editorial material: peer-reviewed scholarly articles, feature articles, and departments. Articles should be organized, written, and formatted for a specific part or section of the journal.

The Journal of Managed Care Pharmacy seeks contributions from authors in the areas of managed care pharmacy practice, pharmacotherapy, research, education, economics, and other areas of pharmacy practice.

Peer-Reviewed Articles
The heart of the journal is its peer-reviewed scholarly research, review, and report articles. JMCP accepts:

• Comparative Research: articles using the scientific method to compare definitively two or more 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.
• Continuing Education: invited reviews of timely topics with continuing education credit.

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Feature articles highlight news and information of 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.

Departments
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• Perspectives: editorials by outside contributors as well as the editors.
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• Caveats: updates from the legal and regulatory world.
• International: articles describing managed care and/or pharmacy developments and emerging markets in foreign countries.
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Mission Statement
JMCP, a publication of the Academy of Managed Care Pharmacists, associates and students with the tools to excel in their daily practices by focusing on:

† Policy: Providing a forum for in-depth discussion of issues of topical and long-term importance.
† Practice: Presenting information of interest and educational value to the membership.
† Research: Publishing research that increases the quality of research standards used in managed care pharmacy practice and helps apply that research to improve the practice of managed care pharmacy.
JMCP accepts for consideration manuscripts prepared in accordance with the Uniform Requirements for the Submission of Manuscripts to Biomedical Journals.1

†† Manuscript Preparation

Manuscript length should be 10–20 typewritten pages (1500–3000 words), including tables, figures, and references. Due to space limitations, authors are encouraged to limit the number of tables/figures to no more than three. Manuscripts should include, in this order, a title page, a separate page identifying all authors (including degrees, employers, contact information, and financial disclosure and conflicts of interest), an 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.

JMCP abstracts should be written narratives and contain the information described for each type of article shown below, where applicable:

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

†† Reference Style

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 four or less; when five 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

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Four complete copies of the manuscript, including originals of figures and tables, should be submitted to the JMCP Managing Editor at Mitchell Petersen, Inc., 1775 Jamieson Ave., Suite 210, Alexandria, VA 22314-5715; 703-518-4700, 703-518-8495 (fax).

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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.

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Once peer review is complete (generally 6–8 weeks), the corresponding author will be notified of the status of the article.

REFERENCES

The Academy of Managed Care Pharmacy (AMCP) has received a major grant from Janssen Pharmaceutica to help finance a coalition initiative to improve the effectiveness of online prospective drug-utilization review (OPDUR).

The AMCP/U.S. Pharmacopeia (USP)-led coalition has proposed the establishment of an OPDUR system that includes “dead stops” in instances in which a drug/drug or drug/class interaction could cause serious harm to the patient. This system would require a pharmacist to document an intervention on behalf of the patient before the prescription could be dispensed. To make the system practical in daily use, these “dead stops” would concentrate only on the potentially most serious interactions, rather than all possible interactions.

Funds such as those received from Janssen Pharmaceutica will be used to defray a variety of expenses, including the development of drug/drug interaction criteria by an expert committee of decision makers, consultants to advise on liability and other legal issues, and the testing of the methodology developed.

Also serving on the Steering Committee for the initiative are the American Society for Automation in Pharmacy, the American Pharmaceutical Association, the National Community Pharmacists Association, the National Association of Chain Drug Stores, and the Pharmaceutical Care Management Association.

Sterler, Nudelman Honored

Lowell Sterler received the 2001 AMCP Distinguished Service Award and Phillip Nudelman received the Foundation for Managed Care Pharmacy’s (FMCP’s) Award for Achievement at AMCP’s 13th Annual Business Meeting in Tampa, Florida.

Sterler, an AMCP member since 1990, is vice president of professional relations at AdvancePCS in Scottsdale, Arizona. He has served as AMCP president, chair of the Nominations Committee, chair of the Legislative Committee, and as president of the Board of Trustees for FMCP, where he led efforts to promote the value of managed care pharmacy and pharmaceuticals.

The AMCP Distinguished Service Award recognizes an AMCP member for exceptional and sustained volunteer service and commitment to the Academy. Candidates for this award must have at least five years of extraordinary volunteer service to the Academy and must have been involved in activities critical to the achievement of AMCP’s mission. A selection committee made up of AMCP board members and committee chairs who are appointed by the AMCP president chooses the award recipient.

In choosing Sterler for this award, the committee recognized not only his many leadership roles within AMCP, but also his continuing efforts to represent the Academy and the profession of pharmacy to external audiences, to educate them about the value and importance of pharmacy. Sterler has represented AMCP before the Food and Drug Administration in discussions regarding the agency’s authority over health plans and pharmacy benefits management companies. He has also participated in the White House Summit and other meetings relating to Y2K planning and drug stockpiling; spearheaded talks with the Centers for Disease Control and Prevention regarding the role of pharmacists in assisting public health initiatives; and has been a frequent participant in AMCP Lobby Days, representing the Academy and its members on Capitol Hill.

Sterler authored the chapter on pharmacy distribution systems and network management in the classic textbook Managed Care Pharmacy Practice; serves as AMCP’s diplomat to his alma mater, South Dakota State University; and was among the first of AMCP’s e-mail mentors, working with students to help them understand the complexities of managed care pharmacy practice.

The FMCP Award for Achievement recognizes an individual for lifetime sustained, exemplary, and distinguished service to managed care pharmacy. Candidates must be professional role models who are making or have made significant and sustained contributions to the advancement of the profession of managed care pharmacy in a clinical or an administrative practice. The recipient is chosen by the Past Presidents and Founders Advisory Council, and is not required to be an AMCP member.

Phillip Nudelman, Ph.D., is the inaugural recipient of this prestigious award. He is chief executive officer of Hope Heart Institute of Seattle, Washington, and former chairman and president of Kaiser/Group Health. Nudelman began his career as a clinical pharmacist before becoming director of professional services at Group Health Cooperative (GHC) of Puget Sound. While at GHC, Nudelman pioneered the use of technology in pharmacy, leading the effort that created and implemented CoopRx, one of the first pharmacy information systems. He also implemented decentralized pharmacy pilots at GHC, and put pharmacy in the lead role in the health care system’s formulation and pharmacy and therapeutics committee processes. He implemented the use of the pharmacy database as a research tool at GHC. As chair of the Washington State Board of Pharmacy (1973–1977), Nudelman led efforts to require pharmacist-patient counseling and mandatory continuing education for pharmacists.


Continued on page 324
Recognizing that tablet splitting has been an accepted practice in health care for many years, AMCP has issued a Professional Practice Advisory to recommend situations in which tablet splitting may be beneficial, when it is inadvisable, and how to ensure patient safety when the practice is used.

Tablet splitting has been used to obtain the appropriate prescribed dose of a medication when the dosage is not available from the manufacturer. It has been particularly useful for pediatric patients and the elderly, who often require doses other than those supplied by manufacturers. Patients on flexible dosing schedules, or those who need to gradually increase or decrease dosages of a medication, may also need to split tablets.

Managed health care systems have used tablet-splitting strategies to help combat the skyrocketing cost of prescription drugs while providing quality, cost-effective care. In many cases, manufacturers price different strengths of the same medication equally. By splitting a tablet that is twice the strength of the dose desired, the cost could be cut in half. Given the extraordinarily high cost of prescription drugs, many life-saving medications are beyond the reach of some patients. Tablet splitting can help preserve access to comprehensive, high-quality drug benefits without impairing the quality of care.

Because patient safety is the primary concern of managed health care systems, health plans should have guidelines in place to determine which medications may be appropriate for tablet splitting. The guidelines should detail precautions that health plans should take when choosing tablets to be split both to obtain accurate dosing and to minimize the chance of error and adverse events.

The Professional Practice Advisory contains suggestions on precautions that health care organizations should take when deciding which medications can be split, advice on types of medications inappropriate for splitting, and the role of the pharmacist in ensuring patient understanding and safety when tablet splitting is required.

To review the Professional Practice Advisory on tablet splitting, see the “Policy Digest and Practice Advisory” category at www.amcp.org.

 Correction
In the list of AMCP Committee Chairs for 2001–2002 in the May/June AMCProgress, the chair of the Past Presidents and Founders Advisory Council was inadvertently omitted. He is Michael Dillon, CHD Meridian Healthcare.